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SHOPS Strengthening Health Outcomes *through* the Private Sector

Availability of HIV Rapid Diagnostic Tests Over the Counter

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REPORT

Abstract: SHOPS conducted assessments of over-the-counter availability of HIV rapid diagnostic tests through private pharmacies in Kenya, Malawi, Tanzania, and Uganda. The objective was to assess the extent to which the tests were readily accessible to and used by consumers for self-testing, in lieu of facility-based HIV testing services. The assessment revealed several findings regarding HIV rapid diagnostic tests, including their regulatory oversight, availability, source, demand, and future role.

Keywords: AIDS, HIV, HIV counseling and testing, Kenya, Malawi, pharmacies, Tanzania, Uganda

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Project Description: The Strengthening Health Outcomes through the Private Sector (SHOPS) project is USAID's flagship initiative in private sector health. SHOPS focuses on increasing availability, improving quality, and expanding coverage of essential health products and services in family planning and reproductive health, maternal and child health, HIV and AIDS, and other health areas through the private sector. Abt Associates leads the SHOPS team, which includes five partners: Banyan Global, Jhpiego, Marie Stopes International, Monitor Group, and O'Hanlon Health Consulting.

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Availability of HIV Rapid Diagnostic Tests Over the Counter

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INTRODUCTION

The Human Resources for Health Crisis

UNAIDS reports that just 54 percent of all PLHIV worldwide are aware of their HIV positive status (UNAIDS, 2015). In order to address this, UNAIDS has set ambitious targets for 2020: 90 percent of all PLHIV will be aware of their status, through extending HIV testing services (HTS) to the estimated 19 million people worldwide who are already infected with HIV but are unaware of their status. Achieving these targets will require overcoming the challenges facing existing HTS approaches, as well as exploring innovative service delivery strategies to expand HTS options for people unaware of their status—particularly in making confidential testing services more accessible to high-risk and hard-to-reach populations at the community level.

Two interrelated strategies offer the potential for rapid gains in global HTS service uptake: strengthening the private health sector's involvement in expanding the availability of HTS; and making available products for HIV self-testing (HIVST). With regard to HIVST, however, historically there have been concerns regarding the quality of test devices, the reliability of results, and how people may react to receiving a positive HIV result without having professional counseling and support immediately available to them (Pant Pai & Klein, 2008).

Purpose of this assessment

SHOPS conducted assessments of over-the-counter (OTC) availability of HIV rapid diagnostic tests (RDTs) through private pharmacies in Kenya, Malawi, Tanzania, and Uganda, countries where there was some evidence that HIV RDTs were already being sold OTC. The overall objective was to assess the extent to which RDTs were readily accessible to and used by consumers in lieu of facility-based HTS. Specific objectives were to:

- Describe the global policy landscape and the national legal and regulatory environments for HIVST and OTC sale of HIV RDTs
- Determine HIV RDT availability in commercial pharmacies (OTC)
- Determine how easily HIV RDTs can be purchased by consumers, what types of tests are available OTC, and what instruction or counseling is provided to the customer at the point of sale
- Document any guidelines from pharmaceutical societies for OTC sales of HIV RDTs
- Identify main suppliers and distributors of HIV RDTs

Potential benefits of HIV RDTs for HIVST

The inclusion of HIVST as part of comprehensive national testing strategies—offered in either partially-supervised or unsupervised settings—can provide a high impact, low-cost approach to increasing global uptake of HTS (Mavedzenge, Baggaley, & Corbett, 2013). Proponents of HIVST highlight how the confidentiality and convenience offered by "at-home" HIV testing options could help reach more people with HTS, especially earlier in disease progression, and reduce stigma, enhance autonomy, and empower potential users (particularly among high risk populations).

Risks and concerns related to HIVST

Public health practitioners have raised concerns about HIVST, including variability in test performance, accuracy, quality, and ease of use, along with concerns for potential risk of user error and misinterpretation of the results (Pant Pai and Klein, 2008). Other concerns relate to possible psychological danger when HTS is decoupled from formal counseling, and the potential difficulty in linking people to ongoing care and treatment, following a positive diagnosis. There is also a concern over unethical and/or illegal use or sale of HIVST commodities in the absence of sufficient regulatory oversight, monitoring, and enforcement. Finally, many implementers have expressed concern about the current lack of guiding policy, regulations, guidelines, or operational experience to implement HIVST approaches.

Policy, Legal, and Regulatory Environment

Some countries have already made HIVST legal and have begun the process of registering and distributing HIV RDTs OTC, including the United States, Australia, China, France, Kenya, and South Africa (World Health Organization, 2015). Others (such as Malawi) are assessing the options of making HIV-RDTs widely available, either OTC or via other commercial distribution methods. Policymakers in several countries have been more cautious about HIVST and have made self-testing explicitly illegal, including Botswana (Southern Africa AIDS Trust, 2014), Uganda (Uganda Ministry of Health, 2010), Singapore (Abu Baker, 2011), and Germany (Deutsche AIDS-Hilfe, 2013).

Status of National HIVST Policies

HIVST policy in place; HIVST product licensed and registered	HIVST policy in place; no HIVST product registered or licensed	HIVST policy in development	HIVST explicitly illegal
France	Australia	Canada	Botswana
United Kingdom	China	Brazil	Germany
United States	Kenya	Malawi	Singapore
	South Africa	Tanzania	Uganda
		Thailand	
		Zambia	
		Zimbabwe	

Globally, there are three HIV RDT products (BioSure, OraQuick and Autotest VIH) that have been officially registered, packaged, and distributed as HIVST products (see table).

Methodology

SHOPS conducted an assessment of OTC availability of HIV RDTs in Kenya, Malawi, Tanzania, and Uganda. These countries were targeted based on anecdotal evidence and local information that suggested that HIV RDTs were already available for self-testing. The assessment included 1) a brief review of the global literature focused on HIV rapid-diagnostic tests in general, with special emphasis on considerations and suitability of HIV RDTs for use in resource-constrained settings; and 2) open-ended interviews with pharmacy staff regarding HIV RDTs, their commercial availability, procurement source, magnitude of sales, and consumer demand for HIVST.

Globally Registered HIVST Products

Manufacturer & Product	Specimen Collection	Regulatory Approval	Country License/ Registered for Use
BioSure	Blood (finger-prick)	UK Medicines and Healthcare Products Agency; European Medicines Agency; CE*	UK
OraQuick In-Home HIV test	Oral-fluid	US Food and Drug Administration; CE*	USA
Autotest VIH	Blood (finger-prick)	French National Agency for Medicines and Health Products Safety, European Medicines Agency, CE*	France

**CE is "Conformite Europeenne," or required conformity marking for medical devices manufactured or sold in the European Community.*

Source: http://www.hivst.org/hiv-rapid-diagnostic-tests-for-hivst

Assessment Findings

Kenya

SHOPS found HIV RDTs for sale OTC at three out of the twelve private pharmacies examined in Kenya, but all were either incomplete or available only in constituent parts. None of the tests were specifically packaged or appropriate for self-testing. There was anecdotal evidence of black market sales from public facilities, but this was not quantified.

Malawi

Malawi's current policies require HTS to be performed in the presence of a clinical health care worker. SHOPS found that a few pharmacies carried HIV RDTs packaged in bulk, for sale to health facilities, but none carried RDTs specifically packaged for HIVST. Pharmacists and other attendants interviewed stated that although regulations prohibit them from selling RDTs for self-testing, such sales are legal as long as HIVST is supervised by a trained health worker. SHOPS found anecdotal evidence that clinical staff may sell HIV RDTs directly to individuals for their own use from stock intended for facility-based testing, and with some effort, individuals can also purchase materials to conduct self-tests from commercial retail establishments.

Tanzania

SHOPS found that current guidelines require HTS to be administered under the supervision of a health care worker, and that HIV RDTs must be procured through approved channels. However, we found that HIV RDT kits and components were available for sale in bulk to health providers in pharmacies. Pharmacies located close to private facilities were more likely to carry HIV RDTs packaged for health provider use, indicating that workers from facilities may be buying tests to be used in a clinical HTS setting. SHOPS found no activity underway to review or update regulations to accommodate testing outside of clinical settings or via HIVST. Stakeholder interviews with suppliers, NGOs, and pharmacies indicated more limited support for HIVST within Tanzania's HIV community, and few champions to push an HIVST agenda forward.

Uganda

Uganda is the only country in this assessment with a policy that explicitly bans the use of HIV RDTs for self-testing. Surprisingly, we found wide availability of HIV RDT components and kits for sale in all the pharmacies visited; however, the HIV RDTs for sale were not packaged or designed for use by lay persons, nor did they contain all the test components in one package. Most distributors refused to talk to the SHOPS data collector when they were told the subject of the survey. Pharmacy staff interviewed reported a demand for an HIV self-testing kit, which they believe is driven by the need for confidentiality as well as by systemic problems of access at public HTS sites.

Discussion

This assessment of OTC availability of HIV RDTs revealed several interesting findings that are informative in the context of private sector expansion of HTS and HIVST:

Lack of sufficient guiding policy or regulatory oversight for HIV RDT sales

Comprehensive policies, laws, and regulations governing the commercial sale or use of HIV RDTs for personal self-testing do not currently exist in any of the four countries included in this assessment. In the absence of adequate technical guidelines and regulatory oversight, it is hard to assess the current or potential formal market for HIV RDTs for OTC sales. The assessment found that—even where allowed by law—there were no systematic and comprehensive efforts underway to appropriately package, market, and distribute HIV RDTs directly to consumers over the counter, as part of a comprehensive regulated national approach.

Availability of HIV RDTs for OTC purchase

No HIV RDTs packaged for consumer use were found in any of the four countries included in this assessment. Where HIV RDTs were available, they were usually un-packaged and sold in bulk to health providers from nearby HTS providing health care facilities. In some private pharmacies, they were sold as individual constituent parts of an HIV test kit (i.e., only the sample test strip without appropriate product inserts, instructions, buffer/reagent, or lancet); in the latter case, none of the pharmacists or retail clerks interviewed had received training in HIV testing and counseling, and very few offered detailed instruction on how to administer and interpret an HIV RDT. However, interviews with private pharmacy staff suggested that the majority of HIV RDTs being sold OTC were purchased by health care providers and facilities, to be used in a clinical setting. The limited availability of HIV RDTs OTC in the four countries suggests that the unregulated sale of HIV RDTs for self-testing purposes may not be a common practice.

Source of HIV RDT and potential black market

Pharmacy staff who admitted selling HIV RDTs OTC stated that they procured the commodities from commercial wholesalers and suppliers. However, the SHOPS assessment revealed some evidence of HIV RDT commodity leakage (i.e., unapproved movement of subsidized commodities) from the public sector to the private sector. In all four countries, staff members at some pharmacies were hesitant to discuss HIV RDTs. This assessment could not determine whether the HIV RDTs available in private pharmacies were procured illegally (as "leakage" from the public sector) or procured legally (via wholesalers). However, the fact that several pharmacies were selling the individual constituent components of HIV RDTs (and some were even informally selling buffer solution in a syringe) suggests questionable procurement methods, and possibly a black market for HIV RDTs sold "under-the-counter."

Demand for HIV RDTs purchased OTC

This assessment did not include any measurement of consumer demand for an HIV RDT sold OTC for self-testing, and we did not interview consumers or potential users of this product. However, pharmacy staff interviewed stated that, based on inquiries and requests they have received, some consumers had tried to obtain HIV RDTs for self-testing.

Role of HIV RDTs sold OTC in future HIV self-testing programs

The findings from this assessment indicate a need for government policymakers to address HIVST and access to HIV RDTs in their national guidelines, to protect consumers via stronger pre- and post-market regulatory oversight of HIV RDTs, and to develop data-driven, client-focused approaches to distributing HIV RDTs for self-testing purposes. The current lack of supportive policy for HIVST in three of the four countries, and regulatory limitation of HIV RDTs to clinical use in all of the countries, has restricted market development for self-purchased and self-administered HIV RDTs. This makes it difficult to assess the potential role or impact of OTC distribution of HIV RDTs as part of any future HIV self-testing program. However, stakeholder responses and pharmacy commodity findings confirm that there is an existing market for HIV RDTs sold in bulk OTC to health care providers/facilities. Moreover, there has been market demand for individual HIV RDTs among lay consumers, as well as an unknown degree of "under-the-counter" sales.

Conclusions and Recommendations

New and innovative approaches to service provision are urgently needed to extend the global coverage of HTS, and to rapidly increase the number of people who are aware of their HIV status. The use of HIV RDT products, in either supervised or unsupervised settings, could be a strong asset in accomplishing these objectives. The findings from this assessment suggest the following recommendations.

1. Strengthen national regulations, guidelines, and enforcement capacity pertaining to self-testing and commercial sale of HIV RDTs.
In view of the potential for HIVST to make a significant public health impact, the current lack of comprehensive HIVST policies and weak regulatory structures related to HIV RDTs and other medical products have limited operational experience with HIVST. Formal HIVST policies and programs must be developed, including clear rules for retailers and providers in order to protect consumers and to formalize the provision of HIV RDTs commercially.

2. Strengthen regulatory and policy frameworks pertaining to private sector import, registration, and commercial sale of HIV RDT products.
There is a need to specifically clarify and strengthen policies and enforcement standards related to the private commercial sale of existing and emerging HIV RDTs and HIVST products. This report presents some evidence of some unregulated sale of HIV RDTs in all four countries, indicating the need for stronger policy and engagement focused on the private sector.

3. Define the components of a best-practice HIVST program.
As countries initiate or prepare to implement national HIVST programs there is a need to define the legal, ethical, technical, and logistic aspects of best practice HIVST approaches. The WHO has provided guidance on possible programmatic models, approaches, and considerations, to inform implementers and national health leadership. Implementation experiences from diverse settings and among different populations and risk groups should be reviewed, to help guide development of HIVST programs and replicable approaches.

HIV_5_hands via Flickr

4. Advocate for novel and consumer-friendly HIV RDT products for HIVST.
None of the HIV RDTs available for sale OTC at pharmacies were packaged for use by lay consumers. While several HIVST products have been recently registered or are under development, there is a need for additional consumer-friendly HIV RDT products designed specifically for HIVST. These products should be easy for lay consumers to use, should be packaged with instructions that are clear to the general public, and should include clear direction and linkage to confirmation testing and support for those with a reactive result.

Although many questions remain regarding comparative risks and benefits, HIVST could prove a critical strategy in closing global HTS gaps and in reaching an AIDS-free generation. Maximizing the potential of HIVST approaches will require careful consideration of RDT product selection and new HIV RDT product development, as well as effective and timely links to care and support for users with a reactive (positive) result. Equally important is adequate government capacity to introduce, monitor, and enforce an HIVST program. Future efforts to incorporate commercial OTC sale of HIV RDTs for HIVST into national HTS programs should be guided by further global research, as well as by the lessons of operational experience.

INTRODUCTION

Scaling-up global access to reliable HIV testing services (HTS) remains a pivotal task in slowing the spread of the HIV epidemic. Increasing the number of people who know their status is crucial in preventing onward transmission of the disease, with HTS serving as the critical first step in connecting people living with HIV (PLHIV) to appropriate long-term care, treatment, and support. PEPFAR reports that globally there are over 40,385 new HIV infections every week, including more than 4,600 newborns and 7,000 adolescent women (Office of the US Global AIDS Coordinator, 2014). However, only a little over half (54 percent) of all PLHIV worldwide are aware of their HIV positive status (UNAIDS, 2015). Even among key populations and risk groups, where significant HTS efforts and resources have been focused, there remain significant gaps in the delivery and uptake of HTS. For instance, only 60 percent of sex workers across 35 sub-Saharan African countries reported receiving an HIV test and their result within the prior 12 months (Figueroa, Johnson, Verster, & Baggaley, 2015).

Testing is the critical first step in connecting people to appropriate care.

Recognizing these gaps, UNAIDS has set a high HIV awareness target—90 percent of all PLHIV in 2020—reachable by extending HTS to the estimated *19 million* people worldwide who are already infected with HIV but unaware of their status. Further, the World Health Organization (WHO) now recommends earlier initiation of antiretroviral therapy (ART)[1], both to improve PLHIV health outcomes and to prevent onward transmission of the disease by reducing patients' viral loads (WHO 2013). Achieving these targets will require (1) overcoming the challenges facing existing HTS approaches, and (2) exploring innovative service delivery strategies to expand HTS options for people unaware of their status—particularly in making confidential testing services more accessible to high-risk and hard-to-reach populations at the community level. Over the past two decades, there have been significant technological advances in HIV rapid diagnostic tests (RDTs), primarily for use by health care professionals at the point of care (POC). Although these advances have enabled health care workers to bring HTS closer to patients, via remote, mobile, and community-based outreach approaches, several studies have shown that higher age, perceived risk, fear of the disease, stigma, and discrimination still continue to delay and restrict uptake of HTS among many people requiring an HIV test (Chesney & Smith, 1999; Mackellar et al., 2011; Pant Pai et al., 2013).

Two strategies have demonstrated potential for rapid gains in global HTS uptake: strengthening the private health sector's involvement, in expanding both the availability of HTS and the options for HIV testing; and introducing products for HIV self-testing (HIVST), in either supervised or unsupervised settings. A study of HTS offered by private health providers across 18 countries was carried out by the USAID Strengthening Health Outcomes through the Private Sector (SHOPS) project, finding that, while private provision of HTS varies widely across countries and by gender, the private health sector delivers a significant portion of HTS services in many high-HIV prevalence settings, and most notably in Haiti, Dominican Republic, Liberia, and Kenya (SHOPS Project, 2015). Moreover, the possibility of introducing HIVST options—where an individual collects his/her own specimen, performs an HIV screening test, and interprets the result in private—has recently gained renewed attention among public health practitioners and governments. Exploring

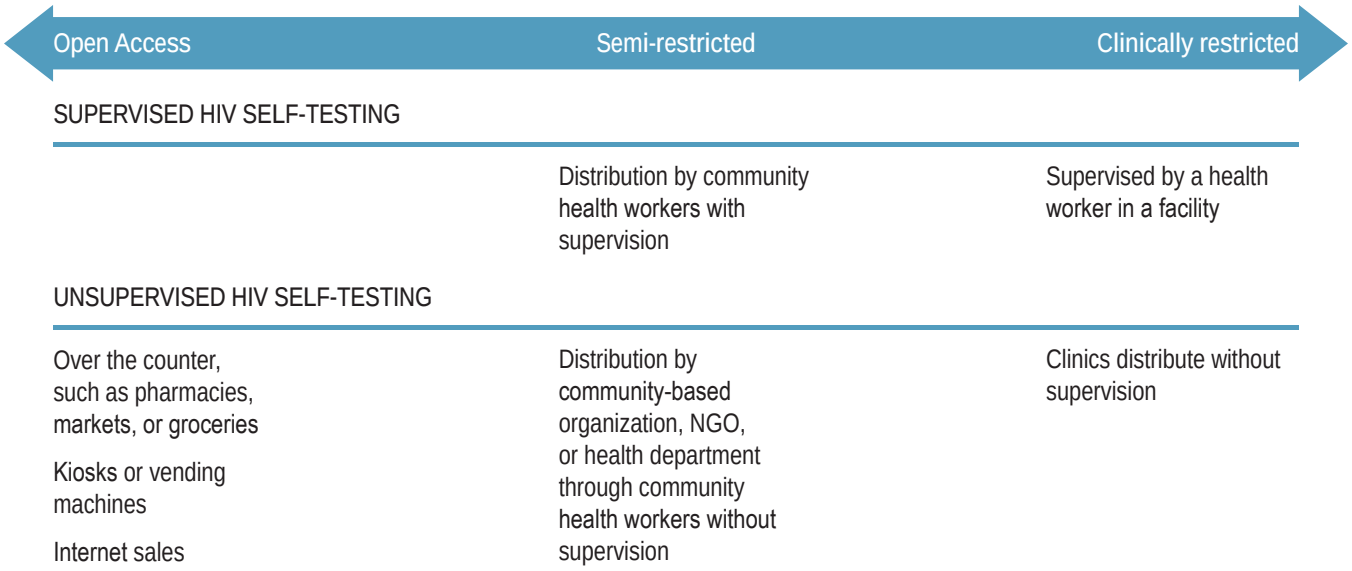
[1] The WHO currently recommends ART initiation at a CD4 T lymphocyte threshold of 500 cells/mm3 or less. Treatment updates encouraging initiation of ART immediately at the time of diagnosis (irrespective of CD4 count) as part of a "test and treat" strategy are expected from the WHO at the end of 2015 or early 2016.

options for HIVST in either a supervised setting or unsupervised setting has been a topic of debate since the emergence of the epidemic in the 1980s (Johnson, Baggaley, Forsythe, Van Rooyen, et al., 2014).

Supervised self-testing involves support from a health worker or volunteer before or after individuals test themselves for HIV. Such support may include a demonstration, in a private setting, of how to use the test, as well as pre- or post-test counseling and referrals to additional services.

Unsupervised self-testing refers to independent or open access to HIV self-testing. Support may or may not be indirectly provided and would require user initiative; examples are telephone hotlines, leaflets, referral information, support groups, legal aid, and HIV treatment, care, and prevention services. (World Health Organization, 2014) (see figure).

Continuum of HIV Self-Testing Approaches



Source: World Health Organization, 2015

There is growing acceptance that HIVST may offer opportunities for people to learn their HIV status, if they are unable or unwilling to seek HTS through other approaches (World Health Organization, 2015). However, questions remain as to the extent of HIVST behavior and especially unregulated HIV RDT commercial activity, in high HIV prevalence settings.

Various reports suggest that HIVST is already occurring in many settings, both formally and informally, through health care workers and possibly through unregulated OTC sale of HIV RDTs (WHO, UNAIDS, Brocher Foundation, 2013; World Health Organization, 2014). Global agencies such as the WHO and UNAIDS, along with national governments, are seeking reliable reporting of operational experience, to inform the design and implementation of potential HIVST policies and initiatives. Although HIVST is now technically feasible, evidence on appropriate use as part of a national testing strategy remains limited. This assessment seeks to help fill that global information gap.

Purpose of this Assessment

USAID asked SHOPS to assess the OTC availability of HIV RDTs in private pharmacies. SHOPS focused on four countries where anecdotal evidence suggested that HIV RDTs were being sold OTC: Kenya, Malawi, Tanzania, and Uganda. The objective of this assessment was to obtain information on the availability of RDTs: to what extent were they readily accessible and used by consumers, in lieu of facility-based testing? This assessment includes (1) a review of national-level legal and regulatory guidelines for each country regarding HIVST and OTC sale of HIV RDTs, and (2) a summary of the data gathered by SHOPS on availability of HIV RDTs in a sample of pharmacies.

To achieve this objective, SHOPS sought to:

- Describe the global policy landscape and the national legal and regulatory environments for HIVST and for OTC sale of HIV RDTs directly to consumers.
- Determine if HIV RDTs are available OTC in commercial pharmacies.
- Determine how easily HIV RDTs can be purchased by consumers, what types of HIV RDTs are available OTC, and what instruction or counseling is provided to the customer at the time of the sale.
- Document any guidelines from pharmaceutical societies for OTC sales of HIV RDTs.
- Identify the main suppliers and distributors of HIV RDTs in each country.

Jessica Scranton

Description of HIV Rapid Diagnostic Tests

Over the past two decades, numerous HIV RDTs have been developed that function as a single-use enzyme-linked immunosorbent assay (ELISA), providing a test result in 5–30 minutes at the point of care. Most RDTs are packaged as a test collection ”kit” or “system” containing all necessary test components: a retractable lancet, pipette, desiccant, reagent, and buffer solution, as well as an interpretation card, strip, or cassette. Depending on the type or brand of test, RDTs can detect the presence of HIV antibodies in either whole blood (by finger-prick sample), in separated serum or plasma, or in oral fluid (i.e., saliva or oral swab). The HIV ELISA remains the most commonly used rapid diagnostic screening test used to identify antibodies to HIV infection. Many RDTs can now also differentiate between HIV-1 and HIV-2 subtypes.

More recent “fourth-generation” RDTs provide combination testing for both HIV antibodies (i.e., evidence of the body’s HIV immune response) and p24 antigen (i.e., evidence of HIV viral proteins in the virus itself) (Macpherson, Taegtmeyer, Ochodo, Adams, & Sands, 2014). Tests that detect p24 antigen claim to be much more effective in detecting recent infections (i.e., within the three-month period between exposure and seroconversion) (Macpherson et al., 2014; Pilcher, Christopoulos, & Golden, 2010). However, PEPFAR has expressed concern regarding the reliability and utility of these fourth-generation RDTs in high-HIV prevalence settings. For example, one large field evaluation in Swaziland demonstrated fourth-generation RDTs’ extremely poor sensitivity to acute infection, their poor positive predictive value (PPV) of 0.00%, and their much higher cost (Duong et al., 2014).

There are substantial differences in the performance and reliability of various HIV RDTs. While the majority are highly *sensitive* to HIV antibodies (i.e., they produce few false negative results), they range widely in level of *specificity* (i.e., the rate of false positive results) (Koblavi-Dème et al., 2001; Kuun, Brashaw, & Heyns, 1997). The specificity and sensitivity of a diagnostic test must also be considered in the context of a population's HIV prevalence and the number of true positive and true negative results the test will yield, a function typically expressed as a test's predictive value (UNICEF, 2008). In low HIV prevalence settings, even a small loss of specificity can reduce a test's positive predictive value (PPV), meaning that a less specific HIV RDT may be most suitable for screening purposes in high HIV prevalence settings where its PPV is likely to be higher, despite a higher possible incidence of false positives (Clark et al., 2006; Klarkowski, O'Brien, Shanks, & Singh, 2014; UNICEF, 2008). Several studies have noted both lower specificity (higher incidence of false positive results) and lower sensitivity (higher incidence of false negative results) of RDTs testing oral fluid, when compared to those testing whole blood (Hamers et al., 2008; Jafa et al., 2007; Pavie et al., 2010).

Use of HIV assays and RDTs within a testing strategy

The WHO recommends that any country considering the selection and use of diagnostics for HIV testing should have a national HIV testing policy, closely aligned with its national laboratory policy and national laboratory strategic plans (World Health Organization, 2012). Such policies and testing strategies can then be populated with the assays available, to develop an "HIV testing algorithm," which describes the combination and sequence of specific HIV assays used in a given HIV testing strategy (World Health Organization, 2015).
The selection and suitability of particular assays in a testing algorithm (HIV RDTs or otherwise) determines how diagnosis is made—an issue of particular importance in resource-limited settings (see Box 1). WHO further recommends that first-line assays (A1; also referred to as screening assays) should have high diagnostic sensitivity, in order to accurately identify true positive and true negative results. Second-line (A2) and third-line (A3) assays (whether HIV RDTs or not) should demonstrate high diagnostic specificity, to confirm initial results and rule out false reactivity. WHO further recommends that all assay selections have the lowest rates of invalid devices and results, and that they show reliability among different users in reading test results (i.e, low inter-reader variability). In most national testing algorithms, a reactive (positive) HIV RDT is followed by a more specific and/or laboratory-based confirmatory test, such as a second RDT brand, a laboratory-based western blot (WB), an immunoflourescent assay (IFA), or a nucleic acid amplification test (NAAT) (Association of Public Health Laboratories & Centers for Disease Control and Prevention, 2009; Centers for Disease Control and Prevention, 2014; Wesolowski et al., 2008).

Kate Holt/Africa Practice

Selection and Suitability of HIV RDTs for National HTS Algorithms

Given the array of HIV RDTs currently available, various technical considerations can assist national governments and public health implementers in determining the suitability of different RDTs for use as part of national HTS algorithms in either supervised or unsupervised settings. Such technical considerations include:

- Clinical sensitivity and specificity of the test
- Predictive value in the context of population HIV prevalence
- Invalid rate (devices/result)
- Shelf-life and storage requirements
- Test format and detection type
- Packaging and clear instructions for use
- Ease of use; ease of interpreting the result
- Specimen type; invasivity of sample collection procedure
- Cost and cost-effectiveness
- Detection of HIV-1 and HIV-2 subtypes
- Time to obtain result

Such factors can help determine a particular RDT's place in a national testing algorithm and/or for HIVST approaches (Kersting, Rausch, Bier, & von Nickisch-Rosenegk, 2014; UNICEF, 2008; World Health Organization, 2015).

Potential benefits of RDTs for HIV self-testing

The inclusion of HIVST as part of comprehensive national testing strategies—offered in either partially-supervised or unsupervised settings—could provide a high impact, low-cost approach to increasing global uptake of HTS (Mavedzenge et al., 2013). Only an estimated 51 percent of PLHIV in sub-Saharan Africa know their HIV status (UNAIDS, 2015), and proponents of HIVST have highlighted how HIVST programs could assist in closing these gaps. A special issue of the journal *AIDS and Behavior* has explored the potential risks and benefit of pursuing HIVST programs (*AIDS and Behavior*, Volume 18, Supplement 4, July 2014).

HIVST could bring HTS to more people.
The WHO's consolidated guidelines on HIV testing services (2015) states that HIVST has the potential to dramatically increase people's knowledge of their HIV status. Proponents of HIVST emphasize that its increased convenience, reduced stigma, and heightened privacy could improve the acceptability of HIV testing among people who might not otherwise seek out a test (Myers, El-Sadr, Zerbe, & Branson, 2013; Walensky & Bassett, 2011). In addition, although most published studies on HIVST come from high-income settings, a systematic review of 11 studies across global contexts found that in most cases HIVST had high acceptability and that it increases the reach of HTS to users that are capable of interpreting accurate results (Krause, Subklew-Sehume, Kenyon, & Colebunders, 2013).

HIVST could help reach people with HTS earlier in disease progression.
Global data also suggests that many patients seeking out an HIV test still do so at a late stage of disease progression, when advanced HIV infection will incur higher costs to the individual and to the health care system (Becker, Tsague, Sahabo, & Twyman, 2009; Girardi, Sabin, & Monforte, 2007; Pant Pai et al., 2013). In addition, the WHO has argued that HIVST could play an important role in the implementation of pre-exposure prophylaxis (PrEP) among key populations (Curran et al., 2014) as well as in post-exposure prophylaxis programs

(particularly among health care workers) (Kalibala et al., 2014). Health care workers (many of whom are already self-testing informally), sero-discordant couples, and the general population in high HIV prevalence areas may also benefit from earlier diagnosis through convenient and accessible HIVST options (Johnson, Baggaley, Forsythe, van Rooyen, et al., 2014; Mavedzenge et al., 2013).

HIVST could reduce stigma, enhance autonomy, and empower potential users (particularly among high risk populations).
The WHO and others assessing the potential of HIVST strategies recognize that the increased convenience, confidentiality, and privacy offered by self-testing enhances a person's autonomy to undergo HTS on their terms, and can empower them with the tools to know and protect their health status (World Health Organization, 2015). HIVST could be a particularly useful tool to increase the coverage and frequency of testing among high-risk populations (Myers et al., 2013), to facilitate repeat testing, to promote earlier diagnosis (Mavedzenge et al., 2013), to enable "at-home" mutual HIV screening among sex partners (Ventuneac et al., 2009), or to encourage testing among marginalized populations who may choose not to go to facilities or do not have access to them (Mavedzenge et al., 2013). Key populations, such as sex workers, men who have sex with men, and injecting drug users—who often express a reluctance to test due to stigma and discrimination within the health system—may find HIVST particularly attractive (Mavedzenge et al., 2013).

HIVST could be cost-saving and improve health outcomes.
Recent studies have argued that, although HIV RDTs for HIVST are expensive, they are less expensive than the costs associated with health care worker time to deliver HTS (Curran et al., 2014). A cost-effectiveness study of a potential HIVST program in Zimbabwe concluded that over a 20-year period, HIVST could lead to a modest cost saving of approximately $75 million, while also averting around 7000 disability-adjusted life-years (DALY).[2] Furthermore, if HIV RDTs were sold commercially in the private sector as part of an open-access or semi-restricted approach, the cost of this initial HTS screening could presumably be affordably borne by health care consumers, with potentially fewer initial costs to health care system.

[2] The WHO defines one DALY as one lost year of "healthy" life. The sum of DALYs across a population, (i.e., the burden of disease) can be considered a measurement of the gap between a population's current health status and the ideal situation where the entire population lives to an advanced age, free of disease and disability.

Risks and concerns related to HIVST

Although there is increasing acceptability of HIVST as a possible strategy to strengthen global HTS efforts, public health practitioners have raised concerns, as highlighted in the special issue on HIVST by AIDS and Behavior (2014) and in the WHO's consolidated guidelines on HIV testing services (2015). While many of the concerns outlined here are also applicable to HTS delivered in other settings and via other methods (World Health Organization, 2014), efforts to explore appropriate HIVST approaches certainly need to be cognizant of these issues.

Ease of HIV RDT product use, HIVST instruction, and accuracy of results

Potential concerns about existing HIV RDTs include: variable test performance, accuracy and quality, ease of use, and the potential risk of user error in conducting the test or interpreting the result (Pant Pai and Klein, 2008). Most existing HIV RDT products are designed for professional use in assisted testing environments, and they would likely require modifications in labeling, packaging, and/or instruction for lay HIVST use (Peck 2014). In particular, HIVST may produce incorrect results in the hands of lay users if HIV RDTs are read too soon or incorrectly, if the RDT tests oral fluid rather than whole blood (reducing specificity), or if the test is performed within the 6–12 week window (i.e., the time between infection and when an assay can detect the production of antibodies) (Pant Pai & Klein, 2008; World Health Organization & UNAIDS, 2013).

Studies conducted in the US have demonstrated that improved instructions for self-testing can reduce the incidence of errors in using existing HIV RDTs for HIVST (Granade, Parekh, Phillips, & McDougal, 2004; Mavedzenge & Corbett, 2014). However, some studies elsewhere have demonstrated high rates of error and invalid results. A study in Singapore reported that a startling 85 percent of self-applied RDTs were performed incorrectly, and 56 percent of participants received an invalid result (Lee et al., 2007)—even though 90 percent

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of the self-testers (n=350) stated that they found the instructions clear and the test easy to use. (The study focused on the self-applied Abbott Determine HIV 1/2 blood-based RDT). Recent studies suggest that lay users have more difficulty performing blood-based HIV RDTs (Peck 2014); while other studies have examined the acceptability, interpretability, and specificity of self-testing with oral fluid-based tests (Choko et al., 2011; Macpherson et al., 2014). In Malawi, the rate of error among untrained, unsupervised users of an oral fluid-based RDT was only slightly higher than among health professionals (Pant Pai et al., 2013). Peck et al. (2014) conducted a study on the usability of five prototype tests for unsupervised self-testing in Kenya, Malawi, and South Africa. They found that among 33 participants using an oral fluid RDT and 117 using blood-based RDTs, fewer than 25 percent of all users performed the test correctly, suggesting that RDTs currently on the market may not be suitable for HIVST; at a minimum, they require more appropriate instructions in order to reduce errors in use by lay consumers. The researchers conclude that the ideal HIV self-test "requires pictorial instructions that are easy to understand, simple sample collection with integrated test components, fewer steps, and results that are easy to interpret" (Peck et al., 2014).

Psychological danger when HTS is decoupled from formal counseling

Historically, HIVST programs have been limited owing to the lack of sufficiently accurate HIV RDTs as well as unease about HIVST in the absence of adequate pre- and post-test psychosocial counseling and information have limited the pursuit of HIVST programs (Johnson et al., 2014). Recently, however, global policies have moved toward more routine and normalized approaches to HTS that do not emphasize the need for extensive pre-test counseling (Mavedzenge et al., 2013). Nevertheless, some public health practitioners continue to stress the importance of providing sufficient post-test counseling and links to care in the case of unsupervised HIVST (Pant Pai et al., 2013; Scott, 2014). Post-test counseling is an important source of prevention messaging as well as linkage to ongoing care, and it has been emphasized as a way to prevent adverse psychological outcomes including suicide attempts and denial of status (Pant Pai & Klein, 2008). As such, the mode and delivery of post-test counseling and support services will be an important consideration in any future HIVST program.

Difficulty in linking people to ongoing care and treatment

Access to formal post-test counseling and transmission of post-test information requires user motivation and initiative to make the initial contact with a health provider following a reactive HIV RDT result, whether by phone, internet, or in person. According to most national algorithms, a typical A1 screening test should not be considered conclusive. This means that HIVST efforts need to focus on ensuring that people who receive a reactive self-test result (outside a health care setting) are successfully linked to post-test information and ongoing care (Walensky & Bassett, 2011).

Scott (2014) points to the ethical dilemma created when HIVST is promoted in contexts where health authorities are struggling or failing to meet the current demand for ART services: user autonomy in learning their status may increase, without an equivalent increase in access to adequate follow-up care, treatment, and psychosocial support.

Unethical or illegal use or sale of HIVST commodities

Health care providers and public health professionals have voiced concern that HIVST, when performed without adequate planning and regulation, could increase the risks of coercive or non-consensual testing, as well as increased misuse or unregulated sale of RDTs, adverse psychosocial distress, or partner-focused violence (Pant Pai et al., 2013; Scott, 2014; World Health Organization, 2014).

A UNAIDS/WHO Policy Statement on HIV Testing sets forth the following list of factors to ensure respect, protection, and fulfillment of human rights standards and norms—especially important for mitigating risks presented by testing outside of clinical settings (World Health Organization & UNAIDS, 2013; (WHO, UNAIDS, Brocher Foundation, 2013; World Health Organization, 2014).

- Protections against stigma and discrimination, including in health care settings. Non-discrimination laws protect HIV-positive individuals in their employment, access to housing, and other benefits.
- Sufficient treatment availability and effective linkage to confirmatory testing, counseling and support. If HIV-positive individuals have limited options to access care and treatment, the potential risks of self-testing may outweigh the potential benefits.
- Issues concerning disclosure of HIV self-testing results to others, including sexual partners. Programs to address stigma are needed to encourage self-testers to disclose their status and seek confirmatory testing and support.
- Protections from coercion or discrimination for vulnerable populations, including possible use of HIV RDTs by employers, guardians, or others in authority without informed consent. Robust protections are needed to prevent risks of coercive testing.

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- Protection from violence and abuse especially for women and girls as a result of their HIV-positive status. Women and girls are most likely to face stigma, violence, and harassment when their HIV-positive status becomes known by their boyfriends, spouses, neighbors, and community members.
- Prevention of harm due to false results: either false positives, causing unnecessary psychological trauma, or false negatives, leading to unknown onward transmission.
- Monitoring of social harms, which should be incorporated in broader programs to reduce stigma and discrimination.
- Special consent procedures for adolescents.

Such issues should be addressed through a rights-based legal framework to supplement laws authorizing regulatory bodies to adopt HIVST implementing policies. Laws that permit and guide the use and sale of approved HIV RDTs OTC for self-testing purposes should include consequences for violations or misuse of HIVST products, in order to ensure that consumer and population protections are upheld.

Lack of guiding policy

Many proponents of HIVST argue that there is existing country-level demand for HIVST products and programs, but other practitioners caution that adequate evidence, policies, and regulatory controls are not yet in place to scale up HIVST programs in a safe and responsible way. In 2000, UNAIDS/WHO stated that, while HIVST and home-testing can increase the number of people who are tested, it is essential to "strengthen quality assurance and safeguards" on HIV home sample collection and self-tests before releasing these products widely (Mavedzenge et al., 2013; UNAIDS, 2000). Efforts to develop new HIV RDT products and to pursue HIVST programs must therefore be pursued within the parameters of the national testing policy, regulatory and importation laws, and other guiding HTS and HIVST policy.

Pursuing Programmatic Evidence for HIVST

In a systematic review, Pai et al. (2013) conclude that the privacy, anonymity, time savings, and convenience offered by HIVST have facilitated high accessibility of both supervised and unsupervised approaches across diverse global settings (Pant Pai et al., 2013). However, global bodies and researchers agree that more studies—preferably randomized controlled trials (RCTs) in resource-poor settings—are needed in order to guide effective design and implementation of global HIVST programs (Pant Pai et al., 2013; World Health Organization, 2014); (Figueroa et al., 2015). Though several pilots have already demonstrated the safety, accuracy, and acceptability of HIV RDTs for HIVST in certain contexts, there is not yet enough evidence on how to effectively implement these programs (World Health Organization, 2015).

The basic test requirements for an ideal HIVST product are specified in the ASSURED criteria for medical diagnostics in the developing world: Affordable, Sensitive, User-friendly, Rapid and robust, Equipment-free, and Delivered to those who need it (Mabey, Peeling, Ustianowski, & Perkins, 2004). However, the actual performance of a self-test in meeting those criteria depends on the features included by the manufacturer and also on the test's usability (Peck 2014). At present, there is limited data or programmatic evidence to guide the development of HIVST product prototypes and/or programmatic approaches to HIVST implementation (Peck 2014).

The WHO HIVST supplement outlines the following three areas of important consideration in exploring HIVST programs (World Health Organization, 2014): support provided to the user before the test, distribution of RDTs for self-testing, and support to the user after the test.

Support provided to the user before the test
Support to the individual seeking an HIV self-test begins by ensuring discreet and easy access to an HIV RDT in appropriate packaging (i.e., as a kit or system), ensuring that the kit components are of high quality, safe, and reliable. Test procurement and distribution must be carefully regulated. HIV RDTs being marketed directly to consumers as part of "open-access" approaches will need to address a range of languages and literacy levels, provide pictorial instructions, contain simple components with easy application, and provide clear interpretation of results (Peck et al., 2014). In any case, providing sufficient pre-test instruction to the user will be key to reducing the incidence of incorrect results, as well as to prepare users to seek out appropriate follow-up after the test.

Distribution of RDTs for HIVST
Governments and health authorities can choose from a range of HIV RDT distribution strategies that vary in level of restriction—ranging from limiting access to HIVST and RDTs to a clinical or health outreach setting, to promoting full "open access," with RDTs marketed directly to consumers via various retail outlets and market strategies.

Key HIVST Knowledge Gaps

- Influence on health-seeking behavior (before and after HIV test)
- Cost-effectiveness and impact of various HIVST approaches
- Feasibility and benefits in specific contexts
- Risks of substituting other HTS approaches with HIVST
- Percentage of people with a reactive HIVST result who obtain confirmatory testing
- Percentage of people diagnosed as HIV-positive who receive care and treatment
- Percentage of people diagnosed negative who are linked to prevention counseling

Source: Johnson, Baggaley, Forsythe, Van Rooyen, et al., 2014

Researchers and global health authorities have identified three possible models (World Health Organization, 2014):

- **Facility-based and clinically restricted**. A health care worker will instruct or supervise at least part of the testing process; or clinics could distribute RDTs for unsupervised HIVST.
- **Community outreach, semi-restricted**. In community-based HIV testing, community health workers or volunteers distribute the tests and may provide some support, such as instructions on use, explanations of how to read the results, counseling both before and after the test, and referrals.
- **Open access—over-the-counter (OTC) or by prescription**. Consumers obtain a test through public distribution or by purchasing it in a commercial outlet such as a retail pharmacy or grocery store, via the internet, or at kiosks and vending machines. In a liberal open access approach, individuals would be able to obtain the test easily and use it at any place and time they choose. A modified open access model might restrict sellers of HIV RDTs to those who have been trained to provide brief pre-test counseling and post-test (follow-up) support and referral. Another modified approach may be to make HIV RDT kits for HIVST available only by prescription.

Milma Kettunen/Global.finland.fi

The open access model of distributing HIV self-tests allows consumers to obtain them over the counter or by prescription.

Arne Hoel/World Bank

Support to the user after the test

The goal of any HTS program is to ensure that patients who receive a reactive result are provided with supportive post-test counseling and are successfully connected to ongoing care, treatment, and support. Numerous retention studies have highlighted the challenges in achieving these outcomes, with high loss to follow-up (LTF) occurring between receiving a positive HIV result and initiating appropriate ART therapy (Rosen & Fox, 2011). Most national testing algorithms will require confirmatory testing after a self-performed HIV RDT, making it especially important that the test instructions and mode of delivery incorporate strong post-test instructions that emphasize result confirmation and links to support. Telephone hotlines or internet-based options are promising for providing both pre-HIVST instructions and post-test information and support (Allais & Venter, 2014; Peck et al., 2014; Scott, 2014; van Zyl, Brown, & Pahl, 2015). However, lessons from mobile and community-based primary health care efforts have demonstrated that, although increased community level access to HTS and other disease screening yields a high number of individuals being screened for disease, successful post-test linkage to care for HIV, TB, and non-communicable diseases remains a significant challenge (Bassett et al., 2014; Govindasamy et al., 2013; Mugglin et al., 2012). Any approach to HIVST will need to support users in taking the next steps along the continuum of HIV testing and care, expediting their next health care contact. As with HTS provided in any setting, HIVST programs will also need to address how stigma and discrimination might discourage self-testers with a reactive result from seeking follow-up facility-based confirmation and care.

HIV self-testing policies can be informed by experience with self-testing options for other conditions such as malaria, or pregnancy (Jacobs et al., 2014); (Mbonye et al., 2014). Although an HIV diagnosis raises complex issues such as risks of stigma and discrimination, all self-applied medical diagnostic products raise potential concerns related to product accuracy and quality, appropriate use, and follow-up care and support. The long-standing acceptability of self-performed pregnancy or malaria testing, and especially the development of numerous at-home tests that have been introduced to markets around the world, could be informative in designing consumer-focused HIV RDTs.

POLICY, LEGAL, AND REGULATORY ENVIRONMENT RELATED TO HIVST AND RDTS

As part of this assessment, SHOPS conducted a brief scan of the policy and regulatory environment affecting both the commercial sale of HIV RDTs and the user's experience of an HIV self-test. A review of global and national policies, laws, and guidelines revealed that legal policies, regulation, and programmatic guidance surrounding commercial purchase and use of HIV RDTs for HIVST are still evolving globally.

National Policies and Regulations: Global Overview

National policies, regulations, and laws related to the use of HIV RDTs for HIVST are at various stages of development globally. While many countries are assessing the option of making HIV-RDTs widely available OTC, or via other commercial distribution methods, other policymakers have been more cautious, citing concerns over accuracy of results, potentially negative psychological responses, and the need to ensure adequate linkages to care for those who test HIV positive (Mavedzenge et al., 2013). Several countries have made HIVST illegal, including Botswana (Southern Africa AIDS Trust, 2014), Uganda[3] (Uganda Ministry of Health, 2010), Singapore (Abu Baker, 2011), and Germany (Deutsche AIDS-Hilfe, 2013). At the other end of the spectrum, several countries have made HIVST legal and have begun the process of registering and distributing HIV RDTs OTC, including Australia, China, France, Kenya, and South Africa (World Health Organization, 2015).

Table 1. National HIVST Policies

HIVST policy in place; HIVST product licensed and registered	HIVST policy in place; no HIVST product registered or licensed	HIVST policy in development	HIVST explicitly illegal
France	Australia	Canada	Botswana
United Kingdom	China	Brazil	Germany
United States	Kenya	Malawi	Singapore
	South Africa	Tanzania	Uganda
		Thailand	
		Zambia	
		Zimbabwe	

In 2012, the United States Food and Drug Administration (FDA) became the first national regulatory body to approve the commercial/OTC sale of an HIV RDT (the OraQuick in-home oral fluid test) for the purpose of HIVST (OraSure Technologies, 2015; Wong et al., 2014). The UK made HIVST legal in April 2015 and recently approved BioSure, a blood-based HIV RDT for home-based HIVST, which went on sale in the UK in April 2015 (BioSure, 2015; Mundasad, 2015). The Autotest VIH (blood-based RDT) went on sale in France in September 2015 (AAZ, 2015). Kenya's National Guidelines for HIV Testing and Counseling made HIVST legal and set out specific requirements for HIVST products, but to our knowledge HIVST polices have not yet been operationalized (Mavedzenge et al., 2013; National AIDS and STI Control Programme, 2009; Wong et al., 2014).

[3] HIVST is not currently legal in Uganda. However, there are ongoing pilots of HIVST there which suggest that the policy environment may change. See "Thematic Window HIV Self-Testing, Uganda," http://www.3ieimpact.org/funding/thematic-window/thematic-window-hiv/thematic-window-hiv-self-testing-uganda/ (accessed October 15, 2015).

Since the WHO's publication of the HIVST supplement to the 2013 Consolidated Guidelines, many countries have legalized or announced their intention to legalize OTC sales of HIV RDTs for HIVST, but most of these have yet to register and approve specific products for HIVST and release them on the market (Wong et al., 2014). In Australia, prospective suppliers have been invited to apply for registration of HIV RDTs intended for personal home use, but none has yet been evaluated or approved by the Australian Therapeutic Goods Administration (Therapeutic Goods Administration, 2014). Other countries still developing policies on HIVST and moving towards legalizing it include Canada (Broeckaert, 2014), Brazil (Lippman et al., 2014), Thailand (Phanuphak, 2015), Zambia (Southern Africa AIDS Trust, 2014), and Zimbabwe (Eyewitness News, 2015).

Table 2. Globally Registered HIVST Products

Manufacturer & Product	Specimen Collection	Regulatory Approval	Country License/ Registered for Use
BioSure	Blood (finger-prick)	UK Medicines and Healthcare Products Agency; European Medicines Agency; CE*	UK
OraQuick In-Home HIV test	Oral-fluid	US Food and Drug Administration; CE*	USA
Autotest VIH	Blood (finger-prick)	French National Agency for Medicines and Health Products Safety, European Medicines Agency, CE*	France

**CE is "Conformite Europeenne," or required conformity marking for medical devices manufactured or sold in the European Community.*

Source: http://www.hivst.org/hiv-rapid-diagnostic-tests-for-hivst

In many resource-limited settings, medical device regulation is not yet well-developed or enforced; thus, HIV RDTs may still be available OTC or via other commercial sources even if not approved by law. South Africa, for instance, has little medical device regulation; HIV RDTs can legally be sold by certain stores and online retailers, but are not available OTC in pharmacies (Wong et al., 2014). In 2012 and 2014, the South African HIV Clinician's Society expressed support for HIVST, but only if it is carefully regulated to ensure that consumers have adequate information and linkages to post-test care (HIVST.org, 2015; Richter, Venter, Gray, & Lim, 2012). With these priorities in mind, South Africa is currently reviewing its HIVST policies and regulations (HIVST.org, 2015; Richter et al., 2012).

In Namibia, HIV RDTs for HIVST are legal and controlled by general medical device regulation, but there are no specific polices or regulations for HIV RDTs for HIVST specifically (Wong et al., 2014). An AIDSTAR assessment team found that RDTs were available at private pharmacies in Namibia despite this lack of regulation (Nersesian, Hullsmann, Cloutier, & Chintalova-Dallas, 2013).

Policy Guidelines

A range of procedural and safety issues should be addressed by policies covering HIVST and commercial/OTC sale of HIV RDTs for HIVST. The following three issues were noted in all discussions of HIVST (Ibitoye, Frasca, Giguere, & Carballo-Diéguez, 2014; Mavedzenge et al., 2013; Nersesian et al., 2013; Wong et al., 2014; World Health Organization, 2014).

- Authorization of HIV self-testing should be limited to specific conditions, including where and by whom the test can be performed.
- Clear standard operating procedures must ensure that health care providers do not treat reported reactive HIVST results as confirmatory, instead encouraging clients to receive a confirmatory test, as directed by national diagnostic and treatment algorithms for HIV.
- Directives and guidelines are needed to ensure post-test linkage to counseling and care, including follow-up and referrals.

Product Regulation

In addition to a broad testing policy and strategy, national governments can create specific laws and regulations to govern the use and quality of HIV RDTs for HIVST. Given that HIV RDTs are considered medical devices that carry risks if not regulated and used properly (Wong et al., 2014), product registration, distribution, and surveillance will likely be governed by national policies pertaining to regulation of general medical devices. Quality assurance (QA) processes for HIV RDTs include standards similar to those applied to other medical devices and products, including adequate pre-market testing, quality assurance, and communicating information to consumers on risks. Not all countries currently regulate the sale of medical devices (Preston, Valdez, & Bond, 2012). For instance, a 2013 AIDSTAR-One assessment confirmed that in Namibia, medical devices are considered unscheduled products and sold OTC without restriction (Nersesian et al., 2013).

For those countries that do regulate medical devices, typical regulations include the following (Preston et al., 2012; World Health Organization, 2003):

- Procedures for registering, importing, and distributing products, including licensing of distributors
- Procedures for quality testing specific batches for meeting minimum qualification standards on sensitivity, accuracy and ease of use, and monitoring of adverse outcomes
- Packaging requirements and instruction for use, with pre-test and post-test information on performing and interpreting the test, actions to be taken, and consultations required, validated in country-specific context
- Marketing and advertising guidelines to ensure informed public education on product use, with appropriate ease of test use and interpretation of results
- Rules to provide evidence of quality manufacturing processes and temperature stability data
- Packaging identification of product type, production lots, and expiration date
- Rules regarding scope of practice, training requirements, and enforcement for pharmacists or other persons involved in the sales of medical devices
- Post-marketing surveillance requirements, such as safety reports and monitoring of user adherence to medical device directions

Monitoring and Enforcement

Many developing countries have limited resources to invest in monitoring and enforcing regulations pertaining to medical devices. The East Africa Community Regional Task Force of the Pan-African Harmonization Working Party (PAHWP), representing Tanzania, Kenya, Uganda, Burundi, and Rwanda, conducted a baseline regulatory survey in 2012 that confirmed weaknesses in the regulatory processes for medical devices across all five countries. Problems included absent or limited regulations as well as inadequate capacity of national regulatory authorities to enforce standards. Similarly, an analysis of South Africa's regulatory barriers to HIVST noted that pharmacy standards prohibit the sale to consumers of HIV RDTs in pharmacies—but because there are no regulations yet in place for medical devices generally, marketing in grocery stores and other retail establishments is permitted (Richter et al., 2012).

In general, strong monitoring and enforcement of HIV RDTs would include four components (Wong et al., 2014):

- Oversight of importation, transport, and storage of HIV RDTs
- Post-market surveillance, including channels for reporting and redress in the event of unapproved or poor-quality diagnostic tests
- Training and supervision of personnel involved in the distribution, sale, re-testing, and counseling of end-users of HIV RDTs
- Alignment of approved HIV RDT products with national algorithms for diagnosis of HIV

As global implementing agencies and national governments consider their policies on HIVST along with the role of various HIV RDTs in that strategy, the development of comprehensive legal and regulatory policies will be critical to guide consumers, commercial retailers, and providers in ensuring patient safety.

METHODOLOGY

In coordination with the United States Agency for International Development (USAID), SHOPS selected four countries for this assessment of OTC availability of HIV RDTs: Kenya, Malawi, Tanzania, and Uganda. These countries were chosen based on anecdotal evidence and local information suggesting that HIV RDTs were already available for self-testing in some settings. SHOPS also explored the possibility of conducting the same assessment in four other countries—Cote d'Ivoire, Zambia, India, and Vietnam—but found no evidence that RDTs were being systematically sold OTC.

SHOPS conducted a thorough assessment of OTC availability of HIV RDTs in those four countries, with the following specific objectives:

1. To ascertain whether HIV RDTs are being sold OTC in private pharmacies
2. To document laws and regulations regarding HIVST as well as the distribution, sale and use of HIV RDTs
3. To identify potential sources of HIV RDTs sold in private pharmacies

Components

The study used mixed research methods that included (a) a brief desk review of global literature on HIV RDTs; (b) open-ended interviews with pharmacy staff regarding OTC sale of HIV RDTs; and (c) key informant interviews with stakeholders from both the public and private sectors in each of the four countries.

a) The brief desk review of global literature focused on HIV rapid-diagnostic tests in general, with emphasis on the suitability of HIV RDTs for use in resource-constrained settings as well as empirical evidence on the benefits, potential impact, and risks associated with HIV RDTs. The findings from the desk review are presented in the introduction of this report.

   As part of this desk review, SHOPS also identified and analyzed relevant laws, regulations, and policy documents (where available), both globally and in each of the four countries, focusing on the following topics:

- National HIV protocols and strategies
- Formal classification of HIV RDTs within the regulatory structure of pharmaceuticals and medical devices
- Existence of any formal approval processes for registering and regulating HIV RDTs
- Existence of approved HIV RDTs for commercial or OTC sale
- Enforcement authority to oversee compliance with regulatory requirements for commercial sale of HIV RDTs
- Requirements for training of pharmacists and assistants relevant to HIV RDT sales
- Norms and regulations for packaging and promotion of HIV RDTs for direct-to-consumer distribution
- Processes for linkages to confirmatory testing and care under national diagnostic and treatment algorithms
- Ethical and legal issues related to HIV testing and counseling
- Programmatic approaches to HIV testing, including review of national HTS guidelines

The findings from this policy review are presented in the Policy, Legal, and Regulatory Environment section.

b) Open-ended interviews with pharmacy staff focused on commercial availability and sale of HIV RDTs, procurement source, magnitude of sales, and consumer demand for HIVST.

In close coordination with in-country SHOPS consultants, private pharmacies in each of the four countries were selected for interviews, using a two-step process. First, SHOPS identified a list of private pharmacies in the capital cities that could be visited for the open-ended interviews. Second, SHOPS categorized those pharmacies as located in low-income or high-income neighborhoods. Third, using a convenience-sampling methodology, SHOPS data collectors visited pharmacies in each category of neighborhood. The objective was to conduct approximately 5–8 interviews in each type of neighborhood, until responses across the pharmacies were similar.

SHOPS visited and interviewed staff in a total of 55 pharmacies: 12 pharmacies in Nairobi (Kenya), 19 in Lilongwe (Malawi), 12 in Dar-es-Salaam (Tanzania), and 12 in Kampala (Uganda). All interviews were conducted in the capital cities with the exception of Tanzania and Uganda, where SHOPS visited a few pharmacies outside the capital to take advantage of consultants conducting similar work in peri-urban areas. The interviews were not recorded; the interviewers took detailed notes.

c) Open-ended interviews were conducted with key informants or stakeholders from the public and private health sectors in each country, to gain a better understanding of how HTS guidelines were being operationalized, to explore the potential role of HIV RDTs, and to ascertain attitudes and beliefs regarding HIVST. The interview guides were designed as semi-structured interviews, allowing data collectors to react to and explore informant responses.

Key stakeholders interviewed in each country included representatives from the Ministry of Health, National HIV and AIDS Councils, pharmaceutical associations, central medical stores, and suppliers and distributors.

In addition, after finding preliminarily confirmation that consumers were able to purchase constituent components of HIV RDTs (i.e., the blood sample test strip), at USAID's request SHOPS interviewed representatives of leading NGOs in each country to ask about informal or formal OTC sale of HIV RDT kits or components. SHOPS identified a short list of reputable and large NGOs operating in each country, to interview their managers or directors.[4]

[4] For this last part of the assessment, SHOPS hired the following consultants: Minnie Wanja Gitau (pharmaceutical consultant for Kenya), Kelvin Balakasi (HIV research consultant for Malawi), Erick Msoffe (Private sector HIV consultant for Tanzania), and Dr. Dennis Buluma (National Program Coordinator, SHOPS, Uganda).

Limitations of This Assessment

The findings of this report have some limitations in terms of external validity. Our sample of pharmacies was drawn mainly from capital cities (46 out of 55), while the rest were from peri-urban areas in Tanzania and Uganda. Interviews were limited to between 12 and 19 facilities in each country. The small sample size and urban concentration of pharmacies makes it impossible to make conclusive statements regarding OTC availability of HIV RDTs nationwide in the four countries. In addition, SHOPS did not collect data from other commercial settings, such as private sector outlets, laboratories, private practitioners' offices, hospitals, or potential vendors in informal settings. However, the pharmacies included in the assessment provide important information in forming a general picture of OTC availability of HIV RDTs in four capital cities.

The sale and distribution of HIV RDTs can be a contentious issue in some settings, and it is highly possible that some of the staff interviewed at pharmacies were not entirely transparent regarding the availability or source of HIV RDTs at their facility. Reliance on self-reported information limits the validity of the findings we obtained. Future studies on this topic could benefit from mystery client surveys.

Regarding the key informant interviews, participation was entirely voluntary and no incentives were provided, both favorable factors for the validity and neutrality of our findings. However, in a few cases, a stakeholder was not available to be interviewed or even opted to discontinue an interview, citing either lack of time or unwillingness to divulge sensitive information related to HIV RDTs.

Responses from NGO representatives were limited, as this component was added to the assessment during the final days of data collection. One final limitation is that SHOPS did not interview end-users or potential consumers of HIV RDTs, which would provide information about potential consumer demand for HIVST and OTC HIV RDTs, potential motivation for buying an HIV RDTs OTC (or not), and preferred points of purchase. Future studies on this topic should consider interviewing potential and actual users of HIV RDTs in a range of contexts. Finally, while the original scope of the assessment included an analysis of market size, this was not possible, given that HIV RDTs for HIVST have not yet been registered, packaged, or distributed directly to consumers in any of the four countries.

FINDINGS: LEGAL AND REGULATORY SUMMARY IN FOCUS COUNTRIES

Table 3 shows the four focus countries along a continuum related to regulatory restriction or permission of HIVST and the sale of HIV RDTs in private retail establishments. Note that there is some uncertainty about the legality of OTC sales of HIV RDTs, where policies do not specifically address this question. Elements considered include the country's policy guidelines, product regulations, and post-market surveillance and enforcement activities, if any.

Table 3. Regulation of OTC Sale of HIV RDTs for Self-Testing in Four Focus Countries

Policy Guidelines on HIVST		
Uganda: National Implementation Guidelines for HIV Counseling and Testing in Uganda explicitly prohibit clients from performing their own HIV tests (Ministry of Health of the Republic of Uganda, 2010).	**Tanzania's** (National AIDS Control Programme, 2012) and **Malawi's** national HIV guidelines (National AIDS Commission, 2009) do not address HIV self-testing. Rules governing all lab procedures apply. In **Tanzania**, all clinical tests are defined as lab procedures and must be conducted by qualified personnel in clinics or hospitals. In **Malawi**, all tests are considered lab procedures and thus they may only be used under supervision of trained health workers.	**Kenya**: The 2009 national guidelines acknowledge the potential for self-testing but policies have not yet been operationalized (Kenya Ministry of Public Health and Sanitation, 2009). Research studies are underway to address policies related to packaging and instructions, age of consent, disclosure and re-testing.
Product Regulations		
Uganda: The National Drug Authority that regulates manufacture, importation and distribution of pharmaceuticals in the country has specifically prohibited the sale or use of HIV RDTs for self-testing.	**Tanzania:** Only registered products may be imported (TFDA, 2015). As of November 2013, no HIV RDTs were registered for self-use (TFDA, 2013).	**Kenya**: Pharmacy, Medicines, and Poisons Board has a mandate (March 2014) to register RDTs; it is in process of listing RDTs currently available in the country as a first step toward legal registration for OTC distribution. **Malawi**: HIV RDTs are treated as any commodity, legally sold as long as they are registered with the Pharmacy, Medicines and Poisons Board, following pre-market testing at the Community Health Sciences Unit HIV Testing Laboratory.

As Table 3 shows, the four countries vary in their inclusion of HIVST in national policies and guidelines, with only Uganda explicitly prohibiting it. Similarly, although policies in each country give the pharmacy or drug board the mandate to register and regulate health commodities (including HIV RDTs), there is little mention of the procurement, distribution, and sale of HIV RDTs directly to consumers for self-testing purposes. As the following detailed country reports demonstrate, availability of HIV RDTs (or their constituent parts) was nearly the same across the four countries, despite the varied policy contexts. This assessment found that there are currently no operational guidelines or regulations to promote, inform, or oversee the sale of HIV RDTs directly to consumers in any of the four countries.

FINDINGS: KENYA

Kenya has a generalized HIV epidemic, especially concentrated in key populations. Table 4 presents some indicators for the country.

Prevalence in Kenya peaked in 1996 and then declined by about 40 percent per year until 2003; it has since remained stable. Infection rates are higher among urban residents, but the difference between urban and rural rates is not as pronounced as in other countries.

Table 4. Key HIV Indicators, Kenya

HIV Indicators	
Adult (15–49) prevalence	6.0%
Estimated adults (15+) living with HIV	1.4M
Estimated women (15+) living with HIV	820,000 (59%)
Estimated children (0–14) living with HIV	190,000
Percentage of women and men aged 15–49 who received an HIV test in the past 12 months and received their results	72% (ever tested) 47.3% women 35.8% men
Percentage of pregnant women who were tested for HIV and received their results	92.2%

Source: UNAIDS, 2013; Kenya AIDS Indicator Survey, 2012; Kenya AIDS Response Progress Report.

Legal and Regulatory Environment for OTC Sale of RDTs

Kenya is the only sub-Saharan African country to adopt national guidelines supporting the provision of RDTs and kits for self-testing (National AIDS and STI Control Programme, 2009). This approach is consistent with WHO guidelines on HIV self-testing, which note the benefits of self-testing among people not currently reached by existing HIV testing and counseling services (World Health Organization, 2014). In contrast to neighboring Uganda, where sale of RDTs is completely prohibited, the sale of RDTs outside of clinical settings in Kenya is not prohibited but is subject to loosely defined rules still in development: “clients can access test kits from pharmacies and other approved suppliers” (National AIDS and STI Control Programme, 2009).

Status of RDTs for self-testing

Under the 2009 Guidelines, new rules governing RDT sales and use are anticipated but have not yet been adopted. The regulations will include revised

job aids, training manuals, and monitoring and evaluation tools to support OTC sales. However, with no rules in place regulating the OTC sales of RDTs, retailers in non-clinic settings face uncertainty. This uncertainty is not unique to HIV, however; similar debates in Kenya concern the OTC sales of malaria RDTs (Rusk et al., 2013).

One factor contributing to the regulatory lag is the lack of demonstrable research and evidence to develop best practices for navigating the benefits and risks of self-testing programs. The National AIDS and STI Control Programme (NASCOP), in collaboration with the International Initiative for Impact Evaluation (3ie), is actively addressing this gap, with research studies underway in the following areas (Kabiru, Sidze, Egondi, Osok, & Izugbara, 2014):

- Understanding user needs and preferences for self-testing information
- Ensuring accurate use through appropriate packaging and labelling for self-test kit information
- Promoting linkages to post-test confirmation, diagnosis, counseling, and uptake to care
- Designing approaches that promote user self-referral to additional points of care

The International Initiative for Impact Evaluation (3ie) has begun to release the preliminary results from its studies. These findings and recommendations will help inform how HIV test kits are packaged, marketed, sold, and used for self-testing. In addition, the U.S. Centers for Disease Control and Prevention is conducting similar studies on self-testing by sex workers (International Initiative for Impact Evaluation, 2015).

Kenya's HIV policy and regulatory environment involves several different agencies. These public sector organizations develop guidelines for HIV-related services, enforce policies, and oversee the delivery of HIV-related services (see Table 5).

Table 5. Key Public Sector Actors in Kenya's HIV Regulatory Environment

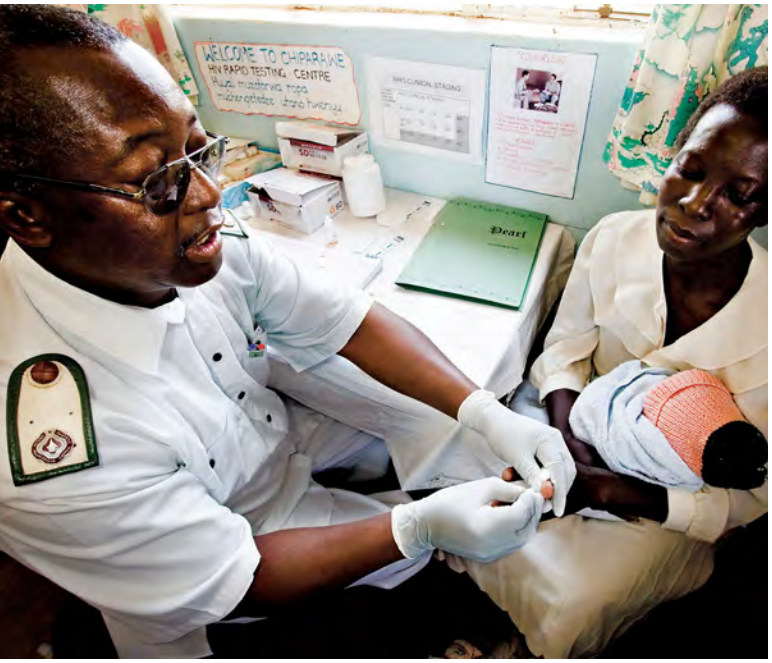
Agency	Role
Kenya Medical Laboratory Technicians and Technologists Board	Registers and accredits medical lab technicians and premises
Kenya Medical Research Institute	Conducts research; currently carrying out a study with the U.S. Centers for Disease Control and Prevention on self-testing among commercial sex workers
Ministry of Health	Provides overall policy for the country for HIV and all other disease areas
National AIDS and STI Control Programme	Develops and implements all policies and guidelines relevant to HIV and AIDS and sexually transmitted infections
National Blood Safety Committee	Evaluates and approves RDTs in Kenya
National Public Health Laboratories	Conducts quality checks on RDTs and HIV commodities; currently lacks capacity and awaits guidance and resources
Pharmacy and Poisons Board (PPB)	Lists RDTs present in the country and approves import licenses

The *Guidelines for HIV Testing and Counseling* in Kenya detail the types of HTS recommended in the country (National AIDS and STI Control Programme, 2009). The main approaches for HTS are:

- **Client-initiated**. An individual or couple actively seeks out HIV testing and counseling at a facility-based, community, or mobile site where these services are available.
- **Provider-initiated**. HTS service provider offers and/or provides an HIV test to patients, regardless of their reasons for attending the facility.

Self-testing for HIV falls into an undefined category. The guidelines give a general description of self-testing and how it should be done, while acknowledging the lack of a proper legal framework. It also recognizes recent advances in testing technology that make self-testing possible.

The National AIDS and STI Control Programme and the Ministry of Health have not yet endorsed self-testing for HIV, because they do not have the means to implement and enforce their minimum standards. They identify the following requirements for self-testing implementation (National AIDS and STI Control Programme, 2009):



U. K. Department for International Development

- HIV RDTs and test kit/system components must be evaluated, pass quality control, and be approved for use in Kenya.
- RDTs and any relevant kit components must be used before the expiration date.
- Storage conditions must be adequate and controlled.
- Pharmacists must be trained and accredited to dispense kits, counsel patients, and demonstrate the use of HIV RDTs for self-testing purposes.
- Follow-up and referral services, including services for confirming positive test results, must be accessible for all clients.

A representative from NASCOP referred to page 5 of the guidelines, which states that vendors must inform clients how to conduct the test and how to correctly interpret the results. Clients must also be informed that they must take a confirmatory test if the result is positive, with guidance to access follow-up and support services in the nearby area.

Regulation of RDT sales and use

HIV RDTs and kits are classified as medical devices and thus should adhere to regulations for diagnostic tests. Currently the rules in place by PPB require that:

- All diagnostic tests be conducted by trained staff
- Drug outlets that provide diagnostic tests be registered with PPB
- Operators of drug outlets be licensed by PPB

In reality, many pharmacies do not have up-to-date registrations, and many staff at retail outlets are not adequately trained or supervised by licensed pharmacists (Rusk et al., 2013). In a research study in Kenya on barriers to availability of malaria RDTs in retail shops, medicine retailers expressed concerns that carrying the tests would garner the attention of the regulatory board, including to unregistered outlets. Additional concerns include cost burdens, such as hiring and training staff to dispense, counsel, or demonstrate the use of the test kits to clients. This restrictive but lightly enforced regulatory environment contributes to a grey zone of market activities, making it difficult to track supply chains and document RDT product sources.

RDT evaluation and quality assurance

Kenya has quality assurance (QA) standards governing the evaluation and approval of medical devices, including registration and import criteria. QA includes rigorous evaluation and approval processes in national labs and post-market surveillance assessments. The PPB of Kenya was recently authorized to carry out the registration of HIV RDTs. As a first step towards registration, PPB is in the process of listing the RDTs that are available on the market. This reflects the reality that wholesalers and importers are currently providing RDTs to pharmacies outside of the formal quality assurance processes, due to regulatory lag in this area. It is anticipated that there will be increased access as well as increased controls in the future.

The Kenya Medical Laboratory Technicians and Technologists Board is mandated to register all test kits, laboratories, and technicians. Currently, this board is in the process of developing protocols relating to the registration and quality assurance of HIV RDTs.

The Kenya Medical Research Institute also conducts studies on those RDTs that have been prequalified by WHO, to ensure that they are sensitive and appropriate in the Kenyan context.

The Kenya Bureau of Standards checks the quality of all RDTs, and the National Public Health Laboratories monitor the quality and standards of HIV RDTs. To date, the PPB does not have protocols for registration of RDTs and other diagnostic tests, but it is in the process of developing them for all diagnostic equipment.

There are currently two types of RDTs available for use in facilities in Kenya: Uni-Gold and Determine. NASCOP, however, is in the process of replacing both tests with two others: the KHB (KHB Shanghai Kehua Bio-engineering Co. Ltd, China) screening test, and First Response confirmatory test. NASCOP reported that KHB is less expensive than Determine, and they consider it more reliable.

OTC Sales

Several HIV RDTs are in the process of product registration for OTC sale in pharmacies, labs, and medical clinics. They cannot be sold in other commercial establishments. All pharmacies meet the same requirements and are registered the same way; pharmacies are run either by a pharmacist or a pharmaceutical technologist.

The SHOPS consultant surveyed 12 pharmacies in the Nairobi area, in neighborhoods of all income levels. Only three of the 12 pharmacies had RDTs in stock, and none sold RDTs in a kit or system packaged specifically for self-testing. These three pharmacies sold the RDT blood sample test strips and the buffer solution separately. The buffer solution was sold in a bottle containing enough for several tests. The HIV RDT test strips were priced at Ksh 100–200 (USD $1–2).

Pharmacy staff reported that the main purchasers of these HIV RDTs were health providers who administered tests in their facilities. One of the pharmacies that stocked the RDT had its own lab on the premises, in which it performed confirmatory tests both for clients who independently requested it and for those referred by a doctor.

The HIV RDT brand found in all three pharmacies was the Alere Determine HIV-1/2 blood-based antibody test. None of the pharmacists offered instructions or counseling before or after the sale of the HIV RDT. The only instruction given with the sale in one of the pharmacies was that the strips did not come with a buffer solution, and the buyer would have to purchase the buffer to carry out the test.

Two out of three Alere Determine HIV RDTs sampled at the facilities had instructions for performing the test. However, these instructions were directed at health care providers and not lay individuals who would be self-applying a test.

Notably, the Alere Determine HIV RDT found in the three pharmacies is the same brand used in the public sector. This assessment did not investigate whether the tests available in the private pharmacies were procured via “leakage” from the public sector (i.e., unapproved movement of a subsidized commodity), or whether private pharmacies had procured them via wholesale. Lack of an included reagent at all three pharmacies, and incomplete test components at one, does raise questions about the source of these available RDTs.

Pharmaceutical Organizations

The Pharmaceutical Society of Kenya (PSK) follows the NASCOP guidelines on HTS; it does not have independent guidelines on this issue. PSK is awaiting clear direction from NASCOP before promoting RDTs for self-testing among its members.

The Kenya Association of Pharmaceutical Technologists is not accredited for HTS and is not involved with any kind of HIV testing. The association covers 3,000 pharmacies owned by pharmaceutical technologists.

Main Suppliers and Distributors

Table 6 below lists the main brands and suppliers of RDTs in Kenya for the public and private sectors.

The distributors listed are large wholesale distributors that supply products throughout the country and the region. It was not possible to obtain reliable information to estimate the size of the market, because none of the suppliers/distributors had information regarding supply to private pharmacies. The largest sales were to larger private hospitals or facilities.

Importers are usually the primary market distributors of the product. They have contractual agreements with the manufacturers, either exclusive or allowing the manufacturer to have one or two other market representatives. The importer supplies the product to the retail or end-user facility, either directly or through a sub-distributor. The sub-distributors supply the product based on the demand from the market. They are not tied to any particular brand.

Table 6. Main Brands and Suppliers of RDTs, Kenya

Importer and Distributor	RDT Brand Name	Manufacturer	Country Origin
Faram East Africa Ltd.	Alere Determine HIV 1/2	Alere Medical Co Ltd.	Japan
Chemoquip Ltd.	Retrocheck/Retroscreen	Qualpro Diagnostics	India
Tempharma Solutions Ltd.	Onsite Rapid Test	Onsite Health Diagnostics	USA
Chemlabs	Hexagon HIV	Human Diagnostics	Germany
Macmed Healthcare (K) Ltd.	Alere Determine HIV 1/2	Alere Medical Co Ltd.	Japan
Pacelab Laboratories	Uni-Gold Recombigen	Trinity Biotech Manufacturing Ltd.	Ireland
Omaera Pharmaceuticals	SD Bioline HIV Ag/Ab Combo	Standard Diagnostics, Inc.	Korea

Faram EA Ltd. supplies AlereDetermine HIV 1/2 RDTs from Alere Medical Company, Ltd. to the government. In 2013, government sales amounted to 28,200 packs of 100, while private sector sales were fewer than 20 packs of 100, mainly to NGOs.

All the interviewees agree there is black market for RDTs within the country (and sometimes in neighboring countries), but none was able to describe or quantify it. A representative at Faram was aware of black market challenges that destabilize the price of HIV RDTs and kits. He said that the landing cost for Faram's kit is KES 9000 (USD $91) each, yet the kits in the black market are sold to clinics and private health facilities at about KES 3000 (USD $30).

NGO Feedback on Self-Testing

The SHOPS consultant also interviewed four NGOs to document their insights about using RDTs for self-testing, including whether they believe their beneficiaries use this method. Overall, the NGOs reported compliance with NASCOP policies; they did not implement or otherwise support self-testing programs. Some, however, spoke in favor of a policy to facilitate self-testing.

The Kenya AIDS NGOs Consortium (KANCO) is a national membership network comprising NGOs, community-based organizations (CBOs), faith-based organizations (FBOs), private sector groups, and public health research and learning institutions involved in HIV and AIDS. The Senior HIV/TB Advocacy Manager for KANCO informed SHOPS that they do not carry out nor are they aware of any initiatives towards self-testing for HIV. According to the Advocacy Manager, the key challenge is dealing with the situation of a positive test. They believe strongly that pre- and post-testing counseling is crucial to managing the outcomes of the test. They also believe that there is no gap that self-testing would address that is not handled by the voluntary counseling and testing (VCT) centers.

The National Empowerment Network of People Living with HIV/AIDS in Kenya (NEPHAK) is a national network that unites people living with HIV and those affected by TB, through post-test clubs, support groups, CBOs, NGOs, and networks. The Executive Director of NEPHAK said that they are not aware of any self-testing interventions; however they would be very supportive of self-testing to reach the high numbers of untested people who are not comfortable approaching formal VCT centers.

Population Services Kenya (PS Kenya) is the leader in social marketing to empower Kenyans to make healthy choices. The director of health service delivery and the HIV manager at PS Kenya are aware of current studies to inform policies on self-testing, and said that the organization has been involved in ongoing formative research. They are sure that there is currently no self-testing in Kenya, as it is not yet supported by NASCOP policy. Their perspective is that self-testing is crucial to ensure that more people become aware of their status, despite the potential negative reactions after testing. They also believe that more testing is always better, even if it creates a data gap in reporting. When self-testing becomes a legal option, PS Kenya sees the organization playing a supportive role in branding, distribution, and behavior change communication aligned with the self-testing kits.

Gold Star Kenya (GS Kenya) is a nonprofit, locally registered NGO and an affiliate of FHI 360. GS Kenya focuses on empowering communities for better health through collaboration with public and private sector partners. The director of the organization said that GS Kenya is not implementing and is not aware of any self-testing interventions in Kenya, because self-testing is not supported by any policy guidelines from NASCOP. They are aware that there have been some discussion and studies on the issue, but the director did not express an opinion on whether self-testing would be advisable and is waiting for more data on the subject.

Conclusions about Kenya

SHOPS found HIV RDTs for sale at three out of 12 private pharmacies in Kenya, all three selling incomplete, constituent parts (blood sample test strips or multi-test bottles of buffer solution). None of the three tests was specifically packaged or appropriate for self-testing. HIV stakeholders confirmed that HIVST is not yet supported by NASCOP regulations. Pharmacies that do sell RDTs report that they sell them to other health facilities, and they do not carry products packaged for direct to consumer or individual use. There was anecdotal evidence of black market sales from public facilities, but this was not quantified.

Beginning in 2009, Kenya has been a leader in sub-Saharan Africa in developing strategies and guidelines for sales of RDTs for HIV self-testing, but there is no regulatory framework in place. The guidelines approving HIVST are not yet operationalized, but significant research is underway to support safe and appropriate access through commercial outlets. 3ie research on user needs, informative packaging, and promotion will be key to inform product registration, pharmacist training, and adequate post-test linkages to care. Kenya is also actively reviewing its regulatory oversight of all medical devices as part of the PAHWP, but challenges will remain due to inadequate enforcement capacity.

FINDINGS: MALAWI

Malawi's HIV epidemic is generalized, with key populations carrying the heaviest burden of disease. Table 7 presents some key indicators within the country.

Table 7. Key HIV Indicators, Malawi

Key HIV Indicators	
Adult (15–49) prevalence	10.3%
Estimated adults (15+) living with HIV	850,000
Estimated women (15+) living with HIV	500,000 (59%)
Estimated children (0–14) living with HIV	170,000
Percentage of women and men aged 15–49 who received an HIV test in the past 12 months and received their results	71.6% women 51.2% men (data from 2010)
Percentage of pregnant women who were tested for HIV and received their results	83%

Source: UNAIDS, 2013; Global AIDS Progress Report, 2014.

HIV prevalence in Malawi among the general population has declined from 14 percent in 2011 to 10.3 percent in 2013 (Avert, 2015; Centers for Disease Control and Prevention, 2015). Prevalence varies by region, gender, and urban or rural setting. Urban dwellers have a higher prevalence as do women, who make up about 59 percent of people living with HIV and AIDS. Heterosexual intercourse is the main mode of transmission, accounting for close to 90 percent of new infections.

Legal and Regulatory Environment for OTC Sale of RDTs

Status of RDTs for self-testing

Malawi has no specific policies or guidelines regarding the use of HIV RDTs for self-testing. Neither the revised HIV Testing and Counseling Guidelines (2009) nor the Pharmacy Medicines and Poisons Act (1988) mentions the use of HIV RDTs for self-testing (Southern Africa AIDS Trust, 2014). Rules governing all medical laboratory tests and procedures apply to HTS using an HIV RDT, which must be done under the supervision of qualified clinical staff.

Three key players formulate HIV and AIDS policy: the Department of Nutrition, HIV and AIDS in the Office of the President and Cabinet; National AIDS Commission (NAC); and Ministry of Health (MOH). The Office of the President and Cabinet defines general policy directions and preferences of the government; the National AIDS Commission implements policies and provides feedback on successes and failures to the other two bodies; and MOH provides technical expertise. Table 8 summarizes these and other key players.

In 2014, Liverpool Welcome Trust began piloting a study on the use of RDTs for self-testing in Malawi, and these findings are expected to inform future guidelines on the topic (Correspondence with Ellious Chasukwa, National AIDS Commission, August 2014).

Table 8. Key Public Sector Actors in Malawi's HIV Regulatory Environment

Agency	Role
Ministry of Health	Provides strategic leadership in HIV and AIDS policy formulation, regulation, enforcement, and oversight in delivering services
Department of Nutrition, HIV and AIDS, Office of the President and Cabinet	Provides policy direction, guidance, oversight, coordination, monitoring and evaluation; supports the creation of implementation facilities; builds capacity on issues of nutrition and HIV and AIDS
National AIDS Commission	Provides leadership and coordinates the national response to HIV and AIDS in Malawi
Community Health Sciences Unit	Provides national leadership in surveillance, research, prevention, and control of HIV and AIDS; ensures quality of HIV RDTs
Central Medical Stores	Procures and distributes HIV and AIDS drugs and HIV test kits
Pharmacy, Medicines, and Poisons Board	Regulates, registers, and controls the quality of drugs; directs registration, ethical conduct, and training of pharmaceutical professionals; regulates and registers pharmaceutical businesses; regulates clinical trials in Malawi

The National HIV Reference Laboratory (NHRL), established within the HIV/AIDS unit in the Ministry of Health, is mandated to evaluate new HIV RDTs and to make recommendations to MOH before the RDT can be released (National AIDS Commission, 2009). However, the unit would need financial and political support (through the Pharmacy, Medicines, and Poisons Act and Regulations) to ensure that only approved RDTs are being used by practitioners. Currently, there are no official policies in existence or being developed with regard to sale or use of RDTs for self-testing.

HTS in Malawi is provided through:

- Facility-based voluntary counseling and testing (VCT)
- Mobile testing, providing VCT from a van
- Moonlight testing, providing VCT in a mobile unit at night
- Door-to-door counselors who sensitize household members on the benefits of knowing their status and offer VCT services to those who want it
- Services for preventing mother-to-child transmission (PMTCT), when Option B+ is offered to pregnant women at antenatal clinics; pregnant women are encouraged but not required to take an HIV test[5]
- Provider-initiated testing and counseling (PITC)

[5] WHO's 2010 PMTCT guidance originally included Options A and B: providing pregnant and lactating women with ARV prophylaxis, but delaying lifelong ART initiation until clinically eligible. In Option B+, all pregnant women living with HIV are offered life-long ART, irrespective of their CD4 count.

Regulation of RDT sales and use

There are no policies specifically prohibiting or regulating the sale of HIV RDTs for self-testing purposes. Thus, anyone with a business license to trade in Malawi could conceivably sell or distribute HIV RDTs. In 2011, in response to government concerns over the quality of HIV RDTs being sold on the open market, the National Auditors Office issued a circular banning procurement of RDTs outside of formal channels established by the PMPB (Correspondence with Ellious Chasukwa, National AIDS Commission, July 2014).

RDT evaluation and quality assurance

The PMPB policies require that HIV diagnostic tests be registered with the Pharmacy Board (National AIDS Commission, 2009). NHRL is mandated to evaluate new HIV RDTs and make recommendations to MOH before a specific RDT can be used in the country. The NHRL unit does not currently have the resources or capacity to enforce this, or to ensure only approved RDTs are being used throughout the country. Currently some HIV RDT brands have been approved by NHRL. However, RDT distribution is not monitored by PMPB, and PMPB does not have adequate information on the suppliers and wholesalers currently offering HIV RDTs (Nation Online, 2013).

A broad law categorizes all medical tests as laboratory procedures and requires that tests be done under the supervision of trained health workers. This requirement means that unsupervised self-testing is essentially not permitted: testing must be carried out by qualified personnel in health facilities, community-based facilities, or mobile locations (Southern Africa AIDS Trust, 2014).

OTC Sales

SHOPS visited 19 pharmacies and drugstores in low- and high-income neighborhoods of Lilongwe. Three of these stores stocked HIV RDTs for sale to facilities, but none carried them packaged individually for self-testing. However, at one low-income area drug store, the pharmacist agreed to sell the consultant a test "off the books." The SHOPS consultant expressed interest and was sold a Uni-Gold blood sample test strip without any instructions or buffer solution. The cost was Malawi Kwacha 1500 (approximately USD $3). The shop assistant at another drug store (i.e., a retail outlet without a pharmacist) told the consultant that the store did not sell HIV RDTs, but the shop owner had a clinic in town where an HIV RDT could be purchased. The consultant went to the clinic and was told that the HIV RDTs were out of stock. Confident that stock would be received, the clinic took the consultant's number and called him the following day when stock became available. Upon returning to the clinic the consultant bought two Alere Determine HIV 1/2 blood sample test strips for MK 2500 (USD $5), and asked for the buffer solution to complete the kit. Initially, the owner said he had only a full bottle for MK 18,000 (USD $36) but eventually prepared a single dose of the buffer in a syringe for the negotiated price of MK 3,500 (USD $7). There were no written instructions provided, but the clinic owner oriented the consultant on how to use the test and interpret the results. He counseled him that if the result was positive, he should not "give up" but rather return to the clinic for a confirmatory test. No other instructions or test kit components (i.e., lancet, pipette, alcohol swab etc.) were mentioned or provided.

The consultant also visited 11 supermarkets and shops, but he did not find any test kits in these venues.

Finally, the consultant followed a lead for a black market purchase of RDT which was not successful. The seller wanted him to pay for the test before showing the product, which the consultant was not willing to do. The seller became worried, asking if he was trying to get him arrested. The interaction ended with no sale of merchandise or confirmation that the seller actually had a functional HIV RDT.

Position of pharmaceutical society

The pharmaceutical association is informal and could not be located during the SHOPS assessment.

Main suppliers and distributors

Rapid test kits are procured by Central Medical Stores with support from the Global Fund. Central Medical Stores distributes the tests to its three Regional Medical Stores, in the southern, central, and northern regions. The Regional Medical Stores then distribute the tests directly to all registered hospitals, clinics, and health centers free of charge,

regardless of whether they are public, private, or dependent on the Christian Health Association of Malawi. Per national guidance, the tests are in turn provided to the beneficiaries free of charge. Informants during the assessment reported periodic stock-outs of the tests, sometimes due to transportation challenges.

Many facilities collect their supplies directly from regional medical stores or from neighboring district or health center pharmacies, using their own transportation. These include "high consumption sites" as well as CBOs, FBOs, local NGOs, youth centers, and small standalone sites.

Uni-Gold, Bioline, and Alere Determine HIV 1/2 are the brands registered in the country (National AIDS Commission, 2009). Alere Determine is administered first, and Uni-Gold and Bioline are used as confirmatory tests.

The two national pharmaceutical suppliers, Pharmamed and Worldwide Pharmaceuticals, as well as a local supplier, Globemed, reported that while they did provide RDTs in the past, they did not sell RDTs packaged specifically for self-testing. They no longer supply RDTs because of low demand (since the government distributes tests at no charge) and the high prices they would have to charge to cover their cost. The brands they previously supplied were:

- Uni-Gold, manufactured by Trinity Biotech in Ireland and Ausdem in UK
- Bioline, manufactured by Standard Diagnostics in North Korea
- Alere Determine HIV 1/2, manufactured by Alere in Japan

In general, the suppliers were not eager to enter into the market for RDTs for various reasons. Profits would be harmed by cross-border competition, which is not regulated. Moreover, Malawi is not a branded market, which makes it unattractive for manufacturers to do business with its suppliers. (In a branded market, only specified brands of a commodity are allowed to trade.) The importation requirements allow anyone who has a business license to import and distribute tests, so pharmacies could bypass the suppliers to obtain RDTs. Other market forces that make the field unattractive are price fluctuations due to exchange rate changes and the large number of low-cost Chinese commodities available for sale that are not certified by WHO or the government.

Mike Dalious

NGO Feedback on Self-Testing

SHOPS's consultant spoke with a manager at the UNC Project-Malawi/Kamuzu Central Hospital, an NGO, about his perceptions of current HIVST practices. The informant said he was unaware of self-testing among the clientele and confirmed that the guidelines specify that only trained counselors can administer the HIV test. He noted that, although employees are not permitted to self-test (as clearly stipulated in their contracts), since they have access to RDTs they may be self-testing.

The consultant also interviewed a senior HIV counselor from Lighthouse, an NGO that provides testing and treatment for HIV and AIDS in Lilongwe. They are aware of the pilot studies for HIVST but do not participate in them. The senior counselor said that it was against the NGO's policies to permit employees to self-test, adding that Lighthouse has very good inventory control and is confident that no RDTs are being used for that purpose. He noted, however, that people can buy RDTs from public sector hospital employees who sell them unofficially.

The Lighthouse counselor also said that the employees have made many requests for RDTs for self-testing, and the management of the NGO is in favor of it. They are ready to provide it when the country's policies support HIVST. They are concerned, however, about the lack of counseling to accompany HIVST, but they believe that as the great fear of the epidemic has now subsided, people can be trusted to self-test.

Conclusions about Malawi

Malawi's current policies require HTS to be performed in the presence of trained clinical and non-clinical staff; however, research is underway exploring options and approaches to self-testing. Stakeholders within the NHRL highlight that any new regulations or approaches to HIVST or HIV RDT access will be insufficient if Malawi's regulatory agencies are not better resourced and staffed to oversee distribution of HIV RDTs outside a facility setting. Suppliers confirmed that as long as HIV RDTs can be imported and sold by anyone with a business license, there will not be a strong commercial market with adequate regulatory oversight.

Jessica Scranton

The SHOPS assessment found that a few pharmacies carried HIV RDTs packaged in bulk for sale to health facilities, but none carried RDTs specifically packaged for HIVST.[6] Pharmacists and other attendants interviewed stated that although regulations prohibit them from selling RDTs for self-testing, the sale is in fact legal as long as HIVST is supervised by a trained health worker. SHOPS found anecdotal evidence that clinical staff may sell HIV RDTs directly to individuals for their own use, out of the stock intended for facility-based testing; and with some effort, individuals can purchase materials to conduct self-tests from retail establishments.

[6] The types of facilities that purchased test kits from private pharmacies are not known, since the assessment focused exclusively on the availability of RDTs for HIVST in private pharmacies.

FINDINGS: TANZANIA

The mainland of Tanzania has a generalized epidemic, while the Zanzibar archipelago has a concentrated epidemic. Table 9 presents some key indicators for the country.

Table 9. Key HIV indicators, Tanzania

HIV Indicators	
Adult (15–49) prevalence	5.0%
Estimated adults (15+) living with HIV	1.2M
Estimated women (15+) living with HIV	690,000 (58%)
Estimated children (0–14) living with HIV	250,000
Percentage of women and men aged 15–49 who received an HIV test in the past 12 months and received their results	28.4%
Percentage of pregnant women who were tested for HIV and received their results	85%

Source: UNAIDS, 2014

Heterosexual transmission drives most of the new infections in the country. Due to intensive prevention interventions, the country has seen a decline in prevalence among adults, especially adult men. There is tremendous variation in prevalence throughout the country, from a low of 1.5 percent in Manyara to a high of 14.8 percent in Njombe. Key populations are still very hard hit, with 16 percent prevalence among people who inject drugs, 22 percent among men who have sex with men (MSM), and 31 percent among female sex workers.

Legal and Regulatory Environment for OTC Sale of RDTs

Status of RDTs for self-testing

The National Guidelines for the Management of HIV and AIDS states that rapid tests must be administered or supervised by trained personnel:

> HIV rapid testing can be performed in the laboratory or in the non-laboratory hospital, clinic or community settings by [health care workers] trained to perform HIV rapid tests. However, all testing done outside a laboratory setting must be supervised by qualified laboratory personnel to ensure accurate and quality results (National AIDS Control Programme (Tanzania), 2012).

The National Guidelines, together with the National HIV and AIDS Policy (March 2011), dictates how HIV testing and counseling should be conducted. The existing rules were not written with HIV self-testing in mind (Southern Africa AIDS Trust, 2014). Table 10 shows the main agencies that set policies and regulate activities for HIV and AIDS.

Table 10. Key Public Sector Actors in Tanzania's HIV Regulatory Environment

Agency	Role
Health Laboratory Practioners Council	Registers and accredits medical lab technicians
Private Health Laboratory Board (PHLB)	Registers and accredits private medical lab premises
National Institute of Medical Research (NIMR)	Conducts research
Ministry of Health and Social Welfare (MOHSW)	Provides overall policy adoption for the country for HIV and all other disease areas
National AIDS Control Programme	Develops and implements all policies and guidelines related to HIV and AIDS
Tanzania Food and Drug Authority	Lists medical equipment (e.g., RDTs) present in the country and approves import licenses

Regulation of RDT sales and use

No regulations are in place specifically relating to HIV RDT sale and use. A news story published November 2013 reported that the Minister of Health and Social Welfare circulated a statement clarifying that HIV RDT self-testing kits were not allowed for sale in Tanzania (Chiwambo, 2013). The original statement, not obtained by SHOPS, was reportedly issued in response to reports that HIV self-test kits were found on the market in Dar es Salaam. The statement clarified that Tanzania policy does not allow a person to self-test, adding that the law on HIV demands that one go to a hospital or health center for HIV testing administered by professional health personnel. The statement emphasized the need for confidentiality between the patient and the health officer.

RDT evaluation and quality assurance

The Tanzania Food and Drug Authority was established by the Tanzania Food, Drugs and Cosmetics Act of 2003. Tanzania Food and Drug Authority (TFDA) regulates all aspects of medical devices, including importation, manufacture, labelling, storage, promotion, sale, and distribution (Fimbo, 2012). TFDA began developing its registration process for medical devices in 2010, and the process is still being finalized. At the time of this assessment, TFDA had 114 registered devices in the country, and no RDTs were listed (Tanzania Food and Drug Authority, 2013). Premises that sell medical devices are required to be licensed.

Enforcement challenges include limited TFDA capacity and lack of reference documents, such as packaging guidelines (Bitegeko, 2014). The representative from TFDA interviewed by SHOPS was aware that some retail pharmacies are selling HIV RDTs, and he was concerned that pharmacies are selling subsidized RDTs procured from NGOs.

OTC sales

The SHOPS data collector visited 12 pharmacies to assess the availability of HIV RDTs: 10 in Dar es Salaam, one in Morogoro, and one in Dodoma. He found that half of the pharmacies (6) sold HIV RDTs, but none packaged specifically for self-testing. Two types of HIV RDTs were found in the six pharmacies: Alere Determine HIV 1/2 and Uni-Gold, both blood-based tests. The tests were typically sold in informal bulk packages, containing multiple tests and a separate bottle of buffer solution that would cover several tests. Other components such as a lancet, pipettes, or written instructions, were not included. One pharmacy administered the HIV RDT on-site, charging Tsh 3,500 (~ USD $2), but it did not sell the blood sample test strip or buffer solution OTC for just one test. At a wholesale pharmacy in Kariakoo, the

consultant found a box of Uni-Gold RDTs containing all test kit components required to perform 60 tests. This was priced at Tsh 60,000 (~USD $34).

The consultant also visited three Accredited Drug Dispensing Outlets: two in Bagamoyo, and one in Lindi. None sold HIV RDTs. No RDTs were sold in the other commercial outlets researched in those areas, i.e., the handful of supermarkets and consumer goods stores visited by the consultant.

Pharmacies located close to health facilities were more likely to carry HIV RDTs, responding to the demand for bulk purchases from nearby HTS providing facilities. This was especially true for pharmacies located near private health facilities, which have no access to public medical supply stores. However, staff members at some of the pharmacies were reluctant to provide information on HIV RDTs, not answering all the questions or in some cases not saying whether they sold HIV RDTs.

There were no apparent restrictions on who could buy the bulk HIV RDT kits; however, the RDTs were stored behind the counter, not on open shelves where buyers could pick them up independently. When the SHOPS data collector approached the seller as a regular customer, speaking the local language, the pharmacy staff would complete the sale. When the pharmacy staff perceived that this was part of a study or assessment, they were less willing to sell or provide information.

There were variations in the type of instruction given to the data collector at the pharmacy. Some pharmacists gave no instructions and just made the sale (of either bulk or individual test strips); some provided directions on how to use the test, but no specific HIV counseling. Others offered to test the client on the premises and provide some counseling, although there was no evidence offered or visible to indicate the staff member was qualified or had received training to provide HTS pre-counseling.

One brand found in the pharmacies, Alere Determine HIV 1/2, is the same brand used in the public sector. Alere RDTs found in public facilities are stamped with the government logo, “GOT” or “Government of Tanzania.” The TFDA looks for that logo on products that are offered for sale when it conducts surveillance of private pharmacies. A TFDA Zonal Manager who was interviewed for this assessment said that TFDA sometimes finds government-labelled HIV RDTs in pharmacies and drug dispensing outlets, suggesting that there is some leakage from the public sector. However, when suppliers were

Sean Callahan

asked about leakage from the public sector to commercial outlets, they said that they believe that there is none because the product is very closely controlled.

Position of pharmaceutical society

The pharmaceutical society does not develop guidelines; that is the role of TFDA. The Society does not have a policy on self-testing.

Main suppliers and distributors

Rapid test kits in Tanzania are imported in three ways, sourced mainly from India and the UK: through the government's Medical Stores Department (MSD, under MOH); directly by NGOs; and via private pharmaceutical wholesale importers and distributors. The pharmaceutical importers sell mainly to private facilities in urban areas. Some NGOs receive donations from Bioline, a London-based company that manufactures and markets reagents. Wholesalers import directly from international companies, pay taxes, and sell to private facilities or retail pharmacies. The four major distributors, aside from the MSD, are Anudha Ltd., Zenufa Group of Companies, and JD Pharmacy Co. Ltd.

The TFDA conducts spot checks of the quality of pharmaceutical products in stores by collecting and testing samples. All importation as well as distribution has to comply with TFDA regulations. If products are found to be counterfeit, the owners must pay fines and will lose their license to operate.

The pharmacies that carry RDTs reported that they buy them from wholesale pharmacies in Dar es Salaam. The wholesalers procure them either from the big suppliers in the country (Zenufa, JD Pharmacy, and others) or they import them directly.

The SHOPS data collector interviewed three suppliers in Dar es Salaam that carry RDTs: Bwire Surgical Care, Eminent Investor, and Health Zone. As private suppliers, they do not have access to MSD commodities; all three have import licenses and order the consignments from overseas. Their clients are health facilities and private pharmacies, in equal proportions. They deal mostly in Alere Determine HIV 1/2, which is cheaper than Uni-Gold (at Tsh 60,000 compared to Tsh 300,000 for 100 tests, i.e., USD $34 versus USD $171).

NGO Feedback on Self-Testing

SHOPS interviewed managers from two NGOs, Management and Development for Health (MDH) and Amref Health Africa, who reported that they use HIV RDTs to test their beneficiaries, but they do not support HIVST. They indicated that they follow national guidelines for testing, and those do not at present include HIVST. They procure their RDTs from international organizations or from MSD, whose test kits carry the GOT logo. If a large number of tests are needed for a campaign, the organization requests government-procured HIV RDTs from the office of the District Medical Officer where the campaign is taking place.

Conclusions about Tanzania

As in Malawi, in Tanzania SHOPS found that current guidelines require that HTS take place under the supervision of a health care worker, and that HIV RDTs must be procured through approved channels. However, sale of HIV RDT kits and components was more prevalent in the Tanzanian pharmacies visited. In half the pharmacies surveyed, SHOPS found that HIV RDTs were available for sale either in bulk to health providers or in piecemeal fashion to individuals. Pharmacies nearby to private facilities were more likely to carry HIV RDTs packaged for health provider use, indicating that workers from facilities are likely buyers. Pharmaceutical attendants displayed uneasiness in responding to questions about selling HIV RDTs directly to consumers, especially when they perceived that it was part of a study. Interviews in this small data set found contradictory perspectives on whether there is leakage of HIV RDTs from the public sector for sale in private pharmacies—an area that would merit further investigation.

SHOPS found no activity underway to review or update the regulatory environment to accommodate testing outside of clinical settings or via HIVST. Stakeholder interviews with suppliers, NGOs, and pharmacies indicate more limited support for HIVST within Tanzania's HIV community, and fewer champions to push an HIVST agenda forward.

FINDINGS: UGANDA

Despite early progress in combatting spread of the disease, Uganda is facing a generalized HIV epidemic that has not improved significantly over the last decade. Table 11 presents some key indicators for the country.

Table 11. Key HIV Indicators, Uganda

HIV Indicators	
Adult (15–49) prevalence	7.4%
Estimated adults (15+) living with HIV	1.4M
Estimated women (15+) living with HIV	790,000 (56%)
Estimated children (0–14) living with HIV	190,000
Percentage of women and men aged 15–49 who received an HIV test in the past 12 months and received their results	59.3% overall 71.3% women 55.7% men
Percentage of pregnant women who were tested for HIV and received their results	93%

Source: UNAIDS, 2013

The HIV and AIDS Uganda Country Progress Report (UNAIDS, 2013) cites the following drivers for the epidemic:

- Personal understanding of and attitude towards HIV
- Awareness about personal and/or partner HIV status
- High risk sexual behaviors including early sexual debut, multiple sexual relationships, limited and inconsistent condom use, and transactional, cross-generational and commercial sex.

Legal and Regulatory Environment for OTC Sale of RDTs

Uganda explicitly prohibits HIV self-testing in its National Implementation Guidelines for HIV Counseling and Testing in Uganda (Uganda Ministry of Health, 2010). The Guidelines require that HIV testing must be provided only by qualified, trained, and supervised health professionals, and section 3.2 clearly states, “In Uganda, clients must NOT perform their own HIV tests” (Uganda Ministry of Health, 2010).

The National Drug Authority does not permit pharmacies to sell HIV RDTs for self-testing to individuals; pharmacies are allowed to sell HIV RDTs only in bulk to health facilities, for provider-led counseling and testing. According to a media report in February 2013, the Health Minister issued a statement saying that the Ministry does not approve the private sale of HIV RDTs for self-testing purposes, and she advised the public to obtain an HIV test through facilities where they can receive counseling and testing (Natukunda, 2013). The article references reports of the public receiving inaccurate HIV test results, specifically mentioning the sale of HIV kits from unnamed providers.

"While the Ugandan government is keen to have more people to know their HIV status … senior health officials say they have not approved the private sale of self-test kits and would prefer the public to continue to use the health provider- or client-initiated HIV counseling and testing model recommended by the country's national HIV strategy… People need to be careful of these kits. There are several mushrooming health service providers [Pharmacies and other unqualified personnel], which are illegal, quack and not genuine at all. They are not approved by us."

– *Christine Ondoa, Uganda's Health Minister* (IRIN News, 2013)

The key agencies that set policies and regulate HIV and AIDS activities in Uganda are listed in Table 12.

Table 12. Key Public Sector Actors in Uganda's HIV Regulatory Environment

Agency	Role
Ministry of Health	Formulates HIV policy; provides supervision and overall leadership
AIDS Control Program (ACP)	Develops and implements HIV related policies and guidelines in MOH
Uganda AIDS Commission (UAC)	Oversees, plans, and coordinates HIV and AIDS prevention and control activities
Uganda National Drug Authority	Regulates and controls HIV test kit production, importation, distribution/sale, and use
Pharmaceutical Society of Uganda (PSU)	Oversees licensing and regulation of pharmacies and pharmacists and their assistants

Status of RDTs for self-testing

The prohibition on self-testing underscores the important linkages between HIV testing and counseling, which opponents of HIVST fear will be weakened through self-testing in private settings. In Uganda, testing is made available at a number of sites, including health facilities and outreach sites. The modalities available include consumer-initiated VCT, routine provider-initiated counseling and testing (PICT), and home-based HIV testing and counseling provided through outreach workers, as well as mandatory HIV testing and counseling under certain conditions.

Regulation of RDT sales and use

Uganda has no legal framework allowing HIVST or sale of HIV RDTs OTC; SHOPS's attempts to discuss this topic with Ministry of Health staff were not successful. There has been limited dialogue among stakeholders.

RDT evaluation and quality assurance

Uganda has no comprehensive system of medical device regulation (Rugera et al., 2014). However, Uganda is part of the PAHWP initiative to strengthen processes and capacity. Provisions have been made under the auspices of MOH for wholesalers or programs to apply to the National Drug Authority for a Certificate of Verification for diagnostic tests to be marketed to buyers. Uganda and other governments face regulatory challenges in ensuring consistency in HIVST policy and operationalization. While Uganda has guidelines for regulation of diagnostic and medical devices, pre- and post-market controls of

these devices are not in place (Rugera et al., 2014). WHO pre-qualification (including pre-testing) is a prerequisite to export HIV diagnostics to Uganda, but enforcement resources are limited (Rugera et al., 2014).

OTC Sales

SHOPS visited 12 pharmacies, five in Kampala and seven in rural districts. HIV RDTs packaged for self-testing were not on sale in any of these pharmacies. However, constituent parts of HIV RDT kits were commonly available for purchase OTC in the private pharmacies; sample test strips for whole blood and lancets, without any restrictions on purchasing, were available at all of them. The buffer solution was sold in a large bottle and accompanies a package of 1,000 blood sample test strips. The assessment team did not find any pharmacy that would sell smaller doses of buffer for individual tests.

Furthermore, the SHOPS team observed that no counseling or instructions were given to the client purchasing the sample test strip; it was always assumed that the person already knew how to use the test kit components. Most test strips had no user information written on the packaging, and when there was some information available (specifically, on the Orem Recombant test kit), it was inadequate for a lay consumer to follow.

Some pharmacy staff interviewed said that, based on inquiries received, many people are trying to obtain HIV RDTs for the purpose of self-testing. Pharmacy staff also shared that they believe the interest in HIV RDTs for self-testing is motivated by long queues, stigma, and the frequent stock-outs of HIV RDT kits at public health facilities. Another contributing factor may be the recent anti-homosexual laws in the country that may drive some key populations away from HTS provided in formal health care settings.

The SHOPS team did not visit any drug stores (establishments with no pharmacist), which are more common in the rural areas. The team did not find test kits in other commercial establishments, such as supermarkets, shops, or other retail outlets.

The cost of one sample test strip ranges from 2500−5000 Uganda shillings (~ USD $0.90–$1.88). The commonly available brands of test strips being sold as RDTs are Orem Recombant, Nova-Test and Alere Determine HIV 1/2. Alere Determine HIV 1/2 is used in both the public and the private health sectors. There could be leakage from the public sector to the private, but this study was not able to gather information on this topic.

There were no advertisements, public notices, or other means to alert people to the possibility and availability of HIV RDTs at any of the visited pharmacies, possibly because OTC sale of HIV RDTs is prohibited by law.

SHOPS interviews were primarily with counter attendants, who were rarely pharmacists. Pharmacists are usually not continuously on the premises but come for limited periods during the day.

The respondents made the following comments regarding the sale of HIV RDTs that may be relevant for future self-testing efforts:

- No additional guidance is provided to clients buying test strips.
- Instructions are not user friendly.
- Pharmacy technicians assume that most clients already know how to use the test strips.
- There is anecdotal evidence that HIV RDTs are being used by men on women prior to engaging in unprotected casual sex, raising concern over potentially coercive testing.

Position of pharmaceutical society

The pharmaceutical society does not have a position on self-testing, and because of the lack of policy guidelines on this subject, it does not offer pharmacy staff any training on providing HIV RDTs for HIVST.

Main suppliers and distributors

In Uganda, the pharmaceutical supply chain goes through three levels:

- Main suppliers/distributors import or manufacture the pharmaceutical products. They are located in the primary business district of Kampala and supply the entire country.
- Regional distributors/wholesalers are often chain outlets of the major suppliers in Kampala. Some are independent companies that buy in bulk from suppliers in Kampala and sell to retailers in the countryside.
- Retailers are widely distributed throughout the country. They buy from wholesalers in the regional towns and sell directly to final consumers.

SHOPS contacted 12 distributors in Kampala; after introductions, nine declined to proceed with the interview. Those who declined to respond cited the recent Ministry of Health/National Drug Authority ban on the sale of HIV RDTs to non-accredited health facilities or persons.

Supplier and distributor information is not readily available from retail pharmacies. Pharmacists referred the SHOPS assessment team to the large drug distributors located in the main business street of Kampala, offering that they are the ones who supply the test strips to pharmacies. Some distributors have regional distribution channels outside Kampala, from which local pharmacies can buy test kits.

The consultant interviewed three large suppliers in Kampala: Abacus Pharmaceuticals Ltd., Gittoes Pharmaceuticals Ltd., and IV Planet Pharmacy, representative of the major suppliers of pharmaceuticals in the country. Most of their RDTs come from India and are intended for provider-performed testing in health facilities. The suppliers could not estimate the size of the potential HIV RDT market. They said there is low demand because there is no marketing campaign to support it. The respondent from Abacus said he believes that there is a black market for HIV RDTs, mostly coming from Kenya and the Democratic Republic of Congo. The respondent from Planet Pharma also believes there is a black market, but he did not know the source of black market commodities.

NGO Feedback on Self-Testing

NGOs do not facilitate HIVST among their clients, and they are unaware of clients self-testing. When they have their own HTS centers, they employ the traditional VCT protocols. Interestingly, NGOs reported that there is a market for fake results, i.e., people who seek to buy a negative test result report for personal reasons, perhaps to show to an employer or partner.

Conclusions about Uganda

Uganda is the only country in this assessment with a policy that explicitly bans the use of HIV RDTs for self-testing. Surprisingly, it is also the country where we found the widest availability of HIV RDT components and kits for sale; some were available in all the pharmacies visited. As in the other three countries, none of the HIV RDTs sold were packaged or designed for use by lay persons or contained all the test components in one package.

Consistent with the government's clear policy against HIVST, Ugandan stakeholders exhibited the most reluctance to answer the survey questions. SHOPS was not able to get an appointment with the MOH to discuss HIVST, and most distributors refused to talk to the data collector when they were told the subject of the survey. However, pharmacy staff interviewed reported a demand for an HIV self-testing kit, which they believe is driven by the need for confidentiality as well as by systemic problems in access at public HTS sites. One NGO observed that there is already a market for "negative tests." The availability of self-testing, away from facilities, may fuel that market.

DISCUSSION OF FINDINGS

Lack of Sufficient Guiding Policy and Regulatory Oversight

Comprehensive policies, laws, and regulations governing the commercial sale or use of HIV RDTs for personal self-testing do not currently exist in any of the four countries included in this assessment. In the absence of adequate technical guidelines and regulatory oversight, the formal market for HIV RDTs purchased OTC appears to be limited. However, although Ugandan policy clearly prohibits the sale of HIV RTDs OTC for self-use, with some effort a consumer is able to obtain OTC individual constituent components of a test kit (i.e., a blood sample strip). In Kenya, while the government has affirmatively supported the concept of HIV self-testing, it has yet to define conditions or operational guidelines.

With no rules in place to regulate the OTC sale of HIV RDTs, private retailers in all four countries expressed uncertainty regarding rules around procurement and commercial sale of HIV RDTs. This uncertainty is not unique to HIV; similar debates are happening in Kenya and other countries in regard to OTC sales of malaria RDTs (Rusk et al., 2013) or self-injection of birth control products (Lakha, Henderson, & Glasier, 2005; PATH, 2012). This assessment found that—even where allowed by law—there were no systematic and comprehensive efforts underway to appropriately package, market, and distribute HIV RDTs directly to consumers as part of a national approach.

Availability of HIV RDTs Over the Counter

No HIV RDTs packaged for consumer use were found in any of the four countries. Where HIV RDTs were available, they were usually unpackaged and sold in bulk to health providers from nearby health care facilities, or, in some private pharmacies, they were sold as individual constituent parts of an HIV test kit (i.e., only the sample test trip without appropriate product inserts, instructions, buffer/reagent, or lancet). Appropriate packaging and instructions, when included, were designed for health care professionals and not intended for use by lay consumers. In the facilities offering to sell the constituent components of HIV RDTs (e.g., a sample test strip), none of the pharmacists or retail clerks interviewed had received training in HIV testing and counseling, and very few offered detailed instruction on how to administer and interpret an HIV RDT. Further, private pharmacy staff interviewed during this assessment suggested that the majority of HIV RDTs being sold OTC were purchased by nearby HTS-providing facilities, where they were being used in a clinical setting.

Due to the relatively small sample size and urban concentration, the findings from this assessment are not conclusive regarding the OTC availability of HIV RDTs for self-testing or otherwise. Nevertheless, the limited availability of HIV RDTs over-the-counter in the four countries suggests that the unregulated sale of HIV RDTs for self-testing purposes may be less common than in Namibia, where similar research questions were studied (Nersesian et al., 2013).

Mansir Petrie

Source of HIV RDT and Potential Black Market

Pharmacy staff that admitted selling HIV RDTs OTC stated that they procured the commodities from commercial wholesalers and suppliers. However, the SHOPS assessment revealed some evidence of HIV RDT commodity leakage (i.e., unapproved movement of subsidized commodities) from the public sector to the private sector. During the assessment, staff members at several pharmacies in all four countries were very reluctant to discuss HIV RDTs, often not answering all the questions asked or even revealing whether they sold HIV RDTs. For example, out of the 12 wholesale pharmaceutical distributors that SHOPS contacted in Kampala, nine declined to proceed with the interview after introductions, citing as their reason the recent MOH/ National Drug Authority bans on the sale of HIV RDTs to non-accredited health facilities.

This assessment could not determine whether HIV RDTs found in the private pharmacies were procured illegally as "leakage" from the public sector or were procured from wholesalers. However, the fact that several pharmacies were selling constituent components of HIV RDTs OTC (and some were even informally selling buffer solution in a syringe) suggests questionable procurement methods or possibly a black market for HIV RDTs sold "under-the-counter." In Tanzania, the TFDA Zonal Manager said that they sometimes find publically procured and branded HIV RDTs in private pharmacies, clearly against regulations. Additionally, a supplier from Uganda, Abacus Pharma, expressed the belief that contraband RDTs come into the country from Kenya and the Democratic Republic of Congo. In Malawi, suppliers suggested that individual retailers could be importing unregistered products directly, thus creating unfavorable trade conditions. Oversight of such practices was low to non-existent in all four countries, with no guidelines regulating the sale of HIV RDTs to consumers either in whole or in part.

Demand for HIV RDTs Over the Counter

This assessment did not include any measurement of consumer demand for an HIV RDT sold OTC for self-testing, and we did not interview consumers or potential users of this product. Pharmacists and facility staff interviewed stated that the greatest demand for OTC access to HIV RDTs was among private health facilities and hospitals. This would be consistent with the fact that several HIV RDTs found during the assessment were packaged in bulk; in Tanzania, SHOPS found the greater supply of HIV RDTs in private pharmacies near private facilities.

However, in all four countries, pharmacy staff interviewed stated that at least some consumers have tried to obtain HIV RDTs for the purpose of self-testing.

Key stakeholders also mentioned that consumers were purchasing constituent parts of RDTs, or purchasing bulk kits to sell on the black market, or purchasing and using HIV RDTs meant for health providers for use outside of clinical supervision. Several informants from pharmacies, NGOs, and other key health stakeholders expressed the opinion that there would be demand for a "self-test RDT" among the general public if one were designed and marketed specifically for individual use. Overall, a strong market for HIV RDTs OTC has not developed in any of the four countries, due to the absence of formal distribution, marketing, and regulation. These results may be reassuring to proponents of HIVST, who advocate for careful introduction of HIV RDTs for self-testing as part of a comprehensive HIVST policy, including regulated commodity supply and appropriate consumer and vendor education. Further research is warranted to assess consumer demand for HIV RDTs sold OTC for self-testing.

Role of HIV RDTs Sold Over the Counter in Future HIV Self-testing Programs

The findings from this assessment indicate a need for government policymakers to address HIVST and access to HIV RDTs in their national guidelines, to protect consumers via stronger pre- and post-market regulatory oversight of HIV RDTs, and to develop data-driven, client-focused approaches to distributing HIV RDTs for self-testing purposes. Assuming that these essential supply-side priorities have been addressed, the private sector could potentially play a key role in the distribution of HIV RDTs OTC or via other commercial approaches. The current lack of supportive policy for HIVST in three of the four countries, and limitation of HIV RDTs to clinical use in all of the countries, has restricted market development for self-purchased HIV RDTs.

This makes it difficult to assess the potential role or impact of OTC distribution of HIV RDTs as part of any future HIV self-testing program. However, stakeholder responses and pharmacy commodity findings confirm that there is an existing market for HIV RDTs sold in bulk OTC to health care providers/facilities, and there has been market demand for (and an unknown degree of "under-the-counter" sale of) individual HIV RDTs among lay consumers.

While only Uganda has prohibited HIVST explicitly, neither Tanzania nor Malawi appears to be moving toward adopting a national HIVST approach. Countries that become early adopters, such as Kenya, will provide invaluable evidence for others to assess the potential benefits and risks of HIVST approaches moving forward. Key components of any future HIVST approach must be developed within a country's framework for the regulation of medical devices in general; these components include retailer and consumer education efforts, developing consumer-focused instructions and packaging for HIV RDTs, and creating strong links to post-test confirmatory testing and support. Improving technologies for HIV RDTs and other self-applied diagnostic tests and medical devices—such as RDTs for malaria, or potential self-injection with Uniject Depo-subQ Provera—may provide momentum for stronger regulatory oversight of HIV RDTs as part of broader changes in medical delivery. In addition, health system strengthening efforts throughout sub-Saharan Africa will be needed to ensure adequate resources and capacity for product registration, quality assurance, supply, and surveillance of HIV RDTs and other self-applied medical technologies.

Mirko Eggert

CONCLUSIONS AND RECOMMENDATIONS

New and innovative approaches to service provision are urgently needed to extend the global coverage of HTS, and to rapidly increase the number of people who are aware of their HIV status. HIVST using an HIV RDT product, in either a supervised or unsupervised setting, could be a strong method in serving these objectives. This paper has outlined the potential benefits and risks of HIVST as currently being debated by public health practitioners and national governments, and has assessed the availability of HIV RDTs OTC in four countries at different stages of HIVST legal and policy development. The findings from this study lead to several important conclusions.

There is a need to strengthen national regulations, guidelines, and enforcement capacity pertaining to self-testing and commercial sale of HIV RDTs.
While there is tremendous potential for HIVST to make a significant public health impact, the current lack of comprehensive HIVST policies and weak regulatory structures related to HIV RDTs translate into limited operational experience with HIVST. Until stronger regulatory structures are put in place, including legislation addressing HIVST and commercial sale of HIV RDTs, many countries operate in a legislative grey area. Isolated findings from private retailers assessed in this report suggest that commercial sale of HIV RDTs OTC is occurring in the private sector in many high-HIV prevalence settings, to least some degree. Components of HIV RDTs were available OTC in some locations in all four countries studied—despite Uganda's restrictions on OTC sale of the product, and despite the absence of adequate processes and procedures to ensure safety and quality of HIV RDTs in all of the countries. At any level of restriction, there is need for formal HIVST policies and programs that can provide guidance to retailers and providers, protect consumers, and formalize the provision of HIV RDTs commercially (for HIVST or otherwise).

There is a specific need to strengthen regulatory and policy frameworks pertaining to private sector import, registration, and commercial sale of HIV RDT products.
Regardless of a country's stance on HIVST, there is a need to clarify and strengthen policies and enforcement standards related to the private commercial sale of existing and emerging HIV RDTs and HIVST products. Safe introduction of HIVST, as part of a national HIV response, would depend on a country's overall capacity to regulate HIV RDT product registration, importation and distribution, to oversee quality of products, and to monitor and enforce regulations pertaining to HIV self-testing. However, policies and regulations governing the sale of HIV RDTs fall within the broader regulatory structure for diagnostic devices generally, which is still in development in many Sub-Saharan African countries.

As HIVST products and approaches gain traction, it will be imperative that national governments adequately address product quality, registration, oversight, and compliance. Although the findings from this report indicate that HIVST may not yet be widespread, evidence of at least some unregulated sale of HIV RDTs in all four countries indicates the need for specific private-sector focused policy and engagement.

There is a need to define the components of a best-practice HIVST program.
As countries initiate or prepare to implement national HIVST programs, there is a need to define the legal, ethical, technical, and logistic aspects of best-practice HIVST approaches. The WHO has provided guidance on possible programmatic models, approaches, and considerations (in both the Technical Update on HIV Self-Testing and the Consolidated Guidelines on HTS) that can be informative to implementers and national health leadership. Part of defining best-practice approaches to HIVST will involve assessing methods of distribution in the public and private sector, selecting products and assays for HIVST as part of national testing algorithms, ensuring adequate pre-test instruction/information, and supporting successful post-test linkage to care for those with reactive results. Early HIVST efforts in some countries have demonstrated the importance of retailer, distributor, and consumer education programs and health care worker sensitization, as well as the creation of indirect support structures (such telephone or internet-based hotlines) to assist consumers in accessing HIV RDTs OTC and in taking appropriate steps after the test. In addition, programs can benefit from adapting systems and policies that are already in place for HIV RDT quality assurance and evaluation, making them specific to HIVST. Implementation experiences from diverse settings and among different populations and risk groups are needed to help guide development of HIVST programs and replicable approaches.

Novel and consumer-friendly HIV RDT products are needed for HIVST.
As with any medical device, HIV RDTs pose some risk of incorrect application, unreliable quality, inaccurate results, or misuse, particularly when self-applied by lay consumers. As indicated in this report, none of the HIV RDTs found through this study were packaged for use by lay consumers. All of the HIV RDTs were found either packaged in bulk or in "kits" with instructions intended for health care professionals in supervised testing settings. In the isolated cases where HIV RDTs were purchased individually, only individual components of an HIV RDT kit were sold, without consumer-focused instruction or verbal direction from the pharmacist. At present, the vast majority of HIV RDTs on the market are designed and packaged for use by health care workers. While several HIVST products have been recently registered or are under development (see Table 2), there is a need to advocate for the design of additional consumer-friendly HIV RDT products specifically for HIVST. These products would have ease of application for lay consumers, would be designed and packaged with instructions that are clear to the general public, and would include clear directions and linkage to confirmation testing and support for those with a reactive result. Such products should be incorporated into future research and development of HIVST programs in low- and middle-income countries.

In conclusion, this report found isolated incidents of unregulated sale of HIV RDTs for HIVST OTC in four high-HIV prevalence countries. However, the vast majority of OTC sales are bulk sales to health care providers, for administering HIV RDTs in a

supervised setting. While HIVST offers tremendous potential to scale up the number of people screened for HIV, there is a need to clarify policies and legal regulations, enforce existing standards, and engage the private health sector to clarify rules and protect patient safety regardless of level of restriction on HIV RDTs and HIVST. Maximizing the potential of HIVST approaches will require careful consideration of RDT product selection, new HIV RDT product development, effective and timely links to care and support for users with a reactive (positive) result, and ensuring adequate government capacity to introduce, monitor, and enforce the program. Especially if commercial OTC sale of HIV RDTs for HIVST is to be incorporated into national HTS programs, further global research and operational experience is needed to inform the development of future HIVST approaches. Learning from early adopters such as the United States, France, and Australia will surely inform and assist high-HIV prevalence countries as they develop their own policies and HIVST approach. In addition, as HIVST programs mature, programmatic lessons from implementation experiences should be broadly disseminated to global implementers to share lessons on quality and safety of HIV RDT products, approaches to commercial sale and regulation of HIV RDTs, consumer experience with HIVST, and methods to guide HIV positive individuals to care and treatment. Although many questions remain regarding the comparative risks and benefits, HIVST could prove a critical tool in closing global HTS gaps and in reaching an AIDS-free generation.

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REFERENCES

AAZ. (2015). Autotest VIH. Retrieved October 15, 2015, from http://www.autotest-sante.com/fr/autotest-VIH-135.html.

Abu Baker, J. (2011, March 1). It's Wise Not to D-I-Y. Retrieved June 1, 2015, from https://www.ttsh.com.sg/about-us/newsroom/news/article.aspx?id=1715.

Allais, L., & Venter, F. (2014). The Ethical, Legal and Human Rights Concerns Raised by Licensing HIV Self-Testing for Private Use. *AIDS and Behavior, 18 Suppl 4*, S433–7.

Association of Public Health Laboratories & Centers for Disease Control and Prevention. (2009). *HIV Testing Algorithms: A Status Report.*

Avert. (2015). HIV & AIDS in Malawi. Retrieved May 28, 2015, from http://www.avert.org/hiv-aids-malawi.htm.

Bassett, I. V, Regan, S., Luthuli, P., Mbonambi, H., Bearnot, B., Pendleton, A., … Mhlongo, B. (2014). Linkage to care following community-based mobile HIV testing compared with clinic-based testing in Umlazi Township, Durban, South Africa. *HIV Medicine*, 15(6), 367–372.

Becker, J., Tsague, L., Sahabo, R., & Twyman, P. (2009). Provider Initiated Testing and Counseling (PITC) for HIV in resource-limited clinical settings: important questions unanswered. *The Pan African Medical Journal*.

BioSure. (2015). BioSure HIV Self Test. Retrieved October 15, 2015, from http://hivselftest.co.uk.

Bitegeko, A. (2014). *Regulation of medical devices: Tanzania's experience*.

Broeckaert, L. (2014). HIV home-based testing: Potential benefits and ongoing concerns. Retrieved June 1, 2015, from http://www.catie.ca/en/pif/spring-2014/hiv-home-based-testing-potential-benefits-and-ongoing-concerns.

Centers for Disease Control and Prevention. (2014). *HIV/AIDS: Home Tests*. Retrieved from http://www.cdc.gov/hiv/testing/lab/hometests.html.

Centers for Disease Control and Prevention. (2015). Global HIV/AIDS: Malawi. Retrieved May 28, 2015, from http://www.cdc.gov/globalaids/Global-HIV-AIDS-at-CDC/countries/Malawi/default.html.

Chesney, M., & Smith, A. (1999). Critical Delays in HIV Testing and Care: The Potential Role of Stigma. *American Behavioral Scientist*, 42(7), 1162–1174.

Chiwambo, Y. (2013). Public alerted on expired HIV testing kit. Retrieved May 28, 2015, from http://www.ippmedia.com/frontend/?l=61994.

Choko, A. T., Desmond, N., Webb, E. L., Chavula, K., Napierala-Mavedzenge, S., Gaydos, C. A., … Corbett, E. L. (2011). The uptake and accuracy of oral kits for HIV self-testing in high HIV prevalence setting: a cross-sectional feasibility study in Blantyre, Malawi. *PLoS Medicine*, 8(10), e1001102.

Clark, J. L., Coates, T. J., Lescano, A. G., Castillo, R., Meza, R., Jones, F. R., … Klausner, J. D. (2006). Different positive predictive values of commercially available human immunodeficiency virus enzyme-linked immunosorbent assays. *Clinical and Vaccine Immunology: CVI*, 13(2), 302–3.

Curran, K., Johnson, C., Ngure, K., Mugo, N., Baeten, J., Heffron, R., … Bagga. (2014). The potential role of HIV self-testing within pre-exposure prophylaxis implementation (presentation). *20th International AIDS Conference*. Retrieved from http://pag.aids2014.org/Session.aspx?s=1106.

Deutsche AIDS-Hilfe. (2013). HIV Home Tests.

Duong, Y. T., Mavengere, Y., Patel, H., Moore, C., Manjengwa, J., Sibandze, D., … Parekh, B. S. (2014). Poor performance of the determine HIV-1/2 Ag/Ab combo fourth-generation rapid test for detection of acute infections in a National Household Survey in Swaziland. *Journal of Clinical Microbiology*, 52(10), 3743–8.

Eyewitness News. (2015). Zimbabwe to introduce HIV self-testing. Retrieved May 28, 2015, from http://ewn.co.za/2014/09/07/Zimbabwe-to-introduce-HIV-self-testing.

Figueroa, C., Johnson, C., Verster, A., & Baggaley, B. (2015). Annex 4: Report on the Attitudes, Values and Preferences on HIV Self-Testing Among Key Populations. *Consolidated Guidelines on HIV Testing Services, World Health Organization*.

Fimbo, A. (2012). *Regulation of Medical Devices in Tanzania*. Retrieved from http://www.tfda.or.tz/index.php?q=medical+devices&option=com_finder&view=search&Itemid=199.

Girardi, E., Sabin, C. A., & Monforte, A. D. (2007). Late diagnosis of HIV infection: epidemiological features, consequences and strategies to encourage earlier testing. *Journal of Acquired Immune Deficiency Syndromes (1999), 46 Suppl 1*, S3–S8.

Govindasamy, D., Kranzer, K., Van Schaik, N., Noubary, F., Wood, R., Walensky, R. P., … Bekker, L. G. (2013). Linkage to HIV, TB and non-communicable disease care from a mobile testing unit in Cape Town, South Africa. *PLoS ONE*.

Granade, T., Parekh, B., Phillips, S., & McDougal, J. (2004). Performance of the OraQuick and Hema-Strip rapid HIV antibody detection assays by non-laboratorians. *Journal of Clinical Virology*, 30(3), 229–32.

Hamers, R., de Beer, I., Kaura, H., van Vugt, M., Caparos, L., & Rinke de Wit,

T. (2008). Diagnostic accuracy of 2 oral fluid-based tests for HIV surveillance in Namibia. *Journal of Aquired Immune Deficiency Syndrome*, 48(1), 116–118.

HIVST.org. (2015). Policy & Regulations for HIVST. Retrieved May 28, 2015, from http://www.hivst.org/policy-regulations-for-hivst-1.

Ibitoye, M., Frasca, T., Giguere, R., & Carballo-Diéguez, A. (2014). Home testing past, present and future: lessons learned and implications for HIV home tests. *AIDS and Behavior*, 18(5), 933–49.

International Initiative for Impact Evaluation. (2015). Thematic Window HIV Self-Testing. Retrieved May 28, 2015, from http://www.3ieimpact.org/en/funding/thematic-window/thematic-window-hiv.

IRIN News. (2013). Ugandan authorities concerned as HIV self-test kits hit the market. Retrieved June 1, 2015, from http://www.irinnews.org/report/97419/ugandan-authorities-concerned-as-hiv-self-test-kits-hit-the-market.

Jacobs, J., Barbe, B., Gillet, P., Aidoo, M., Serra-Casa, E., Van Erps, J., … Visser, T. (2014). Harmonization of malaria rapid diagnostic tests: best practices in labelling including instructions for use. *Malaria Journal*, 13, 505–514. http://doi.org/10.1186/1475-2875-13-505.

Jafa, K., Patel, P., Mackellar, D. A., Sullivan, P. S., Delaney, K. P., Sides, T. L., … Branson, B. M. (2007). Investigation of false positive results with an oral fluid rapid HIV-1/2 antibody test. *PloS One*, 2(1), e185.

Johnson, C., Baggaley, R., Forsythe, S., Van Rooyen, H., Ford, N., Napierala Mavedzenge, S., … Taegtmeyer, M. (2014). Realizing the potential for HIV self-testing. *AIDS and Behavior*.

Johnson, C., Baggaley, R., Forsythe, S., van Rooyen, H., Ford, N., Napierala Mavedzenge, S., … Taegtmeyer, M. (2014). Realizing the potential for HIV self-testing. *AIDS and Behavior, 18 Suppl 4*, S391–5.

Kabiru, C. W., Sidze, E. M., Egondi, T., Osok, D., & Izugbara, C. O. (2014). *Understanding perceived social harms and abuses of oral HIV-self-testing in Kenya: Key findings of a cross-sectional study*. Washington, D.C.

Kalibala, S., Tun, W., Cherutich, P., Nganga, A., Oweya, E., & Oluoch, P. (2014). Factors associated with acceptability of HIV self-testing among health care workers in Kenya. *AIDS and Behavior, 18 Suppl 4*, S405–14.

Kersting, S., Rausch, V., Bier, F. F., & von Nickisch-Rosenegk, M. (2014). Rapid detection of Plasmodium falciparum with isothermal recombinase polymerase amplification and lateral flow analysis. *Malaria Journal*, 13(1), 99.

Klarkowski, D., O'Brien, D. P., Shanks, L., & Singh, K. P. (2014). Causes of false-positive HIV rapid diagnostic test results. E*xpert Review of Anti-Infective Therapy*, 12(1), 49–62.

Koblavi-Dème, S., Maurice, C., Yavo, D., Sibailly, T. S., N'guessan, K., Kamelan-

Tano, Y., … Nkengasong, J. N. (2001). Sensitivity and specificity of human immunodeficiency virus rapid serologic assays and testing algorithms in an antenatal clinic in Abidjan, Ivory Coast. J*ournal of Clinical Microbiology*, 39(5), 1808–12.

Krause, J., Subklew-Sehume, F., Kenyon, C., & Colebunders, R. (2013). Acceptability of HIV self-testing: a systematic literature review. *BMC Public Health*, 13(1), 735.

Kuun, E., Brashaw, M., & Heyns, A. (1997). Sensitivity and specificity of standard and rapid HIV-antibody tests evaluated by seroconversion and non-seroconversion low-titre panels. *Vox Sanguinis*, 72(1), 11–15.

Lakha, F., Henderson, C., & Glasier, A. (2005). The acceptability of self-administration of subcutaneous Depo-Provera. *Contraception*, 72(1), 4–8.

Lee, V. J., Tan, S. C., Earnest, A., Seong, P. S., Tan, H. H., & Leo, Y. S. (2007). User acceptability and feasibility of self-testing with HIV rapid tests. *Journal of Acquired Immune Deficiency Syndromes (1999)*.

Lippman, S. A., Veloso, V. G., Buchbinder, S., Fernandes, N. M., Terto, V., Sullivan, P. S., & Grinsztejn, B. (2014). Over-the-counter human immunodeficiency virus self-test kits: Time to explore their use for men who have sex with men in Brazil. *Brazilian Journal of Infectious Diseases*.

Mabey, D., Peeling, R. W., Ustianowski, A., & Perkins, M. D. (2004). Tropical infectious diseases: Diagnostics for the developing world. *Nature Reviews Microbiology*, 2, 231–240.

Mackellar, D., Hou, S., Whalen, C., Samuelsen, K., Sanchez, T., Smith, A., … Sullivan, P. (2011). Reasons for not HIV testing, testing intentions, and potential use of an over-the-counter rapid HIV test in an internet sample of men who have sex with men who have never tested for HIV. *Sexually Transmitted Diseases*, 38(5), 419–428.

Macpherson, P., Taegtmeyer, M., Ochodo, E., Adams, E., & Sands, A. (2014). Accuracy of 4th generation rapid diagnostic tests for HIV infection: a systematic review and meta-analysis. *PROSPERO International Prospective Register of Systematic Reivews*.

Mavedzenge, S. N., Baggaley, R., & Corbett, E. L. (2013). A review of self-testing for HIV: Research and policy priorities in a new era of HIV prevention. *Clinical Infectious Diseases*, 57(1), 126–138.

Mavedzenge, S. N., & Corbett, E. L. (2014). *A systematic review of HIV self-testing: research, policy and a new era in HIV prevention (abstract)*.

Mbonye, A., Magnussen, P., Chandler, C., Hansen, K., Lal, S., Cundill, B., … Clarke, S. (2014). Introducing rapid diagnostic tests for malaria into drug shops in Uganda: design and implementation of a cluster randomized trial. *Trials*, 15, 303.

Mugglin, C., Estill, J., Wandeler, G., Bender, N., Egger, M., Gsponer, T., & Keiser, O. (2012). Loss to programme between HIV diagnosis and initiation of antiretroviral therapy in sub-Saharan Africa: systematic review and meta-analysis. *Tropical Medicine and International Health*, 17(12), 1509–1520.

Mundasad, S. (2015, April 27). HIV home test kit goes on sale in UK. Retrieved May 28, 2015 from http://www.bbc.com/news/health-32453192.

Myers, J. E., El-Sadr, W. M., Zerbe, A., & Branson, B. M. (2013). Rapid HIV self-testing: long in coming but opportunities beckon. *Wolters Kluwer Health AIDS, 27*, 1687–1695.

Nation Online. (2013). Malawi's Outdated Pharmacy Act Results in Lenient Penalties. Retrieved June 1, 2015, from http://mwnation.com/malawi-s-outdated-pharmacy-act-results-in-lenient-penalties.

National AIDS and STI Control Programme. (2009). Guidelines for HIV testing and counseling in Kenya. Ministry of Public Health and Sanitation, Government of Kenya. Retrieved from http://www.who.int/hiv/topics/vct/policy/KenyaGuidelines_Final2009.pdf.

National AIDS Commission. (2009). Guidelines for HIV Testing And Counseling. Government of Malawi.

National AIDS Control Programme (Tanzania). (2012). National guidelines for the management of HIV and AIDS. Ministry of Health and Social Welfare, United Republic of Tanzania.

Natukunda, C. (2013). Uganda: Health Ministry cautions against HIV self-tests kits. Retrieved June 1, 2015, from http://allafrica.com/stories/201302110512.html.

Nersesian, P., Hullsmann, M., Cloutier, S., & Chintalova-Dallas, R. (2013). Assessment of Over-the-Counter HIV Rapid Test Kits in Namibia. Arlington, VA: USAID'S AIDS Support and Technical Assistance Resources, AIDSTAR-One, Task Order 1.

Office of the US Global AIDS Coordinator. (2014). *PEPFAR 3.0 - Controlling the Epidemic: Delivering on the Promise of an AIDS-free generation*.

OraSure Technologies. (2015). OraQuick. Retrieved October 15, 2015, from http://www.oraquick.com.

Pant Pai, N., & Klein, M. (2008). Are we ready for home-based self-testing for HIV? *Future HIV Therapy*, 2(6), 515–520.

Pant Pai, N., Sharma, J., Shivkumar, S., Pillay, S., Vadnais, C., Joseph, L., … Peeling, R. W. (2013). Supervised and Unsupervised Self-Testing for HIV in High- and Low-Risk Populations: A Systematic Review. *PLoS Medicine*.

PATH. (2012). *Assessment of home and self-injection of depo- subQ in Unijject in the urban private sector in Kenya and Senegal*.

Pavie, J., Rachline, A., Loze, B., Niedbalski, L., Delaugerre, C., Laforgerie, E., … Simon, F. (2010). Sensitivity of five rapid HIV tests on oral fluid or finger-stick whole blood: a real-time comparison in a healthcare setting. *PloS One*, 5(7), e11581.

Peck, R. B., Lim, J. M., Van Rooyen, H., Mukoma, W., Chepuka, L., Bansil, P., … Taegtmeyer, M. (2014). What Should the IDEAL HIV self-test look like? A usability study of test prototypes in unsupervised HIV self-testing in Kenya, Malawi, and South Africa. *AIDS and Behavior, 18*(SUPPL. 4), 422–432.

Phanuphak, P. (2015). HIV Self-Testing: The Thai Experience. Retrieved October 15, 2015, from http://www.hivst.org/directory-list/2015/9/2/hiv-self-testing-the-thai-experience.

Pilcher, C. D., Christopoulos, K. A., & Golden, M. (2010). Public health rationale for rapid nucleic acid or p24 antigen tests for HIV. *The Journal of Infectious Diseases*, 201(Supplement 1), S7–S15.

Preston, C., Valdez, M. Lou, & Bond, K. (2012). Strengthening medical product regulation in low- and middle-income countries. *PLoS medicine2*, 9(10).

Richter, M. L., Venter, W. D., Gray, A., & Lim, B. M. (2012). Enabling HIV self-testing in South Africa. *Southern African Journal of HIV Medicine*, 186(4).

Rosen, S., & Fox, M. P. (2011). Retention in HIV care between testing and treatment in sub-Saharan Africa: a systematic review. *PLoS Medicine*, 8(7), e1001056.

Rugera, S. P., McNerney, R., Poon, A., Akimana, G., Mariki, R. F., Kajumbula, H., … Peeling, R. W. (2014). Regulation of medical diagnostics and medical devices in the East African community partner states. *BMC Health Services Research* 14, 524.

Rusk, A., Goodman, C., Naayan, V., Koech, B., Obala, A., & Prudhomme O'Meara, W. (2013). Expanding access to malaria diagnosis through retail shops in western Kenya: What do shop workers think? *Malaria Research and Treatment*.

Scott, P. A. (2014). Unsupervised self-testing as part public health screening for HIV in resource-poor environments: Some ethical considerations. *AIDS and Behavior*, 18(SUPPL. 4), 438–444.

SHOPS Project. (2015). HIV Testing by Private Health Providers: Evidence from 18 Countries. Bethesda, MD: Abt Associates Inc.

Southern Africa AIDS Trust. (2014). *Southern Africa AIDS Trust Report Regional 2014: Legal Issues Surrounding the Distribution of HIV Self-testing Kits*. Retrieved from http://www.academia.edu/8799694/Legal_Issues_surrounding_the_distribution_of_HIV_self-testing_kits_in_Zimbabwe.

Tanzania Food and Drug Authority. (2013). *List of Registered Medical Devices*. Retrieved from http://www.tfda.or.tz/index.php?option=com_phocadownload&view=category&id=64&Itemid=353.

Uganda Ministry of Health. (2010). Ministry of Health National Implementation Guidelines for HIV Counseling and Testing in Uganda. Kampala: Ministry of Health.

UNAIDS. (2000). *Voluntary Counseling and Testing: UNAIDS Technical Update*.

UNAIDS. (2013). *The HIV and AIDS Uganda country progress report*.

UNAIDS. (2014). *The Gap Report*.

UNAIDS. (2015). *How AIDS changed everything*.

UNICEF. (2008). *HIV Diagnosis: A guide for selected rapid diagnostic test (RDT) kits*.

Van Zyl, M., Brown, L., & Pahl, K. (2015). Using a call center to encourage linkage to care following mobile HIV counseling and testing. *AIDS Care, 27*(7), 921–925.

Ventuneac, A., Carballo-Diéguez, A., Leu, C. S., Levin, B., Bauermeister, J., Woodman-Maynard, E., & Giguere, R. (2009). Use of a rapid HIV home test to screen sexual partners: an evaluation of its possible use and relative risk. *AIDS and Behavior*, 13(4), 731–737.

Walensky, R., & Bassett, I. (2011). HIV Self-testing and the missing link. *PLoS Medicine*, 8(10).

Wesolowski, L. G., Mackellar, D. A., Ethridge, S. F., Zhu, J. H., Owen, S. M., & Sullivan, P. S. (2008). Repeat confirmatory testing for persons with discordant whole blood and oral fluid rapid HIV test results: findings from post marketing surveillance. *PloS One*, 3(2), e1524.

WHO, UNAIDS, Brocher Foundation, L. (2013). Report on the first international symposium on self-testing for HIV: The legal, ethical, gender, human rights and public health implications of self-testing scale-up. *Meeting Report - Geneva, Switzerland. 8-9 April 2013*.

Wong, V., Johnson, C., Cowan, E., Rosenthal, M., Peeling, R., Miralles, M., … Brown, C. (2014). HIV self-testing in resource-limited settings: regulatory and policy considerations. *AIDS and Behavior, 18 Suppl 4*, S415–21.

World Health Organization. (2003). *Medical device regulations: Global overview and guiding principles*. Geneva.

World Health Organization. (2012). *Service delivery approaches to HIV testing and counseling: a strategic HTC programme framework*.

World Health Organization. (2014). *Supplement to the 2013 Consolidated Guidelines on the Use of ARV Drugs for Treating and Preventing HIV*.

World Health Organization. (2015). *Consolidated guidelines on HIV testing services*. Geneva.

World Health Organization, & UNAIDS. (2013). *A short technical update on self-testing for HIV*.

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