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ASSESSMENT OF OVER-THE-COUNTER HIV RAPID TEST KITS IN NAMIBIA

AIDSTAR-One
AIDS SUPPORT AND TECHNICAL ASSISTANCE RESOURCES

DECEMBER 2013

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AIDS Support and Technical Assistance Resources Project

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AIDSTAR-One

John Snow, Inc.
1616 Fort Myer Drive, 16th Floor
Arlington, VA 22209 USA
Phone: 703-528-7474
Fax: 703-528-7480
E-mail: info@aidstar-one.com
Internet: aidstar-one.com

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ACRONYMS

AIDS	acquired immunodeficiency syndrome
CDC	U.S. Centers for Disease Control and Prevention
CMS	Central Medical Stores
FDA	U.S. Food and Drug Administration
FEFO	first-to-expire, first-out
HAART	highly active antiretroviral therapy
HCT	HIV counseling and testing
HIV	human immunodeficiency virus
MOHSS	Ministry of Health and Social Services
NDHS	Namibia Demographic and Health Survey
NGO	nongovernmental organization
NHTC	National Health Training Centre
NIP	Namibia Institute of Pathology
NMRC	Namibia Medicines Regulatory Council
OTC	over-the-counter
PA	pharmacist assistant
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
POCT	point of care testing
QA	quality assurance
RTK	rapid test kit
SHOPS	USAID-funded Strengthening Health Outcomes through the Private Sector Project
SOP	standard operating procedure
SRA	stringent regulatory authority
TPP	target product profile
UNAM	University of Namibia
USAID	U.S. Agency for International Development
VCT	voluntary counseling and testing
WHO	World Health Organization

EXECUTIVE SUMMARY

The Republic of Namibia, a country in southern Africa, has a generalized HIV epidemic with a prevalence of approximately 13 percent as of 2010/2011 (Ministry of Health and Social Services [MOHSS] 2012). Because only 50 percent of women and 32 percent of men had ever been tested for HIV and received their results as of 2006, the Government of Namibia has implemented strategies to increase access and demand for HIV counseling and testing (HCT). Self-testing for HIV, which can be performed by a client in the privacy of his or her home, is a noninvasive and convenient method of *determining possible HIV infection*. However, such a test would not confer a diagnosis of HIV; any results must be confirmed in a clinical setting with proper counseling and referral to care and treatment services, as necessary.

The U.S. Agency for International Development (USAID)/Namibia received anecdotal evidence suggesting that over-the-counter (OTC) HIV rapid test kits (RTKs) were being sold to consumers for HIV self-testing in private pharmacies in the capital, Windhoek; however, no published documentation was uncovered. In an effort to document the availability of HIV RTKs for OTC sale, and to understand the regulatory and policy context that governs these devices, AIDSTAR-One, funded by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), conducted a rapid assessment of the availability of HIV RTKs sold over the counter in private pharmacies, in collaboration with USAID/Washington's Office of HIV/AIDS, USAID/Namibia, and the Namibian Ministry of Health and Social Services (MOHSS). With this report AIDSTAR-One aims to inform policymakers, donors, and other stakeholders' decision making about the potential for private pharmacies in Namibia to increase access to HIV testing.

METHODOLOGY

A mixed methodology was used to obtain data and information on the extent to which HIV RTKs sold over the counter are available at private pharmacies; regulations regarding rapid HIV tests; HCT guidelines regarding the sale of HIV RTKs over the counter; the supply chain; consumer demand; and barriers and opportunities for OTC HIV RTK sale. The methods used included:

- ***Desk review*** of key HCT policy and regulatory documents
- ***Survey administered to*** pharmacists and pharmacy staff to obtain information on HIV RTKs for over-the-counter sale at private pharmacies
- ***Key informant interviews*** with stakeholders involved in relevant public and private sector organizations, HIV-related policy and legislation, and health care service provision and education.

Documents for desk review were selected by the AIDSTAR-One assessment team and approved by the USAID/Washington HIV Testing and Counseling Team, USAID/Namibia, and the Namibian MOHSS.

The AIDSTAR-One assessment team conducted the pharmacy survey in private pharmacies in eight cities in five regions of Namibia. The team initially produced a draft list of private pharmacies from lists provided by the Pharmaceutical Society of Namibia and the Pharmacy Council of Namibia, and

then consulted with the Pharmacy Council of Namibia to finalize the list. In total, the team visited 53 pharmacies in Namibia.

Through key informant interviews, the AIDSTAR-One assessment team aimed to learn about relevant pharmacist and pharmacist assistant (PA) training in HCT; regulatory systems, policies, and guidelines for OTC HIV RTKs; quality of safety, performance of, and quality assurance (QA) of HIV RTKs; among other relevant topics. The team conducted 19 interviews with stakeholders from various MOHSS departments, the Namibia Institute of Pathology (NIP), the Pharmacy Council of Namibia, wholesalers and distributors, and USAID partner organizations, among others.

To preserve confidentiality, the assessment team did not collect survey respondent names and key informants are not identified. The master list of pharmacies with associated codes is confidential.

FINDINGS

The desk review found that current Namibian regulatory documents and HIV guidelines do not address HIV self-testing or HIV RTKs sold over the counter at pharmacies explicitly. However, HIV RTKs fall under the regulatory framework for medical devices.

Most pharmacies operate within the private sector in Namibia. AIDSTAR-One conducted surveys in 53 private pharmacies (47 percent of the total). Twenty-one of the pharmacies surveyed were located in Windhoek, Namibia's largest city. Of 52 pharmacists surveyed, 38 percent (n = 20) reported having received training in HIV rapid testing and 62 percent (n = 32) reported having been trained in HIV counseling; 33 percent (n = 17) had been trained in both HIV rapid testing and HIV counseling. The majority of respondents expressed a desire for additional training on HCT.

Thirty-six pharmacies (68 percent of those surveyed) reported selling HIV RTKs over the counter. Fifty percent of those began selling the kits in 2012. More than half of respondents reported that their pharmacy began selling HIV RTKs over the counter due to customer demand. The majority of these pharmacies (83 percent) had HIV RTKs in stock on the day of the site visit. Further, one-test and five-test kits were the most common HIV RTKs available for purchase, while the storage location in the pharmacies varied from available on the shelves/counter to having to request the product from the pharmacist. The price of test kits containing one test was approximately 41 Namibia dollars (N\$) (approximately 4 U.S. dollars [U.S.\$]) and the cost of test kits containing five tests was N\$125 (approximately U.S.\$12). The assessment team also collected sales data, where available, and results showed that sales volume range varied widely; some pharmacies reportedly sold many OTC HIV RTKs while others sold few; for example, in the previous 30 days, three sites reportedly sold more than 20 OTC HIV RTKs, whereas 14 pharmacies reported having sold between 0 and 2. Most pharmacists reportedly restock HIV RTKs when the pharmacy's inventory is low. The survey identified five primary distributors of the devices, with Nampharm and Geka Pharma cited most frequently.

In terms of services delivered to OTC HIV RTK consumers, most pharmacists reportedly provided information about the kits—for example, instructions on administering the test and the need to seek counseling. Ten respondents said that customers requested help administering the rapid HIV test and most respondents were able to provide support, either directly helping administer the test or providing instructions. Further, most respondents were aware of where HIV counseling and confirmatory testing services were available and referred customers who bought HIV RTKs to these services. Survey respondents reported concerns about selling HIV RTKs over the counter (e.g.,

counseling needs and the customer’s emotional response), as well as advantages of selling the devices (e.g., increasing access to HIV testing and affordability of the devices).

AIDSTAR-One conducted 19 key informant interviews with various stakeholders, including MOHSS staff, the NIP, the Pharmacy Council of Namibia, wholesalers and distributors of health products, USAID partner organizations, education and training institutions, and health professions associations. While the Pharmaceutical Society of Namibia does not provide OTC HIV RTK information to its members, they were aware that some private pharmacies sell the kits and suggested that manufacturers of the devices may provide this information to the pharmacies. According to key informants, HIV RTKs were first introduced for over-the-counter sale in Namibia in 2002. HIV RTKs sold over the counter were classified as medical devices. The Medicines and Related Substances Control Act, 2003, regulates the registration, manufacture, modification, importation, storage, transportation, sale, use, or destruction of a medical device or category of medical devices. However, the team could not readily identify a clear regulatory framework for the quality, safety, or performance of HIV RTKs sold over the counter in the private sector; even so, informants’ responses highlighted a need for regulation. The Central Medical Stores (CMS) are the authorized distributor of HIV rapid tests for the public sector; however, CMS interviewees stated that the HIV RTKs that they procure are not available over the counter. They were unaware that several suppliers were actively distributing HIV RTKs to pharmacies for sale over the counter in Namibia.

DISCUSSION AND RECOMMENDATIONS

Results of this assessment demonstrate that HIV RTKs have been available for OTC sale to consumers in private pharmacies for over 10 years, though most private pharmacies began selling them more recently. The OTC availability of HIV RTKs for use by consumers to screen themselves for HIV puts Namibia in a key position to demonstrate global leadership through attention to the policy, regulatory, and implementation issues outlined in this report. Addressing these issues will help to ensure that Namibia provides quality, safe, and accessible HIV self-screening through private pharmacies. AIDSTAR-One provides recommended actions for next steps regarding the sale of HIV RTKs over the counter at private pharmacies in Namibia, including putting in place appropriate policies, guidelines, and regulations; exploring task-shifting for HCT; ensuring community engagement; establishing authorized private sector distributors; and addressing ethical considerations. Further, AIDSTAR-One identifies recommended future research on HIV RTKs sold over the counter in Namibia.

POLICIES, GUIDELINES, AND REGULATIONS

Over-the-Counter Sales

Given public interest in and use of HIV RTKs for self-testing reported by pharmacists, the assessment team recommends that the Government of Namibia recruit a multidisciplinary task force to develop a policy framework to address 1) quality standards for rapid HIV testing in the context of self-testing, 2) channels for the sale of HIV RTKs, 3) counseling needs, and 4) other practices regarding the availability of HIV self-testing through OTC sale of HIV RTKs directly to consumers.

PROPOSED ACTION STEPS

The assessment team encourages the following action steps for consideration:

- Exercise the authority conferred in the Medicines and Related Substances Control Act, 2003, to develop a regulatory framework for HIV RTKs to be sold over the counter, including technical/laboratory evaluation of devices available, intended use of devices sold in private pharmacies, and registration requirements to sell them.
- Build a partnership with the NIP to establish the country's acceptable target product profile (TPP) for HIV RTKs that may be used by consumers, developing or adapting the technical evaluation process and quality assessment criteria for regulation of HIV screening tests to be sold directly to the public. Careful attention is needed to verify accuracy of the test, ease of use when used by consumers instead of health care providers, and other elements of the TPP for RTKs that will be used by laypersons.¹
- Standardize information provided to customers at the point of sale through on-site and remote counseling options and confirmatory testing using Namibia's nationally approved algorithm for confirmation of test results.
- Establish regulatory enforcement mechanisms, allocate sufficient funding for enforcement, and assign personnel to oversee and undertake enforcement activities.
- Develop a process to disseminate information about HIV RTKs sold over the counter to key professional stakeholders, particularly the Pharmaceutical Association of Namibia, pharmacy educators, and pharmacists.
- Ensure continued and open engagement and dialogue about ways to improve or modify HIV self-testing among key stakeholders, including private sector partners.

Rapid HIV Testing in Private Pharmacies

Several pharmacists interviewed have already received training on HCT and provide informal HIV counseling to some customers purchasing HIV RTKs over the counter. A majority of pharmacy survey respondents expressed interest in receiving training on both the use of HIV RTKs and HIV counseling. Some stakeholders expressed concern, however, regarding pharmacists' busy workloads and potential difficulty with the integration of HIV counseling into a busy routine.

PROPOSED ACTION STEPS

The assessment team encourages consideration of the following action steps:

- Draft regulations, in partnership with the Pharmacy Council of Namibia, requiring pharmacists to receive HCT training, and add it to the Council's updated regulations on good pharmacy practice (scheduled to be published in 2014).
- Include training on rapid HIV testing in preservice training for pharmacists and pharmacist assistants; this training should comply with national standards and be integrated with the content of both the University of Namibia syllabus for pharmacist training and the National Health Training Centre (NHTC) syllabus for pharmacist assistants.

¹ The Program for Appropriate Technologies in Health (PATH) is developing the first TPP for HIV rapid test kits intended for use by laypersonnel in resource-poor settings; this process is under way. There is currently no globally accepted TPP for RTKs used for HIV self-testing, although the United States has one for OraQuick sold in there.

- Provide in-service training on rapid HIV testing that complies with national standards for pharmacists and pharmacist assistants who are already in practice. Consider offering the MOHSS-approved training at annual pharmacy professional gatherings, such as the Pharmaceutical Society of Namibia’s annual congress, and online, because almost all pharmacies have Internet access.
- Develop continuing professional development education materials for pharmacists and pharmacist assistants that include, at minimum, the following information: review of guidelines, standard operating procedures, and regulations related to HCT and rapid HIV testing.
- Expand the availability of MOHSS HCT courses for lay counselors who could be employed at pharmacies.
- Certify that pharmacies providing HIV rapid testing meet the NIP’s site requirements for rapid HIV testing.
- Revise the *National Guidelines for HIV Counseling and Testing in Namibia*, the *Guidelines and Standard Operating Procedures for HIV Rapid Testing*, and the *National Strategic Framework for HIV and AIDS Response in Namibia 2010/1–2015/6* to include HCT in private pharmacies.
- Expand the quality assurance systems at the NIP to include evaluation of the quality of RTKs currently being sold in private pharmacies and their appropriateness for general population HIV screening; this may involve an interim system of random sampling of RTKs at pharmacies and laboratory evaluation until registration requirements are developed.

TASK-SHIFTING FOR HCT

Based on the World Health Organization’s (WHO) report of the first international symposium on self-testing for HIV (WHO 2013), global stakeholders hypothesize that, under ideal circumstances, strategic sale of quality, accurate, and appropriate HIV RTKs for HIV self-screening could shift the initial HIV screening test to the consumer. In circumstances in which tests for HIV screening of appropriate sensitivity and accuracy (in the hands of consumers) are available to the public, consumers *who screen negative* may not need to undergo formal HCT which could, theoretically, help to reduce the workload of overburdened health providers. The validity of this approach remains unknown globally, however, and the RTKs sold over the counter in Namibia do not have a product profile suitable for HIV self-testing.

If Namibia formally supports HIV self-testing in the private sector, concerns will remain regarding the level of counseling services, which may or may not be available. An absence or deficit of counseling around self-testing could result in misinterpretation, or other negative consequences for customers, especially if there is not a process that clarifies the role of the OTC HIV RTK as a *screening* test, the limitations of its results, and the need for repeat testing to confirm preliminary positive results.

PROPOSED ACTION STEPS

The assessment team encourages consideration of the following action steps:

- Explore the feasibility of integration of HIV counseling within pharmacy settings without expanding the workload of pharmacists and pharmacy assistants through the use of:

- HTC counselors working at pharmacies during prespecified windows of time to provide HIV counseling and/or testing for pharmacy customers who are interested
- Lay counselors working at pharmacies to provide HIV information/support to individuals who are seeking HIV OTC RTK for self-screening
- Facilitated referrals to HCT sites that provide HIV counseling, along with more formal testing.

COMMUNITY ENGAGEMENT

Once a policy and regulatory framework has been established, systems are functioning to ensure that appropriate, safe, accurate, and usable HIV RTKs are for sale, and community-based monitoring strategies have been designed and implemented, then the assessment team recommends consideration of a campaign to engage the local communities regarding self-screening for HIV. In particular, AIDSTAR-One encourages information-sharing resources for the following issues that customers who purchase HIV RTKs over the counter currently reportedly face:

- Storage of the kit
- Disposal of the biohazard waste generated by conducting the test
- Test administration and interpretation
- Actions to take if the test is positive or negative, including confirmatory testing resources
- Local resources for HIV counseling, care, support and treatment, and HIV prevention.

PRIVATE SECTOR DISTRIBUTORS

Distributors of the HIV RTKs for sale over the counter and pharmacists in private practice need information about revised policies on HCT and regulations for medical devices once these have been developed. They also need information about the NIP-approved HIV RTKs, since most pharmacists referred to manufacturers' quality data when asked about the quality of the kits; they were unaware of NIP-approved HIV RTKs for use by health care professionals. Until further evaluation by the NIP, it is unclear whether the NIP-approved test kit for HIV screening (Test #1) will retain its accuracy if used by consumers, because its ease of use by laypersons remains unknown. The team does not recommend the substitution and sale of the NIP-approved screening RTK directly to consumers given that its accuracy and ease of use are unknown in this setting.

PROPOSED ACTION STEPS

The assessment team encourages consideration of the following action steps:

- Develop channels for input and exchange of information between public sector partners and private sector stakeholders on rapid HIV testing with attention to areas of mutual benefit.
- Disseminate the list of NIP-approved rapid HIV tests to all distributors, private pharmacies, the Pharmacy Council of Namibia, and the Pharmaceutical Society of Namibia as an interim strategy pending the establishment of medical device regulations. Also recommended is inclusion of a brief description of the nationally approved HIV testing algorithm (the

process used by the NIP to approve RTKs for use in the public sector), and clarification of the difference between self-screening and confirmatory testing.

ETHICAL CONSIDERATIONS

There are a number of ethical considerations associated with self-screening for HIV. Increasing an individual's autonomy is an important ethical consideration within health care. Ensuring that WHO's "five C's" (consent, counseling, correct test results, connection/linkage to prevention, care and treatment, and confidentiality) are upheld in the use of OTC HIV RTKs is possible—however, with several caveats: consent is implied with the assumption that there is no misuse of the HIV RTKs; correct results can be supported, although not ensured; confidentiality can be improved; and linkage to care is unknown. Potential risks to patients include, but are not limited to:

- Risk of user error and potential false-positives and false-negatives
- Risk for misinterpretation of results
- Possible increased risk of misuse (coercive testing of others)
- Risk of point-of-sex testing to screen potential sex partners, given the technological limitations
- Potential risk for non-linkage to care and treatment
- Potential risk for exacerbating violence to self and others (e.g., gender-based violence, partner violence, self-harm)
- Possible human rights violations (e.g., lack of informed consent and coercion)
- Increased risk for discrimination and stigma, especially for key groups such as—
 - Domestic or migrant workers
 - Adolescents
 - Vulnerable family members such as children and married women
 - Sex workers
 - Partners and couples, including those getting married or those in abusive relationships.

FUTURE RESEARCH

To the authors' knowledge, this is the first assessment of the availability of HIV RTKs for sale over the counter to the public in private pharmacies in sub-Saharan Africa. The study highlights issues that are potentially applicable in other developing countries. The Namibia experience can help inform approaches adopted by other countries with similar opportunities for leveraging the private sector as a source of HIV-related services.

The assessment team encourages consideration of the following research and evaluations:

- Studies with private pharmacy customers and the general public that evaluate attitudes about and perceptions of HIV RTKs for sale over the counter in private pharmacies. Topics that could be explored include acceptability of HIV RTKs for sale over the counter, the potential use of private pharmacies as HCT sites, pharmacist or pharmacy staff serving as HCT counselors, knowledge and awareness of HIV RTKs for sale over the counter and how they

are used, ease or difficulty of test use and interpretation of results, perceived trustworthiness of results, reasons for self-screening, and awareness of follow-up options, among others. It may be possible to add questions to the upcoming Namibia Demographic and Health Survey (NDHS) to acquire population-based information. To obtain more-specific perspectives from subgroups, screening questions could be designed to identify if someone has actually bought a kit, used a kit, or would like to do home-based HIV screening. Questions on the use of HIV RTKs may help shed light on the ethical issues related to potential coercive use of the kits on spouses, children, or employees.

- Comparison of monitored and unmonitored pharmacy-based rapid testing for HIV. Such a comparison could inform the evaluation of pharmacies as a venue for rapid HIV testing. Additional models may include counseling and assistance with testing by pharmacists to HIV RTK customers. Careful attention to work-flow requirements during these evaluations may help inform implementation approaches.
- Evaluation of the best approaches to promote confirmatory testing and subsequent linkages to HIV care and treatment for individuals and families with a positive test result. Relatedly, evaluation of self-testing as a demand driver for HTC services generally.
- Investigation of the differences in client type (e.g., demographic characteristics, employment categories [such as health care providers]) for those purchasing HIV RTKs over the counter. If it is found that men purchase HIV RTKs more often than women, this can be used to inform strategic approaches to reach men with services.
- Post-marketing surveillance of rapid test kits sold over the counter, with technical assistance from regulatory experts.
- Following development of regulations of medical devices, evaluation of compliance with regulations by pharmacists and attention to enforcement by the regulatory agency.

SECONDARY DATA ANALYSIS

Additional research questions that can be addressed through secondary data analysis include:

- Impact of pharmacist training on the decision to sell or not sell HIV RTKs over the counter in private pharmacies
- Yearly sales data by: region, who sells the kits
- Client-provider interaction in terms of a pharmacist or pharmacist assistant providing information to customers who are purchasing an OTC HIV RTK.

INTRODUCTION

HIV self-testing, which can be performed in the privacy of an individual's home by taking an oral fluid sample, is noninvasive, private, and convenient. Self-testing, however, is interpreted by the individual and a positive HIV screen requires confirmatory testing in a clinical setting with counseling and linkage to treatment, as necessary (Pant Pai et al. 2013). In an effort to reach individuals and couples not accessing HTC, two pilot studies on HIV self-testing were conducted with health workers and their partners in Kenya (Kalibila et al. 2011) and adults in a community in Malawi (Choko et al. 2011), in which findings support the approach. HIV self-testing has also been incorporated into national HIV policies in Kenya (2009) and Zambia (2011) (WHO 2013). Further, in 2012, the U.S. Food and Drug Administration (FDA) approved over-the-counter sale of OraQuick, an in-home HIV rapid testing kit (U.S. FDA 2013). However, further research on HIV self-testing is required; therefore, WHO held a meeting in 2013 on the legal, ethical, gender, human rights, and public health impact of self-testing scale-up (WHO 2013). Based on the meeting, WHO advocates for governments to explore HIV self-testing as a complementary approach to increase knowledge of HIV status and uptake of care and treatment (WHO 2013). Building on these efforts, at the request of USAID/Namibia, AIDSTAR-One, funded by the President's Emergency Plan for AIDS Relief (PEPFAR) and in collaboration with the HIV Testing and Counseling Technical Working Group, USAID/Namibia, and the Namibian MOHSS, conducted a rapid assessment of the sale of OTC HIV RTKs in Namibia. Anecdotal evidence from USAID/Namibia suggested that OTC HIV RTKs were being sold directly to consumers in private pharmacies in Windhoek; however, no documented evidence or studies were found. USAID/Washington requested that this survey be conducted to determine 1) the availability of HIV RTKs directly sold to consumers for self-use and 2) the contexts in which HIV RTKs are being sold over the counter. Lessons learned from this assessment may be applied to different settings and contexts where there is documented or anecdotal evidence of sales of HIV RTKs over the counter.

HIV IN NAMIBIA

Namibia has a generalized HIV epidemic. The MOHSS 2012 Spectrum Modeling as presented in the national HIV/AIDS profile estimates HIV prevalence for adults was 13.2 percent in 2010/2011 (MOHSS 2012). The estimated number of people living with HIV is approaching 194,000. Sentinel surveillance of antenatal care (ANC) clinics reveals a prevalence rate of 18.2 percent, with higher prevalence in districts bordering Angola. Data on HCT rates from the 2006 NDHS show that a little over 50 percent of females have ever been tested for HIV and received their results, compared with only 32 percent of men. In the 12 months preceding the survey, about 29 percent of females were tested and received results, compared with about 18 percent of males.² Since 2006, implementation of the National Strategic Framework for HIV and AIDS 2010/11 to 2015/16 has resulted in increased HCT uptake, and in 2010/2011 the Framework targets were exceeded.³

² USAID/Namibia, *Namibian National HIV/AIDS Profile* (Windhoek: USAID/Namibia, 2013), compilation of multiple sources.

³ Ministry of Health and Social Services, Namibia, *Global AIDS Response Progress Reporting 2012: Monitoring the 2011 Political Declaration on HIV/AIDS* (Windhoek: MOHSS, 2012), reporting period 2010 & 2011, .

According to the USAID-funded Strengthening Health Outcomes through the Private Sector (SHOPS) project,⁴ 25 percent of private funds spent on health care costs are spent at private pharmacies, about 33 percent at private for-profit hospitals, and 11 percent at private clinics (SHOPS 2010).

OBJECTIVES

The assessment aimed to explore issues related to private pharmacies' sale of HIV RTKs directly to consumers. Specifically, the assessment aimed to elicit data to describe the extent to which HIV RTKs are available for sale through private pharmacies, the regulations addressing rapid HIV tests, whether HCT guidelines include reference to sale of HIV RTKs in private pharmacies, the supply chain, consumer demand for HIV RTKs, and barriers and facilitators that influence product availability.

⁴ The SHOPS project is funded by USAID and implemented by Abt Associates. For more information, please visit the project website, <http://www.shopsproject.org>.

METHODOLOGY

Three data collection methods were used to gather qualitative and quantitative data on HIV RTKs available for sale in private pharmacies. The methods included:

- *Desk review* of key policy and regulatory documents affecting HCT in Namibia
- *Survey* administered to pharmacists and pharmacy staff to obtain information on objective and subjective measures related to HIV RTKs for sale at private pharmacies (no customers were surveyed)
- *Key informant interviews* with stakeholders from the public and private sectors—for-profit and not-for-profit—connected to HTC, HIV-related policy and legislation, and health care service provision and education.

DESK REVIEW

AIDSTAR-One conducted a desk review of the Government of Namibia’s policies, guidelines, and regulations related to HCT and HIV RTKs sold directly to consumers. USAID and AIDSTAR-One collaboratively compiled documents for the desk review (see References). Peer-reviewed literature on HIV rapid testing was not included in the desk review. The desk review was conducted to inform the assessment team of relevant guidelines and reports to inform their data collection. Information gleaned from the key documents is described below (refer to the Findings section).

PHARMACY SURVEY

As shown in Table 1, the pharmacy survey was conducted in private pharmacies located in eight cities that represented the five most populated regions.

Table 1. Pharmacy Survey Sites

Region	Population^a	Cities where pharmacy survey was conducted
Erongo	150,400	Swakopmund and Walvis Bay
Hardap	79,000	Rehoboth
Kavango	222,500	Rundu
Khomas	340,900	Windhoek
Oshana	174,900	Ondangwa, Ongwediva, and Oshakati

^a Namibia National Planning Commission, *Population and Housing Census Preliminary Results* (Windhoek: National Planning Commission, April 2012).

USAID/Namibia selected these cities because of their population density, high HIV prevalence, and their status as target regions for USAID HIV prevention, care, and treatment activities.

The survey questionnaire was designed to elicit quantitative and qualitative data, including the training of pharmacists and PAs; whether HIV RTKs are sold in the pharmacy; year the pharmacy began selling HIV RTKs over the counter; stock information (including any stockouts); sales information; retail cost; wholesale cost; salespeople; consumers; confidentiality; pharmacist consultation; questions from customers; perception of customers' ability to administer the test and interpret results; access to HIV counseling and confirmatory testing in the community; distributors/suppliers of HIV RTKs for sale directly to consumers; storage; inventory management; and concerns and opportunities.

Qualitative information collected through the survey and presented in this report is paraphrased (see Findings section). See Appendix 1 for the pharmacy survey questionnaire.

PHARMACY SELECTION PROCESS

Pharmacy Lists

The Pharmaceutical Society of Namibia provided a list of member pharmacies. A second list provided by the Pharmacy Council of Namibia included pharmacies that were presently operating, pharmacies that recently closed, pharmacies that are approved but not operating yet, close corporations,⁵ hospital pharmacies, and wholesalers. From the lists, AIDSTAR-One developed a draft list of pharmacies for assessment sites, and subsequently consulted with a Pharmacy Council of Namibia representative to finalize the list of private pharmacies. However, while in Oshana region, the assessment team obtained additional information about operational pharmacies, which enabled team members to sample all the pharmacies in the three cities included in the study. The final version of the list was shared with the Pharmacy Council of Namibia, as it was the most accurate and comprehensive compilation of approved pharmacies in Namibia.

The assessment team estimated 110–112 pharmacies operating nationwide in Namibia at the time of the rapid assessment.

Windhoek Sampling Procedure

The assessment team visited all pharmacies in each of the eight cities, except for Windhoek. Fifty-three pharmacies were identified in Windhoek, yet the limited time for data collection allowed for a sample of just 20 pharmacies to be included. To eliminate selection bias, the following sampling procedure was used: All pharmacies in Windhoek were listed alphabetically and every third pharmacy was selected, producing a list of 17 pharmacies, which were plotted on a map to ensure that all areas of the city were included. This resulted in a list in which three neighborhoods were not included; each contained at least one pharmacy so the pharmacy in the center of each of the areas was added to the sample for a total of 20 pharmacies in Windhoek.

Only one pharmacy opted out of the survey. The assessment team employed a substitution rule that drew data from the pharmacy nearest the opted-out site. Pharmacy confidentiality was maintained on the survey document by using a code assigned to each pharmacy and the city name. Names of respondents were not documented, and the master list of pharmacies with their associated codes remains confidential.

⁵ A "close corporation" is a type of company in Namibia. Many pharmacies are classified as close corporations. One close corporation may be comprised of one or many pharmacies.

KEY INFORMANT INTERVIEWS

The assessment team conducted key informant interviews with 19 stakeholders representing selected departments of the MOHSS, the NIP, the Pharmacy Council of Namibia, wholesalers and distributors of health products, USAID partner organizations, education and training institutions, and health professions associations. See Appendix 2 for a list of the key informant organizations. To protect confidentiality, key informants are not identified.

Interviews were conducted using a key informant interview guide (see Appendix 3) that included questions regarding pharmacist and PA training in HTC; HIV RTK information; the regulatory system; quality of safety and performance; quality control and QA; the supply chain for HIV RTKs in the private sector (including number of distributors); HIV RTK availability over the counter; estimated demand based on sales data; policies and guidelines for HIV RTKs; ease of use and clarity of instructions for OTC HIV RTKs (including interpretation of results); access and/or barriers to HCT and other related health care services; usage of confirmatory testing; challenges/concerns to and opportunities/facilitators for effective OTC HIV self-testing; and activism and human rights.

FINDINGS

DESK REVIEW

Overall, the documents and guidelines do not address HIV self-testing or HIV RTKs sold at private pharmacies in Namibia. Pharmacies are not indicated as a setting where HCT occurs according to the National HIV Counseling and Testing Policy. However, there is recognition that a multi-sectoral approach, including the private sector, is needed in the HIV response. Key information from desk review resources are presented below.

NATIONAL GUIDELINES FOR HIV COUNSELING AND TESTING IN NAMIBIA (MOHSS 2011)

These detailed and specific HCT guidelines do not address the topic of HIV self-screening or self-testing or the sale of HIV RTKs directly to consumers in private pharmacies. They describe provider-initiated HIV counseling co-located with HIV testing in health facilities and in people's homes. HIV RTKs are used after they are purchased outside of the pharmacy. If counseling is provided at the pharmacy, it is limited to pre-test counseling upon purchase. Post-test counseling is provided only if the client returns to the pharmacy or independently seeks support services from another source.

GUIDELINES AND STANDARD OPERATING PROCEDURES FOR HIV RAPID TESTING (NIP 2012)

This document serves as the implementation guide for rapid HIV testing in Namibia. It outlines specific conditions that must be met by testing sites. The purchase and use of HIV test kits for self-testing for HIV by lay or trained persons are not mentioned.

NAMIBIA PRIVATE SECTOR ASSESSMENT SUMMARY REPORT (SHOPS 2010)

This report, which was prepared by a USAID-funded project focusing on strengthening private sector health services, provides an overview of Namibian health sector resources that address HIV and AIDS services. It shows that some sectors are not engaged in the HIV epidemic response and that government engagement of the for-profit health sector is "neither transparent nor fully coordinated" (SHOPS 2010, p. 13). The report also notes that there is no forum for the public and private sectors to interact and engage (p. 14). Other notable pieces of information cited in the report are:

- Spending at private pharmacies accounts for 25 percent of private funds expended on health care (p. 16).
- The private sector contributes less than 1 percent to HIV and AIDS services (p. 17).

- Only 2.5 percent of HIV funding is spent at pharmacies (p. 17).

The report indicates that 9 of 10 pharmacists work in the private sector, and that private-sector pharmacies and outpatient-care facilities are resources that could be mobilized for HIV and AIDS programs (p. 17).

HCT services were actively provided through USAID-funded New Start Centers⁶ run by nongovernmental organizations (NGOs). This private, not-for-profit sector HCT resource is complemented by testing done in private hospitals and private outpatient-care centers operated by physicians. Medical Aid, a private health insurance program, covers the cost of testing. Private pharmacies are not identified as a source of HCT in this section of the report (p. 19).

NATIONAL STRATEGIC FRAMEWORK FOR HIV AND AIDS RESPONSE IN NAMIBIA (REPUBLIC OF NAMIBIA 2010/1–2015/6)

This comprehensive framework document covers all the major topics related to HIV and AIDS in Namibia (Republic of Namibia 2010). On page 14, it calls for:

- “A more-proactive strategy that increases the level of financial investment for prevention”
- “Inclusion of the private sector in a manner that capitalizes on their capacity and resources to contribute strategically towards the national response”
- “Expanding the focus of Namibia’s response to a multi-sectorial approach”
- “Strengthening the coordination and management of the multi-sectorial response.”

The HCT situational analysis provided by the framework cites the reduction of non-return rates with the introduction of rapid HIV testing. Community counselors were used in the rollout of rapid testing (p. 27). Capacity development is discussed (p. 98), with a call for a comprehensive national-capacity assessment that includes the private sector. On page 99, there is a call to increase capacity for HIV implementation to 100 percent by fiscal year 2012–13. HIV RTKs sold over the counter are not mentioned in the framework.

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003; PROMULGATION OF MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003; PROMULGATION OF MEDICINES AND RELATED SUBSTANCES CONTROL AMENDMENT ACT, 2007; COMMENCEMENT OF MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

Government Notice No. 192 is the Medicines and Related Substances Control Act, 2003. It is the legislation that authorizes the regulation of medical devices. Point 2.2 of the Act indicates that “the Council may exercise the powers conferred, and must perform the functions assigned, to the Council by or under this Act.” That authority, or “power conferred” has not yet been implemented by the Medicines Control Council.

⁶ New Start Centers are sites for client-initiated voluntary HCT located in high-population areas and staffed by lay HIV and testing counselors trained to conduct rapid HIV testing and pre- and post-test HIV counseling. Centers are funded by USAID and operated by approved NGOs. When the survey was conducted, the New Start Centers were in the process of being phased out per MOHSS direction.

Government Notices No. 177, 178, 179, and 180 are regulations adopted under the 2003 legislation, but they do not address medical devices.

Government Notice No. 233 is the Medicines and Related Substances Control Amendment Act, 2007. There is no reference to “HIV” or “kits,” and there is no reference to regulation of devices. Medical devices are referred to in relation to their role as a possible mechanism to administer a medicinal preparation.

PROMULGATION OF HOSPITALS AND HEALTH FACILITIES ACT, 1994

The Promulgation of Hospitals and Health Facilities Act of 1994 addresses the registration of private health facilities and references the licensing of such facilities. A private health facility is defined as “an institution, facility, building, or place, other than a hospital, where patients receive treatment, diagnostic or therapeutic interventions or other health services” (Republic of Namibia 1994). Pharmacies are listed under Schedule 1, and they renew their licenses annually as a health facility (Republic of Namibia). No specific reference is made to the sale of diagnostic devices, but because the Act refers to the provision of diagnostic services, the administration of an HIV test in a pharmacy by a pharmacist is presumably included. However, it is not clear whether the pharmacist’s license confers the authority to conduct HIV testing in a pharmacy.

SCHOOL OF PHARMACY PROSPECTUS (UNIVERSITY OF NAMIBIA 2013)

The School of Pharmacy is a relatively new institution within the University of Namibia (UNAM). The first cohort of students was about to begin its third year of study at the time of data collection. The prospectus—or program catalog—does not include instruction on the use or interpretation of rapid HIV test kits. However, the prospectus explicitly includes content on managing the pharmaceutical supply chain, contemporary social issues (including HIV), community pharmacies, clinical skills, and primary health care.

PHARMACY SURVEY RESULTS

SURVEY SITES

AIDSTAR-One conducted the pharmacy survey in 53 pharmacies, an estimated 47 percent of the total registered pharmacies in Namibia. The number of pharmacies included in the survey by region and city are presented in Table 2.

Table 2. Number of Pharmacies Surveyed by Site and Region

Region	Cities	Number of pharmacies surveyed	Percentage of pharmacies included in the survey
Khomas	Windhoek	21	40
Erongo	Swakopmund	9	17
Walvis Bay	4	8	
Oshana	Ondangwa	7	13
Ongwediva	1	2	
Oshakati	5	9	

Hardap	Rehoboth	3	6
Kavango	Rundu	3	6
Total		53	

RESPONDENTS

In 52 of the pharmacies visited, at least one pharmacist was interviewed. In one pharmacy, the front shop worker was surveyed because the pharmacist could not participate due to workload. Multiple respondents were surveyed in 18 percent of the pharmacies.

Respondents' HIV-Related Training

Out of 52 pharmacist respondents, 38 percent indicated having received training in HIV rapid testing and 62 percent reported participation in training in HIV counseling. Further, 33 percent of these pharmacists reported having received training in both topics. However, it is unknown if the training was an MOHSS-approved HCT course since no respondent explicitly stated that they attended such a course, and that information was not explicitly requested. Nevertheless, a majority (85 percent) of the respondents indicated a desire to receive training (or additional training), including both those who were and were not already trained.

Respondents who were trained in these topics reported receiving in-service training (47 percent), preservice training (37 percent), and both types of training (16 percent). The duration of training ranged from less than one day to one year; three days was most frequently reported.

Respondents' Information Sources about HIV RTK Sold Over the Counter

Thirty-eight respondents said they independently sought information on OTC HIV RTKs from the following sources: package insert (45 percent), Internet (42 percent), and books (11 percent). Less frequently cited sources included supplier, seminar, colleague, or friend; the InfoCenter in Cape Town, South Africa; manufacturer; another pharmacy; preservice training; self-taught; and WHO. Only three respondents received information on HIV RTKs sold over the counter from the Pharmaceutical Society of Namibia. Sixteen respondents reported having received information from other sources, including distributors (e.g., suppliers or wholesalers), HIV rapid test kit manufacturer representatives, and the HIV Clinicians Society.

OVER-THE-COUNTER SALES OF HIV RAPID TEST KITS

In total, 68 percent (36 pharmacies) reported that they sell HIV RTKs over the counter. The 17 pharmacies that did not sell HIV RTKs over the counter were asked a limited number of follow-up questions compared with respondents who reported selling HIV RTKs over the counter. Ten pharmacies that did not sell HIV RTKs over the counter noted they would consider selling them if they had access to information on HIV RTKs from a source, such as the Pharmaceutical Society of Namibia.

Nearly half of the pharmacies that sell HIV RTKs over the counter began selling them in 2012. The data on initiation of sales are not representative because some pharmacies (the precise number is not known) opened in 2012 and immediately began selling HIV RTKs over the counter, whereas other pharmacies have been open for many years and have added HIV RTKs sold over the counter to their product line at some point.

STOCK ON HAND

Of the 36 pharmacies that reported sales of HIV RTKs over the counter, 83 percent had them in stock during the site visits. The pharmacies that did not have stock on hand on the day of the survey sell the HIV RTKs directly to consumers only on demand; that is, pharmacists do not hold inventory and only order stock from suppliers when a customer requests a test kit.

Table 3 provides information about stock on hand by test kit brand, and Table 4 presents information about stock on hand by region on the day the survey was conducted. Stock on hand data is reported as number of tests because the number of tests per box (or kit) varies and because some boxes (or kits) were not complete. In total, 259 tests were available in all of the pharmacies surveyed.

When interpreting stock on hand data, it is important to note that the lead time for pharmacies to receive new stock from their distributor is typically quite short. For example, in Windhoek, the lead time from placing an order to receiving the requested product ranges from 10 minutes to one day. In the northern regions, lead time ranges from one day to approximately one week. Short lead times, daily ordering, next-day fulfillment, and low sales volume result in pharmacies needing to keep only a small inventory of HIV RTKs.

Table 3. HIV Rapid Tests in Stock on the Day of the Survey

Test kit name	Manufacturer	Tests per box or kit	# of tests
U-Test	Humor Diagnostica	1	79
		5 (Tests not packaged for individual sale)	78
		25 (Tests not packaged for individual sale)	49
Total Humor Diagnostica tests			206
HIV Tri-Line 1/2/0 Rapid Test Device	ACON, now called ABON	5 (Tests packaged for individual sale)	1
		10 (Tests not packaged for individual sale)	27
Total ACON/ABON tests			28
Rapid Anti-HIV (1&2) Point-of-Care Test	Homemed	1	5
Human Immunodeficiency Virus Rapid Test Device	PharmaChem Pharmaceuticals	20 (Tests not packaged for individual sale)	20
Total other tests			25
Total number of tests in stock			259

The Humor Diagnostica's U-Test rapid HIV test kit was sold in 28 of the pharmacies surveyed; therefore, it had the greatest market exposure compared to the other brands of HIV RTKs observed in private pharmacies. The PharmaChem Pharmaceuticals product was special-ordered by one

pharmacy on customer request, but the customer never returned for the product. The Homemed product, which entered the market at the end of 2012, was sold in two pharmacies. Three pharmacies sold the ACON/ABON products.

Table 4 provides additional detail regarding the availability of stock of HIV RTKs for OTC sale by region. The data suggested that pharmacies surveyed in the north typically stock more than one type of OTC HIV RTK and provide the greatest variety of OTC HIV RTK brands. They also had the most pharmacies stocking multi-test kits, compared with pharmacies in the other regions. The available stock data by region also showed that the pharmacies in the north had more HIV RTKs for OTC sale in stock than pharmacies in the other regions.

Table 4. HIV Rapid Tests in Stock on the Day of the Survey by Region

Regions	Pharmacies with stock on hand	Pharmacies selling one or more type of kit				Number of types of kits sold in the region	Pharmacies with multi-test kits in stock (five or more tests per kit)	Number of tests in stock in the region at survey visit
		Sold one type	Sold two types	Sold three types	Sold four types			
Oshana	12	6	5	—	1	7	9	168
Erongo	7	6	1	—	—	3	2	48
Khomas	7	6	1	—	—	2	1	23
Kavango	3	3	—	—	—	1	0	11
Hardap	1	1	—	—	—	1	0	9
Total number of tests in stock								259

OVER-THE-COUNTER HIV RAPID TEST KIT PACKAGING

The one- and five-test kit packages were the most commonly available kits for individual customer purchase. The multi-test kits were packed in a variety of presentations. The Humor Diagnostica five-test kit appeared to be designed for professional use, not for the sale of individual tests, since only one bottle of buffer was included in the box. The Humor Diagnostica U-Test 25-test kit contained individually wrapped devices and buffers, but because the packages did not contain an alcohol swab and lancet, these tests were also likely for use in clinical settings. The ACON/ABON five-test kit was evidently designed for each test to be sold individually, because all the items required to perform the test were packaged together in a sealed foil wrapper. The ACON/ABON 10-test kit and the PharmaChem 25-test kit clearly were not intended for individual sale, because only one bottle of buffer was provided for tests in each kit.

STORAGE LOCATION

Twenty-six of 36 pharmacies stored the HIV RTKs behind the counter and required customers to request a kit from a pharmacist, PA, or pharmacist intern for consideration or purchase. Six pharmacies stored the test kits on the shelves, where they were accessible to customers. In one pharmacy, the HIV RTKs were not sold for home use; they were sold only as part of a package of

testing services, inclusive of HIV counseling on-site. In this pharmacy, the kits were stored in the room where the testing takes place.

Of the pharmacies that stored HIV RTKs for OTC sale behind the counter, two pharmacies also stored the kits in a second location: a locked cupboard and the rear storeroom. Of the six pharmacies that stored the HIV RTKs for OTC sale on the shelves accessible to customers, three pharmacies had arrangements that were different from others commonly observed:

1. Although the pharmacy had the HIV RTKs accessible on the shelves to customers, buyers would need to request a lancet and alcohol swab from the pharmacist because the kits did not include them in the foil package.
2. At another site, the HIV RTKs were stored on the counter where customers could take and purchase them. However, in this pharmacy, the pharmacist chose to sell the HIV RTKs only to nurses in uniform because the pharmacy was located near a hospital, and nurses from the hospital conducted testing privately.
3. Lastly, another pharmacist had previously stored the HIV RTKs for OTC sale behind the counter, but then moved the kits to an accessible location for customers. After moving the kits, sales reportedly increased. Additionally, the assessment team observed that four HIV RTKs sold in the space within a few hours; the team visited the pharmacy twice and counted stock during the morning and afternoon site visits.

SALES DATA

Table 5 presents OTC HIV RTK sales information provided by the pharmacies. Twenty-three (64 percent) of the 36 pharmacies that sell HIV RTKs had sales data available from the past month; 21 pharmacies had sales data from the past year. However, data were not collected in a systematic manner, for the following reasons: 1) pharmacy staff were unable to retrieve the data from the computer; 2) pharmacy staff had inadequate time; 3) data were not available; and 4) date parameters were not uniform (i.e., when only partial-year data were available in pharmacies that opened during the past year). As a result, the analysis of the actual sales data is limited to measures of central tendency.

Table 5. Actual OTC HIV RTK Sales at Private Pharmacies over the Previous Month and Year

	Sales data from past month (n = 23)*	Sales data from past year (n = 21)*
Total kits sold	108	849
Range	0–23	0–196
Mean	5	40

*Number of pharmacies with data available.

Respondents without data provided estimates of their sales based on recall over the last seven days, the last 30 days, and in the last year (Table 6). The assessment team also organized the actual test kit sales data into categorical data. The sales volume range was wide, suggesting that some locations had significant sales, whereas others sold very few HIV RTKs over the counter.

Table 6. Estimated OTC HIV RTK Sales at Private Pharmacies over Last 7 Days, 30 Days, and Year

Number of kits sold	Number of pharmacies	%
Last 7 days		
0-1	23	85
2-5	3	11
> 5	1	4
Last 30 days		
0-2	14	52
3-5	7	26
6-10	3	11
11-20	0	0
> 20	3	11
Last year		
0-2	1	4
3-5	5	19
6-10	7	26
11-20	7	26
> 20	7	26

INVENTORY MANAGEMENT

Most respondents reported that they restock OTC HIV RTKs when their inventory runs low. Other cited reasons for restocking included 1) orders placed at the end of each day, 2) orders placed when kits are sold, and 3) orders placed on demand. Anecdotal information suggested that most pharmacies place daily orders with their supplier for items that sold during the day. Many respondents also anecdotally noted that their minimum restock level is one or two HIV RTKs. Information collected on lead time revealed that the duration is usually one day and less than 12 days, with an average of three days. Only seven pharmacies reported having had a stockout, and three pharmacies reported having had HIV RTKs expire due to poor sales and short shelf life. In summary, the private pharmacies store limited inventory, order frequently, have a short lead time, and experience limited stockouts and expiry.

Stock on hand was examined for application of first-to-expire, first-out (FEFO) inventory management, but most pharmacies kept few HIV RTKs for OTC sale with the same expiration date. The assessment team identified five pharmacies that did not arrange their HIV RTKs for OTC sale according to FEFO.

STORAGE PRACTICES

All but one pharmacy stored their HIV RTKs for OTC sale in a location protected from sunlight. Temperature data were not standardized because the thermometers that pharmacies are required to have were either not visible or their location was not representative of the overall temperature of the pharmacy (e.g., the thermometer was close to the air-conditioning unit, which had insufficient

capacity to cool the entire pharmacy, resulting in health products being exposed to high temperature).

COST INFORMATION

The assessment team collected information on customer cost per kit (retail cost) and pharmacy cost per kit (wholesale cost). Analysis of the actual cost data revealed that the most common cost for a one-test kit was N\$41 and a five-test kit cost N\$125. Table 7 summarizes the price information per test and selected measures of central tendency for the customer and pharmacy test cost for each brand and type of kit sold in the private pharmacies.

Table 7. Customer and Pharmacy Cost per Test by Manufacturer and Type of Kit

Manufacturer	Test name	Number of tests per kit	n	Retail cost in N\$ per test		n	Wholesale cost in N\$ per test	
				Mode	Range		Mode	Range
ACON/ABON	HIV TRI-LINE 1/2/0	5	1	40	40	1	25	25
		10	1	33	33	1	22	22
Homemed	Rapid HIV (1&2) test	1	2	17, 25	17–25	2	11, 12	11–12
PharmaChem	HIV test	20	1		Not provided	1	12	12
Humor Diagnostica	U-Test	1	28	41	33–65	27	27	20–42
		5	8	24, 25	24–50	9	16	14–36
		25	2	16, 19	16–19	2	10, 13	10–13

DISTRIBUTORS

As noted in Table 8, the distributors (also referred to as suppliers or wholesalers) were identified as sources for purchase of HIV RTKs by the private pharmacies. Many pharmacies used more than one distributor.

Table 8. Distributors of HIV RTKs for OTC Sale to Private Pharmacies

Distributor	Pharmacies citing distributor as a source of HIV RTKs for OTC sale
Nampharm	33
Geka Pharma	28
NewMed	5
Erongo Med	1
Upex	1

SALESPEOPLE

Most of the pharmacies surveyed stored HIV RTKs behind the counter, and pharmacists comprised 92 percent of the salespeople of the kits. PAs were not authorized to sell the kits; yet the team identified eight pharmacies where PAs sold HIV RTKs for OTC sale.

CUSTOMER CHARACTERISTICS

Customer information was obtained from pharmacy staff through the pharmacy staff surveys. These qualitative data were derived secondhand through the pharmacists since customer characteristics or data were not routinely collected by pharmacists. Data were based upon their recall of experience and interactions with customers purchasing HIV RTKs, and results are generally presented thematically.

Customers Who Buy HIV RTKs Over the Counter

Pharmacists stated that rapid HIV test kits were most often purchased over the counter by health care providers. None of the respondents reported selling HIV RTKs to other pharmacists, public health care facilities, private health care facilities, NGOs, or “church people” (e.g., pastors and reverends). However, they reported that OTC HIV RTKs are sold to businesspeople, sex workers, soldiers, customers with prescriptions from physicians, tourists, and young couples.

Privacy and Confidentiality

According to the respondents, while some customers requested privacy, most did not; however, most pharmacies reported providing privacy at a customer’s request. The most common method for providing privacy was to place the rapid HIV test kit items in an opaque bag behind the counter before giving it to the customer to take to the cash register. Some pharmacies reported taking customers to the consultation room to give them their items. Other methods to provide privacy included 1) ringing up the sale using the cash register at the back of the pharmacy, 2) having the pharmacist take the kit to the cash register with payment from the customer, 3) giving the OTC HIV RTK to the customer in the back of the pharmacy, and 4) delivering the kit directly to the customer’s home. Four respondents said it is not possible to provide privacy; one said it is not important, and another said patients do not demand privacy.

Information Provided to Customers

Seventy-five percent of respondents reported providing information to customers about the HIV RTKs when customers purchased them. The following information, from most common to least common, was provided to the customer:

- Instructions on performing the test
- The need for counseling before and after administering the test
- Actions to be taken following administration of the test
- Accuracy of the test
- Social considerations (e.g., precautions against administering alone)

- Window period
- HIV prevention
- Instruction on interpreting the test.

Pharmacists who did not provide information on HIV testing to their customers reported the following rationale: 1) customers already knew how to use the product, 2) HIV RTKs are sold “on demand” to health care providers, and 3) kits are available freely on the shelves so there is no opportunity to provide information.

Customers’ Questions

Respondents reported that customers ask questions about HIV RTKs, including how to use them, how to understand the accuracy of HIV test results, and how to interpret the HIV test results.

Customers also asked questions on the following topics, but less frequently than on the topics above:

- What to do about a positive result? Negative result?
- Where to seek help/medical care/treatment following a positive result?
- Where can they buy another HIV RTK?
- Where to seek counseling?
- Where can they get help for family members?
- Can they buy an HIV RTK?
- Can they perform the HIV test at home?
- Do you sell HIV RTKs? Are they in stock?
- How long after exposure is the test accurate?
- How long after sex can one become HIV-positive?
- How long does it take to get the result?
- How long does it take [to do the test]?
- How much does [a test] cost?
- Is a cheaper one available?
- Is it going to hurt?
- What is the possibility of a false-positive or false-negative?
- Do I still have to consider the window period?

Customer Experience with the Rapid HIV Test and Disclosure Reported by Pharmacists

Six of 27 respondents said that customers reported difficulty with using the lancet; one respondent indicated customers had difficulty with the instructions; and one respondent reported that doctors had challenges with the five-pack U-Test because there was only one bottle of buffer.

Over one-third of respondents said customers requested help administering the test, and seven were able to help the customers administer the test. They either directly administered the test in the consultation room or explained how to do the test and then the customer performed the test in the consultation room or at home. Two respondents said they could not assist customers who requested help because they were too busy; one of them referred the customer to a doctor, stating that the test could not be done in the pharmacy.

Most respondents said that customers did not report having difficulty interpreting the test results. Three respondents who did have customers tell them they had problems said they could not interpret the result because they had difficulty seeing or reading the lines. Two respondents said customers asked for help interpreting the result. One pharmacy survey respondent described helping a customer by looking at the device and interpreting the result for the customer, and the other respondent said s/he referred the customer to a doctor with a second kit.

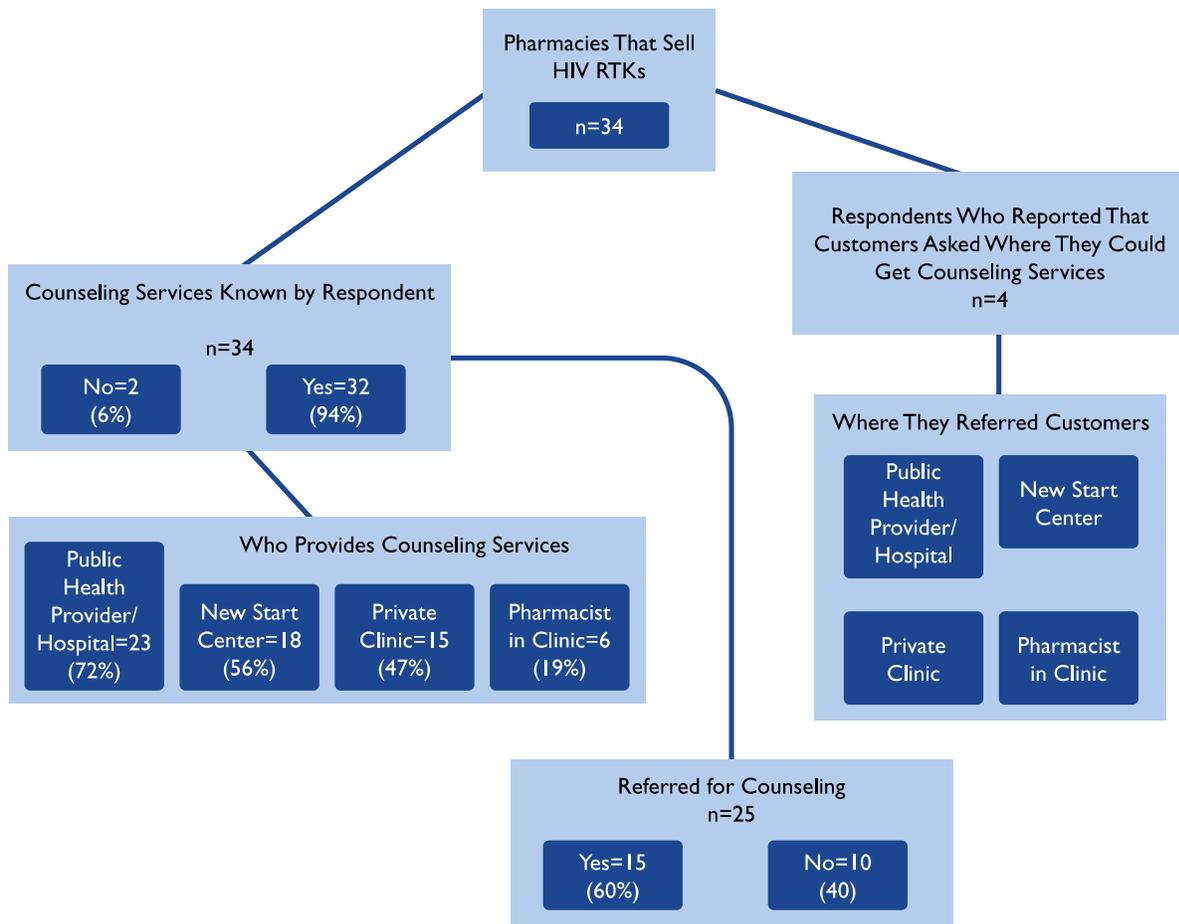
Ten of 27 respondents said that customers disclosed their result, and in most cases, the result was negative. Eighty percent of respondents (21 of 27) said that disclosure of results was uncommon.

Counseling

With the exception of two respondents, pharmacists knew where HIV counseling services were available. They cited “public health provider/hospital” as the most common source of HIV counseling, followed by “New Start Center,” “private clinic,” and “pharmacist in this clinic.” None of the respondents identified lay counselors as sources of HIV counseling. Respondents also mentioned the U.S. Centers for Disease Control and Prevention (CDC) facility, PathCare Lab, and social workers. For those respondents who knew that counseling services were available in their town or city, 60 percent (see Figure 1) referred customers who bought rapid HIV test kits for counseling. Yet only four pharmacists reported that customers who bought an HIV RTK asked where counseling services were available. In those instances, pharmacists referred customers for counseling to a public health service provider, private clinic, New Start Center, or PathCare Lab. None of the pharmacists referred customers to a lay counselor. One pharmacist commented that s/he will not sell an HIV RTK over the counter unless the customer has already been counseled; another said they proactively provide counseling and therefore feel that a referral is not needed.

Figure 1 depicts the various responses in regard to counseling services. The *n* is different for each of the three results presented in the figure because not all respondents answered every survey question.

Figure I. Counseling Services



Confirmatory Testing

Respondents at all the pharmacies that sell HIV RTKs over the counter were aware of a confirmatory testing site to refer customers to, and nearly half knew of more than one site for confirmatory testing. Sources of testing they identified were physicians, hospitals, labs, and New Start Centers. Most respondents said that customers did not request information about confirmatory testing sites.

Opinions and Other Feedback

Pharmacy survey respondents at all sites were asked about 1) their concerns about selling HIV rapid test kits over the counter; 2) their thoughts on HIV self-screening by consumers and whether it provides opportunities for Namibia to increase access to HIV rapid testing; and 3) why they decided to sell or not sell HIV RTKs over the counter. Their responses are summarized according to the themes that emerged during the analysis.

Concerns

A majority (88 percent) of the respondents reported concerns about OTC HIV rapid testing. The three most commonly mentioned themes were 1) lack of counseling, 2) customers' emotional responses to the result, and 3) the need for formal referrals to clinical services. Other concerns included 1) risk of loss of confidentiality, 2) misuse of RTKs (e.g., involuntary testing), 3) need for confirmatory testing, 4) need for follow-up services from a health facility, 5) accuracy of RTKs, 6) lack of current information on RTKs, 7) customers' ability to correctly perform and/or interpret the HIV test, 8) customers' limited knowledge of HIV, 9) customer understanding of proper waste management following using the RTK, and 10) desire for in-pharmacy testing.

Opportunities

However, most (88 percent) respondents indicated that they believe OTC RTKs provide an opportunity for Namibians to increase access to HIV testing. The three most commonly mentioned themes were increased accessibility, enhanced affordability, and increased testing demand. Other considerations mentioned included 1) confidentiality, 2) the possibility of providing counseling with the RTK, 3) efficiency of RTK, 4) reduction of stigma related to HIV testing, 5) increased awareness of HIV, 6) possible increase in people seeking follow-up care, 7) more people knowing their HIV serostatus if the test is administered correctly, and 8) the need to monitor the quality of RTKs.

It is important to note that although a large number of respondents believed that OTC HIV testing provides the opportunity to increase access to HIV testing, many of them offered qualifications and caveats. Their reservations were compiled thematically. The three most commonly mentioned themes were 1) the need for counseling, 2) ensuring referrals for follow-up treatment, and 3) concerns regarding the HIV test kit affordability. Other reservations cited included concerns that a young person's reaction to a positive HIV test could endanger them and that correct administration of an RTK depends on the user-friendliness of the product.

Only six respondents felt that HIV RTKs sold over the counter did not provide an opportunity for increasing access to HIV testing. The following reasons were cited: clients often use HIV RTKs purchased at pharmacies to reconfirm HIV test results previously received; clients who buy HIV RTKs over the counter avoid HIV testing centers because of stigma; and a referral network and follow-up is necessary. Additional reasons given included: HIV testing alone is inadequate, yet counseling and a support system are not available if the person tests positive using an OTC RTK; there is inadequate time to provide referrals and support when RTKs are sold over the counter; impact is minimal; and they refer to doctors and voluntary counseling and testing (VCT) sites.

Reasons for Selling HIV Rapid Test Kits Over the Counter

More than half of the 52 pharmacist respondents who disclosed information on why their pharmacy chose to sell HIV RTKs over the counter indicated this was because of customer demand. Other reasons for selling RTKs over the counter included 1) giving customers a personal choice; 2) customers are comfortable purchasing them from a health care provider (i.e., pharmacist); 3) raising awareness and providing a service to their community; 4) requests from doctors for them to purchase HIV RTKs for their clinics; 5) prescriptions for OTC HIV RTKs to their patients; 6) savings in time and money for consumers; 7) closing of the New Start Centers; 8) suggestions from other pharmacy staff to sell them; 9) manufacturer's representative's suggestion since pharmacies have the capacity to sell OTC HIV RTK, they should sell them; 10) helping to mitigate fears of HIV testing at a health facility; 11) providing confidentiality to consumers; 12) helping customers learn their HIV status; and 13) providing an option for those who want to screen themselves for HIV.

For pharmacies that did not sell HIV RTKs over the counter, the reasons included: 1) no demand; 2) had not considered sales of HIV RTKs over the counter; 3) lack of a consultation room; 4) aging consumer population of some pharmacies; 5) concerns about what a customer would do if s/he had an HIV-positive test result; 6) lack of counseling and follow-up; and 7) lack of qualified staff to counsel patients.

KEY INFORMANT INTERVIEW FINDINGS

TRAINING AND EDUCATION

Key informants from the UNAM Medical School Pharmacy Department,⁷ the institution that prepares professional pharmacists, and the NHTC, the institution that trains and certifies pharmacist assistants, were interviewed regarding their training in HIV counseling and testing. Approximately one-third of NHTC graduates work in the private sector for private hospitals, wholesalers, and private pharmacies.

Findings suggested that PA students at the NHTC received information about HIV RTKs during their training, but pharmacy students at UNAM did not receive this information. HIV-related issues were included in the chemotherapeutics module of the pharmacy students' curriculum, and they participate in a practicum in a rural HIV clinic in their first year of study.

NHTC provides students with instruction in HCT during their hospital practicum by observing HCT, including pre- and post-test counseling, and HIV RTK administration. However, practical training on HIV RTKs was not included since this function is not part of the standard PA job description.

Interviewees said that UNAM teaches counseling skills to pharmacy students in the nursing skills module during their second year of instruction. However, counseling training is not specific to HIV, and UNAM does not plan to add HCT training to the pharmacy curriculum.

INFORMATION ABOUT HIV RAPID TEST KITS SOLD OVER THE COUNTER

Key informants from the Pharmaceutical Society of Namibia, a voluntary association of pharmacists, and the Pharmacy Council of Namibia, a Government of Namibia entity that credentials pharmacists, were interviewed regarding information they provide about HIV RTKs sold over the counter.

The Pharmaceutical Society of Namibia does not provide information about the HIV RTKs sold over the counter to its members, but the society is aware that some private pharmacies sell them. Neither the Pharmaceutical Society of Namibia nor the Pharmacy Council of Namibia was aware of sources of information on HIV RTKs sold over the counter for private pharmacists, but suggested that the manufacturers' representatives may provide this. However, this information would likely be limited to cost information and the names of wholesalers that provide HIV RTKs.

⁷ UNAM School of Pharmacy is a new school within the university. The first cohort of students is in the third of five years of instruction. Most practicing Namibian pharmacists were trained outside of Namibia and many are not Namibian.

REGULATORY SYSTEM

Key informants from the Namibia Medicines Regulatory Council (NMRC), a government entity under the direction of the MOHSS that informs legislation as well as develops and enforces regulations, were interviewed regarding regulations pertaining to HIV RTKs. Informants from the NMRC, HIV RTK distributors, the Pharmaceutical Society, the Pharmacy Council, and the Namibia Institute of Pathology also provided information on the regulatory system for HIV RTKs.

According to key informants, HIV RTKs were first introduced in the public and private sectors in Namibia in 2002. At this time, the HIV RTKs were expensive and had a short shelf life; therefore they often expired before being sold. HIV RTKs were described as medical devices. The Medicines and Related Substances Control Act, 2003, is a regulatory document that addresses medical devices for both the public and private sectors. Although this legislation has been passed, interviewees noted that it has not been implemented for medical devices. In other words, the authority to develop regulations is included in the legislation, but the NMRC has not developed regulations for medical devices.

At the time this assessment was conducted, the MOHSS was considering a proposal, as part of an NMRC restructuring plan, to create a unit to address medical devices, since the NMRC council responsible for the registration of medicines does not address HIV RTKs. At a council meeting that preceded the interview with the NMRC, it was recommended that a committee be developed to address medical devices and equipment, but HIV RTKs were not explicitly mentioned.

While the Medicines and Related Substances Control Act, 2003, addressed the public and private sectors, in practice, the sectors are held to different standards. HIV RTKs imported for use in the public sector are tested and monitored by the Namibia Institute of Pathology, whereas the HIV RTKs imported for use in the private sector are not. All informants confirmed that there are no registration requirements for HIV RTKs, and they are unscheduled products. Further, there is no regulation that prevents the sale of the HIV RTKs at private pharmacies.

According to distributors, HIV RTKs are delivered via road travel either through South Africa or Botswana. The HIV RTKs are manufactured in China, Egypt, India, and South Africa.

Namibia recognizes the following as stringent regulatory authorities (SRAs): the U.S. Food and Drug Administration, the European Medicines Agency, Swiss Med, Health Canada, Therapeutic Goods Administration (TGA)/Australia, and Japan. According to the NIP, an approval process is followed for HIV RTKs proposed for use in the public sector; HIV RTKs approved by accepted SRAs and WHO are then tested/evaluated by NIP. PEPFAR provides funding to the NIP for testing.

QUALITY: SAFETY, PERFORMANCE, CONTROL, AND ASSURANCE

A key informant from the NIP, a parastatal organization that operates on a fee-for-service basis and provides technical oversight on behalf of the Government of Namibia, was interviewed regarding the quality of HIV RTKs.

The key informant noted there are no regulations regarding the quality, safety, or performance of HIV RTKs sold in the private sector; however, the need for a regulatory framework is recognized. Further, the assessment team could not identify any safety and/or performance requirements for medical devices. The NIP provides technical assistance and support for the laboratory QA program for HIV rapid tests used in public sector programs; HIV rapid tests sold in the private sector are not

part of the government’s external quality assurance (EQA) program. The NIP manages quality control for rapid HIV tests that will be used in public sector programs and supports proficiency testing for HCT conducted through community counselors. Their approaches include batch testing, in addition to user and internal controls. For example, a community-based tester’s ability to perform the test properly is assessed based on the results yielded from known/confirmed positive and/or negative samples. The scope of the national and regional quality improvement infrastructures for HCT does not include the private sector.

All public facilities must procure and use only NIP-approved tests. The assessment team could not find evidence that the private pharmacies are required to use NIP-approved tests, resulting in different standards, which appear to conflict with the HIV Counseling and Testing National Guidelines. The list of tests approved by the NIP is included in Appendix 4. According to interviewees, the list was updated in 2010, although the date indicates 2008. All the new generation 4 rapid HIV tests were rejected during 2010 testing, resulting in no new rapid HIV test approvals since 2008.

DISTRIBUTORS/SUPPLIERS AND THE SUPPLY CHAIN

Key informants from the NMRC, the NIP, and the national CMS were interviewed regarding the role of private distributors of HIV RTKs. Key informants from distributors of HIV RTKs for sale over the counter and from the CMS were interviewed regarding of HIV RTK supply chain.

The CMS is the authorized distributor of HIV rapid tests for the public sector; however, interviewees stated that the HIV rapid tests they procure are not available over the counter. The CMS provides the following NIP-approved tests: Unigold®, Determine®, and Clearview®.

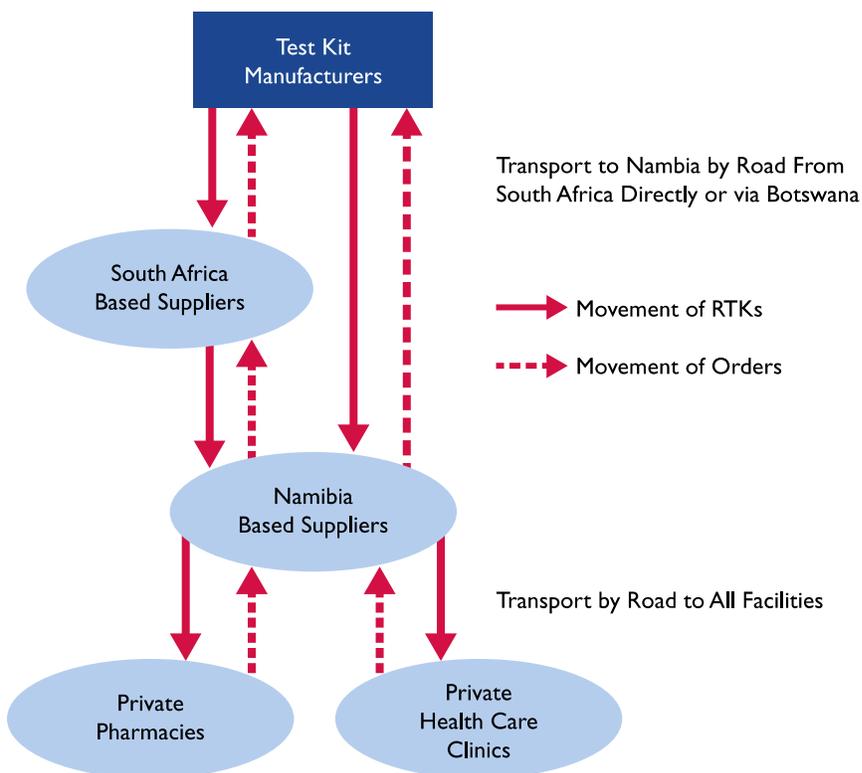
The following suppliers are distributing HIV RTKs to private pharmacies for sale over the counter in Namibia: New Med (part of Erongo Med), Geka Pharma, Nampharm, Medlab, and Genmed. Distribution of rapid HIV test kits to private sector pharmacies is without MOHSS oversight or authorization.

The supply chain for HIV RTKs distributed to the private sector for sale over the counter begins with orders from pharmacies, followed by procurement by distributors. According to one distributor, there are no cold chain requirements, and another interviewee indicated that its South Africa–based supplier provides the HIV RTKs overland, with the courier selected depending on the product and security requirements. Shipments from South Africa are delivered to the distributor’s Windhoek-based warehouse. Further, another distributor based near the Angola border described its supply chain as follows:

1. A monthly order is placed with Upex—a South Africa–based distributor—based on demand.
2. HIV RTKs arrive by truck from South Africa and are delivered to their warehouse.
3. Clients (i.e., private pharmacies and private health care clinics) place orders.
4. Orders are picked and packed in the distributor’s warehouse.
5. Orders are delivered to customers by car.

Figure 2 is a generic depiction of the supply chain that provides customers—private pharmacies and private health care practices—with HIV RTKs sold over the counter.

Figure 2. Private Sector Supply Chain for HIV RTKs Sold Over the Counter



Two informants noted that they do not face challenges or issues with their supply chain. The HIV RTK supply is replenished every two weeks, their lead time is a maximum of 10 days, and orders are typically filled overnight from South Africa. The distributor that supplies both private pharmacies and the MOHSS reported that its lead time is one to two weeks from when the order is received by the Windhoek-based supplier to delivery of the order to non-MOHSS customers. For MOHSS orders, order receipt dates are strictly specified.

Most private medical supply distributors reported that they have not faced significant challenges related to the supply chain for HIV RTKs, except for challenges with outsourced transportation.

HIV RTKs sold over the counter comprise a relatively small volume of distributors' overall sales. For instance, one distributor reported that glucose test and pregnancy test sales volumes are larger than those for HIV RTKs sold over the counter. Even so, sales of HIV RTKs are growing. Another distributor to private pharmacies said HIV RTK sales are divided evenly between private pharmacies and private health care clinics; more specifically, the private pharmacies buy 5- and 1-test/kit packages, and health care clinics buy 25-, 10-, 5-, and 1-test/kit packages.

Further, another distributor supplies HIV RTKs to three customer categories: the MOHSS, doctors, and labs, with one informant noting that pharmacies purchase the largest quantities of HIV RTKs. Lastly, the remaining informant reported that pharmacies and private doctors purchase HIV RTKs with doctors purchasing a greater amount.

HIV RAPID TEST KITS IN STOCK AT DISTRIBUTORS AND THE CENTRAL MEDICAL STORES

Key informants from distributors of HIV RTKs for sale over the counter and from the CMS were interviewed regarding their HIV RTKs stock on hand at the time of the assessment.

The CMS and each of the four private sector distributors all had stock on hand at the assessment visit; however, one did not provide stock figures. Table 9 lists the stock levels for three of the four private distributors interviewed.

Table 9. Available Stock for Three Distributors of HIV RTKs at the Time of Pharmacy Survey

Distributor	U-Test			ACON		Homemed
	1 Test per kit	5 Tests per kit	25 Tests per kit	10 Tests per kit	10 (Triline) Tests per kit	1 Test per kit
#1	120	30	30	30	30	—
#2	155	46	7	—	—	164
#3	7	24	8	—	—	—
TOTAL	282	100	45	30	30	164

Table 10 lists the CMS stock levels and the prices of HIV RTKs.

Table 10. HIV RTK Stock Levels and Associated Prices at the CMS

Product description	Pack size	Quantity on hand	Price N\$*/(U.S.\$)
Determine HIV rapid test kit	100 tests	3,838	1,351.25/ (134.24)
Unigold HIV test kits	20 tests	4,097	450.97/(44.80)
Clearview complete HIV ½ rapid test kit	25 tests	533	1,690.50/(167.94)

*Not known if price includes VAT.

DEMAND FOR HIV RAPID TEST KITS

Key informants from distributors of HIV RTKs to private sector stakeholders were interviewed regarding estimated demand HIV RTKs at private pharmacies using distributor sales data.

Distributor #1's sales data for 2011 and 2012 are provided in Table 11.

Table 11. Distributor #1 HIV RTK Sales in 2011 and 2012

Product	Approximate cost per test without VAT in N\$ (U.S.\$)	Quantity sold in 2011	Quantity sold in 2012	Percentage change
U-TEST AIDS Single Kit	24 (2.41)	292	683	134

U-TEST AIDS Tests 5	15 (1.50)	139	153	14
U-TEST HIV Test 25	10 (1.00)	117	100	-15
ACON HIV Complete 5	30 (3.00)	96	18	-81
ACON HIV Triline Test Device 10	23 (2.31)	39	18	-54
Total		566	972	72

Distributor #2 indicated that demand has been increasing since 2010, in part because the distributor is now covered by Medical Aid. However, there were no documented sales to private pharmacies in 2010, 2011, or 2012.

Distributor #3's sales data for the previous 12 months for two products (for all customers) are shown in Table 12.

Table 12. Distributor #3 HIV RTK Sales from February 2012–January 2013 for Two Products

Manufacturer: Humor Diagnostica	Test name: U-Test											
	Quantity sold to all customers											
Item description	2013 Jan qty	2012 Dec qty	Nov qty	Oct qty	Sep qty	Aug qty	July qty	Jun qty	May qty	Apr qty	Mar qty	Feb qty
1 test per kit	145	230	147	173	140	159	138	156	157	132	140	118
5 tests per kit	62	64	92	47	67	72	96	39	64	74	43	36
25 tests per kit	8	9	7	5	4	3	4	3	1	6	2	2

Manufacturer: Homemed	Test name: HIV 1/2 Point of Care Testing (POCT) Test											
	Quantity sold to all customers											
Item description	2013 Jan qty	2012 Dec qty	Nov qty	Oct qty	Sep qty	Aug qty	July qty	June qty	May qty	Apr qty	Mar qty	Feb qty
HIV 1/2 POCT TEST KIT INTEC	36	28	71	0	0	0	0	0	0	0	0	0

POCT = point of care testing.

Table 13 shows yearly sales data for 2010, 2011, and 2012 for different brands (Humor Diagnostica's U-Test and Homemed's HIV 1/2 POCT test) and package sizes.

Table 13. Distributor #3 HIV Test Kit Sales in 2010, 2011, and 2012 for Four Products

Description	Manufacturer: Humor Diagnostica Test name: U-Test			Homemed's HIV 1/2 POCT test
	2010 quantity sold	2011 quantity sold	2012 quantity sold	2012 quantity sold
1 test per kit	417	1254	1808	113

5 tests per kit	311	527	765	<i>Product only available as 1 test/kit</i>
25 tests per kit	Not sold in 2010	Not sold in 2011	47	

Distributor #4 started selling HIV RTKs in 2011. Table 14 summarizes its sales data from February 2012.

Table 14. Distributor #4 HIV RTK Sales and Estimates since February 2012 for Three Package Sizes

Number of tests per kit	1 Test/kit	5 Tests/kit	25 Tests/kit
Approximate number sold per month		10	5
August 2012	2 sold		
September 2012	5 sold		
October 2012	0 sold		
November 2012	8 sold		
January 2013	7 sold		

POLICIES AND GUIDELINES ADDRESSING HIV COUNSELING AND TESTING

Key informants from the MOHSS and NIP were interviewed regarding policies and guidelines on HCT.

The MOHSS Directorate of Special Programmes has responsibility for policy development related to HCT. They have oversight for implementation in both public and private sectors, but the approach varies between the sectors. According to the MOHSS, health workers, community counselors, and local NGOs are allowed to conduct HIV testing, so that those who provide HCT are trained and certified in counseling and test administration. Approved test administrators must also be associated with an organization responsible for QA. The National HCT Guidelines mention licensing private providers but do not specifically indicate pharmacies, HIV self-testing, or self-screening.

Requirements for HIV rapid testing in private facilities (e.g., doctor- and nurse-run primary care centers), and for local NGOs are addressed in the National HCT Guidelines. However, sale of HIV RTKs in private pharmacies is not highlighted in the guidelines.

Nevertheless, key informants from the MOHSS indicated that a pharmacist could provide assistance to the customer seeking help with administering the HIV RTK if the pharmacist was a trained and licensed HCT service provider and the pharmacy met physical site requirements, both of which points are outlined in the guidelines. If these conditions are not met, the guidelines support pharmacist explanation of HCT, but not specifically the performance of HIV testing in the pharmacy.

CONSUMER ABILITY TO PERFORM THE TEST

Key informants from the MOHSS, USAID partners, and private physician representatives were interviewed regarding their perceptions of a customer's ability to accurately administer a rapid HIV test.

Overall, most informants believe that if lay customers are trained correctly, they can perform a rapid HIV test. However, other key informants strongly disagreed, noting that some counselors who have completed six weeks of training still face challenges. Some believed that rural and low-literacy populations might also face challenges administering the test. Therefore, clear instructions and sufficient literacy and educational levels were described as necessary; and two informants highlighted the need for proper storage of HIV RTKs, which could pose a challenge.

Interviewees were aware of challenges with the finger-prick procedure and obtaining a correct sample (by discarding the first drop of blood) for HIV rapid test administration. One interviewee admitted to not being aware of specific difficulties, but commented that the complexity combined with stress of the implications of a HIV-positive test could result in incorrect administration of the test.

INTERPRETATION OF RESULTS

Key informants from the MOHSS, USAID partners, and private physician representatives were interviewed regarding their perceptions of a customer's ability to accurately interpret the results of a rapid HIV test.

Many informants were concerned about a customer's ability to interpret the test result correctly because of low English literacy. However, one interviewee thought customers could interpret the result correctly because, during community-based testing, counselors perform the test and show the client the device. Therefore, those who individually repeat the HIV RTKs have some experience interpreting the result. Nevertheless, the interviewee expressed concern that some clients do not understand the control line that appears, even though it is addressed in pre-test counseling and the device is shown to them.

Regarding HIV self-testing, many informants were concerned that a negative HIV result could provide a false sense of security if customers are not aware of the window period. They also mentioned that although the test is available through physicians, going to the doctor for the test poses a potential bottleneck. Another interviewee said s/he would like to see HIV RTKs immediately available with good instructions and guidance.

ACCESS TO HIV COUNSELING AND TESTING

Key informants from the MOHSS, USAID partners, and private physician representatives were interviewed regarding their perceptions around access to HCT services.

Many interviewees were aware of counseling services available in the private sector, including private physicians, private nurses, New Start Centers, medical clinics, primary health care centers in rural areas, NGOs, mining companies, and insurance companies. However, informants had some uncertainty and skepticism about whether private sector counselors adhere to the rapid testing HCT algorithm consistently, while some private services were believed to adhere (e.g., New Start Centers). Respondents also reported that HIV testing may be conducted as part of a screening or diagnostics panel of blood tests, in which clients are not always told before the HIV test is performed, thus conflicting with the algorithm.

BARRIERS TO HIV COUNSELING AND TESTING

Key informants from the MOHSS, USAID partners, and private physician representatives were interviewed regarding their perceptions around barriers to HCT services.

Various barriers to accessing or seeking HCT were discussed, including stigma; fear of receiving a positive result; lack of privacy/confidentiality (e.g., other customers or staff seeing purchases); cost; limited transportation/distance; women dependent on their husbands who are seasonal workers; denial or low perceived risk; feeling powerless at a clinic; long queues; lack of translation of services and written materials into local languages; fear of public health facilities; preferring to see witch doctor/traditional healer instead of allopathic caregivers; religious beliefs; or other personal beliefs.

CONFIRMATORY TESTING

Key informants from the MOHSS, USAID partners, and private physician representatives were interviewed regarding availability of HIV confirmatory testing.

With the exception of one, all informants indicated that confirmatory testing is available for a customer with a HIV-positive result from a HIV RTK that he or she may have purchased over the counter. In this context, confirmatory testing would involve the standard HCT testing algorithm, because the HIV RTKs sold over the counter have not been evaluated for use in series or parallel with other tests for confirmation of a diagnosis. This HIV counseling and testing may be performed at a physician's office, a PathCare lab,⁸ or a public hospital; although wait times vary from none (immediate testing is available) to two weeks depending on the location.

According to interview findings, in the public sector, a follow-up face-to-face appointment is scheduled when the sample is taken for a confirmatory test in order to provide the result. In the private sector, the office staff will call the client when the results are ready to schedule a follow-up appointment. Yet this protocol may not be adhered to in all cases, and health care providers may not follow up with clients.

ACCESS TO FOLLOW-UP CLINICAL CARE

Key informants from the MOHSS, USAID partners, and private physician representatives were interviewed regarding their perceptions around barriers to successful referral to services following HCT.

One informant suggested having a phone line for counseling and referral. Most informants discussed the following referral sites for HIV treatment and care for persons who test HIV-positive.

- Public sector: “One-stop shop” through either a pre–highly active antiretroviral therapy (pre-HAART) or HAART clinic, depending on the results. NIP processes labs.
- Private sector: PathCare does the lab workup.
- Local organizations: Bidirectional referrals occur. NGOs refer to the public sector and the public sector refers to NGOs, depending on the patient's test result and the services available in her/his locale.

⁸ Because the testing conducted at a physician's office or lab may rely on the same HIV RTKs that consumers are using at home, it is not possible to determine whether a diagnosis can be confirmed in these venues.

Following the interviews, there were mixed findings as to whether a standard referral process for people with a positive confirmatory test exists. For instance, one informant noted that HIV and tuberculosis are not considered “notifiable” diseases and therefore there is no mandated follow-up. Anonymous testing, which is reported to be phasing out, creates barriers that prevent health care providers from monitoring clients across the continuum of care. However, some informants noted that people with a positive test are referred to the communicable disease clinic for initial screening, which includes counseling, pre-HAART, HAART, CD4 count, and other services.

Additional challenges to referring clients with a positive HIV test were discussed. In the public sector, clients are referred but sometimes they do not show up for appointments. Standardized referral forms are available for public sector services. In the private sector, workplace programs have reported referral challenges, because there is no established referral system for HIV care and treatment.

CONCERNS ABOUT HIV RAPID TESTING BY CONSUMERS

Key informants from the MOHSS, USAID partners, distributors, and private physician representatives were interviewed regarding their concerns about consumer HIV rapid testing.

Informants cited many concerns about HIV rapid testing by consumers; the two most common themes that emerged were the lack of counseling and post-test reactions of people conducting the test alone. Other concerns mentioned included lack of assurance that the test is administered or interpreted correctly; that testing may be coercive; and that the quality of the testing device cannot be assured. Interestingly, distributors generally had limited or no concerns about HIV rapid testing by consumers.

With a few exceptions, most informants also indicated the potential risk that people could be forcibly tested with the OTC HIV RTKs. Common themes included the belief that forcible testing is possible, such as employers (illegally) forcing employees to be tested for HIV, forcible HIV testing of a spouse, HIV testing without consent in health care settings, and parents forcing children to test.

Some informants were supportive of this type of testing since they believe that it is a right to know one’s HIV status. Yet they also recognized that systems for counseling for HIV testing and referrals for post-test services are necessary.

OPPORTUNITIES WITH OVER-THE-COUNTER HIV RAPID TESTING

Many interviewees discussed that HIV self-screening could provide opportunities to increase access to HIV testing in Namibia. They argue that the opportunity for self-screening for HIV could provide another venue for and expanding HIV testing access, especially in remote areas. Further, this testing option allows customers the flexibility of testing at their own convenience if they cannot reach testing sites during operational hours. Self-testing also allows people who do not want to test at a hospital to find out their preliminary status privately, without queues and wait times.

Overall, more informants were supportive of HIV self-testing than opposed. In terms of the future of HIV RTK over-the-counter sales, some key informants argued that HIV self-testing should be introduced in a systemized manner, under the oversight of health care providers (including trained pharmacists), with clear instructions and follow-up options for referral, care, and support.

DISCUSSION AND RECOMMENDATIONS

The goals of this rapid assessment were to document the availability of HIV RTKs for sale over the counter in Namibia, and to gain an understanding of the regulatory and policy context that governs their availability. The findings can inform policymakers', donors', and other stakeholders' decision making regarding the potential for private pharmacies to help bridge gaps in public access to HIV testing.

HIV rapid test kits have been available for sale directly to consumers for more than a decade. This assessment raised several key policy, regulatory, and implementation issues that require careful consideration to enable Namibia to provide quality, reliable HIV self-screening to the public through private pharmacies.

LIMITATIONS OF THE ASSESSMENT

This rapid assessment had a number of limitations. First, the survey tool for data collection at private pharmacies was pre-tested for only one day prior to use in this assessment, which allowed only limited adjustments to be made. Second, in-country data collection was limited to a two-week period, which resulted in the small assessment team having to limit the number of pharmacies that could be visited and the number of key informant interviews that could be conducted. The total number of pharmacies included in the sample ($n = 53$) is too small for statistical tests other than univariate analysis. In addition, some respondents did not answer all questions in the survey, resulting in an even-smaller sample for some variables.

The number of variables included in the survey was large for a rapid assessment, and some respondents in busy pharmacies did not have the time to answer all questions. Recall bias or hasty responses may have resulted in erroneous information provided by survey respondents.

Customer perspectives and characteristics, although of interest to the study designers, were available only through survey respondents (pharmacists and pharmacy staff), which may have resulted in the assessment's not capturing accurate customer views. Further, since customer data were not routinely collected at the pharmacies, pharmacists relied on recall of experience and interactions with customers purchasing HIV RTKs for this survey. Further study is warranted to validate these qualitative findings regarding customers.

While this assessment did include distributors as key stakeholders, the team was unable to fully evaluate the supply chain for HIV rapid test kits sold to pharmacies; for instance, the team did not interview customs officials, test kit manufacturers, or those involved in transportation.

The scope of this assessment did not include the sale or use of HIV RTKs in private sector clinics, hospitals, doctor's offices, or laboratories.

Despite these limitations, a wealth of descriptive information was collected that sheds light on a wide range of topics related to HIV RTKs being sold over the counter directly to consumers in Namibia. A larger sample collected over a longer period of time with a validated survey instrument

may provide the ability to generalize. In addition, direct access to customers would allow the ability to draw conclusions about customer perspectives and characteristics.

POLICIES, GUIDELINES, AND REGULATIONS

OVER-THE-COUNTER SALES

The data collected reveal that there is public demand for HIV RTKs from private pharmacies. Although the extent of demand could not be precisely quantified, distributor sales suggest that demand has increased over recent years. According to the Medicines and Related Substances Control Act, 2003, and as confirmed by the NRMC, medical devices are unscheduled. As a result, distributors and pharmacists legally sell the devices in private pharmacies over the counter.

Consequently, private HIV RTK sales are not closely monitored or guided by a process that evaluates the quality or appropriateness of their use as an HIV screening test by lay consumers. As noted earlier, none of the HIV RTKs sold in the private pharmacies are on the NIP's list of approved HIV RTKs, and therefore they do not fit into the nationally established algorithm for the diagnosis of HIV in Namibia.

Given public interest in and use of HIV RTKs, the assessment team recommends that the Government of Namibia recruit a multidisciplinary task force including private pharmacists, doctors and nurses, representatives of the Pharmaceutical Association of Namibia, experts in HCT, experts in laboratory evaluation of RTKs, NIP staff, donors, customs officials, legal advisors, global regulatory experts, and other key stakeholders to conduct a detailed review of the following:

- Laws that govern entry of medical devices, particularly HIV rapid test kits, into the country for sale in the private sector
- Quality standards for HIV rapid tests with attention to the identification of HIV rapid test kit specifications for RTKs that may be sold to consumers
- Availability of HIV RTKs in private pharmacies
- Pharmacists' and pharmacist assistants' scope of practice in relation to HIV testing
- Government of Namibia–authored guidelines and standard SOPs related to HIV counseling and HIV testing.

Action Steps

The assessment team encourages consideration of the following action steps:

- Exercise the authority conferred in the Medicines and Related Substances Control Act, 2003, to develop a regulatory framework for HIV RTKs that may be sold over the counter, including technical/laboratory evaluation of devices available, intended use of devices sold in private pharmacies, and registration requirements to sell them. Development of the framework could include the following:
 - Develop the technical evaluation process and quality assessment criteria for regulation of HIV RTKs that will be sold as HIV screening tests to the public. Careful attention is needed to accuracy of the test and ease of use when used by

laypersons. The Government of Namibia will need to establish the target product profile and operational characteristics most appropriate for rapid HIV tests used in self-testing. There are global efforts to define these features in the context of HIV self-testing; it will be important for Namibia to be aligned with the international standards that are developing in this area.⁹ The type of information that manufacturers can be asked to provide includes the scope of a test: the definition of what it does and is intended to do, including risks and limitations.

- Develop a sample of the device, packaged as it would be if distributed.
 - Collect evidence, including analysis reports that verifies all claims made about the device, including intended use, intended users, distribution channels, storage requirements, shelf life, labeling requirements, safety reports, lay user studies, and instructions.
 - Develop instructions that are appropriate for intended users and that provide the information required to perform and interpret the test correctly, what actions should be taken based on the test result, and information to consult a health professional.
 - Establish post-marketing surveillance to monitor the quality of the product in the marketplace (e.g., safety reporting systems, risk-management assessments, ongoing monitoring of the accuracy of the tests, and the ability of intended users to administer and interpret the test).
- Partner with the NIP to identify the quality assurance needs for HIV RTKs to work correctly in the hands of lay users. In particular, the Government of Namibia will need to specify how HIV RTKs are sold in the private sector as well as how results arising from self-testing are considered within the national validated testing algorithm.
 - Standardize information provided to customers at the point of sale through development of systems for counseling, and repeat testing using the nationally approved algorithm for confirmation of test results.
 - Address in policies and regulations addressing private sale of HIV RTKs whether HIV RTKs may be stored on the shelves freely available to customers or must be stored behind the pharmacy counter.
 - Within the quality assurance system for HIV RTKs, integrate regulatory monitoring and enforcement mechanisms, allocate sufficient funding for enforcement, and assign personnel to oversee and undertake enforcement activities.
 - Develop a process to disseminate this information to key professional stakeholders, particularly the Pharmaceutical Association of Namibia, pharmacy educators, pharmacists, pharmacist assistants, and private sector physicians and laboratory and hospital administrators.
 - Ensure continued and open engagement and dialogue among key stakeholders, including private sector partners.

⁹ World Health Organization (WHO), *Report on the First International Symposium on HIV Self-testing for HIV: The Legal, Ethical, Gender, Human Rights, and Public Health Implications of HIV Testing Scale-Up* (Geneva: WHO, 2013), http://apps.who.int/iris/bitstream/10665/85267/1/9789241505628_eng.pdf.

RAPID HIV TESTING IN PRIVATE PHARMACIES

Several pharmacists interviewed received training on HCT and provided informal HIV counseling to some customers who purchased HIV RTKs, and a majority (85 percent) of pharmacy survey respondents expressed interest in receiving training on HIV RTK use and HIV counseling. Although the Pharmaceutical Society of Namibia does not provide information about HIV RTKs to pharmacists in the private sector, the society is open to exploring the setting of the pharmacy as a place to provide HIV counseling in the context of OTC sale of RTKs or in the provision of HIV rapid testing on-site. Multiple stakeholders expressed concern, however, that pharmacists were too busy to integrate counseling into their work flow. As noted earlier, competency-based training in HIV rapid testing is not yet included in the curricula for pharmacists or pharmacist assistants.

Action Steps

After regulations are established to support improved quality of HIV RTKs sold over the counter to the public for HIV screening, the assessment team recommends HCT capacity building for pharmacists to standardize how HIV rapid tests are administered in eligible pharmacies, as this may increase access to HIV counseling among those who elect to go to the pharmacy for HIV testing. This will create market opportunities for pharmacists and may increase access to HCT in the private sector. The following action steps should be considered:

- Include training on rapid HIV testing in preservice training for pharmacists and PAs that complies with national standards by integrating the content into the UNAM syllabus for pharmacist training and the NHTC syllabus for PAs.
- Provide in-service training on rapid HIV testing that complies with national standards for pharmacists and PAs already in practice. Consider offering the MOHSS-approved training at annual pharmacy professional gatherings, such as the Pharmaceutical Society of Namibia's annual congress, and online, because almost all pharmacies have Internet access.
- Develop continuing professional development education materials for pharmacists and PAs that include review of guidelines, SOPs, and regulations related to HCT and rapid HIV testing.
- Draft a regulation through the Pharmacy Council of Namibia that requires pharmacists to receive HCT training, and add it to the council's updated regulations on good pharmacy practice (scheduled to be published in 2014).
- Expand the availability of MOHSS HCT courses for lay counselors who could be employed at pharmacies.
- Certify that pharmacies providing HIV rapid testing meet the NIP's site requirements for rapid HIV testing.
- Revise the *National Guidelines for HIV Counseling and Testing in Namibia*, the *Guidelines and Standard Operating Procedures for HIV Rapid Testing*, and the *National Strategic Framework for HIV and AIDS Response in Namibia 2010/1–2015/6* to include HCT in private pharmacies and to establish guidelines for HIV self-testing.
- Include pharmacies that provide on-site HIV rapid testing with monitoring and supervision through the existing system of HIV counseling and testing QA supervisors.

- Develop a post-marketing surveillance system at the NIP to evaluate the quality of RTKs currently being sold in private pharmacies; this may involve an interim system of random sampling of RTKs at pharmacies and laboratory evaluation until registration requirements are developed.

TASK-SHIFTING FOR HCT

Health workforce overload was referred to in the desk review materials. Several survey respondents and key informants noted that HCT at public facilities and labs requires long wait times and is associated with opportunity costs. Multiple pharmacists reported that, although they would like to provide pre-test counseling for customers who buy rapid HIV tests, they do not currently have enough time.

A protocol is recommended that emphasizes that the use of HIV RTKs for self-testing constitutes HIV *screening*, not HIV diagnosis, and that follow-up confirmatory testing is required. Diagnosis of HIV would require repeat testing using the Namibia national HIV testing algorithm to confirm preliminary positive results.

Action Steps

- Explore the feasibility and cost-effectiveness of:
 - HCT counselors working at pharmacies during prespecified windows of time to provide HIV counseling
 - Lay counselors working at pharmacies to provide HIV information/support to individuals who are seeking HIV RTKs over the counter for self-screening
- Consider policy and/or regulatory changes, if feasibility is demonstrated.

An additional potential benefit of the use of OTC HIV RTKs is that they may provide increased options for HIV screening if the Government of Namibia decides to close the remaining stand-alone VCT centers as well as in the case of individuals who may not seek HCT in a formal setting.

COMMUNITY ENGAGEMENT

Until policies and regulations address the multitude of issues around HIV RTKs sold over the counter, it is premature to increase community-level awareness raising about the kits.¹⁰ Since none of the HIV RTKs for sale are on the NIP-approved list and no appropriate rapid test kit platforms exist that have been developed and validated for HIV self-testing, increasing awareness in the community may lead to increased uptake of tests of unknown quality and performance standards. After a policy and regulatory framework has been established, systems are functioning to ensure that appropriate, safe, accurate and usable HIV RTKs are for sale, and community-based monitoring strategies have been designed and implemented, then a process can be designed for engaging the community around self-screening for HIV.

¹⁰ Popular media in Namibia have briefly covered the issue of HIV RTKs since the data collection phase of this assessment. The May 23, 2013, *Namibian Sun* newspaper cites the MOHSS's willingness to provide awareness raising around HIV rapid testing: "If the community requests awareness training on the kit, the ministry is willing to do so." (Muraranganda, Elvis. "Ministry Breaks Silence on Aids Self-Testing." *Namibian Sun*, May 23, 2013.).

Survey respondents and key informants articulated a need for information and counseling services for customers using over-the-counter HIV RTKs. In this important period before the strengthening of policy and development of regulations for HIV RTKs sold over the counter, the assessment team encourages consideration of information-sharing resources relevant to issues that customers currently face, including, but not limited to:

- Storage of the kit
- Disposal of the biohazard waste generated by conducting the test
- Finger-stick procedures for sample collection, sharps safety, test administration, and interpretation
- Actions to take if the test is positive or negative, including processes for receiving additional testing using the national HIV testing algorithm for confirmation of diagnosis
- Local resources for HIV care and treatment, primary health care, psychosocial support, and HIV prevention strategies.

The assessment team suggests consideration of interim solutions such as a telephone hotline or another information system in local languages, where consumers can ask questions about test administration and interpretation and obtain key information; a location-specific referral directory; a Namibia-specific information leaflet (which could be developed in collaboration with manufacturers) to accompany each test kit; and training for pharmacists and pharmacy staff to enable them to provide accurate information to customers.

PRIVATE SECTOR DISTRIBUTORS

Distributors of the HIV RTKs and pharmacists in private practice need information about revised policies on HCT and regulations for medical devices once these are developed. They also need information about the NIP-approved HIV RTKs. It is important to note, however, that sale of NIP-approved RTKs would not address concerns about the quality of HIV RTKs sold to consumers because these kits have not been tested or approved for use by laypersons in any country. Most distributors and pharmacists interviewed relied on quality data provided by manufacturers because they were not aware of the NIP-approved list of HIV RTKs, given that the NIP efforts focus only on public sector HCT. One respondent's concern about quality was exemplified in this comment made during the interview: *"We're all concerned with the same issues of quality."*

Action Steps

The assessment team encourages consideration of the following action steps:

- Develop communication systems between the Government of Namibia and distributors of medical devices for sale in private pharmacies to facilitate updates as the regulatory framework evolves.
- Seek input and establish information exchange between the public sector partners and private sector stakeholders on rapid HIV testing, with attention to areas of mutual benefit.
- Disseminate the list of NIP-approved rapid HIV tests to all distributors, private pharmacies, the Pharmacy Council of Namibia, and the Pharmaceutical Society of Namibia as an interim strategy pending the establishment of a medical device regulatory framework. Also include a

brief description of the nationally approved HIV testing algorithm (the process used by the NIP to approve RTKs for use in the public sector) and clarification of the difference between self-screening and confirmatory testing.

ETHICAL CONSIDERATIONS

Increasing an individual's autonomy is an important ethical consideration within health care. HIV RTKs sold to consumers, if they are accurate and usable, could offer opportunities for individuals to screen themselves for HIV when they may not otherwise seek HIV testing and counseling from a clinic or mobile HCT outreach site. Yet self-screening for HIV may increase ethical challenges because of the responsibility to notify a partner or disclose test results.

In addition, some users may not realize that the self-test does not provide a diagnosis, but instead provides a preliminary screening result. There is also an absence of linkage to the broader health system.

It is not possible to ensure that the “five Cs”—consent, counseling, correct results, connection/linkage to prevention, care and treatment, and confidentiality—articulated by WHO are upheld with the use of HIV RTKs for self-screening for HIV because application of the test is not controlled. There are also real and potential risks that include but are not limited to:

- Risk of misclassification of results (i.e., the end test results are incorrect):
 - Due to user error in performing the test
 - Due to test kit limitations or errors and potential false-positive and false-negative results
 - Due to a user's misinterpretation of results
- Possible increased risk of misuse and justification to engage in risk behavior (self-harm or suicide)
- Risk of coercive testing
- Risk of point-of-sex testing to screen potential sex partners
- Potential risk for non-linkage to HIV confirmatory testing (using the national algorithm) and to HIV care and treatment for individuals who are found to be positive
- Potential risk for violence to self and others (e.g., gender-based violence, partner violence, self-harm)
- Possible human rights violations (e.g., lack of informed consent and coercion)
- Increased risk for discrimination and stigma especially for key groups, such as—
 - Domestic or migrant workers
 - Adolescents
 - Vulnerable family members such as children and married women
 - Sex workers
 - Partners and couples in abusive relationships.

Concern over forcible testing should be balanced against an individual's interest to test him- or herself outside of a health facility. In this case, consent is implicit in the purchase of the kit for personal use, counseling may not be needed if they have or previously had access to counseling, and they hold the responsibility for maintaining confidentiality of their results or choosing to share them.

As with other forms of testing, if Namibia develops and implements a regulatory framework that introduces safe, accurate HIV RTKs for OTC sale that have demonstrated safety, accuracy, and usability among laypersons, and if in-home screening is regulated within a human rights framework and with community involvement, many of these theoretical harms may be preventable. There will be a critical need for monitoring of misuse, and the regulatory framework should include legal consequences for violations of use.

FUTURE RESEARCH

This assessment raises issues for further evaluation and areas where more in-depth analysis of the existing data could assist in informing decision making around policies, regulations, and implementation approaches for HIV RTKs sold in private pharmacies in Namibia. To the authors' knowledge, this is the first assessment of the availability of HIV RTKs for sale to the public in private pharmacies in sub-Saharan Africa. The study highlights issues potentially applicable in other developing countries, and the Namibia experience can help inform approaches adopted by other countries, with similar opportunities for leveraging the private sector as a source of HIV-related services.

Following is a list of possible future research and secondary analysis of the data generated during this rapid assessment.

- More research and development at a global level are needed to further encourage and guide investment in rapid HIV testing platforms appropriate for self-testing and use by untrained individuals. The current tests available on the “gray market” are designed for clinical use and are likely unsuitable for self-testing; this technology gap must be addressed.
- Studies are needed with a focus on private pharmacy customers and/or the general public to evaluate attitudes, demand, and perceptions toward HIV RTKs' availability and sale over the counter in private pharmacies. Topics that could be explored include the acceptability of HIV RTKs sold over the counter; private pharmacies as HCT sites, with pharmacists or pharmacy staff serving as HCT counselors; and knowledge and awareness of HIV RTKs sold over the counter and how they are used and interpreted. It may be possible to add questions to the upcoming NDHS to acquire population-based information. To obtain more specific perspectives from subgroups, screening questions could be designed to help identify if someone has actually bought a kit, used a kit, or would like to do home-based HIV screening. Questions on the use of HIV RTKs may help shed light on the ethical issues related to potential coercive use of the kits on spouses, children, or employees.
- A comparison of different models of HIV self-testing in Namibia is needed. A recent international symposium on HIV self-testing led to the proposal of three potential models; two of them could leverage the private pharmacy settings. They are 1) the clinically restricted model, in which HIV rapid test kits are given to consumers by health workers (e.g., pharmacists and pharmacy assistants) in specific situations, and 2) open access, which is essentially the current system in Namibia.¹¹ In particular, a comparison of different types of pharmacy-based models could help evaluate pharmacies as a venue for rapid HIV testing. Additional ideas for pharmacy-based models include, but are not limited to, counseling and assistance with testing by pharmacists to HIV RTK customers; counseling by HCT counselors hired by pharmacies; and partnerships between pharmacies and HIV counseling and testing sites to facilitate effective referrals for confirmatory testing. Careful attention to

¹¹ WHO 2013.

work-flow requirements during these evaluations may help inform implementation approaches.

- An evaluation should be done of the best approaches for promoting confirmatory testing and subsequent linkages to HIV care and treatment for individuals and families with a positive test result. This will involve evaluation of the quality of HIV RTKs sold over the counter and whether they will qualify for consideration as part of a testing algorithm through the NIP.
- An investigation should be done of whether there are gender differences and differences in client type (e.g., sex workers, health care providers) in the use of HIV RTKs through gender stratification in other studies. If it is found that men purchase HIV RTKs more often than women, then increasing the availability of HIV RTKs for sale over the counter may be an effective strategy for increasing the number of men tested. An important caveat, however, is that although men may be buying the kits, they may not be using them to test themselves. As such, the gender of the kit user would be important to explore in tandem with identification of who buys more HIV RTKs.
- Post-marketing surveillance should be conducted, with technical assistance from regulatory experts.
- Following development of regulations of medical devices, an evaluation should be done as to whether they are adhered to by pharmacists and whether they are enforced by the regulatory agency.

CONCLUSION

This rapid assessment report highlights a range of policy, regulatory, and implementation opportunities to strengthen the quality of individual HIV testing using HIV RTKs sold over the counter and to expand access to HIV screening beyond the formal health system. Regulatory and diagnostic technology challenges remain; addressing these will help to build a foundation on which HIV self-screening can become established as a safe, accurate, and reliable way to obtain information on HIV status. In the long term, increasing access to HIV RTKs sold over the counter may improve uptake of HIV testing, as a first critical step in addressing the HIV epidemic in Namibia.

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APPENDIX I.

PHARMACY SURVEY QUESTIONNAIRE

Namibia OTC HIV RTK Study

Pharmacy Survey

Final

DO NOT INTERVIEW PHARMACY CUSTOMERS

Time allocation: Pharmacy survey: 15 minutes minimum/45 minutes maximum

Information about Interview	
Interviewer/s: _____	DAY ____ MONTH ____ YEAR ____

Information about the Facility	
Facility Location City/Town: _____	Interview ID Number: _____ (assigned by assessment team) <idnum>

Introduction
Ask for the person in-charge and show the letter of authorization for the study.
Introduce all team members. Explain the objectives of this assessment:
Hello. My name is_____. My colleague and I are OR I am representing the USAID-funded AIDSTAR-One Project.
We are visiting pharmacies all over the country because we learned that some pharmacies are now selling HIV test kits over the counter. Use of these kits may increase the number of people who have access to HIV testing, so we are trying to find out more about them.
We would like to get a sense of where over-the-counter rapid HIV test kits are available. This is not a regulatory or supervisory visit and we will not ask questions that are sensitive or personal. We are not looking at your performance or the performance of your pharmacy. And we will not ask for personal identifying information about customers who buy the kits. The interview will take about 15 minutes.

Topic	Question
Questions to ask regardless of whether they sell kits or not	
I. Training of Pharmacists and Pharmacist Assistants (PA) in HCT	<p>I.1 Are you a Pharmacist, a Pharmacist Assistant, or another category or worker (specify _____)? (Circle one or tick here to indicate if there are multiple respondents <input type="checkbox"/>)</p> <p>I.2 Did you receive training in rapid HIV testing? (Yes/No)</p> <p> I.2.1 If yes, where were you trained?</p> <p> If no, skip to next question.</p> <p>I.3 Have you received training in HIV counseling? (Yes/No)</p> <p> I.3.1 If yes, where were you trained?</p> <p> If no, skip to last question.</p> <p> I.3.1.1 Was the training—</p> <p> <input type="checkbox"/> in-service (after you finished your formal training)?</p> <p> <input type="checkbox"/> preservice (part of your formal training)?</p> <p> <input type="checkbox"/> both</p> <p> <input type="checkbox"/> other</p> <p> I.3.1.2 How long did the training last? (indicate units: days or months)</p> <p> I.3.1.2a (Number)</p> <p> I.3.1.2b (Days or months)</p> <p> I.3.1.3 What topics were covered?</p> <p> <input type="checkbox"/> _____</p> <p> <input type="checkbox"/> _____</p> <p> Skip to next section.</p> <p>I.3.2 If you did not receive training, would you like to be trained if a training course was available? (Yes/No)</p>

Topic	Question
2. Information about the kits	<p>2.1 Do <u>you seek out</u> information about rapid HIV test kits? (Yes/No)</p> <p>If no, skip to the next question. If yes, where do you seek out the information?</p> <p>2.1.1 <input type="checkbox"/> Internet 2.1.2 <input type="checkbox"/> Books 2.1.3 <input type="checkbox"/> Package insert 2.1.4 <input type="checkbox"/> Other _____</p> <p>2.2 Has information about the kits been <u>provided to you</u> from the Pharmaceutical Society? (Yes/No)</p> <p>If no, skip to last question. 2.2.1 If yes, what information has been provided?</p> <p>2.3 Have <u>you received</u> information about the HIV RTKs from a different source, such as from a test kit distributor or manufacturer? (Yes/No)</p> <p>If no, skip to next section. If yes, what source provided the information: _____</p> <p>2.3.1 <input type="checkbox"/> Distributors 2.3.2 <input type="checkbox"/> Manufacturer representatives 2.3.3 <input type="checkbox"/> Other _____</p>
3. Screening question	<p>3.1 Do you sell HIV test kits? (Yes/No)</p> <p>If yes, skip to “Sells kits questions”</p> <p>If no, ask “Doesn’t sell kits questions”</p>
Doesn’t sell kits questions	
	<p>3.1.1 Would you consider selling HIV test kits if you had access to information from a source such as the Pharmaceutical Society? (Yes/No)</p> <p><i>After asking this question, skip to open-ended closing questions, then end the survey at this pharmacy.</i></p>
Sells kits questions	
4. Initiation of sales	<p>4.1 When did you start selling over-the-counter rapid HIV test kits? (year)</p>

Topic	Question
5. Availability of kits	<p>5.1 Do you currently have kits in stock? (Yes/No)</p> <p>If no, skip to next section, or</p> <p>5.1.1 If the pharmacist says they obtain kits only on demand, skip to next section.</p> <p><input type="checkbox"/> Only sells on demand</p> <p>If yes, how many kits do you have on hand today? (Ask to see the kits, physically count them, and record data here.)</p> <p>5.1.2.</p> <p>(a) Brand name _____</p> <p>(b) Number of tests per pack: _____</p> <p>(c) Number in stock _____</p> <p>5.1.3.</p> <p>(a) Brand name _____</p> <p>(b) Number of tests per pack: _____</p> <p>(c) Number in stock _____</p> <p>5.1.4.</p> <p>(a) Brand name _____</p> <p>(b) Number of tests per pack: _____</p> <p>(c) Number in stock _____</p> <p>5.1.5.</p> <p>(a) Brand name _____</p> <p>(b) Number of tests per pack: _____</p> <p>(c) Number in stock _____</p> <p>5.1.6a Where are they stored?</p> <p><input type="checkbox"/> On the shelves behind the counter</p> <p><input type="checkbox"/> On shelves freely accessible to customers</p> <p><input type="checkbox"/> In the store room in the back of the pharmacy</p> <p><input type="checkbox"/> Other</p> <p>(5.1.6b) _____</p>

Topic	Question
<p>6. Sales of kits in private pharmacies (Determine demand based on sales data from distributors, suppliers, and pharmacies)</p>	<p>6.1 Do you have sales data on rapid HIV test kits <u>from the past month</u> that you can share with me? (Yes/No)</p> <p>6.1.1 If yes, review the data and record it on this page If no, ask the next question.</p> <p>6.2 Do you have sales data <u>for the past year</u>? (Yes/No)</p> <p>6.2.1 If yes, review the data and record it on this page. If no, ask the following questions.</p> <p>6.2.2 Within the last 7 (seven) days, on average how many kits did you sell per day?</p> <p><input type="checkbox"/> 0-1 (A)</p> <p><input type="checkbox"/> 2-5 (B)</p> <p><input type="checkbox"/> More than 5 (C)</p> <p>6.2.3 In the past month (in other words, in the past 30 days), how many kits, on average, did you sell?</p> <p><input type="checkbox"/> 0-2 (A)</p> <p><input type="checkbox"/> 3-5 (B)</p> <p><input type="checkbox"/> 6-10 (C)</p> <p><input type="checkbox"/> 11-20 (D)</p> <p><input type="checkbox"/> > 20 (E)</p> <p>6.2.4 In the past year (in other words, over the past 12 months), how many kits, on average, did you sell?</p> <p><input type="checkbox"/> 0-2 (A)</p> <p><input type="checkbox"/> 3-5 (B)</p> <p><input type="checkbox"/> 6-10 (C)</p> <p><input type="checkbox"/> 11-20 (D)</p> <p><input type="checkbox"/> > 20 (E)</p> <p>6.2.5a When do you restock your supply of the kits?</p> <p><input type="checkbox"/> At the end of each day</p> <p><input type="checkbox"/> When I stock out</p> <p><input type="checkbox"/> When my stock runs low (indicate minimum order level, if known: _____)</p> <p><input type="checkbox"/> Other (6.2.5b) _____</p>

Topic	Question
7. Retail cost	<p>What is the customer's cost for the rapid HIV test kit? (includes VAT)</p> <p>7.1. (a) Brand name _____ (b) Number of tests per pack _____ (c) Customer price _____</p> <p>7.2. (a) Brand name _____ (b) Number of tests per pack _____ (c) Customer price _____</p> <p>7.3. (a) Brand name _____ (b) Number of tests per pack _____ (c) Customer price _____</p> <p>7.4. (a) Brand name _____ (b) Number of tests per pack _____ (c) Customer price _____</p>
8. Wholesale cost	<p>What is your cost for the rapid HIV test kit? (including VAT)</p> <p>8.1. (a) Brand name _____ (b) Number of tests per pack _____ (c) Your cost _____ (d) or the mark-up used _____</p> <p>8.2. (a) Brand name _____ (b) Number of tests per pack _____ (c) Your cost _____ (d) or the mark-up used _____</p> <p>8.3. (a) Brand name _____ (b) Number of tests per pack _____ (c) Your cost _____ (d) or the mark-up used _____</p> <p>8.4. (a) Brand name _____ (b) Number of tests per pack _____ (c) Your cost _____ (d) or the mark-up used _____</p>

Topic	Question
9. Salespeople	<p>Who sells the test kits in your pharmacy? <i>Tick all that apply.</i></p> <p>9.1 <input type="checkbox"/> Pharmacist</p> <p>9.2 <input type="checkbox"/> Pharmacist assistant</p> <p>9.3 <input type="checkbox"/> Front shop staff</p> <p>9.4 <input type="checkbox"/> Patients take it from the shelf</p> <p>9.5 <input type="checkbox"/> Other _____</p>
10. Consumers of OTC HIV RTKs in private sector	<p>Who purchases kits from you? <i>Tick all that apply.</i></p> <p>10.1 <input type="checkbox"/> Adults</p> <p>10.2 <input type="checkbox"/> Teenagers</p> <p>10.3 <input type="checkbox"/> Church people</p> <p>10.4 <input type="checkbox"/> Health care providers/private physicians <i>(If health care providers/physicians or health facilities only, mark NA in the next five sections and resume at "Access to HIV testing and counseling services" on page 10).</i></p> <p>10.5 <input type="checkbox"/> Nongovernmental organizations</p> <p>10.6 <input type="checkbox"/> Private health facilities</p> <p>10.7 <input type="checkbox"/> Public health facilities</p> <p>10.8 <input type="checkbox"/> Other pharmacists</p> <p>10.9 <input type="checkbox"/> Other _____</p> <p>10.10 Which of the groups listed above do you sell the most kits to? _____ 10.10.1 <i>(Provide age range if mentioned by the interviewee: _____)</i></p> <p>10.11 Do you sell more kits to men or to women? <i>(circle one)</i> <i>(men/women/same/don't know)</i></p>
11. Confidentiality	<p>11.1 Do customers request privacy when they purchase HIV test kits over the counter? <i>(Yes/No/NA)</i></p> <p>11.2 When a customer wants to purchase a test kit, is it possible to sell them the kit without other customers seeing what they're buying? <i>(Yes/No/NA)</i></p> <p>11.2.1 If yes, how do you do it?</p> <p>If no, why don't you?</p> <p>11.2.2 <input type="checkbox"/> Not possible</p> <p>11.2.3 <input type="checkbox"/> It's not important</p> <p>11.2.4 <input type="checkbox"/> Other _____</p>
12. Pharmacist consultation	<p>12.1 Do you provide any information to customers about the kit when they buy it? <i>(Yes/No/NA)</i></p> <p>12.1.1 If yes, what do you tell them?</p> <p>12.1.2 If no, why don't you provide information?</p>

Topic	Question
13. Customers' questions	<p>13.1 Do customers ask you questions about the kit?</p> <p><input type="checkbox"/> Most of the time</p> <p><input type="checkbox"/> Some of the time</p> <p><input type="checkbox"/> Rarely</p> <p><input type="checkbox"/> Never</p> <p><input type="checkbox"/> NA</p> <p>What questions do they ask (tick all that apply)</p> <p>13.1.1 <input type="checkbox"/> How to use the test kit?</p> <p>13.1.2 <input type="checkbox"/> How to interpret the test kit results?</p> <p>13.1.3 <input type="checkbox"/> Accuracy of the test result?</p> <p>13.1.4 <input type="checkbox"/> What to do if they get a positive result?</p> <p>13.1.5 <input type="checkbox"/> What do if they get a negative result?</p> <p>13.1.6 <input type="checkbox"/> How to get help if they have a positive result?</p> <p>13.1.7 <input type="checkbox"/> If they can buy another kit to check the results?</p> <p>13.1.8 <input type="checkbox"/> Where they can get medical care and treatment?</p> <p>13.1.9 <input type="checkbox"/> Ask for counseling?</p> <p>13.1.10 <input type="checkbox"/> Where they can get help for family members?</p> <p>13.1.11 <input type="checkbox"/> Other</p> <hr/> <p>13.2 Have any customers told you their HIV test results after using an over-the-counter test kit? (Yes/No/NA)</p> <p>If NA or no skip to next section.</p> <p>13.2.1 If yes, how often does this happen</p> <p><input type="checkbox"/> Most of the time</p> <p><input type="checkbox"/> Some of the time</p> <p><input type="checkbox"/> Rarely</p> <p><input type="checkbox"/> Never</p> <p>13.2.2 What results do they reveal to you? (Circle one) (positive, negative, unable to determine)</p>

Topic	Question
<p>14. Ability to administer the test (ease of use and clarity of instructions)</p>	<p>Have any customers told you that they had difficulty with the following aspects of administering the test? (<i>Prompt for each</i>)</p> <p>14.1 Lancet (Yes/No/NA)</p> <p>14.2 Instructions (Yes/No/NA)</p> <p>14.3 Device (Yes/No/NA)</p> <p>14.4 Other (Yes/No/NA) Describe _____</p> <p>14.5 Have any of your customers ever asked you for help administering the test? (Yes/No/NA)</p> <p>If NA or no, skip to next section</p> <p>14.5.1 If yes, were you able to help them administer the test? (Yes/No)</p> <p>14.5.1.1 If yes, how did you help them?</p> <p>14.5.1.2 If no, why were you not able to help them?</p>
<p>15. Interpretation of results</p>	<p>15.1 Have any of your customers told you that they had difficulty interpreting the results? (Yes/No/NA)</p> <p>If NA or no, skip to next question.</p> <p>15.1.1 If yes, please describe the difficulty.</p> <p>15.2 Has anyone ever asked you for help interpreting their results? (Yes/No/NA)</p> <p>If NA or no, skip to next section.</p> <p>15.2.1 If yes, how did you help them?</p>

Topic	Question
16. Access to HIV testing and counseling services	<p>16.1 Do you know if HIV counseling services are available in this town (city)? (Yes/No)</p> <p>If no, skip to next question.</p> <p>If yes, who provides the counseling?</p> <p>16.1.1 <input type="checkbox"/> Public health clinical care provider/state hospital</p> <p>16.1.2 <input type="checkbox"/> Lay counselor</p> <p>16.1.3 <input type="checkbox"/> Private clinic</p> <p>16.1.4 <input type="checkbox"/> The pharmacist in this clinic</p> <p>16.1.5 <input type="checkbox"/> New Start Center clinic</p> <p>16.1.6 <input type="checkbox"/> Other</p> <hr/> <p>16.1.7 Do you refer clients who buy an OTC kit for counseling services? <i>(Tick NA if only selling kits on demand to health care providers/physicians, or health facilities and skip to next section.)</i> (Yes/No/NA)</p> <p>16.2 Has anyone ever asked you where they could get counseling when they bought the test? (Yes/No/NA)</p> <p>If NA or no, skip to next section</p> <p>If yes, who do you refer them to?</p> <p>16.2.1 <input type="checkbox"/> Public health clinical care provider</p> <p>16.2.2 <input type="checkbox"/> Lay counselor</p> <p>16.2.3 <input type="checkbox"/> Private clinic</p> <p>16.2.4 <input type="checkbox"/> Other</p> <hr/> <p>16.2.5 <input type="checkbox"/> Can't refer because I either don't know if counseling services are available or counseling services are not available.</p>
17. Confirmatory testing	<p>17.1 Do you know where people can obtain confirmatory testing services? (Yes/No)</p> <p>If no, skip to the next question.</p> <p>17.1.1 If yes, what is the name of place?</p> <p>17.2 Have any customers who bought a test kit asked where they could get a test to confirm their rapid test result? <i>(Tick NA if only selling kits on demand to health care providers/physicians or health facilities and skip to next section.)</i> (Yes/No/NA)</p>

Topic	Question
18. Number of distributors	<p data-bbox="451 249 1081 279">Please list all the distributors that supply you with the kits.</p> <p data-bbox="451 321 1218 350">18.1 Distributor 1 (insert name): _____</p> <p data-bbox="451 357 1218 386">18.2 Distributor 2 (insert name): _____</p> <p data-bbox="451 392 1218 422">18.3 Distributor 3 (insert name): _____</p> <p data-bbox="451 468 1393 525">Please provide their contact information. We will not tell them we received their name and contact details from you.</p> <p data-bbox="451 569 1390 598">Distributor 1: _____</p> <p data-bbox="451 625 1354 655">_____</p> <p data-bbox="451 682 1390 711">Distributor 2: _____</p> <p data-bbox="451 739 1354 768">_____</p> <p data-bbox="451 795 1390 825">Distributor 3: _____</p> <p data-bbox="451 852 1354 882">_____</p> <p data-bbox="451 909 1354 938">_____</p> <p data-bbox="451 1003 1393 1060">If these are not pharmaceutical and medical supply distributors, what type of companies are they?</p> <p data-bbox="451 1104 1005 1134">Distributor 1: _____</p> <p data-bbox="451 1178 1005 1207">Distributor 2: _____</p> <p data-bbox="451 1251 1005 1281">Distributor 3: _____</p>
19. Stockouts	<p data-bbox="451 1329 1292 1381">19.1 Have you ever stocked out of the kits? <i>(Minimum reorder level of zero with next day delivery/restock should not be considered a stockout.)</i></p> <p data-bbox="451 1388 878 1417">(Yes/No/NA) <i>(Tick NA if order on demand only)</i></p> <p data-bbox="500 1423 789 1453">If no, skip to next section.</p> <p data-bbox="500 1497 1076 1526">19.1.1a If yes, what was the reason for the stockout?</p> <p data-bbox="500 1533 1096 1671"> <input type="checkbox"/> Distributor didn't have any <input type="checkbox"/> Didn't realize my stock was low and then we ran out <input type="checkbox"/> Customer demand was higher than expected <input type="checkbox"/> Other </p> <p data-bbox="500 1677 1338 1707">19.1.1b) _____</p>

Topic	Question
20. Expiry	<p>20.1 Have any of your kits ever expired? (Yes/No)</p> <p>If no, skip to next section.</p> <p>20.1.1a If yes, what was the reason for the expiry?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Poor sales <input type="checkbox"/> Estimate of demand was lower than expected <input type="checkbox"/> Short shelf life <input type="checkbox"/> Other <p>(20.1.1b) _____</p> <p>20.1.2 Where do you store the expired kits?</p>
Open-ended closing questions to ask everyone	
21. “Concerns,” “Barriers,” or “Obstacles” to effective OTC HIV testing	<p>21.1 Do you have any concerns about OTC HIV testing? In other words, what are the “cons” for OTC HIV testing? (Yes/No)</p> <p>If no, skip to next section.</p> <p>21.1.1 If yes, please describe.</p>
22. “Opportunities” or “Facilitators” for effective OTC HIV testing	<p>22.1 Do you think OTC HIV testing provides opportunities for Namibia to increase access to HIV testing? (Yes/No)</p> <p>22.1.1 If yes, please describe.</p> <p>22.1.2 If no, why not?</p>

Topic	Question
23. Activism	Why did you decide to sell or not sell OTC HIV RTKs? 23.1 <input type="checkbox"/> To help slow the HIV epidemic 23.2 <input type="checkbox"/> To make more money 23.3 <input type="checkbox"/> Because my customers requested that I sell them 23.4 <input type="checkbox"/> To remain competitive with other suppliers 23.5 <input type="checkbox"/> The distributor or manufacturer suggested I sell them 23.6 <input type="checkbox"/> Other _____
Storage & inventory management: observations (Interviewers make objective observations of the following conditions by physically observing the kits.)	
24. Storage	Are the kits — 24.1 protected from direct sunlight? (Yes/No) 24.2 stored at temperature greater than 25°C (Yes/No)
25. Inventory management	25.1 Are the kits stored and organized in a manner accessible for first-to-expire, first-out (FEFO) if expiry dates are different? (Yes/No)
26. Questions or comments from respondent	26a 26b

APPENDIX 2.

KEY INFORMANT ORGANIZATIONS

Key informant interviews were conducted with representatives of the following organizations.

Ministry of Health and Social Services, Republic of Namibia

Directorate of Special Programmes, HIV Counseling and Testing Department

Namibia Medicines Regulatory Council

Pharmaceutical Services

Central Medical Stores (CMS)

Namibia Institute of Pathology (NIP)

Namibia Institute of Pathology (NIP), Ltd.

Pharmacy Council of Namibia (PCN) (Health Professions Councils of Namibia)

Pharmacy Council of Namibia

Wholesalers and distributors of medical supplies in the private sector

GEKA Pharma (Pty) Ltd.

Nampharm

GENMED

NewMed Namibia

USAID partners

SHOPS Project, Abt Associates

Capacity Project, IntraHealth International

LifeLine/ChildLine Namibia

Society for Family Health

Education and training institutions

UNAM (University of Namibia) School of Pharmacy, Faculty of Health Sciences

National Health Training Centre

Health Professional Associations

HIV Clinicians Society

Namibia Medical Society

Pharmaceutical Society of Namibia

APPENDIX 3.

KEY INFORMANT INTERVIEW GUIDE

Namibia OTC HIV RTK Study

Key Informant Interview Guide (Final)

Pharmacy consumers and other health sector clients shall not be interviewed.

Time allocation: 30 minutes minimum/60 minutes maximum

Before the interview begins, mention to the key informant that we need honest answers of the actual situation on the ground.

Emphasize that we are not looking for the ideal situation; we are trying to understand what is actually happening.

Interviewer: _____

Interviewee: _____

Organizational affiliation: _____

Topic	Target Interviewee(s)	Questions
<p>I Pharmacist and Pharmacist Assistant (PA) training in HIV counseling and testing (HCT)</p> <p><i>(Pharmacist Assistants are allowed to sell OTC products)</i></p>	<p>UNAM Medical School, Pharmacy Department & NHTC (National Health Training Centre) for PAs</p>	<p><i>Some pharmacists have reported that pharmacy customers ask them questions about HIV when they buy rapid HIV test kits over the counter. We are interested in learning more how pharmacy training prepares pharmacists and Pharmacist Assistants for HIV counseling.</i></p> <p>Do pharmacists, pharmacist assistants, and/or pharmacy or pharmacist assistant students receive information or education about rapid HIV test kits during their training? (Yes/No)</p> <p>If no, skip to next section.</p> <p>Do pharmacists, pharmacist assistants, and students receive training in HIV counseling and/or HIV testing at your institution? (Yes/No)</p> <p>If yes, please tell me more about how the training is provided and what content is included.</p> <p>If no, is training provided through other sources?</p> <p>Are you aware of any plan to add training on HIV counseling and testing to pharmacist and/or pharmacist assistant training at your institution? (Yes/No)</p> <p>If yes, do you think it's needed?</p> <p>If no, why do you think it's not being added?</p>

Topic	Target Interviewee(s)	Questions
<p>2 Information about the kits</p>	<p>Pharmaceutical Society of Namibia</p> <p>Pharmacy Council of Namibia</p>	<p>Is information about rapid HIV test kits made available to pharmacists through the Pharmaceutical Society of Namibia? (Yes/No)</p> <p>If yes, what information has been provided and in what format? <i>(Request to see a copy of the information. Note that it may have been provided as a circular/flyer/notice, presentation, or manual.)</i></p> <p>If no, skip to next question.</p> <p>Is information provided to pharmacists through other sources? (Yes/No)</p> <p>If no, skip to next section. If yes, what sources?</p> <p>What information is provided?</p>

Topic	Target Interviewee(s)	Questions
<p>3 Describe regulatory system</p>	<p>Namibia Medicines Regulatory Council (NMRC)</p>	<p><i>Introductory language: We are trying to understand the pathway and regulatory requirements of OTC rapid HIV test kits from importation to the pharmacy counter.</i></p> <p>When were OTC RTKs first approved from sale in private pharmacies? (month/year)</p> <p>What regulatory document provides for the approval of sale of the kits in private pharmacies?</p> <p><i>Regarding importation—</i></p> <ul style="list-style-type: none"> • Through which port do these kits enter the country (sea, land, air)? • Where are they manufactured? (e.g., South Africa, China, India) • From which countries are they imported? • Do the import regulations for the public health system also apply to these products? (Yes/No) • What government entity has responsibility for managing importation of OTC RTKs? <p><i>Regarding registration—</i></p> <ul style="list-style-type: none"> • What are the registration requirements for companies that manufacture OTC RTKs? • Is the Namibia Medicines Regulatory Council responsible for registration of the RTKs? (Yes/No) <p><i>Regarding other regulations—</i></p> <ul style="list-style-type: none"> • Besides registration, what other regulations guide the sale of these devices? • What other document(s) describe requirements for these products? • Are different or the same regulatory processes applied to RTKs sold in pharmacies compared with RTKs used in public health or private clinics or laboratories? (different/same) <p><i>If different, please describe.</i></p>

Topic	Target Interviewee(s)	Questions
Describe the regulatory system (continued)	Namibia Medicines Regulatory Council (continued)	<p>What <u>regulatory category</u> applies to rapid HIV test kits?</p> <p>Are they considered medical devices, diagnostic devices, or something else? (circle one)</p> <p>Does the NMRA accept other stringent regulatory authority determinations (such as U.S. FDA or EU/CE) for medical or diagnostic devices?</p> <p>What are the regulatory elements for diagnostic devices?</p> <p>Are all regulatory elements reflected in the specifications for OTC RTKs? (Yes/No)</p> <p>If no, what elements are missing?</p> <p>Are HIV confirmatory tests also regulated by the NMRC?</p> <p>Are there laws specifying who can purchase and/or use rapid HIV test kits?</p> <p>(Yes/No)</p> <p>Are there other government and nongovernmental stakeholders with whom we should meet to learn more about the pathway and regulatory requirements of rapid test kits from import to counter?</p> <p>For example, should we speak with one of the pharmacists that serve on the Medicines Control Council?</p> <p>Is there a committee on OTC RTKs under the Medicines Control Council?</p> <p>(Yes/No)</p>

Topic	Target Interviewee(s)	Questions
<p>4 Quality: safety and performance</p>	<p>Namibia Medicines Regulatory Council (continued)</p> <p>NIP</p>	<p>Are there rules regarding the <u>safety and performance</u> of OTC RTKs sold in the private sector? (Yes/No)</p> <p>If yes—</p> <ul style="list-style-type: none"> • Describe the rules/requirements/standards for safety and performances of OTC RTKs. • Are there requirements to monitor the safety and performance of OTC RTKs? • What documents describe the safety and performance requirements for OTC RTKs? <p>If yes—</p> <ul style="list-style-type: none"> • What are their titles? • Where can we obtain copies? • Describe the format? <p>If no, are there safety and performance requirements for medical or diagnostic devices? (Yes/No)</p>

Topic	Target Interviewee(s)	Questions
<p>5 Quality control and quality assurance</p>	<p>Namibia Medicines Regulatory Council (continued)</p> <p>NIP</p>	<p>Are there rules regarding the <u>quality</u> of OTC RTKs sold in the private pharmacies? (Yes/No)</p> <p>If yes— Are there any <u>quality control protocols</u> to ensure standards for RTKs sold in private pharmacies are met? (Yes/No)</p> <p>If yes, can a protocol be shared, or can you describe minimum standards?</p> <p>If no, is there a need for quality control protocol for items sold in the private sector? (Yes/No)</p> <ul style="list-style-type: none"> • How do you—or the relevant government entity—ensure that quality standards are met? • Who conducts the testing on kits sold in the private sector to ensure they meet quality standards? <p>Is there a process for quality assurance monitoring of the OTC RTKs? (Yes/No)</p> <p>If yes, who monitors the quality of the kits?</p> <p>Do the Regional QA Officers perform monitoring of the kits in private pharmacies? (Yes/No)</p> <p>Are private pharmacies held to the same standard of being obligated to procure only tests approved by NIP? (Yes/No)</p> <p>May I see the list of nationally approved RTKs? (available from NIP) <i>Indicate if a copy of the list can be provided.</i></p> <p>When was the last time it was updated? (<i>provide date</i>)</p>

Topic	Target Interviewee(s)	Questions
<p>6</p> <p>Number of distributors</p>	<p>Namibia Medicines Regulatory Council</p> <p>NIP</p> <p>CMS</p>	<p>Who are the authorized distributors of OTC HIV RTKs in Namibia?</p> <p>1. _____</p> <p>2. _____</p> <p>3. _____</p> <p>4. _____</p> <p>5. _____</p> <p>Who are the top three distributors, and do you have contact information for someone that we could speak with?</p>
<p>7</p> <p>Describe the supply chain for the kits in the private sector</p>	<p>Wholesalers and distributors</p> <p>CMS</p>	<p>Please describe how OTC HIV RTKs move through the supply chain in Namibia, beginning with procurement and ending with customers purchasing a kit in the private sector.</p> <p><i>(Draw a diagram of product and information flow for the private sector supply chain for RTKs on the notes page.)</i></p> <p>What aspects of this process work well?</p> <p>In what parts of the supply chain do you face problems?</p> <p>Where do OTC HIV kits fit in relation to volume of medical or diagnostic device sales (relatively large portion of the market, or relatively small)?</p> <p>Who purchases the largest quantities of OTC HIV test kits? (pharmacies, hospitals, private doctors)</p>
<p>8</p> <p>Availability of kits</p>	<p>Wholesalers and distributors</p> <p>CMS</p>	<p>Do you have any kits in stock? (Yes/No)</p> <p>If yes, how many kits do you have in stock today? (fill in brand name and # in stock, and circle number of tests/kit)</p> <p>Brand name _____ Number in stock _____ Number of tests/kit: 1 or 5</p> <p>Brand name _____ Number in stock _____ Number of tests/kit: 1 or 5</p> <p>Brand name _____ Number in stock _____ Number of tests/kit: 1 or 5</p>

Topic	Target Interviewee(s)	Questions
<p>9</p> <p>Determine demand based on sales data from distributors, suppliers, and pharmacies</p>	<p>Wholesalers and distributors</p>	<p>Do you have sales reports from the past— year? (Yes/No) month? (Yes/No) week? (Yes/No)</p> <p>May I see them and copy the sales data? <i>(Copy data here or on the notes page.)</i></p> <p>Year Year 2012 Year 2011 Year 2010</p> <p>Month (2012 data) January February March April May June July August September October November December</p>

Topic	Target Interviewee(s)	Questions
<p>I0</p> <p>Describe policies associated with the OTC HIV RTKs</p> <p>Describe guidelines for OTC HIV RTK usage</p>	<p>MOHSS</p> <ul style="list-style-type: none"> ● HCT ● NIP ● Human Resource Management and General Services 	<p>What government entity has responsibility for policy development related to HIV counseling and testing?</p> <p>Does this entity have oversight of private sector sales? (Yes/No)</p> <p>Based on the national HCT or other guidelines, who is allowed to conduct HIV testing in Namibia?</p> <p>Is there a provision for licensing pharmacies to be HCT providers? (Yes/No)</p> <p>Do the guidelines address the practice of <u>self-testing</u> for HIV by the public? (Yes/No)</p> <p>Are there national government policies or guidance that describe the use of OTC RTKs in the private sector? (Yes/No)</p> <p style="padding-left: 40px;">If yes, do these government directives include the sale of OTC RTKs in private pharmacies? (Yes/No)</p> <p style="padding-left: 80px;">If yes, please describe.</p> <p>Does the policy address all necessary aspects of use of the kits by pharmacists in the private sector? (Yes/No)</p> <p style="padding-left: 40px;">If no, what elements are missing?</p> <p>Considering the licensing requirements for HCT, could a pharmacist help a customer perform a test in the pharmacy if the customer asks the pharmacist for help? (Yes/No)</p> <p>Is blood or oral fluid used in the OTC RTKs? (Blood/Oral/Both options available)</p> <p>Is blood or oral fluid used in RTKs used in licensed HCT facilities? (Blood/Oral/Both options available)</p> <p>Please comment on why the RTKs sold in pharmacies either use the same or different rapid testing technique(s) as the test(s) used in licensed HCT facilities.</p>

Topic	Target Interviewee(s)	Questions
<p>I 1</p> <p>Ability to administer the test (ease of use and clarity of instructions)</p>	<p>MOHSS</p> <ul style="list-style-type: none"> ● HCT ● NIP ● Human Resource Management and General Services <p>USAID partners</p> <p>Private physicians and community counselors</p>	<p>Based on your knowledge of the OTC RTK, can community members administer the test correctly? (Yes/No)</p> <p>Are you aware of any difficulties people have when administering the test? (Yes/No)</p> <p>If yes, please describe the difficulties.</p>
<p>I 2</p> <p>Interpretation of results</p>	<p>MOHSS</p> <ul style="list-style-type: none"> ● HCT ● NIP ● Human Resource Management and General Services <p>USAID partners</p> <p>Private physicians and community counselors</p>	<p>Based on your knowledge of the OTC RTK, can community members interpret the results correctly? (Yes/No)</p> <p>If yes, why do you think their interpretation is correct?</p> <p>If no, why do you think they are not able to correctly interpret the result?</p> <p>Are you aware of any difficulties people have had interpreting the results? (Yes/No)</p> <p>If yes, what difficulties did they have?</p> <p>Please share any anecdotal experiences related to HIV self-testing that may help us.</p>

Topic	Target Interviewee(s)	Questions
<p>13</p> <p>Access to HIV testing and counseling services</p>	<p>MOHSS</p> <ul style="list-style-type: none"> ● HCT ● NIP ● Human Resource Management and General Services <p>USAID partners</p> <p>Private physicians and community counselors</p>	<p>Do you know if HIV counseling services are available in the private sector in Windhoek? (Yes/No)</p> <p>If yes, who provides the counseling?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Private physician <input type="checkbox"/> Private nurse <input type="checkbox"/> Community counselor <input type="checkbox"/> Other _____ <p>Do private sector counselors follow a testing and counseling algorithm? (Yes/No)</p>
<p>14</p> <p>Barriers to HCT</p>	<p>MOHSS</p> <ul style="list-style-type: none"> ● HCT ● NIP ● Human Resource Management and General Services <p>USAID partners</p> <p>Private physicians and community counselors</p>	<p>Why do some people not seek HIV counseling and testing? <i>Tick all that apply (don't prompt).</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> Cost <input type="checkbox"/> Limited transportation/distance <input type="checkbox"/> Lack of services <input type="checkbox"/> Lack of privacy/confidentiality (e.g., other customers or staff see what you purchase) <input type="checkbox"/> Not seen as a priority <input type="checkbox"/> Too busy <input type="checkbox"/> Afraid of receiving a positive result <input type="checkbox"/> Stigma <input type="checkbox"/> Other _____

Topic	Target Interviewee(s)	Questions
15 Confirmatory testing	MOHSS <ul style="list-style-type: none"> ● HCT ● NIP ● Human Resource Management and General Services USAID partners Private physicians and community counselors	<p>Is confirmatory testing available in the private sector for people who test positive on an OTC RTK? (Yes/No)</p> <p>If yes, where can people receive confirmatory testing in the private sector?</p> <p>If no, is the public sector system the only option for confirmatory testing? (Yes/No)</p> <p>If no, what are the other options for confirmatory testing?</p> <p>What is the typical waiting time before a confirmatory result is available?</p> <p>When someone gets a confirmatory test, what process is used to ensure that they receive the result since it is not immediately available?</p>
16 Access to health care services for clinical care	MOHSS <ul style="list-style-type: none"> ● HCT ● NIP ● Human Resource Management and General Services USAID partners Private physicians and community counselors	<p>Are people with a positive HIV confirmatory test referred for treatment and care? (Yes/No)</p> <p>If yes, where are they referred?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Public health service provider <input type="checkbox"/> Private provider <input type="checkbox"/> Other _____ <p>Is there a standard referral process for people with a positive confirmatory test? (Yes/No)</p> <p>If yes, can you describe it?</p> <p>Do you experience challenges referring clients? (Yes/No)</p> <p>If yes, describe the challenges?</p>
17 “Concerns,” “Barriers,” and “Obstacles” to effective OTC HIV testing	All interviewees	<p>Do you have any concerns about OTC HIV testing being accessible through private sector sales directly to consumers? (Yes/No)</p> <p>If yes, please describe. <i>(Possible concerns may include: cost, stigma, embarrassed to ask for test kit, can’t follow directions, etc.)</i></p>

Topic	Target Interviewee(s)	Questions
<p>18</p> <p>“Opportunities” and “Facilitators” for effective OTC HIV testing</p>	<p>All interviewees</p>	<p>Do you think OTC HIV testing provides opportunities to increase access to HIV testing in Namibia? (Yes/No) If yes, please elaborate.</p> <p>If no, why not?</p> <p>Do you think HIV self-testing should be encouraged or promoted? (Yes/No) Please elaborate.</p>
<p>19</p> <p>Activism</p> <p>Human rights</p>	<p>All interviewees</p>	<p>Are you supportive of increasing access to HIV testing through over-the-counter test kits? (Yes/No) If yes, what are the reasons why you think OTC HIV RTKs should be sold?</p> <ul style="list-style-type: none"> <input type="checkbox"/> To help slow the HIV epidemic <input type="checkbox"/> To boost the economy <input type="checkbox"/> Because community members have demanded they be provided OTC <input type="checkbox"/> Other <hr/> <p>If no, why not?</p> <p>What do you think the future of OTC RTKs should be?</p> <p>Do you think there is a potential risk that people could be forcibly tested with the OTC RTKs? For example, could employers be using the kits to test potential or existing employees?</p>

APPENDIX 4.

NAMIBIA INSTITUTE OF PATHOLOGY LIST OF APPROVED HIV RAPID TEST KITS



**ANNEXURE A: APPROVED TESTING ALGORITHM
LIST OF APPROVED HIV RT KITS**

Information on HIV Rapid Test kits evaluated in Namibia

	HIV Rapid Test Kit Name	Manufacturer	Approved for International use by	Approved for Namibian use	Namibian Evaluation done
1	Capillus™ HIV-1/HIV-2	Trinity Biotech	USAID	yes	2003/4
2	Determine™ HIV -1/2	Abbott Laboratories	USAID	yes	2003/4
3	Uni-Gold™ HIV	Trinity Biotech	USAID	yes	2003/4
4	OraQuick Rapid Test	OraSure Technologies	USAID	yes	2003/4
5	Hemastrip	Chembio Diagnostic Systems, Inc	USAID	yes	2003/4
6	HIV 1-2 Stat Pak	Chembio Diagnostic Systems, Inc	USAID	yes	2003/4
7	SD Bioline HIV 1/2 3.0	Standard Diagnostics	USAID	for surveillance	2006
8	OraQuick (OMT)	OraSure Technologies	FDA	for surveillance	2006
9	OraSure (OMT)	OraSure Technologies	FDA	for surveillance	2006
10	Clearview® Complete HIV1/2 (Formerly Sure Check HIV 1/2)	Chembio Diagnostic Systems, Inc	USAID	yes	2007
11	ICT Rapid HIV 1/2	ICT Diagnostics	Evaluated by NICD	No	2007
12	SD Bioline HIV 1/2	Standard Diagnostics	USAID	Pending	2008
13	Hexagon HIV 1/2	Human Diagnostics		Pending	2008

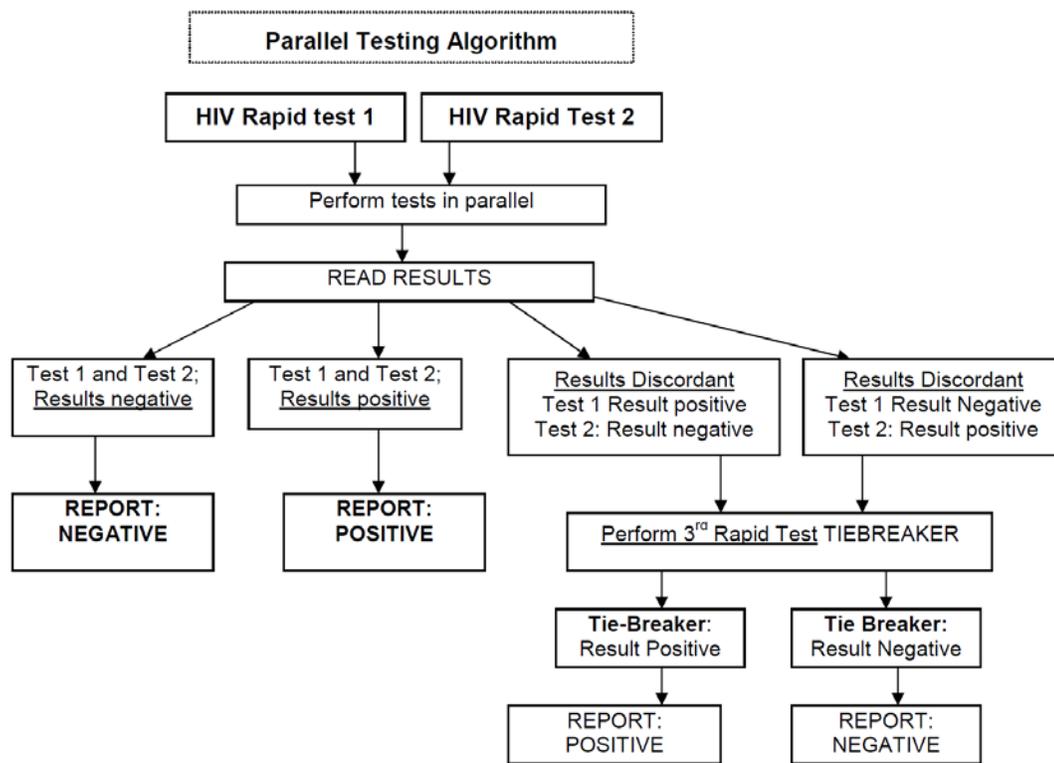
APPENDIX 5.

NAMIBIA INSTITUTE OF PATHOLOGY APPROVED TESTING ALGORITHM



**ANNEXURE A: APPROVED TESTING ALGORITHM
LIST OF APPROVED HIV RT KITS**

Generic parallel testing algorithm for the use of Rapid tests in diagnosis of HIV infection



For more information, please visit aidstar-one.com.

AIDSTAR-One

John Snow, Inc.

1616 Fort Myer Drive, 16th Floor

Arlington, VA 22209 USA

Phone: 703-528-7474

Fax: 703-528-7480

Email: info@aidstar-one.com

Internet: aidstar-one.com