Evaluating the Acceptability, Feasibility, and Linkage to Care in a Pharmacy-Based HIV Self-Testing Program in Zambézia Province, Mozambique

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Summary

Introduction

HIV self-testing (HIVST) is a WHO recommended strategy to increase testing, especially among key populations, specifically, men and young adults (18-29 years of age). From May to December 2019, a pilot was implemented in Zambézia province involving 3 public and 11 private pharmacies, allowing clients to purchase up to two HIV self-tests at a subsidized price of 50Mzn (~USD 0.80). The study assessed the acceptability and uptake of this strategy.

Methods

During the pilot project, pharmacy-based exit-surveys were conducted in a random sample of 10 clients (≥18 years of age), at initiation and three months later, independent from test purchase. A pharmacy-based survey was also done for a random sample of up to 10 clients per pharmacy who purchased a test and accepted being contacted 1-12 weeks later. Both surveys used structured questionnaires on acceptability, with additional questions on use of the test for the latter group. Univariate analysis (Chi-squared (x^2) test) was done comparing clients who purchased an HIVST versus not. In-depth qualitative interviews were done with pharmacy staff/managers. In the amended protocol, we performed an evaluation of self-test performance and results interpretation among different target groups (students, employees, and community members). Trained observers watched silently how participants performed the HIV self-test, and a checklist was used to evaluate performance. Participants were asked to interpret the result(s) of a previously processed (anonymous) self-test to assess the participants' interpretation of test results. The participants were then asked to complete a questionnaire regarding the acceptability of HIVST and their personal experience with performing a self-test.

Results

Overall, during the pilot period, 1,139 adults purchased 1,344 tests. Those purchasing tests were predominantly male (70%), from age group 15-34 years (69%); 58% visited one of the six rural pharmacies.

A total of 280 pharmacy clients participated in the exit-survey, with 83 pharmacy clients completing the additional post-purchase survey. Of the total of 363 interviewed people, median age was 29 years (IQR; 22-38 years), 168 (65%) were male and 252 (69%) attended a rural pharmacy. The main advantage found for HIVST was confidentiality, while primary disadvantages were fear of the result and lack of counseling.

Among the 83 pharmacy clients who purchased a test, 78 (94%) performed the test. Self-reported ease (varying from 'very easy' or 'easy') of test instructions and of test performance was 91% and 89%, respectively. Almost all (97%) were confident in their test result. Self-test results were revealed to the interviewer by 45 (58%), with 10 (13%) reporting linking to a health facility to confirm their result.

Overall, 45 pharmacy staff/ managers were interviewed in the qualitative component. Males were thought to be the main target group for HIVST, but demand creation for the search and purchase of tests was felt as a need. Pharmacy employees/managers thought that a pharmacy is a good place to get an HIVST, however,

the desire for more privacy for testing procedures within the pharmacy was highlighted, which would require appropriate conditions/infrastructure, such as an available private room or meeting corner. In addition, to bolster the uptake of such an approach if pharmacies are to be utilized, a major challenge that was mentioned was human resources, as currently available pharmacy technicians reported not having the time to provide counseling and information for HIVST.

Overall, 312 persons participated in the performance evaluation (131, 42% community members; 71, 23% students; 110, and 35% employees); of these, the majority (239 (77%)) were male; having a median age of 24 years [IQR 21-30]. Overall, 260 (83%) were previously tested for HIV, and 9 (3%) had ever done HIVST prior to study participation.

Major errors observed included incorrect tube positioning into the stand (152, 49%); incorrect specimen collection (134, 43%); and incorrect waiting time for result reading (130, 42%). The average usability index was 80%, 86%, and 77%, among employees, students and community members, respectively. Seventy-five percent (n=234) correctly interpreted all presented test results, and 9 (3%) persons failed to correctly interpret all presented tests. Overall, 36 (12%) gave a false negative result interpretation, 21 (7%) gave a false positive result interpretation, and 14 (4%) gave both false negative and false positive result interpretations. Community members had generally a lower performance when compared to the other evaluated groups.

Conclusions

Offering HIVST at public and private pharmacies is acceptable for those able to purchase a test and is reached by younger adults and male populations. The perceived lack of counseling is concerning, suggesting the need for counseling tools at pharmacies and/or offering assisted self-testing options. Purchased tests were utilized, but additional demand creation initiatives are needed. Despite testing procedure errors, overall usability of HIVST process was favorable. To attain the first 95 of the UNAIDS 95-95-95 goals, HIVST is one of the various strategies for HIV testing (health facility and community-based) that should be considered/continued. Continuous information and educational sessions focused on proper procedures offered at strategic community locations such as schools and workplaces may improve HIVST quality.

Program Background

The greatest burden of the HIV/AIDS epidemic continues to be shared across the sub-Saharan African (SSA) region, where approximately 47% of all new cases occurred in 2018. Globally, Mozambique continues to rank among the top five countries most severely affected by the disease, with an estimated 2.2 million HIV-infected Mozambicans in 2018 (1). The national HIV survey (2015) data show that 39% of women and 60% of men have never been tested for HIV (2).

In 2013, the Government of Mozambique's Ministry of Health (MOH) announced their commitment to a new National HIV and AIDS Response Acceleration Plan, which prioritized increasing access to combination antiretroviral therapy (ART) as a key method for prevention of new infections and for decreasing rates of morbidity and mortality among persons living with HIV (3).

Consistent with individual countries' HIV acceleration plans, the global community is now working toward achievement of the Joint United Nations Programme on HIV/AIDS (UNAIDS) recently announced 95-95-95 goals. One of the strategies to attain the first goal is the use of HIV self-tests (HIVST) as recommended by the World Health Organization (WHO) (4). Despite being a promising strategy, various aspects need to be addressed to achieve effective implementation and outcomes, including counseling, linkage to care, privacy/ human rights considerations, and quality of services (5). In addition, consensus in terms of deciding the optimal locations for making HIVST available has not been reached. The majority of HIVST evaluations or pilot studies to date in SSA have been performed through partner mobile clinics or health facilities (6). In Kenya, the majority of people preferred the government health facility as a place for receiving self-testing (7). However, public pharmacies have been explored to identify clients and refer for HIV screening at the clinic (8, 9).

At the time of the protocol writing of the study in 2018 (see *Study setting* section below), Mozambique did not have a national guideline or guide for implementing HIVST. Through means of a public-private partnership, a pharmacy-based HIV self-testing strategy was piloted. The overall objective of the study was to assess the acceptability, feasibility, and linkage to care through the availability of HIV self-tests at pharmacies as a means to engage individuals and link them to care in Zambézia Province. With the amendment to the main protocol, we aimed to evaluate the quality of HIVST performance and result interpretation.

The costs of the evaluation were estimated at $USD 83,000, as per approved protocol, which included purchase of tablets for the implementation, hiring of research assistants, training, supervision, airtime, and staff. The HIV self-tests were received as a donation from the manufacturer.

Purpose and questions

In line with President's Emergency Plan for AIDS Relief (PEPFAR) and MOH guidelines, Friends in Global Health (FGH)'s HIV program goals include ensuring that a large majority of the general population knows their serostatus, and that those who test positive are linked in a timely manner to HIV services and initiated on treatment.

To explore additional evidence-based strategies for increasing HIV testing, especially among key populations such as men and adolescents, we conducted this pilot study to evaluate the acceptability and

feasibility of making HIV self-tests available (at a relatively affordable price of 50 Mzn (~$US 0.80) at participating pharmacies.

Specific objectives were:

1. To assess acceptability of HIV self-testing among pharmacy clients and pharmacy employees/ managers;
2. To assess feasibility as ascertained via uptake of HIVST as a means for HIV testing, specifically the number of HIV self-tests performed;
3. To assess linkage to health care rates among persons undergoing HIV self-testing using kits purchased in a pharmacy setting.
4. To evaluate HIV self-test performance and results interpretation among students, employees, and community members.

This evaluation is meant to inform FGH's and the MOH's current HIV prevention, care and treatment programming so that the number of people who know their HIV status might increase and options for linkage to care and treatment were assessed.

Design/ Methods/ Limitations

Evaluation type

The evaluation completed was an internal process evaluation.

Study setting

The evaluation was conducted in Zambézia province, Central Mozambique. The province's HIV prevalence in 2015 was estimated at 15.1% (15-49 years of age), 16.8% among females, and 12.5% among males [2], and had a coverage of HIV testing (ever tested for HIV) of 30% among men, and 51% among women [2].

The HIV self-testing pilot was implemented between May and December 2019, while the surveys took place between May and November 2019.

Pilot description

Pharmacies (public – those which are managed under the state pharmacy company "FARMAC"--and private) that were registered at the provincial health authorities were approached and assessed for eligibility for participation in the HIVST pilot program (i.e., to offer HIVST kits for purchase at their pharmacy location).

To be eligible to participate, pharmacies needed to meet the following criteria:

- Be a registered pharmacy at Provincial Health Directorate;

- Be located in a district that was supported by FGH at the time of protocol writing;
- Provided services to a minimum of 20 clients per day on average;
- Confirmed their willingness to participate;
- Have a functional climate-controlled storage area for the HIVST kits.

Fourteen eligible pharmacies agreed to participate; these were located within seven Zambézian districts (two urban and five rural) (**Table 1**).

Table 1. List of participating pharmacies

District		**Type of pharmacy**	**Number of pharmacies**
Urban	Quelimane	Public	1
		Private	3
	Mocuba	Public	1
		Private	3
Rural	Nicoadala	Private	1
	Alto Molócuè	Private	1
	Milange	Private	1
	Gurué	Private	1
		Public	1
	Ile	Private	1

Before project implementation, the following activities were provided to prepare the participating pharmacies/ pharmacy staff for offering HIVST at their locations:

1. Training for pharmacy technicians who served clients interested in obtaining an HIVST:

- Basic counseling: HIV education, the benefits of HIV testing, diagnostic disclosure, and the available options for receiving support and care after self-testing for HIV;
- Instruction on using the HIVST kit including practical experience and guidance on teaching the technique to clients.

2. Creation of a 'corner' within the pharmacy setting that offered privacy for clients to receive information on HIV, on what self-testing is, pre-test instructions and advice.

3. Provision of information through leaflets and posters on self-testing to distribute to clients.

The HIV test that was used was the Oraquick HIV1/2® (Orasure Technologies Inc., Bethlehem, PA, US), through a donation from Orasure Technologies. This test is an FDA-approved oral home test for HIV (10) and has been pre-qualified by the WHO (11).

Any person aged 15 years or older could purchase a maximum of two (for client and potentially his/her partner) HIV self-tests at a fixed price of 50 Mzn (~USD 0.80) per test which was based on existing prices of other self-tests (i.e., pregnancy, malaria test).

Interested pharmacy clients were asked to watch a demonstration video with duration of maximum five minutes, which explained how to perform the self-test, before they could buy an HIVST kit. The video was adapted from the manufacturers' video (http://www.oraquick.com/Taking-the-Test/How-To-Video) to local context and language. After purchasing a self-test kit, clients who agreed to could leave their contact information for a possible follow-up survey after purchase.

Activities to spread awareness regarding the availability of HIVST were done mainly through distribution of leaflets, posters at the pharmacies and local radio messages. Clients who bought a test were given: 1) an information booklet with general information about HIV, instructions for HIV self-testing, information on linkage to care, and answers to frequently asked questions; 2) a leaflet with summary information; and 3) a reference voucher to the respective health facility (HF) (see **Appendix 3**). They could also be sent a demonstration video about HIVST via WhatsApp, either in Portuguese or local language, if desired. Counseling and HIV testing staff at six public health facilities located nearby seven of the participating pharmacies were provided orientation regarding the pilot program and were trained on how to screen patients for previous HIV self-testing (**Table 2**).

Table 2. List of participating health facilities (HF)

District	**Health Facility**
Quelimane	HF Coalane
	HF 24 de Julho
	HF 17 de Setembro
	HF 4 de Dezembro
Alto Molócuè	HF Alto Molócuè
Mocuba	HF Mocuba

At the community level, demand generation was done through the provision of various information, education and communication (IEC) activities such as local radio spots and educational messages broadcast on television.

Evaluation design

The study used a mixed-method design:

- Key-informant interviews (via in-depth interview) were done with pharmacy technicians and managers, to understand their perceptions regarding HIV self-testing in terms of perceived acceptability among clients, as well as cost, barriers, facilitators, and sustainability;
- Exit-survey using a structured guide at the participating pharmacies were conducted with clients of the pharmacy to understand knowledge regarding HIV and HIVST, willingness to buy and use an HIVST, and to explore barriers and facilitators of purchasing and using HIV self-tests;
- Post-purchase surveys using a structured guide were done with pharmacy clients who purchased an HIVST and accepted (i.e., shared their contact information) to be called for follow-up and scheduling of an in-person survey, to ask additional questions about their experience in the use of HIVST;

- Observation of HIVST procedures among students, employees and community members in three districts where the pilot project was implemented;
- Survey on interpretation of pre-defined HIVST results.

Eligibility criteria for the different groups of participants (for above-mentioned activities) included being 18 years of age or older and providing written informed consent. For the pharmacy staff, additional eligibility criteria included being an employee or manager at the participating pharmacy for at least six months and being an employee or manager who attends clients at the pharmacy. For the pharmacy clients invited for an exit-survey, seeking any pharmacy service at one of the participating pharmacies was the additional eligibility criterion. For the evaluation of performance and acceptability of the HIVST, participants had to meet the following inclusion criteria:

- Willingness to know their HIV status
- Students: less than 25 years of age; studying in one of the recognized educational institutions in either Quelimane, Mocuba, or Alto Molócuè district
- Employees: employee for at least one month at a registered enterprise
- Community members: members living in either Quelimane, Mocuba, or Alto Molócuè district (who do not otherwise qualify as a "student" or "employee")

Stakeholder engagement

Various staff from the MOH and FGH/Vanderbilt University Medical Center (VUMC) have been involved in these program pilot and evaluation activities. From the MOH, this included the Health Counseling and Testing Focal Point, and the head of the MOH's National STI and HIV/AIDS Control Program (Maputo). The Supervisor of HIV Program also participated from the Provincial Health Directorate of Zambézia (DPS-Z). All collaborators have been involved since the design of the study, through the monitoring of the evaluation implementation, and throughout discussion of evaluation results. The summary of each role can be found in Appendix 1. From the CDC Mozambique (Maputo), the Project Officer has been involved since the beginning of the evaluation. At FGH, aside from the Evaluation team members who have led and managed the pilot and evaluation activities, the HIV Prevention Advisor has been involved since the design of the evaluation.

Sampling strategy

Systematic random sampling was used for the exit-surveys, whereby every third person exiting the pharmacy was approached and invited to participate in the HIVST acceptability survey, independent of self-test purchase. The survey was done after confirming eligibility criteria and obtaining informed consent (Appendix 1). Pharmacy clients who purchased a self-test between study initiation and August 30th, 2019 and agreed to be contacted were randomly selected to participate in the survey. In-depth interviews were conducted via convenience sampling with pharmacy staff and managers, whereby research team members invited those who met eligibility criteria and were available on the day of the data collection. For objective 4, at the randomly selected school and company/employer (who are receptive to collaboration for this study), a group information session was convened by the research staff prior to the activity to inform about the study. For the implementation in the community, an information session was presented to community

leaders who then disseminated the information about the study within the community. Interested persons were referred to the designated place at the respective locations (i.e., a separated room such as a meeting room at the company location; a separated room such as classroom or meeting room at the school; a separated room such as meeting room in the health facility or school for community members).

Procedures

Before any data collection, participants signed the informed consent.

For all exit-surveys and post-purchase surveys, a structured survey guide was used and included questions on previous HIV testing, knowledge of HIVST, willingness to purchase an HIVST, perceived advantages and disadvantages of HIVST, preferred testing modality, perceptions regarding cost of HIV self-test, perceived benefits, and preferred place of acquiring the HIV self-test. Clients who purchased an HIV self-test were also asked about the experience of HIV self-testing, receiving the test result, and about linkage to the health facility. Participants' responses to the surveys were introduced (by trained study interviewer) directly into the electronic data capture software using tablets, and were stored in a cloud-based secure data repository (REDCap™). Additional quantitative data on linkage were extracted from the MOH register books on Counseling and Testing for HIV(VCT) at indicated referral health facilities.

During the qualitative interviews among pharmacy technicians and managers, questions from a semi-structured interview guide were asked to participants about perceptions regarding acceptability, potential barriers and facilitators of HIV self-testing and linkage to care, readiness to give information on HIV and HIV testing, and perceived needs for implementation of the strategy. Data were collected via tape recorder and/or notes, if consent was given for these. All interviews were done in Portuguese, and transcriptions of the interviews were written in Portuguese by evaluation team members fluent in Portuguese.

For the evaluation of performance of the HIVST, participants who signed a consent were asked to do an HIV self-test. Trained observers watched silently how participants performed the HIV self-test, without interfering or responding to any question related to the procedure of the test. It was not required to share the test result after completing the procedures (and results were not seen by the research assistants/trained observers).
The manufacturers' instructions were available in Portuguese (Appendix 4). A checklist was used by the research assistants with questions/checklist items based on other performance evaluations (12, 13) and adapted for the Mozambican context.
Additionally, participants were asked to interpret the result(s) of a previously processed (anonymous) self-test (with either a HIV-negative, HIV-positive or invalid result, shown at random to the participants) to assess the participants' interpretation of test results. The participants were then asked to complete a questionnaire regarding the acceptability of HIVST and their personal experience with performing a self-test.

Sample size

For exit-surveys: Consistent with routine practice for exploratory studies, we interviewed a total of 10 pharmacy clients exiting each of the participating pharmacies, at baseline and three months later (i.e., 10 different clients at each of the two time points). This sample was expected to i) provide us with the requisite

baseline preliminary data, and ii) be able to inform regarding a possible implementation (or not) of this intervention.

For post-purchase surveys: A random sample of maximum 10 pharmacy clients who purchased a self-test and agreed to be contacted were selected from each of the participating pharmacies, using random.org software. In the case of any person who did not accept to participate in the follow-up survey or was not reachable at the time of inquiry, the next randomly selected client on the list was contacted.

In-depth interviews were done with one to two people (employees or managers) at each pharmacy, at baseline and three months later. Sample size was based on saturation.

The sample size for the performance evaluation was calculated based on pilot studies (14, 15), where performance without errors was seen at 85%. We anticipated that approximately 85% of students would be able to perform the HIVST with no errors, as well as approximately 70% and 50% of employees and community members, respectively. Assuming a confidence interval of 95%, we estimated that a sample size of at least 65 students, 55 employees and 35 community members from each district selected would be sufficient to estimate this probability of success using Wilson Score interval and assuming a margin of error of 10%.

Ethical aspects

The protocol (including the protocol amendment) and all protocol-related instruments were approved by the institutional health ethics committee of the "Instituto Nacional de Saúde" (INS) (CIBS-INS, reference 080/CIBS-INS/2018), the VUMC Institutional Review Board (IRB) (#181834), and the National Directorate of Pharmacies, and was reviewed in accordance with the Centers for Disease Control and Prevention (CDC) human research protection procedures and was determined to be research, but CDC investigators did not interact with human subjects or have access to identifiable data or specimens for research purposes. All participants gave written informed consent prior to data collection (for all respective study activities).

Deviations from the protocol

Two protocol deviations occurring during evaluation data collection phase (neither of which resulted in any harm to the participants involved) and were reported to the local ethics committee on i) July 26th, 2019, with response from CIBS-INS on August 21st, 2019; and ii) October 22nd, 2019, with response from CIBS-INS on October 30th, 2019 (100/CIBS-INS/2019). These deviations were also reported to the VUMC IRB (i) submitted July 31, 2019 with response letter August 7th, 2019; ii) Submitted October 22nd, 2019 with response received October 29th, 2019). Notification was provided to the CDC-MZ on July 30th, 2019 and October 22nd, 2019, respectively. Based on guidance provided by the MOH, the amendment activities were not implemented in Quelimane district as planned, due to the initiation of community based HIVST programming implementation in Quelimane and the risk of overlap of activities. During the implementation of amendment activities, due to internet connection issues, data of 65 participants were not successfully uploaded to the central database and were subsequently lost from the tablet device, preventing inclusion in the analyses.

Quality Assurance

Training

Before data collection, trainings were provided to the pharmacy technicians and health counselors (at health facilities) on the implementation of the pilot program, and to the evaluation team members on the study protocol procedures. A refreshment training was provided to the evaluation team before the second round (month three) of data collection. Training for the protocol amendment activities was done before the start of amendment data collection.

Monitoring and data safety

Continuous monitoring and mentoring were done by the FGH Evaluation Officer, in coordination with the DPS-Z Focal Point. Survey data were entered in a password-secured cloud-based repository (REDCap), only accessible to the study investigators.

Analysis plan

Descriptive statistics were used and presented as medians (with interquartile ranges [IQR]) for continuous variables and frequency breakdown (percentages) for categorical variables. Univariate analysis using Chi-square test for categorical variables and Mann-Whitney test for continuous variables was done for covariates, comparing clients who purchased an HIVST versus those who did not. Qualitative data were analyzed using thematic analysis (16). Coding was done by two independent researchers and compared to assess inter-rater reliability. The software STATA.SE Version 15.0 (StataCorp LLC, Texas, USA) supported the quantitative analysis and the software MAXQDA Standard 12 (Verbi GmbH Berlin, Germany) was used in the qualitative analysis.

The structured checklist/guide for the observation of HIVST performance included questions on how the different steps for HIVST procedures were done. A usability index (UI) was calculated, where for the questions with a positive inflection, the "YES-response" was used to indicate usability, while for those with a negative inflection, the "NO-response" was used to indicate usability. An average (of all the questions) was calculated, with a percentage ranging from 0% (not usable) to 100% (very usable).

For the test interpretation, descriptive statistics were used and presented as frequency breakdown (percentages). Univariate analysis using Chi-square test was done for covariates, comparing the different target groups.

Limitations of the study

Data are not representative for the country, as the study was only done in select sites in one province in Mozambique. Additionally, only pharmacy clients having the capacity to buy an HIVST were included in the post-purchase survey, thus the opinions of those unable to buy were not captured in the results of that survey. Data of registration of any HIV self-test result confirmation done in private clinics were not

available, and some pharmacy clients who purchased and used an HIVST could also have registered in a health facility from another province to do confirmatory HIV testing. Both of these possibilities could have led to an underestimation of the linkage to care following HIVST.

Activities for Objective 4 of the evaluation (protocol amendment) were performed in two of the three districts planned, per MOH guidance, as implementation of the community-based HIV self-testing was planned to start in Quelimane district and the MOH wanted to avoid possible conflict with the study activities. Additionally, the manufacturers' instructions are only available in Portuguese, and could have influenced performance for participants who are not Portuguese native speaking, despite containing clear illustrations.

Results

Main study (Objectives 1-3)

The pilot was implemented in the period May to December 2019, while the surveys and in-depth interviews were held in May/June (baseline) and in September/October (month three).

During the total pilot period (May - December 2019), 1,344 HIV self-tests were sold to 1,139 persons. The majority (636, 70%) of buyers were male, and younger than 35 years of age (613, 69%). Fifty-eight percent (658) of people bought in a rural setting (**Table 3**).

Table 3. Characteristics of individuals purchasing HIVST (n=1139)

Urban/rural (n=1139)	Urban (8 pharmacies of 2 districts)	481 (42%)
	Rural (6 pharmacies of 5 districts)	658 (58%)
Sex (n=906)	Male	636 (70%)
	Female	270 (30%)
Age (categories), years (n=894)	15-24 years	186 (21%)
	25-34 years	427 (48%)
	35-44 years	177 (20%)
	45+ years	104 (11%)

1. *Characteristics*

A total of 363 participants responded to the surveys. The flow chart (**Figure 1**) shows the number of persons interviewed: 280 pharmacy clients were interviewed at the time they exited the pharmacy, and 83 people who bought an HIV self-test and consented for a follow-up survey were interviewed at a later time. From the 280 exit-surveys, 20 people reported they purchased an HIV self-test.

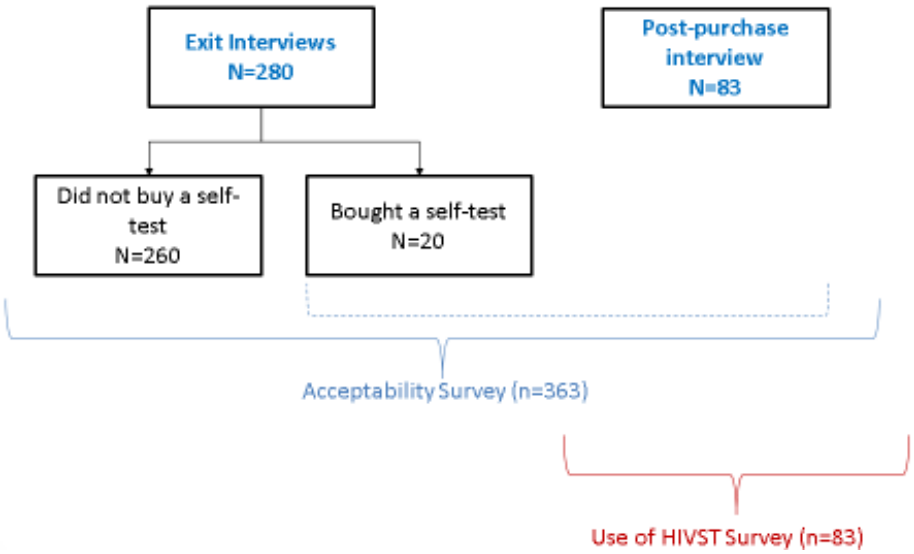

Figure 1. Flow chart of people who were interviewed (via survey) during the pilot project (n=363).

In terms of aggregate interview completion data, 252 (69%) of 363 participants visited one of the urban pharmacies. Two thirds (66%) of the participants were male, and the majority (70%) were less than 35 years of age, with 29% being 15-24 years of age and 41% being between 25-34 years of age (**Table 4**). Pharmacy clients who purchased an HIVST were more educated with 81% of participants, compared to 57% of participants who did not purchase an HIVST, completing advanced education in the form of secondary (12^{th} grade) and/or advanced/university level training ($p < 0.0001$; **Table 4**). There were no significant differences among participants purchasing an HIVST versus not by religion, occupation, and/or marital status. However, consistent with educational level, participants who purchased an HIVST had higher levels of self-reported Portuguese language skills, with 87% of those purchasing HIVST reporting good/very good Portuguese language skills, compared to 76% of those not purchasing an HIVST reporting good/very good Portuguese language skills ($p = 0.034$). Of note, there was no difference among those purchasing an HIVST versus not when asked about their preferred language to receive information and converse in ($p = 0.18$)

with similar high proportions (87% among those purchasing an HIVST and 92% among those not purchasing an HIVST) preferring local language over Portuguese.

Table 4. Characteristics of the participants (n = 363)

	Pharmacy clients who did not buy an HIVST (n=260)	Pharmacy clients who bought an HIVST (n=103)	Total (n=363)	p-value*
Sex				
Male	168 (65%)	73 (71%)	241 (66%)	0.255
Female	92 (35%)	30 (29%)	122 (34%)	
Age (years) (median, IQR)	29 (22-38)	29 (26-35)	29 (23-37)	0.467*
Age (years) (categories)				
18-24 years	87 (33%)	17 (17%)	104 (29%)	***<0.001***
25-34 years	90 (35%)	60 (58%)	150 (41%)	
35-44 years	50 (19%)	18 (17%)	68 (19%)	
45+ years	33 (13%)	8 (8%)	41 (11%)	
Level of education				***<0.001***
Never went to school/ alphabetization	20 (8%)	3 (3%)	23 (6%)	
Primary (7th grade)	49 (19%)	4 (4%)	53 (15%)	
Basic (10th grade)	43 (17%)	12 (12%)	55 (15%)	
Secondary (12th grade)	116 (45%)	56 (54%)	172 (47%)	
Superior / University	32 (12%)	28 (27%)	60 (17%)	
Religion				0.111
Muslim	34 (13%)	14 (14%)	48 (13%)	
Catholic	132 (51%)	58 (56%)	190 (52%)	
Protestant	80 (31%)	31 (30%)	111 (31%)	
Other	14 (5%)	0 (0%)	14 (4%)	
Occupation				0.234
No income	22 (8%)	6 (6%)	28 (8%)	
Agriculture/ Fishing	20 (8%)	3 (3%)	23 (6%)	
Sales	32 (12%)	14 (14%)	46 (13%)	
Health Care Professional	14 (5%)	12 (12%)	26 (7%)	
Teacher	42 (16%)	23 (22%)	65 (18%)	
Domestic workers	4 (2%)	1 (1%)	5 (1%)	
Guard	2 (1%)	0	2(1%)	
Police	7 (3%)	2 (2%)	9 (2%)	
Other	117 (45%)	42 (41%)	159 (44%)	
Marital status				0.416
Married/ officially living together	156 (60%)	60 (58%)	216 (60%)	
Divorced	5 (2%)	1 (1%)	6 (2%)	

Widow	5 (2%)	0	5 (1%)	
Single (not living with partner)	94 (36%)	42 (41%)	136 (37%)	
Location of pharmacy visited				***<0.001***
Rural	56 (22%)	55 (53%)	111 (31%)	
Urban	204 (78%)	48 (47%)	252 (69%)	
Mother Language				0.18
Portuguese	21 (9%)	13 (13%)	34 (9%)	
Other	239 (92%)	90 (87%)	329 (91%)	
Self-evaluation Portuguese reading skills				***0.034***
Cannot read Portuguese	6 (2%)	0	6 (2%)	
Not good	20 (8%)	5 (5%)	25 (7%)	
Moderate	38 (15%)	8 (8%)	46 (13%)	
Good	77 (30%)	26 (25%)	103 (28%)	
Very good	119 (46%)	64 (62%)	183 (50%)	
HIV testing history				
Ever done an HIV test before				0.487
No	43 (17%)	14 (14%)	57 (16%)	
Yes	217 (83%)	89 (86%)	306 (84%)	
Place of last HIV test (not including self-test) (n=306)				0.133
HF near where I live	173 (80%)	71 (80%)	244 (80%)	
HF in a different district	22 (10%)	9 (10%)	31 (10%)	
Private clinic	4 (2%)	0	4 (1%)	
Community testing	10 (5%)	1 (1%)	11 (4%)	
Other	7 (3%)	8 (9%)	11 (4%)	
No response	1 (0%)	0	1 (0 %)	
Time of last HIV test (not including self-test) (n=306)				***0.042***
<3 months ago	96 (44%)	22 (25%)	118 (39%)	
3-5 months ago	34 (16%)	18 (20%)	52 (17%)	
6-11 months ago	24 (11%)	15 (17%)	39 (13%)	
12-23 months ago	37 (17%)	17 (19%)	54 (18%)	
>2 years ago	23 (11%)	16 (18%)	39 (13%)	
Don't remember	3 (1%)	1 (1%)	4 (1%)	
Result of last HIV test (not including self-test) (n=306)				***0.009***
HIV negative	182 (84%)	86 (97%)	268 (88%)	
HIV positive	26 (12%)	2 (2%)	28 (9%)	
Prefer not to say	9 (4%)	1 (1%)	10 (3%)	

*Mann-Whitney test

2. Acceptability of HIV self-testing among the interviewed population

As anticipated, a low proportion (28% overall) of participants had ever heard about HIVST, with a significantly higher proportion (51%) having heard about the HIVST strategy among those pharmacy clients purchasing an HIVST ($p < 0.0001$; **Table 5**). The most frequently reported advantage of HIVST was that it maintained confidentiality, highlighted as being a main advantage in 291 (80%) of 363 participants overall and among a slightly higher proportion (84%) of those that purchased an HIVST. Another significant advantage of HIVST that was highlighted by 51% of participants overall and a significantly higher proportion (64%; $p = 0.001$) of those purchasing an HIVST was that the test was simple with no need to interface with a health provider. Other reported advantages that were not significant between the groups, those purchasing an HIVST versus not, included HIVST being fast and providing the opportunity for people to test with their partners, which were reported by 37% and 13% of overall respondents, respectively. In terms of disadvantages, a sizable proportion (31%) of overall respondents reported the lack of nearby counseling, which was not significant ($p = 0.26$) by HIVST purchase status, despite a slightly higher proportion (35% vs. 29%) of those purchasing an HIVST reporting that this was a disadvantage. The only significant disadvantage reported in a small proportion (9% overall) of participants, by 11% of those not purchasing a test compared to 3% of those purchasing an HIVST, was the fear of someone discovering their test results ($p = 0.016$). Other reported disadvantages that were not significant by HIVST purchase status included fear of test results, doubts on the quality of the test itself, and the test being too expensive, reported by 24%, 10%, and 6% of overall respondents, respectively (**Table 5**). Regarding price of the HIV self-test (which in the pilot project was offered at a fixed price of 50 Meticals (~USD 0.80)), approximately one quarter (24%) of overall respondents perceived the HIVST as being too expensive, with a significantly higher proportion of clients not purchasing an HIVST (28%) compared to 14% among those purchasing the test ($p = 0.034$). Overall, only 4% of the interviewed pharmacy clients were not willing to pay for an HIVST. Clients who purchased an HIVST were also willing to pay more for the test compared to those who did not buy an HIVST. While the majority (59%) of respondents stated that the pharmacy was a preferred setting to undergo HIV self-testing, one third (33%) of people completing the surveys still preferred to get a self-test at a public health facility. No difference in preference of modality of self-testing was seen (oral versus finger-prick) among respondents, with more than one third (37%) still favoring finger-prick over saliva-based testing.

Table 5. Acceptability of the use of an HIV self-test (n = 363)

	Pharmacy clients who did not buy an HIVST (n=260)	**Pharmacy clients who bought an HIVST (n=103)**	**Total (n=363)**	
	n (%)	n (%)	n (%)	p-value
Ever heard about HIV self-testing				***<0.001***
No	211 (81%)	51 (50%)	262 (72%)	
Yes	49 (19%)	52 (51%)	101 (28%)	
Advantages of HIVST*				
Maintains confidentiality	204 (78%)	87 (84%)	291 (80%)	0.196
Simple/ no need of health provider	118 (45%)	66 (64%)	184 (51%)	***0.001***
Result is fast	89 (34%)	44 (43%)	133 (37%)	0.130
To be able to test with my partner	35 (13%)	26 (12%)	47 (13%)	0.643
Disadvantages of HIVST*				
No counseling nearby	75 (29%)	36 (35%)	111 (31%)	0.255
Fear of test result	65 (25%)	22 (21%)	87 (24%)	0.464
Doubts on the quality of the test	28 (11%)	9 (9%)	37 (10%)	0.564
Fear of somebody discovering	28 (11%)	3 (3%)	31 (9%)	***0.016***
Do not know how to use it	17 (7%)	5 (5%)	22 (6%)	0.544
Too expensive	18 (7%)	2 (2%)	20 (6%)	0.061
Not able to read the instructions	4 (2%)	2 (2%)	6 (2%)	0.786
Opinion on price of the test				***0.034***
Very cheap	22 (8%)	7 (7%)	29 (8%)	
Cheap	22 (8%)	9 (9%)	31 (9%)	
Acceptable price	142 (55%)	73 (71%)	215 (59%)	
Expensive	73 (28%)	14 (14%)	87 (24%)	
Price willing to pay for HIVST				***<0.001***
Do not want to pay	14 (5%)	0 (0%)	14 (4%)	
Up to 10 Mzn	77 (30%)	16 (16%)	93 (26%)	
Up to 50 Mzn	131 (50%)	48 (47%)	179 (49%)	
Up to 100 Mzn	20 (8%)	25 (24%)	45 (12%)	
Up to 200 Mzn	8 (3%)	8 (8%)	16 (4%)	
Up to 500 Mzn	4 (2%)	3 (3%)	7 (2%)	
More than 500 Mzn	4 (2%	2 (2%)	6 (2%)	
Preferred place to get an HIVST				0.108
Private/public pharmacy	145 (59%)	70 (68%)	215 (59%)	
Public health facility	97 (37%)	24 (23%)	121 (33%)	
Private clinic	9 (3%)	6 (6%)	15 (4%)	
Other	8 (3%)	3 (3%)	11 (3%)	
Preferred testing modality (oral versus finger-prick self-test)				0.231
Oral	141 (54%)	67 (65%)	208 (57%)	

Finger-prick	103 (40%)	30 (29%)	133 (37%)
Either	15 (6%)	5 (5%)	20 (6%)

* Participants were instructed to mark all that apply for these survey questions.

3. Use of HIV self-test

In the period of May - August 2019, 614 individuals bought a test, and post-purchase follow-up contact was successful for 143 people. Of those, 83 (58%) consented for the survey.

Among the 83 surveyed people who bought an HIV self-test, 78 (94%) used it. Description of their reported experiences are shown in **Table 6**. Most felt the use instructions were clear (71, 91%) and procedures were easy to understand (69, 89%). Those survey respondents who reported difficulty felt that preparation of the kit and reading the results were the more difficult steps of all the procedures. However, 29 individuals (37%) felt they needed additional information or counseling before taking the self-test.

Among the survey respondents who performed the HIV self-test, 45 (58%) revealed their HIVST results, with 43 reporting HIV negative, and two HIV positive. Of the respondents reporting HIV negative self-test results, nine stated that they went to the health facility to confirm their (HIV-negative) result, and one of the two people reporting a positive HIV self-test result stated that they linked to the health facility to confirm.

Registered linkage to the health facility (for anyone having done an HIVST) was very low: the routine HIV testing register books at the public health facilities supported by FGH in Zambézia reported only three people who confirmed their positive HIV self-test result.

Table 6. Experience of the use of HIV self-test by participants (n=78)

		n (%)
Did the test alone or with somebody		
	Alone	53 (68%)
	With family member or friend	17 (22%)
	In the pharmacy	3 (4%)
	With other	5 (6%)
Clearness of the instruction		
	Very easy	27 (35%)
	Easy	44 (56%)
	Difficult	1 (1%)
	Very difficult	0 (0%)
	No information	6 (8%)
Difficulties in reading and understanding instructions		
	Very easy	24 (31%)
	Easy	45 (58%)
	Difficult	2 (3%)
	Very difficult	0 (0%)
	No information	7 (8%)

Difficulties in doing test		
	Very easy	32 (41%)
	Easy	39 (50%)
	Difficult	5 (6%)
	Very difficult	2 (3%)
Most difficult step		
	Step 1 - preparing the kit	13 (17%)
	Step 2 - taking the sample	6 (8%)
	Step 3 - doing the test	2 (3%)
	Step 4 - reading the results	11 (14%)
	No step was difficult	45 (58%)
Feeling if test was correctly done		
	Yes	78 (100%)
	No	0 (0%)
Belief in the test result		
	Yes	76 (97%)
	No	2 (3%)
Did you feel you needed additional information or counseling before the test		
	Yes	29 (37%)
	No	49 (63%)
Preference of doing test alone or with help of somebody		
	Unassisted, alone	67 (86%)
	Assisted at home	3 (4%)
	Assisted at pharmacy	3 (4%)
	Assisted at health facility	3 (6%)
You recommend HIVST to somebody		
	Yes	76 (97%)
	No	1 (1%)
	Do not know	1 (1%)
Preference for HIVST or test at a Voluntary Counseling and Testing (VCT) site		
	HIVST	65 (83%)
	VCT	13 (17%)
You want to reveal the result of the HIVST?		
	HIV negative	43 (55%)
	HIV positive	2 (3%)
	Invalid	0 (0%)
	Prefer not to say or no response	33 (42%)
Did you go to the HF after doing the HIVST		
	Yes	10 (13%)
	No	68 (87%)
You want to reveal result of HIV test done at health facility?		
	HIV negative	9 (90%)
	HIV positive	1 (10%)
	Indeterminate/Invalid	0 (0%)
	Prefer not to say or no response	0 (0%)

4. Perceptions of Pharmacy Technicians and Managers

Over the study period, in-depth interviews were conducted with 45 pharmacy managers/employees, 28 at baseline (i.e., at study start, prior to self-tests being available for purchase at these pharmacies) and 17 during implementation (four months after pilot initiation). The socio-demographics data of the participants is shown in **Table 7**.

Table 7. Sociodemographic data of the pharmacy staff

		Baseline (n, %)	Implementation (n, %)	Total (n, %)
District				
	Urban	15 (58)	13 (68)	28 (62)
	Rural	11 (42)	6 (32)	17 (38)
Sex				
	Male	15 (58)	10 (53)	25 (56)
	Female	11 (42)	9 (47)	20 (44)
Age, years (median, IQR)		29 (27-41)	28 (23-41)	28 (25-41)
Years since graduation (median, IQR)		4 (3-7)	6 (2-18)	5 (2-14)
Years working at the pharmacy (median, IQR)		2 (1-6)	3 (1-7)	3 (1-7)

It was observed that many of the answers provided in the initial phase of the pilot project, where the respondents gave opinions about how they anticipated their customers would react/ behave towards the HIV self-test in a more hypothetical situation, were similar to responses and experiences provided related to what was observed during the period of self-test sales.

- **Target population and interest in HIVST purchase**

Respondents indicated at the initial round and second round of interviews that young males would be the group most interested in the tests.

Before starting sales, pharmacy staff predicted that HIVST users would use the tests for a variety of reasons, with the main reason being that it would maintain confidentiality. The respondents also said that people would use it because this test is easy to use and because they do not have to go to the health facility. In the second phase of data collection, it was observed that these continued to be the same reasons and in the same order of perceived importance.

Regarding the reasons for not using the tests, the respondents foresaw (and confirmed during the second round of interviews) that the possibility for some users to not trust the results of this type of HIV test could compromise the use of this self-test. Another perceived barrier mentioned was fear of seeing the test result.

- **Preference of acquiring an HIVST**

Most pharmacy employees, both before starting the sale of oral HIV self-tests as well as after they were already selling them, thought that pharmacies were the best places to sell this test, and most believed that this was also the opinion of users. Some pharmacy staff, although few, said that users could consider health facilities the best place to get such a test.

- **Pharmacy needs**

In terms of resources needed to make sales feasible, in addition to providing the self-tests, pharmacies participating in this pilot project received a set of informational/educational materials, as a resource to provide information to potential users.

As such, pharmacies received the following informational/educational materials 1) advertising posters that were posted in the pharmacies' windows, 2) fold-out information leaflets to display on the countertops, 3) laminated forms with testing procedures and test result explanations so they could offer additional information if needed. To enrich the information for those customers who were interested in buying the test, pharmacies also received a tablet device on which a pre-recorded demonstration video was uploaded to show test procedures. Booklets with additional information on the HIV self-test and on HIV prevention in general was offered to those who bought a self-test, as well as a reference voucher for linking to the nearest health facility.

During the interviews, pharmacy staff were asked their opinion for any additional needed material(s) to provide information to users, and respondents indicated they relied on the materials made available to them prior to study implementation; no one mentioned any other materials they would suggest as needed. One respondent, when asked about the materials to be used when meeting with a potential user/ purchaser, stated they made use of:

> *"Yes, first the pamphlets, then the explanation that is already here at the counter and the information leaflets that we have and the video." (Baseline, Pharmacy technician, Urban)*

Although the video explaining the testing procedures was designed to be watched by customers who had already purchased the test, it also was widely used as an advertising video; most respondents reported that they let customers watch the video to see if it aroused their interest in purchasing/using the HIV self-test. Despite receiving information on the objective/intended use of the video, the same was mentioned during the second round of interviews.

> *"We have that video that we already, sorry (pause), so we show the video, then he watches, besides the video, if he didn't notice we tried to explain it in a more current way and, in the true sometimes what is missing is this, no, our advice is just not enough, it is not enough, of course it is always full here so it makes it difficult." (Baseline, Pharmacy Technician, Urban)*

> *"In the beginning, every customer who comes here we have to inform, give pamphlets for the person to take. Usually the customer arrives, says he is in a hurry, another patiently reads, and we also give the person the option to watch the video." (Baseline, Pharmacy Technician, Rural)*

Some respondents informed that as they had to explain HIV self-test and its procedures many times, they chose after a while to send the demonstration video via WhatsApp so that those interested could watch it at home, consider and decide whether or not they would like to buy the self-test. In fact, the video was often referred to as the material used for advertising the test; some said that if the client was in a hurry they would provide the information leaflet and ask if they could send them the video to watch at home.

> *"Of all the resources, the tablet is because nowadays you read to someone you will get tired of listening to that reading, show leaflets he will take the leaflet and leave it alone and the video is more practical." (Implementation, Pharmacy technician, Rural)*

In some cases, the respondents mentioned that they chose to show the video, not only because they perceived it to be more practical, but also because their pharmacies do not have the necessary conditions/space for the discussion of private issues or counseling within the pharmacy.

> *"Many times, because the place is not an adequate place at first, I often use video." (Implementation, Pharmacy Technician, Rural)*

Pharmacy technicians requested more brochures, a table and chair, screens, and cell phone credit to be able to send WhatsApp videos on the spot (instead of the client sending a request to the helpline). Some respondents suggested to have the video displayed in the pharmacy and that the space in the pharmacy be improved to have the necessary privacy restrictions.

> *"First I would ask you to add more brochures, because it is easier with the brochure than the video, it takes a little more time and the person will read at home, when walking, instead of (watching in the pharmacy), if you have to the watch the video here, he/she will stay here for a long time, the brochure is faster." (Implementation, Pharmacy Technician, Urban)*

- **Sales challenges**

The biggest challenge mentioned at project initiation and during implementation was human resources, as a greater dedication of time is needed from the pharmacy technicians for additional explanation and registration of the HIVST. Additionally, because of the sensitivity of the type of test in question, pharmacists said that one of their main challenges in selling these self-tests was the absence of a trained psychologist; they felt having this resource would greatly help in advising clients who buy the HIV self-test.

> *"A psychologist would help a lot considering that this test is psychological and people are afraid so the existence of a psychologist would help in the sale because he will advise potential clients." (Baseline, Pharmacy Manager, Urban)*

- **Pre- and Post-test Counseling**

Pharmacy staff reported that the pharmacy (i.e., where the test is purchased) is the location where clients/users should receive counseling on using the HIVST prior to doing the self-test.

> *"..In the pharmacies who sell the tests, right? Because the patient needs first the psychological preparation, right? So I don't see any other place outside the place where he buys the test." (Implementation, Pharmacy Manager, Urban)*

However, recognizing the complexity and sensitivity of the counseling needed after taking an HIV test (in any setting), respondents felt the health facility is the best place where users should go to receive counseling after taking the self-test.

> *"After taking the test, I think it is better that the client has more advice, more information in the health units, because there are people more equipped to address this." (Baseline, Pharmacy Technician, Urban)*

Comparing interview results before and after the initiation of the HIVST sales, it was notable that before starting sales there was a large number of pharmacy staff respondents that mentioned that pharmacies could be an equally good place for counseling both before and after the test, but after starting sales most respondents thought that for post-HIVST counseling users should be counseled at the health facility and not at the pharmacy as had been indicated before starting sales.

- **Demand creation**

As a way of supporting sales, pharmacists suggested that there should be actions to create demand in public places, such as markets and other mass assemblies of individuals within the community. They also mentioned the need to advertise the HIV self-tests more frequently on television channels, in health facilities, and on the radio.

According to the pharmacy staff respondents, and more frequently mentioned at initiation (i.e., interviews done prior to HIV self-tests being sold), the tests are not widely known about in the communities; the few who do know of the test are those who visited the pharmacy for other reasons and the pharmacists took advantage of the opportunity to tell them about the existence and availability of the HIV self-test.

- **Linkage to care**

Pharmacy technicians reported that they advised HIVST users to go to the health facility for follow-up in the event of a positive result for confirmation and enrollment in care. Some proposed that to facilitate linkage, there should be a first phase of more in-depth counseling at the pharmacy, but the technicians and the pharmacies themselves are not (yet) prepared for this as such. Two respondents said that clients/users should receive all their counseling and (if found to be HIV-positive) their initial care (i.e., opening of a patient file) at the pharmacy; if conditions to offer these services at the pharmacy would be met, then the person should be referred to the health facility to collect their medications.

"… this is what I meant, I think there should have been a first linkage if it (the test) was positive; there had to be a confirmation right away and there had to be a counselor there who understands well about the not even talk to the person to make them understand more." (Baseline, Pharmacy Manager, Rural)

Pharmacy respondents were aware of the need for HIV test confirmation at the health facility; they recognized that this is where follow-up care is given. However, the technicians reported that people often do not go to the HF for necessary follow-up.

"One of the disadvantages is that we never know if the result, since the person does it alone, and not all of them, when positive, go to a health unit." (Baseline, Pharmacy Technician, Urban)

One of the respondents suggested that a client with a positive result should return to the pharmacy who then should contact the health facility to ensure better linkage to care.

"We just sell it so at some point there is a disadvantage. So if they compared if they were positive, they would return to the pharmacy, at some point the pharmacy would enter the unit, in, in communication with the health facility, maybe we would have a little advantage." (Baseline, Pharmacy Technician, Quelimane)

The technicians suggested that users should also be given clear information about the specific place/location where they should seek follow-up care at the health facility, with a detailed explanation of who will receive them there.

Although many stated that they never received users who returned to the pharmacy with a positive result, they communicated a clear knowledge on how to guide them if they return. Even in the second round of interviews, it was noted that many of the pharmacy customers did not return.

"No, they never came back, never came back." (Implementation, Pharmacy Technician, Rural)

"Some, some usually come even after buying or even after buying but not having used it, others bought it used it, some do, not so many, but they do come."(Implementation, Pharmacy Technician, Rural)

For the few people that did return after buying an HIVST, the interviewed staff said they advised these individuals to go to the health facility if the self-test result was positive, and if it was negative, they advised to re-test three months later.

"I could tell the person to continue taking care of themselves, if the result is negative. If the result is positive, I would advise you to go to the nearest health facility to be able to do the other confirmation test with blood." (Implementation, Pharmacy Technician, Mocuba)

Amendment study results (Objective 4)

Data collection was done during the months of February-March 2021. A total of 312 persons participated, 131 (42%) of whom were community members, 71 (23%) students and 110 (35%) employees. The majority were male (239, 77%). Among all participants, 99 (32%) reported having Portuguese as their mother language, and 223 (71%) said their reading abilities in Portuguese were good to very good (**Table 8**).

Table 8. Sociodemographic characteristics of participants of performance evaluation (n=312)

	Employees N=110	Students N=71	Community Members N=131	[ALL] N=312	p-value
Sex					**<0.001**
Female	13 (11.8%)	12 (16.9%)	48 (36.6%)	73 (23.4%)	
Male	97 (88.2%)	59 (83.1%)	83 (63.4%)	239 (76.6%)	
Age, years, mean (sd)	31.6 (11.6)	22.2 (2)	27.9 (9.7)	27.9 (10)	**<0.001**
Category age range, years:					**<0.001**
18-24	38 (34.5%)	61 (85.9%)	65 (49.6%)	164 (52.6%)	
25-34	39 (35.5%)	10 (14.1%)	40 (30.5%)	89 (28.5%)	
35-44	15 (13.6%)	0 (0%)	14 (10.7%)	29 (9.3%)	
>44	18 (16.4%)	0 (0%)	12 (9.2%)	30 (9.6%)	
Residence (1 missing)					0.998
Alto Molócuè	55 (50%)	35 (50%)	65 (49.6%)	155 (49.8%)	
Mocuba	55 (50%)	35 (50%)	66 (50.4%)	156 (50.2%)	
Educational level (1 missing)					**<0.001**
Never went to school or had alphabetization	14 (12.7%)	0 (0%)	15 (11.5%)	29 (9.3%)	
Primary school (7th grade)	24 (21.8%)	0 (0%)	34 (26.2%)	58 (18.6%)	
Basic school (10th grade)	24 (21.8%)	8 (11.3%)	38 (29.2%)	70 (22.5%)	
Secondary school (12th grade)	48 (43.6%)	63 (88.7%)	40 (30.8%)	151 (48.6%)	
Superior	0 (0%)	0 (0%)	3 (2.3%)	3 (1%)	
Religion (7 missing)					0.319
Catholic	57 (52.8%)	41 (57.7%)	61 (48.4%)	159 (52.1%)	
Muslim	10 (9.3%)	11 (15.5%)	14 (11.1%)	35 (11.5%)	
Protestant	41 (38%)	19 (26.8%)	51 (40.5%)	111 (36.4%)	
Occupation					**<0.001**
Do not work (no income)	1 (0.9%)	24 (33.8%)	37 (28.2%)	62 (19.9%)	
Agriculture	0 (0%)	3 (4.2%)	20 (15.3%)	23 (7.4%)	
Guard	1 (0.9%)	0 (0%)	3 (2.3%)	4 (1.3%)	
Health care worker	0 (0%)	0 (0%)	1 (0.8%)	1 (0.3%)	
Sales	3 (2.7%)	3 (4.2%)	15 (11.5%)	21 (6.7%)	
Teacher	0 (0%)	0 (0%)	5 (3.8%)	5 (1.6%)	
Other	105 (95.5%)	41 (57.7%)	50 (38.2%)	196 (62.8%)	
Marital status					**<0.001**
Married/Living together	78 (70.9%)	4 (5.6%)	50 (38.2%)	132 (42.3%)	
Single (not living with partner)	30 (27.3%)	67 (94.4%)	68 (51.9%)	165 (52.9%)	
Divorced	1 (0.9%)	0 (0%)	10 (7.6%)	11 (3.5%)	
Widowed	1 (0.9%)	0 (0%)	3 (2.3%)	4 (1.3%)	
Mother language					**0.033**
Portuguese	30 (27.3%)	17 (23.9%)	52 (39.7%)	99 (31.7%)	
Other	80 (72.7%)	54 (76.1%)	79 (60.3%)	213 (68.3%)	
Portuguese language reading skills					**<0.001**
Do not read in Portuguese	1 (0.9%)	0 (0%)	3 (2.3%)	4 (1.3%)	

Reads not well	7 (6.4%)	5 (7%)	7 (5.3%)	19 (6.1%)
Reads moderately	24 (21.8%)	3 (4.2%)	39 (29.8%)	66 (21.2%)
Good	44 (40%)	22 (31%)	52 (39.7%)	118 (37.8%)
Very good	34 (30.9%)	41 (57.7%)	30 (22.9%)	105 (33.7%)

Eighty three percent of participants had ever done a HIV test, and 19% reported that the test was more than two years ago. One participant reported that the last HIV test result was positive, while 5% (n=13) reported a current positive HIV self-test result (i.e., while participating in evaluation activities) (**Table 9**).

Table 9. HIV testing information among the study participants (n=312)

	Community N=110	**Employees N=71**	**Students N=131**	**[ALL] N=312**	**p-value**
Ever did a HIV test:					0.16
No	14 (12.7%)	10 (14.1%)	28 (21.4%)	52 (16.7%)	
Yes	96 (87.3%)	61 (85.9%)	103 (78.6%)	260 (83.3%)	
Where did you do last HIV test:					**<0.001**
HF in selected district	44 (45.8%)	29 (47.5%)	71 (68.9%)	144 (55.4%)	
HF in another district	10 (10.4%)	26 (42.6%)	23 (22.3%)	59 (22.7%)	
Community testing	1 (1%)	2 (3.3%)	1 (1%)	4 (1.5%)	
NGO	1 (1%)	0 (0%)	2 (1.9%)	3 (1.2%)	
Other	40 (41.7%)	4 (6.6%)	6 (5.8%)	50 (19.2%)	
When did you do last HIV test:					0.053
< 3m ago	38 (39.6%)	15 (24.6%)	20 (19.4%)	73 (28.1%)	
12-23m ago	14 (14.6%)	14 (23%)	16 (15.5%)	44 (16.9%)	
3-5m ago	13 (13.5%)	11 (18%)	17 (16.5%)	41 (15.8%)	
6-11m ago	17 (17.7%)	13 (21.3%)	23 (22.3%)	53 (20.4%)	
More than 2 years ago	14 (14.6%)	8 (13.1%)	27 (26.2%)	49 (18.8%)	
Last HIV test result:					0.228
prefer not to say	0 (0%)	1 (1.6%)	0 (0%)	1 (0.4%)	
yes, negative	95 (99%)	60 (98.4%)	103 (100%)	258 (99.2%)	
yes, positive	1 (1%)	0 (0%)	0 (0%)	1 (0.4%)	
HIV self-test result (test done on day of evaluation)					0.153
Negative	88 (91.7%)	55 (90.2%)	88 (85.4%)	231 (88.8%)	
Positive	2 (2.1%)	1 (1.6%)	10 (9.7%)	13 (5%)	
Indeterminate-invalid	3 (3.1%)	3 (4.9%)	4 (3.9%)	10 (3.9%)	
prefer not to say	3 (3.1%)	2 (3.3%)	1 (1%)	6 (2.3%)	

Observation

Table 10 demonstrates the results of the performance observation. Among the participants, 181 (58%) read the provided written instructions, of whom 22 (12%) showed difficulties in reading the instructions. Major performance errors observed were incorrect tube positioning into the stand (152, 49%); incorrect specimen collection (134, 43%); and incorrect waiting time for result reading (130, 42%).

Table 10. Observation results and usability index, per target group (See **Appendix 4** for the instructions of HIVST as per Manufacturer's Manual that is offered with the Kit)

	Employees N=110	**Students** N=71	**Community Members** N=131	**ALL** N=312	**p-value**
STEP 1 - PREPARE					
Did the participant inform about having eaten?					0.89
No	105 (95.5%)	67 (94.4%)	125 (95.4%)	297 (95.2%)	
Yes	5 (4.6%)	4 (5.6%)	6 (4.6%)	15 (4.81%)	
Did the participant read the instructions? (1missing)					0.159
No	41 (37.3%)	26 (37.1%)	63 (48.1%)	130 (41.8%)	
Yes	69 (62.7%)	44 (62.9%)	68 (51.9%)	181 (58.2%)	
Did the participant show difficulties in reading instructions (among those who read)? (1 missing)					0.183
No	58 (84%)	42 (95%)	58 (85%)	158 (87.8%)	
Yes	11 (15.9%)	2 (4.6%)	9 (13.4%)	22 (12.2%)	
Did the participant watch the video? (1 missing)					0.512
No	0 (0%)	0 (0%)	2 (1.5%)	2 (0.64%)	
Yes	110 (100%)	71 (100%)	128 (98.5%)	309 (99.4%)	
In what language did the participant watch? (1 missing)					1
Chuabo	1 (0.9%)	0 (0%)	1 (0.8%)	2 (0.765%)	
Manhuiwa	3 (2.7%)	1 (1.4%)	3 (2.4%)	7 (2.327%)	
Portuguese	106 (96.4%)	70 (98.6%)	123 (96.9%)	299 (97.1%)	
Did the participant have difficulties in opening the components in the box? (1 missing)					**0.02**
No	94 (85.5%)	59 (83.1%)	93 (71.5%)	246 (79.1%)	
Yes	16 (14.5%)	12 (16.9%)	37 (28.5%)	65 (20.9%)	
Did the participant find the test tube? (1 missing)					1
Yes	110 (100%)	71 (100%)	130 (100%)	311 (100%)	
Did the participant remove the test tube from the box? (1 missing)					1
Yes	110 (100%)	71 (100%)	130 (100%)	311 (100%)	
Did the participant remove the cap from the test tube? (1 missing)					0.247
No	0 (0%)	0 (0%)	3 (2.3%)	3 (1%0.96%)	
Yes	110 (100%)	71 (100%)	127 (97.7%)	308 (99.0%)	
Did the participant put the holder correctly (horizontally) on the table? (1 missing)					**0.031**
No	8 (7.3%)	0 (0%)	10 (7.7%)	18 (5.879%)	
Yes	102 (92.7%)	71 (100%)	120 (92.3%)	293 (94.2%)	
Did the participant put the tube correctly in the support (45-degree angle)? (2 missing)					**0.024**
No	61 (55.5%)	25 (35.2%)	66 (51.2%)	152 (49.0%)	
Yes	49 (44.5%)	46 (64.8%)	63 (48.8%)	158 (51.0%)	
Did the participant have any difficulties with the test tube? (2 missing)					**0.018**
No	85 (78%)	61 (85.9%)	89 (68.5%)	235 (75.8%)	
Yes	24 (22%)	10 (14.1%)	41 (31.5%)	75 (24.2%)	

Did the participant find the test stick? 1 missing)					0.582
No	1 (0.9%)	0 (0%)	0 (0%)	1 (0.32%)	
Yes	109 (99.1%)	71 (100%)	130 (100%)	310 (99.7%)	
Did the participant remove the test device from the package? (1 missing)					1
Yes	110 (100%)	71 (100%)	130 (100%)	311 (100%)	
STEP 2 - COLLECT					
Did the participant touch the flat pad? (1 missing)					**0.013**
No	92 (83.6%)	69 (97.2%)	109 (83.8%)	270 (86.8%)	
Yes	18 (16.4%)	2 (2.8%)	21 (16.2%)	41 (13.2%)	
Did the participant collect the sample correctly? (2 missing)					0.571
No	48 (43.6%)	27 (38%)	59 (45.7%)	134 (43.2%)	
Yes	62 (56.4%)	44 (62%)	70 (54.3%)	176 (56.8%)	
STEP 3 - MIXING					
Did the participant place the test stick correctly in the test tube? (2 missing)					**0.028**
No	1 (0.9%)	0 (0%)	7 (5.4%)	8 (2.6%)	
Yes	108 (99.1%)	71 (100%)	123 (94.6%)	302 (97.4%)	
Did the participant use the silica for some procedure? (1 missing)					0.347
No	109 (99.1%)	71 (100%)	127 (97.7%)	307 (98.7%)	
Yes	1 (0.9%)	0 (0%)	3 (2.3%)	4 (1.329%)	
Did the participant remove the silica? (1 missing)					0.476
No	81 (73.6%)	56 (78.9%)	104 (80%)	241 (77.5%)	
Yes	29 (26.4%)	15 (21.1%)	26 (20%)	70 (22.5%)	
STEP 4 - READING					
Did the participant wait the correct period of time for reading (20 to 40 minutes)? (4 missing)					0.092
No	50 (45.9%)	22 (31%)	58 (45.3%)	130 (42.2%)	
Yes	59 (54.1%)	49 (69%)	70 (54.7%)	178 (57.8%)	
GENERAL					
Did the participant perform the test steps in correct order (steps 1-4)? (1 missing)					0.107
No	9 (8.2%)	1 (1.4%)	11 (8.5%)	21 (6.875%)	
Yes	101 (91.8%)	70 (98.6%)	119 (91.5%)	290 (93.2%)	

The average usability index (UI) was 80%, 86%, and 77%, among community members, employees and students, respectively (**Table 11**).

Table 11. Average usability index, per target group.

	Employees			**Students**			**Community Members**		
	Yes	No	UI	Yes	No	UI	Yes	No	UI
Did the participant read the instructions?	69 (62.7%)	41 (37.3%)	63%	44 (62.9%)	26 (37.1%)	63%	68 (51.9%)	63 (48.1%)	52%
Did the participant show difficulties in reading instructions?	11 (15.9%)	58 (84.1%)	84%	2 (4.6%)	42 (95.5%)	96%	9 (13.4%)	58 (86.6%)	87%
Did the participant have difficulties in opening the components in the box?	16 (14.5%)	94 (85.5%)	86%	12 (16.9%)	59 (83.1%)	83%	37 (28.5%)	93 (71.5%)	72%
Did the participant remove the cap from the test tube?	110 (100%)	0 (0%)	100%	71 (100%)	0 (0%)	100%	127 (97.7%)	3 (2.3%)	98%

Did the participant put the holder correctly (horizontally) on the table?	102 (92.7%)	8 (7.3%)	93%	71 (100%)	0 (0%)	100%	120 (92.3%)	10 (7.7%)	92%
Did the participant put the tube correctly in the support (45-degree angle)?	49 (44.5%)	61 (55.5%)	45%	46 (64.8%)	25 (35.2%)	65%	63 (48.8%)	66 (51.2%)	49%
Did the participant have any difficulties with the test tube?	24 (22%)	85 (78%)	78%	10 (14.1%)	61 (85.9%)	86%	41 (31.5%)	89 (68.5%)	69%
Did the participant remove the test device from the package?	110 (100%)		100%	71 (100%)		100%	130 (100%)		100%
Did the participant touch the flat pad?	18 (16.4%)	92 (83.6%)	84%	2 (2.8%)	69 (97.2%)	97%	21 (16.2%)	109 (83.8%)	84%
Did the participant place the test stick correctly in the test tube?	108 (99.1%)	1 (0.9%)	99%	71 (100%)	0 (0%)	100%	123 (94.6%)	7 (5.4%)	95%
Did the participant perform the test steps in correct order (steps 1-4)?	101 (91.8%)	9 (8.2%)	92%	70 (98.6%)	1 (1.4%)	99%	119 (91.5%)	11 (8.5%)	92%
Did the participant wait the correct period of time for reading (20 to 40 minutes)?	59 (54.1%)	50 (45.9%)	54%	49 (69%)	22 (31%)	69%	70 (54.7%)	58 (45.3%)	55%
Average			**80%**			**86%**			**77%**

Interpretation

All participants received three (anonymous) predefined HIVST results and were asked to provide the interpretation of the result. A total of 936 tests were presented (three different results shown to each participant), with a correct interpretation response found for 823 (88%) presented test results. A slightly lower proportion (332, 84%) of correct answers was seen among the community members, and the best interpretation performance was among the students (203, 95%) (**Table 12**).

Table 12. Test interpretation performance, by test

	Employees (n=110)	**Students (n=71)**	**Community (n=131)**	**[ALL] (n=312)**	**p-value**
Test1:					0.134
Correct	90 (81.8%)	67 (94.4%)	110 (84%)	267 (85.6%)	
Wrong	16 (14.5%)	3 (4.2%)	18 (13.7%)	37 (11.9%)	
Don't Know	4 (3.6%)	1 (1.4%)	3 (2.3%)	8 (2.6%)	
Test2:					**0.024**
Correct	100 (90.9%)	69 (97.2%)	108 (82.4%)	277 (88.8%)	
Wrong	7 (6.4%)	2 (2.8%)	16 (12.2%)	25 (8%)	
Don't Know	3 (2.7%)	0 (0%)	7 (5.3%)	10 (3.2%)	
Test3:					0.244
Correct	98 (89.1%)	67 (94.4%)	114 (87%)	279 (89.4%)	
Wrong	7 (6.4%)	4 (5.6%)	14 (10.7%)	25 (8%)	
Don't Know	5 (4.6%)	0 (0%)	3 (2.3%)	8 (2.6%)	

Seventy-five percent (234) responded correctly to all three presented tests, where employees scored a higher interpretation performance (63, 89%), p=0.031. Nine (3%) persons failed in all three presented tests (6

students, 3 community members). Overall, 36 (12%) gave a false negative result interpretation, 21 (7%) gave a false positive result interpretation, and 14 (4%) gave both false negative and false positive result interpretations. Community Members had generally a lower performance (**Table 13**).

Table 13. Interpretation results of pre-defined HIVST results, as per total number of tests, and per person.

	Employees (n=110)	Students (n=71)	Community Members (n=131)	[All] (n=312)	p-value
Correct test interpretations for three tests (n, %)					0.08
0	3 (2.7%)	0 (0%)	6 (4.6%)	9 (2.9%)	
1	7 (6.4%)	2 (2.8%)	8 (6.1%)	17 (5.5%)	
2	19 (17.3%)	6 (8.5%)	27 (20.6%)	52 (16.7%)	
3	81 (73.6%)	63 (88.7%)	90 (68.7%)	234 (75%)	
False negative interpretation (n, %)					0.08
Yes	14 (12.7%)	3 (4.2%)	19 (14.5%)	36 (11.5%)	
No	96 (87.3%)	68 (95.8%)	112 (85.5%)	276 (88.5%)	
False positive interpretation (n, %)					**0.03**
Yes	6 (5.5%)	1 (1.4%)	14 (10.7%)	21 (6.7%)	
No	104 (94.5%)	70 (98.6%)	117 (89.3%)	291 (93.3%)	
False positive and false negative interpretation (n, %)					0.22
Yes	4 (3.6%)	1 (1.4%)	9 (6.9%)	14 (4.5%)	
No	106 (96.4%)	70 (98.6%)	122 (93.1%)	298 (95.5%)	

Experience of doing the HIV self-test

We asked the participants about the experience of doing an HIV self-test. Almost half (144, 46%) reported they did not feel anxious before doing the test, and 278 (89%) did not feel anxious after doing the test. Among those who read the instructions, 64% reported they were easy or very easy to understand. Only 15 (5%) felt that it was difficult to do the HIVST. The most difficult step was the preparation of the kit (71, 23%). Almost all felt they did the test correctly, and trusted the test result they received. There were no differences seen among the three target groups (**Table 14**).

Table 14. Perceived experience of performing HIV self-test (n=312)

		Employees (n=110)	Students (n=71)	Community Members (n=131)	[ALL] (n=312)	p-value
Do you feel you received sufficient information on how to do the HIVST?						0.174
	Yes	110 (100%)	69 (97.2%)	130 (99.2%)	309 (99%)	
	No	0 (0%)	2 (2.8%)	1 (0.8%)	3 (1%)	
Where you anxious before doing HIVST?						0.295

Not anxious	56 (50.9%)	25 (35.2%)	63 (48.1%)	144 (46.2%)	
Little bit anxious	18 (16.4%)	17 (23.9%)	22 (16.8%)	57 (18.3%)	
Very anxious	36 (32.7%)	29 (40.8%)	46 (35.1%)	111 (35.6%)	
Where you anxious after doing HIVST?					0.351
Not anxious	102 (92.7%)	62 (87.3%)	114 (87%)	278 (89.1%)	
Little bit anxious	7 (6.4%)	5 (7%)	11 (8.4%)	23 (7.4%)	
Very anxious	1 (0.9%)	4 (5.6%)	6 (4.6%)	11 (3.5%)	
Are instructions easy to understand?					.
Did not read instructions	25 (22.9%)	23 (32.4%)	53 (40.5%)	101 (32.5%)	
Very easy	30 (27.5%)	21 (29.6%)	23 (17.6%)	74 (23.8%)	
Easy	51 (46.8%)	26 (36.6%)	48 (36.6%)	125 (40.2%)	
Difficult	2 (1.8%)	0 (0%)	7 (5.3%)	9 (2.9%)	
Very Difficult	1 (0.9%)	1 (1.4%)	0 (0%)	2 (0.6%)	
Are instructions easy to read?					.
Did not read instructions	27 (24.5%)	24 (33.8%)	53 (40.5%)	104 (33.3%)	
Very easy	26 (23.6%)	19 (26.8%)	23 (17.6%)	68 (21.8%)	
Easy	54 (49.1%)	26 (36.6%)	49 (37.4%)	129 (41.3%)	
Difficult	2 (1.8%)	0 (0%)	6 (4.6%)	8 (2.6%)	
Very Difficult	1 (0.9%)	2 (2.8%)	0 (0%)	3 (1%)	
Was it difficult to do HIVST?					0.199
Very easy	39 (35.5%)	28 (39.4%)	36 (27.5%)	103 (33.0%)	
Easy	66 (60%)	41 (57.7%)	87 (66.4%)	194 (62.2%)	
Difficult	5 (4.6%)	1 (1.4%)	8 (6.1%)	14 (4.5%)	
Very Difficult	0 (0%)	1 (1.4%)	0 (0%)	1 (0.3%)	
What step was most difficult?					0.117
No step was difficult	82 (74.5%)	48 (67.6%)	98 (74.8%)	228 (73.1%)	
Step 1 - prepare kit	20 (18.2%)	20 (28.2%)	31 (23.7%)	71 (22.8%)	
Step 2 - Sample	2 (1.8%)	3 (4.2%)	1 (0.8%)	6 (1.9%)	
Step 3 - Do the test	3 (2.7%)	0 (0%)	0 (0%)	3 (1%)	
Step 4 - read result	3 (2.7%)	0 (0%)	1 (0.8%)	4 (1.3%)	
Do you think HIVST was correctly done?					0.653
Yes	106 (96.4%)	66 (93%)	123 (93.9%)	295 (94.6%)	
No	2 (1.8%)	4 (5.6%)	4 (3.1%)	10 (3.2%)	
Don’t remember	2 (1.8%)	1 (1.4%)	4 (3.1%)	7 (2.2%)	
Do you trust HIVST test result?					0.777
Yes	106 (96.4%)	68 (95.8%)	123 (93.9%)	297 (95.2%)	
No	1 (0.9%)	2 (2.8%)	4 (3.1%)	7 (2.2%)	
Don’t remember	3 (2.7%)	1 (1.4%)	4 (3.1%)	8 (2.6%)	
Do you feel you needed more information or counseling?					0.697
No	64 (58.2%)	37 (52.1%)	71 (54.2%)	172 (55.1%)	
Yes	46 (41.8%)	34 (47.9%)	60 (45.8%)	140 (44.9%)	
Was information given with the kit sufficient?					**0.043**
Not sufficient	7 (6.4%)	4 (6.5%)	19 (15.8%)	30 (10.3%)	
Sufficient	102 (93.6%)	57 (91.9%)	99 (82.5%)	258 (88.7%)	

Don’t know	0 (0%)	1 (1.6%)	2 (1.7%)	3 (1%)	
Prefer assisted or non-assisted HIVST?					0.238
Non-assisted	77 (70%)	57 (80.3%)	93 (71%)	227 (72.8%)	
Assisted HIVST (with counselor) at health facility	18 (16.4%)	7 (9.9%)	19 (14.5%)	44 (14.1%)	
Assisted HIVST (with counselor) at home	14 (12.7%)	5 (7%)	19 (14.5%)	38 (12.2%)	
Assisted HIVST (with counselor) at pharmacy	1 (0.9%)	2 (2.8%)	0 (0%)	3 (1%)	
Would you recommend HIVST?					0.19
No	5 (4.6%)	2 (2.8%)	12 (9.2%)	19 (6.1%)	
Yes	105 (95.5%)	69 (97.2%)	119 (90.8%)	293 (93.9%)	
You prefer HIVST over VCT at HF?					0.396
Yes (prefer HIVST)	98 (89.1%)	62 (87.3%)	106 (80.9%)	266 (85.3%)	
No (prefer VCT at HF)	11 (10%)	9 (12.7%)	23 (17.6%)	43 (13.8%)	
Don't know	1 (0.9%)	0 (0%)	2 (1.5%)	3 (1%)	
Would you do HIVST again in the future?					0.588
No	1 (0.9%)	1 (1.4%)	4 (3.1%)	6 (1.9%)	
Yes	108 (98.2%)	70 (98.6%)	127 (96.9%)	305 (97.8%)	
Don't know	1 (0.9%)	0 (0%)	0 (0%)	1 (0.3%)	

Acceptability

A survey was done on the acceptability of doing an HIVST (**Table 15**). Advantages reported were (the test) being simple (157, 50%), keeping confidentiality (113, 36%). Disadvantages are fear of test result (32, 10%), and not having counseling nearby (28; 9%). Most (256, 82%) preferred oral test over finger prick, and the majority preferred to get the test at a public health facility.

Table 15. Acceptability of HIV self-test among the participants (n=312)

	Employees (n=110)	**Students (n=71)**	**Community Members (n=131)**	**[ALL] (n=312)**	**p-value**
Have you ever done HIVST (before today's test)					1
No	107 (97.3%)	69 (97.2%)	127 (96.9%)	303 (97.1%)	
Yes	3 (2.7%)	2 (2.8%)	4 (3.1%)	9 (2.9%)	
Did you do (previous) HIVST alone?					0.222
Alone	3 (100%)	1 (50%)	4 (100%)	8 (88.9%)	
Pharmacy	0 (0%)	1 (50%)	0 (0%)	1 (11.1%)	
Advantages of HIVST (select all that apply)					
Simple/ no need of health provider	56 (50.9%)	37 (52.1%)	64 (48.9%)	157 (50.3%)	0.896
Maintains confidentiality	36 (32.7%)	31 (43.7%)	46 (35.1%)	113 (36.2%)	0.308
Result is fast	23 (20.9%)	12 (16.9%)	28 (21.4%)	63 (20.2%)	0.731
Does not have advantage	2 (1.8%)	1 (1.4%)	3 (2.3%)	6 (1.9%)	1
To be able to test with my partner	1 (0.9%)	0 (0%)	3 (2.3%)	4 (1.3%)	0.552

Other	66 (60%)	45 (63.4%)	75 (57.3%)	186 (59.6%)	0.695
Disadvantages of HIVST (all that apply)					
Fear of test result	10 (9.1%)	5 (7%)	17 (13%)	32 (10.3%)	0.366
No counseling nearby	9 (8.2%)	4 (5.6%)	15 (11.5%)	28 (9%)	0.361
Doubts on the quality of the test	3 (2.7%)	7 (9.9%)	3 (2.3%)	13 (4.2%)	0.037
Do not know how to use it	3 (2.7%)	6 (8.5%)	5 (3.8%)	14 (4.5%)	0.188
Not able to read the instructions	2 (1.8%)	0 (0%)	1 (0.8%)	3 (1%)	0.609
Do not feel at risk	1 (0.9%)	1 (1.4%)	1 (0.8%)	3 (1%)	1
Do not know where to get	1 (0.9%)	2 (2.8%)	1 (0.8%)	4 (1.3%)	0.448
too expensive	0 (0%)	0 (0%)	1 (0.8%)	1 (0.3%)	1
No disadvantage	84 (76.4%)	44 (62%)	92 (70.2%)	220 (70.5%)	0.116
Fear of somebody discovering	0 (0%)	1 (1.4%)	3 (2.3%)	4 (1.3%)	0.283
Other disadvantage	8 (7.3%)	10 (14.1%)	10 (7.6%)	28 (9%)	0.229
No response	1 (0.9%)	0 (0%)	0 (0%)	1 (0.3%)	0.58
Would you fear that your partner would hurt you if discovering you did a HIVST? (3 missing)					0.95
No	103 (93.6%)	68 (95.8%)	118 (92.2%)	289 (93.5%)	
Yes	5 (4.6%)	2 (2.8%)	7 (5.5%)	14 (4.5%)	
Maybe	1 (0.9%)	0 (0%)	2 (1.6%)	3 (1%)	
Don't know	1 (0.9%)	1 (1.4%)	1 (0.8%)	3 (1%)	
What is your preferred type of HIV self-test (oral or finger prick)?					0.15
Oral test	85 (77.3%)	59 (83.1%)	112 (85.5%)	256 (82.1%)	
Finger prick	15 (13.6%)	11 (15.5%)	14 (10.7%)	40 (12.8%)	
Any of both	10 (9.1%)	1 (1.4%)	5 (3.8%)	16 (5.1%)	
Do you think the pharmacy is a good place to get a HIVST? (3 missing)					0.106
No	60 (56.1%)	29 (40.8%)	60 (45.8%)	149 (48.2%)	
Yes	47 (43.9%)	42 (59.2%)	71 (54.2%)	160 (51.8%)	
What is preferred place to get self-test?					**0.008**
Public HF	85 (77.3%)	40 (56.3%)	97 (74%)	222 (71.2%)	
Private pharmacy	24 (21.8%)	22 (31%)	23 (17.6%)	69 (22.1%)	
Community HCW	0 (0%)	0 (0%)	2 (1.5%)	2 (0.6%)	
Pharmacy at HF	0 (0%)	1 (1.4%)	3 (2.3%)	4 (1.3%)	
Private clinic	0 (0%)	1 (1.4%)	0 (0%)	1 (0.3%)	
Public pharmacy	1 (0.9%)	6 (8.5%)	5 (3.8%)	12 (3.9%)	
Other	0 (0%)	1 (1.4%)	1 (0.8%)	2 (0.6%)	
Do you know the price of HIVST?					0.243
No, don't know the price	108 (98.2%)	67 (94.4%)	129 (98.5%)	304 (97.4%)	
Yes, know the price	2 (1.8%)	4 (5.6%)	2 (1.5%)	8 (2.6%)	
what do you think of price? (for those who responded knowing the price)					0.314
Accessible	1 (50%)	0 (0%)	1 (50%)	2 (25%)	
Cheap	1 (50%)	1 (25%)	0 (0%)	2 (25%)	
Expensive	0 (0%)	3 (75%)	1 (50%)	4 (50%)	
How much would you pay for HIVST? (9 missing)					**<0.001**
Don't want to pay for test	9 (8.3%)	2 (2.9%)	12 (9.5%)	23 (7.6%)	

Up to 10Mzn	12 (11.1%)	7 (10.1%)	4 (3.2%)	23 (7.6%)	
Up to 50mzn	26 (24.1%)	18 (26.1%)	24 (19%)	68 (22.4%)	
Up to 100Mzn	24 (22.2%)	20 (29%)	31 (24.6%)	75 (24.8%)	
Up to 200Mzn	25 (23.1%)	11 (15.9%)	37 (29.4%)	73 (24.1%)	
Up to 500Mzn	10 (9.3%)	8 (11.6%)	12 (9.5%)	30 (9.9%)	
More than 500Mzn	2 (1.9%)	3 (4.4%)	6 (4.8%)	11 (3.6%)	
Is pharmacy good place for counseling?					0.194
No	92 (83.6%)	52 (73.2%)	103 (78.6%)	247 (79.2%)	
Yes	17 (15.5%)	19 (26.8%)	28 (21.4%)	64 (20.5%)	
Don't know	1 (0.9%)	0 (0%)	0 (0%)	1 (0.3%)	
Most comfortable place for pretest counseling:					0.11
HF	92 (83.6%)	53 (74.6%)	112 (85.5%)	257 (82.4%)	
Community Health Worker	5 (4.6%)	1 (1.4%)	7 (5.3%)	13 (4.2%)	
Pharmacy where bought	8 (7.3%)	11 (15.5%)	9 (6.9%)	28 (9%)	
Other	5 (4.6%)	6 (8.5%)	3 (2.3%)	14 (4.5%)	
Most comfortable place for posttest counseling:					0.779
Public HF	98 (89.1%)	61 (85.9%)	119 (90.8%)	278 (89.1%)	
Community Clinic	1 (0.9%)	1 (1.4%)	2 (1.5%)	4 (1.3%)	
Private clinic	0 (0%)	1 (1.4%)	1 (0.8%)	2 (0.6%)	
Private pharmacy	3 (2.7%)	5 (7%)	4 (3.1%)	12 (3.9%)	
Public pharmacy	2 (1.8%)	0 (0%)	1 (0.8%)	3 (1%)	
Other	6 (5.5%)	3 (4.2%)	4 (3.1%)	13 (4.2%)	

Discussion

The study implemented in Mozambique evaluated acceptability of the use of HIVST through a pharmacy-based strategy. The results showed that HIVST at public/private pharmacies was successfully implemented, reaching primarily males and younger adult persons. Acceptability was high, but routine reporting of linkage to care was very poor.

We found that keeping confidentiality was the main advantage reported, and this is in line with what is seen in other SSA countries (9, 17). Not having to reveal to somebody about your desire or need to get an HIV test can increase testing coverage, but can also create uncertainty and insecurity for people, as no additional counseling or information is readily available. Health literacy, particularly on HIV prevention and HIV testing, is crucial when expanding HIV self-testing strategies. Mozambique has a low literacy rate of 52%(18), and knowledge regarding HIV transmission remains less than desirable, with only 30% of young adults (15-24 years of age) having a comprehensive knowledge on HIV prevention (2). This could explain why lack of counseling nearby was seen as a disadvantage for HIVST. In our context, additional strategies of information and education regarding HIVST are needed, and could be offered at pharmacies, or through community initiatives.

The pilot program in Mozambique was a pharmacy-based strategy, as a way of not putting any additional burden on the weak, often overloaded, health system. The cost per test may be a barrier for individuals, as found in our study (mainly reported in rural settings). In Tanzania, where clinic-based HIV testing is also provided free of charge, costs associated with the purchase of an oral HIV self-test outweigh the disadvantages of losing time by going to and from the health facility and travel costs(9). In Zimbabwe, the demand was price sensitive where different approaches were suggested for different settings(19). Mozambique is one of the poorest countries in the world, and our finding that a quarter of the pharmacy clients found the test expensive was expected, especially as HIV testing (and treatment) services are free of charge within the national health system. Our study population were pharmacy clients, who usually have a higher purchase possibility, and this might explain why about half of them were willing to pay 50 Mzn or ~0.80 USD for a self-test. However, the network of private pharmacies countrywide consists of 793 private pharmacies(20). This network will not be able to cover the demand, if only a pharmacy-based strategy would be offered. Additionally, it is not certain that the private network would be able to fix the HIV self-test at a lower price as was done in this pilot, if manufacturers would not be able to adjust selling prices. Health insurances can contribute to increasing coverage of HIV testing, as also proposed by the WHO(21). Unfortunately, health insurance coverage remains low in Mozambique, limiting the potential for increased coverage and promotion of HIVST use.

This strategy requires the buy-in of the pharmacies and pharmacy staff. The study shows some of the first data of pharmacy technicians' perceptions on the use of HIVST. The findings are important to have a successful pharmacy-based strategy. The majority of pharmacy staff (technicians and managers) thought that the strategy can specifically reach young male populations. Counseling can be a challenge, but with training, and additional human resources allotted to the pharmacy locations, this can be overcome and HIVST could successfully be offered at pharmacies. The pharmacy could play an active role in HIVST user linkage to the health facility through establishment of a helpline at the health facility where a dedicated health care worker can guide the client to the specific location for HIV test result confirmation and further follow-up as needed.

Linkage to health facilities was measured through self-reported use of HIVST, with a very low registration in the HF followed in this study. It could be that individuals do not want to report their results, or they could have sought follow-up at a private clinic (since the study tracked only registration at six public health facilities), or they registered in a health facility outside the province. Additionally, linkage confirmation depends as well on patient disclosure (of HIVST) at health facilities. Linkage to care after HIV self-testing is a known challenge, with various success rates in the context of free distribution (community- or health facility-based)(22). Individual follow-up, for example, by lay counselors can be beneficial but seems only practical when HIVST is offered through community- or health facility-based distribution. Pharmacy-based strategies could be strengthened by adapting other mechanisms, where mobile-based health (mHealth) initiatives can play a role, by sending messages with key information, and reminders on linkage to care.

Different HIVST strategies have been studied, from community-based to health facility distribution. Eswatini adopted HIVST as a national strategy, after it was shown to be feasible and successful under routine conditions, using a combination of offering HIVST as an alternative at the health facility and mobile community-based distribution and testing(23). Uptake of enrollment into HIV care was 51% when clinic-based HIVST was done compared to standard counseling and testing strategy(24). Mozambique has not (yet) adopted any additional HIVST strategies, however, community distribution is currently being piloted.

Performance of the HIVST is crucial when countries plan to expand the strategy. The evaluation showed that persons from potential target groups have some challenges in following the correct procedures. Completing procedures incorrectly could result in invalid results and/or inaccurate interpretation. Important errors seen are incorrect sample collection procedures and not following the wait time instructions for result reading. Despite the procedure errors, the overall usability was in general acceptable. Other studies show usability of 98% (25) and 89% (12) among community members, but other HIVST and slightly different questionnaires were used.

False negative result interpretation was given by 12% of the participants, which (if interpreting one's own results) puts the person at risk of not identifying a possible positive result, and for missing the need for a confirmatory test and/or initiating necessary care and treatment. The proportion of false negative result interpretation was higher among community members, and if/when HIV prevention methods are not used among this population, there is potential for putting other people (e.g., sexual partners) at risk. False positive result interpretation was also more frequent among community members. However, if linkage mechanisms are put in place and adhered to, a confirmation test can easily correct this interpretation error.

The MOH adopted a national community-based HIV self-testing strategy as of December 2021, after a pilot that was done between March-November 2021. The evaluation amendment results show that continuous demonstration of HIVST procedures through different formats (e.g., instructions, video, etc.) is necessary to maintain quality of test procedures. Social media are easily available communication sources, as well as information obtained through health facility-based talks (*palestras* in Portuguese).

Conclusions/Recommendations

This is one of the first studies in Mozambique on a successfully implemented pharmacy-based strategy for HIV self-testing. Pharmacy clients show a high degree of acceptability, although the price of the test can be a barrier, as well as lack of counseling nearby following use of self-test. More men and young people might benefit from this strategy. Strategies to improve post-HIVST linkage to health facilities need to be explored. Pharmacy-based HIV self-test distribution appears to be a feasible approach for mainly male and young people, who have financial means to get an HIV self-test. Engaging the private sector should be seen as an additional strategy in order to achieve the first 95 of the UNAIDS 95-95-95 goals.

In the qualitative component, the desire for more privacy within the pharmacy was highlighted, explaining why many interviewed reported that clients preferred to watch the HIVST video on their own time and schedule. In addition, to bolster the uptake of a self-testing approach if pharmacies are to be utilized, a major remaining challenge noted and needing to be addressed is the human resources gap, as per reported concerns of available pharmacy technicians regarding not having the necessary time and/or the appropriate training to provide high quality, detailed counseling that is required for HIVST. For this to be effective in a larger roll-out, dedicated, trained staff will need to be allocated at participating pharmacy locations.

Communication and information strategies need to be put in place regarding HIVST procedures, to promote optimal test performance, with quality procedures and educational components included to ensure the proper interpretation of HIVST results.

Dissemination Plan

Preliminary and final results have been discussed within a priority stakeholders' group of investigators and collaborators. The preliminary results have been discussed with the Mozambique Ministry of Health (MOH), and Public Health Directorate in Zambézia (DPS-Z), and were used to support the development of and update to the national HIVST guidelines.

Preliminary results were also presented as a poster exhibit at the 2020 Conference on Retroviruses and Opportunistic Infections (CROI) (abstract #TUPEE648). Additionally, a manuscript is currently being developed to submit to a peer-reviewed journal for wider public dissemination.

Once approved for dissemination, the findings from this evaluation will be made publicly available through the posting of this report in a VUMC/FGH public website (https://www.vumc.org/friends-in-global-health/evaluations).

Acknowledgements

We want to thanks to all participants for their involvement in this evaluation. We thank OraSure Technologies Inc. for kindly donating the HIV self-tests used in the pilot program and study.

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Appendices

Appendix 1. Approved protocol (Version 5.0), including all instruments, consent forms, co-investigator biosketches, conflict of interest statements

Bio-sketches *(provided for main investigators of this evaluation)*

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Caroline De Schacht

eRA COMMONS USER NAME (credential, e.g., agency login): cdeschacht

POSITION TITLE: Director of Evaluations

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Ghent University, Ghent, Belgium	Licentiate	07/1998	General Medicine
Ghent University, Ghent, Belgium	Specialization	07/2000	Family Medicine
Prince Leopold Institute of Tropical Medicine, Antwerp, Belgium	Diploma	02/2001	Tropical Medicine
London School of Hygiene and Tropical Medicine (Distance learning)	MSc	07/2008	Clinical Trials
Ghent University, Ghent, Belgium	PhD	11/2015	Biomedical Science

A. Personal Statement

For about 20 years, I have been working as an HIV technical advisor and researcher in resource-poor settings, including the last 16 years in Mozambique. As technical advisor, I worked closely with the Ministry of Health and the Provincial Health authorities, and have gained valuable insight into the Mozambican Health System which I will use to help develop study protocols and design. In addition, I managed the start-up of an HIV care and treatment project in Tete and Gaza Provinces, which involved bringing together and coordinating a diverse group of stakeholders. As a researcher, I have been coordinating clinical and operational research activities since 2008. I have been the lead investigator on several studies in Mozambique, of which several related to PMTCT/ HIV prevention. I have been collaborating with the Polana Caniço Research Centre in HIV prevention research among young adults, such as the HIV incidence study, HIV vaccine trial (Tamovac I) and socio-behavioral studies on HIV prevention trials in Maputo city. In my current position, I am the lead of several HIV-related operational research projects in Zambézia province, and manage various secondary data analyses of HIV-program results.

Together with the Provincial Health services, and/ or National Institute of Health Mozambique, I have been serving as a trainer in different capacity building areas (quantitative and qualitative research

methods, GCP/research ethics, protocol/abstract/manuscript writing, etc.), and mentor/supervise young researchers and PhD students, since 2005. I am also invited member of the UEM/INS Jury for the Masters in Field Epidemiology (FELTP), and member of the scientific committee of the Mozambican Health Conference where capacity building on dissemination of scientific results is an important component.

I'd like to highlight the following ongoing projects:

Ongoing Research Support

R01MH113478-01 (Audet, PI)
05/14/2017-05/30/2022
The primary objectives of Partners-based HIV Treatment for Sero-concordant Couples attending Antenatal Care are to evaluate the impact and cost-effectiveness of couples-centered services for HIV-infected seroconcordant pregnant women and their partners. Our intervention includes: (1) ANC-based couples HIV testing, ART enrollment, and care for HIV+ expectant couples; (2) Couple-based treatment in the post-partum period; (3) Couple-based education and skills building; and (4) Treatment continuity with the support of expert-patient (peer) supporters from couples who have successfully navigated EMTCT.
Role: In-Country Principal Investigator

U2GGH001943 Centers for Disease Control and Prevention
06/01/2020-12/01/2022
Title: Impact of COVID-19 epidemic on clinical outcomes and service delivery among people living with HIV and health care workers in Mozambique. The goal of this protocol is to determine the incidence, prevalence, and clinical manifestations of SARS-CoV-2 among adults living with HIV and healthcare the health care providers, and to assess the impact that COVID-19 has on them and on the healthcare system.
Role: Co-principal Investigator

GH002367-01-00 Centers for Disease Control and Prevention (PI: Wester) 9/30/2021 - /29/2026
Title - Quality Improvement for HIV Care and Treatment in Zambézia province of the Republic of Mozambique under the President´s Emergency Plan for AIDS Relief (PEPFAR)
The purpose of the protocol is to review and summarize all routinely collected data from the HIV care and treatment program in Zambézia province from 2012 onwards. This data will be used for program evaluation, continuous program improvement, and to help inform evidence-based decisions on policies/guidelines, approaches, programs, and interventions that can best address the HIV/AIDS epidemic in Zambézia province. Key programmatic areas include: i) prevention; ii) adult care, support and treatment; iii) HIV/TB; and iv) pediatric care, support, and treatment.
Role: Co-Investigator

B. Positions and Honors

2017 - present Evaluations Director, Friends in Global Health, Mozambique
2014 - 2017 Project Coordinator/Research Advisor, Health Alliance International, Maputo, Mozambique
2008 - 2014 Public Health Evaluation Coordinator, Elizabeth Glaser Pediatric AIDS Foundation, Maputo, Mozambique
2006 - 2008 Clinical Advisor, Care and Treatment, Elizabeth Glaser Pediatric AIDS Foundation, Gaza, Mozambique
2005 - 2006 HIV Advisor/Project Manager, Pharmaccess Foundation, Maputo, Mozambique

2003 - 2004 HIV Clinical Advisor, Prince Leopold Institute of Tropical Medicine, Tete, Mozambique
2003 - 2004 HIV Clinical Advisor, Médecins sans Frontières, Ethiopia and Cambodia
2002 - 2003 HIV Clinician, Prince Leopold Institute of Tropical Medicine, Antwerp, Belgium
2001 - 2002 Project Coordinator, Médecins sans Frontières, Benin

2015; 2018; 2019 Member of Scientific Committee Provincial and National Health Conferences Mozambique
2016- Member of Jury – Masters Course in Field Epidemiology and Laboratory Practices
2010- Member of International Aids Society (IAS)

C. Contributions to Science

HIV epidemiology

Dr. De Schacht contributed to major studies in the epidemiology of HIV in Mozambique. She participated in the first cohort HIV incidence studies among vulnerable populations in Mozambique (youth, pregnant and breastfeeding women). She was PI on the HIV incidence cohort study of pregnant and breastfeeding women. Through the research work, we have been able to estimate the incidence of HIV among pregnant and breastfeeding women in a high HIV prevalence regions of Mozambique, found to be very high.

Viegas EO, Tembe N, Macovela E, Gonçalves E, Augusto O, Ismael N, Sitoe N, ***De Schacht C***, Bhatt N, Meggi B, Araujo C, Sandström E, Biberfeld G, Nilsson C, Andersson S, Jani I, Osman N. Incidence of HIV and the prevalence of HIV, hepatitis B and syphilis among youths in Maputo, Mozambique: a cohort study. PLoS One. 2015 Mar 23;10(3):e0121452

Caroline De Schacht, Heather J. Hoffman, Nédio Mabunda, Carlota Lucas, Catharina L. Alons, Ana Madonela, Adolfo Vubil, Orlando C. Ferreira Jr, Nurbai Calú, Iolanda S. Santos, Ilesh V. Jani, Laura Guay High HIV seroconversion in pregnant women and low reported levels of HIV testing among male partners in Southern Mozambique: results from a mixed methods study. PlosOne 9(12): e115014

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Mother-to-Child Transmission of HIV
These publications are result of the contributions to research on mother-to-child transmission of HIV, looking at several aspects that influence retention to PMTCT care, and interventions to decrease vertical transmission rate, such as partner-based treatment.

Jani IV, De Schacht C. Innovations and challenges in early infant diagnosis of HIV. Curr Opin HIV AIDS 2018 Nov 1

Sack DE, Frisby MB, Diemer MA, De Schacht C, et al. Interpersonal reactivity index adaptation among expectant seroconcordant couples with HIV in Zambézia Province, Mozambique. BMC Psychol. 2020 Aug 28;8(1):90

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HIV and TB Care

Arinze F, Gong W, Green AF, ***De Schacht C***, Carlucci JG, Silva W, Claquin G, Tique JA, Stefanutto M, Graves E, Van Rompaey S, Alvim MFS, Tomo S, Moon TD, Wester CW. Immunodeficiency at Antiretroviral Therapy Start: Five-Year Adult Data (2012-2017) Based on Evolving National Policies in Rural Mozambique. AIDS Res Hum Retroviruses. 2020 Jan;36(1):39-47

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Lynen L, Zolfo M, Huyst V, Louis F, Barnardt P, Van de Velde A, ***De Schacht C***, Colebunders R. Management of Kaposi's sarcoma in resource-limited settings in the era of HAART. AIDS Rev. 2005 Jan-Mar; 7(1):13-21

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Callens S, ***De Schacht C***, Huyst V, Colebunders R. Pancreatitis in an HIV-infected person on a tenofovir, didanosine and stavudine containing highly active antiretroviral treatment. J Infect 2003; 47(2):188-9

Mother and Child Health Care/ EPI program

Main achievements are the results of research understanding coverage of the vaccination program in Mozambique, contributing to improvement of access to health care for mothers and children.

Small area estimation of under-5 mortality in Bangladesh, Cameroon, Chad, Mozambique, Uganda, and Zambia using spatially misaligned data. Dwyer-Lindgren L, Squires ER, Teeple S, Ikilezi G, Allen Roberts D, Colombara DV, Allen SK, Kamande SM, Graetz N, Flaxman AD, El Bcheraoui C, Asbjornsdottir K, Asiimwe G, Augusto Â, Augusto O, Chilundo B, **De Schacht C**, Gimbel S, Kamya C, Namugaya F, Masiye F, Mauieia C, Miangotar Y, Mimche H, Sabonete A, Sarma H, Sherr K, Simuyemba M, Sinyangwe AC, Uddin J, Wagenaar BH, Lim SS. Popul Health Metr. 2018 Aug 13;16(1):13.

Jani JV, **De Schacht C**, Jani IV, Bjune G. Risk factors for incomplete vaccination and missed opportunity for immunization in rural Mozambique. BMC Public Health. 2008 May 16

Arts M, Geelhoed D, ***De Schacht C***, Prosser W, Alons C, Pedro A. Knowledge, beliefs and practices regarding exclusive breastfeeding of infants younger than 6 months in Mozambique: a qualitative study. J Hum Lact. 2011 Feb;27(1):25-32

Co-Principal Investigator - C. William Wester, M.D., M.P.H.:

BIOGRAPHICAL SKETCH
Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: Wester, C. William

eRA COMMONS USER NAME (agency login): wwester

POSITION TITLE: Associate Professor of Medicine

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Bowdoin College , Brunswick, ME	BA	06/1987	Biology and Economics
Dartmouth Medical School , Hanover , NH	MD	06/1991	Medicine
Harvard School of Public Health, Boston, MA	MPH	11/2010	Quantitative Methods

A. Personal Statement

The goal of my present research includes long-term HIV complications with a focus on implementation science and HIV-associated kidney disease and in resource-limited settings of the world. In addition, I have served as Co-Chair of the IeDEA Site Assessment Working Group (with Denis Nash and Stephany Duda) for the past 3 years and have been actively engaged in the collection and analysis of site level data for the purposes of informing and improving ongoing clinical initiatives/programs in such settings. Recently completed grant-funded studies include the determination of clinical, laboratory, and host genetic risk factors associated with the development of lactic acidosis, pancreatitis, nevirapine-related cutaneous hypersensitivity reactions, and other metabolic/potentially inflammatory mediated complications including HIV-associated renal, hepatic, and cardiovascular disease. This work has bridged outcomes-epidemiology and clinical-translational research domains and has allowed me to successfully attain NIH-funded grants on which I serve as Principal or Co-Principal Investigator.

With my extensive implementation science research experience in resource-limited settings, focused on long-the scale-up of comprehensive HIV services, the prevention of mother-to-child transmission, complications of HIV, as well as work focused on identifying risk factors for untoward outcomes, coupled with my extensive regional experience, namely working (and residing full-time) in Botswana for 8 years (2000-2008) where I worked for the T.H. Chan Harvard School of Public Health and was actively involved in clinical trials, as well as my active involvement (including frequent travel to Mozambique) as Project Director of our large (currently supporting > 110 ART sites) ongoing U.S. government Centers for Disease Control and Prevention (CDC) / President's Emergency Plan for AIDS Relief (PEPFAR)-funded "*Avante: Towards Epidemic Control"* (Cooperative agreement 1NUGGH001943) technical assistance initiative (with renewed funding through 2021), I am uniquely qualified to serve as primary research mentor for team members (both in Mozambique as well as Vanderbilt-based) for many of the program evaluations (plus relevant research protocols) that the "*Avante: Towards Epidemic Control*" team is conducting. Specifically, in this leadership role, I will continue to mentor technical staff and assist them to: a) develop stakeholder-informed context-specific interventions, b) learn approaches to community engagement and intervention design, c) further develop their research skills in HIV implementation science, and d) help them garner the requisite skills to independently lead HIV research studies in Mozambique and other similar settings.

B. Positions and Honors

Positions and Employment

1994 - 1998	Clinical Instructor, Rush Medical College , Chicago, IL
1998 - 2000	Infectious Diseases Attending Physician, Cook County (Stroger Memorial) Hospital, Chicago, IL
1998 - 2000	Assistant Professor of Medicine , Rush Medical College, Chicago, IL
1999 - 2000	Principal Investigator, Terry Beirn Community Programs for Clinical Research on AIDS (CPCRA) , The Core Center, Cook County Hospital, Chicago, IL
1999 - 2000	Co-Investigator, Adult Clinical Trials Group (ACTG) Research Trials, The CORE Center, Cook County Hospital, Chicago, IL
2000 -	Research Associate, Harvard School of Public Health, Boston, MA
2000 - 2008	Co-Study Coordinator/Site Leader/Site PI; Adult Antiretroviral Treatment and Drug Resistance ("*Tshepo*") Study, Botswana-Harvard School of Public Health AIDS Initiative Partnership for HIV Research and Education (BHP), Gaborone
2001 - 2002	Director; Infectious Disease Care Clinic (outpatient HIV/AIDS clinic) , Princess Marina Hospital; Ministry of Health, Botswana, Gaborone
2007 - 2008	Site Leader/Site Principal Investigator, ACTG and the Gaborone PTT/CRS , Botswana-Harvard School of Public Health AIDS Initiative Partnership Clinical Trials Unit (CTU), Gaborone
2008 - 2014	Assistant Professor of Medicine, Vanderbilt University School of Medicine, Vanderbilt Institute for Global Health (VIGH), Nashville, TN
2014 -	Associate Professor of Medicine, Vanderbilt University School of Medicine, Vanderbilt Institute for Global Health (VIGH), Nashville, TN
2014 -	Co-Director of Global Health Pathway (Internal Medicine Residency, Vanderbilt University School of Medicine)

Other Experience and Professional Memberships

1994 -	Member, Alpha Omega Alpha (AOA) Honor Medical Society
2011 -	Member, International AIDS Society (IAS)
2014 -	Member, International Society of Nephrology (ISN)

Honors

1991	Outstanding Medical Resident Teaching Award, (Six Consecutive and Maximum Eligible Terms), Rush-Presbyterian St. Luke's Medical Center
1992	Outstanding Internal Medicine Resident Annual Award, Rush-Presbyterian St. Luke's Medical Center
1994	Full Scholarship Recipient, SHEA-CDC Training Course
1994	Aesculapios Award (Outstanding Medical Resident), Rush Medical College
2010	William Schaffner Teaching Award Recipient in Infectious Diseases, Vanderbilt University School of Medicine, Division of Infectious Diseases
2010	Teacher Recognition Award , Vanderbilt University School of Medicine
2016	Selected for Vanderbilt University Department of Medicine Mid-Career Leadership Program (year-long leadership skills development program; commenced January 2017)

C. Contribution to Science

Scale-up of Comprehensive HIV/AIDS Services in Resource-limited settings / Implementation Science:
Wester CW, Bussmann H, Koethe J, Moffat C, Vermund S, Essex M, Marlink RG. Adult combination antiretroviral therapy in sub-Saharan Africa: lessons from Botswana and future challenges. *HIV Ther*. 2009 Sep 1;3(5):501-526. PMCID: PMC2774911.
Aliyu MH, Blevins M, Audet C, Shepherd BE, Hassan A, Onwujekwe O, Gebi UI, Kalish M, Lindegren ML, Vermund SH, Wester CW. Optimizing PMTCT service delivery in rural North-Central Nigeria: protocol and

design for a cluster randomized study. *Contemp Clin Trials*. 2013 Sep;36(1):187-97. PMCID: PMC3786261.
Aliyu MH, Blevins M, Parrish DD, Megazzini KM, Gebi UI, Muhammad MY, Ahmed ML, Hassan A, Shepherd BE, Vermund SH, Wester CW. Risk factors for delayed initiation of combination antiretroviral therapy in rural north central Nigeria. *J Acquir Immune Defic Syndr*. 2014 Feb 1;65(2):e41-9. PMCID: PMC3818360.
Moon TD, Jequicene T, Blevins M, José E, Lankford JR, Wester CW, Fuchs MC, Vermund SH. Mobile clinics for antiretroviral therapy in rural Mozambique. *Bull World Health Organ*. 2014 Sep 1;92(9):680-4. PMCID: PMC4208568.
Complications of HIV/AIDS (including antiretroviral medication-related toxicity and end-organ complications):
Wester CW, Koethe JR, Shepherd BE, Stinnette SE, Rebeiro PF, Kipp AM, Hong H, Bussmann H, Gaolathe T, McGowan CC, Sterling TR, Marlink RG. Non-AIDS-defining events among HIV-1-infected adults receiving combination antiretroviral therapy in resource-replete versus resource-limited urban setting. *AIDS.* 2011 Jul 31;25(12):1471-9. PMCID: PMC3188442.
Wester CW, Eden SK, Shepherd BE, Bussmann H, Novitsky V, Samuels DC, Hendrickson SL, Winkler CA, O'Brien SJ, Essex M, D'Aquila RT, DeGruttola V, Marlink RG. Risk factors for symptomatic hyperlactatemia and lactic acidosis among combination antiretroviral therapy-treated adults in Botswana: results from a clinical trial. *AIDS Res Hum Retroviruses.* 2012 Aug; 28(8):759-65. PMCID: PMC3399551.
Abraham AG, Althoff KN, Jing Y, Estrella MM, Kitahata MM, Wester CW, Bosch RJ, Crane H, Eron J, Gill MJ, Horberg MA, Justice AC, Klein M, Mayor AM, Moore RD, Palella FJ, Parikh CR, Silverberg MJ, Golub ET, Jacobson LP, Napravnik S, Lucas GM. End-stage renal disease among HIV-infected adults in North America. *Clin Infect Dis*. 2015 Mar 15;60(6):941-9. PMCID: PMC4357817.
Erlandson KM, Kitch D, Wester CW, Kalayjian RC, Overton ET, Castillo-Mancilla J, Koletar SL, Benson CA, Campbell TB, Robertson K, Lok JJ. The Impact of Statin and Angiotensin-Converting Enzyme Inhibitor/Angiotensin Receptor Blocker Therapy on Cognitive Function in Adults with Human Immunodeficiency Virus Infection. *Clin Infect Dis*. 2017 Nov 29;65(12):2042-2049. doi: 10.1093/cid/cix645.
Prevention of Mother-to-Child Transmission (PMTCT):
Aliyu MH, Blevins M, Audet C, Shepherd BE, Hassan A, Onwujekwe O, Gebi UI, Kalish M, Lindegren ML, Vermund SH, Wester CW. Optimizing PMTCT service delivery in rural North-Central Nigeria: protocol and design for a cluster randomized study. *Contemp Clin Trials*. 2013 Sep;36(1):187-97. PMCID: PMC3786261.
Dunlap J, Foderingham N, Bussell S, Wester CW, Audet CM, Aliyu MH. Male involvement for the prevention of mother-to-child HIV transmission: A brief review of initiatives in East, West, and Central Africa. *Curr HIV/AIDS Rep*. 2014 Jun;11(2):109-18. PMCID: PMC4371528.
Audet CM, Chire YM, Vaz LM, Bechtel R, Carlson-Bremer D, Wester CW, Amico KR, Gonzaléz-Calvo L. Barriers to Male Involvement in Antenatal Care in Rural Mozambique. *Qual Health Res*. 2015 Apr 8; PMID: 25854615. PMCID: PMC4598282. [Available 10/01/2017].
Aliyu MH, Blevins M, Megazzini KM, Parrish DD, Audet CM, Chan N, Odoh C, Gebi UI, Muhammad MY, Shepherd BE, Wester CW, Vermund SH. Pregnant women with HIV in rural Nigeria have higher rates of antiretroviral treatment initiation, but similar loss to follow-up as non-pregnant women and men. *Int Health*. 2015 May 25; PMCID: PMC4654753.
Risk Factors for Untoward HIV/AIDS Outcomes (mortality, loss to follow-up, etc.):
Mujugira A, Wester CW, Kim S, Bussmann H, Gaolathe T. Patients with advanced HIV type 1 infection initiating antiretroviral therapy in Botswana: treatment response and mortality. *AIDS Res Hum Retroviruses*. 2009 Feb; 25(2):127-33. PMID: 19239353.
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da Silva M, Blevins M, Wester CW, Manjolo J, José E, Gonzalez LC, Shepherd BE, Moon TD, Vaz LM. Patient loss to follow-up before antiretroviral therapy initiation in rural Mozambique. *AIDS Behav*. 2015 Apr;19(4):666-78. PMID: 25096897.
Aliyu MH, Blevins M, Megazzini KM, Parrish DD, Audet CM, Chan N, Odoh C, Gebi UI, Muhammad MY, Shepherd BE, Wester CW, Vermund SH. Pregnant women with HIV in rural Nigeria have higher rates of

antiretroviral treatment initiation, but similar loss to follow-up as non-pregnant women and men. *Int Health*. 2015 May 25; PMCID: PMC4654753.
A full list of my publications (67+) may be found at:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1HSsewwv6gd5A/bibliography/43390763/public/?sort=date&direction=ascending.
D. Research Support
Active Research Support
1NU2GGH001943-02 (PI: Wester) 9/30/2016 - 9/29/2021 6.48 calendar
CDC (PEPFAR)

Avante: Towards Epidemic Control
The purpose of the Avante program is to control the HIV epidemic by supporting the sustainable implementation of Ministry of Health (MOH) HIV and TB services in Zambézia province. Avante will provide technical assistance (TA) to the Government of the Republic of Mozambique (GRM) at the national, provincial, district and health facility level for activities that have a significant impact to control the epidemic, leveraging community structures that can catalyze program implementation. Key programmatic areas include: i) prevention; ii) adult care, support and treatment; iii) HIV/TB; and iv) pediatric care, support, and treatment.

1U01DK1122770 (MPI/Contact PI: Wester) 9/15/2017 – 8/31/2022 2.4 calendar
NIH/NIDDK
Optimal Management of HIV Infected Adults at Risk for Kidney Disease in Nigeria
In this clinical trial, we plan to determine the optimal means to prevent or slow the progression of kidney disease among genetically at-risk northern Nigerian HIV-infected adults. Based on data from studies of diabetic kidney disease that used medications that block the renin angiotensin aldosterone system (RAAS), we plan to evaluate whether or not RAAS inhibition (using a widely available medication that blocks RAAS) in HIV-infected adults produces similarly promising results.

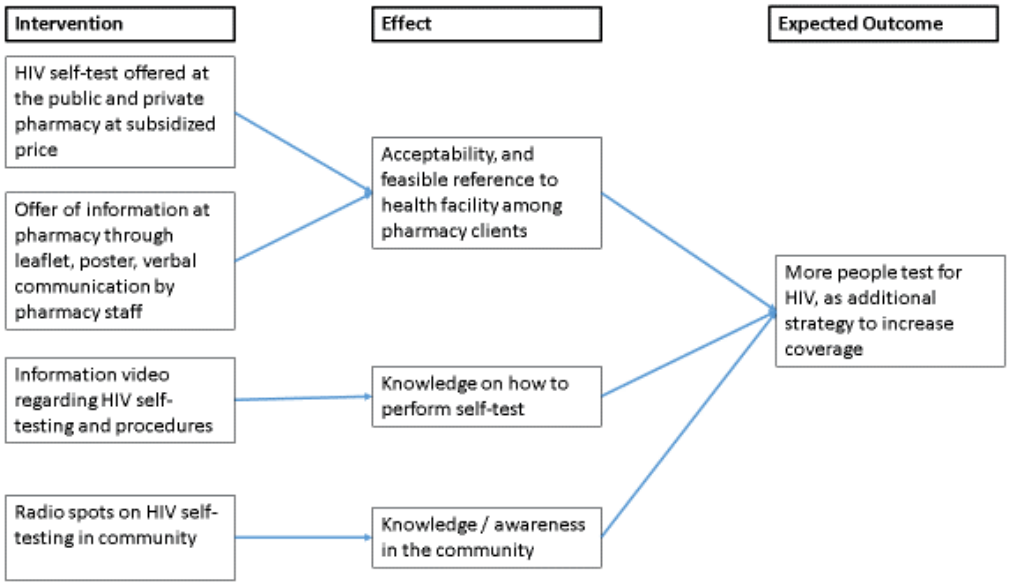
Integrated Malaria Program (IMaP) in Mozambique
Chemonics International, Inc. (PI: Wester) 12/05/2017 - 07/30/2022
0.72 calendar
U.S. Agency of International Development

Brief description of the roles of other evaluation collaborators:

Collaborator	**Description of role in evaluation**
CL	concept note development, data collection, results interpretation, report development
PP	concept note development, data collection, results interpretation, report development
SVR	concept note development, results interpretation, report development
ANF	technical oversight of program, data collection, result interpretation, report development
JEC	data collection, results interpretation, report development

NC	concept note development, results interpretation, report development
WS	concept note development, results interpretation, report development
GA	concept note development, results interpretation, report development
SV	concept note development, laboratory input, results interpretation, report development
NS	concept note development, laboratory input, results interpretation, report development
TS	concept note development, laboratory input, results interpretation, report development
NH	technical oversight of program, result interpretation, report development
SW	Concept note development, technical oversight of program, result interpretation, report development
IM	technical oversight of program, result interpretation, report development
AC	concept note development, results interpretation, report development
ZY	Data analysis, report development

Appendix 2. Framework



Appendix 3. Communication materials

1. Poster at pharmacy

	Nome	Local
1	Calêndula	Quelimane
2	Coalane	Quelimane
3	Patrício	Quelimane
4	Quelimane	Quelimane
5	Nicoadala	Nicoadala
6	Licungo	Mocuba
7	Lugela	Mocuba
8	Mocuba	Mocuba
9	24	Mocuba
10	Milange	Milange
11	Molócuè	Alto-Molócuè
12	Ile	Ile
13	Gurúè	Gurúè
14	Faude	Gurúè

2. Leaflet

Como faço para obter ajuda caso o resultado do autoteste seja positivo?

Se o resultado confirmar-se positivo, você deve iniciar o tratamento o mais cedo possível. Se feito correctamente o tratamento do HIV pode mantê-lo saudável por muitos anos e reduzir o risco de transmitir o vírus para outras pessoas.

Caso você obtenha um resultado positivo poderá ir a qualquer Unidade Sanitária para poder receber os serviços necessários, como testes de confirmação, tratamento de HIV e outros, incluindo:

- aconselhamento
- apoio psicossocial
- teste de contagem de células da defesa (chamadas células CD4)
- teste para saber se tem a tuberculose
- assistência para referência para tratamento
- outro apoio que você pode precisar.

Se você for HIV positivo e estiver a receber o tratamento para o HIV (TARV), não faça o autoteste de HIV, porque você pode obter um falso resultado.

AUTOTESTE DE HIV

O TESTE ORAL
que podes fazer no conforto da tua casa

O autoteste está disponível para compra por um período limitado nas seguintes farmácias:

	Nome	Local
1	Calêndula	Quelimane
2	Coalane	Quelimane
3	Patrício	Quelimane
4	Quelimane	Quelimane
5	Nicoadala	Nicoadala
6	Licungo	Mocuba
7	Lugela	Mocuba
8	Mocuba	Mocuba
9	24	Mocuba
10	Milange	Milange
11	Molócuè	Alto-Molócuè
12	Ile	Ile
13	Gurúè	Gurúè
14	Faude	Gurúè

O nosso maior valor é a vida!

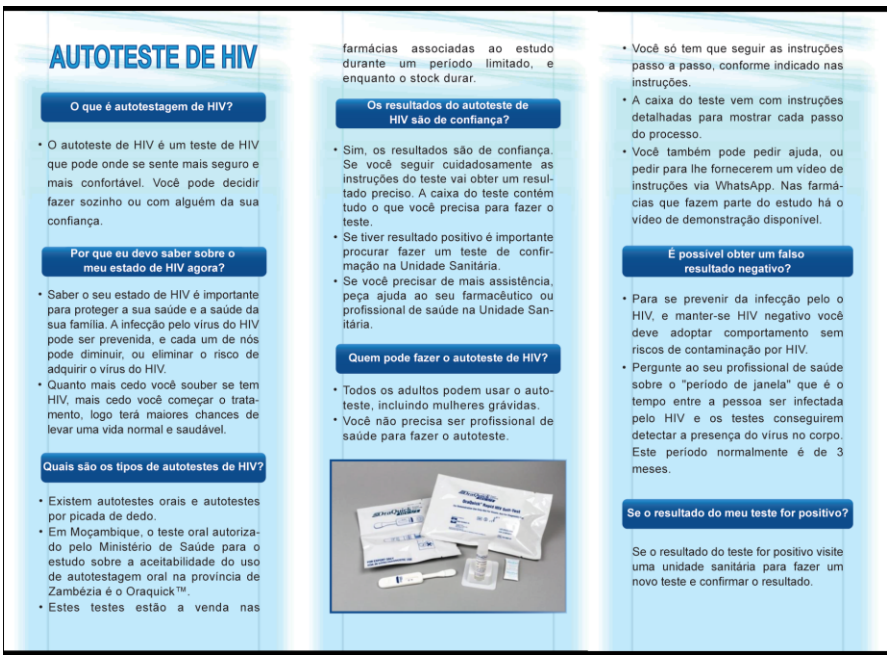
FGH
Friends in Global Health

AUTOTESTE DE HIV

Apenas 50,00 meticais

O TESTE
que posso fazer em qualquer lugar da minha escolha

Folheto informativo



AUTOTESTE DE HIV

O que é autotestagem de HIV?

- O autoteste de HIV é um teste de HIV que pode onde se sente mais seguro e mais confortável. Você pode decidir fazer sozinho ou com alguém da sua confiança.

Por que eu devo saber sobre o meu estado de HIV agora?

- Saber o seu estado de HIV é importante para proteger a sua saúde e a saúde da sua família. A infecção pelo vírus do HIV pode ser prevenida, e cada um de nós pode diminuir, ou eliminar o risco de adquirir o vírus do HIV.
- Quanto mais cedo você souber se tem HIV, mais cedo você começar o tratamento, logo terá maiores chances de levar uma vida normal e saudável.

Quais são os tipos de autotestes de HIV?

- Existem autotestes orais e autotestes por picada de dedo.
- Em Moçambique, o teste oral autorizado pelo Ministério de Saúde para o estudo sobre a aceitabilidade do uso de autotestagem oral na província de Zambézia é o Oraquick™.
- Estes testes estão a venda nas farmácias associadas ao estudo durante um período limitado, e enquanto o stock durar.

Os resultados do autoteste de HIV são de confiança?

- Sim, os resultados são de confiança. Se você seguir cuidadosamente as instruções do teste vai obter um resultado preciso. A caixa do teste contém tudo o que você precisa para fazer o teste.
- Se tiver resultado positivo é importante procurar fazer um teste de confirmação na Unidade Sanitária.
- Se você precisar de mais assistência, peça ajuda ao seu farmacêutico ou profissional de saúde na Unidade Sanitária.

Quem pode fazer o autoteste de HIV?

- Todos os adultos podem usar o autoteste, incluindo mulheres grávidas.
- Você não precisa ser profissional de saúde para fazer o autoteste.

- Você só tem que seguir as instruções passo a passo, conforme indicado nas instruções.
- A caixa do teste vem com instruções detalhadas para mostrar cada passo do processo.
- Você também pode pedir ajuda, ou pedir para lhe fornecerem um vídeo de instruções via WhatsApp. Nas farmácias que fazem parte do estudo há o vídeo de demonstração disponível.

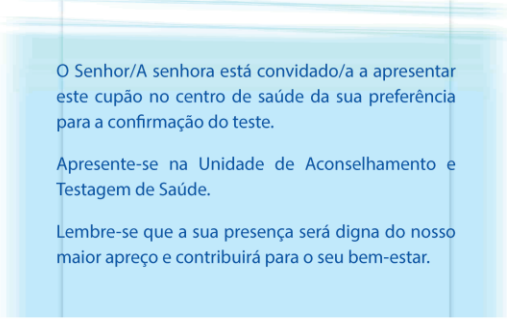
É possível obter um falso resultado negativo?

- Para se prevenir da infecção pelo o HIV, e manter-se HIV negativo você deve adoptar comportamento sem riscos de contaminação por HIV.
- Pergunte ao seu profissional de saúde sobre o "período de janela" que é o tempo entre a pessoa ser infectada pelo HIV e os testes conseguirem detectar a presença do vírus no corpo. Este período normalmente é de 3 meses.

Se o resultado do meu teste for positivo?

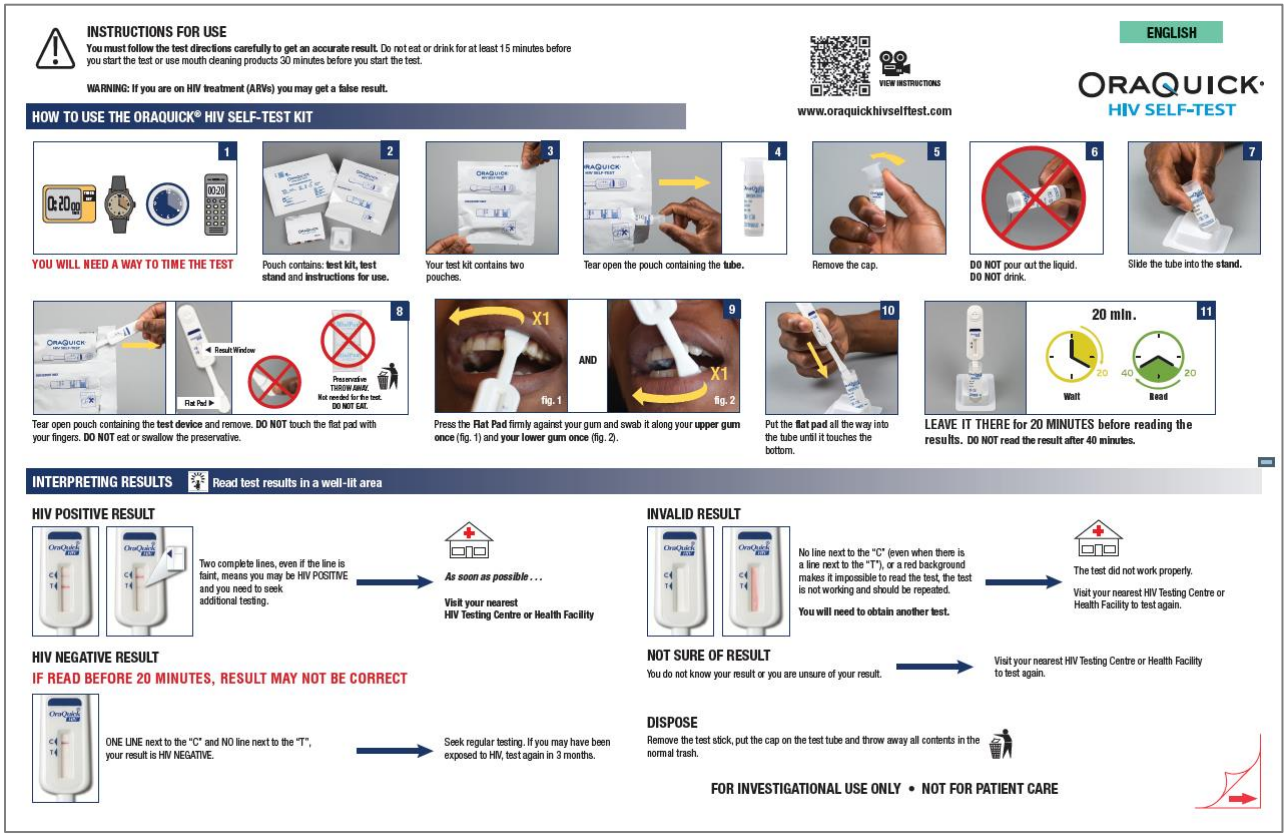
Se o resultado do teste for positivo visite uma unidade sanitária para fazer um novo teste e confirmar o resultado.

3. Reference voucher



4. Booklet (see separate document)

Appendix 4. Instructions of HIV Self-testing procedures and product information as per Manufacturers' manual



PRODUCT INFORMATION

REF 6XA-1000, 6XA-1001, 6XA-2001

For Outside USA Use Only
***In Vitro* Diagnostic Use • Do Not Reuse**

INTENDED USE
The OraQuick® HIV Self-Test is an *in-vitro* diagnostic medical device (IVD) that is used for self-testing of antibodies for HIV-1 and HIV-2 in oral fluid. This test is intended as an aid to detect antibodies to HIV-1 and HIV-2 from infected individuals.

SUMMARY OF THE TEST
The OraQuick® HIV Self-Test is a single-use, qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in oral fluid. The OraQuick® HIV Self-Test is intended for use by lay users as a self-test to aid in the diagnosis of infection with HIV-1 and HIV-2. The device is placed into the mouth, so that the flat pad is between the cheek and the outer gums, then swabbed across the outer gum line. The device is then placed into a tube containing a premeasured amount of solution. Fluid from the surface of the gums enters the device through the flat pad, then flows onto a test strip. As it flows across the strip, a colored line forms in the "T" (test) area of the result window if HIV antibodies are detected. If no HIV antibodies are detected, no line forms there. If the test is performed correctly, a line forms in the "C" area of the result window. This is called the control line.

TEST PERFORMANCE
In a clinical study, 900 people who were unaware of their HIV status were given the OraQuick® HIV Self-Test to use. The results were compared to a 4th generation laboratory test. The laboratory results show that a total of 153 people were HIV positive and 724 people were HIV negative. Seven (7) people were excluded from the study. The comparison of results was as follows:

- 99.4% of people (152 out of 153) correctly reported their result as positive. This means that 1 out of 153 people infected with HIV reported a negative test result. This is called a false negative.
- 99.0% of people (717/724) correctly reported their result as negative. This means that 7 out of 724 people not infected with HIV reported a positive test result. This is called a false positive.
- In addition, only 1.8% of study subjects (16 out of 900) failed to obtain a test result.

KIT CONTENTS

- One pouched kit containing:
  - Divided Pouch (6X4-0064) with single use Test Device, Preservative and a Developer Solution Vial
  - Test Stand
  - Instructions for Use

Materials required but not provided: Clock, watch, or timing device

WARNINGS AND PRECAUTIONS

- Most people feel a little bit nervous when taking an HIV test. But, if you feel very nervous about taking the test, you may want to wait until you are calmer to take it, or get tested by your doctor or local clinic.
- **DO NOT** use the test if you are HIV positive.
- Use with oral fluid only. The test is not for use with blood, serum, breast milk, plasma, semen, urine, vaginal fluid or sweat.
- **DO NOT** eat or drink for at least 15 minutes before starting the test.
- **DO NOT** use mouth cleaning products (such as mouthwash) 30 minutes before starting the test.
- Remove dental products such as dentures or any other products that cover your gums prior to the oral fluid collection.
- If the tamper-evident seal is broken or if any of the package contents are missing, broken, or open, do not use this test.
- If today is after the 'Use By' on the outside of the pouch, do not use this test.
- Individuals must have adequate lighting to read a test result. If two lines are present at areas marked "T" and "C" on the Test Device at any visible intensity, the test result is interpreted as positive.
- **DO NOT** open any of the pouches until you are ready to begin your test.
- **DO NOT** use the test if it has been exposed to household cleaning products (i.e. bleach).
- If you have participated in a HIV vaccine clinical trial, you may get a positive result using this test, but it may not mean that you are infected with HIV. You should seek follow-up with your health facility.
- **DO NOT** use this test if you are age 11 or younger.

STORAGE
2 °C – 30 °C

- Store and perform this test in a cool area.
- **DO NOT** use this test if it has been stored outside the acceptable temperature of 2°-30° C (36°-86° F).
- This test should be performed at temperatures in the range of 15°-37° C (59°-99° F).

LIMITATIONS OF THE TEST

- The OraQuick® HIV Self-Test kit instructions for use must be followed carefully to get an accurate result.
- If you are on HIV treatment (ARVs) you may get a false result.
- If you are HBV, HCV or HTLV (I/II) positive, you may get a false result.
- Oral bleeding may result in an invalid result. If the test result is invalid, visit your nearest testing center or healthcare facility.
- Clinical data has not been collected to demonstrate the performance of OraQuick® HIV Self-Test in individuals that are undergoing PrEP.
- The OraQuick® HIV Self-Test may not detect HIV infections that have occurred within the last 3 months.
- For a positive result, the intensity of the test line does not necessarily equal the amount of antibody in the specimen.
- Positive results should be verified using another test performed by a trained professional to confirm an HIV diagnosis.

QUESTIONS & ANSWERS

1. ***What does the test do?***
   The OraQuick® HIV Self-Test is an in-vitro diagnostic self-test for HIV (HIV-1 and HIV-2) in oral fluid. The test works by detecting your body's natural antibodies that help you fight infection. A positive result is preliminary and additional testing at a health facility is required to confirm the result as true.
2. ***What is a 'risk event' for HIV?***
   A risk event is defined by any of the below activities:
   - Sex (vaginal, oral or anal) with multiple sex partners
   - Sex with someone who is HIV positive or whose HIV status you don't know
   - Sex between a man and another man
   - Using illegal injected drugs or steroids
   - Shared needles or syringes
   - Exchanged sex for money
   - Having been diagnosed or treated for hepatitis, tuberculosis or a sexually transmitted disease like syphilis
3. ***How soon after a risk event can I test myself?***
   You can test any time, if you are using this test earlier than 3 months since a risk event and your test is negative, your result may not be accurate. You should test again 3 months after the risk event to be sure. You can also be tested at a health facility.
4. ***Why shouldn't I use this test right after a risk event?***
   When you have been infected with the HIV virus, your body tries to fight the HIV virus by producing natural antibodies. These antibodies can be found in your oral fluid. It takes your body up to 3 months to make these antibodies at levels that can be detected by this test.
5. ***How accurate is the test?***
   In a clinical study, 900 people who were unaware of their HIV status were given the OraQuick® HIV Self-Test to use. The results were compared to a 4th generation laboratory test. The laboratory results show that a total of 153 people were HIV positive and 724 people were HIV negative. Seven (7) people were excluded from the study. The comparison of results was as follows:
   - 99.4% of people (152 out of 153) correctly reported their result as positive. This means that 1 out of 153 people infected with HIV reported a negative test result. This is called a false negative.
   - 99.0% of people (717/724) correctly reported their result as negative. This means that 7 out of 724 people not infected with HIV reported a positive test result. This is called a false positive.
   - In addition, only 1.8% of study subjects (16 out of 900) failed to obtain a test result.
6. ***Can I get HIV by using this test?***
   This test does not contain any materials or HIV virus that can cause HIV infection.
7. ***How often should someone test for HIV?***
   If you have never been tested for HIV, you should be tested at least once. If you do things (risk events) that can result in HIV infection you should be tested at least once per year (World Health Organization recommendation). **If you feel you are at increased risk for being infected with HIV, you should test regularly.**
8. ***What does a negative result mean?***
   A negative result means that the test has not detected any antibodies; however, it may take up to 3 months from a risk event for the test to detect HIV. If it has been **at least 3 months** since you had a risk event and you followed the instructions for use carefully, you likely do not have HIV. If it has been less than **3 months** since you had a risk event, **wait the full 3 months** since the risk event to take the test or go to your health facility.
9. ***What should I do if I get a negative result?***
   If you have not had any risk events within the past **3 months**, and you followed the instructions for use carefully, then you are most likely HIV negative. If you did not follow the instructions for use carefully, you should take the test again to be sure your result is correct. If you had any risk events in the past **3 months**, you could be in the 'window period'. The window period is when a person has been infected with HIV, but their body has not made antibodies yet. **If you think you may have been exposed to HIV within the past 3 months**, you should retest for HIV **3 months** following any risk event. If you continue to engage in risk events that could put you at risk for HIV, you should test on a regular basis.
10. ***What does a positive result mean?***
    A positive result means that you may have HIV. **Additional testing must be conducted at a health facility to confirm the result.**
11. ***What should I do if I get a positive result?***
    You need to follow up with a health facility to get additional testing to confirm the result. At that time your local clinic, doctor, or healthcare professional will discuss the next steps that need to be taken.
12. ***Can I get an Incorrect 'false' negative result with this test?***
    An Incorrect 'false' negative result can occur for any of the following reasons:
    - If you had a risk event less than 3 months prior to taking the test
    - Incorrectly reading test result as negative
    - Not following the instructions for use carefully
    - If you wore dental products such as dentures or any other products that cover your gums while swabbing your gums
    - If you are taking an oral PrEP regimen or if you are on HIV treatment (ARV)
13. ***Can I get an Incorrect 'false' positive result with this test?***
    An Incorrect or 'false' positive result can occur for any of the following reasons:
    - Incorrectly reading test result as positive
    - Not following the instructions for use carefully
    - Not waiting 15 minutes after eating, drinking, or 30 minutes after using oral care products before taking the test
    - Having received an HIV vaccine
    - Swiping each gum several times during oral collection
14. ***Where can I get additional help or care for HIV?***
    You can get additional help through a local clinic, doctor, or healthcare professional.
15. ***Can I use this test if I am taking medicine to prevent HIV (oral PrEP)?***
    If you are taking oral PrEP for HIV, you may get false result.
16. ***How can I tell if my test is working correctly?***
    If your test is working correctly you will see a line next to the "C" on your test device. If there is no line next to the "C" your test did not work.
17. ***Can I use this test if I am pregnant?***
    Yes, if you are pregnant you can test at anytime.

INTERFERING SUBSTANCES AND UNRELATED MEDICAL CONDITIONS
As part of the oral fluid clinical studies, information was collected from the participants regarding concurrent diseases or medical conditions, oral pathologies, non-HIV viral infections, and other factors (e.g., use of tobacco products, mouthwash within 24 hours of testing, concomitant medications, dental fixtures, and food or drink immediately prior to testing). In a separate study of 40 individuals, consumption of alcohol, brushing of teeth, use of mouthwash or smoking tobacco 5 minutes prior to testing, were shown to have no effect on test specificity. **If you are HBV, HCV or HTLV (I/II) positive, you may get a false result.** It is recommended that users observe a 15 minute wait period after food and drink and a 30-minute wait period after using oral care products.

EXPLANATION OF SYMBOLS

LOT Batch Code	REF Catalog Number	Caution, Consult Accompanying Documents	Consult Instructions for Use
Do Not Reuse	IVD *In Vitro* Diagnostic Medical Device	Manufacturer	EXP Date of Expiration
Temperature Limitation	Use By		DOM Date of Manufacturing

Manufactured in Thailand for

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