Evaluation of the impact of lay counselor-led intensified HIV risk screening on the coverage and yield of HIV testing services as well as ART initiation and retention in care rates

FINAL REPORT

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**at the time of the evaluation*

Contents

Abstract

Introduction

To optimize the scale-up of routine opt-out and efficient HIV testing services (HTS) in high-yield geographic settings in order to maximize the identification of remaining undiagnosed persons living with HIV (PLHIV) coupled with their timely linkage to antiretroviral therapy (ART) services, FGH initiated an innovative strategy to improve provider-initiated counseling and testing (PITC) using Mozambique Ministry of Health (MOH)-approved HIV risk-based screening algorithms. Activities include intensified/focused HIV counseling and testing, HIV risk-based behavior assessment, the screening of clinical signs and symptoms of acute or chronic infection, as well as the in-depth evaluation of HIV exposure to assess the risk of recent/acute HIV infection within specific PITC service delivery points. The intervention was piloted in 18 health facilities within Zambézia Province. The overarching aim of this evaluation was to evaluate the effect of lay counselor-led intensified HIV risk-based screening on the coverage and yield (i.e., identification of new positives) of HIV testing services as well as ART initiation and retention in care rates among persons testing HIV-positive.

Methods

We performed an internal outcomes evaluation, in which programmatic data were analyzed, for 22 health facilities in 12 FGH-supported districts. Trends analysis comparing pre-intervention (6 months before) with intervention period (6 months after), was done using regression models (mixed-effect logistic model) that allow for adjusting for covariates (such as urban/rural, patient volume) that may be related to uptake, while considering similarities between health facilities and districts. Aggregated data from PITC services and individual patient-level data of patients enrolled in care in the evaluation period were used for the analyses.

Results

Aggregate data for 115,782 HIV counseling and testing sessions were evaluated in the 22 supported health facilities, with 101,478 being included in the final trend analyses. Of those, 55% of HIV testing and counseling sessions involved females, with the majority (78%) being offered to reproductive-aged adults (20-49 years of age). The intervention had an immediate positive impact on the number of tests performed: immediately after intervention initiation (level change), there were on average an increase of 46 (95% CI: 21-71; $p<0.001$) tests performed in the 20-49 age group. This effect was sustained over time (slope change): on average 17 (95% CI: 12-22; $p<0.001$) additional HIV tests were performed monthly in this age group, compared to the counterfactual scenario of no intervention. Similar results were seen in the other age groups. The number of positive tests among the patients in the 20-49 age-group was higher post-intervention: on average, an immediate increase of 5 (95% CI:1-9; $p=0.008$) additional positive tests per month were observed. Overall, we did not detect an impact of the intervention on the HIV positivity rate.

Among patients enrolled in HIV care, no differences in retention in care was seen before and after initiation of the strategy. Differences were seen between the different health facilities.

Conclusions

The intervention implemented in the selected health facilities contributed to an increase in the number of persons tested at the high-risk entry points. Although the positivity rate did not increase, the intervention resulted in more newly identified patients, especially younger patients, significantly contributing to progress made towards the first UNAIDS 95-95-95 target.

1. Project Background

In light of the lofty HIV performance UNAIDS 90-90-90 targets (by 2020) and now their new fast track 95:95:95 (by 2030) goals, the most critical step in the HIV cascade includes achieving 95% of people living with HIV (PLHIV) knowing their status, which will become increasingly difficult with program expansion and maturation. As a result, novel strategies for the identification of persons with unknown status are urgently needed.

In Mozambique, more than 9.8 million people were tested for HIV during 2021 [1]. The overall HIV seropositivity rate among those tested was 4.1%. When looking at this large number of persons undergoing HIV testing services (HTS), 8% received HTS within a voluntary counseling and testing (VCT) context, 47% within maternal and child health (MCH) services, 39% as provider-initiated testing and counseling (PITC) (including all PITC service delivery points excluding MCH which is categorized separately), and 6% as part of community-based HIV testing initiatives.

The number of people tested for HIV has increased by approximately 41% per year since 2016, with approximately 84% of PLHIV knowing their serostatus by the end of 2021 [1]. The more recent national HIV survey showed that 72% of all 15+ years old PLHIV knew their HIV status [2].

Despite a large percentage of testing being performed within PITC services, the positivity rate has been low and decreasing over the years (**Figure 1**).

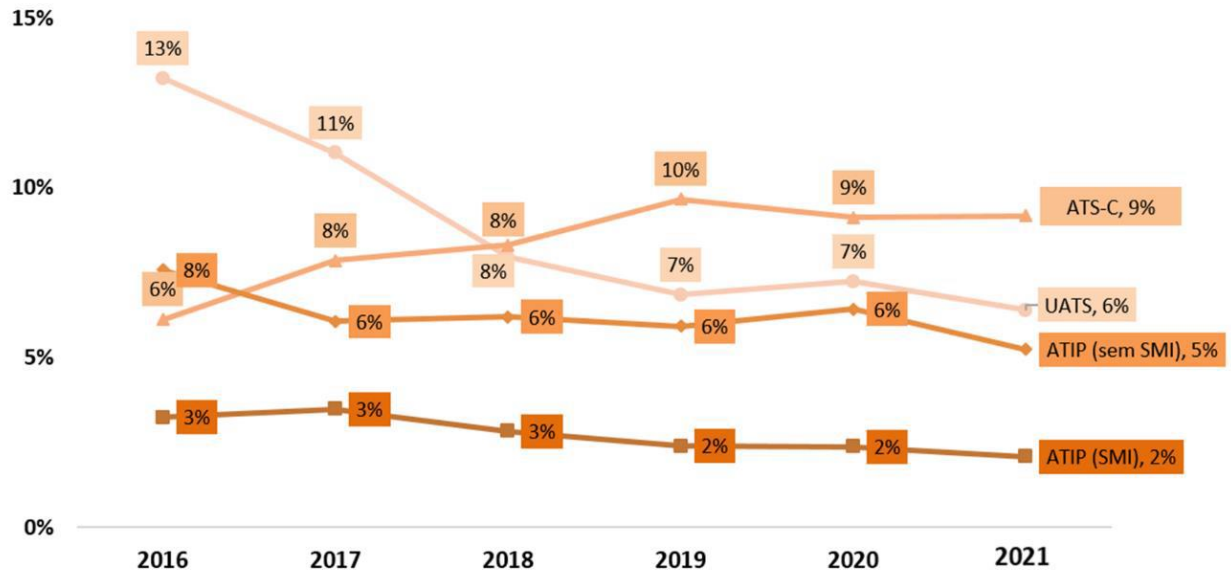


Figure 1. HIV positivity rate in Mozambique, 2014-2021. (Source: MOH Annual report HIV/SIDA 2021).

Friends in Global Health (FGH), a wholly owned subsidiary of Vanderbilt University Medical Center (VUMC), has been operating in Zambézia Province since 2006.

However, with a larger and larger number of supported health facilities (HF) in districts with varying HIV disease burden (i.e., a wide range of population densities and HIV prevalence), there is a significant need to more efficiently provide HTS in the highest yield geographic settings as well as higher yield HTS service delivery points in order to optimize the identification of new HIV-positive individuals.

Currently, approximately 31% of the persons undergoing HIV counseling and testing originate from the emergency ward and outpatient clinic (FGH, Program Data, Power BI, FY2022).

To improve the scale up of routine opt-out and efficient HIV counseling and testing in high-yield geographic settings and in order to maximize identification of remaining undiagnosed PLHIV coupled with their timely linkage to ART services, FGH initiated a novel strategy to improve the PITC using Mozambique Ministry of Health (MOH)-approved differentiated service delivery (DSD) models. Activities include intensified/focused HIV counseling and testing, HIV risk-based behavior assessment, the screening for clinical signs and symptoms suggestive of underlying acute and chronic HIV infection, as well as the in-depth evaluation of HIV exposure to assess the risk of recent/acute HIV infection within specific PITC service delivery points (using approved MOH job aids; **Appendix 1**) (e.g., emergency ward and outpatient clinic).

Program description:

1. When patients attend one of the service delivery points (i.e., emergency ward or outpatient clinic), a dedicated lay counselor will offer HIV counseling and testing to each individual patient, including intensified/focused HIV counseling and testing based on HIV risk-based behavior assessment, the screening for clinical signs and symptoms acute and chronic HIV infection, as well as the in-depth evaluation of HIV exposure to assess the risk of recent/acute HIV infection (using approved MOH job aids);
2. Following the results of the screening and risk evaluations, HIV counseling and testing will be offered by the lay counselor for each eligible patient;
3. When a screened patient tests HIV-positive, the patient will be enrolled into HIV care (opening the master card, including unique patient identification number [NID] attribution) services and referred to the clinician for additional clinical follow-up including ART initiation.

The overarching aim of this evaluation is to evaluate the effect of lay counselor-led intensified HIV risk-related behavior assessment on the coverage and yield (i.e., identification of new

positives) of HIV test services as well as ART initiation and retention in care rates among persons testing HIV-positive via this novel approach.

The hypothesis is that by adopting lay counselor-led intensified HIV risk-based screening (previously led only by clinicians), the coverage of counseling and testing will increase, the yield in terms of numbers of new HIV-positive individuals being identified via this intervention will increase, and persons accessing HIV services via this approach (those testing positive) will have comparable (non-inferior) rates of timely ART initiation and early retention in care outcomes.

2. Evaluation Purpose and Questions

The primary objective of the evaluation is to evaluate, using a pre-post study design, the effect of lay counselor-led intensified HIV risk screening (within emergency room and outpatient clinic settings) on the coverage and yield (i.e., identification of new positives) of HIV test services as well as ART initiation and retention in care among persons testing HIV-positive via this novel approach.

Specific objectives:

1. Compare trends in the number of HIV counseling and testing sessions at the PITC entry points (emergency room and adult outpatient services), before and after initiation of the intervention;
2. Compare trends in the yield (i.e., test positivity yield) at the PITC entry points (emergency room and adult outpatient services), before and after initiation of the intervention;
3. Compare ART initiation rates among patients newly testing HIV-positive via this intervention (in emergency room and outpatient clinic settings), before and after initiation of the intervention;
4. Compare early retention (i.e., 1- and 3-month retention) in HIV care trends among patients newly testing HIV-positive via this intervention (in emergency room and outpatient clinic settings), before and after initiation of the intervention.

3. Evaluation Design/ Methods/ Limitations

1. *Evaluation type*

We conducted an internal outcomes evaluation, in which programmatic data were analyzed to evaluate the outcomes of interest.

2. *Evaluation design*

To meet the above objectives and assess the effect of this intervention, our team conducted an internal outcome evaluation, in which routine process measures were used to evaluate the outcomes. We performed a trend analysis over time (from March 21st, 2019 to April 20th, 2021) evaluating the effect of the intervention (pre-post analysis), with the intervention being implemented in select FGH/VUMC-supported HF as per **Table 1**.

Definitions used:

- HIV positivity = number of positive HIV test results among those tested, in the same period
- One-month retention = return for ART pick-up within 33 days post-ART initiation
- Three-month retention = having three ART pick-ups within a period of 99 days

The evaluation was conducted in 22 HF (18 HF with intervention; 4 without). The health facilities will be stratified into three groups, depending on the number of HIV positive tests in the pre-intervention period (e.g., <200, 200-400, >400 positive tests results, or "small", "medium", "large" size HF, respectively) (**Table 1**).

Table 1. FGH/VUMC-supported health facilities initially selected for inclusion in the evaluation.

District	Health Facility	Number of HIV-positive persons identified during 6-months before implementation	Size	Intervention initiation date at time of the evaluation
Intervention sites				
Quelimane	HF Icidua	49	small	August 21st, 2019
Quelimane	HF Micajune	72	small	August 21st, 2019
Quelimane	HF Maquival Sede	45	small	August 21st, 2019
Quelimane	HF Namuinho	93	small	August 21st, 2019
Inhassunge	HF Inhassunge	108	small	August 21st, 2019
Pebane	HF 7 de Abril	96	small	August 21st, 2019
Quelimane	HF Chabeco	101	small	August 21st, 2019
Quelimane	HF 4 de Dezembro	104	small	August 21st, 2019
Mocuba	HF Mocuba	146	small	August 21st, 2019
Nicoadala	HF Licuare	122	small	August 21st, 2019
Pebane	HF Pebane	157	small	August 21st, 2019
Milange	HF Milange	217	medium	August 21st, 2019
Quelimane	HF 24 de Julho	197	small	August 21st, 2019
Quelimane	HF 17 de Setembro	265	medium	August 21st, 2019
Maganja da Costa	HF Maganja da Costa	293	medium	August 21st, 2019
Nicoadala	HF Nicoadala	300	medium	August 21st, 2019
Namacurra	HF Namacurra	535	large	August 21st, 2019
Quelimane	HF Coalane	208	medium	August 21st, 2019

Comparison sites				
Mopeia	HF Mopeia	52	small	(not yet initiated)
Morrumbala	HF Morrumbala	116	small	(not yet initiated)
Gurue	HF Gurue	124	small	(not yet initiated)
Alto Molócuè	Rural Hospital Alto Molócuè	137	small	(not yet initiated)

3. *Sampling strategy*

Health facility-level programmatic data available from the FGH-DHIS2 database on HIV testing and HIV test results were included in the analysis. Routinely collected, de-identified data were also extracted from the electronic patient database OpenMRS for the evaluation on access to ART services and retention rates.

Indicators used to measure the objectives:

1. Compare trends in number of people counseled and tested for HIV at the PITC entry points (emergency room and adult outpatient services), before and after initiation of the approach:
    - Number of patients counseled and tested for HIV at emergency wards and adult outpatient services, by HF
2. Compare trends in yield (i.e., test positivity yield) at the PITC entry points (emergency wards and adult outpatient services), before and after initiation of the approach:
    - Number of patients counseled and tested, by HF and by entry point
    - Number of patients with HIV-positive result, by HF and by entry point
3. Compare initiation of ART rates among patients newly testing HIV-positive via this approach (in emergency wards and outpatient clinic settings), before and after initiation of the approach:
    - Number of patients enrolled in HIV care services, by HF
    - Number of patients initiating ART, by HF
4. Compare early retention in HIV care trends (i.e., 1- and 3-month retention) among patients newly testing HIV-positive via this approach (in emergency wards and outpatient clinic settings), before and after initiation of the approach:
    - Number of patients initiating ART, by HF
    - Number of patients initiating ART who had a pick-up within 33 days, by HF
    - Number of patients initiating ART who had three pick-ups within the 99 days after ART initiation, by HF.

4. *Methods*

We included data from all patients (children and adults of all ages) who attended HTC services at emergency ward and adult outpatient clinic settings, from the period March 21st, 2019 to April 20th, 2021, and data from patients registered in HIV care at PITC services from the period March 21st, 2019 to April 20th, 2021.

5. *Analysis plan*

Frequency tables and trend plots were used to explore and summarize the data. We used an interrupted time series model to estimate the effect of the intervention on the following outcomes: total number of tests performed, number of positive tests, positivity rate, and number of patients enrolled in care. We used linear (total number of tests and positive tests) and logistic (positivity rate) mixed-effects models, with districts set as random effects. All regressions adjusted for baselined variables that could be related to uptake. The pre-intervention period was defined as March 21st, 2019 - August 20th, 2019. The post-period was defined as the period August 21st, 2019 - April 20th, 2020.

The R statistical software supported the quantitative analysis [3].

6. *Limitations of design*

It was originally planned to evaluate the coverage of HIV counseling and testing (i.e., the proportion of those tested among all health facility clients), however, due to lack of available data on the number of patients attended at emergency rooms and adult outpatient services, it was not possible to determine the proportion of those tested among health facility clients. Therefore, we instead have analyzed the trend of absolute number for this indicator.

As routine programmatic data were used, these results/findings are subject to the quality and completeness of data registry and entry into the electronic patient tracking system (i.e., OpenMRS).

Additionally, as datasets for uptake and yield of HIV testing and for uptake and retention to ART are different, interpretation is challenging. Therefore, the report is focused on the main objective of the pilot implementation (Objectives 1-2) and other results (Objectives 3-4) were added as additional information in appendices (below, Appendices 8-9).

It was not possible to perform the difference-in-difference analysis, as the parallel assumption was not met for this analysis. That is, the average number of tests performed before the intervention among sites that received the intervention did not follow the same trend as the average number of tests obtained from comparison sites (i.e., the four sites that did not receive the intervention during the evaluation period). The two lines (average number of tests) were far from a parallel line, limiting any conclusions that could be drawn from a difference-in-difference analysis. Thus, to

avoid making incorrect causal conclusions, we preferred to refrain from reporting on the difference-in-difference analysis, focusing rather on the pre- and post-analysis restricted to HF sites that received the intervention.

7. *Ethical considerations*

This secondary data analysis is covered under the approved blanket protocol for program evaluations, titled "*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 data use and evaluation plan were approved the VUMC Institutional Review Board (IRB) (#201887), the Institutional Research Ethics Committee for Health of Zambézia Province (*Comité Institucional de Bioética para Saúde – Zambézia*; 01/CIBS-Z/22), and was reviewed in accordance with the U.S. 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 data included in this analysis were de-identified programmatic data and aggregated data. The electronic databases outlined in the *Methods* section were stored on password-protected and encrypted servers at FGH offices. De-identified data were extracted from these secure databases and sent via secure file transfer to relevant key FGH and VUMC personnel (i.e., the biostatisticians) to conduct analyses.

8. *Stakeholder engagement*

FGH technical teams have ongoing collaborations with key stakeholders working in the health facilities and the surrounding communities in which we are supporting and engaged. The concept note and evaluation plan for this secondary data analysis evaluation was elaborated with support from the provincial- and district-level authorities, and approved by the sponsoring institution CDC-Mozambique.

9. *Deviations from Scope of Work (SOW)/protocol*

There was no significant deviation from the proposed concept note for this evaluation. However, as detailed in the *Limitations* section above, there was one intended outcome that we were unable to evaluate for in these analyses.

10. *Data quality assurance*

Programmatic data used in this evaluation were subject to routine data verification processes conducted by trained members of FGH's Monitoring and Evaluation (M&E) team. All data were stored securely on password-protected databases at district- and provincial level FGH offices. The performance of the program indicators was continuously monitored by HF staff. All subsequent indicators were collected and internally reported on a monthly frequency by the FGH Health Information Systems (HIS) team, following the regular reporting period for program data.

Upon receipt of the requested extracted dataset for this evaluation/analysis, data were cleaned and reviewed to ensure they were consistent and appropriate with the evaluation inclusion and exclusion criteria.

4. Findings

4.1. Demographics

Aggregate data for 115,782 HIV testing and counseling testing sessions were evaluated in the 22 supported health facilities, with 101,478 being included in the final trend analyses. Of those, 55% of HIV testing and counseling sessions involved females, with the majority (78%) being offered to reproductive-aged adults (20-49 years of age) (**Table 2**).

Table 2. Sociodemographic characteristics of clients attended at the selected health facilities (emergency room and adult outpatient clinic settings) (n=115782).

Variable	**N (%)**	**Before intervention N (%)**	**After intervention N (%)**	**No intervention N(%)**
Sex				
Female	63699 (55%)	19103 (55%)	36864 (55%)	7732 (54%)
Male	52083 (45%)	15854 (45%)	29666 (45%)	6563 (46%)
Age Group (years)				
15-19	16905 (15%)	4902 (14%)	9833 (15%)	2170 (15%)
20-49	90804 (78%)	27610 (79%)	52243 (79%)	10951 (77%)
50+	8073 (7%)	2445 (7%)	4454 (7%)	1174 (18%)
Health Facility				
Intervention				
17 de Setembro	9801 (10%)	3278 (9%)	6523 (10%)	-
24 de Julho	9522 (9%)	3616 (10%)	5906 (9%)	-
4 de Dezembro	2498 (2%)	756 (2%)	1742 (3%)	-
7 de Abril	2161 (2%)	727 (2%)	1434 (2%)	-
Chabeco	3413 (3%)	829 (2%)	2584 (4%)	-

Coalane	9104 (9%)	3374 (10%)	5730 (9%)	-
Icidua	2922 (3%)	471 (1%)	2451 (4%)	-
Inhassunge	4137 (4%)	1117 (3%)	3020 (5%)	-
Licuare	4002 (4%)	1262 (4%)	2740 (4%)	-
Maganja da Costa	9328 (9%)	4148 (12%)	5180 (8%)	-
Maquival Sede	4233 (4%)	824 (2%)	3409 (5%)	-
Mijacune	2683 (3%)	1103 (3%)	1580 (2%)	-
Milange	8637 (9%)	3618 (10%)	5019 (8%)	-
Mocuba	4455 (4%)	1804 (5%)	2651 (4%)	-
Namacurra	10310 (10%)	3868 (11%)	6442 (10%)	-
Namuinho	3502 (3%)	1176 (3%)	2326 (3%)	-
Nicoadala	6360 (6%)	1658 (5%)	4702 (7%)	-
Pebane	4419 (4%)	1328 (4%)	3091 (5%)	-
Non-intervention				
Alto Molócuè	4128 (3%)	-	-	4128 (29%)
Gurue	6322 (5%)	-	-	6322 (44%)
Mopeia	1621 (1%)	-	-	1621 (11%)
Morrumbala	2224 (2%)	-	-	2224 (16%)

4.2. Compare trends in number of people counseled and tested for HIV at the PITC entry points (emergency ward and adult outpatient services)

Table 3 shows the point estimate and respective 95% confidence intervals for the association between intervention and all three outcomes: number of tests, number of positive test results, and positivity rate. The results are displayed for the overall population as well as disaggregated by age groups. The variable *Intervention* is a binary variable taking the value 1 if the intervention had begun or 0 otherwise, and the variable *Calendar time* are the months before and after intervention and it was modelled as a numerical variable, varying from -6 to +6 (t months before and after intervention). All analyses adjust for sex and the overall analysis, which considers all patients from all health facilities, and also adjusts for age groups plus the interactions between calendar time and intervention (variable *Calendar time : Intervention*), calendar time and age groups (*Calendar time : 20-49 years* and *Calendar time : 50+ years*), and intervention and age groups (*Intervention : 20-49 years* and *Intervention : 50+ years*). The variables of interest are *Intervention*, which shows the immediately effect of the intervention on the outcomes (level change), and in the interaction between *Calendar time and Intervention* (*Calendar time : Intervention*), which shows the sustained increase in the number of tests or positivity.

The intervention had a positive impact on the number of tests performed: immediately after the intervention began (level change), there was an average increase of 10.68 (95% CI: 2.93-18.43; p=0.007), 46.23 (95% CI: 21.26-71.20; p<0.001), and 4.69 (95% CI: -0.26-9.64; p=0.063) tests performed for the different age groups of 15-19 years, 20-49 years and 50+ years, respectively. This increase was sustained over time for each age group, as shown by the positive slopes after the

intervention in **Figure 2** and **Table 3**. Differences were seen between the health facilities (**Appendix 8**).

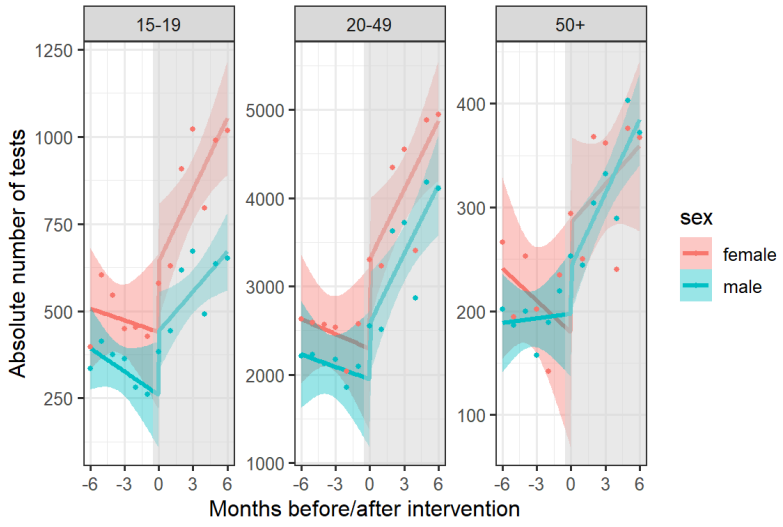


Figure 2. Number of HIV tests done at emergency ward and adult outpatient clinic (2018-2021), by age group and by sex (all health facilities combined).

Table 3. Regression analysis of number of HIV tests done, number of HIV-positive test results received and positivity rate, before and after initiation of intervention (all health facilities combined).

Variables	**Number of tests**		**Number of positive test results**		**Positivity rate**	
	Estimates (95% CI)	p-value	Estimates (95% CI)	p-value	OR (95% CI)	p-value
Overall						
(Intercept)	345.0 (31.3-658.7)	**0.03**	2.6 (-25.3 – 30.5)	0.85	0.04 (0.0 – 105)	**<0.001**
Calendar time	- 56.4 (-130.4-17.6)	0.13	-5.1 (-11.7 – 1.5)	0.13	0.96 (0.9 – 1.1)	0.09
Intervention	256.7 (-197.6-711.0)	0.26	17.6 (-22.8 – 58.1)	0.39	1.18 (0.8 – 1.7)	0.36
Age group:						
15-19 years	Ref		Ref		Ref	
20-49 years	2289.9 (1913.4-2666.4)	**<0.001**	233.7 (200.1 – 267.2)	**<0.001**	2.6 (2.1 – 3.3)	**<0.001**
50+ years	-264.6 (-641.1-111.9)	0.17	7.1 (-26.4 – 40.7)	0.67	3.03 (2.23 – 4.1)	**<0.001**
Sex [male]	-267.9 (-397.0- -138.7)	**<0.001**	-3 (-14.5 – 8.5)	0.60	1.2 (1.2 – 1.3)	**<0.001**
Calendar time : intervention	134.6 (63.6-205.5)	**<0.001**	7.5 (1.2– 13.8)	**0.02**	0.97 (0.9 – 1.0)	**0.01**
Calendar time : 15-19 years	Ref		Ref		Ref	
Calendar time : 20-49 years	113.6 (29.0-198.1)	**0.009**	9.4 (1.9 – 17.0)	**0.02**	1.05 (1.0 – 1.1)	**0.03**
Calendar time : 50+ years	-17.1 (-101.7-67.4)	0.69	1.6 (-5.9 – 9.1)	0.68	1.08 (1.0 – 1.2)	**0.01**
Intervention: 15-19 years	Ref		Ref		Ref	
Intervention : 20-49 years	398.7 (-235.9-1033.2)	0.21	59.4 (2.9 – 115.9)	**0.04**	0.87 (0.6 – 1.3)	0.44
Intervention : 50+ years	-68.3 (-702.9-566.3)	0.83	-10.9 (-67.4 – 45.6)	0.70	0.61 (0.4 – 1.0)	**0.05**
Age group 15-19 years						
(Intercept)	25.6 (18.0-33.3)	**<0.001**	1.6 (1.0 – 2.17)	**<0.001**	0.06 (0.0 – 0.1)	**<0.001**

Calendar time	-0.93 (-2.2-0.95)	0.33	-0.06 (-0.2 – 0.1)	0.34	0.97 (0.9 – 1.1)	0.49
Intervention	10.7 (1.6-19.7)	**0.02**	0.6 (0.01 – 1.2)	**0.047**	1.2 (0.8 – 1.7)	0.46
Sex [male]	-12.4 (-16.7- -8.0)	**<0.001**	-1.4 (-1.7 – -1.1)	**<0.001**	0.39 (0.3 – 0.5)	**<0.001**
Calendar time : Intervention	3.9 (1.5-6.3)	**0.001**	0.06 (-0.1 – 0.22)	0.49	0.94 (0.9 – 1.0)	0.22
Age group 20-49 years						
(Intercept)	133.51 (100.0-167.0)	**<0.001**	10.92 (7.0 – 14.9)	**<0.001**	0.09 (0.1 – 0.1)	**<0.001**
Calendar time	-2.87 (-11.1-5.4)	0.50	-0.25 (-1.2 – 0.7)	0.61	1 (1.0 – 1.0)	0.87
Intervention	46.23 (6.5 – 86.0)	**0.02**	5.08 (0.4 – 9.8)	**0.03**	1.04 (0.9 – 1.7)	0.45
Sex [male]	-31.42 (-50.6- -12.3)	**0.001**	0.8 (-1.4 – 3.1)	0.48	1.3 (1.2 – 1.4)	**<0.001**
Calendar time : Intervention	17.29 (6.8-27.8)	**0.001**	1.22 (-0.0 – 2.5)	0.05	0.98 (1.0 – 1.0)	0.08
Age group 50+ years						
(Intercept)	10.38 (6.7 – 14.1)	**<0.001**	1.3 (0.8 – 1.8)	**<0.001**	0.14 (0.10 – 0.19)	**<0.001**
Calendar time	-0.55 (-1.5-0.4)	0.24	0.05 (-0.1 – 0.2)	0.42	1.1 (1.02 – 1.18)	**0.02**
Intervention	5.18 (0.75 – 9.61)	**0.022**	0.02 (-0.56 – 0.59)	0.954	0.65 (0.46 – 0.92)	**0.015**
Sex [male]	- 0.82 (-2.96-1.33)	0.454	0.14 (-0.14 – 0.42)	0.33	1.19 (1.00 – 1.40)	**0.044**
Calendar time : Intervention	1.46 (0.28 – 2.64)	**0.016**	-0.01 (-0.16 – 0.15)	0.948	0.89 (0.81 – 0.98)	**0.014**

Note: *Calendar time*, number of months before/after intervention; *Intervention*, binary variable indicating whether intervention had begun, *Variable A* : *Variable B*, notation to describe the interaction between variables A and B.

4.3. Compare trends in number of people with a positive HIV test result at the PITC entry points (emergency ward and adult outpatient services)

The number of positive test results were positively associated with the intervention in the younger age groups. When the intervention started, on average 0.62 (95% CI: 0.01-1.23; p=0.047) and 5.08 (95% CI: 0.41-9.75; p=0.033) more tests came back positive compared to the previous (pre-intervention) period, for the 15-19 years and 20-49 years age groups, respectively. This increased number of positive tests results, however, was not sustained over time, at 5% level of significance (**Figure 3, Table 3**).

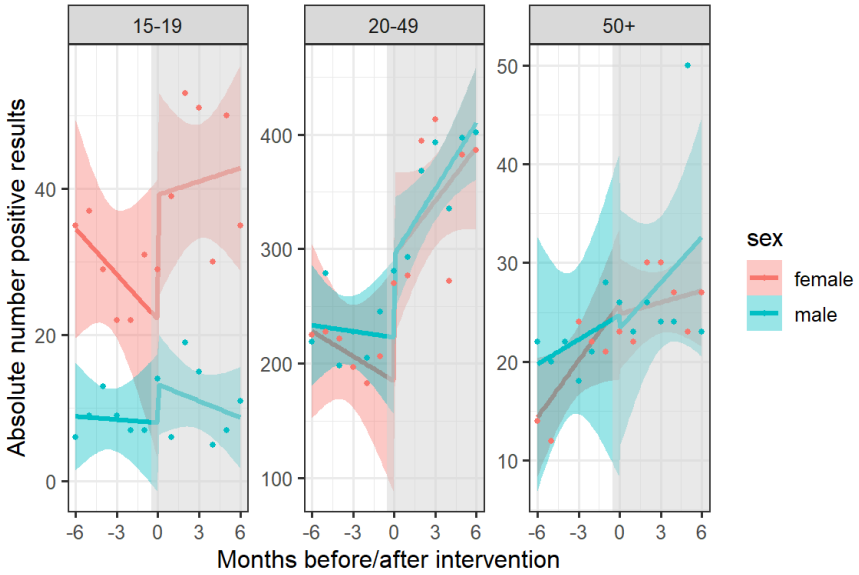


Figure 3. Trends in number of positive test results, by sex and age group (all health facilities combined).

4.4. Compare trends in yield (i.e., test positivity yield) at the PITC entry points (emergency ward and adult outpatient services)

Overall, when looking at all health facilities combined, the intervention had a slightly negative impact on the proportion of tests that returned positive. For the three different age groups, the odds of having a positive test result were 1.15 (95% CI: 0.79-1.70; p=0.461), 1.04 (0.94 – 1.16; p=0.447), and 0.65 (0.46 – 0.92; p=0.015), respectively, after the intervention started (**Figure 4, Table 3**).

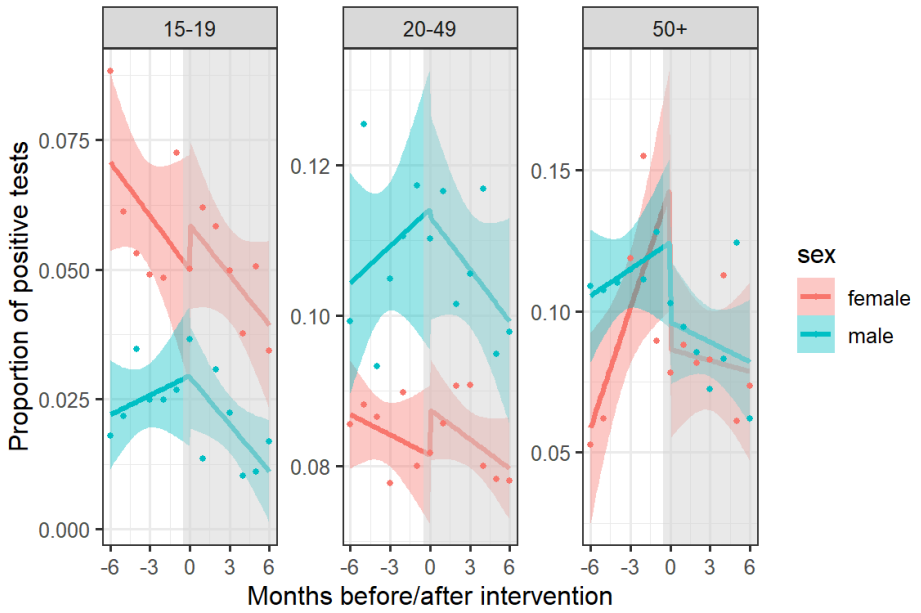


Figure 4. Trend in positivity rate, by sex and age group (all health facilities combined).

5. Discussion and Conclusions

This program evaluation was designed to describe the effect of a lay counselor-led HIV screening strategy on the volume of persons undergoing HTS in adult outpatient clinic and emergency ward settings, and to evaluate if this strategy increases the number of people being newly diagnosed with HIV. With this strategy, lay counselors screen people attending health facility services for risk of HIV, using an MOH-approved risk-based screening tool.

We found that the intervention had a positive impact on the number of tests being performed in the pilot sites. However, differences between the health facilities were seen, and reasons for these variations in performance seen warrant further investigation. We also found that since the implementation of the strategy, more individuals have been newly diagnosed as being HIV positive, mainly among reproductive-aged adults (20-49 years of age).

Despite this increase in testing volume, positivity rate did not show the anticipated increase. The screening tool has a low cut-off to ensure that no individual with a risk for HIV would be missed.

Strategies where lay staff support HIV counseling and testing have been piloted in Malawi, where an increase of the number of counseling and testing and positivity rate was seen, with 34% of all testing being attributed to the novel strategy, as well as 17% of those newly testing positive [4].

Health counselors have been included in the counseling and testing strategies for many years, and with this evaluation, we showed that counselors who additionally use the HIV screening tool to identify people at higher risk, can contribute to an increase in the number of people tested. HIV risk screening tools have been successfully used in other contexts, such as in pediatric and adolescent care service sectors [5, 6].

The evaluation had several limitations, some of which were mentioned above. Additionally, the evaluation was not able to assess direct association of lay counselors implementing the strategy as no individual-level data were available to indicate who was screened by a lay counselor versus who was screened by a clinician. To have extended the evaluation over a longer period would have included the first year of the COVID-19 pandemic, where restrictions were put in place by the government, including reducing/avoiding visits to health facilities when possible, and it was decided to exclude this period from the evaluation as this could have altered results and the findings for the effect of the pilot intervention.

This program evaluation, using routine data, showed that HIV risk screening done by lay-counselors at PITC sectors can result in an increase of the number of people tested, though without an increase in the positivity yield.

6. Dissemination Plan

Once cleared by the funder (CDC), the report will be translated into Portuguese and shared/disseminated with stakeholders/partners at the local/district levels, where results will be discussed as needed to reflect on improvement strategies aiming at increasing the number of patients identified as HIV-positive in PITC and other services, as well as patient retention in care.

7. Appendices

1. Approved protocol/ SOW

This secondary data analysis is covered under the blanket protocol for program evaluations, titled, "*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)*", approved by the Mozambique provincial-level ethics committee (CIBS-Z) and the VUMC IRB. The approved concept note is submitted along with this final report for reference.

2. Informed consent

Informed consent was not required for use of data in this evaluation, as it was a secondary analysis of routinely collected, de-identified, programmatic data. A waiver of consent was approved, as the evaluation involved no more than minimal risk, would not have been possible without the waiver, and the waiver did not adversely affect the rights nor welfare of the patients whose data were included in the evaluation.

3. Biosketches

Provided for first (Caroline De Schacht) and senior (C. William Wester) co-authors of this evaluation.

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

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.

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 06/01/2020-09/01/2023
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

R34 MH131417-01 (Audet, PI) 10/2022 - 09/2025
The long-term goal of this research is to develop an intervention to improve resilience and reduce stigmatizing behaviors among health care workers, and test two such interventions in 4 health care facilities in Zambézia province, Mozambique.
Role: In-Country Principal 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; 2021; 2022 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

Publications to be found in https://www.ncbi.nlm.nih.gov/myncbi/collections/mybibliography/

HIV epidemiology

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

De Schacht C, Mabunda N, Ferreira Jr OC, Ismael N, Calú N, Santos I, Hoffman JH, Alons C, Guay L, Jani IV. High HIV incidence in the postpartum period sustains vertical transmission in settings with generalized HIV epidemics: a cohort study in Southern Mozambique. JIAS 2014, 17:18808

HIV prevention

De Schacht C, Lucas C, Paulo P, et al. Reaching Men and Young Adults in a Pharmacy-Based HIV Self-Testing Strategy: Results from an Acceptability Study in Mozambique. AIDS Res Hum Retroviruses. 2022 Aug;38(8):622-630

De Schacht C, Paulo P, Van Rompaey S, et al. Health care services for survivors of gender-based

violence: a community and clinic-based intervention in Zambézia province, Mozambique. AIDS Care. 2022 May 16:1-9

Capitine IPU, Macicame IB, Uanela AM, Bhatt NB, Yates A, Milazzo M, Nwoga C, Crowell TA, Michael NL, Robb ML, Jani IV, Kroidl A, Polyak CS, ***De Schacht C***; RV363 Study Group. Young at risk-people in Maputo City, Mozambique, present a high willingness to participate in HIV trials: Results from an HIV vaccine preparedness cohort study. PLoS One. 2021 Dec 2;16(12):e0260126

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.

Carlucci JG, Yu Z, González P, Bravo M, Amorim G, das Felicidades Cugara C, Guambe H, Mucanhenga J, Silva W, Tique JA, Sardella Alvim MF, Graves E, ***De Schacht C***, Wester CW. The effect of a Mentor Mothers program on prevention of vertical transmission of HIV outcomes in Zambézia Province, Mozambique: a retrospective interrupted time series analysis. J Int AIDS Soc. 2022 Jun;25(6):e25952

Audet CM, Graves E, Emílio AM, Matino A, Paulo P, Aboobacar AM, Fonseca CL, Van Rompaey S, ***De Schacht C***. Effect of a storytelling intervention on the retention of serodiscordant couples in ART/PrEP services at antenatal clinic in Namacurra province in Zambézia, Mozambique. Contemp Clin Trials Commun. 2021

Sack DE, ***De Schacht C***, Paulo P, et al. Pre-exposure prophylaxis use among HIV serodiscordant couples: a qualitative study in Mozambique. Glob Health Action. 2021 Jan 1;14(1):1940764
Jani IV, *De Schacht C*. Innovations and challenges in early infant diagnosis of HIV. Curr Opin HIV AIDS 2019 Jan;14(1):55-59

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

Audet CM, Graves E, Barreto E, ***De Schacht C***, et al. Partners-based HIV treatment for seroconcordant couples attending antenatal and postnatal care in rural Mozambique: A cluster randomized trial protocol. Contemp Clin Trials. 2018 Jun 5;71: 63-69

Impact of a systems engineering intervention on PMTCT service delivery in Côte d'Ivoire, Kenya, Mozambique: the SAIA cluster randomized trial. Oral Abstract Presentation (TUAE0103). IAS 2016 – July 18-22, 2016, Durban, South-Africa

De Schacht C, Lucas C, Mboa C, Gill M, Macasse E, Stélio AD, Bobrow EA, Guay L. Access to HIV prevention and care for HIV-exposed and HIV-infected infants: a qualitative study in rural and urban Mozambique. BMC Public Health 2014, 14:1240

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

De Schacht C, Mutaquiha C, Faria F, Castro G, Manaca N, Manhiça I, Cowan J. Barriers to access and adherence to tuberculosis services, as perceived by patients: A qualitative study in Mozambique. PLoS One. 2019 Jul 10;14(7):e0219470

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

De Schacht C, Smets RME, Callens S, Colebunders R. Bilateral blindness after starting Highly Active Retroviral Treatment in a patient with HIV infection and cryptococcal meningitis. Acta Clin Belg. 2005 Jan-Feb;60(1):10-2

Colebunders R, ***De Schacht C***, Vanwolleghem T, Callens S. Lopinavir/ritonavir- and indinavir-induced thrombocytopenia in a patient with HIV infection -Letter to the editor. Int J Infect Dis. 2004; 8(5):315-6

Colebunders R, Schueremans L, Robertson-Bell D, Alvarez-Valdes VG, ***De Schacht C***, Mispelters J, Gillisjans F, De Lee G, Ostyn B. Optimal delivery of HAART during hospitalisation. AIDS Read. 2004; 14(4): 198-200. Review

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.

McDonald B, Moyo S, Gabaitiri L, Gaseitsiwe S, Bussmann H, Koethe JR, Musonda R, Makhema J, Novitsky V, Marlink RG, Wester CW, Essex M. Persistently elevated serum interleukin-6 predicts mortality among adults receiving combination antiretroviral therapy in Botswana: results from a clinical trial. *AIDS Res Hum Retroviruses*. 2013 Jul; 29(7):993-9. PMCID: PMC3685692.

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 roles of other evaluation collaborators:

Collaborator	Description of role in evaluation
WS	concept note development, technical oversight of program, data collection, result interpretation, and leading of action plan development (based on findings)
BA, EF, AF, CP	program implementation
GA, NC, AC, NH, IM	concept note development, technical oversight of program, results interpretation
FA	technical support for program data extraction
GA	data analysis, results interpretation, report preparation
CWW, CDS	concept note development, technical oversight of program and data collection, report writing
JT, TN	concept note development, results interpretation

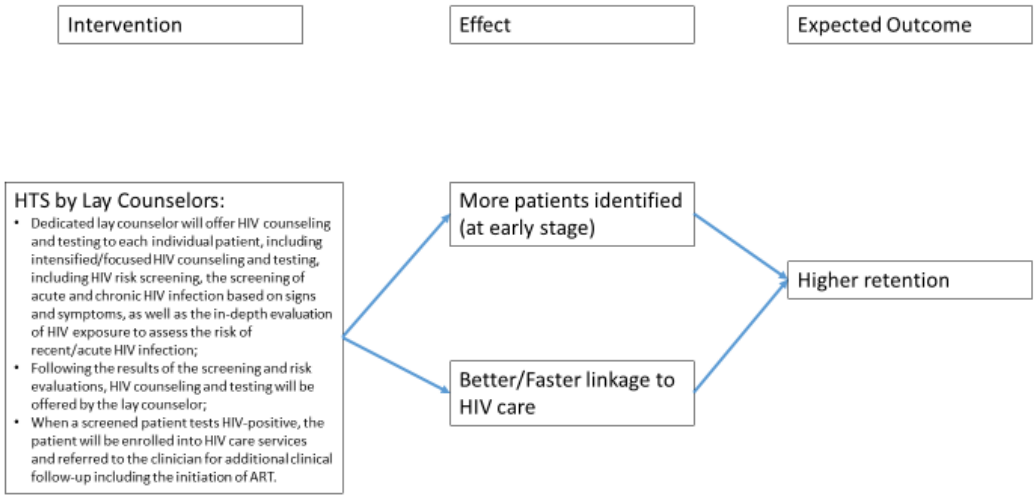
4. Conflict of interest statement

The collaborators in this evaluation have no conflicts of interest to declare.

5. Evaluation costs

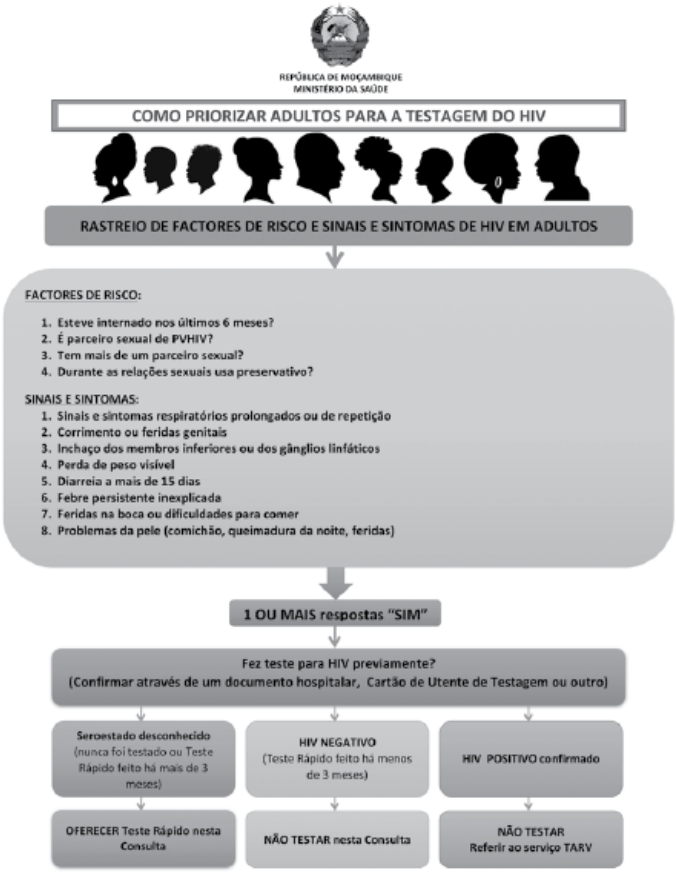
Evaluation costs were limited to the personnel time required for extraction and analysis of routine secondary data, results review and discussion, and report preparation, with estimated expenditures equal to $16,654.00 for the FGH personnel effort and $19,946.86 for the VUMC personnel effort, for an estimated total of $36,600.86.

6. *Evaluation logical framework*

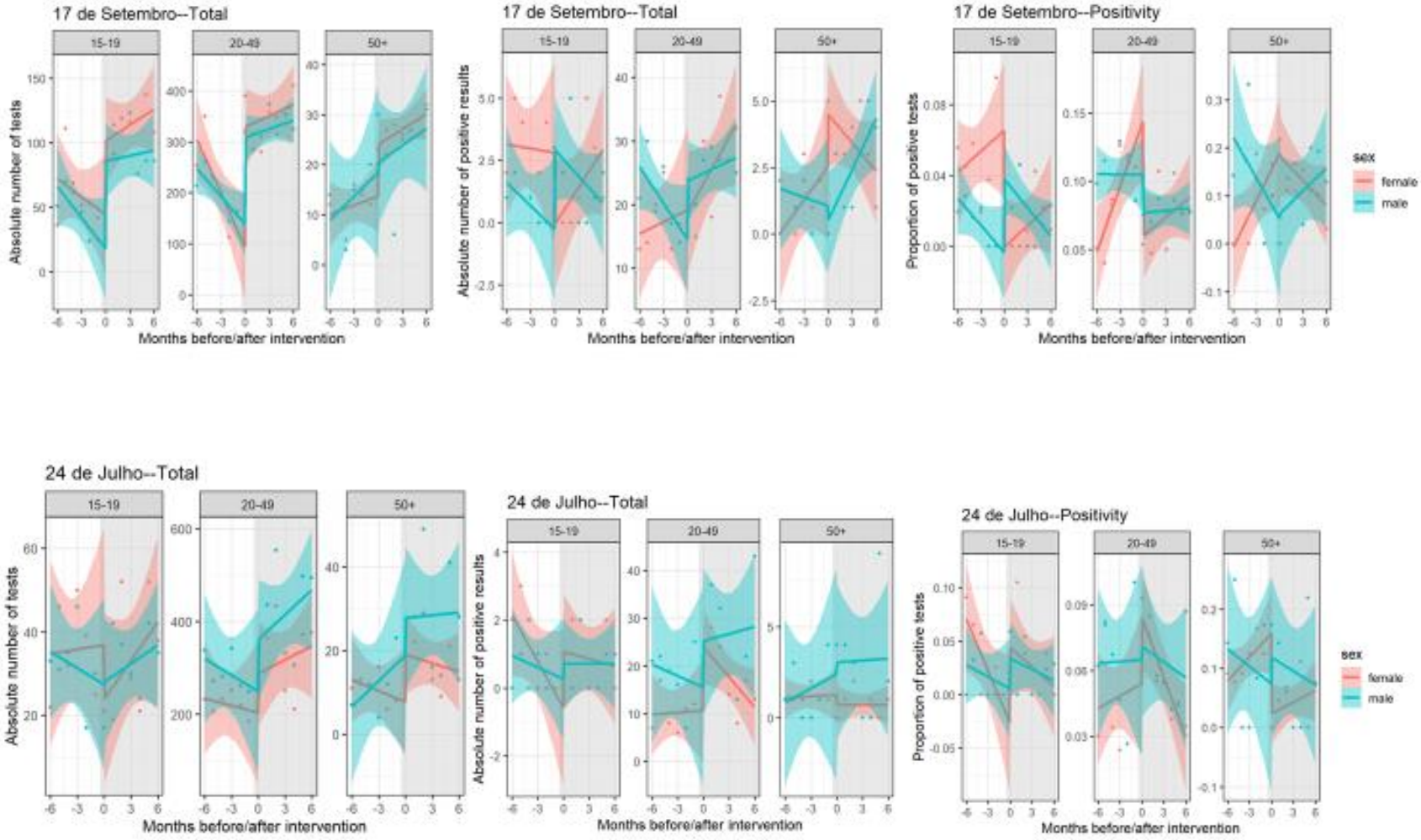


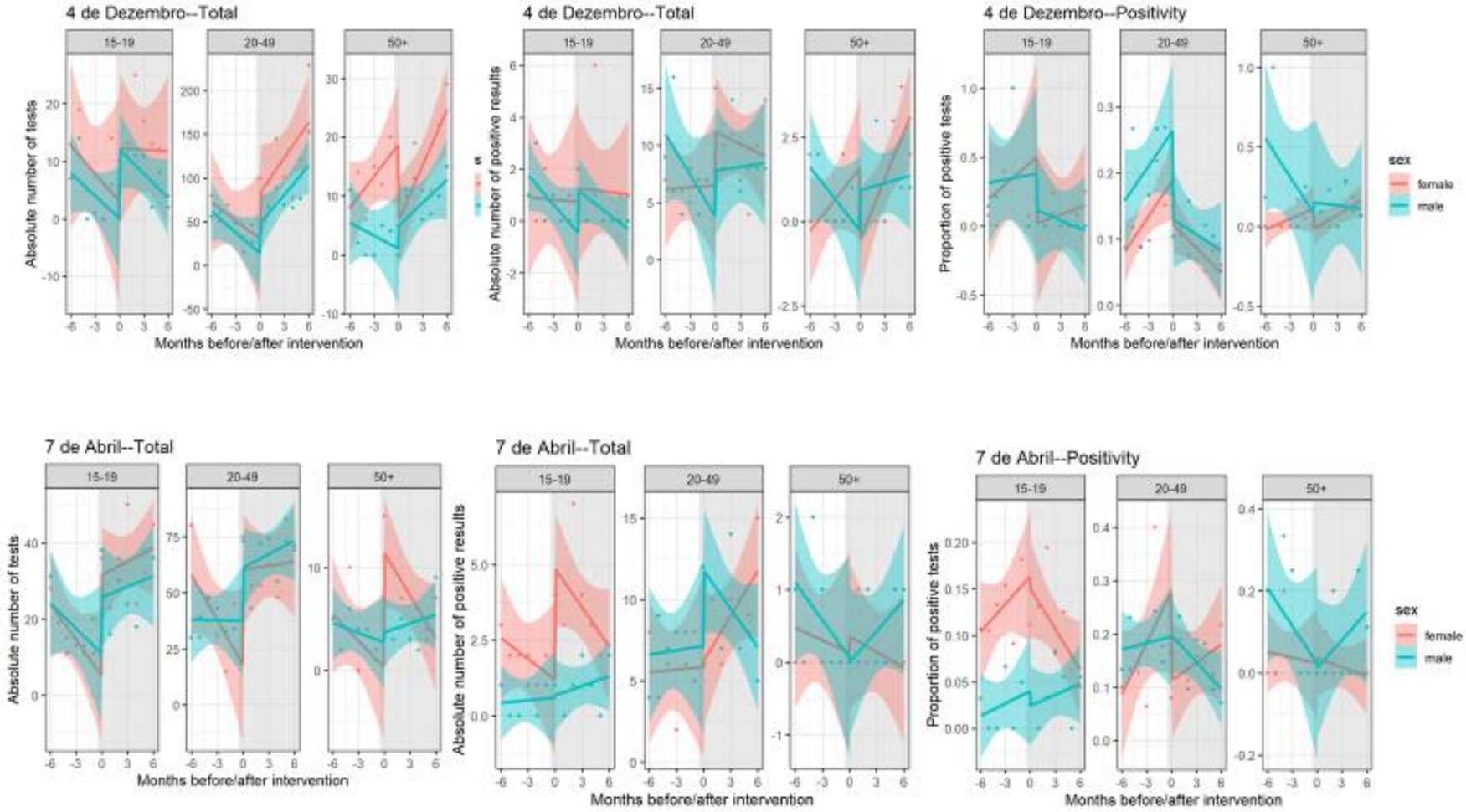
7. MOH approved HIV Screening tool

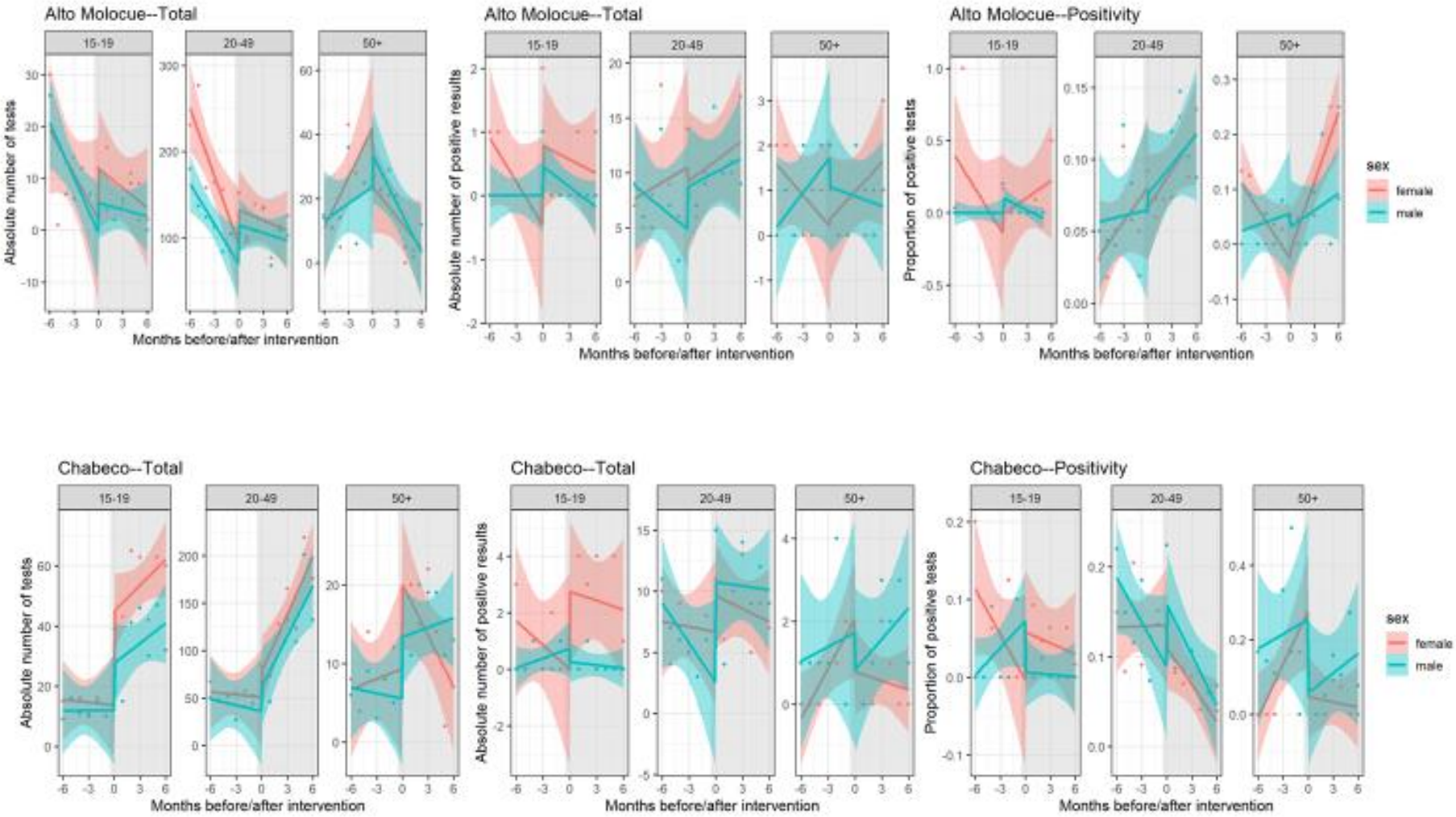
Anexo 3: Algoritmo para rastreio de factores de risco e sinais e sintomas de HIV em adultos

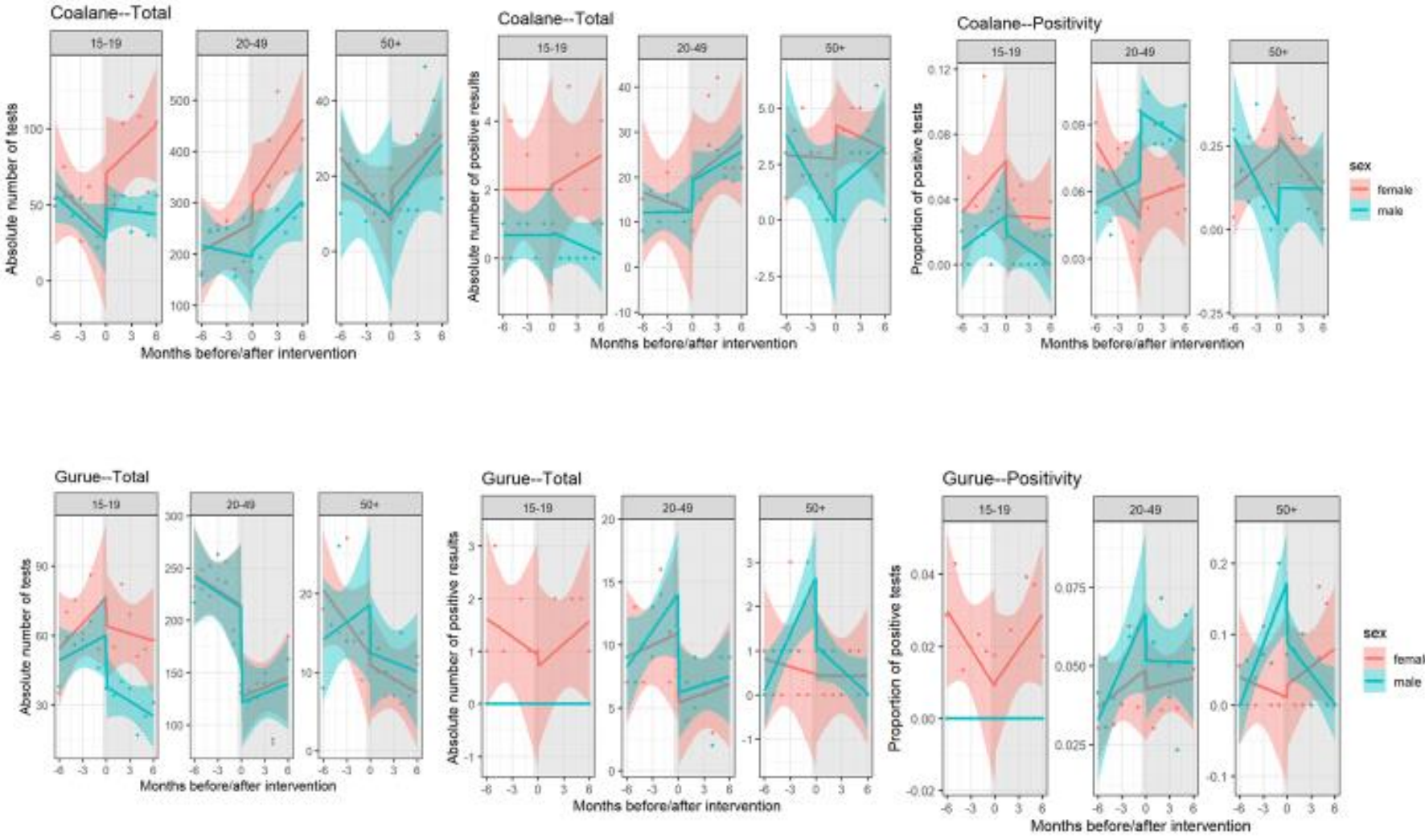


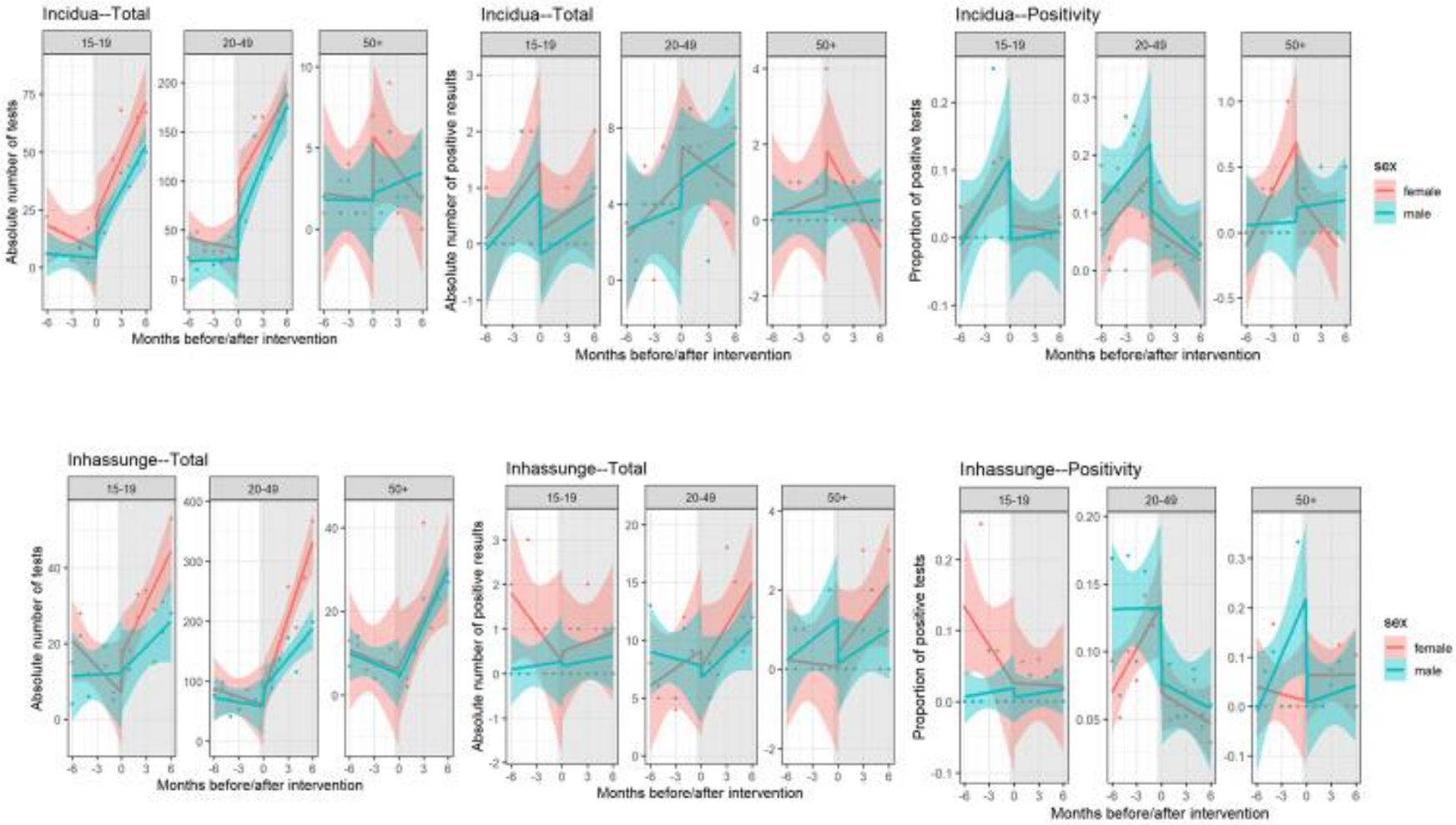
8. Results per health facility – trends of number of tests, positivity rate, number of positive test

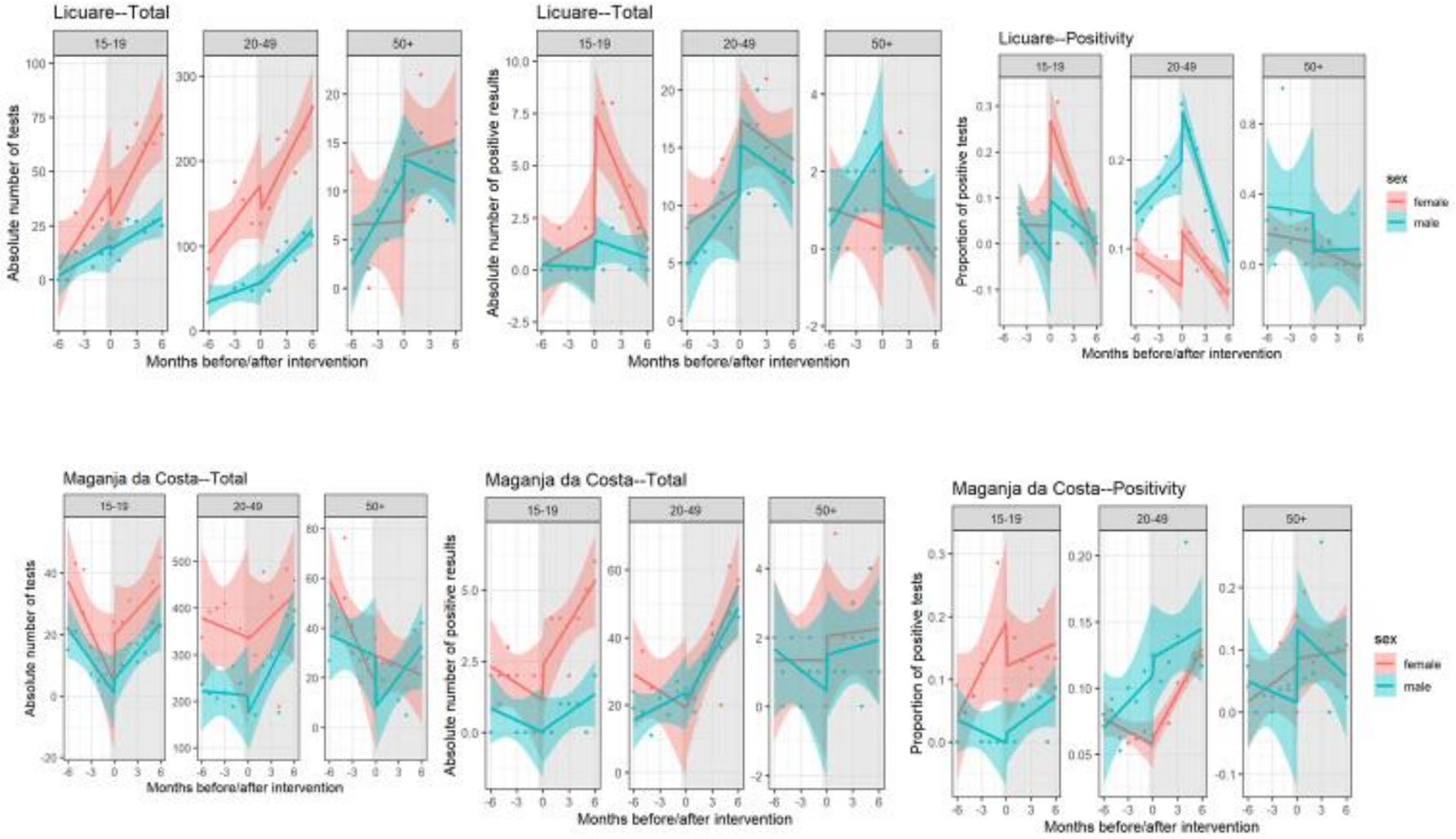


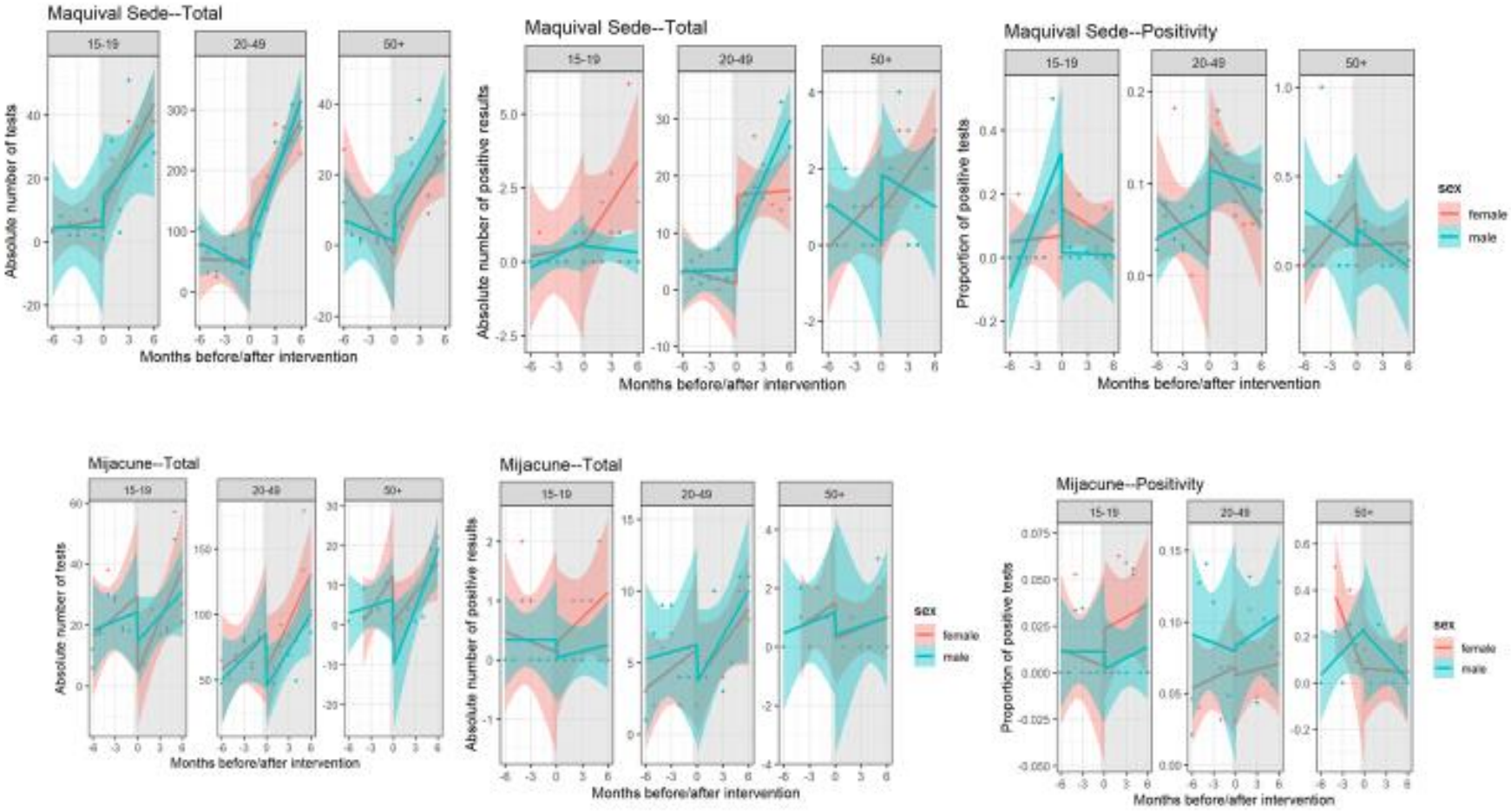

4 de Dezembro--Total
15-19
20-49
50+
Absolute number of tests
Months before/after intervention
4 de Dezembro--Total
Absolute number of positive results
Months before/after intervention
4 de Dezembro--Positivity
Proportion of positive tests
Months before/after intervention
sex
female
male
7 de Abril--Total
Absolute number of tests
Months before/after intervention
7 de Abril--Total
Absolute number of positive results
Months before/after intervention
7 de Abril--Positivity
Proportion of positive tests
Months before/after intervention
sex
female
male

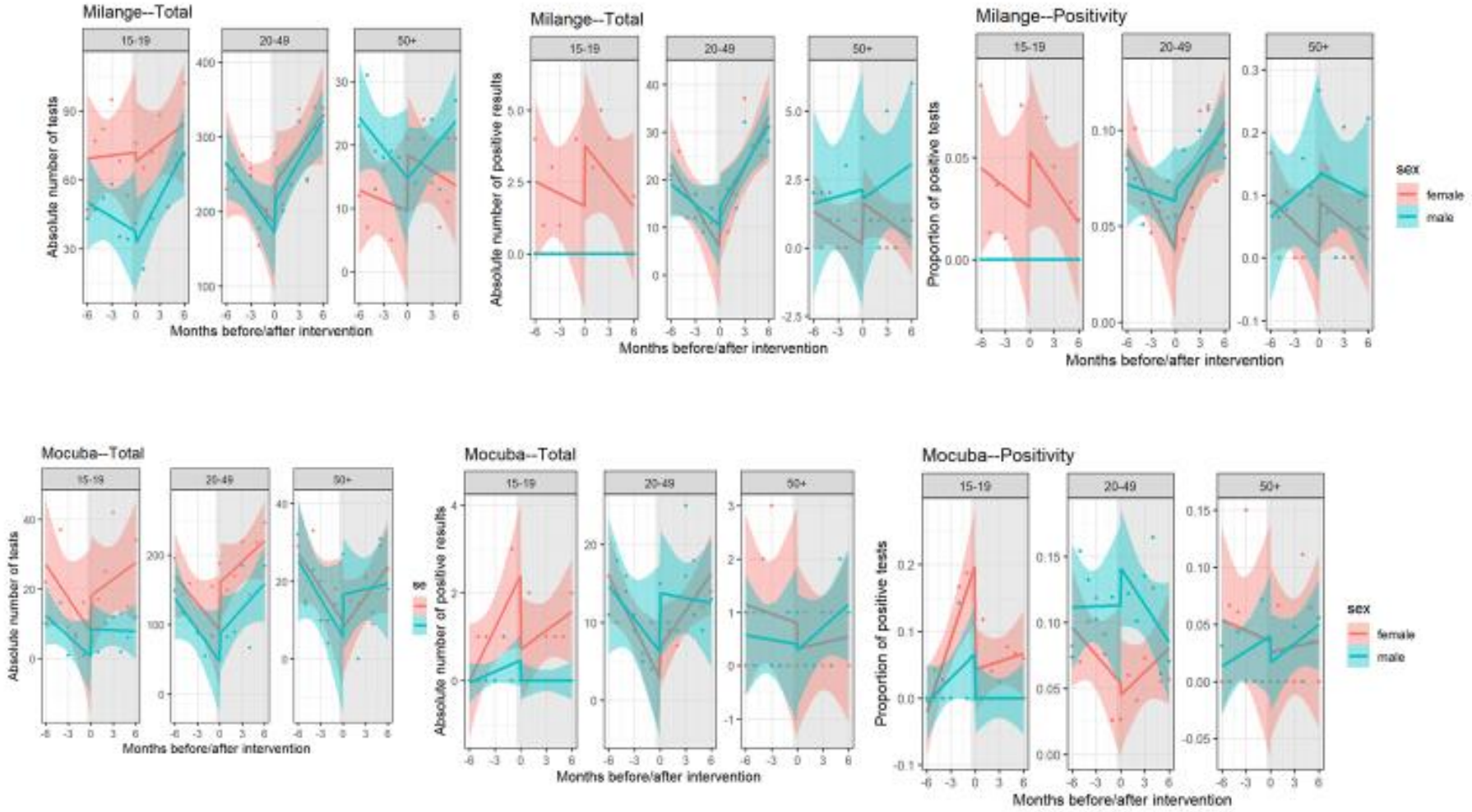

Alto Molocue--Total
Absolute number of tests
Months before/after intervention
Alto Molocue--Total
Absolute number of positive results
Months before/after intervention
Alto Molocue--Positivity
Proportion of positive tests
Months before/after intervention
Chabeco--Total
Absolute number of tests
Months before/after intervention
Chabeco--Total
Absolute number of positive results
Months before/after intervention
Chabeco--Positivity
Proportion of positive tests
Months before/after intervention
15-19
20-49
50+
sex
female
male

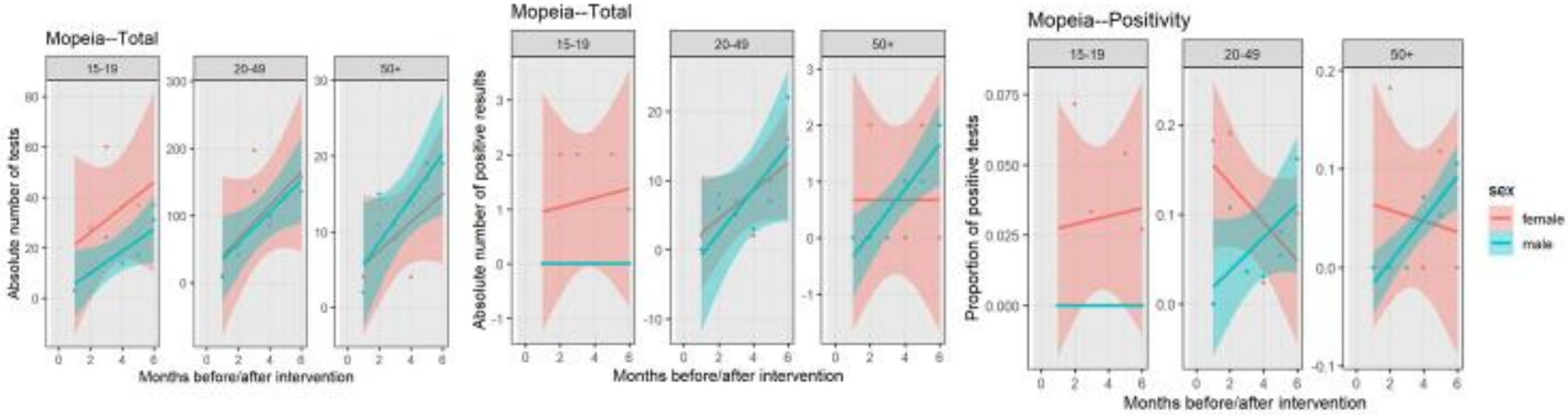

Coalane--Total
Absolute number of tests
15-19
20-49
50+
Months before/after intervention
Coalane--Total
Absolute number of positive results
Months before/after intervention
Coalane--Positivity
Proportion of positive tests
Months before/after intervention
sex
female
male
Gurue--Total
Absolute number of tests
Months before/after intervention
Gurue--Total
Absolute number of positive results
Months before/after intervention
Gurue--Positivity
Proportion of positive tests
Months before/after intervention
sex
female
male

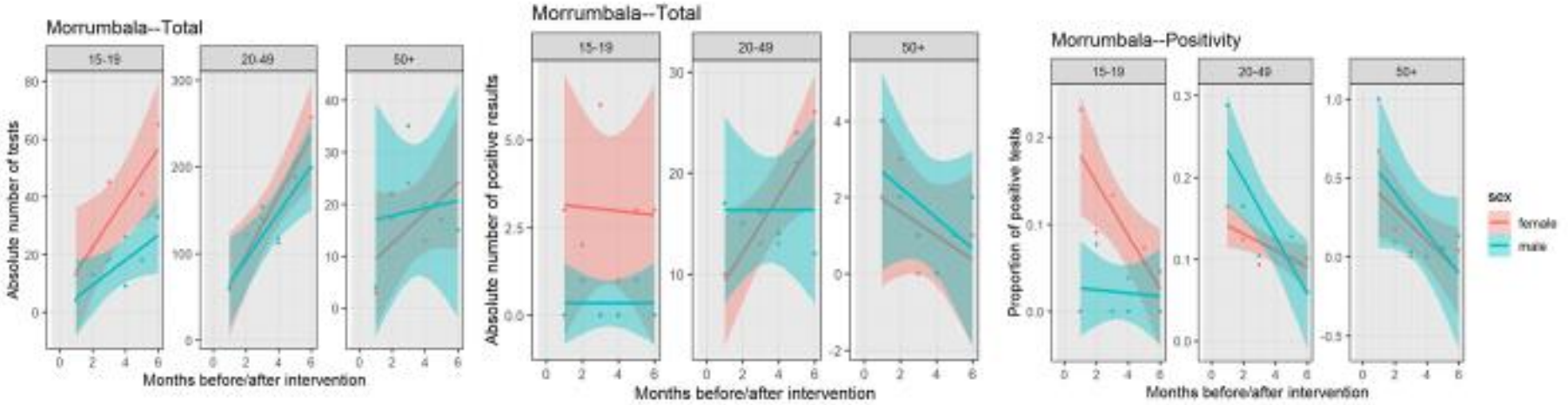

Incidua--Total
Absolute number of tests
15-19
20-49
50+
Months before/after intervention
Incidua--Total
Absolute number of positive results
Months before/after intervention
Incidua--Positivity
Proportion of positive tests
Months before/after intervention
sex
female
male
Inhassunge--Total
Absolute number of tests
Months before/after intervention
Inhassunge--Total
Absolute number of positive results
Months before/after intervention
Inhassunge--Positivity
Proportion of positive tests
Months before/after intervention
sex
female
male

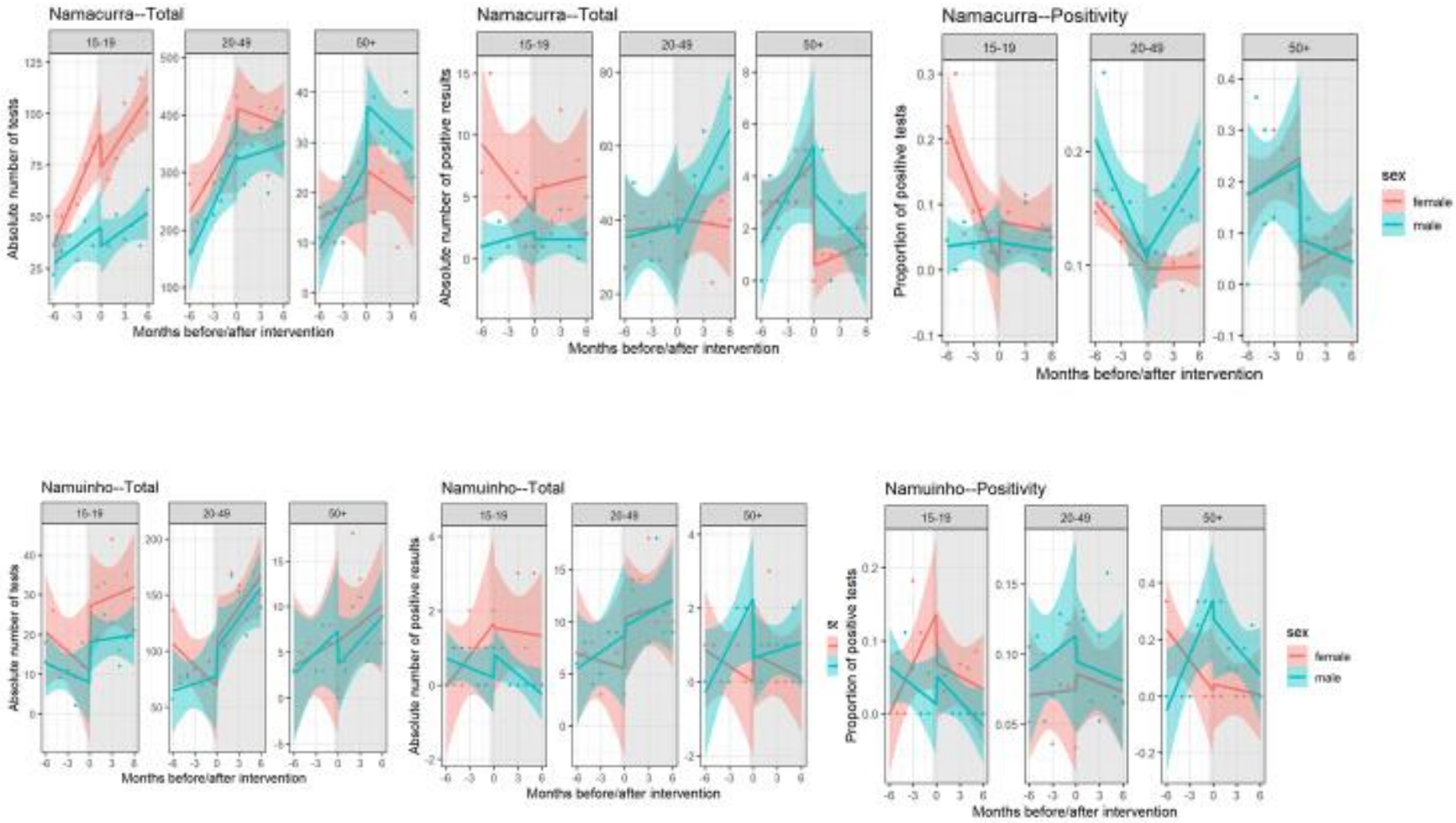

Licuare--Total
15-19
20-49
50+
Absolute number of tests
Months before/after intervention
Licuare--Total
Absolute number of positive results
Months before/after intervention
Licuare--Positivity
Proportion of positive tests
Months before/after intervention
sex
female
male
Maganja da Costa--Total
Absolute number of tests
Months before/after intervention
Maganja da Costa--Total
Absolute number of positive results
Months before/after intervention
Maganja da Costa--Positivity
Proportion of positive tests
Months before/after intervention
sex
female
male

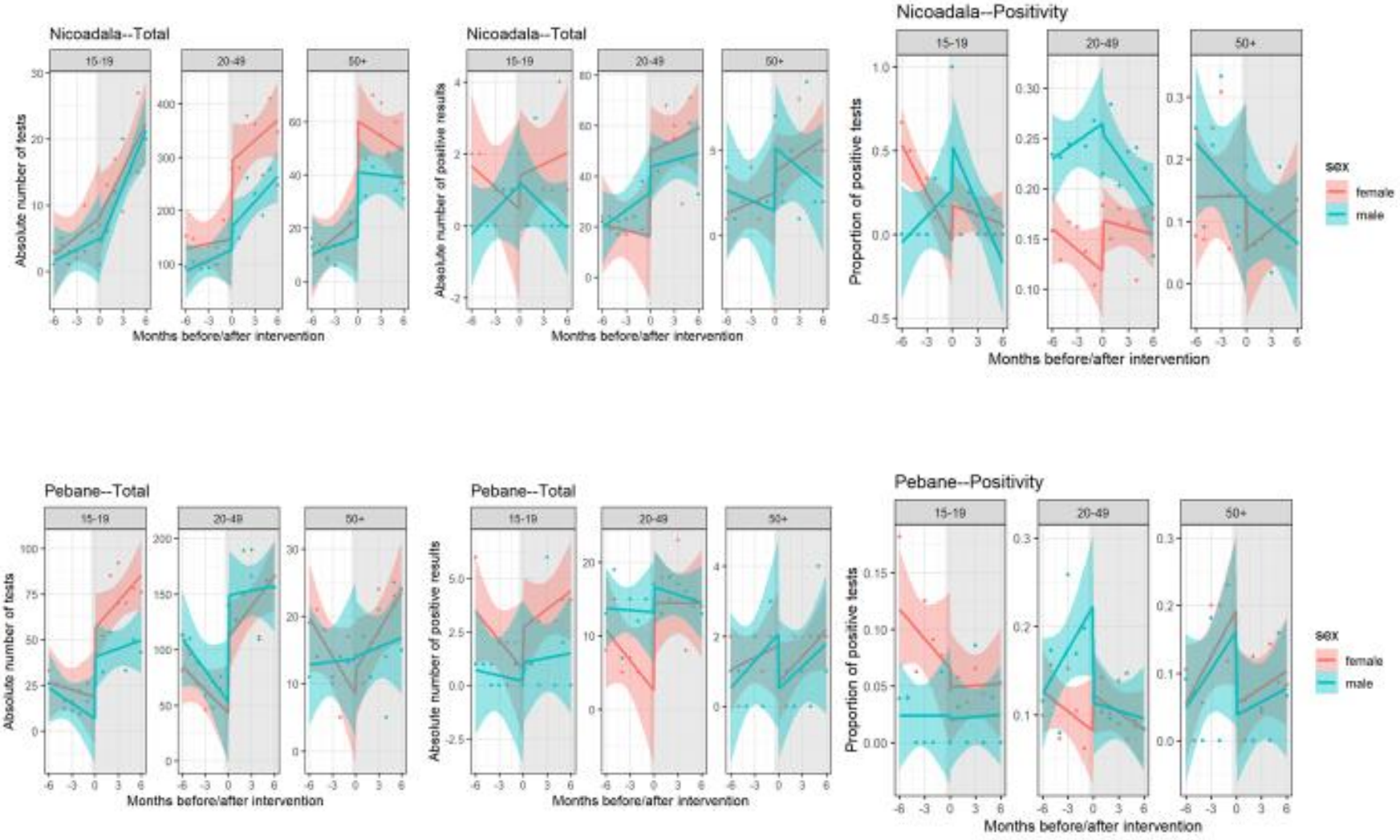

Maquival Sede--Total
15-19
20-49
50+
Absolute number of tests
Months before/after intervention
Maquival Sede--Total
Absolute number of positive results
Months before/after intervention
Maquival Sede--Positivity
Proportion of positive tests
Months before/after intervention
sex
female
male
Mijacune--Total
Absolute number of tests
Months before/after intervention
Mijacune--Total
Absolute number of positive results
Months before/after intervention
Mijacune--Positivity
Proportion of positive tests
Months before/after intervention


Milange--Total
15-19
20-49
50+
Absolute number of tests
Months before/after intervention
Milange--Total
Absolute number of positive results
Months before/after intervention
Milange--Positivity
Proportion of positive tests
Months before/after intervention
sex
female
male
Mocuba--Total
Absolute number of tests
Months before/after intervention
Mocuba--Total
Absolute number of positive results
Months before/after intervention
Mocuba--Positivity
Proportion of positive tests
Months before/after intervention


Mopeia--Total
15-19
20-49
50+
Absolute number of tests
Months before/after intervention
Mopeia--Total
Absolute number of positive results
Months before/after intervention
Mopeia--Positivity
Proportion of positive tests
Months before/after intervention
sex
female
male


Morrumbala--Total
15-19
20-49
50+
Absolute number of tests
Months before/after intervention
Morrumbala--Total
Absolute number of positive results
Months before/after intervention
Morrumbala--Positivity
Proportion of positive tests
Months before/after intervention
sex
female
male


Namacurra--Total
15-19
20-49
50+
Absolute number of tests
Months before/after intervention
Namacurra--Total
Absolute number of positive results
Months before/after intervention
Namacurra--Positivity
Proportion of positive tests
Months before/after intervention
sex
female
male
Namuinho--Total
Absolute number of tests
Months before/after intervention
Namuinho--Total
Absolute number of positive results
Months before/after intervention
Namuinho--Positivity
Proportion of positive tests
Months before/after intervention
sex
female
male


Nicoadala--Total
15-19
20-49
50+
Absolute number of tests
Months before/after intervention
Nicoadala--Total
Absolute number of positive results
Months before/after intervention
Nicoadala--Positivity
Proportion of positive tests
Months before/after intervention
sex
female
male
Pebane--Total
Absolute number of tests
Months before/after intervention
Pebane--Total
Absolute number of positive results
Months before/after intervention
Pebane--Positivity
Proportion of positive tests
Months before/after intervention
sex
female
male

9. Results from analyses of patients diagnosed through PITC and enrolled in care

Sociodemographic information

For the uptake to ART and retention to ART care, a dataset from the electronic database was extracted. **Table 4** describes the sociodemographic information.

Table 4. Patient-level data (n=24572).

Variable	*N=24572; n(%)*
Age at enrollment, years (median, IQR)	29.0 [23.0;37.0]
Sex	
Female	13225 (53.8%)
Male	11347 (46.2%)
Marital status	
Married/living together	3366 (56.9%)
Single/widowed/ separated	2550 (43.1%)
Educational level	
Primary school	11204 (63.9%)
Secondary/technical school	6139 (35.0%)
University	181 (1.03%)
Urban	
No	28156 (75%)
Yes	9471 (25%)
Main HF	
No	15377 (41%)
Yes	22250 (59%)
Health facility	
17 de Setembro	976 (4%)
24 de Julho	1561 (6%)
4 de Dezembro	856 (3%)
Chabeco	453 (2%)
Coalane	1059 (4%)
Incidua	518 (2%)
Inhassunge	812 (3%)
Licuare	1723 (7%)
Maganja da costa	2757 (11%)
Maquival sede	802 (3%)
Micajune	727 (3%)
Milange	1859 (8%)
Mocuba	866 (4%)
Namacurra	3102 (13%)
Namuinho	896 (4%)
Nicoadala	3584 (15%)
7 de Abril	713 (3%)
Pebane	1308 (5%)

ART initiation: Comparison of ART initiation rates among patients newly testing HIV-positive via this approach (in emergency room and outpatient clinic settings) compared to clinician-based screening.

The number of people enrolled in ART varied substantially over time. The total number of patients (n = 9272) newly enrolled was regressed on calendar time (months), intervention (indicator variable), and the interaction term. The estimated number of patients enrolled in ART are displayed in **Figure 5**, with the respected 95% confidence interval.

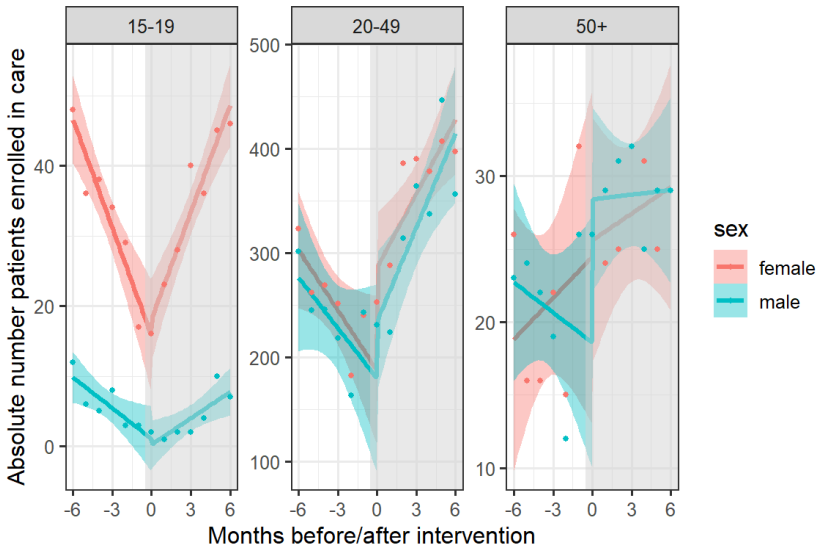


Figure 5. Average number of new patients enrolled in care (2018 – 2021), estimated an interrupted time series model.

Table 5 below shows that the intervention had a positive impact on the number of newly enrolled patients. The odds of patients enrolled right after the intervention took place was 27.72 (95% CI: 0.39-55.04; p=0.047).

Table 5. Regression analysis for trend in absolute number of patients enrolled in care (all health facilities combined, n = 9272 patients).

Predictors	**Estimated (95% CI)**	**p-value**
(Intercept)	-14.25 (-39.06 – 10.57)	0.256
Calendar time	-11.7 (-17.89 – -5.52)	**<0.001**
Intervention	27.72 (0.39 – 55.04)	**0.047**
Age group		
15-19 years	Ref	
20-49 years	277.42 (261.33 – 293.51)	**<0.001**
50+ years	5.58 (-10.51 – 21.67)	0.492
Sex:male	-17.97 (-31.11 – -4.84)	**0.008**
Calendar time : Intervention	17.07 (9.86 – 24.29)	**<0.001**

Calendar time : 15-19 years	Ref	
Calendar time : 20-49 years	13.43 (9.13 – 17.73)	**<0.001**
Calendar time : 50+ years	0.84 (-3.46 – 5.14)	0.697

Of all enrolled patients, only 261 patients did not have registration of ART initiation (98.6% of the cohort started ART). Among the patients that started ART, 91.1% of them initiated ART at the time of enrollment into HIV care and 99.5% started ART between ± 1 month of enrollment. Because of the very low numbers of patients per health facility (with a minimum of 2 and maximum of 72 overall), no further analysis was performed to evaluate uptake to ART services.

Retention to ART Care: Comparison of early retention in HIV care trends (i.e., 1- and 3-month retention) among patients newly testing HIV-positive via this approach (in emergency room and outpatient clinic settings) compared to clinician-based screening.

A total of 13959 (80%) and 14603 (50%) patients were retained at 1- and 3-months after ART initiation. Comparisons between baseline characteristics of patients retained versus not retained in care are displayed in **Table 6**.

Table 6. 1-and 3-month retention in care among patients identified through PITC (not including MCH or Youth Clinic services), registered in HIV care.

		1-month retention			**3-month retention**		
	Total (n=17477)	**Not retained (n=3518)**	**Retained (n=13959)**	**p-value**	**Not retained (n=8710)**	**Retained (n=8767)**	**p-value**
Age at enrollment	29.0 [23.0;37.0]	29.0 [23.0;36.0]	29.0 [23.0;37.0]	0.002	29.0 [23.0;36.0]	29.0 [24.0;37.0]	<0.001
Sex				0.92			0.003
Female	9400 (53.8%)	1889 (20.1%)	7511 (79.9%)		4585 (48.8%)	4815 (51.2%)	
Male	8077 (46.2%)	1629 (20.2%)	6448 (79.8%)		4125 (51.1%)	3952 (48.9%)	
Marital status				0.626			0.475
Married/living together	2933 (56.8%)	678 (23.1%)	2255 (76.9%)		1241 (42.3%)	1692 (57.7%)	
Single/widowed/ Separated	2231 (43.2%)	502 (22.5%)	1729 (77.5%)		921 (41.3%)	1310 (58.7%)	
Educational Level				0.022			0.184
Primary school	8063 (63.7%)	1680 (20.8%)	6383 (79.2%)		4039 (50.1%)	4024 (49.9%)	
Secondary/technical school	4462 (35.2%)	838 (18.8%)	3624 (81.2%)		2190 (49.1%)	2272 (50.9%)	
University	134 (1.06%)	28 (20.9%)	106 (79.1%)		58 (43.3%)	76 (56.7%)	
Started ART				<0.001			<0.001
Before intervention	7032 (40.2%)	1712 (24.3%)	5320 (75.7%)		3037 (43.2%)	3995 (56.8%)	
After intervention	10445 (59.8%)	1806 (17.3%)	8639 (82.7%)		5673 (54.3%)	4772 (45.7%)	

TB at enrollment				0.426			0.009
Negative	15433 (98.4%)	2904 (18.8%)	12529 (81.2%)		7344 (47.6%)	8089 (52.4%)	
Positive	258 (1.64%)	43 (16.7%)	215 (83.3%)		101 (39.1%)	157 (60.9%)	
Urban				0.004			0.001
No	11674 (66.8%)	2277 (19.5%)	9397 (80.5%)		5923 (50.7%)	5751 (49.3%)	
Yes	5803 (33.2%)	1241 (21.4%)	4562 (78.6%)		2787 (48.0%)	3016 (52.0%)	
Main HF				0.491			<0.001
No	9361 (53.6%)	1903 (20.3%)	7458 (79.7%)		4419 (47.2%)	4942 (52.8%)	
Yes	8116 (46.4%)	1615 (19.9%)	6501 (80.1%)		4291 (52.9%)	3825 (47.1%)	

A multivariable logistic regression was used to assess the impact of the intervention on 3-month retention, while adjusting for age at baseline (i.e., enrollment in care), sex, marital status, education level, and whether the health facilities were in urban or rural areas. A total of 17477 patients were included in the analysis. Multiple imputation was used to impute missing values for marital status (73% missing) and education level (28% missing), which were assumed to be missing at random. Imputation was carried out via chained equations, using the MICE package in R. A total of five imputations were used and the final estimates were combined via Rubin's rule. Patients that started ART after the intervention had, in general, a slightly lower retention compared to those that started ART before the intervention: OR = 0.84, 95% CI = [0.76; 0.92]. Women and patients from rural areas, however, were more likely to be retained at 3-months (**Table 7**).

Table 7. Multivariable regression analysis to assess the effect of intervention on 3-month retention (n = 17477 patients).

	OR (95% CI)	**p-value**
Started ART: After intervention	0.84 (0.76-0.92)	**<0.001**
Age at enrollment	1.06 (1.03-1.09)	**<0.001**
Sex: Male	0.89 (0.84-0.95)	**<0.001**
Marital status: Single/widowed/separated	1.05 (0.98-1.11)	1.50
Educational level: Secondary/technical school	1.05 (0.99-1.12)	0.11
Educational level: University	1.29 (0.96-1.73)	0.09
Urban: Yes	1.10 (1.04-1.18)	**0.003**

8. References

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6. Bandason, T., et al., *Screening tool to identify adolescents living with HIV in a community setting in Zimbabwe: A validation study.* PLoS One, 2018. **13**(10): p. e0204891.