

Evaluation of barriers and facilitators to receiving and adhering to Option B+ for the prevention of mother-to-child HIV transmission services in Zambézia province, Mozambique
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List of Acronyms and Abbreviations

ADS	Associate Director for Science
AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal Care
ART	(combination) Antiretroviral therapy
ARV	Antiretroviral (medications)
CDC	Centers for Disease Control and Prevention
CHW	Community health worker
CIBS-Z	“ <i>Comité Institucional de Bioética para Saúde-Zambézia</i> ” (English: Institutional Research Ethics Committee for Health of Zambézia)
DPS-Z	“ <i>Direcção Provincial de Saúde-Zambézia</i> ” (English: Zambézian Provincial Directorate of Health)
FGD	Focus group discussion(s)
FGH	Friends in Global Health
F/U	Follow-up
HF	Health facility
HIV	Human Immunodeficiency Virus
IDI	In-depth interview(s)
IIT	Interruption in treatment
IQR	Interquartile range
IRB	Institutional Review Board
LTFU	Lost to follow-up
M&E	Monitoring and Evaluation
MCH	Maternal and child health
MOH	Ministry of Health
MTCT	Mother-to-child transmission
PI	Principal Investigator(s)
PLW	Pregnant and lactating women
PMTCT	Prevention of mother-to-child transmission
PP	Positive prevention
PSS	Psychosocial support
RA	Research Assistant
SMS	Short message system
SSA	Sub-Saharan Africa
UNAIDS	Joint United Nations Programme on HIV/AIDS
VT	Vertical transmission
VUMC	Vanderbilt University Medical Center
WHO	World Health Organization

Summary

Background

Following rapid scale-up of the provision of comprehensive HIV services to supported health facilities in Zambézia province, where VUMC/FGH has been working since 2007, as part of the national acceleration plan, VUMC/FGH staff had seen in the past that pregnant and lactating women had lower retention in care rates when compared to age-matched females and males. Specifically, in 2018-2019 (per PEPFAR programmatic reporting), the 12-month retention in care rates among pregnant and lactating women were on average five to eight percentage points lower when compared to age-matched females and males. Since 2013, Mozambique has adopted Option B+ for the prevention of mother-to-child transmission (PMTCT), which specifically is the provision of combination antiretroviral therapy (ART) to all pregnant women for life regardless of immune status/CD4+ cell count. However, for Option B+ to achieve its maximum public health benefit from a reduction in vertical transmission (MTCT) perspective, it is essential for HIV-positive women enrolled into Option B+ services to remain engaged in care. Much has been published on Option B+ in neighboring countries such as Malawi, but the literature describing identified barriers that limit Option B+ uptake, adherence and retention in Mozambique is less robust. Therefore, in this evaluation, we aimed to better understand the factors influencing the short- and long-term retention of pregnant women in care in order to ascertain the optimal means to identify women most at-risk for interruption in treatment (IIT) in Zambézia province, Mozambique. This understanding could lead to improved ART program design to reduce attrition among women on ART during pregnancy.

Materials & Methods

A mixed methods study was done: 1) Focus group discussions were held among HIV-positive pregnant and lactating women (PLW) in eight health facilities (HF) (five rural, three urban) to assess barriers and facilitators of retention to the Option B+ care cascade; 2) In four health facilities (two rural, two urban), we conducted a short exit-survey among HIV-positive pregnant women (≥ 18 years of age) at their first antenatal care (ANC) visit. The survey contained 12 Likert-scale questions, ranging from 1 (not confident) to 5 (highly confident), quantifying the level of confidence to return to the clinic in the presence of a hypothetical risk factor. The questions were based on results from a preceding qualitative study among pregnant/lactating women and covered the following factors: individual factors (understanding the need for a lifelong treatment, side effects, belief in accuracy of HIV result, belief in efficacy of treatment), social factors (partner understanding the need for a lifelong treatment, partner permission, partner encouragement, partner participation), structural factors (distance), institutional factors (staff attitude, wait time). The Likert scores were collapsed into two categories (“not confident” [scores 1-3] and “confident” [scores 4-5]); Clinical data were extracted from electronic medical records. Logistic regression analysis, adjusted for age, education, residence, occupation, and antiretroviral therapy (ART) experience, was performed to assess associations between various factors (individual and grouped) and 3-month retention (defined as ≥ 3 ART drug pick-ups within 99 days after survey date); 3) In the same four HF (two rural, two urban), for the assessment of psychosocial support, exit surveys were conducted with HIV-positive women attending

antenatal care services, together with a clinical file review to assess completeness of the psychosocial support (PSS) forms, including the positive prevention (PP) components; and 4) still in the same four HF (two rural, two urban), in-depth interviews were completed with health care providers to assess their knowledge in relation to the PSS form.

Results

In January and February 2019, 60 pregnant and lactating women were included in focus groups at eight health facilities (HF) in Quelimane, Namacurra, and Inhassunge. Side effects of medications, the way in which health care workers treat patients, the time it takes to be seen and the distance from home to the HF were considered as the main barriers to retention in the services. On the other hand, the perception that taking ART can help one to stay healthy and take care of the children, that they will have healthy children, and the counseling they receive at the HF and the follow-up done in their homes through the visits of Mentor Mothers (peer educators), were reported as facilitators which encouraged women to return to the HF.

Between February and April of 2019, 123 women completed the (level of confidence) exit survey and had clinical data available. Median age at survey date was 25 years [IQR 18-40], 52% (64) resided in urban areas, and 30% (34) had no formal education. The confidence levels were high for all factors. A positive but not statistically significant association was seen for confidence scores as they relate to patient desire to remain in care despite geographic distance and the possibility of ARV medication-related side effects on 3- and 6-month retention rates.

From September to November 2019, 17 health professionals (5 counselors, 6 nurses, and 6 managers), 13 (77%) of whom were female, were interviewed to assess their knowledge in relation to the PSS form. They generally demonstrated sound knowledge of the PSS form and the importance of its use to properly capture data including data related to retention in PMTCT services. Work overload was indicated as one of the main reasons for poorly completed or incomplete PSS forms. Respondents also mentioned that they recognized their own lack of understanding or mastery of some concepts in the form, aggravated by the fact that not everyone had been trained on how to complete/fill out the documents.

Between September and November 2019, 189 interviews were conducted among pregnant women on the perception of PSS services received. Women reported that nurses did not discuss all aspects during the visit, but 150 (81%) women reported that the nurse explained how to take ART and half (50%) reported that the nurse discussed ART side effects. About a third (35%) said that the nurse asked about partner/family support, and 76 (41%) reported that the nurse asked about difficulties in getting to the HF. Of all participants, 116 (62%) reported they had also seen a counselor, and for 43 (37%) of them, this happened in a different room at the HF. Similar as to the visit with the nurse, most (104, 90%) reported receiving information about treatment, and 69 (59%) said ART side effects were discussed. The importance of partner involvement was discussed according to 80 (69%) women, and about two-thirds (66%) of the women said that disclosure was discussed. In about half of the cases, advice was given by counselors on who can give support within the family or community (56, 48%) and how to disclose one's serostatus (61, 53%).

Completeness of the PSS/PP form was reviewed for the 186 participants of the (psychosocial support) exit survey. The component of the PSS factors influencing adherence was complete for 73% of the files,

incomplete for 24%, and for 4 (2%), no information was filled in. Only 26% of the PP sessions component was correctly filled in, while for 72% this section was incomplete.

Conclusions

There was a lack of association found between HIV-positive women's survey responses related to their level of confidence regarding their intention to return to the health facility (i.e., remain in care) after their first ANC visit and their actual 3- and 6-month retention. This suggests that although women may have good intentions initially, other barriers related to ANC might play a role, counteracting their intention to remain in care. Comprehensive antenatal care counseling from early pregnancy remains critical to prevent early attrition.

To improve the adherence of women in Option B+ and PMTCT services in general, strategies that involve Mentor Mothers offering psychosocial support, and different models such as quarterly or semi-annual medication dispensation should be promoted to increase demand and uptake of these support options for those eligible. Additionally, the provision of empathetic services, the transition to dolutegravir (an integrase strand inhibitor) from non-nucleotide reverse transcriptase inhibitor, Efavirenz-based regimens to improve treatment tolerability, and additional information/counseling regarding treatment and discussion of potential barriers and how to overcome them, can contribute to retaining women in care.

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Project Background

The World Health Organization (WHO) prevention of mother-to-child transmission (PMTCT) guidelines in 2010 recommended initiation of combination antiretroviral therapy (ART) for life in women with CD4+ cell count values of ≤ 350 cells/mm³ and/or WHO Clinical Stage 3 or 4 disease (1). Two antiretroviral (ARV) prophylaxis strategies were recommended for women ineligible for treatment; Option A and Option B involved the initiation of ARV medications as early as 14 weeks gestation and continued until seven days postpartum or cessation of breastfeeding (2). In an attempt to effectively address the vertical transmission (VT) of HIV and expand coverage, Malawi adopted Option B+ in 2011, which recommended ART initiation regardless of CD4+ cell count, as soon as a pregnant or lactating woman (PLW) was diagnosed and then continued for life. The WHO guidelines were updated in 2013 to endorse Option B+ as the preferred PMTCT strategy in countries with the highest HIV burden (3) and has since been adopted by the majority of those high burden countries, including Mozambique.

By 2020, the percentage of pregnant women living with HIV who were receiving antiretroviral therapy (ART) had increased to more than 95%, while 13,000 new HIV infections occurred among children (0-14 years of age) in Mozambique (4).

The effectiveness and sustainability of these scale-up programs are dependent on minimization of the lost to follow-up (LTFU) rate (i.e., interruptions in treatment, IIT), which remains an issue in sub-Saharan Africa (SSA). Numerous interventions to improve retention in PMTCT programs in SSA have been undertaken. These include mobile phone-based (short message system [SMS]) reminders, use of community health workers (CHW) for contact tracing, male partner engagement/involvement, conditional cash transfers, peer support (e.g., Mother to Mother), and integration of PMTCT services (5, 6).

Systematic reviews of these interventions support male partner engagement/involvement and mobile phone-based SMS reminders as effective retention strategies with varying levels of success (7, 8). With significant efforts to improve retention, Mozambique's retention rates show that in 2020, the 3-month retention rate among pregnant women was 83% (9).

A study implemented in three regions of Mozambique prior to the introduction of the PMTCT Option B+ strategy revealed several barriers/obstacles for women seeking healthcare. These barriers included the following: preference for seeking care outside of health facility (HF) (e.g., receiving care from traditional healers), disbelief of test result, fear of disclosure, and prolonged clinic waiting times. Hope for the future of their child was seen as an important facilitator for health seeking for HIV-exposed and HIV-infected children (10).

A 2014 formative study in Sofala and Manica provinces showed stigma, prolonged clinic wait times, and perceived poor-quality counseling as barriers, while support groups were seen as being beneficial, i.e. promoting retention in care (11). In their review, Hogdson et al. noted that in-depth understanding of individual, interpersonal, and community-level factors was necessary to improve retention rates in PMTCT programs in SSA (12).

This evaluation sought to understand the barriers and facilitators for retention to Option B+ care in Zambézia province. Additionally, we aimed to complete an evaluation of the service provision of psychosocial support (PSS) for HIV-positive pregnant women.

Evaluation Purpose and Questions

The information obtained from this evaluation will allow for a better understanding of the short- and long-term factors that influence retention of pregnant and lactating women in the PMTCT care cascade in Zambézia province. Through engagement of relevant stakeholders, such as patient participants and Ministry of Health (MOH) staff, we hope to gain further insight that will assist in the design of specific interventions targeted towards women at high risk for interruption in treatment (IIT), which will aid in the achievement of elimination of mother to child transmission of HIV.

Evaluation Objectives:

Objective 1: Determine perceived barriers and facilitators to ART initiation and retention among women receiving PMTCT services at select facilities in the districts of Namacurra, Quelimane, and Inhassunge.

Objective 2: Using a newly developed survey tool, i) assess perceived confidence level regarding retention in care among HIV-positive women at their first antenatal care (ANC) visit, ii) quantify the barriers and risk factors among those women who disengage from care, and iii) evaluate the association between perceived confidence and retention in care.

Objective 3: To better understand how psychosocial support and counseling on adherence and positive prevention is being offered, including difficulties in the monitoring (data capture) of such activities.

Table 1: Indicators of Interest

Indicators of Interest	
Objective 1	Factors that serve as facilitators and as barriers to retention in care, on different levels: <ul style="list-style-type: none"> - Individual level (stigma, knowledge/educational level, marital status, age, etc.) - Environmental and social (discrimination, social support, cultural habits, etc.) - Institutional level (Health Facility) (waiting time, perception of quality of care provided, geographic distance, patient flow, etc.)
Objective 2	<ul style="list-style-type: none"> - Level of risk for LTFU/IIT - Retention of women initiating Option B+ at antenatal care
Objective 3	<ul style="list-style-type: none"> - Factors related to the use of the psychosocial support tool (training needs, factors and/or complications of counseling, difficulties with tool format, etc.) - Coverage of offer/provision of services (i.e., adherence counseling, psychosocial support (counseling), family planning, etc.). - Coverage of registration of services (i.e., adherence counseling, psychosocial support (counseling), family planning, etc.).

Evaluation Design, Methods and Limitations

Evaluation type

The evaluation completed was an internal process evaluation.

Evaluation Setting

The evaluation was done in Zambézia province, in both rural (i.e., less densely populated, more peripheral from the district capital) and urban (i.e., more densely populated, within or closer to the district capital) areas. Though not a nationally representative sample, these eight HF sites included in this evaluation are important in our efforts, in that as of June 2021, they collectively represented approximately 12% of the total patient population on ART (~ 31,000 of 245,596; TX_CURR) among persons with HIV (PWH) living in the overall catchment area of the 144 FGH-supported health facilities in Zambézia province.

The focus group discussions (FGD) were held in each of the following eight health facilities: Macuse, Namacurra Sede, Furquia, and Mbaua in the district of Namacurra; 17 de Setembro, 24 de Julho and Namuinho in the district of Quelimane City; and Palane-Mucula in the district of Inhassunge. These eight sites were selected based on high relative patient volume, diversity in retention rate, and location. In order to ensure representativeness of the region, they are comprised of urban, peri-urban, and rural health facilities.

The exit-interview surveys, and clinical file review among pregnant women, and the in-depth interviews (IDI) with health staff were performed at four health facilities: Macuse and Furquia in the district of Namacurra (considered rural areas), and 17 de Setembro and 24 de Julho in the district of Quelimane City (considered urban areas).

Evaluation Design

The evaluation used a mixed methods design.

- To assess perceived barriers and facilitators to ART initiation and retention among women receiving PMTCT (Objective 1), a qualitative methodology was used with **focus group discussions** among HIV-positive women during the pregnancy or breastfeeding period.
- An **exit-interview survey** was done among HIV-positive women attending their first ANC visit to evaluate their perceived confidence in returning to the health facility amid several possible influencing factors (Objective 2). **Clinical chart review** was performed to evaluate retention in HIV care.
- To assess the psychosocial services provided in the ANC setting (Objective 3), qualitative **in-depth interviews** were done with Maternal and Child Health (MCH) nurses, counselors or HF managers, and

a **quantitative survey** was done among HIV-positive women attending ANC care to assess their perception of psychosocial services received. **Clinical chart review** was performed to evaluate retention in HIV care.

Inclusion criteria:

(For Objectives 1, 2, and 3) Pregnant and/or lactating women (PLW) between 18 and 49 years of age who sought PMTCT care at one of the selected HF. A minimum of 25% of focus group participants must have completed three or less ANC visits (i.e., at least four participants per focus group).

(For Objective 3) Health care workers (i.e., MCH nurses, counselors, and/or HF managers) at least 18 years of age and older working at one of the selected HF were eligible to participate (IDI).

Inclusion criteria are summarized in **Table 1**.

Table 1. Inclusion criteria, per objective

	Objective 1	Objective 2	Objective 3	
	<i>Focus group discussions</i>	<i>Exit-interview surveys</i>	<i>Surveys</i>	<i>In-depth interviews</i>
Age	18-49 years of age	18-49 years of age	18-49 years of age	18+ years of age
Group	Pregnant or lactating women	Pregnant women	Pregnant women	MCH nurses, Counselors, and HF Managers
Setting	Attending any MCH visit	Attending first ANC visit only	Attending any ANC visit	N/A
HIV status	Positive	Positive	Positive	N/A
HIV disease status	No specific CD4 cell count and/or WHO clinical stage disease parameters	No specific CD4 cell count and/or WHO clinical stage disease parameters	No specific CD4 cell count and/or WHO clinical stage disease parameters	N/A

Exclusion criteria: Individuals who were unable to provide informed consent due to mental limitations and/or intoxication (i.e., from alcohol or drugs) at the time of eligibility determination.

Sampling Strategy

A convenience sampling strategy was used for the focus group discussions (Objective 1). For the focus groups, interested women who attended an MCH visit (being antenatal care visit or any post-partum visit for the woman or the HIV-exposed child) were referred to the evaluation team to verify they met the eligibility criteria. If eligible, they were invited to participate in the discussion within the health facility after normal routine clinic working/operation hours, or outside of working hours, whichever was most convenient for the study participants. Among those eligible for and invited to participate in the FGD, there were no refusals to participate (i.e., all eligible persons opted to enroll and participate in the FGD activity).

A convenience sampling strategy was also used for the in-depth interviews (Objective 3). Interviews were done with interested and eligible staff available at the time of the evaluation; those interested were invited to meet privately with an evaluation team member who confirmed their eligibility and facilitated the informed consent process. The individual interviews were scheduled at a time and place that was convenient for the participants.

The two surveys (i.e., exit-interview survey for Objective 2, and survey for Objective 3) used a convenience sample. HIV-positive women attending their first ANC visit (Objective 2) or HIV-positive women attending any ANC visit (Objective 3) were invited to participate. Recruitment was done consecutively with those eligible until the desired sample size had been attained. Among those eligible for and invited to participate in the exit-interview surveys and interviews for Objectives 2 and 3, 7% and 6%, respectively, declined to participate.

Written consent was obtained from all eligible and willing participants in accordance with standard human subjects' research practice only after each study participant had been provided ample time to ask questions and have any/all questions addressed satisfactorily.

Evaluation Procedures

1. **Objective 1** – Assessment of barriers and facilitators

In coordination with the staff at each selected HF, women attending MCH visits were informed about the evaluation activities and interested women were referred by HF staff to the evaluation team. After checking eligibility criteria, written consent was obtained from each participant. The FGD was scheduled at a place and time agreed upon by the participants. The discussions were conducted by trained FGH personnel and included questions about: (1) patient demographics, (2) pregnancy history, (3) patient recall of PMTCT services received, (4) patient perception of their experiences at the health-facilities; and (5) barriers and facilitators to ART initiation and retention in PMTCT care. The focus groups were recorded via a digital recorder (once consent had been obtained), and notes were also taken by a designated notetaker.

2. **Objective 2** – Quantification of risk factors influencing retention

Based on the responses from the FGD, the selected survey tool (based on existing evidence of barriers/facilitators from the literature) was adapted to the local context. The paper-based draft tool was administered to 20 participants to field test for clarity.

We performed an exit-interview survey among HIV-positive pregnant women (≥ 18 years of age) attending their first ANC visit to assess their confidence that they would return to the HF for scheduled clinical visits. The survey contained 12 Likert-scale questions, graded from 1 (not confident) to 5 (highly confident). Socio-demographic information was collected and the short survey with 12 questions was conducted by evaluation team members.

Clinical data of the participating women were extracted from the electronic patient database (OpenMRS) to evaluate the association between the confidence for each factor and the 3-month and 6-month retention.

3. **Objective 3** – Assessment of psychosocial support services and association with retention in care

Maternal and Child Health nurses, counselors and HF managers who were determined eligible, were invited to participate in IDI, as per their interest and availability at the time of data collection. In-depth interviews were conducted after obtaining written consent. Audio recordings were taken if the participant consented to it, and notes were taken by the evaluation team member.

Exit-surveys were done with HIV-positive women attending ANC care who met the eligibility criteria and consented to participate in the interview. Questions were asked about the offer of psychosocial services during the clinic visit, what topics were discussed and what advice was given. A specific chart review was done to assess the completeness of the psychosocial support/ positive prevention (PSS/PP) forms (i.e., clinical documentation completed by HF staff) of the women who participated in the survey. Clinical data were extracted for the participating women from the electronic patient database (OpenMRS) to evaluate the association between the PSS offered (as registered/documentated on the form) for each PSS factor and 3-month and 6-month retention.

Sample Size

The sample size is shown in **Table 2**.

Table 2. Sample size estimations and achievements.

Objective	Target group	Sample size as per protocol	Sample size achieved
Objective 1	HIV-positive PLW at any MCH visit	6-8 per FG (total of 8 FGs) (total estimated 48-64)	8 groups with a total of 60 participants
Objective 2	HIV-positive pregnant women at first ANC visit	50 in each HF (total of 4 HF, estimated 200)	135 (68% of sample achieved)*

Objective 3	HIV-positive pregnant women at any ANC visit	50 in each HF (total of 4 HF, estimated 200)	186 (93% of sample achieved)
	MCH nurses, MCH counselors and HF managers	1-3 counselors, 1-3 nurses, 1-2 managers per HF (total of 4 HF) (total estimated 12-24)	17 individual interviews (6 nurses; 5 counselors; 6 managers)

* Note: For 12 of these 135 participants, clinical data were not available or not valid, thus these 12 participants were excluded from the analysis (total sample size included was 123).

The low sample size achieved for Objective 2 was mainly due to the non-eligibility of women attending first ANC services. Additionally, data collection in this phase coincided with the region's rainy season, including floods, which may have influenced the decreased demand for health services by pregnant women.

Stakeholder Engagement

Various departmental leads, staff, and counterparts from the MOH and FGH/ VUMC have been involved in this evaluation from its inception. The implementation of this evaluation had the involvement of partners from the MOH at national level, including the lead person for PMTCT within the National HIV program, and the provincial level, including the PMTCT Supervisor from the Provincial Health Authorities (DPS-Z). Both of these individuals have been involved since the design of the evaluation, during the monitoring of evaluation implementation, and in discussing the evaluation results.

At the HF level, MCH nurses were involved during training activities and during the implementation of the evaluation, ensuring coordination with, and identification and referral of potential participants to the evaluation team members.

The FGH/VUMC Evaluation team members led the design, implementation, and management of all the evaluation activities, as well as analysis and results reporting efforts.

Ethical aspects

The original protocol was approved by the local ethics committee, the Institutional Research Ethics Committee for Health of Zambézia (*Comité Institucional de Bioética para Saúde – Zambézia*, [CIBS-Z]), (approval letter reference: 14/CIBS-Z/2017, dated 10 August 2017), and the VUMC Institutional Review Board (IRB) (reference #171124; approval date 18 July 2017 for non-research determination status, and 26 August 2017 for approval of submitted local ethics approval documents).

The evaluation activity 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.

The activity was conducted consistent with applicable federal law, CDC policy, and guiding principles of ethical research.

Additionally, two protocol amendments were approved during the period of evaluation implementation:

- Version 4.0 and instruments were approved by the CIBS-Z (reference 08/CIBS/18; 17 September 2018) and the VUMC IRB (#171124; 25 June 2018).
- Version 5.0 and instruments were approved by the CIBS-Z (reference 04/CIBS-Z/19; 17 June 2019) and the VUMC IRB (#191175; 22 August 2019).

All participants gave written informed consent prior to evaluation activity participation and data collection. As signed consent forms contained identifying information (participant names), the evaluation team ensured these were kept securely and separately from any participant data collected during evaluation activities to maintain participant confidentiality. In addition to steps taken to maintain participant dignity and privacy during evaluation activities, all participants were informed of their right to decline or withdraw at any point during the evaluation procedures, without any impact on their right to access health services.

Deviations from the protocol

During the total study implementation period, four protocol deviations were reported. No injuries or damage resulted from these incidents.

- Reported in October 2019: Consent form was signed by the witness only, having omitted fingerprint signature of the illiterate participants (8 participants). These participants and their data were excluded from the study.
- Reported in October 2019: Consent form without signature of the witness while illiterate participant signed with fingerprint only. Correct re consenting was done for these participants (2 participants).
- Reported in November 2019: Health care workers were recruited for the in-depth interview without meeting the inclusion criteria (minimum of six months in their position at the HF) (2 participants). These participants and their data were excluded from the study.
- Reported in November 2019: Participant was recruited for exit-interview survey without meeting the inclusion criteria (of attending their first prenatal care visit) (1 participant). This participant and their data were excluded from the study.

These deviations were reported to the ethics committees and to the Centers for Disease Control and Prevention (CDC) Mozambique-based Associate Director for Science (ADS).

Quality Assurance

Training

Before data collection, trainings were provided to the study team on the implementation of the project, and to the evaluation team on the protocol procedures and supervision activities. A five-day training was provided for the first phase of the evaluation implementation (Objectives 1 and 2), and a second five-day training was provided for the implementation of the amendment (Objective 3 of the protocol).

Monitoring and data safety

Continuous monitoring and mentoring activities were carried out by the FGH Evaluation Officer in coordination with the DPS-Z focal point, with routine oversight by the evaluation PIs. Data collected via the surveys were entered into a password-secured cloud-based repository (REDCap™), only accessible to the investigators and trained evaluation team members.

The paper-based data collection instruments are stored in a locked file cabinet at the FGH office in Quelimane, accessible only for the study investigators.

Audio recordings were destroyed after transcription (to electronic file) was finalized and verified. The transcripts are password-protected Word-documents and kept in a password-secure computer, only accessible for research staff involved in the evaluation.

All data from participants were collected using a specific evaluation-code.

Patient retention data stored in the electronic patient tracking system (OpenMRS) are entered and routinely monitored by FGH data entry specialists within the Monitoring and Evaluation (M&E) team. These staff members have received specific training on data confidentiality and must sign confidentiality agreements before handling/using patient clinical files. The OpenMRS databases are password-protected and can only be accessed by FGH M&E staff.

Analysis plan

Objective 1

The qualitative data collected from the FGD were analyzed using content analysis to code and group themes and responses for each question. A codebook was developed with deductive codes based on the significant factors previously identified from the literature. Inductive codes were added during the initial analysis, following the qualitative analysis standards. Transcriptions were coded for content and mapped onto key domains under study by two researchers working independently. The results of the two researchers were compared to assess inter-rater reliability. Reduction was done to summarize the information and organized per theme.

Objective 2

Descriptive analysis using proportions and medians (IQR) was done to describe the population and participants' confidence levels (regarding continuation in care). Confidence levels were scored using a Likert scale from 1 to 5. Univariate logistic regression model was built to assess the univariate association between 3- / 6-month retention and each factor (e.g., survey question 1 to 12), some patient characteristics (e.g., age at survey, education, occupation, marital status) and clinical factors (e.g., whether being in ART before the first ANC visit, the duration of ART, WHO stage), and some HF-related features (e.g., district, whether the HF is in an urban or rural area, whether the HF is the district referral center). The association between individual survey question and 3- / 6-month retention was also evaluated with single adjustment of district, marital status, education, and the ART status before the first ANC visit, as well as with multiple adjustment of district, age at time of survey, and education. By considering the results of unadjusted/adjusted association analyses and the degree of freedom that a multivariable model can bear for current study cohort, a multivariable logistic regression model was built to show the effect of certain factors on the 3- / 6-month retention with adjustment of district.

Retention in care in current study was defined as:

- *3-month retention*: having at least three ART pick-ups within the 99 days after the exit-interview.
- *6-month retention*: having at least six ART pick-ups within the 198 days after the exit-interview.

Objective 3

The qualitative data from the interviews were transcribed and analyzed in the same way used for Objective 1. The coding results of the two researchers were compared to assess inter-rater reliability. Reduction was done to summarize the information and organized per theme.

Descriptive analysis was done with quantitative data from exit-interview surveys to calculate the proportion of participants who reported receiving information/ counseling regarding the importance of adherence and other PSS components as outlined in the PSS tool.

Limitations of the evaluation

The evaluation was done in a limited number of health facilities in one province of Mozambique. Results are therefore not representative for the entire province nor the country. However, they offer important information for the region. For Objective 2 specifically, the sample size achieved was small, mainly due to non-eligibility of the HF clients during the period available for data collection.

Much of the data collection period coincided with the region's rainy season, such that at some selected evaluation sites, inclement weather conditions limited the travel of research assistants to reach sites during planned intervals, and also possibly deterred and/or prevented patients (i.e., potential participants) from traveling to the HF.

At the time that these evaluation activities were conducted, the participants recruited and included in these activities were active in care and were asked about their perception of barriers to continuing in care. We

recognize that by recruiting participants who were (at the time) active in care (and not individuals who were in fact not retained in care), we were limited in capturing data/information on actual barriers to retention.

Another limitation of the design of this evaluation was that we measured participants' *perceptions* of barriers to retention, and not actual barriers to retention. This limited our ability to interpret the associations found between perceptions of barriers to retention and actual retention to care.

Evaluation cost

The total estimated cost for completion of this evaluation project was \$59,939 USD.

Results

Results of Objective 1

Sociodemographic characteristics

A total of eight FGD were held with 60 participants: 24 pregnant and 36 lactating women, between January 28th and February 5th, 2019. The socio-demographic data are shown in **Table 3**. The median duration of the focus groups was 90 minutes. At the time of the FGD, participants' median age was 24 years; the vast majority (80%) were married or living with a partner and had completed less than seven years of formal education. At the time of the FGD, approximately 1 in 5 participants did not yet have children, and another 20% had only one living child. Most participants (83%) reported a monthly income of less than 500 Mzn (less than USD \$10.00).

Table 3. Sociodemographic characteristics of women participating in the FGD (n=60)

	N(%)
District	
Quelimane City District	23 (38%)
Namacurra District	29 (48%)
Inhassunge District	8 (13%)
Age, years (median, IQR) (n=46)*	24 (22-28)
Marital status	
Single	9 (15%)
Married/Living with partner	48 (80%)
Separated/divorced	0
Other	2 (3%)
Missing	1 (2%)

Educational level (completed)	
Less than basic education	25 (42%)
Basic (6 th grade)	23 (38%)
Primary (10 th grade)	3 (5%)
Pre-university (12 th grade)	8 (13%)
Missing	1 (2%)

Number of (living) children	
No children	13 (22%)
1 child	14 (23%)
2 children	11 (18%)
3 children	11 (18%)
>3 children	10 (17%)
Missing	1 (2%)

Monthly income (of participant)	
0-500 Mzn	50 (83%)
501-1000 Mzn	1 (2%)
>1000 Mzn	2 (3%)
Missing	7 (12%)

*Age was missing for 14 participants

Barriers to retention in Option B+ care

Women highlighted the main barriers to retention in care to be: the side effects of ARV medications, the way they are treated at the HF, the time it takes to be seen at the HF (i.e., wait time), and the distance from home to the HF (e.g. long distances).

Factors serving as barriers are grouped by level as described below:

a. Individual level

Side effects of medications were in general the most mentioned barrier by participants; while it was presented as a barrier by women in both urban and rural settings, this was mentioned more frequently in rural areas than urban.

“One of the barriers I had that was going to make me stop taking the medication was when I went to bed and I was not sleeping well, dizziness and in the morning when I woke up vomiting nonstop, then I wanted to be nervous and let it go, and even after vomiting outside, for me to get up and go inside there was always a lot of pasta, and then I started to see to let it go.” (FGD, Rural, PAL-03)

Although not mentioned as frequently, some women mentioned the experience of feeling healthy or feeling an improvement in their health, which led to not feeling the need to go to the HF for further care. Another

barrier mentioned by the respondents was negligence where some women said they do not have time to go to the HF for follow-up.

b. Environmental and social level

In terms of social barriers, in general, fear of unintentionally revealing one's serostatus to other people, and fear of stigma and lack of support were also mentioned as factors that hinder women's adherence and retention in Option B+ services. In urban areas, the fear of stigma was most mentioned compared with rural areas.

“A person is afraid of her husband, that when I inform him, he will run away or run away from home (he will divorce me) and I will be left with no one. Others remain silent, others pick up the medication and are afraid to take it, or throw them away to prevent their husband from knowing.”
(FGD, Urban, NAM-01)

c. Institutional/ health facility level

Participants both in rural and urban settings mentioned as other barriers: the time it takes to be seen (i.e., wait time) at the HF, and the way they are treated at the HF (i.e., the perceived level of care and attention they receive from health care workers), like when give them messages of encouragement, counseling and explanations of side effects for example). Wait time was reported as a barrier mainly in urban areas.

Additionally, the distance from one's home to the HF was most mentioned in rural areas as a main barrier to adhering to ART services.

Facilitators for retention in Option B+ care

In terms of facilitators, the responses from participants living in the urban settings were very similar to the responses from participants living in rural areas. Some differences in responses were noted. For example, though it was mentioned as a facilitating factor at all sites, the considerable contribution of the Mentor Mothers (a group of volunteer women who serve as peer mentors/educators for PLW) was mentioned more frequently by the participants in the rural areas than the urban areas.

“In real life she usually helps us a lot, she comes to take me whenever my date arrives, I go to the hospital, pick up my pills, she and a great mother help us a lot.” (FGD, Rural, MBA-06)

The factors serving as facilitators are grouped by level as described below:

a. Individual level

An important factor reported by women was the self-confidence to continue with treatment. Women reported that despite all barriers such as fear of stigma, side effects of ARVs, distance from home to HF, lack of support from partner for treatment, among others, if they had a sense of commitment and self-confidence, they would continue to stay in treatment.

“I can already say that I have no barrier, because I have no prejudice in this disease, because a person cannot laugh at me before proving the opposite, I come normally ... no matter who I find in the hospital. I pick up my medication and go home.” (FGD, Urban, SET-01)

Another facilitator mentioned by participants was the desire to stay alive to be able to care for their children. Women mentioned the belief/understanding that if they take ART, they can remain healthy and take care of their children, as well as the belief that their children will also be healthy; thus, their belief that ART can lead to better health for themselves and their children were important facilitators for remaining in care.

b. Environmental and social level

The disclosure of one’s serostatus to other people and the support received from family, friends and, above all, support from one’s partner were reported as positive influencers for the retention of women in care.

c. Health facility level

Being well attended to and receiving good counseling at the HF was mentioned by participants as a facilitator for staying in care at the HF. Specifically, receiving support from HF-linked Mentor Mothers, including the follow-up home visits they made, was reported as a main facilitator (i.e., it was the fifth most frequently mentioned facilitator) that prompted women to return to HF, and was mentioned in discussions at each selected HF.

R06: “Yes, because when she comes to the home, we talk, she also tells her story, she talks about how it is to take [ART], how she talks to her husband and deals with the subject, when she starts talking about it in the bedroom, she encourages me now.” (FGD, Urban, 24JUL-06)

Participants described that receiving good care at the HF, and a clear explanation of HIV and of possible ART side effects are facilitators for retention in care, insofar as when patients already have good information about possible side effects and how to proceed in the case of experiencing any, they no longer give up/abandon treatment the moment they encounter them.

Suggestions for improving the program

To improve adherence and retention in care, participants recommended that ART be distributed for three or six months at a time (i.e., 3- or 6-month drug dispensation) so that women do not have to travel long distances every month to pick up their medication, and also to reduce the volume of patients and the improve the flow for attending patients in the HF.

“We say what we say, where we come is far, we can’t walk, we don’t have a bike, maybe if it’s possible that they give us two, three bottles, we have nothing to talk about, every month we come and give us our bottle for 30 days.” (FGD, Rural, FUR-03)

Results of Objective 2

Sociodemographic and clinical characteristics

A total of 135 exit-interview surveys were done in the period February--May 2019. For 12 participants, clinical data were either not available or were not valid, thus the regression analysis was done using data from 123 participants. About half of the participants (48%) were from rural areas, median age at survey date was 25 years (IQR 21-29), 72 (59%) were married or living with a partner; 34 (28%) did not have any schooling. About one third (42, 34%) were treatment naïve (**Table 4**).

Table 4. Socio-demographic characteristics (n=123)

Variable	n(%) / median, IQR
Health facility	
Furquia	47 (38%)
Macuse	12 (10%)
17 de Setembro	44 (36%)
24 de Julho	20 (16%)
Rural vs. urban area	
Rural	59 (48%)
Urban	64 (52%)
Age at ART enrollment, years (median, IQR)	
	23 (20-29)
Age at survey date, years (median, IQR)	
	25 (21-29)
Marital status	
Single/ Widowed	28 (23%)
Living with partner/ Married	72 (59%)
Missing	23 (19%)
Highest completed educational level	
None	34 (28%)
Primary School	54 (44%)
Secondary/Technical	26 (21%)
Missing	9 (7%)
Occupation	
Domestic	76 (62%)
Farmer	23 (19%)
Sales	7 (6%)
Student	15 (12%)
Missing	2 (2%)
WHO clinical stage at enrollment	
I	94 (76%)

	II	18 (15%)
	III	11 (9%)
	IV	0 (0%)
Disclosure of serostatus		
	No	8 (7%)
	Yes	37 (30%)
	Missing	78 (63%)
Serostatus of partner		
	Negative	6 (5%)
	Positive	9 (7%)
	Does not know	26 (21%)
	Missing	82 (67%)
ART history		
	ART experienced	76 (62%)
	ART naïve	42 (34%)
	Missing	5 (4%)
Time on ART, months (median, IQR)		14 (0-46)
CD4 cell count at ART enrollment		
	Median (IQR)	426 (264-755)
	<200	10 (8%)
	>199	49 (40%)
	Missing	64 (52%)

Factors influencing confidence to stay in care

Participants felt confident or very confident in almost all factors that were mentioned, with the exception of continued partner involvement, to which respondents reported a lower level of confidence (**Table 5**). Including all surveyed participants (n=135), similar results are seen and added in additional table (Appendix 1).

Table 5. Confidence perceived by participants regarding staying in care, per influencing factor (n=123)

	<i>Not confident at all (n, %)</i>	<i>A little confident (n, %)</i>	<i>Not sure (n, %)</i>	<i>Moderately confident (n, %)</i>	<i>Extremely confident (n, %)</i>
Individual factors					

How confident are you that you understand why you have to take ART every day for the rest of your life? (“ <i>Lifelong</i> ”)	3 (2.4%)	8 (6.5%)	0 (0.0%)	22 (17.9%)	90 (73.2%)
As you know, some of the ARV medications that you take may cause side effects. How confident are you that even if you would feel side effects of the medication, you would still come back to the clinic visits? (“ <i>Side effects</i> ”)	1 (0.8%)	6 (4.9%)	0 (0.0%)	50 (40.6%)	66 (53.7%)
How confident are you that when having doubts about the accuracy of your HIV test results, you would still come back to the clinic to receive care? (“ <i>Accuracy</i> ”)	2 (1.6%)	7 (5.7%)	0 (0.0%)	29 (23.6%)	85 (69.1%)
How confident are you that when having doubts about the efficacy /effectiveness of the HIV treatment (ART) itself, that you would still come back to the clinic to receive care? (“ <i>Efficacy</i> ”)	1 (0.8%)	5 (4.1%)	0 (0.0%)	17 (13.8%)	100 (81.3%)
Social Factors					
How confident are you that your partner will understand why you need to take ART every day for the rest of your life? (“ <i>Partner Understand</i> ”)	6 (4.9%)	12 (9.8%)	4 (3.3%)	26 (21.3%)	74 (60.7%)
How confident are you that your partner will give you permission to take ART every day for the rest of your life? (“ <i>Partner Permission</i> ”)	1 (0.8%)	11 (8.9%)	2 (1.6%)	26 (21.1%)	83 (67.5%)
How confident are you that your partner will encourage you to attend all of your scheduled ANC visits? (“ <i>Partner Encourage</i> ”)	6 (4.9%)	16 (13.1%)	1 (0.8%)	18 (14.8%)	81 (66.4%)
How confident are you that your partner will return with you for future clinic consultation visits/ appointments? (“ <i>Partner Return</i> ”)	7 (5.7%)	20 (16.3%)	2 (1.6%)	42 (34.2%)	52 (42.3%)
Structural Factors					
If you feel that the clinic is very distant from your house, how confident are you that you would still come back to the clinic visits? (“ <i>Clinic Visits</i> ”)	0 (0.0%)	2 (1.6%)	0 (0.0%)	32 (26.0%)	89 (72.4%)
If you feel that the clinic is very distant from your house, how confident are you that you would still come back to pick up your medication? (“ <i>ART Pick Up</i> ”)	0 (0.0%)	2 (1.6%)	0 (0.0%)	24 (26.0%)	97 (72.4%)
Institutional Factors					

How confident are you that the way/manner in which you are cared for/treated by the clinic staff will not prevent you from returning? (“Care”)	2 (1.6%)	5 (4.1%)	0 (0.0%)	24 (19.7%)	91 (74.6%)
As you know, the health facilities are often very busy. How confident are you that even with long queues/long wait times, you would still come back to the clinic visits? (“Wait time”)	0 (0.0%)	2 (1.6%)	0 (0.0%)	20 (16.3%)	101 (82.1%)

Comparing ART-experienced with ART-naïve women, a difference was seen for confidence of herself and her partner understanding the need for lifelong ART, where ART-experienced women reported a higher confidence than ART-naïve women (Appendix 2).

Retention in care outcomes

Among the 123 survey participants for whom clinical data was available, 3-month retention was estimated at 79%, while the 6-month retention was 68%. Across the four HF included, 3-month retention results ranged from 60% to 100%, and 6-month retention results ranged from 55% to 80%. Please see **Appendix 3** for a descriptive analysis of retention by participant demographics.

Living in urban areas showed a statistically significant positive association towards a higher retention at 3-months (94% urban vs 63% rural) and 6-months (78% vs 58%, respectively). Having a higher level of education also showed a statistically significant positive association with higher retention at 3-months (92% with secondary/technical schooling compared to 80% with primary schooling and 65% with no formal schooling) and 6-months (89% compared to 61% and 68%, respectively). There was no significant association seen between age category and retention status at 3- or 6-months, though both age groups (18-24 years of age, 25-40 years of age) saw decreases in retention from 3- to 6-month points (78% to 66%, and 80% to 70%, respectively). Though no significant association was seen between marital status and retention at either 3- or 6-months, participants who reported being single had slightly higher retention at both 3- and 6-months than did those reporting other marital statuses. Being a student showed an association (though not significant) on retention at 3-months (100%) and at 6-months (93%), while working in sales also showed an association (not significant) with higher retention at 3-months (100%), though not sustained at 6-months (71%). Being treatment naïve showed a positive association on retention at 3-months but a negative association on 6-month retention.

Unadjusted univariate analysis showed a significant association between confidence regarding willingness to return to the HF in spite of potential structural barriers (namely the distance to the HF, OR = 3.55; 95% CI 1.41-8.94; p = 0.007) and 3-month retention (**Figure 1**). In addition, a positive association on 3-month retention was seen for confidence regarding belief in ART treatment efficacy, and confidence they would return for care despite possible long wait times (i.e., queue) at the HF. A negative association for 3-month retention was seen for confidence about returning to care despite i) understanding of the need for lifelong use of medications, ii) perceived partner’s permission to take ART and iii) perception of the health care workers’ attitude/manner of treating patients. Looking at 6-month retention, confidence in remaining in

care despite the possibility of ART side effects, belief in treatment efficacy, and distance to the HF remained factors showing a positive association although without statistical significance, while a negative association continued to be seen with confidence in continuing in care despite perceived manner of treatment by health care workers.

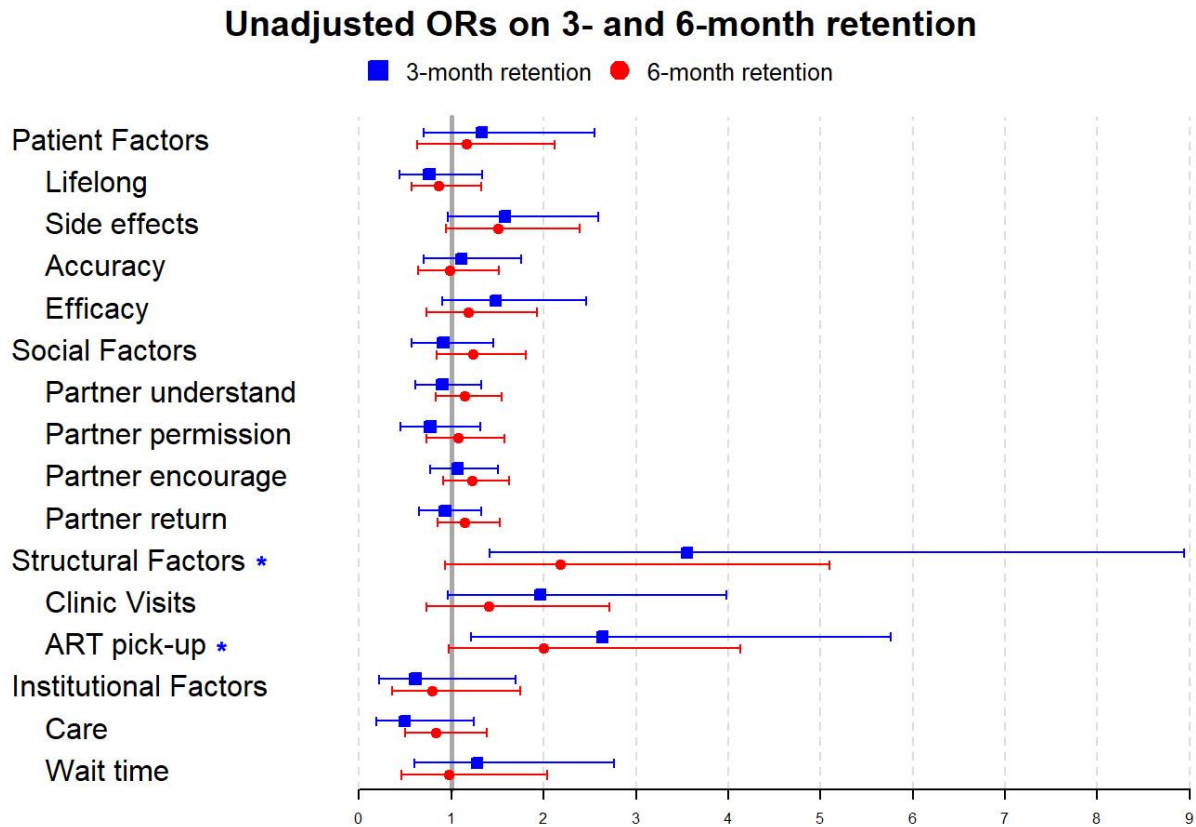


Figure 1. Unadjusted univariate logistic regression analysis on the effect of confidence level for different factors on 3- and 6-month retention (n=123). The blue asterisks denote the two terms which had a significant association to 3-month retention (based on p-values).

Logistic regression analysis adjusting for district, age (at the time of survey) and education (**Figure 2**) showed that the significant positive effect for confidence in one's willingness to remain in care despite structural factors (i.e., distance to the HF) on 3-month retention reduced to a positive association without significance (OR = 2.15; 95% CI 0.73-6.34; p = 0.166). Besides this, a positive association on 3-month retention for confidence to return to care despite awareness of the possibility of ART side effects, one's belief in treatment efficacy, and the potential for long wait times was identified. A negative association for 3-month retention was still seen for confidence about staying in care despite understanding the need for lifelong use of medications, partner's understanding and permission to take ART, perceived health care workers' attitudes/manner towards patients. For 6-month retention, a positive association was seen for the confidence in one's willingness to stay in care despite structural factors related to distance to the HF, the individual/patient factors related to understanding about ART side effects and belief in treatment efficacy,

and all social factors. A negative association was seen for understanding of the need for lifelong use of medications and health care workers' attitudes/care.

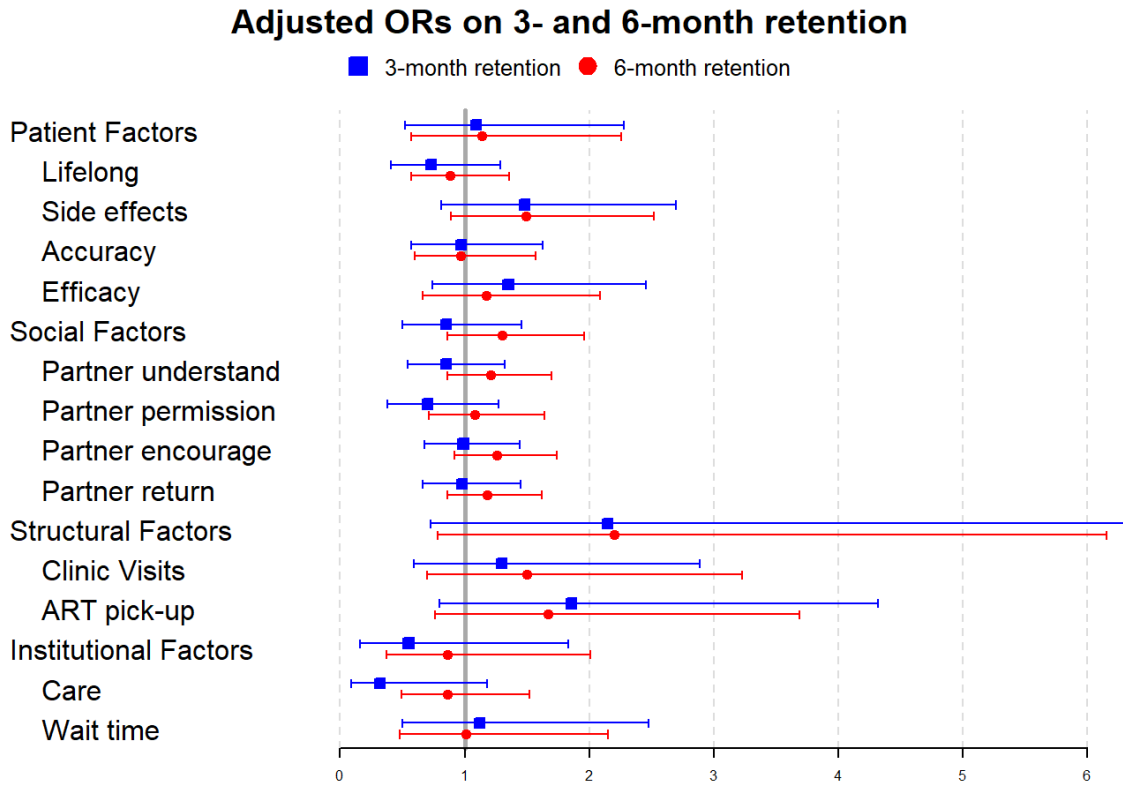


Figure 2. Adjusted logistic regression analysis on the effect of confidence level for different factors on 3- and 6-month retention (n=123).

Multivariable logistic regression model (**Figure 3**) showed with statistical significance that the odds of being retained in care at 3-months was almost seven times higher when living in urban areas, namely Quelimane (OR = 6.93; 95% CI: 2.27-26.11; p = 0.001). After adjusted by district, confidence to return for care even living distant from the HF (OR = 1.79; 95% CI: 0.66-5.0; p = 0.252), and confidence to return even understanding that ART side effects may appear (OR = 1.37; 95% CI: 0.76-2.48; p = 0.285), showed a positive but non-significant effect on 3-month retention.

For 6-month retention, the odds of being retained in care in urban areas (in Quelimane, in this case) was about 2.2 times that of odds in rural areas, but without statistical significance (OR = 2.16; 95% CI: 0.93-5.13; p=0.076). Similar non-significant associations for 6-month retention were seen for the factors of living distant from the HF (OR = 1.46; 95% CI: 0.57-3.73; p=0.423) and understanding about possible ART side effects (OR = 1.36; 95% CI: 0.83-2.23; p=0.219).

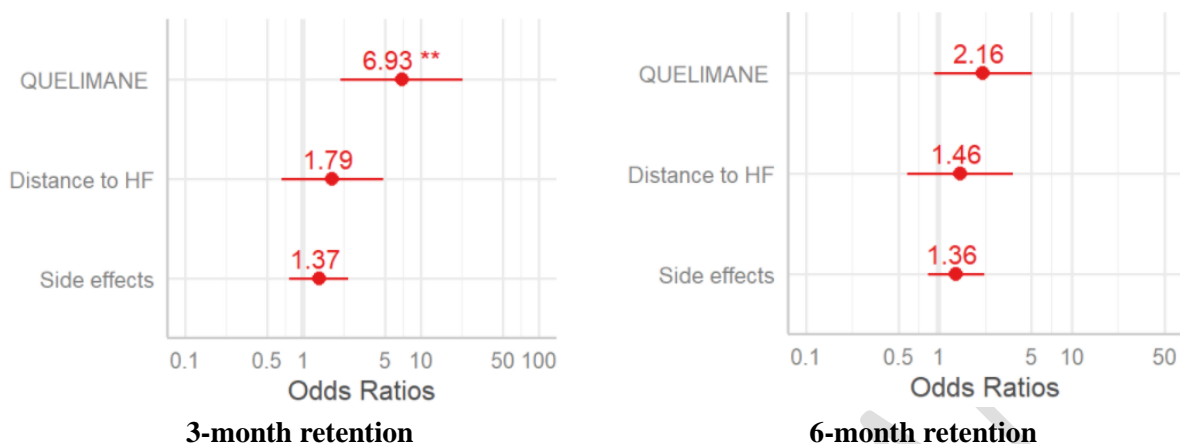


Figure 3. Multivariable regression analysis of effect of specific factors on 3- and 6-month retention.

Results of Objective 3

Sociodemographic characteristics

To evaluate the psychosocial support service delivery, 186 HIV-positive women attending ANC services were surveyed to understand what services were perceived to have been offered at the visit. Data were collected between September and November 2019.

The median age was 27 years (IQR 23-30), 164 (88%) were married, 51 (27%) reported having no formal education, and 86 (46%) lived in rural areas (**Table 6**). For 59 (32%) women, they were attending their first ANC visit (of the current pregnancy) at the time of the survey.

Table 6. Sociodemographic characteristics of the participants (n=186)

	n, %
Health facility	
Macuse	30 (16%)
Furquia	56 (30%)
17 Setembro	50 (27%)
24 de Julho	50 (27%)
Urban vs. rural	
Rural	86 (46%)
Urban	100 (54%)
Age (years)	
Median (IQR)	27 (23-30)
ANC visit	
First	58 (31%)
Follow-up	127 (68%)
Missing	1 (1%)

Marital status		
	Single	14 (8%)
	Married	164 (88%)
	Separated/Divorced	6 (3%)
	Widow	2 (1%)
	Other	2 (1%)
Number of (living) children		
	No children	27 (15%)
	1 child	51 (27%)
	2 children	43 (23%)
	3 children	38 (20%)
	>3 children	27 (14%)
	Missing	1 (1%)
Educational level (completed)		
	No education	51 (27%)
	Alphabetization	51 (27%)
	7th grade	34 (18%)
	10th grade	22 (12%)
	Pre-university (12th grade)	24 (13%)
	Superior	2 (1%)
	Missing	2 (1%)
Work status		
	No job	149 (80%)
	Formal job	14 (8%)
	Informal job	22 (12%)
	Missing	1 (1%)

Report of perceived quality of psychosocial support (PSS/PP) services

Table 7 shows the reporting of received services by the 186 participants who had a visit with the MCH nurse. Women reported that nurses did not discuss all aspects during the visit, but 150 (81%) women reported that the nurse explained how to take ART and half (50%) reported that the nurse talked about ART side effects. About a third (35%) said that the nurse asked about partner/family support, and 76 (41%) reported that the nurse asked about difficulties in getting to the HF.

Differences were seen between first and follow-up ANC visits in certain information received, whereby more women who had attended their first ANC visit (on the day surveyed) reported receiving information from the nurse regarding how to take their ART (93% vs. 75%) and possible side effects (61% vs. 45%).

Table 7. Services received by the MCH nurse during the ANC visit, comparison between first and follow-up (F/U) visit (n=186).

	Total (n=186)	First visit (n=59)	F/U visit (n=127)	p*
	n (%)	n (%)	n (%)	

Did the nurse talk to you about:

How to take the medicines					<0.01
	No	36 (19%)	4 (7%)	32 (25%)	
	Yes	150 (81%)	55 (93%)	95 (75%)	
Side effects					0.04
	No	93 (50%)	23 (39%)	70 (55%)	
	Yes	93 (50%)	36 (61%)	57 (45%)	
Alcohol use					0.054
	No	107 (58%)	32 (54%)	75 (59%)	
	Yes	79 (43%)	27 (46%)	52 (41%)	
Stigma and how to deal with it					0.87
	No	117 (63%)	37 (63%)	80 (63%)	
	Yes	67 (36%)	22 (37%)	45 (35%)	
	Missing	2 (1%)	0	2 (2%)	
Feeling sad / depressed					0.87
	No	120 (65%)	38 (64%)	82 (65%)	
	Yes	64 (34%)	20 (34%)	44 (35%)	
	Don't remember	1 (1%)	0	1 (1%)	
	Missing	1 (1%)	1 (2%)	0	
Importance of partner involvement					0.33
	No	79 (43%)	24 (41%)	63 (47%)	
	Yes	107 (58%)	35 (59%)	64 (50%)	
Importance of disclosure to your partner or other family member					0.26
	No	87 (47%)	24 (41%)	63 (50%)	
	Yes	99 (53%)	35 (59%)	64 (50%)	
<i>Did the nurse ask you:</i>					
If you believe the treatment is working					0.92
	No	91 (49%)	29 (49%)	62 (49%)	
	Yes	93 (50%)	29 (49%)	64 (50%)	
	Missing	2 (1%)	1 (2%)	1 (1%)	
If you are sad / depressed					0.5
	No	123 (66%)	37 (63%)	86 (68%)	
	Yes	60 (32%)	21 (36%)	39 (31%)	
	Missing	3 (2%)	1 (2%)	2 (2%)	
If you get support from partner or other family member					0.66
	No	119 (64%)	39 (66%)	80 (63%)	
	Yes	66 (35%)	20 (34%)	46 (36%)	
	Missing	1 (1%)	0	1 (1%)	
If you have difficulties in getting here to the health facility (transport)					0.12
	No	110 (59%)	30 (51%)	80 (63%)	
	Yes	76 (41%)	29 (49%)	47 (37%)	
What job you have – or if you are unemployed at this moment?					0.82
	No	129 (59%)	40 (68%)	89 (70%)	
	Yes	55 (30%)	17 (29%)	38 (30%)	
	Missing	2 (1%)	2 (3%)	0	

<i>Did the nurse give <u>advice</u> on:</i>					
How to take the medications					0.09
	No	50 (27%)	11 (19%)	39 (31%)	
	Yes	136 (73%)	48 (81%)	88 (69%)	
Condom use					0.82
	No	116 (62%)	38 (64%)	78 (61%)	
	Yes	66 (35%)	21 (36%)	45 (35%)	
	Don't remember	1 (1%)	0	1 (1%)	
	No information	3 (2%)	0	3 (2%)	
Who can give support within the family or within the community					0.49
	No	112 (60%)	34 (58%)	78 (61%)	
	Yes	71 (38%)	25 (42%)	46 (36%)	
	Missing	3 (2%)	0	3 (2%)	
Prevention to transmit the virus to the baby					0.12
	No	48 (26%)	11 (19%)	37 (29%)	
	Yes	137 (74%)	48 (81%)	89 (70%)	
	Missing	1 (1%)	0	1 (1%)	
How to disclose your serostatus to another family member					0.25
	No	108 (58%)	31 (53%)	77 (61%)	
	Yes	76 (41%)	28 (47%)	48 (38%)	
	Missing	2 (1%)	0	2 (2%)	

*Wilcoxon test

Of all participants, 116 (62%) reported they had seen a counselor, and for 43 (37%) of them, this happened in a different room at the HF. Similar as to the visit with the nurse, most (104, 90%) reported receiving information about treatment, and 69 (59%) said ART side effects were discussed (**Table 8**). The importance of partner involvement was discussed according to 80 (69%) women, and about 2/3 (66%) of the women said that disclosure was discussed. In about half of the cases, advice was given by counselors on who can give support within the family or community (56, 48%) and how to disclose one's serostatus (61, 53%).

No differences in information received by the counselor between those who came at their first ANC visit and those in their Follow-up visit.

Table 8. Services received by the counselor during the ANC visit, comparison between first and follow-up visit (n=116).

	Total (n=116)	First visit (n=45)	FU visit (n=71)	P*
	N, %	N, %	N, %	
<i>Did the counselor <u>talk</u> to you about:</i>				

How to take the medicines					0.84
	No	11 (9%)	4 (9%)	7 (10%)	
	Yes	104 (90%)	41 (91%)	63 (89%)	
	Missing	1 (1%)	0	1 (1%)	
Side effects					0.89
	No	45 (39%)	17 (38%)	28 (39%)	
	Yes	69 (59%)	28 (62%)	39 (58%)	
	Don't remember	1 (1%)	0	1 (1%)	
	Missing	1 (1%)	0	1 (1%)	
Alcohol use					0.68
	No	56 (48%)	22 (49%)	34 (48%)	
	Yes	57 (49%)	21 (47%)	36 (51%)	
	Don't remember	1 (1%)	0	1 (1%)	
	Missing	2 (2%)	2 (4%)	0	
Stigma and how to deal with it					0.38
	No	65 (56%)	27 (60%)	38 (54%)	
	Yes	49 (42%)	17 (38%)	32 (45%)	
	Don't remember	1 (1%)	0	1 (1%)	
	Missing	1 (1%)	1 (2%)	0	
Feeling sad / depressed					0.17
	No	65 (56%)	29 (64%)	36 (51%)	
	Yes	50 (43%)	16 (36%)	34 (48%)	
	Missing	1 (1%)	0	1 (1%)	
Importance of partner involvement					0.42
	No	36 (31%)	12 (29%)	25 (35%)	
	Yes	80 (69%)	33 (71%)	44 (62%)	
Importance of disclosure to your partner or other family member					0.42
	No	38 (33%)	13 (29%)	25 (35%)	
	Yes	76 (66%)	32 (71%)	44 (62%)	
	Missing	2 (2%)	0	2 (3%)	
<i>Did the counselor ask you:</i>					
If you believe the treatment is working					0.01
	No	40 (34%)	22 (49%)	18 (25%)	
	Yes	75 (65%)	23 (51%)	52 (73%)	
	Don't remember	1 (1%)	0	1 (1%)	
If you are sad/ depressed					0.73
	No	65 (56%)	26 (58%)	39 (55%)	
	Yes	48 (41%)	19 (42%)	29 (41%)	
	Don't remember	2 (2%)	0	2 (3%)	
	Missing	1 (1%)	0	1 (1%)	
If you get support from partner or other family member					0.13
	No	57 (49%)	26 (58%)	31 (44%)	
	Yes	57 (49%)	18 (40%)	39 (55%)	
	Missing	2 (2%)	1 (2%)	1 (2%)	

If you have difficulties in getting here to the health facility (transport)					0.78
	No	56 (48%)	21 (47%)	35 (49%)	
	Yes	60 (52%)	24 (53%)	36 (51%)	
What job you have – or if you are unemployed at this moment?					0.21
	No	69 (59%)	24 (53%)	45 (63%)	
	Yes	45 (39%)	21 (47%)	24 (34%)	
	Missing	2 (2%)	0	2 (3%)	
<i>Did the counselor give <u>advice</u> on:</i>					
How to take the medications					0.64
	No	11 (9%)	5 (11%)	6 (8%)	
	Yes	105 (91%)	40 (89%)	65 (92%)	
Condom use					0.3
	No	59 (51%)	25 (56%)	34 (48%)	
	Yes	53 (46%)	18 (40%)	35 (49%)	
	Don't remember	1 (1%)	0	1 (1%)	
	Missing	3 (3%)	2 (4%)	1 (1%)	
Who can give support within the family or within the community					0.25
	No	57 (49%)	25 (56%)	32 (45%)	
	Yes	56 (48%)	20 (44%)	36 (51%)	
	Don't remember	2 (2%)	0	2 (3%)	
	Missing	1 (1%)	0	1 (1%)	
Prevention to transmit the virus to the baby					0.39
	No	11 (9%)	5 (11%)	6 (8%)	
	Yes	103 (89%)	40 (89%)	63 (89%)	
	Missing	2 (2%)	0	2 (3%)	
How to disclose your status to another family member					0.6
	No	48 (41%)	19 (42%)	29 (41%)	
	Yes	61 (53%)	22 (49%)	39 (55%)	
	Don't remember	1 (1%)	0	1 (1%)	
	Missing	6 (5%)	4 (9%)	2 (3%)	

*Wilcoxon test

Among the 116 women who received support from both an MCH nurse and counselor, almost all (113, 97%) women reported receiving information on how to take medications, and 99 (85%) received this information from both health workers. It was reported that side effects were not discussed in 30% of the cases. Stigma was discussed in 55% of the cases, and 46 (40%) received from both, while 3 (3%) women reported they only received this information from the counselor. Depression was reportedly not discussed with 57 (49%) of the women. Two thirds (63%) of the women received advice on how to disclose to another family member, for 55 (48%) from both health staff. **Table 9** shows the topics discussed by health staff.

Table 9. Number and type of health staff discussing topics (n=116)

	None of the two discussed	Only counselor discussed	Only nurse discussed	Both discussed
<i>Did the person <u>talk</u> to you about:</i>				
How to take the medicines	3 (3%)	5 (4%)	9 (8%)	99 (85%)
Side effects (n=114)	34 (30%)	9 (8%)	11 (10%)	60 (53%)
Alcohol use (n=114)	45 (39%)	2 (2%)	12 (11%)	55 (48%)
Stigma and how to deal with it (n=115)	52 (45%)	3 (3%)	14 (12%)	46 (40%)
Feeling sad / depressed	57 (49%)	4 (3%)	9 (8%)	46 (40%)
Importance of partner involvement	28 (24%)	5 (4%)	8 (7%)	75 (65%)
Importance of disclosure to your partner or other family member(s) (n=115)	28 (24%)	10 (9%)	11 (10%)	66 (57%)
<i>Did the person <u>ask</u> you:</i>				
If you believe the treatment is working (n=115)	27 (23%)	8 (7%)	13 (11%)	67 (58%)
If you are sad/ depressed (n=114)	52 (46%)	9 (8%)	14 (12%)	39 (34%)
If you get support from partner or other family member(s) (n=114)	50 (44%)	8 (7%)	7 (6%)	49 (43%)
If you have difficulties in getting here to the health facility (transport)	41 (35%)	11 (9%)	15 (13%)	49 (42%)
What job you have – or if you are unemployed at this moment?	61 (53%)	10 (9%)	10 (9%)	35 (30%)
<i>Did the person give <u>advice</u> on:</i>				
How to take the medications	8 (7%)	5 (4%)	3 (3%)	100 (86%)
Condom use (n=113)	52 (46%)	4 (4%)	8 (7%)	49 (43%)
Who can give support within the family or within the community (n=113)	47 (42%)	4 (4%)	10 (9%)	52 (46%)
Prevention to transmit the virus to the baby	8 (7%)	5 (4%)	5 (4%)	98 (84%)
How to disclose your status to another family member (n=114)	42 (37%)	6 (5%)	11 (10%)	55 (48%)

Completeness of the PSS/PP forms

Completeness of the PSS/PP form was reviewed for the 186 survey participants (**Table 10**). The assessment showed that only one participant's file (1%) did not have a PSS/PP form available, and in almost all (96%), there was some information filled in on the form. The component of the PSS factors influencing adherence was complete for 73% of the files, incomplete for 24%, and for 4 (2%), no information was filled in. Only 26% of the PP sessions component was correctly filled in, while for 72% this section was incomplete.

Table 10. Completeness of the forms of the interviewed participants (n=186).

		N, %
General		
Is the form available in the clinical file?		
	No	1 (1%)
	Yes	185 (99%)
Is there information in the forms?		
	No	0 (0%)
	Yes, there is information	179 (96%)
	No response	7 (4%)
New form or old form used?		
	Old form	105 (56%)
	New form	80 (43%)
	Missing	1 (1%)
Identification patient		
Are all fields filled in as per guidelines?		
	Not filled in	0 (0%)
	Correct and complete	80 (43%)
	Not complete	104 (57%)
	Missing	0 (0%)
Sector of referral filled in? ("proveniência")		
	Not filled in	18 (10%)
	Correct and complete	137 (74%)
	Not complete	6 (3%)
	Missing	25 (13%)
Disclosure		
Are all fields filled in as per guidelines?		
	Not filled in	6 (3%)
	Correct and complete	141 (76%)
	Not complete	38 (20%)
	Missing	1 (1%)
Psychosocial (PSS) factors influencing adherence		
Are all fields filled in as per guidelines?		
	Not filled in	4 (2%)
	Correct and complete	136 (73%)
	Not complete	45 (24%)
	Missing	1 (1%)
Is there information on the factors that could influence adherence for each visit, for each visit?		
	Not filled in	35 (19%)
	Correct and complete	81 (44%)
	Not complete	67 (36%)
	Missing	3 (2%)
PP sessions		
If a session is done, are the fields PP1-PP7 filled in for each visit?		
	Not filled in	1 (1%)
	Correct and complete	48 (26%)
	Not complete	134 (72%)

	Missing	3 (2%)
Informed consent		
Information filled in on the client's field?	Not filled in	19 (10%)
	Correct and complete	103 (55%)
	Not complete	63 (34%)
	Missing	1 (1%)
Information filled in on the confident field?	Not filled in	28 (15%)
	Correct and complete	85 (46%)
	Not complete	71 (38%)
	Missing	2 (1%)
Signature field filled in?	Not filled in	22 (12%)
	Correct and complete	45 (24%)
	Not complete	116 (62%)
	No information	3 (2%)

Perceptions of health care staff on the psychosocial support service provision

Sociodemographic characteristics of HCW interviewed

Seventeen health staff participated in the in-depth interviews, and respondent characteristics are shown in **Table 11**.

Table 11. Sociodemographic characteristics of health care workers (n=17)

	N (%)
Sex	
	Male 4 (24%)
	Female 13 (76%)
Age, years (median, IQR)	32 (28-36)
Urban/rural	
	Urban 8 (47%)
	Rural 9 (53%)
Type of HCW	
	Manager 6 (35%)
	MCH Nurse 6 (35%)
	Counselor 5 (30%)
Time working at the HF, years (median, IQR)	3 (2-5)

Knowledge on use of the PSS forms

All participants demonstrated having knowledge of the PSS form, but in terms of filling in/completing the form, counselors reported feeling more confident to complete them than the HF managers or nurses. In terms of frequency of filling out the form, counselors were the only group who reported that they always fill out the form, while some nurses fill out the form only when the counselor is absent. All participants recognized the importance of the PSS form and its completion to monitor patients' adherence to care.

“We have really emphasized this issue of positive prevention and the psychological factors that can affect, in a certain way, what is the patient's adherence to treatment, so we do this to be able and... see how we can... support that pregnant, right, specifically speaking about the pregnant woman, that's why we have support groups, so that's why I said we improved because we managed to insert many women in support groups from the moment we noticed that she has both difficulties for ... that can make it impossible to adhere to treatment”. (Manager, Urban, JUL-001)

Participants reported that filling out the PSS form is the responsibility of health counselors, but facility managers recognized that all health providers should fill out the form as long as they have been trained in how to do so.

Barriers to filling the PSS form reported by HCW

The perceived lack of time (resulting from heavy workloads and long patient queues in the HF) was reported by HCW as the main barrier to filling out the PSS forms, leading health care staff to either forget about the form altogether, or leave the form to fill out at a later time and ultimately not complete it or not in its entirety.

“... Usually the flow of our users' stuff, right, sometimes we have a lot of patients out there, and we want to do the work against time and then we can jump, we can go unnoticed in some fields, not fill in, I think that, and also lack of resources can also be right, because the nurse is unique and sometimes she has to collect blood, she has to do this and the time has passed and it is full, so sometimes she shuffles us a little.” (Nurse, Urban, JUL-001)

On the other hand, some providers reported that negligence and forgetfulness were reasons for not completing the PSS form, and the fact that the form has many fields to be filled in which can lead to the form not being filled out completely (i.e., not all sections are documented on).

Additionally, participants reported that a lack of understanding about the PSS form and/or not receiving adequate training on the use and completion of the form, leads to situations in which a provider sees a patient and does not know how to fill out the form and thus, leaves the form blank or incomplete.

“Good according to what I have seen and that some have difficulty, others say difficulty in perception, how to fill in the form so when there is difficulty in some items they choose to leave it out, not having to make mistakes, so there are some forms that are not well filled out, because every day I questioned a colleague, said that I left that part, we were aaa on the TARV [ART] committee,

so we questioned some colleagues then said why they didn't understand what and what I should tell.” (Manager, Urban, JUL -002)

“(Laughter), for such a training as this, yes it’s needed. Fill-, we try to fill in but no, not with a training on filling in the proper form but we try to complete”. (Nurse, Rural, MAC-003)

Facilitators for completing the PSS form reported by HCW

Health care providers, mainly nurses and counselors reported that when the PSS form is completed correctly, it allows monitoring of patients’ adherence and scheduling appointments, making it possible to follow up with the patient when there are interruptions in care or signs of poor adherence.

“Yeah, it makes it easy for me to be able to see the patient's adherence if she is at fault, depending on his card and on this form there depending on the date I set this month I can see that this patient was supposed to come on day X but she arrived on day Y and then I have to talk about what was due in order to be absent and was taking what during that time interval, this is where I put wrong or abandon depending on this form I pay attention I start to see that patient is adherent or not.” (Counselor, Urban, SET- 001)

“... The factor that facilitates me, maybe being there with the patient, right, so as not to lose the thread of thought, so it is simpler for me to fill out the form there at the moment than to wait for the patient and go and then to fill it out.” (Counselor, Urban, JUL-001)

Suggestion by HCW for improving the completion of PSS form

To improve the filling in/completion of the PSS form, the managers and nurses suggested the provision of frequent training (e.g., refreshment training) to clarify the concepts of the form. This could instill HCW with greater motivation and commitment to fill in the form in a proper and timely manner, since some HCW reported that the poor or total lack of form completion is due to lack of adequate training. The HCW also suggested that clarifying some of the language and reduction of components of the form would improve correct completion of the form.

Discussion

This mixed method evaluation was done to assess factors influencing retention to HIV care for HIV-positive pregnant and lactating women, and associations between potentially influencing factors and retention were measured.

The discussions with HIV-positive PLW informed that women receiving ART (via Option B+ strategy) at the HF recognized that there are some factors that facilitate continuation in care and other factors that make it difficult to continue in the PMTCT care cascade. The main facilitators identified were the desires to stay

healthy and have a healthy baby, while the main barriers that respondents pointed to were the distance from home to HF and side effects of the ARV medications.

Women surveyed after their first ANC visit showed a high degree of confidence in returning to care despite the hypothetical barriers (related to individual, social, structural and institutional factors) that might occur/be faced.

Retention in PMTCT care was moderate at three months and decreased when looking at six months after participants' first ANC visit. A positive association towards higher retention at 3- and 6-months was seen among those living in an urban area (i.e., the provincial capital area) and those having a higher level of education. Positive associations were seen towards higher retention for those who were confident that despite the distance to the HF they would return, and for those who were more confident that despite possible ART side effects they would return. This effect of confidence related to distance to the HF was stronger for short term (3-month) versus mid-term (6-month) retention. The effect of confidence related to understanding the risk for ART side effects was similar for 3-month and 6-month retention. In a paradoxical finding, a negative association was seen for short-term (3-month retention) and women's reported confidence in the understanding of the need for lifelong use of ART medication.

The lack of association seen between the survey responses related to women's confidence regarding their intention to remain in care and their actual retention suggest either that drop-out from care is due to unanticipated barriers, or that many respondents felt social pressure to report a willingness to remain in care that was not congruent with their personal intentions/planning, or it may be related to a limitation in our evaluation design (measuring perceived barriers, i.e., attitudes, and not actual barriers). At the time of entry into ANC/PMTCT services, the majority of women reported they had a moderate to high level of confidence for adhering to treatment and confidence that various factors would not limit their ability to stay in care and on ART. However, despite their reported confidence, the retention results found among this population suggest that over time the barriers mentioned by women with experience in the HIV/ART program may emerge and from there some women start to miss scheduled appointments and experience unintended abandonments of care. Other studies in sub-Saharan countries have demonstrably shown that stigma-related barriers (13, 14), the cost of transportation to the HF, and disclosure of serostatus can have significant impacts on a woman's medication adherence and engagement in care (15, 16). When asked in other studies how retention in care can best be supported, women and health care workers alike have noted the importance of counseling, education, psychosocial support, and encouragement (14, 17). Additionally, since women who do disclose their status are often more likely to do so with their partner, it remains critical for the professional and/or peer support provided through the health system to promote safe and effective communication strategies for disclosure (18).

Factors at the individual, structural and social levels influence the retention of PMTCT services in Zambézia. Some of the barriers mentioned were already anticipated, but the frequency with which participants mentioned ARV medication-related side effects drew attention for this being one of the major challenges faced among this population. As of October 30, 2019, the MOH has recommended TDF/3TC/DTG (fixed-dose combination ART) as preferred first line ART regimen for adults (with TDF/3TC/EFV still preferentially offered to pregnant women in first trimester, after they will be switched to TDF/3TC/DTG). With the evolving prevalence of DTG as first line therapy, it's anticipated that there

will be a decline in medication-related side effects experienced by patients and impacting their retention in care.

Regarding the facilitators, there was a consistent sharing of experiences that conveyed that women's self-determination and commitment encourages them to continue with treatment, even if they face barriers. An important facilitator that was mentioned, particularly in the rural areas, was the fact that women receive support from a Mentor Mother during home visits. Other studies have also found that interventions with lay health workers or peer support in the community help increase not only service uptake but adherence and retention (19-21), addressing known barriers through counseling, education, and/or support/encouragement (22-24). Strategies that are multi-component (to address diverse barriers), involve the support of peer/mentoring mothers, and offer different service models such as quarterly dispensation of medications should be explored to improve patient retention in PMTCT services (25, 26).

Psychosocial support (PSS) is crucial and to understand the needs of PLW enrolled in HIV care, as well as the effect on patient outcomes, documentation related to this routine health care activity is important. This evaluation found that the PSS form is being used, however, in many cases, it is not completed as per guidelines. As PSS services are a principal component in the prevention and resolution of issues that may lead a patient to miss a scheduled visit or experience an IIT, the finding that risk factors screening results were not consistently recorded in the patient records leads to a lost or weakened objective of tracking patient-specific factors and being able to support patients in prevention of LTFU.

Demanding provider workloads and lack of sufficient training seem to be two of the main reasons to explain why the patients' PSS forms/records are not consistently being completed correctly. Most of the health providers interviewed reported that they received in-service training related to the PSS documentation; only one interview participant reported receiving formal training in PSS documentation; and some participants affirmed that they were trained but unfortunately did not indicate if they received formal or in-service training. This would be very important to track and further evaluate, as the type of training received may influence a provider's motivation and preparedness to complete the screening and document the findings (i.e., fill out the PSS form) correctly.

Failure to complete the PSS forms, especially the component related to a patient's risk factors for care abandonment, compromises the provision of adequate support to and follow-up of patients. It should be considered urgent to sensitize and train the appropriate HCW to do these assessments per guidelines and document their findings correctly on the form, whereby creating conditions to facilitate specific follow-up tailored to each patient's needs.

Conclusions and Recommendations

This mixed method evaluation was done to assess factors influencing retention to HIV care for HIV-positive pregnant and lactating women, and associations between potentially influencing factors and retention were measured. Despite the fact that no significant associations were seen in the adjusted analyses, factors related to retention were identified and can assist in targeting retention support strategies. Consistent, timely psychosocial support is critical for HIV-positive pregnant and lactating women. To this end, uniform PSS

training for all MCH health care workers and routine active screening for patients' psychosocial status and potential needs are necessary for providing patient-specific, tailored support as soon as possible to prevent the loss to follow-up of the mother and child from care.

To improve the retention in care of women receiving Option B+ and PMTCT services in general, strategies that involve the support of Mentor Mothers and differentiated care models such as quarterly or semi-annual medication dispensation should be promoted to increase demand and uptake of these support options among those eligible. Considering the concerns found related to treatment side effects and their influence on retention in care, it will also be important to continuously monitor retention rates in the period following the roll-out of DTG-based ART regimens.

Dissemination Plan

Preliminary and final results have been discussed within a priority stakeholders' group of investigators and collaborators. The preliminary results have been discussed at the MOH and the Provincial Health Directorate (DPS-Z). Preliminary results were presented during the provincial health conference in Zambézia (Jornadas Provinciais de Saúde, 2019).

Acknowledgements

We wish to thank all participants for their involvement in this evaluation.

Appendices

Appendix 1. Confidence perceived by participants regarding staying in care, per influencing factor (n=135)

	<i>Not confident at all</i>	<i>A little confident</i>	<i>Not sure</i>	<i>Moderately confident</i>	<i>Extremely confident</i>
	<i>n (%)</i>	<i>n (%)</i>	<i>n (%)</i>	<i>n (%)</i>	<i>n (%)</i>
Individual factors					
How confident are you that you understand why you have to take ART every day for the rest of your life?	3 (2%)	9 (7%)	0	25 (19%)	98 (73%)
As you know, some of the ARV medications that you take may cause side effects. How confident are you that even if you would feel side effects of the medication, you would still come back to the clinic visits?	1 (1%)	6 (4%)	0	54 (40%)	74 (55%)
How confident are you that when having doubts about the accuracy of your HIV test results, you would still come back to the clinic to receive care?	3 (2%)	7 (5%)	0	32 (24%)	93 (69%)
How confident are you that when having doubts about the efficacy/effectiveness of the HIV treatment (ART) itself, that you would still come back to the clinic to receive care?	1 (1%)	5 (4%)	0	19 (14%)	110 (82%)
Social Factors					
How confident are you that your partner will understand why you need to take ART every day for the rest of your life?	7 (5%)	12 (9%)	4 (3%)	28 (21%)	83 (62%)
How confident are you that your partner will give you permission to take ART every day for the rest of your life?	2 (2%)	11 (8%)	2 (2%)	28 (21%)	92 (67%)
How confident are you that your partner will encourage you to attend all of your scheduled ANC visits?	6 (5%)	16 (12%)	1 (1%)	20 (15%)	91 (68%)
How confident are you that your partner will return with you for future clinic consultation visits/appointments?	7 (5%)	21 (16%)	2 (2%)	44 (33%)	61 (45%)
Structural Factors					
If you feel that the clinic is very distant from your house, how confident are you that you would still come back to the clinic visits?	0	2 (2%)	0	34 (25%)	99 (73%)
If you feel that the clinic is very distant from your house, how confident are you that you would still come back to pick up your medication?	0	2 (2%)	0	25 (19%)	108 (80%)
Institutional Factors					
How confident are you that the way/manner in which you are cared for/treated by the clinic staff will not prevent you from returning?	2 (2%)	5 (4%)	0	29 (22%)	98 (73%)
As you know, the health facilities are often very busy. How confident are you that even with long queues/long wait times, you would still come back to the clinic visits?	0	2 (2%)	0	21 (16%)	112 (83%)

Appendix 2. Confidence perceived by participants regarding staying in care, per influencing factor, comparing ART-experienced with ART-naïve women (n=118) (Note: 5 missing values for ART experience)

	[ALL] N=118	Experienced N=76	Naive N=42	p.overall	N
Individual factors					
How confident are you that you understand why you have to take ART every day for the rest of your life?				0.003	118
Not at all	3 (2.54%)	2 (2.63%)	1 (2.38%)		
A little	8 (6.78%)	2 (2.63%)	6 (14.3%)		
Moderately	21 (17.8%)	9 (11.8%)	12 (28.6%)		
Extremely	86 (72.9%)	63 (82.9%)	23 (54.8%)		
As you know, some of the ARV medications that you take may cause side effects. How confident are you that even if you would feel side effects of the medication, you would still come back to the clinic visits?				0.285	118
Not at all	1 (0.85%)	1 (1.32%)	0 (0.00%)		
A little	6 (5.08%)	3 (3.95%)	3 (7.14%)		
Moderately	46 (39.0%)	26 (34.2%)	20 (47.6%)		
Extremely	65 (55.1%)	46 (60.5%)	19 (45.2%)		
How confident are you that when having doubts about the accuracy of your HIV test results, you would still come back to the clinic to receive care?				0.926	118
Not at all	2 (1.69%)	2 (2.63%)	0 (0.00%)		
A little	7 (5.93%)	5 (6.58%)	2 (4.76%)		
Moderately	26 (22.0%)	17 (22.4%)	9 (21.4%)		
Extremely	83 (70.3%)	52 (68.4%)	31 (73.8%)		
How confident are you that when having doubts about the efficacy/effectiveness of the HIV treatment (ART) itself, that you would still come back to the clinic to receive care?				0.128	118
Not at all	1 (0.85%)	1 (1.32%)	0 (0.00%)		
A little	5 (4.24%)	1 (1.32%)	4 (9.52%)		
Moderately	16 (13.6%)	12 (15.8%)	4 (9.52%)		
Extremely	96 (81.4%)	62 (81.6%)	34 (81.0%)		
Social Factors					
How confident are you that your partner will understand why you need to take ART every day for the rest of your life?				0.01	117
Not at all	6 (5.13%)	3 (4.00%)	3 (7.14%)		
A little	11 (9.40%)	5 (6.67%)	6 (14.3%)		
Not sure	4 (3.42%)	1 (1.33%)	3 (7.14%)		
Moderately	25 (21.4%)	12 (16.0%)	13 (31.0%)		
Extremely	71 (60.7%)	54 (72.0%)	17 (40.5%)		
How confident are you that your partner will give you permission to take ART every day for the rest of your life?				0.144	118
Not at all	1 (0.85%)	0 (0.00%)	1 (2.38%)		
A little	10 (8.47%)	4 (5.26%)	6 (14.3%)		
Not sure	2 (1.69%)	1 (1.32%)	1 (2.38%)		
Moderately	25 (21.2%)	15 (19.7%)	10 (23.8%)		
Extremely	80 (67.8%)	56 (73.7%)	24 (57.1%)		
How confident are you that your partner will encourage you to attend all of your scheduled ANC visits?				0.357	117
Not at all	6 (5.13%)	5 (6.58%)	1 (2.44%)		
A little	16 (13.7%)	8 (10.5%)	8 (19.5%)		
Not sure	1 (0.85%)	0 (0.00%)	1 (2.44%)		
Moderately	17 (14.5%)	11 (14.5%)	6 (14.6%)		
Extremely	77 (65.8%)	52 (68.4%)	25 (61.0%)		
How confident are you that your partner will return with you for future clinic consultation visits/appointments?				0.886	118
Not at all	7 (5.93%)	5 (6.58%)	2 (4.76%)		
A little	19 (16.1%)	12 (15.8%)	7 (16.7%)		

Not sure	2 (1.69%)	1 (1.32%)	1 (2.38%)
Moderately	42 (35.6%)	29 (38.2%)	13 (31.0%)
Extremely	48 (40.7%)	29 (38.2%)	19 (45.2%)

Structural Factors

If you feel that the clinic is very distant from your house, how confident are you that you would still come back to the clinic visits? 0.846 118

A little	2 (1.69%)	2 (2.63%)	0 (0.00%)
Moderately	32 (27.1%)	20 (26.3%)	12 (28.6%)
Extremely	84 (71.2%)	54 (71.1%)	30 (71.4%)

If you feel that the clinic is very distant from your house, how confident are you that you would still come back to pick up your medication? 0.911 118

A little	2 (1.69%)	1 (1.32%)	1 (2.38%)
Moderately	22 (18.6%)	15 (19.7%)	7 (16.7%)
Extremely	94 (79.7%)	60 (78.9%)	34 (81.0%)

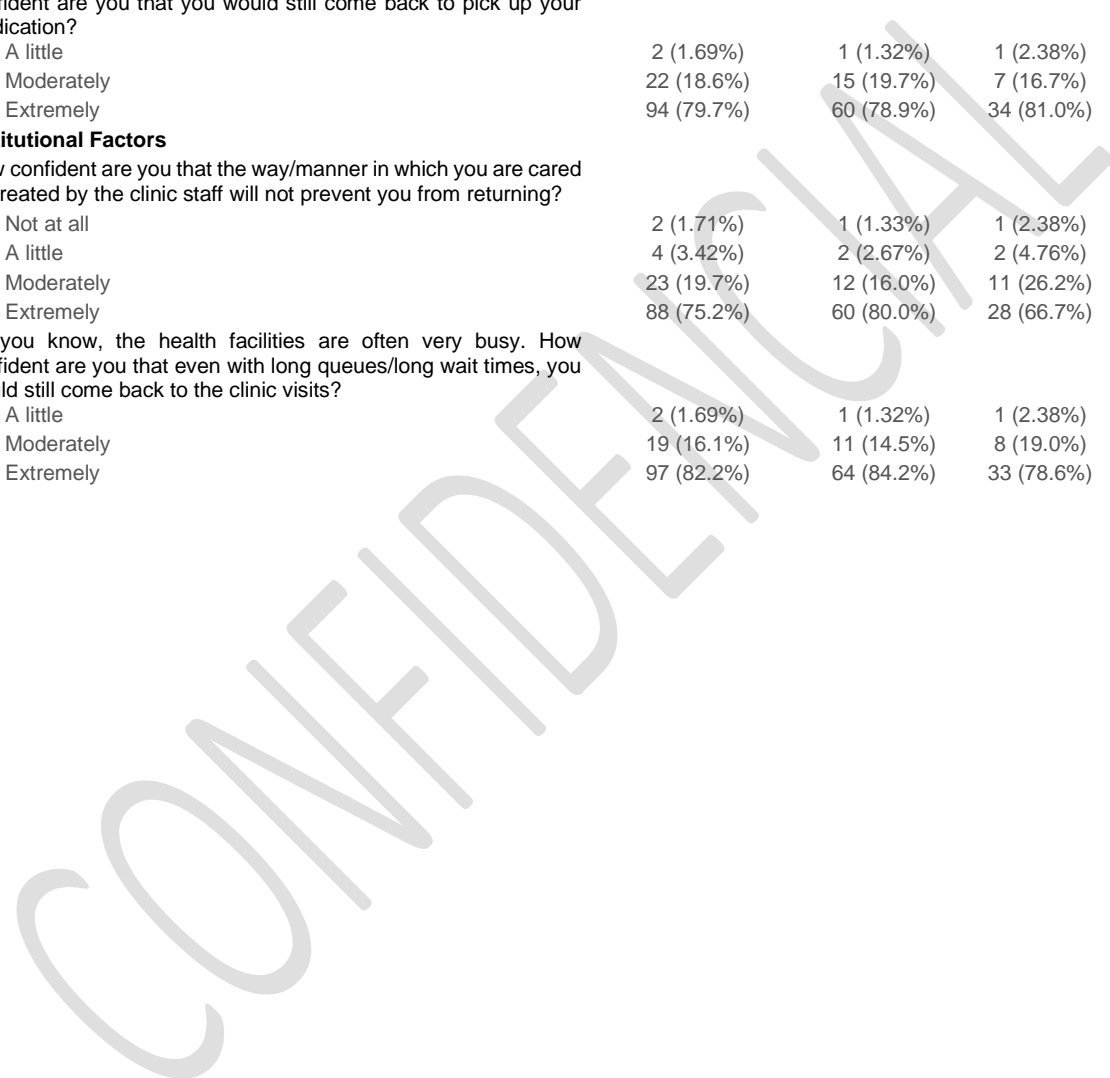
Institutional Factors

How confident are you that the way/manner in which you are cared for/treated by the clinic staff will not prevent you from returning? 0.409 117

Not at all	2 (1.71%)	1 (1.33%)	1 (2.38%)
A little	4 (3.42%)	2 (2.67%)	2 (4.76%)
Moderately	23 (19.7%)	12 (16.0%)	11 (26.2%)
Extremely	88 (75.2%)	60 (80.0%)	28 (66.7%)

As you know, the health facilities are often very busy. How confident are you that even with long queues/long wait times, you would still come back to the clinic visits? 0.653 118

A little	2 (1.69%)	1 (1.32%)	1 (2.38%)
Moderately	19 (16.1%)	11 (14.5%)	8 (19.0%)
Extremely	97 (82.2%)	64 (84.2%)	33 (78.6%)



Appendix 3. Descriptive analysis of 3- and 6-month retention stratified by participant demographic variables.

3-month retention

	Total ^a (n=123) N, %	Retained ^b (n=97) N, %	Not retained ^b (n=26) N, %	p ^c
HF ^d				<0.001
Furquia	47 (38.2%)	28 (59.6%)	19 (40.4%)	
Macuse	12 (9.8%)	9 (75%)	3 (25%)	
17 de Setembro	44 (35.8%)	40 (90.9%)	4 (9.1%)	
24 de Julho	20 (16.2%)	20 (100%)	0 (0%)	
District ^d				<0.001
Namacurra	59 (48%)	37 (62.7%)	22 (37.3%)	
Quelimane	64 (52%)	60 (93.8%)	4 (6.2%)	
Age category (<i>at time of survey</i>)				0.99
18 – 24 years of age	59 (48%)	46 (78%)	13 (22%)	
25 – 40 years of age	64 (52%)	51 (79.7%)	13 (20.3%)	
Education level (n=114)				0.04
None	34 (27.6%)	22 (64.7%)	12 (35.3%)	
Primary school	54 (43.9%)	43 (79.6%)	11 (20.4%)	
Secondary/technical school	26 (21.1%)	24 (92.3%)	2 (7.7%)	
Marital status (n=100)				0.86
Single	22 (17.9%)	18 (81.8%)	4 (18.2%)	
Living with partner	55 (44.7%)	44 (80%)	11 (20%)	
Married	17 (13.8%)	13 (76.5%)	4 (23.5%)	
Widowed	6 (4.9%)	4 (66.7%)	2 (33.3%)	
Occupation (n=121)				0.06
Domestic worker	76 (61.8%)	56 (73.7%)	20 (26.3%)	
Farmer	23 (18.7%)	17 (73.9%)	6 (26.1%)	
Sales	7 (5.7%)	7 (100%)	0 (0%)	
Student	15 (12.2%)	15 (100%)	0 (0%)	

^a The proportions for the *Total* variable results were calculated as percentages within the column (i.e., out of total *N*).

^b The proportions for the *Retained* and *Not retained* variables results were calculated as percentages of the total within each row (to more easily interpret retention percentage in each strata).

^c Chi-square test was performed.

^d The district of Namacurra (where Furquia and Macuse HF are located) is considered a more rural district, compared to the district of Quelimane (where 17 de Setembro and 24 de Julho HF are located) which is considered a more urban district.

6-month retention

	Total ^a (n=123) N, %	Retained ^b (n=84) N, %	Not retained ^b (n=39) N, %	p ^c
HF ^d				0.09
Furquia	47 (38.2%)	26 (55.3%)	21 (44.7%)	
Macuse	12 (9.8%)	8 (66.7%)	4 (33.3)	
17 de Setembro	44 (35.8%)	34 (77.3%)	10 (22.7%)	
24 de Julho	20 (16.2%)	16 (80%)	4 (20%)	
District ^d				0.02
Namacurra	59 (48%)	34 (57.6%)	25 (42.4%)	
Quelimane	64 (52%)	50 (78.1%)	14 (21.9%)	
Age category (<i>at time of survey</i>)				0.76
18 – 24 years of age	59 (48%)	39 (66.1%)	20 (33.9%)	
25 – 40 years of age	64 (52%)	45 (70.3%)	19 (29.7%)	
Education level (n=114)				0.04
None	34 (27.6%)	23 (67.6%)	11 (32.4%)	
Primary school	54 (43.9%)	33 (61.1%)	21 (38.9%)	
Secondary/technical school	26 (21.1%)	23 (88.5%)	3 (11.5%)	
Marital status (n=100)				0.84
Single	22 (17.9%)	16 (72.7%)	6 (27.3%)	
Living with partner	55 (44.7%)	37 (67.3%)	18 (32.7%)	
Married	17 (13.8%)	10 (58.8%)	7 (41.2%)	
Widowed	6 (4.9%)	4 (66.7%)	2 (33.3%)	
Occupation (n=121)				0.15
Domestic worker	76 (61.8%)	48 (63.2%)	28 (36.8%)	
Farmer	23 (18.7%)	16 (69.6%)	7 (30.4%)	
Sales	7 (5.7%)	5 (71.4%)	2 (28.6%)	
Student	15 (12.2%)	14 (93.3%)	1 (6.7%)	

^a The proportions for the *Total* variable results were calculated as percentages within the column (i.e., out of total *N*).

^b The proportions for the *Retained* and *Not retained* variables results were calculated as percentages of the total within each row (to more easily interpret retention percentage in each strata).

^c Chi-square test was performed.

^d The district of Namacurra (where Furquia and Macuse HF are located) is considered a more rural district, compared to the district of Quelimane (where 17 de Setembro and 24 de Julho HF are located) which is considered a more urban district.

Appendix 4. Protocol and all evaluation-related materials

The protocol (version 5.0) is submitted along with this report, and contains all instruments, consent forms, PI biosketches, and conflict of interest statements.

Brief description of the roles of other evaluation collaborators:

Name	Organization	Title	Role in the Evaluation	Responsibilities in the Evaluation
Caroline De Schacht	FGH	Evaluations Director	Co-Principal Investigator	Design, analysis, report writing/manuscript preparation, and overall protocol coordination
C. William Wester	VUMC	Professor of Medicine	Co-Principal Investigator	Design, analysis, report writing/manuscript preparation, overall protocol coordination
Cristina Cugara	MOH	Maternal Child Health Nurse; Operational Investigation Committee of Zambézia (NIOZ)	Co-investigator	Technical oversight; coordination at provincial and district level
Carlota Lucas Fonseca	FGH	Senior Evaluation Officer	Co-investigator	Coordination of study implementation, analysis, report writing/manuscript preparation
Magdalena Bravo	FGH	Maternal and Child Health Advisor	Co-investigator	Clinical Oversight
Gustavo G.C. Amorim	VUMC	Biostatistician, Research Assistant Professor of Biostatistics	Co-investigator	Support analysis
Zhihong Yu	VUMC	Biostatistician	Collaborator	Support analysis and results interpretation
Sara Van Rompaey	FGH	Quality Improvement Technical Advisor	Collaborator	Clinical oversight
Gael Claquin	FGH*	Technical Director	Collaborator	Clinical oversight
Julieta Matsimbe	FGH	Clinical Director	Collaborator	Ensure smooth implementation at study sites; coordination and communication with Provincial Health Directorate and FGH teams

Fernanda Alvim	FGH	Strategic Information Director	Collaborator	Facilitate data extraction and interpretation
Erin Graves	VUMC	Senior Program Manager	Collaborator	Administrative oversight, support design, analysis, and reporting
Folasade Arinze	WellStar Health System	Attending Physician Hospital	Collaborator	Design, participate in abstract/manuscript development

* At the time of evaluation.

Conflict of Interest

The evaluation report provides evidence of the management of conflict of interest for both internal and external evaluations, including statements of conflict of interest procedures and declarations to ensure credibility and mitigate bias.

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Appendix 5. Evaluation Framework

The framework detailing the pathway of inquiries, strategies, effort allocation and intended outcomes for this Option B+ / PMTCT evaluation project is presented in Figure 4.

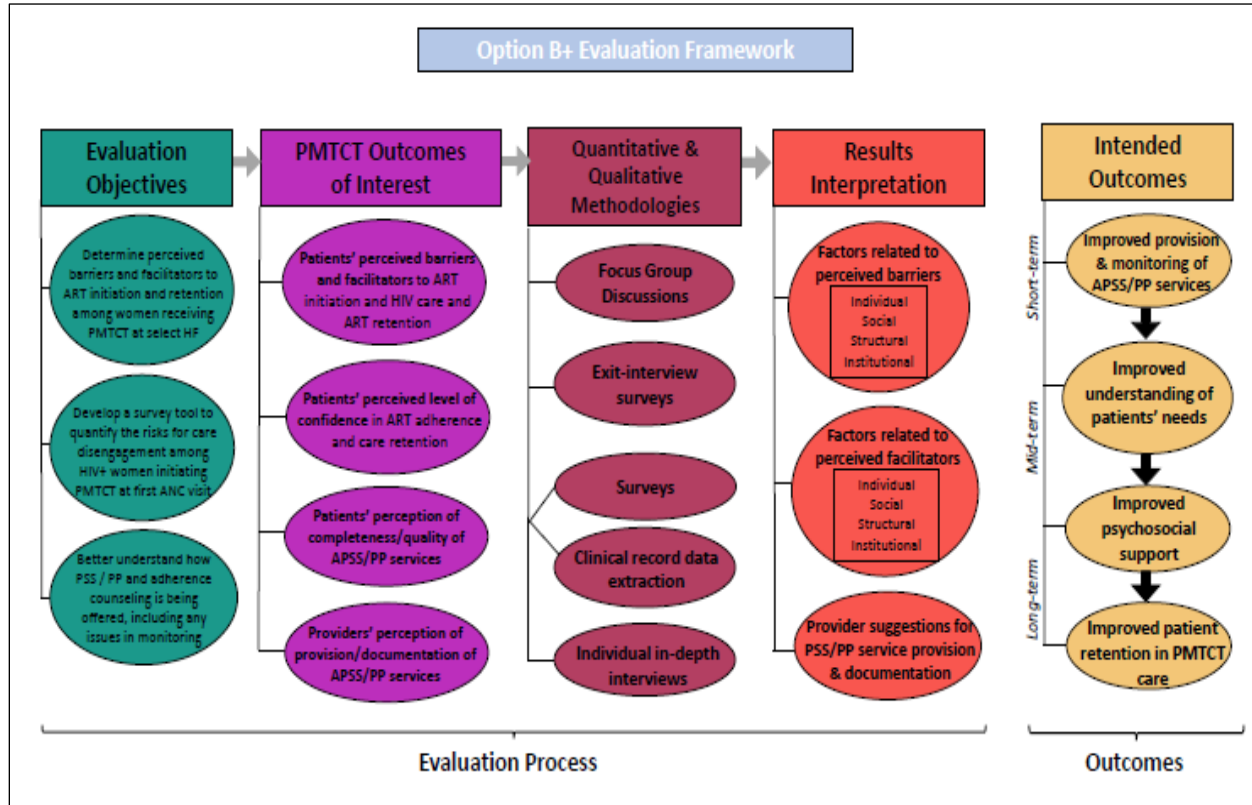


Figure 4. Logic framework for intended pathway for evaluation and, longer-term, for improved maternal and child retention.

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