MPH DISSERTATION:

Patterns of HIV care prior to antenatal care, and the impact on later outcomes, among pregnant women living with HIV in Gugulethu, South Africa: a retrospective cohort

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(0) PREAMBLE

(i) Declaration

I, Bryan Mark Leonard, Student Number: LNRBRY001, declare that the work on which this thesis is presented is my original work (unless the endorsements indicate otherwise) and the whole or any part thereof it is not in progress or to be submitted for another degree at this or any other university. I give permission to the university to reproduce this study for the purposes of all or part of the content in any way.

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(ii) List of Abbreviations

ANC	Antenatal Care
ART	Antiretroviral (ARV) Therapy
CI	Confidence Intervals
CRF	Case Report Form
GCHC	Gugulethu Community Health Centre
GMOU	Gugulethu Midwife Obstetric Unit
HIV	Human Immunodeficiency Virus
LMIC	Low to middle-income countries
LTFU	Loss to follow-up
MTCT	Mother-to-child transmission
PHDC	Provincial Health Data Centre
PI	Principal Investigator
REDCap	Research Electronic Data Capture
REMInD	Routine Electronic Mother-Infant Data
RR/aRR	Risk Ratio/adjusted Risk Ratio
UCT HREC	University of Cape Town Human Research Ethics Committee
UNAIDS	The Joint United Nations Programme on HIV/AIDS
VL	Viral Load
VTP	Vertical Transmission Prevention
WHO	World Health Organization
WLHIV	Women living with HIV

(iii) Dissertation Abstract

Introduction: Women living with HIV (WLHIV) entering antenatal care (ANC) are at high risk of disengagement from antiretroviral therapy (ART). Increasing numbers of women conceiving are already on ART, but little is known about their patterns of care before ANC. We described ART history patterns before ANC among WLHIV and the association with maternal outcomes.

Methods: We used existing data from a prospective cohort that enrolled WLHIV attending ANC in Gugulethu, South Africa. Data were collected through interviews and abstraction of electronic medical records. Self-reported ART history was examined, and women were grouped into (1) Newly starting ART, (2) ART-experienced without any interruptions, (3) ART-experienced with interruption. Log-binomial models were used to assess the association between ART history, viral suppression at delivery and engagement in care at 12 weeks postpartum.

Results: Among 321 women (median age 32.3 years, IQR 28.1–35.9; 61.4% in their first pregnancy), 52% were ART-experienced with no interruption (median years on ART 6.1, IQR 3.3–10.1), 32.7% were ART-experienced with at least one interruption (median years on ART 6.9, IQR 4.4–9.4), and 15.3% were newly starting ART in pregnancy. Among the 105 ART-experienced women with interruption, 94.3% reported only one interruption. After adjusting for age, women newly initiating ART (adjusted risk ratio (aRR): 1.78; 95% CI: 0.91–3.79) and ART-experienced women with interruption (aRR: 2.39; 95% CI 1.39–4.35) were more likely to have a viral load >50 copies/ml at delivery when compared to ART-experienced women without interruption. After adjusting for age and relationship status, ART-experienced women with interruption (aRR: 6.20; 95% CI: 2.05–18.77) and without interruption (aRR: 3.10; 95% CI 0.99–9.71) were more likely to be disengaged from care at 12 weeks postpartum when compared to women newly starting ART.

Conclusion: Most women in this study were ART-experienced before pregnancy, and a third had treatment interruption history. Women with any interruption had increased risk of being unsuppressed at delivery and disengaged from care at 12 weeks postpartum. These findings highlight the need to explore mechanisms driving these associations and examine possible interventions to support continuous engagement in HIV care postpartum.

(iv) Acknowledgements

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A Protocol

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(A) PROTOCOL

(1) Protocol Synopsis

Background: Vertical transmission of Human Immunodeficiency Virus (HIV) remains a problem globally. Vertical transmission prevention (VTP) is vital for women living with HIV (WLHIV) and their HIV-exposed infants. Continuous engagement in antiretroviral therapy (ART) is required to maintain viral suppression and prevent vertical transmission of HIV during pregnancy or postpartum by breastfeeding. However, around 30% of women in Africa are estimated to be lost to follow-up from HIV care (1–4) and women may return to HIV care during a pregnancy. Currently, the ART history patterns of women presenting for antenatal care (ANC) and the impact of prior ART history is poorly understood. This gap in research has led us to design a study where we aim to evaluate patterns of HIV care in WLHIV at the time, they present for ANC in Gugulethu, Cape Town, South Africa.

Methods: The proposed study will be a secondary data analysis of data retrieved from a prospective cohort study, the Routine Electronic Mother-Infant Data (REMInD) study, HREC REF 513/2020, conducted at a primary health care facility in Gugulethu, Cape Town, South Africa. The main objectives of the proposed study will be to (1) describe the sociodemographic and clinical characteristics of pregnant women entering ANC, specifically: those who have newly started ART, are ART-experienced (without interruptions), and those who are ART-experienced (with interruptions), but not currently on ART; (2) describe and evaluate patterns of HIV care interruptions among the ART-experienced (with interruptions) women by describing their ART history before pregnancy; and to (3) examine the association between the ART history exposure, maternal HIV viral suppression at delivery and maternal engagement in care at 12 weeks postpartum, respectively.

Ethical Considerations: The REMInD parent study has previously received ethical approval from the University of Cape Town Human Research Ethics Committee (UCT HREC), since this proposed study is a secondary data analysis there is no direct contact with the participants of the parent study. An anonymized dataset will be extracted from the parent study Research Electronic Data Capture (REDCap) database for this secondary data analysis.

(2) Literature Review

(2.1) Introduction

The human immunodeficiency virus (HIV) is one of the most complex infectious diseases that has challenged pregnant women and women of reproductive age globally, especially in sub-Saharan Africa (2,5). Many African nations classified as low- and middle-income countries (LMIC) succumb to the high burden of HIV due to the lack of public health infrastructure and accessibility to treatment (6). In Africa, approximately 30% of pregnant women living with HIV (WLHIV) are lost to follow-up from antiretroviral therapy (ART) programs during the prenatal, perinatal, and postpartum periods (1). In South Africa, it is estimated that 30% of pregnant and postpartum women WLHIV experience loss to follow-up (LTFU) from ART (7,8). Poor engagement in ART care among pregnant women entering antenatal care (ANC) and among postpartum women remains a challenge (9,10).

(2.2) Search Strategy

A literature search was conducted electronically to find relevant research on antenatal and postpartum populations of women living with HIV and their ART experiences before, during, and after pregnancy. PubMed and Google Scholar were used to conduct the literature search. The search strategy contained a combination of the search terms and keywords listed below and their synonyms and antonyms. Only studies that included antenatal or postpartum ART or discussion of vertical transmission prevention (VTP) were considered for the review. This is not meant to be an exhaustive systematic review; rather, it seeks to synthesize the essential literature relevant to the proposed study.

Literature review search strategy terms and keywords

HIV: Human immunodeficiency virus.

ART: Antiretroviral therapy.

Pregnancy: antenatal, prenatal, before birth, during birth, after birth, perinatal.

Postpartum: Maternal, perinatal, postnatal.

Engagement: Disengagement, loss to follow-up, retention, retained, non-retention.

Adherence: Non-adherence, compliance, non-compliance.

(2.3) Significance of antiretroviral therapy during pregnancy and postpartum

ART is very effective for managing HIV and is important in preventing maternal mortality, as well as vertical transmission during and after pregnancy through breastfeeding (11). Pregnant WLHIV who enter ANC are at high risk of transmitting HIV to their unborn infants if they are not on ART and virally suppressed. When the viral load (VL) increases, the risk of vertical transmission increases as well (2,12,13). However, engagement in care and adherence to ART during this period significantly increases viral suppression and decreases the risk of vertical transmission (3,10,12). Equally, once women have delivered their infant, it is vital that they remain adherent to ART and continue engaging in HIV care services to achieve viral suppression postpartum, thus preventing HIV transmission through breastfeeding (9). As such, VTP programs that support women's engagement in care and their adherence to ART during pregnancy and postpartum are pivotal in decreasing the burden and transmission of HIV in infants (1,3,14,15).

Existing research has shown that movement in and out of HIV care negatively impacts health benefits associated with ART treatment. Primarily this is facilitated by increased viraemia from suboptimal ART during periods of poor engagement in care that may lead to new HIV infections and drug resistance to existing treatments (3,10,16,17). Pregnant and postpartum women on ART who disengage from care are at a high risk of developing viral mutations that could lead to drug resistance. In addition to adverse effects on women's health, such outcomes may also pose challenges to already resource-constrained health systems, as additional funds will have to be allocated to address the impact of further increases in HIV burdens across the population (3,10,16,17).

(2.4) Vertical transmission prevention and antiretroviral therapy guideline changes over time

Continued ART is important for many reasons, including preventing vertical transmission. Vertical transmission is the phenomenon whereby HIV is transferred from a mother to their infant either before delivery, i.e., in utero or after delivery via breastfeeding (9). VTP can only be achieved through continued ART use before and after delivery. Table A1 below illustrates how VTP and ART policy guidelines in South Africa have changed over the years (12). The current guidelines, rolled out in 2016 (14,15), recommend universal ART for all people living with HIV, regardless of their CD4 count. From 2013 to 2016, all pregnant and breastfeeding women were eligible for lifelong ART under World Health Organization (WHO) Option B+ (18). The policy changes have been made and set in place to expand access to lifelong ART and

enable the prevention of HIV transmission and possible eradication of vertical transmission. As a result, many women are already on ART before conception. However, sustained engagement in care during ANC and postpartum is essential to prevent vertical transmission (2,3,14,19).

Table A1: Timeline of national vertical transmission prevention and antiretroviral therapy guidelines, South Africa

YEAR	VERTICAL TRANSMISSION PREVENTION GUIDELINES	ANTIRETROVIRAL THERAPY GUIDELINES
2002	Single dose nevirapine to the mother in labour, and to the infant within 72 hours of birth.	
2004	AZT to mother from 28 weeks gestation; single dose nevirapine to mother in labour and to infant within 72 hours of birth.	National roll-out of Antiretroviral programme. Eligibility: CD4<200 cells/mm^3, or WHO stage 4 disease.
2008	AZT to mother from 28 weeks gestation; single dose nevirapine to mother in labour and to infant within 72 hours of birth.	
2010	AZT from 14 weeks gestation: single dose nevirapine plus tenofovir/3TC in labour; infant prophylaxis with nevirapine for 6 weeks if mother on HAART or formula feeding, or until the end of all breastfeeding if mother not eligible for HAART.	Eligibility for HAART includes CD4<350 cell/mm^3, and all people with TB irrespective of CD4 count.
2013	All pregnant women eligible for HAART, irrespective of CD4 count. Infant prophylaxis with nevirapine for 6 weeks. Women initiating HAART with CD4<350 and no other indication for HAART, to stop treatment after all breastfeeding has ceased.	
2015	All pregnant and breastfeeding women eligible for lifelong HAART.	Eligibility for HAART includes CD4<500 cells/mm^3.
2016	New HIV Guideline: Universal ART for all, test and treat.	All HIV-positive children, adolescents, and adults, regardless of their CD4 count, will be offered ART treatment, prioritizing those with CD4<350 cells/mm^3 (14,20)
2019/2020	Amended HIV Guideline: Universal ART for all, test and treat.	All people living with HIV are eligible for ART regardless of age, CD4 count and clinical stage (14,20)

ART: Antiretroviral therapy; AZTL: zidovudine; HAART: highly active antiretroviral therapy; VTP: Vertical Transmission Prevention; WHO: World Health Organization. *Note: adapted from Burton R, Giddy J, Stinson K. Prevention of mother-to-child transmission in South Africa: an ever-changing landscape. Obstet Med. 2015;8(1):5-12. Doi:10.1177/1753495X15570994*

(2.5) Factors, challenges and barriers associated with engagement in care for antiretroviral therapy during pregnancy and postpartum period

Various factors have been associated with engagement in ART care, including individual, socioeconomic, and service-level factors.

Individual-level factors

Individual-level factors look at demographic and clinical variables, including age, VL and CD4 count. It has been found that younger women are more likely to experience LTFU from HIV care when compared to older women (21). Disengagement from care, specifically in younger women, tends to affect VL (viraemia) and CD4 counts (10,22). Other factors, such as gestational age, pregnancy status and pregnancy intentions, also affect engagement in HIV care. A previous study found that initiating pregnant women on ART during an ANC ART programme was feasible, safe, and effective. However, treatment initiation and LTFU has been identified as crucial challenges in this population of women with advanced gestational age (21). Research has shown that WLHIV who receive ART and remain in HIV care tend to have better health outcomes. Women starting ART during pregnancy can significantly decrease their risk of vertical transmission (12,14,23). WLHIV who engage in care during their pregnancy are more likely to achieve improved viral suppression and a reduced risk of HIV transmission to their child. However, pregnant WLHIV may face challenges when it comes to adhering to their HIV care. Research suggests that concerns, around their health and the well-being of their infant may motivate them to seek HIV care (4,7,9,24,25). However, factors like stigma, fear of disclosing their HIV status and social support can also influence their engagement in HIV care during pregnancy (5,22). Previous studies have indicated that women with planned pregnancies are more likely to engage in HIV care and adhere to ART compared to those with unplanned pregnancies (7,9,24,26,27). Women who desire to have a child are aware of their HIV status and may be more proactive in seeking HIV care and adhering to their ART regimen, for the well-being of themselves and their baby (3,9,13). The extent and intensity of these associations can differ based on individual situations, cultural contexts, and accessibility of healthcare services (3,5,11).

Socioeconomic factors

Socioeconomic factors such as relationship status, education, and employment status adversely affect engagement in HIV care (1,3,26). It has been reported that married women are more likely to experience LTFU when compared to single women (4,9). In addition, fear of HIV status disclosure and lack of transparency in relationship may limit support received from their partners, which may cause unnecessary trust issues within the relationship (26). Partner support and involvement during ANC have been found to be generally low in South Africa (11). Higher levels of education are often associated with better health literacy. An increased health literacy, enables WLHIV to be more aware of the importance of HIV care and ART adherence, leading to better engagement in HIV care (3,25,27). Education can impact an individual's socioeconomic status, which affects their access to HIV care and engagement. Individuals with higher levels of education and stable employment have better access to healthcare facilities and qualified healthcare providers, making it easier for them to engage in HIV care consistently (5,11,18,22,26). Individuals with lower levels of education and limited employment opportunities may experience higher levels of stigma and discrimination related to their HIV status (11,18,22,29). Stigma can act as a barrier to seeking HIV care and disclosing their HIV status, leading to reduced engagement in HIV care (3,9,13,18,27). Employment status can impact a person's ability to attend healthcare appointments regularly. Individuals with unbalanced or unstable employment may face challenges in scheduling and attending HIV care visits, leading to ART interruptions in HIV care (5,22,30). Education and employment can influence a person's financial resources. Sufficient financial means can help cover healthcare expenses and transportation costs, facilitating better engagement in HIV care (3,13,27). Education and employment play a significant role in an individual's mental health and coping capabilities. Higher education levels and stable employment lead to better mental well-being, positively impacting one's commitment to their HIV care. Individuals with higher education levels and stable employment are more likely to remain in HIV care over the long term, reducing the risk of ART interruptions and associated adverse health outcomes. It’s important to note that the direction and strength of these relationships can vary depending on cultural, social, and economic backgrounds (3,9,10,13).

Service-level factors

Service-level factors strongly impact engagement in HIV care and adherence to ART through patient-provider relationships and ART stock-outs (7,11,13). Issues relating to trust toward healthcare providers, fear of HIV status disclosure, and lack of confidentiality affect the level of service received within a healthcare facility (11,13). One health service factor that heavily

impacts engagement in HIV care during and after pregnancy is the structure of the healthcare services where women need to access care over time. Figure A1 illustrates the flow of two common care routes before and after delivery offered in South Africa for WLHIV. Upon the delivery of their baby, women in ANC transferred to general ART services to continue with HIV care. However, this period often challenges success in postpartum HIV care. The growing concern stems from the lack of support women may experience in navigating changes between ANC and general ART services, which further adds to the risk of disengagement from HIV care (30).

Challenges and barriers experienced in postpartum women

The two primary challenges of adherence to lifelong ART in pregnant women and those of childbearing age are that they may feel healthy upon initiating ART and get overwhelmed by the lifetime commitment of being on treatment (11). Also, there appears to be more social support for WLHIV when pregnant than after pregnancy when they are just living with HIV. Given that in the ANC setting, there is ample support throughout the pregnancy of WLHIV, with less social support, postpartum WLHIV may portray signs of depression and stress and often feel lonely (11,18,26,29). Furthermore, studies have noted barriers to engagement in ART health care due to side effects to treatment, financial problems—resulting in lack of food and transport—stigma, and discrimination. As such, barriers heavily impact continuous engagement in ART health care during pregnancy and postpartum; mitigating them with the necessary support may reconcile WLHIV to ART health care (5,11).

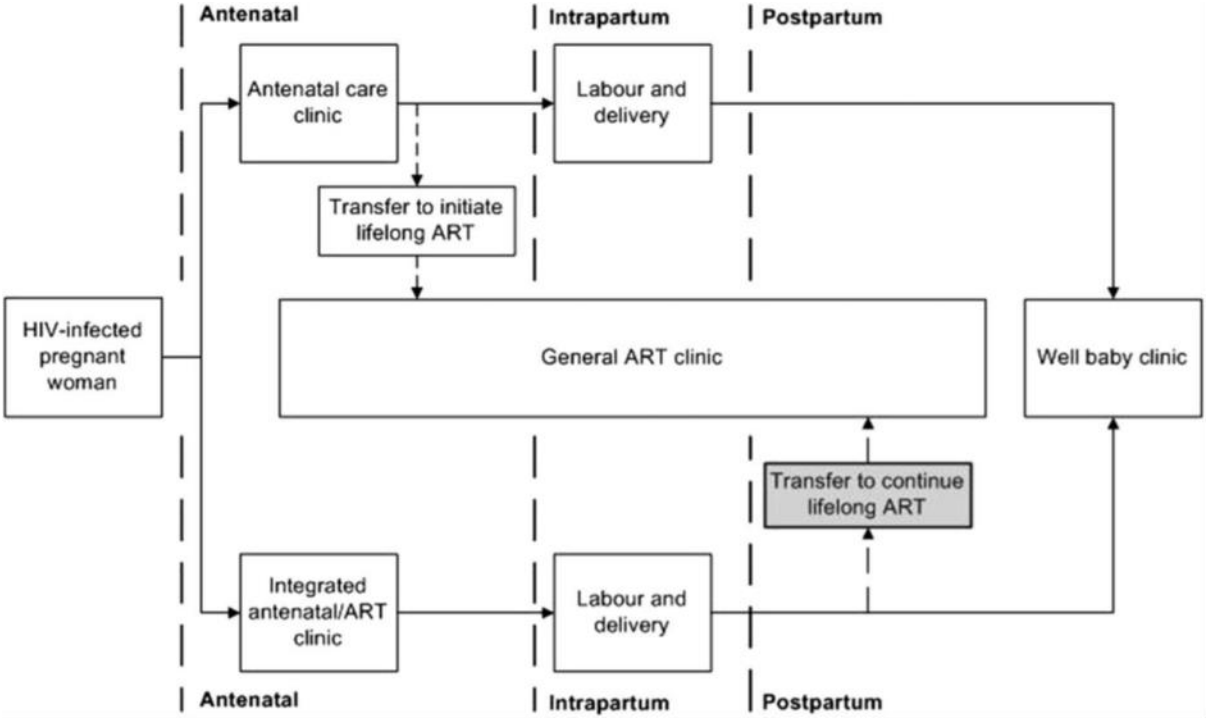

Figure A1: Flow diagram of antiretroviral therapy vertical transmission prevention cascade, including antiretroviral therapy services during pregnancy and postpartum

(Note: Reprinted from Phillips T, McNairy ML, Zerbe A, Myer L, Abrams EJ. Implementation and Operational Research: Postpartum Transfer of Care Among HIV-Infected Women Initiating Antiretroviral Therapy During) Pregnancy. J Acquir Immune Defic Syndr. 2015 Nov 1;70(3):e102-9. Doi: 10.1097/QAI.0000000000000771. PMID: 26470033.)

(2.6) Impact of antiretroviral therapy history on engagement in care

Existing research has highlighted growing concerns about the prevalence of ART interruptions among people living with HIV. Moreover, people starting ART under test and treat policies, ART interruptions might occur before or between pregnancies among women on ART (5,30,31). For example, postpartum women may experience ART interruptions resulting from challenges with accessing HIV care after periods of mobility. These challenges may include relocation away from usual and familiar healthcare services, changes in transport costs or misplacing health care documentation (8,30). Access to consistent and responsive ART services can be challenging for WLHIV who experience mobility (5,8,11,30). Previous research suggests that health systems may struggle to adequately address the needs of mobile WLHIV, leading to interruptions in ART and suboptimal health outcomes (5,30). Mobility, including migration and travel, are one factor in ART interruption. However, disruptions in HIV care access and continuity thereof can occur when individuals move to new locations, which may affect their ability to adhere to ART. Limited access to healthcare facilities, particularly in rural or remote areas, can make it challenging for individuals to obtain

their treatment regularly. Adverse side effects of ART or the burden of adhering to a strict ART regimen may lead some individuals to interrupt their ART (5,23,27,30,32). ART interruption before pregnancy may introduce complexities in HIV care, and some individuals may interrupt ART during pregnancy due to concerns around potential effects on their baby or for other reasons related to family planning (5,11,30). WLHIV who has been on ART that engaged in HIV care are likely familiar with HIV care engagement and adherence thereof. This experience could lead them to be more proactive in seeking HIV care before pregnancy. WLHIV who have successfully managed their infection through ART adherence may be more aware of the importance of vertical transmission during pregnancy. WLHIV that adhered to long-term ART have likely learnt the importance of maintaining good health overall, before and during pregnancy, and it may motivate them to engage and remain in HIV care (1,3,9,11,18).

(2.7) Conclusion

There is sufficient literature available that investigates women during pregnancy. However, the women entering ANC with or without prior ART experience are poorly understood and explored. The impact of previous ART interruptions on WLHIV that are either non-pregnant, pregnant, or postpartum may have long-term detrimental effects on their later health outcomes, i.e., influencing postpartum engagement in HIV care and viral suppression at delivery.

(2.8) Study Rationale

Limited data investigate the pre-pregnancy ART history of WLHIV who enter ANC services. The above literature review shows that pregnant and postpartum WLHIV are susceptible to LTFU (4). The existing literature indicates a higher risk of LTFU during the postpartum period than in the ANC period (26,28). Because of the scale-up of universal ART, there are lots of women starting lifelong ART before pregnancy. Still, there is a poor understanding about the patterns of HIV care for the group of women presenting for ANC or the impact of ART history on future maternal outcomes. In this study, we aim to explore patterns of HIV care in WLHIV receiving antenatal care in Gugulethu, South Africa.

(3) Background

(3.1) Background for the proposed dissertation

The proposed research will be based on a secondary analysis of data collected from the Routine Electronic Mother Infant Data (REMInD) study, a prospective cohort study conducted at a primary healthcare facility in Gugulethu Midwife Obstetric Unit (GMOU), Cape Town, South Africa. The parent study took place between March 2021 and March 2022. This cross-sectional, retrospective cohort study explores patterns of HIV care in women living with HIV receiving ANC in Gugulethu, South Africa. Furthermore, the study will assess the associations relating to ART history and HIV treatment outcomes at and after delivery.

(4) Study aims and objectives

(4.1) Research question

What are the patterns of HIV care in women living with HIV when presenting for antenatal care in Gugulethu, Cape Town, South Africa, and how do these patterns affect later HIV outcomes?

(4.2) Study aim

To explore patterns of HIV care in women living with HIV receiving antenatal care in Gugulethu, Cape Town, South Africa, and the impact of ART history on maternal HIV delivery viral suppression and early postpartum engagement in HIV care.

(4.3) Objectives

(4.3.1) To describe the proportion of women entering antenatal care based on their ART history exposure. The three levels of ART history exposure can be defined as ART-experienced without interruption, ART-experienced with interruption, and newly starting ART at the time of pregnancy and ANC enrolment. Compare sociodemographic and clinical characteristics of these ART history groups.

(4.3.2) To describe and evaluate ART history, gaps, and patterns of HIV care in the ART-experienced proportion of pregnant women having ever interrupted.

(4.3.3) To examine the association between the ART history exposure prior to pregnancy and their later HIV outcomes, i.e., a) maternal HIV viral suppression at delivery, and b) maternal engagement in HIV care at 12 weeks postpartum.

(5) Methodology

(5.1) Study Design

This is a retrospective, cross-sectional study using data from the REMInD parent study that enrolled a prospective cohort of 300-400 pregnant and early postpartum WLHIV in Gugulethu, Cape Town, South Africa.

(5.2) Sampling and study population

Enrolment data and early follow-up data from the cohort of approximately 300-400 WLHIV enrolled in the REMInD study will be used for this proposed secondary analysis. The women were recruited from antenatal and early postnatal care at GMOU. Women attending HIV care at the GMOU were screened for eligibility. Eligible women provided written informed consent and were enrolled in the parent study.

(5.2.1) Inclusion criteria

• Aged 18 or older.

• Peripartum women either in the third trimester of pregnancy (at least 28 weeks) or recently postpartum (up to 3 weeks after delivery) based on their medical record.

• Living with HIV (confirmed in the medical record).

• Accessing antenatal or early postnatal care at the study site.

• Able to provide informed consent, including consent to having study personnel access her and her baby's medical records.

(5.2.2) Exclusion criteria

• Failure to meet any of the above inclusion criteria

• Significant pre-existing psychiatric comorbidity at enrolment that may impact the ability to consent according to the judgment of study personnel (including cognitive impairment or known psychotic disorder per medical record).

(5.3) Study setting

The GMOU and Gugulethu Community Health Centre (GCHC) in Cape Town, South Africa, serves approximately 5000 pregnant women annually. In this setting, the antenatal HIV prevalence is approximately 25%. Women receive integrated antenatal and ART services during pregnancy but transition to routine ART and childcare clinics after delivery. All patients attending public sector services are issued a unique patient identifier used across multiple electronic health information systems. The Provincial Health Data Centre (PHDC) combines these data sources for patient care and reporting purposes, enabling the linkage of records across facilities in the province (33).

(5.4) Data Collection

No new data will be collected for this proposed study. Data collected during the REMInD study will be used. Enrolment data were collected on paper forms during face-to-face or telephonic interviews (due to the COVID-19 pandemic) and entered into a custom-designed Research Electronic Data Capture (REDCap) database, maintained in a firewall-protected UCT server.

During the REMInD study, data were collected as follows:

On the same day as the enrolment or within two weeks, women completed the following study procedures:

• Questionnaires to collect sociodemographic and clinical information, HIV treatment history, and details on planned clinic attendance postpartum.

• All the above questionnaires provide information that may influence women's ability to remain engaged in HIV care.

• Linkage information: Patient identifiers of the mother and her baby were collected and stored by the study to allow linkage to therapist medical records. These included name, surname, date of birth, ID number and clinic folder number. This information was stored separately from all other study documentation and will not be accessed for this secondary analysis. Additional data were abstracted from the routine health information system to ascertain HIV and pregnancy care. This data included ART dispensing, VL, delivery date, and pregnancy outcome.

Key variables

The primary exposure variable in this analysis was ART history which was determined using self-reported ART initiation timing and ART interruptions up to the time of enrolment into the study. ART history groups were defined as follows:

- Newly starting ART: A woman who was starting ART for the first time during this pregnancy.
- ART-experienced without interruption: A woman who was ART-experienced and had not ever interrupted HIV care at the time of enrolment.
- ART-experienced with interruption: A woman who was ART-experienced and who had ever interrupted ART at the time of enrolment.

The outcome measures will be maternal VL suppression at delivery and engagement in HIV care at 12 weeks postpartum. The data will be abstracted from the routine health information system during the parent study and are defined as follows:

VL suppression: The HIV VL of women at delivery, ≤50 (suppressed) or >50 – ≤1000 (unsuppressed) or >1000 (unsuppressed) copies/ml will be used for descriptive statistics. However, two VL thresholds will be used for bivariate statistics and regression modelling, i.e., (a) VL≤50 or VL>50 and (b) VL≤1000 or VL>1000 copies/ml.

Engagement in HIV care at 12 weeks postpartum – defined using pharmacy refill data as to whether a woman had no ART in hand for 30 days or more at 12 weeks postpartum (not in care). This time point was chosen as it is expected that by 12 weeks postpartum, a woman should have connected to and been dispensed ART from a general ART clinic after delivery. A 30-day window is given as we know that women sometimes receive additional ward stock of ART at the time of delivery that is not captured in the pharmacy data.

(5.5) Data Management and Analysis Plan

The study database is access controlled through UCT credentials only to study staff allocated by the Principal Investigator (PI). The database was designed and maintained by the PI with support from a research coordinator. All study records contain anonymized participant identification numbers, and no participant names or identifiers are recorded in the database. The anonymized datasets will be exported from the REDCap database and provided for use in this secondary analysis by a designated staff member of the parent study. The exported datasets will include questionnaires from enrolment data and additional abstracted data from

the PHDC as described above in section 5.4. All parent study electronic databases are password protected.

(5.5.1) Data Analysis Plan as specified by objectives:

All statistical analyses will be conducted using R Studio (Boston, Massachusetts, United States), with a selection of R packages. The initial exploration of all variables will be completed to identify missing data and any patterns related to missing data. Descriptive statistics will be used to describe the demographic and clinical characteristics of the study participants. Specific analysis plans for each objective are shown below.

Objective 1: To describe the proportion of women entering antenatal care based on their ART history exposure. The three levels of ART experience exposure can be defined as ART-experienced without interruption, ART-experienced with interruption, and newly starting ART at the time of the pregnancy and ANC enrolment. Compare sociodemographic and clinical characteristics of these ART history groups.

The initial exploration of all variables will be completed to identify missing data and any patterns related to missing data. Descriptive statistics will be used to describe the sociodemographic and clinical characteristics of the study participants. This analysis will include medians and interquartile ranges for numerical variables and frequencies with proportions for categorical variables.

Demographic and clinic characteristics will be compared by looking at the summary /bivariate statistics and using simple bivariate tests such as chi-squared tests, Fisher's exact tests, rank-sum tests, or t-tests, as will be appropriate for the variables of interest (Table A2).

Table A2: Sociodemographic and clinical characteristics of women at enrolment, grouped by ART history prior to pregnancy

Characteristics	***Newly starting ART***	***ART-experienced without interruption***	***ART-experienced with interruption***	***Total***	***P-value***
Number of pregnant women (n)					
Maternal characteristics at enrolment					
Pregnant or delivered					
Gestational age at presentation for antenatal care, weeks					
Pregnant at enrolment					
Early postpartum at enrolment					
Median age (IQR)					
Age category					
<25 years					
25 years or older					
Relationship status					
Married					
Not Married					
Pregnancy intention					
Planned pregnancy					
Unplanned pregnancy					
Educational attainment					
Less than secondary					
More than secondary/any tertiary education					
Employment status					
Employed					
Unemployed					
Clinical Characteristics					
Viral load suppression near pregnancy (IQR) (only those on ART)					
VL≤50 copies/ml					
VL>50 copies/ml					

NB: ANC, antenatal care; IQR, interquartile ranges; Results are n (column %) with P-value from chi-square test; median (interquartile range, IQR) with P-value from Wilcoxon rank-sum or Kruskal–Wallis tests. Please note this table may be modified in manuscript.

<u>Objective 2:</u> To describe and evaluate ART history, gaps, and patterns of care in the ART-experienced proportion of pregnant women having ever interrupted.

Data collected on self-reported ART interruptions will be explored to detect any patterns of treatment breaks or gaps among the women with ART experience before their pregnancy. To describe the patterns of ART in the study, descriptive statistics summarising different aspects of participant ART history will be used. This will include: the number of times (including durations) participants stopped ART, the number of times participants started and re-started ART; and visually illustrating this using a timeline plot of participant treatment history. The reasons for stopping and starting/re-starting treatment will also be explored and described qualitatively in discussion.

<u>Objective 3</u>: To examine the association between the ART history prior to pregnancy and their later HIV outcomes: a) maternal HIV VL suppression at delivery, and b) maternal engagement in care at 12 weeks postpartum.

The appropriate regression model will be selected after data exploration, and it will likely be a log-binomial regression model reporting risk ratios with 95% confidence intervals (CI). In addition to the primary ART history exposure, covariates such as maternal age, relationship status, pregnancy intention, educational attainment, gravidity, HIV disclosure status and employment status will be examined to explore possible associations with binary outcomes. The two VL thresholds that will be used for the regression modelling are (a) VL≤50 (suppressed) or VL>50 (unsuppressed) and (b) VL≤1000 or VL>1000 copies/ml, and postpartum engagement at 12 weeks postpartum (in care versus out of care).

(6) Ethical considerations

(6.1) Ethical review

This study will seek ethical clearance from University of Cape Town Human Research Ethics Committee (UCT HREC) for the secondary data analysis. The REMInD parent study received ethical approval from the UCT HREC (REF 513/2020). As this study is a secondary data analysis, there will be no direct contact with the participants of the parent study. An anonymized dataset will be provided for analysis.

(6.2) Informed Consent

This study used secondary data from the parent study which didn't require informed consent. However, the parent study required informed consent by participants. Informed consent before enrolment was delivered in 'participants' home language (predominantly isiXhosa) by a trained fieldworker following a standardized script. This script had details on the purpose of the study, study procedures, as well as the risks and benefits that were encountered during the study including linkage of paper and electronic medical records using identifiers (provincial folder number, name, date of birth).

(6.3) Risks

As this is a secondary analysis, there are no direct risks for this study as there is no direct contact with the parent study participants. Nonetheless, a possible risk in this research is a breach of confidentiality. However, only anonymized data will be received to ensure that the study participants will remain anonymous during the study period.

Personal identifying information was collected in the parent study to allow linkage to medical records. Linkage is done by the study PI, and only anonymized data using the unique study identifier will be provided for this secondary analysis.

(6.4) Benefits

The major potential direct benefit from participating in the parent study is optimized engagement in routine VTP services during the postpartum period, which will benefit maternal and child health and potentially VTP. This secondary analysis does not directly benefit patients, but this study may indirectly benefit, inform, and contribute to HIV/AIDS initiatives

locally and globally. These benefits would identify and inform mitigation strategies to potentially target LTFU and ART disengagement among WLHIV. In the parent study, women requiring social support or psychosocial referral were referred to Ilitha Labantu, a local organization providing counselling and support services.

(6.5) Confidentiality

Parent study data will be accessed by authorized personnel only. It will be stored on password-protected devices. For this secondary analysis, there will be no contact with the parent study's participants. However, efforts will be made to protect participant confidentiality during the study process. No participant identification information will be attached to participant data, and anonymous participant identification numbers will be used for the analysis.

(6.6) Timeline Scheduling

Table A3: Timeframe for dissertation activities

Activities	**January 2022**	**February**	**March**	**April**	**May**	**June**	**July**	**August**	**September**	**October**	**November**	**December**	**January 2023**	**February**
Protocol Completion/ Submission to HREC														
Data Analysis Completion														
Manuscript Completion														
Dissertation submission														

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(B) MANUSCRIPT

(1) Manuscript title page

Patterns of HIV care prior to antenatal care, and the impact on later outcomes, among pregnant women living with HIV in Gugulethu, South Africa: a retrospective cohort

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Main text: 3496/3500

The article meets the requirements set out in the Instructions for Authors for the Journal of the International AIDS Society (JIAS). As per the MPH dissertation guidelines, co-authors and their contributions are noted in the acknowledgments section of this dissertation. The JIAS Instructions for Authors are included in Appendix G of the dissertation.

(2) Abstract

Introduction: Women living with HIV (WLHIV) entering antenatal care (ANC) are at high risk of disengagement from antiretroviral therapy (ART). Increasing numbers of women conceiving are already on ART, but little is known about their patterns of care before ANC. We described ART history patterns before ANC among WLHIV and the association with maternal outcomes.

Methods: We used existing data from a prospective cohort that enrolled WLHIV attending ANC in Gugulethu, South Africa. Data were collected through interviews and abstraction of electronic medical records. Self-reported ART history was examined, and women were grouped into (1) Newly starting ART, (2) ART-experienced without any interruptions, (3) ART-experienced with interruption. Log-binomial models were used to assess the association between ART history, viral suppression at delivery and engagement in care at 12 weeks postpartum.

Results: Among 321 women (median age 32.3 years, IQR 28.1–35.9; 61.4% in their first pregnancy), 52% were ART-experienced with no interruption (median years on ART 6.1, IQR 3.3–10.1), 32.7% were ART-experienced with at least one interruption (median years on ART 6.9, IQR 4.4–9.4), and 15.3% were newly starting ART in pregnancy. Among the 105 ART-experienced women with interruption, 94.3% reported only one interruption. After adjusting for age, women newly initiating ART (adjusted risk ratio (aRR): 1.78; 95% CI: 0.91–3.79) and ART-experienced women with interruption (aRR: 2.39; 95% CI 1.39–4.35) were more likely to have a viral load >50 copies/ml at delivery when compared to ART-experienced women without interruption. After adjusting for age and relationship status, ART-experienced women with interruption (aRR: 6.20; 95% CI: 2.05–18.77) and without interruption (aRR: 3.10; 95% CI 0.99–9.71) were more likely to be disengaged from care at 12 weeks postpartum when compared to women newly starting ART.

Conclusion: Most women in this study were ART-experienced before pregnancy, and a third had treatment interruption history. Women with any interruption had increased risk of being unsuppressed at delivery and disengaged from care at 12 weeks postpartum. These findings highlight the need to explore mechanisms driving these associations and examine possible interventions to support continuous engagement in HIV care postpartum.

(3) Introduction

Antiretroviral therapy (ART) has been used as the preferred method of HIV treatment for many years (1–3). There has been massive scale up of universal ART and ART coverage in Africa and South Africa (4). This has considerably improved the maternal HIV outcomes of women living with HIV (WLHIV). Therefore, lifelong ART improves the overall health of WLHIV. ART facilitates viral suppression and is pivotal in vertical transmission prevention (VTP) during pregnancy, birth, and breastfeeding (5–9). There are increasing numbers of women conceiving who are already using ART, but little is known about their patterns of HIV care before antenatal care (ANC) and how these patterns might impact later HIV outcomes postpartum.

WLHIV who are entering ANC are at high risk of disengagement from HIV care during pregnancy and the postpartum period (4,10,11). WLHIV with suboptimal ART adherence are at a high risk of transmitting HIV to their HIV-exposed infants during pregnancy or breastfeeding (6). Previous studies have shown that 30% of WLHIV in Africa are lost to follow-up from HIV care within the first six months of starting ART during pregnancy and postpartum (6,12).

HIV transmission during pregnancy and after delivery now is extremely low amongst virally suppressed women in South Africa (3,8,10,13). However, loss to follow-up (LTFU) from ART considerably increases viraemia and the risk of vertical transmission over time (12,14). Sasse and colleagues found in a study conducted in Malawi that ART interruption is associated with younger age, having less than primary education, ART initiation during pregnancy and breastfeeding, as well as non-disclosure of HIV status to partner. The reasons for ART interruption have been linked to relocation, transportation cost and misplacing health care documents (15). Furthermore, a study conducted in Johannesburg that focused on encouraging ART users who have interrupted to return to care, found that common reasons for disengaging from care were mobility, ART related factors, work commitments and changing life circumstances (16). WLHIV have to access ANC and routine ART facilities in order to sustain their adherence and have continuous engagement in HIV care for their own health and the health of their infants (9,11,13). Therefore, addressing the barriers to HIV care mentioned above is necessary to ensure that WLHIV can access and remain engaged in HIV care during their pregnancy and postpartum period (1,7).

The rationale of this study is to address the gap in literature surrounding ART history prior to pregnancy and the associations it has on maternal HIV outcomes. ART history and interruption patterns are not well documented among WLHIV in the context of pregnancy. How these patterns may impact maternal outcomes and in turn vertical transmission of HIV is unknown (15,16). The aim of this study was to explore patterns of HIV care in WLHIV before receiving ANC in Gugulethu, Cape Town, South Africa, and to examine the associations between ART history and the outcomes of maternal viral load (VL) suppression at delivery and early postpartum engagement in HIV care at 12 weeks.

(4) Methods

(4.1) Study design and setting

A secondary analysis of data from the Routine Electronic Mother-Infant Data (REMInD) study was conducted. The REMInD study enrolled a prospective cohort of pregnant WLHIV in Gugulethu, South Africa between March 2021 and April 2022. The Gugulethu Midwife Obstetric Unit (GMOU) at the Gugulethu Community Health Centre (GCHC) serves approximately 5000 pregnant women annually. The antenatal HIV prevalence is approximately 25%. WLHIV receive integrated ANC and ART services during pregnancy, but transition to other primary care clinics for routine ART and infant care after delivery. All patients attending public sector services in the Western Cape are issued a unique patient identifier that is used across multiple electronic health information systems. The Provincial Health Data Centre (PHDC) combines these data sources for patient health care and reporting purposes, enabling linkage of electronic records across multiple facilities in Western Cape (17).

(4.2) Data sources

The data used for this secondary analysis were collected during the REMInD study. The enrolment data, including sociodemographic characteristics and details of HIV and ART history, were collected during face-to-face or telephonic interviews, and captured in a custom designed Research Electronic Data Capture (REDCap) database, maintained in a firewall protected UCT server. Viral load at delivery and ART pharmacy dispensing data through 12 weeks postpartum were abstracted from routine electronic medical records and reports produced by the PHDC (17).

(4.3) Measurements

The primary exposure variable in this analysis was ART history which was determined using self-reported ART initiation timing and ART interruptions (stopped ART for one month or more) up to the time of enrolment into the study. ART history groups were defined as follows:

- Newly starting ART: A woman who was starting ART for the first time during this pregnancy.
- ART-experienced without interruption: A woman who was ART-experienced and had not ever interrupted HIV care at the time of enrolment.

- ART-experienced with interruption: A woman who was ART-experienced and who had ever interrupted ART at the time of enrolment

Outcomes of interest included maternal HIV VL at delivery and maternal postpartum engagement in care at 12 weeks after delivery.

Outcomes were determined based on routine clinical data and electronic medical records abstracted from the PHDC, assessed at a single time point, and defined as follows:

Maternal HIV VL suppression was defined as having a VL≤50 copies/ml at delivery. A threshold of 1000 copies/ml was also examined in secondary analyses. Maternal engagement in HIV care at 12 weeks postpartum was defined using pharmacy refill data. Women were considered not in care if they had no ART in hand for 30 days or more at 12 weeks postpartum.

(4.4) Data analysis

All statistical analyses were conducted using R Studio (Boston, Massachusetts, United States). Summary statistics were used to describe the sociodemographic and clinical characteristics of the study participants. Categorical variables were described using frequencies and proportions, while numerical variables were described using medians and interquartile ranges. Statistical tests included chi-squared tests, Fisher's exact tests, rank sum tests or t-tests, as appropriate for the variables of interest. A two-sided alpha of 0.05 and 95% confidence intervals were used throughout. For women who were ART-experienced and having ever interrupted, we described the number of times the participant interrupted ART and the number of times the participant restarted ART. An estimate of duration for interruption was calculated by subtracting the reported ART stop date from the reported restart date. We were not able to accurately describe duration of interruption as women did not always report the exact date. Where the day of the month was not reported the first was assumed; where the month was not reported January was assumed. We examined the associations between the ART history as the exposure before pregnancy and two outcomes of interest: (a) maternal HIV VL suppression at delivery and (b) maternal postpartum engagement in HIV care at 12 weeks after delivery. Log-binomial regression models were used to identify associations with maternal HIV VL suppression and maternal postpartum disengagement from HIV care, with covariates being included as predictors in multivariable models if they reached a p-value <0.1 in univariable models.

(4.5) Ethics Statement

The REMInD parent study and this secondary analysis received ethical approval from the University of Cape Town Human Research Ethics Committee (UCT HREC). All participants in the parent study provided written informed consent.

(5) Results

(5.1) Cohort description

A total of 321 women were included in this analysis. The median age was 32.3 years (IQR: 28.1 - 35.9) and 86.3% (n=277) of the women were older than 25 years of age. Overall, 79.4% (n=255) of the women were unmarried, 78.7% (n=253) reported an unplanned pregnancy, and 88.8% (n=285) of the women had at least one pregnancy before the most recent one. Approximately 71.3% (n=229) of women had not completed secondary schooling, while 69.8% (n=224) were unemployed. Almost all women (96.6%, n=310) had disclosed their HIV status to a non-healthcare professional (Table B1).

(5.2) Maternal characteristics stratified by antiretroviral therapy history status

When comparing ART history exposure status, 15.3% (n=49) of women were newly starting ART during the most recent pregnancy, 52% (n=167) of women were ART-experienced with no ART interruption, and 32.7% (n=105) of women were ART-experienced having ever interrupted treatment. The median age was the highest in ART-experienced women without any interruptions [33.2 years (IQR 29.9 – 37.5)], followed by ART-experienced women having ever interrupted [31.0 years (IQR 27.3 – 35.4)] and lowest among women who were newly starting ART [29.3 years (IQR 24.7 – 32.9)], p=0.004. The median ART duration at enrolment was 5.4 years (IQR: 1.8 – 8.9) among all women. The median ART duration at enrolment was significantly longer in ART-experienced women with interruptions [6.9 years (IQR: 4.4 – 9.4)], followed by ART-experienced women without any interruptions [6.1 years (IQR: 3.3 – 10.1)] and the shortest among women newly starting ART, [0.4 years (IQR: 0.0 – 0.6)], p<0.001. ART-experienced women without interruption were mostly unmarried (73.7%, n=123), 73.1% (n=122) had unplanned pregnancies and 95.2% (n=159) were not in their first pregnancy. These proportions were lower among ART-experienced women with interruptions and lowest among women newly starting ART (all p<0.05). The disclosure of HIV in all three groups of women was more than 90%. There were no substantial differences in educational attainment and employment status between ART history exposure groups (Table B1).

Table B1: Baseline socio*demographic and clinical characteristics of 321 participants stratified by ART history status relative to covariates*

Characteristics	***ART History Status***			***Total***	***P-value***
	Newly starting ART	***ART-experienced without interruption***	***ART-experienced with interruption***		
Number of women	49 (15.3)	167 (52.0)	105 (32.7)	321 (100)	
Maternal characteristics at enrolment					
Median age, years	29.3 (24.7, 32.9)	33.2 (29,9, 37.5)	31.0 (27.3, 35.4)	32.3 (28.1, 35.9)	**0.004**
Age categories (years)					
≤25 years	13 (26.5)	19 (11.4)	12 (11.4)	44 (13.7)	**0.018**
>25 years	36 (73.5)	148 (88.6)	93 (88.6)	277 (86.3)	
ART duration (years)					
Median ART duration at enrolment, years	0.4 (0.0, 0.6)	6.1 (3.3, 10.1)	6.9 (4.4, 9.4)	5.4 (1.8, 8.9)	**<0.001**
Pregnancy status at enrolment					
Pregnant	30 (61.2)	100 (59.9)	67 (63.8)	197 (61.4)	0.810
Early postpartum	19 (38.8)	67 (40.1)	38 (36.2)	124 (38.6)	
Relationship status					
Married	5 (10.2)	44 (26.3)	17 (16.2)	66 (20.6)	**0.020**
Unmarried	44 (89.8)	123 (73.7)	88 (83.8)	255 (79.4)	
Pregnancy intention					
Planned pregnancy	4 (8.2)	45 (26.9)	19 (18.1)	68 (21.3)	**0.012**
Unplanned pregnancy	45 (91.8)	122 (73.1)	86 (81.9)	253 (78.7)	
Gravida status					
1	19 (38.8)	8 (4.8)	9 (8.6)	36 (11.2)	**<0.001**
>1	30 (61.2)	159 (95.2)	96 (91.4)	285 (88.8)	
Educational attainment					
Completed secondary education	13 (26.5)	55 (32.9)	24 (22.9)	92 (28.7)	0.189
Incomplete or less than secondary education	36 (73.5)	112 (67.1)	81 (77.1)	229 (71.3)	

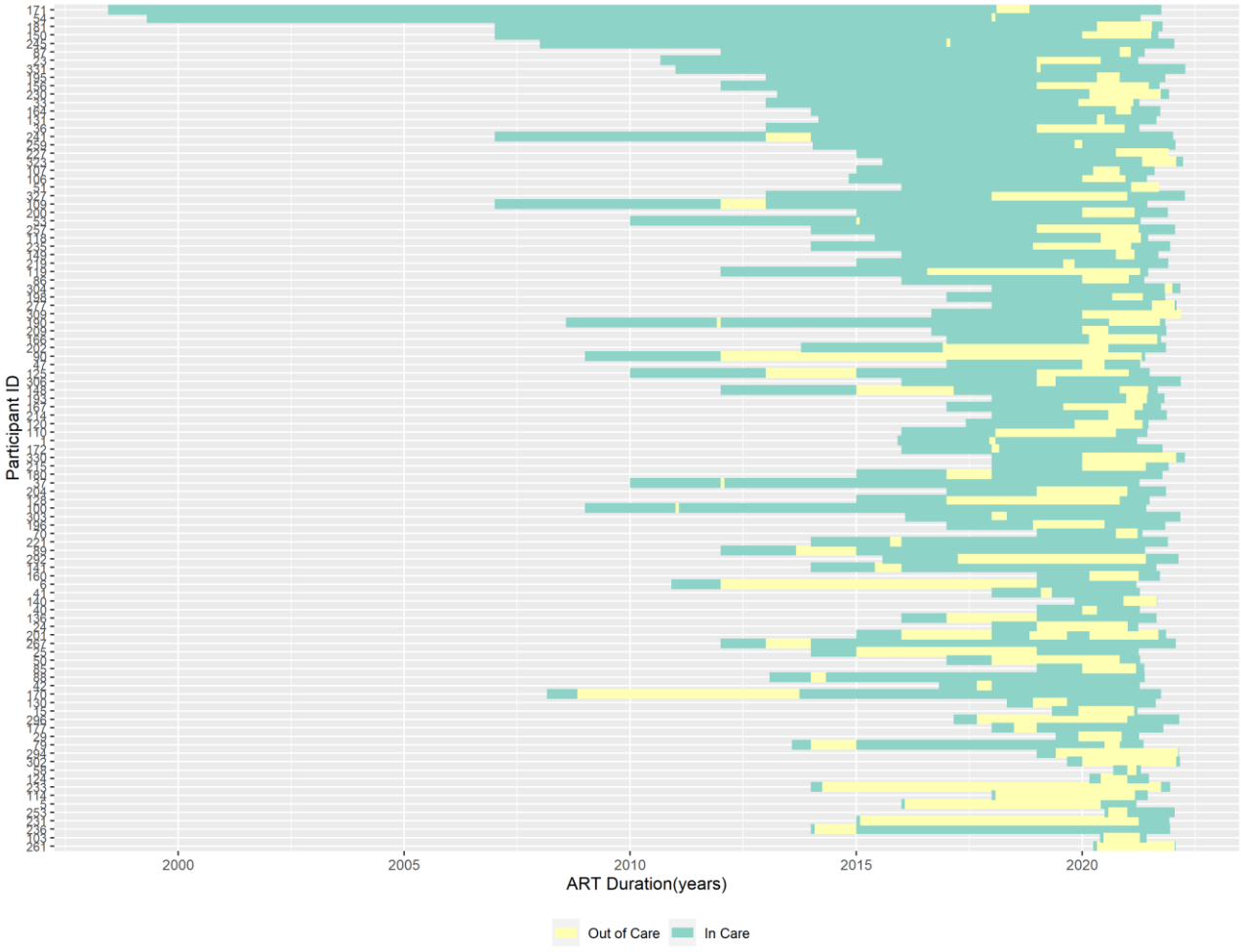
Employment status					
Employed	15 (30.6)	53 (31.7)	29 (27.6)	97 (30.2)	0.770
Unemployed	34 (69.4)	114 (68.3)	76 (72.4)	224 (69.8)	
HIV disclosure to any non-healthcare professionals					
Undisclosed	4 (8.2)	3 (1.8)	4 (3.8)	11 (3.4)	0.095
Disclosed	45 (91.8)	164 (98.2)	101 (96.2)	310 (96.6)	

ANC, antenatal care; IQR, interquartile ranges; Results are n (column %) with p-value from chi-square test; median (IQR) with P-value from Wilcoxon rank-sum or Kruskal–Wallis tests. ***Bold*** *indicates statistically significant p-values.*

(5.3) Participant specific antiretroviral therapy interruption timeline

The ART interruption patterns were plotted for 105 women who were ART-experienced and reported any interruption (Figure B1). Each row on the y-axis represents one participant. The x-axis indicates time from first ART initiation date up to the date of enrolment in the study. Overall, 94.3% (n=99) of women with an interruption had only one ART interruption, 4.8% (n=5) had two ART interruptions and 0.9% (n=1) had three ART interruption events. The estimated median duration of interruption was 1 year (IQR 0.5-2).

Figure B1: Antiretroviral therapy interruption timeline plot among women living with HIV having prior ART experience at ANC presentation (n=105)



(5.4) Viral suppression at delivery

Overall, 298 women had a viral load available at delivery. Of these, 83.6% (n=249) were virally suppressed at VL≤50 copies/ml and 88.9% (n=265) at VL≤1000 copies/ml. Women with VL≤50 copies/ml were significantly older than those with VL>50 copies/ml [>25 years, 87.1% (n=217) vs 75.5% (n=37), p=0.036]. When comparing viral suppression in ART history groups, women who were ART-experienced without interruption had the highest proportion of viral suppression. Of these, women with VL≤50 copies/ml were significantly more than those with VL>50 copies/ml [55.4% (n=138) vs 30.6% (n=15), p=0.005]. Relationship status, pregnancy intention, gravida status, educational attainment, employment status and HIV disclosure status did not differ by viral suppression (Table B2). The results using VL threshold of 50 copies/ml were similar using a VL threshold of 1000 copies/ml (Table C1). The descriptive results (Table B2 and C1) were similar in unadjusted log-binomial regression models (Table B3 and C2).

In a multivariable log-binomial regression model, after adjusting for maternal age, women who were newly initiating ART (aRR=1.78, 95% CI 0.91 – 3.79) and women who were ART experienced with any interruption (aRR=2.39, 95% CI 1.39 -4.35) were more likely to have a VL above 50 copies/ml at delivery when compared to women who were ART experienced without any interruption. Women older than 25 years (aRR=0.50, 95% CI 0.25-1.01) were less likely to have a VL above 50 copies/ml at delivery when compared to younger women (Table B3). Similar associations were noted for VL threshold of 1000 copies/ml (Table C2).

(5.5) Engagement in care at 12 weeks postpartum

Overall, 309 women had pharmacy dispensing data available 12 weeks postpartum. Of these, 81.2% (n=251) who were engaged in care at 12 weeks postpartum.

There was a higher proportion of women older than 25 in the group engaged in care when compared to the group that disengaged from care (89.6% (n=225) vs 70.7% (n=41), p=0.006). There was a lower proportion of unmarried women in the group engaged in care when compared to the group that disengaged from care (76.5% (n=192) vs 89.7% (n=52), p=0.030). There was a lower proportion of unmarried women in the group engaged in care when compared to the group that disengaged from care (76.5% (n=192) vs 89.7% (n=52), p=0.030). There was a higher proportion of ART-experienced women without interruptions in the group engaged in care when compared to the group that disengaged from care (55.8% (n=140) vs 41.4% (n=24), p=0.004). Pregnancy intention, gravida status, educational attainment, employment status and HIV disclosure status did not differ by postpartum engagement in care (Table B2). The descriptive results (Table B2) were similar in unadjusted log-binomial models (Table B4).

In a multivariable log-binomial regression model, after adjusting for maternal age and relationship status, women who were ART-experienced without any interruption (aRR=3.10, 95% CI 0.99-9.71) and women who were ART-experienced with any interruption (aRR=6.20, 95% CI 2.05-18.77) were more likely to disengage from care when compared to women who were newly starting ART. Women older than 25 years (aRR=0.37, 95% CI 0.25 – 0.56) were less likely to disengage from care when compared to younger women. The association with relationship status did not persist in the adjusted model (aRR=1.89, 95% CI 0.84 – 4.22) (Table B4).

Table B2: Socio*demographic and clinical characteristics of a) 298 participants stratified by viral load suppression (threshold 50) at delivery, and b) 309 participants stratified by postpartum engagement*

Characteristics	***Total***	***a) Viral Load Suppression***			***b) Postpartum Engagement***		
		VL≤50 copies/ml	***VL>50 copies/ml***	***P-value***	***In care***	***Out of care***	***P-value***
Number of women	298 (100)	249 (83.6)	49 (16.4)		251 (81.2)	58 (18.8)	
Maternal characteristics at enrolment							
Median age, years	32.3 (28.1, 35.9)	32.1 (28.1, 35.5)	30.3 (25.1, 37.4)	**0.041**	32.6 (29.1, 36.2)	29.6 (24.7, 34.5)	**0.004**
Age categories (years)							
<=25 years	44 (14.8)	32 (12.9)	12 (24.5)	**0.036**	26 (10.4)	17 (29.3)	**0.006**
>25 years	254 (85.2)	217 (87.1)	37 (75.5)		225 (89.6)	41 (70.7)	
Relationship status							
Married	59 (19.8)	52 (22.9)	7 (12.3)	0.289	59 (23.5)	6 (10.3)	**0.030**
Unmarried	239 (80.2)	197 (77.1)	42 (87.7)		192 (76.5)	52 (89.7)	
Pregnancy intention							
Planned pregnancy	66 (22.1)	57 (21.6)	9 (18.4)	0.486	56 (22.3)	11 (19.0)	0.909
Unplanned pregnancy	232 (77.9)	192 (78.4)	40 (81.6)		195 (77.7)	47 (81.0)	
Gravida status							
1	35 (11.7)	27 (10.8)	8 (16.3)	0.276	25 (10.0)	9 (15.5)	0.760
>1	263 (88.3)	222 (89.2)	41 (83.7)		226 (90.0)	49 (84.5)	
Educational attainment							
Completed secondary education	88 (29.5)	75 (30.1)	13 (26.5)	0.615	75 (29.9)	14 (24.1)	0.788
Incomplete or less than secondary education	210 (70.5)	174 (69.9)	36 (73.5)		176 (70.1)	44 (75.9)	
Employment status							
Employed	90 (30.2)	73 (29.3)	17 (34.7)	0.454	81 (32.3)	13 (22.4)	0.527
Unemployed	208 (69.8)	176 (70.7)	32 (65.3)		170 (67.7)	45 (77.6)	
HIV disclosure to any non-healthcare professionals							
Undisclosed	11 (3.7)	8 (3.2)	3 (6.1)	0.323	7 (2.8)	3 (5.2)	0.902
Disclosed	287 (96.3)	241 (96.8)	46 (93.9)		244 (97.2)	55 (94.8)	

ART History Status							
Newly starting ART	45 (15.1)	36 (14.5)	9 (18.4)	**0.005**	43 (17.1)	3 (5.2)	**0.004**
ART-experienced without interruption	153 (51.3)	138 (55.4)	15 (30.6)		140 (55.8)	24 (41.4)	
ART-experienced with interruption	100 (33.6)	75 (30.1)	25 (51.0)		68 (27.1)	31 (53.4)	

NB: ANC, antenatal care; IQR, interquartile ranges; Results are n (column %) with P-value from chi-square test; median (interquartile range, IQR) with P-value from Wilcoxon rank-sum or Kruskal–Wallis tests. Only 298 women had a viral load at delivery and 309 with engagement data. There were 10 women outside of Western Cape without pharmacy data and 7 women without demographic data that were excluded from the analysis. ***Bold*** *indicates statistically significant p-values.*

Table B3: Unadjusted and adjusted log binomial regression models predicting viral load above 50 copies/mL among women with available viral loads (n = 298)

Outcome 1: Viral Load Suppression	Crude models				Adjusted model			
Log Binomial Regression Model	**RR**	**95% CI (lower)**	**95% CI (upper)**	**P-value**	**aRR**	**95% CI (lower)**	**95% CI (upper)**	**P-value**
ART history status								
ART-experienced without interruption	1	Referent	Referent		1	Referent	Referent	
Newly starting ART	2.04	0.96	4.35	0.065	1.78	0.91	3.79	**0.048**
ART-experienced with interruption	2.55	1.42	4.59	**0.002**	2.39	1.39	4.35	**0.001**
Age category								
<=25 years	1	Referent	Referent		1	Referent	Referent	
>25 years	0.53	0.30	0.94	**0.030**	0.50	0.25	1.01	**0.054**
Relationship status								
Married	1	Referent	Referent					
Unmarried	1.48	0.70	3.13	0.303				
Pregnancy intention								
Planned pregnancy	1	Referent	Referent					
Unplanned pregnancy	1.26	0.65	2.47	0.492				
Gravida status								
1	1	Referent	Referent					
>1	1.47	0.75	2.87	0.263				
Educational attainment								
Completed secondary education	1	Referent	Referent					
Incomplete or less than secondary education	0.86	0.48	1.54	0.617				
Employment status								
Employed	1	Referent	Referent					
Unemployed	0.81	0.48	1.39	0.451				
HIV disclosure to any non-healthcare professionals								
Undisclosed	1	Referent	Referent					
Disclosed	0.59	0.22	1.60	0.298				

RR, Risk Ratio(s) for univariable model(s); aRR, adjusted Risk Ratio(s) for multivariable model(s); CI, Confidence Interval(s). ***Bold*** *indicates statistically significant p-values.*
Only p<0.1 for univariable models (unadjusted) were forward selected in building the multivariable model (adjusted).

Table B4: Unadjusted and adjusted log binomial regression models predicting postpartum disengagement from care (n = 309 with data available through 12 weeks)

Outcome 2: Postpartum Disengagement	Crude models				Adjusted model			
Log Binomial Regression Model	**RR**	**95% CI (lower)**	**95% CI (upper)**	**P-value**	**aRR**	**95% CI (lower)**	**95% CI (upper)**	**P-value**
ART history status								
Newly starting ART	1	Referent	Referent		1	Referent	Referent	
ART-experienced without interruption	2.24	0.71	7.12	0.170	3.10	0.99	9.71	**0.053**
ART-experienced with interruption	4.80	1.55	14.90	**0.006**	6.20	2.05	18.77	**0.001**
Age category								
<=25 years	1	Referent	Referent		1	Referent	Referent	
>25 years	0.39	0.25	0.62	**<0.001**	0.37	0.25	0.56	**<0.001**
Relationship status								
Married	1	Referent	Referent		1	Referent	Referent	
Unmarried	2.31	1.04	5.14	**0.040**	1.89	0.84	4.22	0.123
Pregnancy intention								
Planned pregnancy	1	Referent	Referent					
Unplanned pregnancy	1.18	0.65	2.15	0.582				
Gravida status								
1	1	Referent	Referent					
>1	0.67	0.36	1.25	0.208				
Educational attainment								
Completed secondary education	1	Referent	Referent					
Incomplete or less than secondary education	1.27	0.74	2.20	0.392				
Employment status								
Employed	1	Referent	Referent					
Unemployed	1.51	0.86	2.67	0.152				
HIV disclosure to any non-healthcare professionals								
Undisclosed	1	Referent	Referent					
Disclosed	0.61	0.23	1.63	0.326				

NB: RR, Risk Ratio(s) for univariable model(s); aRR, adjusted Risk Ratio(s) for multivariable model(s); CI, Confidence Interval(s). ***Bold*** *indicates statistically significant p-values. Only p<0.1 for univariable models (unadjusted) were forward selected in building the multivariable model (adjusted).*

(6) Discussion

In this study describing patterns of HIV care leading up to pregnancy in WLHIV receiving ANC in Gugulethu, Cape Town, South Africa, we found that many women were ART-experienced before their pregnancy, and a third had treatment interruption history. Women's ART history was associated with viral suppression at delivery and with engagement in care at 12 weeks postpartum. Therefore, those with history of any interruption appeared to have an increased risk of poor maternal outcomes.

When evaluating the patterns of HIV care, overall, a third of the women had any interruption and most of these women reported only one interruption. This indicates that even one prior interruption increased the risk of having other poor maternal outcomes in our analyses. This finding adds to limited literatures on patterns of HIV care before pregnancy. Subsequently, translating this research into other settings would be useful for a broader understanding of patterns of HIV care and how this impacts maternal outcomes. In this way one would be able to make inferences between different populations and geographical settings (4,15,16).

Most women in this study were found to be virally supressed at delivery. This may be due to the large number of women who were already ART-experienced and on ART entering the pregnancy (1,6,7,11). This finding is reassuring in terms of the risk for vertical transmission. It is consistent with previous studies noting that ART-experienced women have decreased viraemia which enables treatment success (8,13). This is crucial as treatment success is dependent on lifelong ART and continuous engagement in HIV care (3,8,10,11,13).

Our study found that older women were less likely to have viraemia when compared to younger women. This finding is consistent with previous literature on viral suppression and engagement in HIV care (7,8,10). Humphrey and colleagues have shown that viral suppression (decreased viraemia) increased by 18% for each additional year of age (8). In this study older women were more likely to be engaged in HIV care when compared to younger women. Previous research has demonstrated that a substantial proportion of women disengaged from HIV care and noted that younger women are especially vulnerable to disengagement (10). The reason for this association could point toward younger women lacking the needed social support and motivation from their family and/or partner to maintain their adherence and continuous engagement in HIV care (7,10,18–22).

Women newly starting ART and ART-experienced women with interruptions were more likely to have an unsuppressed delivery VL when compared to ART-experienced women without any interruptions. This finding aligns with research previously conducted as it states that 22% women initiating ART during pregnancy experiences viraemic episodes. Another study suggests that viraemic episodes are associated with younger age and viral suppression with older age in women initiating ART during pregnancy (8,18). Depending on the timing of presentation for ANC, women staring ART or restarting ART in pregnancy may not have enough time on ART to fully suppress by the time of delivery and there may be adherence challenges among those with history of interruptions.

The findings presented for engagement in care indicated that 18% of the cohort were disengaged from care at 12 weeks postpartum. Previous studies have reported that women commonly disengage from care during the first few months after delivery (as early as 6-10 weeks postpartum) which is consistent with our findings (10,11,15). The proportion of women that disengaged from HIV care was higher in the ART-experienced groups with and without interruption. This finding is consistent with previous studies noting that ART-experienced women that have previously interrupted, are more likely to interrupt again, and disengage from HIV care being a contributor of treatment failure (4,15,16). Treatment success is dependent on lifelong ART and continuous engagement in HIV care; thus it is concerning that almost 20% of women had evidence of disengagement by 12 weeks postpartum (6,7,14,23). Lastly, ART-experienced women having ever interrupted and those never interrupted were more prone to disengage from HIV care when compared to women newly starting ART. A possible reason for this is that women newly starting ART never engaged with a routine HIV clinic before entry into ANC. Pregnant women newly starting ART may engage in HIV care better during ANC and early postpartum there is a strong focus to prevent vertical transmission of HIV to their infant during pregnancy and upon delivery. They may receive additional counselling as they are starting ART for the first time, compared to women who are already on ART (5,6,9,10,12). HIV care disengagement is a multi-layered challenge influenced by various factors. These factors include barriers, such as, poverty, lack of access to healthcare, stigma and mental health concerns, transportation difficulties and healthcare system inefficiencies. When addressing disengagement in HIV care it requires a broader approach that considers the interaction of these complex factors to ensure consistent and effective HIV care and ART adherence (1,3,15,16,23–25).

When interpreting these findings, it's important to note various study limitations. The ART history data from the study participants were self-reported. There may be recall bias where study participants had difficulty recalling information relating to timeframes of interruption. Therefore, inaccurately describing durations of interruptions, because of imprecise dates. Other limitations are social desirability where a participant may have given a socially acceptable or favourable answer in a questionnaire to avoid it being seen as unacceptable in a social setting, which may cause bias, and potentially underestimating interruptions by imprecise dates and ART durations. The key strength of this study is that the maternal outcomes data were not self-reported but abstracted from electronic medical records and reports. However, routine data also have limitations due to incorrect transcription into electronic records. The maternal delivery VL data were limited to 298 women who had a VL taken at delivery. The PHDC data is limited to health facilities in the Western Cape only. Women who moved and accessed care outside of the Western Cape would be considered as disengaged from HIV care as the electronic medical records from other provinces are not linked to the PHDC (17). Participants in this study were recruited from Gugulethu, and while these findings may be generalizable to similar settings, it may not reflect the situation in other settings in Western Cape or in South Africa. The sample size of the women that are newly starting ART was very small which may have limited our power to detect small associations. The following strategies would improve the study design of future studies: increasing the sample size to increase statistical power, enhancing data quality to improve validity of results, refining the study design to establish causal relationships, and incorporating follow-up data to identify health outcome changes over time.

This study contributes to very limited literature describing ART history prior to entering ANC and exploring associations between ART history and maternal HIV outcomes. The results presented support previous studies showing that continuous engagement in HIV care is an important enabler of future lifelong ART adherence and engagement in HIV care (7,9,11,13,24). HIV treatment success requires lifelong treatment with high adherence and engagement in HIV care and ART history is one factor that influences these future maternal outcomes (9,11). ANC provides an important opportunity for adherence counselling and interventions to support women to remain on ART (25). Additional research is required to help understand these associations and their impact on pregnancy and the postpartum period. When addressing these individual concerns, such as ART side effects or fears related to pregnancy, it could improve HIV care acceptance and long-term ART adherence. Peer support programs, for WLHIV who provide support and guidance to others facing similar challenges, can play a vital role in improving ART adherence for others (1,3,6,9,11). In addition, further

research is needed to expand on the impact and patterns of ART interruption in the context of Dolutegravir-based ART which may be more forgiving of imperfect ART adherence and where resistance is unlikely (26,27).

Conclusion

In conclusion, many women are coming into ANC with a history of ART and a large proportion have history of interruptions. ART history may be an important factor contributing to later maternal outcomes. Therefore, pregnancy is an opportunity for interventions to be introduced as part of ANC to sustain engagement in HIV care postpartum. Current routine ANC and HIV services need to be aware of women's ART history to better facilitate and accommodate women in providing support for adherence, uninterrupted and continuous engagement in HIV care.

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(C) APPENDICES

Appendix A: REMInD Study Case Report Form Questionnaires

Visit Date	D	D	M	M	M	Y	Y	Y	Y

A: SOCIODEMOGRAPHIC INFORMATION

1. Uzelwe Nini? *What is your date of birth?*	_____ /_____ /_____ DD MMM YYYY
2. Uthetha oluphi ulwimi ekhaya? *What language do you speak at home?*	☐ isiXhosa ☐ isiZulu ☐ isiBhulu *Afrikaans* ☐ isiNgesi *English* ☐ Olunye *Other* Cacisa *Specify:* _____
3. Leliphi elona banga liphezulu oliphumeleleyo? *What is the highest level of schooling/education that you have completed?*	☐ Inqanaba: _____ *Grade* **Okanye** ***Or*** Ibanga: _____ *Standard* ☐ Imfundo ephezulu: cacisa _____ *Postsecondary, specify* ☐ Akukho nenye *None*
4. Are you currently in a relationship?	☐ Ewe *Yes* ☐ Hayi *No* ❼ **Gqithela ku Q6**

	SKIP to Q6
5. How would you describe your current relationship?	☐ Married = 1 ☐ Not married, living together = 2 ☐ Married, not living together = 3 ☐ Not married, not living together = 4 ☐ Other = 5, specify:_____
6. Regardless of if you are in a relationship or not, describe the nature of your sexual partners/relationships in the past 12 months: Mark all that apply.	☐ Spouse/ married ☐ Boyfriend ☐ Casual Partner/One Night Stands ☐ Other, specify:_____
7. Ingaba uyasebenza na ngoku kwaye/okanye uyafunda? *Are you currently working and/or studying?*	☐ Ewe *Yes* ☐ Hayi *No* ❼ **Gqithela ku Q9** ***SKIP to Q9***

8. Ukuba nguEwe, yeyiphi kwezi zilandelayo eyichaza ngcono into oyenzayo? *If yes, which one of the following best describes what you do?* Khetha ibenye kuphela *Choose ONE only*	☐ Uphangela isigxina *Employed full-time* ☐ Uphangela manqapha-nqapha *Employed part-time* ☐ Umsebenzi onjengokuthengisa endlini okanye esitalatweni. *Informal job/hawker* ☐ Uhamba isikolo/ngumfundi *Attending school/learner* ☐ Uhamba isikolo eYunivesithi/Kholeji *Attending tertiary education (University/College)*
9. Oku kuquka nawe, bangaphi abantu (abadala nabantwana) abahlala endlini yakho. *Including yourself, how many people (adults and children) live in your house?*	Inani Labantu:_____ *Number of people*
10. How many adults (18 and older) live in your household?	Inani Labantu:_____ *Number of people*
11. How many minors (younger than 18) live in your household?	Inani Labantu:_____ *Number of people*

12. Ingaba ungakanani umvuzo owufumanayo ngenyanga? *On average, how much total income do your household earn per month (including grants)?*	☐ Ngaphantsi kwe waka lerandi ngenyanga *Less than R1 000 per month* ☐ Iwaka ukuya kumawaka amahlanu erandi ngenyanga *R1 000 to R5 000 per month* ☐ Amawaka amahlanu ukuya kumawaka alishumi erandi ngenyanga *R5 000 to R10 000 per month* ☐ Amawaka alishumi ukuya kumawaka alishumi elinesihlanu erandi ngenyanga *R10 000 to R15 000 per month* ☐ Ngaphezu kwamawaka alishumi elinesihlanu erandi ngenyanga. *More than R15 000 per month*
13. Ingaba lukhona naluphi na uhlobo lwesibonelelo sika rhulumente olufumanayo? *Do you currently receive any social assistance in the form of government grants? (grants in your name, for yourself or your children)*	☐ Ewe *Yes* ☐ Hayi *No* ❼ **Gqithela ku Q15** ***SKIP to Q15***
14. Loluphi uhlobo lwesibonelelo sika rhulumente olufumanayo ? *Which type of government grant do you receive? (grants in your name, for yourself or your children)*	☐ Isibonelelo sabantwana *Children's grant* ☐ Isibonelelo sokukhubazeka *Disability grant* ☐ Isibonelelo sokukhathalela *Care Dependency grant* ☐ Okunye , nceda cacisa: _____ *Other, please* specify

15. Ufumana izibonelelo ezingaphi kwezi zikhankanywe ngasentla (Q9)? ***Nceda ucacise inani*** *How many of each of each of these grants are received in your household?* ***: specify number***	☐ Isibonelelo sabantwana inani lezibonelelo ____ *Children's grant* # of grants ☐ Isibonelelo sokukhubazeka inani lezibonelelo ____ *Disability grant* *# of grants* ☐ Isibonelelo sokukhathalela inani lezibonelelo ____ *Care Dependency grant* *# of grants* ☐ Ezinye, nceda cacisa inani lezibonelelo ____ *Other, please specify*:_____ *# of grants* ☐ No grants in household
16. Uhlala kwikhaya elinjani? *What kind of home do you live in?*	☐ Ityotyombe/ uhlaliso olungahlelwanga *Shack/informal dwelling* ☐ Indlu yesitena *Formal house* ☐ Ifleti/ indlu kamasipala *Flat/council home* ☐ Elinye, Cacisa: _____ *Other Specify:*

17. Ingaba indlu yakho inazo ezi zinto zilandelayo: *Does your house have the following:* **Phendula kuzo ZONKE** ***Respond to ALL***	a. Indlu yangasese engaphakathi *A toilet inside* ☐ Ewe *Yes* ☐ Hayi *No*	b. Amanzi empompo ngaphakathi endlini *Running water inside* ☐ Ewe *Yes* ☐ Hayi *No*
	c. Umbane ngaphakathi endlini *Electricity inside* ☐ Ewe *Yes* ☐ Hayi *No*	d. Isikhenkcezisi *A refrigerator* ☐ Ewe *Yes* ☐ Hayi *No*
	e. Umnxeba wasendlini *A mobile telephone* ☐ Ewe *Yes* ☐ Hayi *No*	f. Umabonakude *A television* ☐ Ewe *Yes* ☐ Hayi *No*

B. PREGNANCY AND CHILDREN

18. Are you currently pregnant	☐ Ewe *Yes* ☐ Hayi *No* ❼ **Gqithela ku Q21** ***SKIP to Q21***
19. If yes, how many weeks pregnant are you?	_____ weeks
20. What is your estimated delivery date?	_____ /_____ /_____ ❼ **Gqithela ku Q23** ***SKIP to Q23*** DD MMM YYYY
21. If no, when did you deliver?	_____ /_____ /_____ DD MMM YYYY

22. Where did you deliver?	☐ Gugulethu MOU ☐ Mowbray Maternity Hospital ☐ Groote Schuur ☐ Other: _____

23. When you found out you were pregnant in the most recent pregnancy, were you planning to be pregnant?	☐ Ewe *Yes* ☐ Hayi *No*
24. Which clinic do you plan to attend for your HIV care when you leave the MOU?	☐ Hannan *(Gugulethu CHC)* ☐ Nyanga CHC ☐ Cross Roads ☐ Mzamomhle ☐ Masincedane ☐ Vuyani ☐ Other: _____
25. Which clinic do you plan to attend for your baby's care?	☐ NY1 (Gugulethu Clinic) ☐ Nyanga CHC ☐ Cross Roads ☐ Mzamomhle ☐ Masincedane ☐ Vuyani

	☐ Other: _____
26. Ukhulelwe kangaphi (kuquka noku kukhulelwa kwangoku)? *How many times have you been pregnant (including current pregnancy if pregnant)?*	Inani lokukhulelwa: _____ *Number of pregnancies*
27. Bangaphi abantwana obazeleyo? *How many children have you given birth to?*	Inani labantwana: ☐ _____ ☐ Abekho *Number of children* *None*
28. Bangaphi kwaba bantwana abaphilayo? *How many of these children are living?*	Inani labantwana: ☐ _____ ☐ Abekho *Number of children* *None*
29. How many of your children are living with HIV?	Inani labantwana: ☐ _____ ☐ Abekho *Number of children* *None*
C. HIV and ART history	
30. Ubuqala ukufumanisa ukuba unentsholongwane kagawulayo <u>koku kukhulelwa</u> okanye <u>phambi koku kukhulelwa</u>? *Did you first test HIV-positive <u>in this pregnancy</u> or <u>before this pregnancy</u>?*	☐ Koku kukhulelwa *In this pregnancy* ☐ Phambi koku kukhulelwa *Before this pregnancy*
31. Kwakunini ukuqala kwakho ukufumanisa ukuba unentsholongwane kagawulayo? *When did you first test HIV-positive?*	_____ /_____ /_____ DD MMM YYYY

32. Are you currently taking ART?	☐ Ewe *Yes* ❼ **Gqithela ku Q35** ***SKIP to Q35*** ☐ Hayi *No*
33. Have you ever taken triple drug antiretroviral therapy (lifelong ART)?	☐ Ewe *Yes* ❼ **Gqithela ku Q35** ***SKIP to Q35*** ☐ Hayi *No*

34. When will you start ART	_____ /_____ /_____ ❼ **Gqithela ku Q45** ***SKIP to Q45*** DD MMM YYYY
35. Did you start taking ART in this pregnancy or before this pregnancy?	☐ Koku kukhulelwa ❼ **Gqithela ku Q38** ***SKIP to Q38*** *In this pregnancy* ☐ Phambi koku kukhulelwa *Before this pregnancy*
36. What date did you first start to take ART?	_____ /_____ /_____ DD MMM YYYY
37. Where did you receive your ART before the Gugulethu MOU?	☐Hannan *(Gugulethu CHC)* ☐Nyanga CHC ☐Cross Roads ☐ Mzamomhle ☐Masincedane ☐Vuyani ☐Other: _____

38. Njengoko wathi waqala ukusebenzisa iART, wawukhe wayiyeka? *Since you first started taking ART, have you ever stopped?*	☐ Ewe *Yes* ➹ **also complete (O)ART table** ☐ Hayi *No*
39. When was the last day you took ART?	_____ /_____ /_____ DD MMM YYYY
40. Yintoni igama le ARVs ozisebenzisayo ngoku? *What are the names of the ARVs you are currently taking?*	☐ TDF-3TC-DTG (DLT) ☐ TDF-FTC-EFV (Tribuss/Odimune/Atripla) ☐ TDF-3TC-EFV ☐ TDF-3TC-NVP ☐ AZT-3TC-NVP ☐ AZT-3TC-EFV ☐ TDF-3TC-LPV/r ☐ AZT-3TC-LPV/r ☐ Other: _____
D. ADHERENCE	
41. Kwezi ntsuku zingamashumi amathathu zidlulileyo, zintsuku ezingaphi owathi walibala ngazo ubuncinane bomlinganiselo omnye walo naliphi na iyeza lakho lentsholongwane ka gawulayo? *In the last 30 days, on how many days did you miss at least one dose of any of your HIV medicines?*	Inani lentsuku: _____ *(0-30)* *Number of days*
42. Kwezi ntsuku zingamashumi amathathu zidlulileyo, kukangakanani apho wathi wawasebenzisa ngendlela ekwakufaneleke uwasebenzise ngayo amayeza entsholongwane ka gawulayo? *In the last 30 days, how often did you take your HIV medicines in the way that you were supposed to?*	☐ Zange *Never* ☐ Ibingaxhaphakanga *Rarely* ☐ Ngamanye amaxesha *Sometimes* ☐ Ngesiqhelo *Usually* ☐ Phantse oko *Almost always* ☐ Oko *Always*

43. Kwezi ntsuku zingamashumi amathathu zidlulileyo, wabamhle kangakanani umsebenzi owathi wawenza ngendlela ekwakufaneleke uwasebenzise ngayo amayeza entsholongwane ka gawulayo? *In the last 30 days, how good a job did you do at taking your HIV medicines in the way that you were supposed to?*	☐ Kakubi kakhulu *Very poor* ☐ Kakubi *Poor* ☐ Phakathi *Fair* ☐ Kakuhle *Good* ☐ Kakuhle kakhulu *Very good* ☐ Kakuhle ngokugqithisileyo *Excellent*
44. Do any of these things ever make it difficult to take your treatment every day?	☐ Being away from home ☐ Being at home when others are home ☐ Sometimes I get busy and forget ☐ Side effects ☐ Pregnancy sickness ☐ Being around other people ☐ Change in daily routine ☐ Being at work ☐ Feeling overwhelmed ☐ Feeling depressed ☐ Feeling unwell ☐ I think the pills will still work if I miss a few days ☐ Any other things not listed here: _____ _____ _____ _____ _____ ☐ I never have difficulty taking my treatment

E: DISCLOSURE

Ngoku sizokubuza imibuzo ethile malunga nomntu (ukuba ukhona) othe wamxelela malunga nesimo sakho sentsholongwane kagawulayo.

We are going to ask you some questions about whom (if at all) you have disclosed to about your HIV status.

45. Ingaba ukhona na umntu owathi wamxelela ngesimo sakho sentsholongwane kagawulayo, ngaphandle kwengcaphephe zempilo? H*ave you told anyone about your HIV status, other than health professionals?*	☐ Ewe *Yes* ☐ Hayi *No* ❼ **Gqithela ku Q47** ***SKIP to Q47***
46. Ingaba wamxelele na u_____ukuba wena unentsholongwane kagawulayo? *Have you told your_____ that you are HIV-positive?*	
a. Umyeni/ umlingane/iqabane *Husband/boyfriend/partner*	☐ Ewe *Yes* ☐ Hayi *No*
b. Amalungu osapho angamadoda *Male family member*	☐ Ewe *Yes* ☐ Hayi *No* ☐ N/A (Awekho amalungu osapho angamadoda) *No male family member*
c. Amalungu osapho angomama *Female family member*	☐ Ewe *Yes* ☐ Hayi *No* ☐ N/A (Awekho amalungu osapho angomama) *No female family member*
d. Abahlobo angamadoda *Male friends*	☐ Ewe *Yes* ☐ Hayi *No* ☐ N/A (Andinabahlobo) *Do not have male friends*

e. Abahlobo angomama *Female friends*	☐ Ewe *Yes* ☐ Hayi *No* ☐ N/A (Andinabahlobo) *Do not have female friends*
F: CORONAVIRUS	
47. Do you feel that COVID-19 or the lockdown has impacted your access to routine health services (pregnancy care, other chronic care, HIV care) in any way?	☐ Ewe *Yes* ☐ Hayi *No*
48. Did you delay coming for antenatal care because of COVID-19/lockdown?	☐ Ewe *Yes* ☐ Hayi *No*
49. Were you late/did you miss an ART pick up because if COVID-19/lockdown?	☐ Ewe *Yes* ☐ Hayi *No*
50. Were you late/did you miss a visit for another health condition because if COVID-19/lockdown?	☐ Ewe *Yes* ☐ Hayi *No*
51. Did COVID-19/lockdown result in lost income in your household?	☐ Ewe *Yes* ☐ Hayi *No*
52. Did COVID-19/lockdown stop someone from being here to support you in pregnancy/after delivery?	☐ Ewe *Yes* ☐ Hayi *No*
53. Have you ever been diagnosed with COVID-19?	☐ Ewe *Yes* ☐ Hayi *No* ❼ **Gqithela ku Q52** ***SKIP to Q52***
54. If yes, when were you diagnosed?	_____ /_____ /_____ DD MMM YYYY

55. Please briefly describe any other impact you have experienced	

In following questions we're going to ask you about things that may be sensitive for you. Remember you can refuse to answer any questions. We can also refer you for more support on any issues that you raise during the interview. If you are uncomfortable at any time please let me know.

G: HOUSEHOLD FOOD SECURITY

Ngoku sizakubuza imibuzo malunga nokuba kunzima okanye kulula kangakanani kuwe ukuthenga ukutya kwendlu yakho. Xa sithetha "ngendlu" yakho sibhekisa kuye wonke ubani ohlala endlwini kunye nawe.

We are now going to ask you some questions about how difficult or easy it is for you to buy food for your household. When we talk about a "household" we are referring to everyone who lives in your house with you.

Score	Hayi No	Ewe,kodwa ayixhaphakanga Yes, but rarely	Ewe ngamanye amaxesha Yes, sometimes	Ewe ixhaphakile Yes, often	Andiqinisekanga Unsure
FS1	Ingaba ukhe ukhathazeke ngokuba indlu yakho ayizukuba nokutya okwaneleyo? Do you ever worry that your household will not have enough food?				
	0	**1**	**2**	**3**	**9**

FS2	Indlu yakho ikhe iphelelwe yimali yokuthenga ukutya? Does your household ever run out of money to buy food?				
	0	**1**	**2**	**3**	**9**
FS3	Ukhe uxhomekeke kukutya okulinani eliqingqiweyo ukondla umntwana/abantwana kuba uphelelwa yimali yokuthenga ukutya kwesidlo? Do you ever rely on a limited number of foods to feed your child/children because you are running out of money to buy food for a meal?				
	0	**1**	**2**	**3**	**9**
FS4	Ukhe unciphise umlinganiselo wesidlo okanye utsibe izidlo kuba kungekho mali yaneleyo yokutya? Do you ever cut the size of meals or skip meals because there is not enough money for food?				
	0	**1**	**2**	**3**	**9**
FS5	Ukhe utye ngaphantsi kunokuba ufanelekile kuba kungekho mali yaneleyo yokutya? Do you ever eat less than you should because there is not enough money for food?				
	0	**1**	**2**	**3**	**9**
FS6	Umntwana/abantwana bakho bakhe batye ngaphantsi kokuba kufanelekile kuba kungekho mali yaneleyo yokutya? Do your child/children ever eat less than you feel they should because there is not enough money for food?				
	0	**1**	**2**	**3**	**9**
FS7	Umntwana/abantwana bakho bakhe bathi yena/bona balambile kuba kungekho kutya kwaneleyo endlwini yakho? Do your child/children ever say he/she/they are hungry because there is not enough food in the house?				
	0	**1**	**2**	**3**	**9**
FS8	Ukhe unciphise umlinganiselo wezidlo zabantwana bakho okanye bakhe baphose izidlo kuba kungekho mali yaneleyo yokuthenga ukutya? Do you ever cut the size of your children's meals or do they ever skip meals because there is not enough money to buy food?				
	0	**1**	**2**	**3**	**9**
FS9	Abanye babantwana bakho bakhe baya kulala belambile kuba kungekho mali yaneleyo yokuthenga ukutya? Do any of your children ever go to bed hungry because there is not enough money to buy food?				
	0	**1**	**2**	**3**	**9**

FS10	Wena okanye omnye umntu omdala endlwini yakho nikhe niye kulala nilambile kuba kungekho mali yaneleyo yokuthenga ukutya? Do you or any other adult in your household ever go to bed hungry because there is not enough money to buy food?				
	0	**1**	**2**	**3**	**9**

H: AVAILABILITY OF SOCIAL SUPPORT

Le mibuzo ilandelayo imalunga nenkxaso oyifumanayo kubantu abasondeleyo kuwe. Ndizakukufundela uluhlu lwemibuzo malunga neendidi ezahlukaneyo zoncedo abanokuthi abantu bakunike. Ndicela undixelele okokuba unaye na umntu onokuthi akunike olo hlobo loncedo okanye inkxaso xa uyifuna. Khumbula okokuba andikubuzi ukuba uyaludinga okanye akuludingi na.

Nceda ukhethe inani ukusukela ku 1-5 njengoko kubonisiweyo kumlinganiselo ongezantsi ukubonisa ubungakanani bovakalelelo lwakho ngohlobo lwenkxaso enokuthi ifumaneke xa uyifuna. Khetha u 1 ukuba impendulo yakho 'Akunjalo konke-konke' ukuya ku 5 ukuba 'uqinisekile'. Ukubaphezulu kwenani kubonisa ukuba ubona ngokungathi ingabankulu inkxaso onokuyifumana xa uthe wayidinga.

The following questions have to do with the support you get from people close to you. I'm going to read you a series of questions about the different types of help people might give you. Please tell me whether someone would be available to provide that kind of help or support if you needed it. Remember that I'm not asking whether or not you need this kind of help at this time, but whether someone could help you if you needed it.

Please choose a number from 1 to 5 as shown in the scale below to show how available you feel each kind of support would be if you needed it.
Choose from "1" if your answer is "definitely not" up to "5" if it is "definitely yes." The higher the number is, the more available you feel the support is.

	Akunjalo konke-konke Definitely Not	**Mhlawumbi Kungangabinjalo Possibly Not**	**Mhlawumbi Maybe**	**Mhlawumbi kunganjalo Possibly yes**	**Ngokuqinisekiley kunjalo Definitely Yes**	**Andizukuphendula Refuse**
ASS1	Ingaba ukhona umntu onoku thetha nawe xa ukhathazekile, unobuphakuphaku okanye udakumbile Would someone be available to talk to you if you were upset, nervous or depressed?					
	1	2	3	4	5	9

ASS 2	Ingaba ukhona umntu onokuqhakamshelana naye xa ufuna ukuthetha ngengxaki ebalulekileyo onayo? Is there someone you could contact if you wanted to talk about an important personal problem you were having?					
	1	2	3	4	5	9
ASS 3	Ingaba ukhona umntu onokunceda ngokuthi akonge xa unokuthi ulale ebhedini kuqengqeleke iiveki? Is there someone who would help take care of you if you had to stay in bed for several weeks?					
	1	2	3	4	5	9
ASS 4	Ingaba ukhona umntu onokubhenela kuye xa ufuna ukuboleka imali engange R10, akuncede ngokuya ekliniki, okanye nangaluphi na olunye uncedwana olukhawulezileyo? Is there someone you could turn to if you needed to borrow R10, get a ride to the doctor, or some other small immediate help?					
	1	2	3	4	5	9
ASS 5	Ingaba ukhona umntu onokubhenela kuye xa ufuna ukuboleka imali enokuthi ikuncede uhlawule irenti isithuba esingange nyanga? Is there someone you could turn to if you needed to borrow some money to help pay your rent for one month?					
	1	2	3	4	5	9
ASS 6	Izalamane zakho zingakwazi na ukukunika ulwazi, iingcebiso nokhokelo xa ulufuna? Would the people in your personal life give you information, suggestions, or guidance if you needed it?					
	1	2	3	4	5	9
ASS 7	Ukhona umntu onokuthembela kuye xa ufuna icebo elinokunceda ekuthatheni isigqibo? Is there someone you could turn to if you needed advice to help make a decision?					
	1	2	3	4	5	9
ASS 8	Ukhona umntu ongajongana nabantwana bakho xa unokugula? Is there someone who could take care of your children if you got sick?					
	1	2	3	4	5	9

I: AUDIT

AUDIT-C prior to pregnancy *Ngoku sizakubuza imibuzo ngokusebenzisa kwakho utywala. Nceda urhangqe impendulo engqamene nawe kumbuzo ngamnye:*

We are now going to ask you some questions about your use of alcohol before you found out you were pregnant. Please circle the relevant answer for each question below:

AUDIT -1	**Ubusela kangakanani utywala?** How often do you have a drink containing alcohol?					
	Score	**0**	**1**	**2**	**3**	**4**
		Zange/ Never	Kanye ngenyanga nangaphantsi/ Monthly or less	Kabini ukuya kwisine enyangeni/ 2-4 times a month	Kabini ukuya kwithathu enyangeni/ 2-3 times a week	Kane nangaphezulu evekini/ 4 or more times a week
AUDIT -2	**Zingaphi iiglasi zesiselo esinxilisayo oziselayo ngemini?** How many standard drinks containing alcohol do you have on a typical day when drinking?					
	Score	**0**	**1**	**2**	**3**	**4**
		1-2	3-4	5-6	7-9	≥10
AUDIT -3	**Kukangaphi usela iiglasi ezintandathu nangaphezulu ngexesha?** How often do you have six or more drinks on one occasion?					
	Score	**0**	**1**	**2**	**3**	**4**
		Zange/ Never	Ngaphantsi kwenyanga/ Less than monthly	Ngenyanga/ Monthly	Ngeveki/ Weekly	Ngosuku okanye malunga nosuku/ Daily or almost daily

AUDIT-C prior during pregnancy *Ngoku sizakubuza imibuzo ngokusebenzisa kwakho utywala. Nceda urhangqe impendulo engqamene nawe kumbuzo ngamnye:*

We are now going to ask you some questions about your use of alcohol since you found out you were pregnant. Please circle the relevant answer for each question below:

AUDIT -1	**Ubusela kangakanani utywala?** How often do you have a drink containing alcohol?					
	Score	**0**	**1**	**2**	**3**	**4**

		Zange/ Never	Kanye ngenyanga nangaphantsi/ Monthly or less	Kabini ukuya kwisine enyangeni/ 2-4 times a month	Kabini ukuya kwithathu enyangeni/ 2-3 times a week	Kane nangaphezulu evekini/ 4 or more times a week
AUDIT -2	**Zingaphi iiglasi zesiselo esinxilisayo oziselayo ngemini?** How many standard drinks containing alcohol do you have on a typical day when drinking?					
	Score	**0**	**1**	**2**	**3**	**4**
		1-2	3-4	5-6	7-9	≥10
AUDIT -3	**Kukangaphi usela iiglasi ezintandathu nangaphezulu ngexesha?** How often do you have six or more drinks on one occasion?					
	Score	**0**	**1**	**2**	**3**	**4**
		Zange/ Never	Ngaphantsi kwenyanga/ Less than monthly	Ngenyanga/ Monthly	Ngeveki/ Weekly	Ngosuku okanye malunga nosuku/ Daily or almost daily
Required referral	No=0 Yes =1 ❼ complete referral form					

J: DUDIT

DUDIT-C before pregnancy: *Sizakubuza imibuzo malunga nokusebenzisa iziyobisi. We are now going to ask you some questions about your use of drugs before you found out you were pregnant.*
Nceda urhangqe impendulo eyiyo ngombuzo ngamnye kule ingezantsi.
Please circle the relevant answer for each question below:

DUDIT -1	**Uzisebenzisa kangakanani iziyobisi ngaphandle kotywala?** How often do you use drugs other than alcohol?					
	Score	**0**	**1**	**2**	**3**	**4**
		Zange/ Never	Kanye ngenyanga nangaphantsi/ Monthly or less	Kabini ukuya kwisine enyangeni/ 2-4 times a month	Kabini ukuya kwithathu enyangeni/ 2-3 times a week	Kane nangaphezulu evekini/ 4 or more times a week
DUDIT -2	**Usebenzisa ngaphezu kohlobo olunye lweziyobisi ngexesha?** Do you use more than one type of drug on the same occasion?					
	Score	**0**	**1**	**2**	**3**	**4**

		Zange/ Never	Kanye ngenyanga nangaphantsi/ Monthly or less	Kabini ukuya kwisine enyangeni/ 2-4 times a month	Kabini ukuya kwithathu enyangeni/ 2-3 times a week	Kane nangaphezulu evekini/ 4 or more times a week
DUDIT -3	**Mangaphi amaxesha osebenzisa iziyobisi ngosuku?** How many times do you take drugs on a typical day when you use drugs?					
	Score	**0**	**1**	**2**	**3**	**4**
		0	1-2	3-4	5-6	≥7
DUDIT -4	**Kuxhaphake kangakanani ukuba uchaphazeleke kanobom ziziyobisi?** How often have you been influenced heavily by drugs?					
	Score	**0**	**1**	**2**	**3**	**4**
		Zange/ Never	Ngeneno kunakanye ngenyanga/ Less often than once a month	Ngenyanga zonke/ Every month	Qho ngeveki/ Every week	Ngosuku okanye ngemini zonke/ Daily or almost every day
DUDIT-C during pregnancy: *Sizakubuza imibuzo malunga nokusebenzisa iziyobisi.* *We are now going to ask you some questions about your use of drugs since you found out you were pregnant.*						
DUDIT -1	**Uzisebenzisa kangakanani iziyobisi ngaphandle kotywala?** How often do you use drugs other than alcohol?					
	Score	**0**	**1**	**2**	**3**	**4**
		Zange/ Never	Kanye ngenyanga nangaphantsi/ Monthly or less	Kabini ukuya kwisine enyangeni/ 2-4 times a month	Kabini ukuya kwithathu enyangeni/ 2-3 times a week	Kane nangaphezulu evekini/ 4 or more times a week
DUDIT -2	**Usebenzisa ngaphezu kohlobo olunye lweziyobisi ngexesha?** Do you use more than one type of drug on the same occasion?					
	Score	**0**	**1**	**2**	**3**	**4**
		Zange/ Never	Kanye ngenyanga nangaphantsi/ Monthly or less	Kabini ukuya kwisine enyangeni/ 2-4 times a month	Kabini ukuya kwithathu enyangeni/ 2-3 times a week	Kane nangaphezulu evekini/ 4 or more times a week
DUDIT -3	**Mangaphi amaxesha osebenzisa iziyobisi ngosuku?** How many times do you take drugs on a typical day when you use drugs?					
	Score	**0**	**1**	**2**	**3**	**4**
		0	1-2	3-4	5-6	≥7
DUDIT -4	**Kuxhaphake kangakanani ukuba uchaphazeleke kanobom ziziyobisi?** How often have you been influenced heavily by drugs?					

	Score	0	1	2	3	4
		Zange/ Never	Ngeneno kunakanye ngenyanga/ Less often than once a month	Ngenyanga zonke/ Every month	Qho ngeveki/ Every week	Ngosuku okanye ngemini zonke/ Daily or almost every day
Required referral		No=0 Yes =1 ❼ complete referral form				

K: SOCIAL IMPACT SCALE

Okulandelayo, ndicela ubonise ukuba uvumelana okanye awuvumelani kangakanani na nezintetho zilandelayo: Next
I would like you to indicate how much you agree or disagree with the following statements:

Khetha phakathi ko1-5 apho u-1 “Andivumi konke-konke” kwaye no-5 “ndiyavuma ngamandla”. Choose
between 1 and 5 where “1” is “strongly disagree” and “5” is “strongly agree”

	Andivumingamandla Strongly Disagree	**Andivumi Slightly Disagree**	**Andiniqinisekanga Neither Agree or Disagree**	**NdiyavumaSlightly Agree**	**Ndiyavuma ngamandla Strongly Agree**	**Ndiyala Refuse**
S1	Ndicinga ukuba abantu banoloyiko lokuba ndingabosulela ngentsholongwane ngokubambana ngezandla okanye ngokutya ukutya okwenziwe ndim. I feel others are concerned they could “catch” my HIV through contact like a handshake or eating food I make.					
	1	2	3	4	5	9
S2	Ndicinga ukuba abanye bayandichasa kuba ndinentsholongwane I feel others avoid me because of my HIV.					
	1	2	3	4	5	9
S3	Ndiziva ndingenakho ukuchazela abanye abantu ngokuphila nentsholongwane ngokuphandle I do not feel I can be open with others about my HIV.					
	1	2	3	4	5	9
S4	Ndiziva ndifuna ukuyigcina iyimfihlo ukuba ndiphila nentsholongwane I feel I need to keep my HIV a secret.					
	1	2	3	4	5	9
S5	Ngenxa yokuba ndiphila nentsholongwane ndiziva ndingathathwa ngokulinganayo ebuhlobeni ngabanye Due to my HIV, I have a sense of being unequal in my relationships with others.					
	1	2	3	4	5	9
S6	Ndiziva ndingumama ongalunganga kuba ndiphila nentsholongwane I feel like I am a bad mother because I am HIV-positive.					
	1	2	3	4	5	9

S7	Ndinexhala lokuba ingangubani onokuze ahoye umntwana wam xa ndingagula I worry about who will take care of my child if I become sick.					
	1	2	3	4	5	9

L: KESSLER 10

Initials of interviewer: _____

REMInD: Combined enrolment CRFs
Version 1, 20 Jan 2021

PID: _ _ _ _ _ _ - _ _

Lemibuzo ilishumi ilandelayo ikubuza ukuba ubuziva njani kwezintsuku ziyi-30 zidlulileyo. Kumbuzo ngamnye, rhangqa inani elisondele kakhulu ekuchazeni ubude bexesha uziva ngaloondlela.
The following questions ask about how you have been feeling in the past 30 days. For each question, circle the option that best describes the amount of time that you feel that way.

	Score	Akukho nalinye ixesha None of the time	Ixesha elincinci A little of the time	Ngelinye ixesha Some of the time	Ixesha elininzi Most of the time	Lonke ixesha All of the time
K10 -1	Kwezintsuku ziyi-30 zidlulileyo, kukangakanani uziva udiniwe ngaphandle kwesizathu? During the last 30 days, about how often did you feel tired out for no good reason?					
	Score	**1**	**2**	**3**	**4**	**5**
K10 -2	Kwezintsuku ziyi-30 zidlulileyo, kukangakanani uziva unexhala? During the last 30 days, about how often did you feel nervous?					
	Score	**1**	**2**	**3**	**4**	**5**
K10 -3	Kwezintsuku ziyi-30 zidlulileyo, kukangakanani uziva unexhala kangangokuba kwakungekho nento engakuthomalalisa? During the last 30 days, about how often did you feel so nervous that nothing could calm you down?					
	Score	**1**	**2**	**3**	**4**	**5**
K10 -4	Kwezintsuku ziyi-30 zidlulileyo, kukangakanani uziva ungenathemba? During the last 30 days, about how often did you feel hopeless?					
	Score	**1**	**2**	**3**	**4**	**5**
K10 -5	Kwezintsuku ziyi-30 zidlulileyo, kukangakanani uziva ungazinzanga? During the last 30 days, about how often did you feel restless or fidgety?					
	Score	**1**	**2**	**3**	**4**	**5**
K10 -6	Kwezintsuku ziyi-30 zidlulileyo, kukangakanani uziva ungazinzanga ungakwazi nokuhlala kakuhle? During the last 30 days, about how often did you feel so restless you could not sit still?					
	Score	**1**	**2**	**3**	**4**	**5**

K10 -7	Kwezintsuku ziyi-30 zidlulileyo, kukangakanani uziva unoxinzelelo? During the last 30 days, about how often did you feel depressed?					
	Score	**1**	**2**	**3**	**4**	**5**
K10 -8	Kwezintsuku ziyi-30 zidlulileyo, kukangakanani uziva ukuba kungumzamo ukwenza yonke into? During the last 30 days, about how often did you feel that everything was an effort?					
	Score	**1**	**2**	**3**	**4**	**5**
K10 -9	Kwezintsuku ziyi-30 zidlulileyo, kukangakanani uziva ulusizi kangangokuba kwakungekhonto eyayingakonwabisa? During the last 30 days, about how often did you feel so sad that nothing could cheer you up?					
	Score	**1**	**2**	**3**	**4**	**5**
K10 -10	Kwezintsuku ziyi-30 zidlulileyo, kukangakanani uziva ungenaxabiso? During the last 30 days, about how often did you feel worthless?					
	Score	**1**	**2**	**3**	**4**	**5**
K-10 score:			Required referral: If yes ❼ complete referral form		No=0 Yes =1	

Initials of interviewer: ____

M: EPDS

Singathanda ukwazi ukuba ubuziva njani kuleveki iphelileyo. Nceda ukhethe esondeleyo kwindlela obuziva ngayo kwiveki edluleyo, hayi nje indlela oziva ngayo namhlanje. Nceda ufunde lonke uluhlu lwenkcaza ngenye.

We would like to know how you have been feeling in the past week. Please choose the answer that comes closest to how you have felt in the past week, not just how you feel today. Please read all the options for each statement.

EPDS 1	Ndibenako ukuhleka ndikwazi nokuphawula izinto ezihlekisayo I have been able to laugh and see the funny side of things				
	Score	**0**	**1**	**2**	**3**
		Njengoko bendihleli ndisenza. As much as I always could	Hayi kangako okwangoku Not quite so much now.	Ngokucacileyo hayi kangako okwangoku. Definitely not so much now.	Hayi kwaphela Not at all.
EPDS 2	Bendikuthakazelela ukonwabela izinto I have looked forward with enjoyment to things.				
	Score	**0**	**1**	**2**	**3**
		Njengoko ndandisenza. As much as I ever did.	Kancinci kunendlela endandisenza ngayo A little less than I used to.	Ngaphantsi kunendlela endandisenza ngayo Much less than I used to.	Kungqabile ukuba kubenjalo. Hardly at all.
EPDS 3	Ndasola isiqu sam ngokungeyomfuneko xa izinto zazihamba kakubi. I have blamed myself unnecessarily when things went wrong				
	Score	**0**	**1**	**2**	**3**
		Ewe, ixesha elininzi Yes, most of the time.	Ewe, ngenyelinye ixesha Yes, some of the time.	Hayi kangako Not very much.	Hayi, zange No, never
EPDS 4	Bendinexhala ngaphandle kwesizathu. I have been anxious or worried for no good reason				
	Score	**0**	**1**	**2**	**3**

		Hayi, konke-konke No, not at all.	Kungqabile ukuba kubenjalo.. Hardly ever.	Ewe, ngamanye amaxesha. Yes, sometimes.	Ewe, kakhulu. Yes, very much.
EPDS 5	Ndaziva ndisoyika okanye ndiduduzela ngaphandle kwesizathu. I have felt scared or panicky for no very good reason				
	Score	**0**	**1**	**2**	**3**
		Ewe, kaninzi. Yes, quite a lot.	Ewe, ngamanye amaxesha. Yes, sometimes.	Hayi kakhulu No, not much.	Hayi konke konke No, not at all
EPDS 6	Izinto zindongamele Things have been getting on top of me				
	Score	**0**	**1**	**2**	**3**
		Ewe, amaxesha amaninzi bendingakwazi ukwenzanto kwaphela. Yes, most of the times I haven't been managing at all.	Ewe, ngamanye amaxesha bedingankwazi ukwenzanto njengesiqhelo Yes, sometimes I haven't been managing as well as usual.	Hayi, ixesha elininzi bendikwazi ukwenza izinto kakuhle No, most of the time I have managed quite well.	Hayi, bendikwazi ukwenza izinto kakuhle oko No, I have been managing as well as ever.
EPDS 7	Bendingonwabanga kangangokuba bekubanzima nokulala. I have been so unhappy that I have had difficulty sleeping				

Initials of interviewer: _____

PID: _ _ _ _ _ _ - _ _

	Score	**0**	**1**	**2**	**3**
		Ewe, ixesha elininzi Yes, most of the time.	Ewe, ngamanye amaxesha Yes, sometimes.	Hayi kakhulu Not very much.	Hayi konke konke No, not at all.
EPDS 8	Ndaye ndaziva ndilusizi okanye ndinxunguphele I have felt sad or miserable				
	Score	**0**	**1**	**2**	**3**

		Ewe, ixesha elininzi Yes, most of the time.	Ewe, kaninzi. Yes, quite a lot.	Hayi kakhulu Not very much.	Hayi konke konke No, not at all
EPDS 9	Bendingonwabanga kangangokuba bendikhala I have been so unhappy that I have been crying				
		0	**1**	**2**	**3**
	Score	Ewe, ixesha elininzi Yes, most of the time.	Ewe, kaninzi. Yes, quite a lot.	Ngamanye amaxhesa qha Only sometimes.	Hayi Azange No, never
EPDS 10	Ingcinga yokuzenzakalisa ithe yandifikela The thought of harming myself has occurred to me				
		0	**1**	**2**	**3**
	Score	Ewe, kaninzi. Yes, quite a lot	Ngamanye amaxesha Sometimes	Zange ifane yenzeke. Hardly ever	Azange Never

EPDS score:		Required referral: If yes ❼ complete referral form	No=0 Yes =1

N: WHO VAW

Siza kubuza imibuzo embalwa malunga nobundlobongela bokudlakathiswa liqabane.
We are going to ask you a few questions relating to partner violence.

Kwezi nyanga ziyi-12 zidlulileyo wakhe wazifumana ukwezinye zezimeko zilandelayo?
In the last 12 months, have you experienced any of the following?

	Score	**Ewe/Yes=1**	**Hayi/No=0**
UKUDLAKATHISWA NGOKWASENGQONDWENI / Psychological Violence			
1.	Iqabane lakho likhe lakuthuka okanye lakwenza uzive ungalunganga? Has your partner insulted you or made you feel bad about yourself?	1	0
2.	Likhe lakwenza wazifumanisa ukuba usithobile isidima sakho phambi kwabanye abantu? Has he belittled or humiliated you in front of other people?	1	0
3.	Likhe lakoyikisa lakuphatha kakubi ngabom? Has he done things to scare or intimidate you on purpose?	1	0
4.	Likhe lakugrogrisa ngokonzakalisa wena okanye umntu omkhathaleleyo? Has he threatened to hurt you or someone you care about?	1	0
UKUDLAKATHISWA NGOKWASEMZIMBENI / Physical Violence			

5.	Likhe lakuqhwaba ngempama okanye lakugibisela ngento enokwenzakalisa? Has he slapped you or thrown something at you that could hurt you?	1	0
6.	Likhe lakutyhala okanye lakunyola? Has he pushed or shoved you?	1	0
7.	Likhe lakubetha ngenqindi okanye ngento enokonzakalisa? Has he hit you with a fist or with something else that could hurt you?	1	0
8.	Likhe likukhabe,likurhuqe okanye likubethe? Has he kicked you, dragged you or beaten you up?	1	0
9.	Likhe likukrwitshe okanye likutshise ngabom? Has he choked or burnt you on purpose?	1	0

Initials of interviewer: ____

10.	Likhe likugrogrise okanye lisebenzise umpu,imela okanye nasiphi isixhobo kuwe? Has he threatened to use or actually used a gun, knife or other weapon against you?	1	0
UKUDLAKATHISWA NGOKWESONDO / Sexual Violence			
11.	Likhe likunyanzele ngokwabelana ngesondo ngaphandle kwemvume yakho? Has he physically forced you to have sexual intercourse when you didn't want to?	1	0
12.	Wakhe wabelana nalo ngesondo ungafuni kuba unoloyiko lwento anokuthi ayenze? Did you ever have sexual intercourse when you didn't want to because you were afraid of what he might do?	1	0
13.	Likhe likunyanzele ngokwabelana ngesondo ngendlela ofumanisa ukuba ukuthathela phantsi okanye uyakwenyelisa? Has he forced you to do something sexual that you found degrading or humiliating?	1	0
Required referral	No=0 Yes =1 ❼ complete referral form		

We've reached the end of the interview. Thank you very much/ Enkosi kakhulu

Signed Interviewer completing CRF: _____ Date: _____ / _____ / _____
DD MMM YYYY

Signed QC Officer: _____ Date: _____ / _____ / _____
DD MMM YYYY

Signed Data capturer: _____ Date: _____ / _____ / _____
DD MMM YYYY

PID: _ _ _ _ _ _ - _ _

O: ART INTERRUPTION TABLE (ONLY IF ANSWERED YES TO Q38 IN PART A)

In the previous questions you mentioned that you had stopped taking your ART at some time in the past.

We would like to ask you about the times that you were and were not taking your ART right from the time you first started on treatment. We will complete the table below. When did you first start taking ART?

Example:

	Month/Year (re) starting ART	Reason for (re) starting ART	Month/Year stopped ART	Reason for stopping	Still taking ART (1/0)
1	Dec 2010	I was pregnant	June 2014	Moved to EC	
2	Aug 2015	I was ill with TB	May 2020	I was unable to get to the clinic during COVID lockdown	
3	Jan 2021	I'm pregnant			1
4					
5					

	a) Month/Year (re) starting ART	b) <u>Reason</u> for (re) starting ART	c) Month/Year stopped ART	d) <u>Reason</u> for stopping	e)
1	D: _ _ M: _ _ _ Y: _ _ _ _		D: _ _ M: _ _ _ Y: _ _ _ _		
2	D: _ _ M: _ _ _ Y: _ _ _ _		D: _ _ M: _ _ _ Y: _ _ _ _		
3	D: _ _ M: _ _ _ Y: _ _ _ _		D: _ _ M: _ _ _ Y: _ _ _ _		
4	D: _ _ M: _ _ _ Y: _ _ _ _		D: _ _ M: _ _ _ Y: _ _ _ _		
5	D: _ _ M: _ _ _ Y: _ _ _ _		D: _ _ M: _ _ _ Y: _ _ _ _		
6	D: _ _ M: _ _ _ Y: _ _ _ _		D: _ _ M: _ _ _ Y: _ _ _ _		

7	D: _ _ M: _ _ _ Y: _ _ _ _		D: _ _ M: _ _ _ Y: _ _ _ _		
8	D: _ _ M: _ _ _ Y: _ _ _ _		D: _ _ M: _ _ _ Y: _ _ _ _		
9	D: _ _ M: _ _ _ Y: _ _ _ _		D: _ _ M: _ _ _ Y: _ _ _ _		
10	D: _ _ M: _ _ _ Y: _ _ _ _		D: _ _ M: _ _ _ Y: _ _ _ _		

Initials of interviewer: ____

Appendix B: UCT HREC Protocol Approval for REMInD Study

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room G50- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-enquiries@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

07 October 2020

HREC REF: 513/2020

Dr T Phillips
Division of Epidemiology & Biostatistics
Office 5.38, Entrance 4 Level 5 Falmouth Building
Email: - tammy.phillips@uct.ac.za

Dear Dr Phillips

PROJECT TITLE: ROUTINE ELECTRONIC MOTHER-INFANT DATA (REMIND) TO SUPPORT RETENTION IN POSTPARTUM HIV TREATMENT AND EARLY INFANT DIAGNOSIS SERVICES IN SOUTH AFRICA

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, dated 17 March 2020 & 06 July 2020.

Approval is granted for one year until the 30 October 2021.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

Signed by candidate

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

HREC/REF:513/2020sa

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

Appendix C: UCT HREC Protocol Approval for Proposed Study

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room 45 E-52-E-Floor- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-submissions@uct.ac.za
Website: www.health.uct.ac.za/home/human-research-ethics

19 October 2022

HREC REF: 641/2022

Dr T Phillips
Division of Epidemiology & Biostatistics
Office 5.42 Level 5, Falmouth Building-FHS
Email: Tammy.phillips@uct.ac.za
Student: LNRBRY001@myuct.ac.za

Dear Dr Phillips

PROJECT TITLE: PATTERNS OF HIV CARE PRIOR TO ANTENATAL CARE, AND THE IMPACT ON LATER OUTCOMES, AMONG PREGNANT WOMEN LIVING WITH HIV IN GUGULETHU, SOUTH AFRICA: A RETROSPECTIVE COHORT-
(MASTERS CANDIDATE--MR BRYAN LEONARD)-SUB-STUDY LINKED TO 513/2020

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 October 2023.

Please submit a progress form, using the standardised Annual Report Form (FHS016) if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

The HREC acknowledge that the student: Mr Bryan Leonard will also be involved in this study.

Please quote the HREC REF 641/2022 in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

Signed by candidate

PROFESSOR M BLOCKMAN
CHAIRPERSON, FACULTY OF HEALTH SCIENCES HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637. Institutional Review Board (IRB) number: IRB00001938 NHREC-registration number: REC-210208-007

HREC/ref 641.2022

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2020), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

Appendix D: Informed Consent Form for the REMInD Study

TITLE OF RESEARCH: Routine Electronic Mother-Infant Data (REMInD) to support retention in postpartum HIV treatment and early infant diagnosis services in South Africa

WHAT IS THE PURPOSE OF THIS STUDY?

We are researchers from the University of Cape Town. We are doing a study that aims to support mothers living with HIV care to complete the care required for them and their baby to prevent mother-to-child transmission of HIV. We are using the information that is recorded during routine clinic visits to help us to identify when mothers or babies have a gap in care, and then to follow up with you to help you link to the services you or your baby need.

We know that lots of women struggle to stay in HIV care after having a baby and we would like to understand how we can use the data that is already collected in the clinic to identify mothers and babies who need support and to assist them to stay in care. You are being invited to participate because you are age 18 or older, living with HIV and currently receiving her pregnancy or postpartum care at the Gugulethu MOU.

The purpose of this consent form is to give you information to help you decide if you want to take part in this study.

WHAT DO I HAVE TO DO IF I AGREE TO TAKE PART?

Enrolment visit

If you agree to take part, you will be asked to complete the following activities (approx 2 hour). If possible, these activities will take place in person today. However, if necessary, we will complete these activities over the phone at the soonest time in the next two weeks that is convenient for you.

- You will be allocated a unique study number that we will use on your study records instead of using your identifying information.
- A questionnaire to collect: your demographic information and some details about your pregnancy and HIV history, HIV stigma, mental health (including drug and alcohol use), food security, social support, and partner violence.
    - The reason we are asking you these questions is because we know that women's mental health and social circumstances can make it difficult to remain engaged in HIV services. We will use this information to help us to understand the results of this study and to see whether the intervention works differently for different women. If needed, we will refer you to the clinic social worker or to a local organization so you can access any counselling and support that you need.
- A linkage form: we will ask you to provide us with your clinic folder number, your name, surname, date of birth and ID number, as well as these details for your baby if you

have already delivered. This information will be used to link to your medical records both in the clinics you go to and the electronic information that is normally stored by the department of health. This information will be kept safely and separately from the questionnaire.

- We will ask you to provide your contact information (telephone numbers and addresses) as well as alternative contacts. This information will be used to update the contact information with the clinic clerk if needed, so that if we need to trace you, we have up to date information.

After the enrolment visit

Monitoring of medical records

If you choose to enroll in the study we will monitor your and your baby's medical records for the next 9-18 months. We will be looking at the information that is normally collected by the clinic when you attend for your health or for the baby's health including information about your delivery, clinic visits, laboratory tests and dispensing of medication. We will look at the electronic records from the clinics you attend to check that you and your baby are receiving the HIV care you need. We will also look at the paper records in the clinics to make sure the electronic information is correct.

The kind of information that we will be looking for in the data are:

- For the baby ○ Did your baby have an HIV test when they were supposed to ○ If your baby does test positive for HIV, are they getting the care they need
- For your health ○ Did you link to HIV care after you had the baby ○ Are you regularly accessing HIV care

If we pick up that you or your baby have had a gap in the normal care we would expect you to have, then we will:

- Try to make sure that the gap we see is real and is not a mistake in the data
- Contact you to see how we can help you access the care that you or your baby needs If we see that you or your baby has had a gap in care, one of our study staff will try to contact you by phone. If they are not able to get you on the phone, they will try to visit you at home using the information you provided to the clinic clerk at enrolment into the study. During this phone call or visit, they will ask you some questions to understand whether you really had a gap in care and why it may have happened. We will offer you support and assistance to access the care you need.

During this telephone call or visit, we might ask you to share a picture of your baby's road to health card to check the information we have about when the baby attended the clinic. If you need to send this to us we will provide you with a small data bundle to cover this cost.

Follow-up call for a sample of women

At the end of the study period, when the baby is about 9-18 months old, we will also phone a sample of women who did not have any gaps in care to check that we had the correct information. If you are selected for this phone call, the study staff will ask you some questions to check which clinics you and your baby have been attending and whether you have had any difficulties staying in care. We might ask you to share a picture of your baby's road to health card to help us better understand the accuracy of the data we have. If you need to send this to us we will provide you with a small data bundle to cover this cost.

In-depth interview

A sample of women who did have gaps in care will be invited to take part in a longer interview about the challenges they experienced and how they found the support offered to them during this study. If you are selected, we will call you to invite you to take part in this interview. At that time you will be able to decide whether or not you would like to participate and you will complete another consent form like this one to see whether you want to take part.

Contact for future study

After the completion of this study, it is possible that we will contact you again at your next clinic visit or at another time in the future to take part in additional research studies. At that time, you would be asked to review and sign another consent form like this one. If you are asked to take part in any future studies, you can choose not to.

WHAT ARE THE POTENTIAL RISKS?

You may feel uncomfortable about some of the personal questions you are asked and some of the questions we ask may make you feel distressed. You may refuse to answer any question that you do not want to answer. If anything raised during the interview today or during the study followup makes you want to talk more with someone or you need additional support, we will refer you to counselling services either in the Gugulethu Community Health Centre or nearby organisations providing counselling and support services. If you are experiencing partner violence, we will help you to link with MOSAIC, an organisation that provides both legal and psychosocial support.

There is always some risk in sharing your personal and medical information. The interview will take place in a private room and will be a safe space to talk. The information you share with us will not be stored with your name or any other identifying information. We will be very careful to keep all your information as private as possible.

Confidentiality

If you agree to take part, all information collected during the study will be kept strictly confidential. Your identifying information will only be used to link to your medical records, and to make contact with you if needed. All the study information will be stored securely and only the study staff will access to it.

All staff involved in the study will get specific training in confidentiality. If we need to phone you or do a home visit, we will not mention HIV or any details of the study until we are sure we are speaking to you and you are in a private and comfortable place to speak.

Even with these procedures in place, if the study staff learns that you are a risk to yourself or someone else or of possible child abuse and/or neglect, study staff will tell the proper authorities.

When we report the results of this research, almost all results will be reported as grouped information and not individual responses. The only exception is if you take part in an in-dept interview, we might report specific quotes from the interview. These quotes will not contain any identifying information and no identifiers will be attached to it.

WHAT ARE THE POTENTIAL BENEFITS?

If you or your baby are identified as having a gap in care during the study period, the study will try to understand why and to provide support for you to access the care you and your baby need. If we identify any other health care problem for you or your child during the course of the study, we will make sure you are referred to the appropriate health care services.

In addition, the information gained in this study may help to improve HIV care for women and their children in Cape Town, the Western Cape Province, and across South Africa.

WHAT ARE THE ALTERNATIVES TO TAKING PART?

You can choose not to take part in this study. If you decide not to take part, you will continue your routine care as usual. Whether or not you decide to take part will not affect the standard health care services you receive, at this or at any other facility.

WILL I BE GIVEN ANYTHING FOR TAKING PART?

At the end of this visit, you will be given R150 in grocery vouchers to thank you for your time and contribution to this study.

ARE THERE ANY COSTS?

There is no cost for being in this study.

CAN I LEAVE THE STUDY?

You have the right to decide not to take part in this study, to refuse to answer any questions, or to withdraw from the study at any time without any penalty. It will have no effect on the care that you receive at the Gugulethu Community Health Centre or any other health facility.

DO YOU HAVE ANY QUESTIONS?

If there is anything that is unclear or if you need further information, please ask us and we will provide it.

Do you have any questions?

FOR ADDITIONAL INFORMATION:

If you have any questions or have any problems while taking part in this research study, you should contact:

Dr Tammy Phillips

School of Public Health and Family Medicine

Faculty of Health Sciences, University of Cape Town

Tel: 021 6501646

Email: tammy.phillips@uct.ac.za

If you have any questions about your rights as a research participant, you may contact the following member of the ethics committee:

Prof Marc Blockman

Chair, Human Research Ethics Committee

Faculty of Health Sciences, University of Cape Town

Tel: 021 406 6338

CONSENT STATEMENT:

I have read this form, or someone has read it to me. I have been offered a copy of this consent form. I was encouraged and given time to ask questions. I agree to be in this study. I agree to allow the investigators to use my and my baby's identifying information including provincial folder number, name and date of birth, to request health information directly from the

Department of Health. I know that after choosing to be in this study, I may withdraw at any time. My being in the study is voluntary. I understand that whether or not I participate will not affect my health care services received today, or at any time in the future.

Please indicate your consent with your signature.

_____	_____	_____
Volunteer's name	Signature	Date
_____	_____	_____
Staff member's name	Signature	Date

If the volunteer is unable to read or write the entire counselling process must be observed by an independent witness who can then confirm the procedure once the she has given consent.

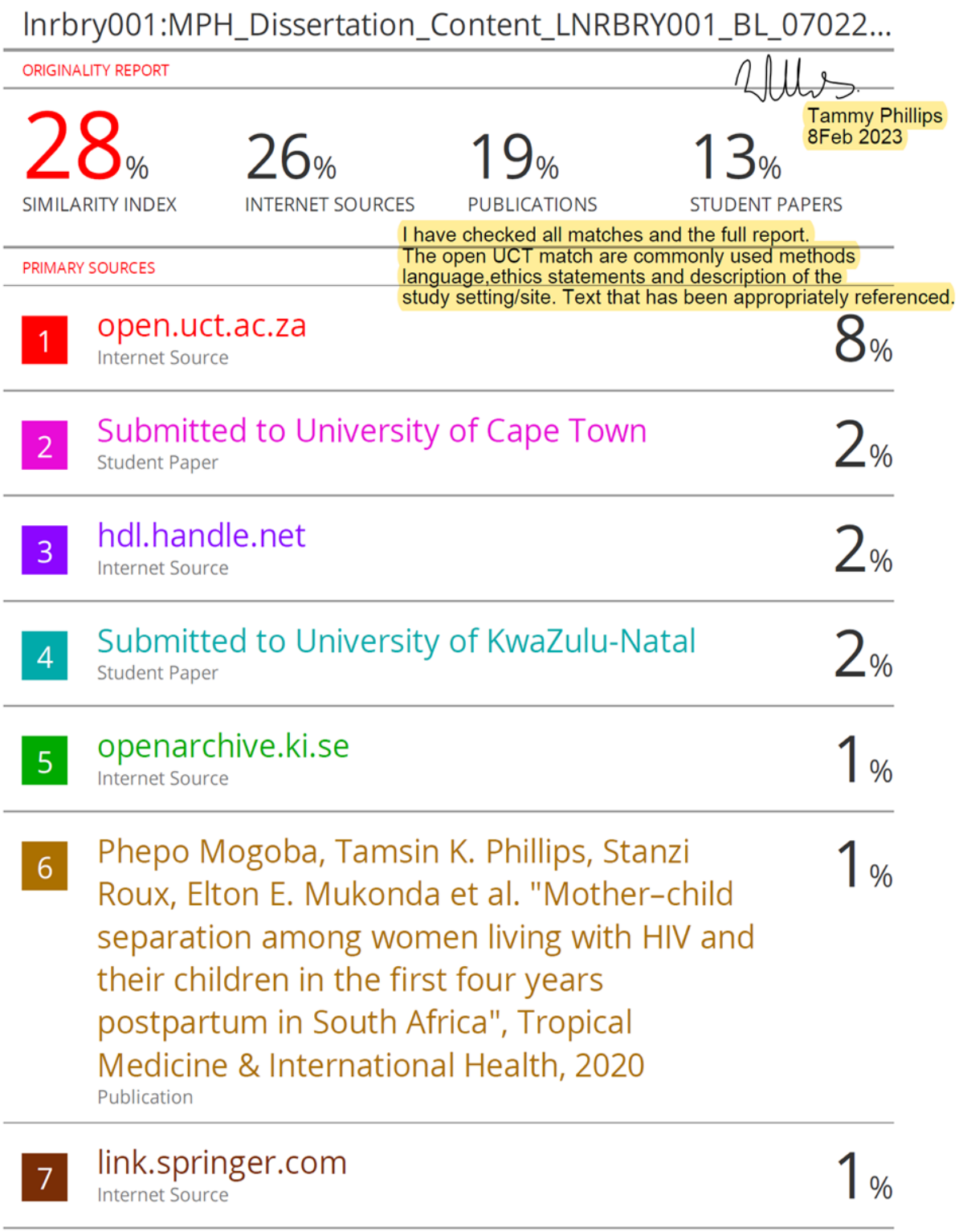
Fingerprint of volunteer:

Witness: I confirm that I am independent of the study and that I witnessed the entire informed consent counselling process in the home language of the volunteer

_____	_____	_____
Witness name	Signature	Date

Thank you.

Appendix E: Turnitin Originality Report



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Appendix F: Supplementary Tables

Table C1: Socio*demographic and clinical characteristics of 298 participants stratified by viral load suppression (threshold 1000) at delivery*

Characteristics	***Viral Load Suppression***		***Total***	***P-value***
	VL≤1000 copies/ml	***VL>1000 copies/ml***		
Number of women	265 (88.9)	33 (11.1)	298 (100)	
Maternal characteristics at enrolment				
Median age, years	32.1 (28.1, 35.9)	29.9 (24.2, 34.4)	32.3 (28.1, 35.9)	**0.036**
Age categories (years)				
<=25 years	35 (13.2)	9 (27.3)	44 (14.8)	**0.032**
>25 years	230 (86.8)	24 (72.7)	254 (85.2)	
Relationship status				
Married	54 (20.4)	5 (15.2)	59 (19.8)	0.477
Unmarried	211 (79.6)	28 (84.8)	239 (80.2)	
Pregnancy intention				
Planned pregnancy	62 (23.4)	4 (12.1)	66 (22.1)	0.141
Unplanned pregnancy	203 (76.6)	29 (87.9)	232 (77.9)	
Gravida status				
1	30 (11.3)	5 (15.2)	35 (11.7)	0.519
>1	235 (88.7)	28 (84.8)	263 (88.3)	
Educational attainment				
Completed secondary education	80 (30.2)	8 (24.2)	88 (29.5)	0.480
Incomplete or less than secondary education	185 (69.8)	25 (75.8)	210 (70.5)	
Employment status				
Employed	81 (30.6)	9 (27.2)	90 (30.2)	0.698
Unemployed	184 (69.4)	24 (72.8)	208 (69.8)	

HIV disclosure to any non-healthcare professionals				
Undisclosed	10 (3.8)	1 (3.0)	11 (3.7)	0.831
Disclosed	255 (96.2)	32 (97.0)	287 (96.3)	
ART History Status				
Newly starting ART	38 (14.3)	7 (21.2)	45 (15.1)	**0.004**
ART-experienced without interruption	145 (54.7)	8 (24.2)	153 (51.3)	
ART-experienced with interruption	82 (31.0)	18 (54.6)	100 (33.6)	

NB: ANC, antenatal care; IQR, interquartile ranges; Results are n (column %) with P-value from chi-square test; median (interquartile range, IQR) with P-value from Wilcoxon rank-sum or Kruskal–Wallis tests. Only 298 women had a viral load at delivery. ***Bold*** *indicates statistically significant p-values.*

Table C2: Unadjusted and adjusted log binomial regression models predicting viral load above 1000 copies/mL among women with ART history at ANC presentation (n = 298)

Outcome 1: Viral Load Suppression	**Crude models**				**Adjusted model**			
Log Binomial Regression Model	**RR**	**95% CI (lower)**	**95% CI (upper)**	**P-value**	**aRR**	**95% CI (lower)**	**95% CI (upper)**	**P-value**
ART history status								
ART-experienced without interruption	1	Referent	Referent		1	Referent	Referent	
Newly starting ART	2.98	1.14	7.76	**0.026**	2.57	0.97	6.77	**0.056**
ART-experienced with interruption	3.44	1.56	7.61	**0.002**	3.39	1.54	7.48	**0.002**
Age category								
<=25 years	1	Referent	Referent		1	Referent	Referent	
>25 years	0.46	0.23	0.93	**0.030**	0.50	0.25	1.00	**0.050**
Relationship status								
Married	1	Referent	Referent					
Unmarried	1.38	0.56	3.43	0.242				
Pregnancy intention								
Planned pregnancy	1	Referent	Referent					
Unplanned pregnancy	2.06	0.75	5.66	0.397				
Gravida status								
1	1	Referent	Referent					
>1	1.34	0.55	3.25	0.257				
Educational attainment								
Completed secondary education	1	Referent	Referent					
Incomplete or less than secondary education	0.76	0.36	1.63	0.589				
Employment status								
Employed	1	Referent	Referent					
Unemployed	1.15	0.56	2.38	0.399				
HIV disclosure to any non-healthcare professionals								
Undisclosed	1	Referent	Referent					
Disclosed	1.23	0.18	8.18	0.795				

NB: RR, Risk Ratio(s) for univariate model(s); aRR, adjusted Risk Ratio(s) for multivariate model(s); CI, Confidence Interval(s). ***Bold*** *indicates statistically significant p-values.*
Only p<0.1 for univariable models (unadjusted) were forward selected in building the multivariable model (adjusted).

Table C3: Socio*demographic and clinical characteristics of 298 participants stratified by viral load suppression at delivery*

Characteristics	***Viral Load Suppression***			***Total***	***P-value***
	VL≤50 copies/ml	***VL>50 – ≤1000 copies/ml***	***VL>1000 copies/ml***		
Number of women	249 (83.6)	16 (5.4)	33 (11.0)	298 (100)	
Maternal characteristics at enrolment					
Median age, years	32.0 (28.1, 35.5)	32.1 (28.5, 39.6)	29.9 (24.2, 34.6)	32.3 (28.1, 35.9)	0.087
Age categories (years)					
<=25 years	32 (12.9)	3 (18.8)	9 (27.3)	44 (14.8)	0.081
>25 years	217 (87.1)	13 (81.2)	24 (72.7)	254 (85.2)	
Relationship status					
Married	52 (20.9)	2 (12.5)	5 (15.2)	59 (19.8)	0.557
Unmarried	197 (79.1)	14 (87.5)	28 (84.8)	239 (80.2)	
Pregnancy intention					
Planned pregnancy	57 (22.9)	5 (31.3)	4 (12.1)	66 (22.1)	0.250
Unplanned pregnancy	192 (77.1)	11 (68.7)	29 (87.9)	232 (77.9)	
Gravida status					
1	27 (10.8)	3 (18.8)	5 (15.2)	35 (11.7)	0.516
>1	222 (89.2)	13 (81.2)	28 (84.8)	263 (88.3)	
Educational attainment					
Completed secondary education	75 (30.1)	5 (31.3)	8 (24.2)	88 (29.5)	0.776
Incomplete or less than secondary education	174 (69.9)	11 (68.7)	25 (75.8)	210 (70.5)	
Employment status					
Employed	73 (29.3)	8 (50.0)	9 (27.3)	90 (30.2)	0.202
Unemployed	176 (70.7)	8 (50.0)	24 (72.7)	208 (69.8)	
HIV disclosure status to any non-healthcare professionals					
Undisclosed	8 (3.2)	2 (12.5)	1 (3.0)	11 (3.7)	0.158
Disclosed	241 (96.8)	14 (87.5)	32 (97.0)	286 (96.3)	

ART History Status					
Newly starting ART	36 (14.5)	2 (12.4)	7 (21.2)	45 (15.1)	
ART-experienced without interruption	138 (55.4)	7 (43.8)	8 (24.3)	153 (51.3)	
ART-experienced with interruption	75 (30.1)	7 (43.8)	18 (54.5)	100 (33.6)	**0.015**

NB: ANC, antenatal care; IQR, interquartile ranges; Results are n (column %) with P-value from chi-square test; median (interquartile range, IQR) with P-value from Wilcoxon rank-sum or Kruskal Wallis tests. ART History Status, missing information: Newly starting ART (4), Currently on ART (14), Previously ART experienced (5) and Total (25). ***Bold*** *indicates statistically significant p-values.*

Appendix G: Journal Submission Guidelines for JIAS

Sections

1. SUBMISSION

Please carefully read through the Instructions for Authors and prepare your manuscript according to the guidelines, including structuring it manuscript based on the chosen article category. Manuscripts that do not follow the instructions may be returned to the authors for corrections.

Authors should kindly note that submission implies that the content has not been published or submitted for publication elsewhere except as a brief abstract in the proceedings of a scientific meeting or symposium.

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The *JIAS* welcomes submissions on HIV-related topics from across all scientific disciplines, including but not limited to:

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• Behavioural sciences
• Epidemiology
• Clinical sciences
• Health economics and health policy

• Operations research and implementation sciences
• Social sciences and humanities, including political sciences and media

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The *JIAS* accepts submissions in the following categories:

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• Short report
• Review
• Debate
• Commentary
• Letter to the Editor
• Viewpoint
• Field notes

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Abstract:
Headings: Introduction, Methods, Results, Conclusions
Word limit: 350 words

Main text:
Headings: Introduction, Methods, Results, Discussion, Conclusions
Word limit (quantitative): 3500 words; Tables do not contribute to the word count
Word limit (qualitative and mixed methods): 5000 words; tables with quotes contribute to the word count
Numbers of figures and tables: Unlimited
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Field Notes – focused articles providing timely insights regarding contemporary challenges in HIV public health practice. This includes observations about the mechanisms of change, contextual influences, and findings that emerge from implementation of evidence-based interventions and programmes. Field Notes can inform others, spread best practices and promote innovative ideas.

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