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Factors Associated with ART Initiation among Eligible HIV Positive Pregnant Women in Swaziland

By

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DECLARATION

I, Dr Caspian Chouraya, hereby declare that the dissertation which I hereby submit for the degree Master of Science in Epidemiology at the University of Pretoria is my own work and has not previously been submitted by me for a degree at another university. All the sources that have been used or quoted have been indicated and acknowledged by means of complete references.

Dr Caspian Chouraya

Date

DEDICATION

I would to dedicate this thesis to my family which has been a huge pillar of support throughout my studies. To my beautiful wife Caroline and my lovely children, Takudzwa and Tinotenda, this thesis is dedicated to you for being the best people for me in the world.

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ABBREVIATIONS

95% CI	Ninety-five percent confidence interval
AAC	Academic Advisory Committee
AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal Care
aOR	Adjusted Odds Ratio
ART	Antiretroviral Therapy
ARVs	Antiretroviral drugs
AZT	Zidovudine
CD4	Cluster of Differentiation 4
CI	Confidence Interval
EID	Early Infant Diagnosis
HCW	Health Care Worker
HIV	Human Immunodeficiency Virus
HTC	HIV testing and counselling
IATT	Inter-Agency Task Team
MCD	Minimal Clinical Difference
MTCT	Mother-To-Child Transmission of HIV
OR	Odds Ratio
PHU	Public Health Unit
PMTCT	Prevention of Mother-To-Child Transmission of HIV
PNC	Postnatal Care
SEC	Swaziland Ethics Committee
SEM	Socio-Economic Model
STI	Sexually Transmitted Infections
SZL	Swaziland Lilangeni
TB	Tuberculosis
UNAIDS	Joint United Nations Program on HIV/AIDS
WHO	World Health Organization

ABSTRACT

Background: More than 90% of children with human immunodeficiency virus (HIV) infection become infected through vertical transmission; therefore prevention of mother to child transmission (PMTCT) of HIV is a critical intervention. Without intervention, approximately 30-45% of children born to HIV positive women get infected. Antiretroviral therapy (ART) for eligible women is one of the pillars for PMTCT. However, in Swaziland not all eligible women are receiving ART.

Objectives: The objectives of this study were to determine the ART initiation proportion among eligible pregnant women in Swaziland; and to determine factors (intrapersonal, interpersonal, and organizational) associated with ART initiation among eligible pregnant women in Swaziland.

Setting: The study was conducted in the postnatal wards in all 11 public hospitals and health centres in Swaziland

Study design and method: An analytic cross sectional survey was performed through the administration of a questionnaire to, and review of antenatal care cards of women who had just delivered in the maternity wards in Swaziland. Patients were selected consecutively until the sample size was reached. Variables collected included intrapersonal factors (e.g. age, parity, level of education), interpersonal factors (e.g. HIV disclosure status, partner support) and organizational factors (e.g. nurses' attitudes, distance to clinic).

Main outcome measures: The main outcome of the study was ART initiation by time of delivery.

Results: Among the 163 pregnant women who were eligible for ART, 110 (67.5%) were initiated on ART by the time of delivery. The most common cited reasons for not initiating ART (n=53) were: not being ready for ART (24.5%), delay by clinic procedures (17%); partner or family refusal for woman to start ART (13.2%), limited ANC visits such that

woman delivered before ART initiation (13.2%) and women not offered ART (13.2%). On univariate analysis; favourable perceptions of the benefits of ART (OR: 3.49; p<0.001), favourable perceptions of the need for ART (OR: 1.94; p=0.011), favourable perceptions of access to the clinic (OR: 1.68; p=0.032) and favourable perceptions of health care workers' attitudes (OR: 3.21; p=0.007) were significantly associated with ART initiation. Lower negative perceptions of the harms of/difficulties with ARVs (OR: 2.14; p=0.002) and being less afraid of stigma and discrimination (OR: 1.70; p=0.011) were also associated with ART initiation. Additionally, disclosing HIV status (OR: 8.29; p=0.002) and presence of partner support for ART (OR: 7.66; p<0.001) were also significantly associated with ART initiation. On multivariate logistic regression, only favourable perceptions on benefits of ART (aOR: 3.04; p=0.007) and presence of partner support (aOR: 4.75; p<0.001) were significantly associated with ART initiation.

Conclusions: ART initiation is very important for HIV positive women both for their own health and for prevention HIV transmission to their children. This study found that ART initiation among eligible pregnant women in Swaziland was statistically associated with the presence of partner support and favourable perceptions of benefits of ART after multiple logistic regression analysis. Stronger counselling and education for pregnant women and male involvement strategies need to be implemented as momentum gathers towards elimination of paediatric HIV by 2015.

Key Words: ART initiation, pregnant women, prevention of mother to child transmission of HIV (PMTCT)

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1. LITERATURE OVERVIEW AND MOTIVATION

1.1. Mother to child transmission of human immunodeficiency virus

Mother to child transmission (MTCT) of HIV is the transmission of the human immunodeficiency virus (HIV) from HIV positive pregnant and lactating women to their children. This transmission can occur during pregnancy, labour and delivery or during breastfeeding. MTCT is the most common source of HIV infection in children under the age of 15 accounting for more than 90% of all paediatric HIV infections.[1] Without intervention, approximately 30-45% of children born to HIV positive women become infected. The chances of MTCT are highest during labour and delivery (15 – 20%) followed by during breastfeeding (10 – 15%), then during pregnancy (5 – 10%).[2]

Maternal viral load is the most important predictor of MTCT.[3,4] For this reason, suppression of the maternal viral load and improvement of the maternal immune status are very critical for prevention of mother-to-child transmission of HIV and for reducing morbidity and mortality in women. Several studies[5-9] have identified other factors that increase MTCT rates: these factors are summarized in table 1 below.

Mother to child transmission of HIV has severe consequences to the children as HIV progresses rapidly in young children. Studies have shown that without treatment, 35% of children with HIV die by one year of age, 52% by two years, 75% by five years and 85% by ten years.[10] It is against this background that mother-to-child transmission of HIV should be prevented at all costs.

Table 1: Risk Factors of mother to child transmission during pregnancy, labour and delivery, and breastfeeding (Adapted from Bulletin of World Health Organization[11])

Pregnancy	Labour and Delivery	Breastfeeding
• New HIV infections during pregnancy • High maternal viral load • Low maternal CD4 count • Malaria infection • Sexually transmitted infections (STIs), viral or bacterial infections • Maternal malnutrition • Anaemia • Chorioamnionitis (from untreated STI or other infections) • Maternal Tuberculosis (TB)	• High maternal viral load (especially with recent HIV infection) • Low maternal CD4 count • Rupture of membranes more than four hours before delivery • Invasive delivery procedures (e.g., episiotomy, artificial rupture of membranes, amniocentesis, vacuum or forceps) • Chorioamnionitis (from untreated STI, other infection or due to ascending infection following prolonged rupture of membranes) • Premature delivery • Low birth weight • Breaks in skin or mucous membranes of the baby	• New maternal HIV infection • High maternal viral load • Low maternal CD4 count • Duration of breastfeeding • Mixed feeding (e.g., food or fluids in addition to breast milk) • Breast abscesses, nipple fissures, mastitis • Poor maternal nutritional status • Oral disease in the baby (e.g., thrush or sores)

1.2. Prevention of mother to child transmission of HIV

The prevention of mother to child transmission of HIV (PMTCT) program is one of the few HIV prevention strategies that have been shown to be effective if properly implemented. MTCT rates can be reduced to very low levels with effective programming and use of antiretroviral drugs. In the United States of America, for example, MTCT rates have been reduced to less than 2%.[12] PMTCT is programmatically implemented using a four pronged approach.[13] The first prong focuses on prevention of HIV infection among women of reproductive age; the second prong deals with prevention of unintended pregnancies among child bearing women who are HIV positive; the third prong is the use of antiretroviral drugs (ARVs) to prevent HIV transmission from HIV positive pregnant and lactating women to their children; and the fourth prong is the provision of care and treatment services to HIV positive women and their families. The third prong has been the

major focus of research on how to prevent MTCT in HIV positive women who are already pregnant or are lactating. Several studies have been done to determine the most effective antiretroviral regimen for PMTCT purposes. The regimens have evolved over time, starting with the use of single dose of nevirapine to the use of multiple antiretroviral drug combinations.

The 2010 WHO guidelines[14] presented countries with two options for regimens to use for HIV positive women for PMTCT: The first option (popularly known as Option A) uses triple antiretroviral therapy (ART) only for women who are eligible based on CD4 count and/or World Health Organization (WHO) clinical stage (eligible women have a CD4 count less than 350cells/mm3 or WHO clinical stage 3 and 4. Pregnant women not eligible for ART under option A are given a dual combination of Zidovudine (AZT) from 14 weeks of pregnancy and a single dose of Nevirapine is given at the beginning of labour. The single dose of Nevirapine is then "tailed" off with a seven day regimen of Zidovudine and Lamivudine to prevent Nevirapine resistance. Under option A, children receive daily Nevirapine until 6 weeks of age. Only those children who are on replacement feeding or whose mothers are on triple ART stop the Nevirapine at 6 weeks. Breastfeeding children continue the Nevirapine and only stop one week after cessation of breastfeeding. The second option (Option B) uses triple ART for all HIV positive pregnant women regardless of CD4 count level or WHO clinical stage. Under this option, children also receive daily Nevirapine until 6 weeks and then stop even if they are breastfeeding. Both options have equal efficacy provided that all women who are eligible for triple ART are initiated under Option A.[15]

In 2013, WHO released new guidance on use of ARVs for PMTCT purposes.[16] In these guidelines, WHO now recommend triple ART for all HIV positive women regardless of CD4 count and clinical stage. The women can stop the ARVs after breastfeeding (option B) or continue for life (Option B plus). It should be noted that this study was conducted and report compiled at a time when Swaziland was still implementing Option A.

1.3. Role of antiretroviral therapy in PMTCT

Antiretroviral drugs play a major role in reduction of mother-to-child transmission of HIV. According to the Joint United Nations Program on HIV/AIDS (UNAIDS)[17], mother-to-child

transmission rates range from 1% to 16% depending on ARVs given to the woman and also to the infants feeding option (see table 2 below).

Table 2: Rates of mother-to-child transmission and the impact of different PMTCT regimens.[17])

ARV Regimen	MTCT rate with breastfeeding	MTCT rate with replacement feeding
Single dose nevirapine	16%	10%
Zidovudine plus single dose nevirapine	10%	2%
Triple ART	1%	<1%

Since 2009, most countries have shifted their policies away from the use of single-dose nevirapine to more effective regimens for PMTCT; however, access to PMTCT ARVs is still low.[18]

Pregnant women with advanced HIV disease, defined as a CD4 count less than 350cells/mm^3 or a WHO clinical stage of 3 or 4[19], benefit from life-long triple ART as compared to short courses of ARV prophylaxis. ART initiated for these women is both for their own health and also for PMTCT purposes. Antiretroviral therapy reduces MTCT through two ways: by reducing the plasma viral load in the pregnant women and/or through post-exposure prophylaxis in the newborn.[20] MTCT rates remain high for women who are eligible for ART but are not initiated on ART or are initiated on an inferior regimen. In a Cote d'Ivoire study[21], MTCT proportions were 2.3% in women eligible for ART, and who received it, while the proportions were 16.1% in women who were eligible for ART but received an inferior regimen. If women eligible for ART receive nothing at all, MTCT proportions can be as high as 0.45 (45%).[2] It is therefore imperative that women eligible for ART get initiated on ART to reduce MTCT transmission.

1.4. Prevention of mother-to-child transmission of HIV program in Swaziland

Approximately 35,000 deliveries are registered every year in Swaziland.[22] 95% of pregnant women attend ANC at least once while 74% deliver at a health facility.[23] Swaziland has the world's highest HIV prevalence among pregnant women of 41.1%[24], which means that over

13,000 HIV-exposed infants are delivered annually.

Five types of health facilities exist in Swaziland: National Referral Hospitals, Regional Hospitals, Health Centres, Public Health Units (PHUs) and primary health clinics. Most of the deliveries in Swaziland occur in the eleven maternity units based in the health centres (five in total) and hospitals (six in total).[25] ART services in Swaziland are mainly provided at the referral hospitals, regional hospitals, health centres, PHUs and some primary care clinics.[25]

Swaziland has made good progress in implementation of PMTCT services: 88% of facilities that provide ANC services also provide PMTCT services[25]; 73% of women attending ANC were tested for HIV, and received results, in 2009; and 88% of all HIV infected pregnant women in Swaziland received a complete course of PMTCT prophylaxis in 2009.[26] In 2012, close to 9% of all women coming for ANC were already on triple ART prior to current pregnancy.[27] This is good as MTCT rates in these women are usually very low compared to those initiating ART during pregnancy,[28] however, this might also be a sign of weak prong two activities (prevention of unintended pregnancies).

In 2009, Swaziland chose Option A under the new WHO PMTCT Guidelines. Despite the great efforts mentioned above, data review using the Early Infant Diagnosis (EID) database in Swaziland has shown that only approximately 50% of eligible women do initiate ART.[29] If Swaziland is to achieve its goal of eliminating paediatric HIV by 2015, initiation of treatment for women eligible for ART is very important. This study therefore tries to determine the rate of initiation of ART among eligible women and also determine the factors that are associated with ART initiation and non-initiation. Understanding of these factors will result in designing of programs in Swaziland to improve ART uptake.

1.5. ART initiation among eligible pregnant women

Studies and experiences in different countries have shown that ART uptake in pregnant women is lower than in non-pregnant populations. In Zambia[30], a stepped-wedged evaluation study was done to evaluate whether providing antiretroviral therapy (ART) integrated in antenatal care (ANC) clinics resulted in a greater proportion of treatment-eligible women initiating ART during pregnancy compared with the existing approach of

referral to ART treatment centres. The study results showed that 32.9% of eligible pregnant women initiated ART in the integrated sites compared to 14.4% in the non-integrated sites. Though ART uptake was better in the integrated sites, it was still very low. In a routine services data review in South Africa[31], only 51% of eligible pregnant women successfully initiated ART before delivery. These two studies reflect that ART uptake among eligible pregnant women is low as has been noticed in Swaziland.

Several factors have been found to impede ART initiation in individuals eligible for ART. In one observational longitudinal study done in Kenya, pregnancy was identified as one of the risk factors for ART non-initiation.[32] A qualitative study in Botswana[33] identified fear of knowing one's own HIV status, lack of male partners' support and negative attitudes of health workers as barriers to PMTCT services' access by pregnant women. In South Africa, presenting late in pregnancy, advanced HIV disease, lack of finances, and fear of stigma and discrimination have been identified as some of the factors that affect ART access and uptake.[34,35,36] In an observational longitudinal study analysed by logistic and cox regression models in Kenya; lower level of education, higher age and advanced AIDS disease were associated with ART non initiation.[32] A qualitative study in Uganda found that stigma, non-disclosure of HIV status, long waiting times at the clinic and sub-optimal provider-patient interactions were significant barriers to ART uptake by pregnant women.[37] A cross sectional survey done in Zimbabwe found out that women enrolled in a support group were more likely to access care and treatment; women living with a male partner were less likely to access care and treatment and long queues and inadequate referral information were barriers to accessing care and treatment.[38]

Most of the studies done were qualitative and few studies have been done to quantify these factors as barriers or facilitators so that PMTCT programs can be appropriately designed to address the most common barriers to uptake of ART. Additionally, no study has been done to determine and quantify these factors in Swaziland.

1.6. Theoretical framework for ART Initiation

This research will use the socio-ecological model (SEM) to study the factors associated with ART initiation among eligible pregnant women. The model outlines multiple levels of influence for actions of individuals which include intrapersonal, interpersonal,

organizational, community and policy levels.[39,40] In this research, three of these levels will be studied i.e. intrapersonal, interpersonal and organizational. The intrapersonal level will be further divided into socio-demographic factors (age, parity, level of education, employment status), disease factors (CD4 count, clinical stage) and perceptions towards ARVs (fear of side effects, fear of stigmatization, lack of understanding on need for ARVs). The interpersonal level will include issues of disclosure, support from partner, religion etc. The organizational level will include attitudes of health workers, availability of ART on site, and distance to clinic. Figure 1 below summarizes this model in the context of this research.

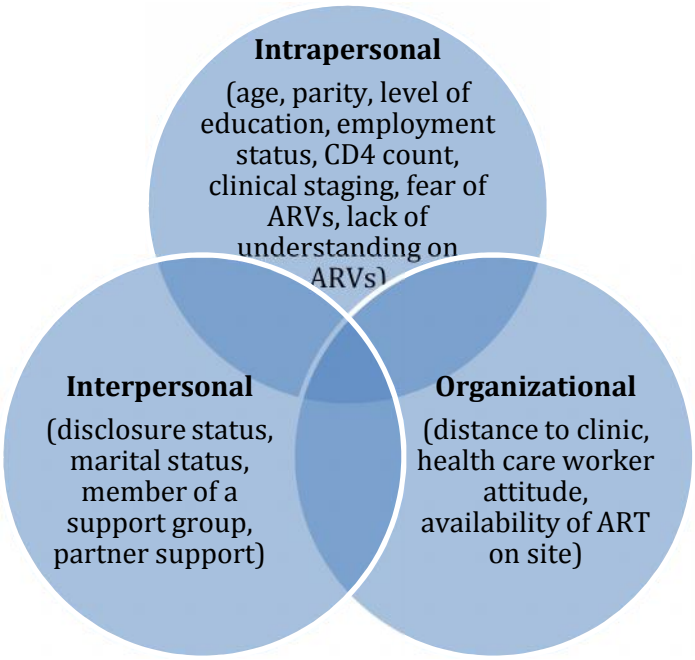

Figure 1: Socio-ecologic model for barriers to ART Initiation

1.7. Rationale for this study given the literature review

Without any intervention, over 6000 children in Swaziland will be HIV-infected annually. HIV has detrimental effects on the children infected. However, MTCT can be prevented to a great extent through successful implementation of PMTCT interventions. One such intervention is ensuring that all pregnant women who are eligible for ART are initiated onto treatment. It is therefore important to determine the proportion of eligible women

who experience ART initiation; and also to determine and quantify the factors that are associated with ART initiation as this will help design interventions to increase uptake of ART among eligible pregnant women. Currently the level of ART initiation by pregnant women in Swaziland is not established. Factors associated with ART initiation among the pregnant women in Swaziland are also not known.

2. AIM AND OBJECTIVES

2.1. Aim:

The aim of this study was to determine the facilitating factors and barriers associated with ART initiation among eligible HIV positive women during pregnancy among women who deliver in public hospitals and health centres in Swaziland

2.2. Objectives:

The objectives of this study were:

- To determine the ART initiation proportion among eligible pregnant women in Swaziland
- To determine factors (intrapersonal, interpersonal, organizational) associated with ART initiation among eligible pregnant women in Swaziland

2.3. Hypothesis

- Null hypothesis: ART initiation among eligible pregnant women in Swaziland is not affected by intrapersonal, interpersonal and organizational factors
- Alternative hypothesis: ART initiation among eligible pregnant women in Swaziland is increased or reduced by intrapersonal, interpersonal and organizational factors

3. METHODS

3.1. Study design

An analytic cross sectional study was performed through administration of a pre-tested questionnaire to, and review of antenatal care cards of women soon after delivery in maternity wards in Swaziland.

3.2. Setting

Interviews were conducted in the postnatal wards in all 11 public hospitals and health Centres in Swaziland. Women who have delivered usually stay 1-3 days (depending on mode of delivery) in the post-natal wards before being discharged.

3.3. Client selection

Clients were selected consecutively according to the criterion below from March to August 2013.

3.3.1. Inclusion criteria

The inclusion criteria for the study were:

- Women in the postnatal wards in public hospitals and health centres in Swaziland
- The woman should be HIV positive and eligible for ART i.e. CD4 < 350cells/mm3 or WHO Clinical stage 3 or 4 as documented in the patient ANC card
- The women should have attended at least one ANC visit

3.3.2. Exclusion criteria:

The exclusion criteria for the study were:

- Women with no ANC card available
- Women who never attended ANC
- Women who became pregnant while already on ART
- Women not eligible for ART as described above

All clients excluded from the study were noted and reasons for exclusion were tracked.

3.3.3. Sample size

The initial Sample size calculation was carried out using Stata version 11 based on the following:

- α was set at 0.05; β was set at 0.20 (power of the study was set at 80%)
- Minimal Clinical Difference (MCD) was set at 15%
- ART initiation among eligible pregnant women was assumed to be 50%

The sample size for the study was calculated to be 380.

3.4. Measurements

The variables were collected using an interviewer-administered structured questionnaire and record review of clinical information from the ANC records. The interviews were conducted by trained midwives in a private room within the postnatal ward in the hospitals and health centres. The interviews were conducted approximately two hours after delivery for women with a normal vaginal delivery and on the day of discharge for women delivering through caesarean section. The variables collected were:

- Intrapersonal
- Interpersonal
- Organizational

3.4.1. Intrapersonal variables

Intrapersonal variables collected included: socio-demographic factors (age, parity, level of education, employment status); disease factors (CD4 count, clinical staging); and perceptions towards ART (fear that ARV might hurt baby, lack of understanding of need for ART, fear of side effects from ART, and fear to commit to taking ART for life). Age, parity, place of residence and all disease factors were collected from the clients' ANC cards while level of education, employment status, religion and perceptions towards ART were collected through client interviews.

3.4.2. Interpersonal variables

Interpersonal variables collected were marital status, HIV disclosure status, partner support, and being a member of support group. All this information was collected through client interviews.

3.4.3. Organizational variables

Organizational factors collected during the study were distance to clinic, bus fare to clinic, health care workers' attitude, lack of proper counselling from health care worker, and easy access to ARVs (ART initiated on site, no stock out of ARVs). All this information was collected through interview with clients.

3.5. Data collection and management

3.5.1. Data collection:

Data collection was done by midwives working at the identified maternity units. These midwives were trained on the data collection for a day through didactic and practical sessions. After the training, a pilot study was done to determine problems with the design of the questionnaire and record review tool and also assess ability of the midwives to collect the data. Identified weak areas for the midwives in data collection were corrected after the pilot. The midwives also received ongoing supportive supervision on data collection through the Regional PMTCT Program Coordinators who had received training on the study from the principal investigator.

3.5.2. Data management

Data were entered using EpiData 3.1 software by the principal investigator. Double data entry was done to minimize errors. The data were exported to Stata version 11 for analysis. The data were kept in a computer with a password and could only be accessed by the principal investigator and supervisors. The database was managed and supervised by the principal investigator.

3.5.3. Construct variables

Ary[41] defines construct variables as "highest highest-level abstractions" of complicated objects and events, created by combining concepts and less complex constructs which are used to account for observed regularities and relationships, and to summarize observations and explanations. In this study, three groups of construct variables were used: client's perceptions on ARVs, client's perceptions towards access to the health facility and perceptions of clients on health care workers' attitudes.

Perceptions towards ARVs

This was adapted from a study done in Zambia on barriers to ART initiation[42]. It was divided into four sections (perceptions of benefits of ART, perceptions of harms of/difficulties with ARVs, perceptions of the need for ART, and perceived stigma and discrimination towards people taking ARVs). Each section had 4-5 statements where clients had to rate the degree to which they agreed with each statement. The rating was done using a Likert scale i.e. strongly agree, agree, uncertain, disagree and strongly disagree. "Strongly agree" was scored "5" in a statement that was expected to be positive and "1" in a statement expected to be negative. For example, clients who strongly agreed with the statement that said "ART makes one feel better/stop being sick" *(see question 17 in annex 9)* would be scored "5" while those who strongly disagreed would be scored "1". Similarly, clients who strongly agreed with the statement saying "if a person starts ART, people will not like him/her" *(see question 31 in annex 9)* would be scored "1" while those who strongly disagreed were scored "5". The maximum score for each statement was "5" representing excellent perception. Average scores for each of the four sections were then used as predictors of ART initiation.

Perceptions towards access to health facility

This section initially had nine statements assessing perceptions of the clients towards accessing the health facility. The first four statements were assessing access to the ANC facility and the last five assessed access to the ART clinic. However, only the first four statements were used for analysis as almost all clients received ART at the same ANC facility. The rating was done using Likert scale i.e. strongly agree, agree, uncertain, disagree and strongly disagree. All the four statements were in the negative therefore clients who strongly agreed were scored "1" and those who strongly disagreed were scored "5". The maximum score for each statement was "5" representing excellent perception. The average score from all four statements were then used as predictors of ART initiation.

Perceptions on health care workers' attitudes

Perceptions on health care workers' attitudes were assessed using fourteen statements adapted from a study conducted in South Africa by the Medical Research Council Unit for Maternal and Infant Health Care Strategies.[43] The rating was done using Likert scale i.e. always, most times, sometimes, never and no experience.

"Always" scored "4" in a statement that was expected to be positive and "1" in a statement expected to be negative. For example, clients who indicated that health care workers always listened to them *(see question 59 in annex 9)* would be scored "4" while those who indicated nurses never listened to them were scored "1" and those who had no experience were scored "0". Similarly, clients who indicated that health care workers always made them wait too long *(see question 69 in annex 9)* would be scored "1" while those who said "never" scored "4". The maximum score for each statement was "4" representing excellent perceptions towards the health care workers' attitudes. The average score from all fourteen statements were then used as predictors of ART initiation.

3.6. Statistical analysis

3.6.1. Descriptive statistics

All variables (intrapersonal, interpersonal and organizational) were described using percentages and proportions for categorical data and mean, medians, standard deviation, ranges and inter-quartile ranges for continuous data (depending on the distribution of the data). The proportion of eligible women initiating ART was also computed.

3.6.2. Analytic statistics

The outcome of the study was ART initiation by the time of delivery which is a binary variable. Logistic regression models were used to calculate crude (univariate) and adjusted (multivariate) measures of association between the outcome and the independent variables (intrapersonal, interpersonal and organizational variables- see section 3.4 above) which were measured as odds ratios with p-values and 95% confidence intervals. These determined the strength of association of these independent variables as predictors of ART initiation among the eligible pregnant women. The Cronbach's alpha statistic was calculated for each construct variable (variables that consisted of scores derived from

responses to a number of questionnaire items). Scores were used as predictor variables if their Cronbach alpha statistics were 0.70 or higher. Potential predictor variables were included in the model if there was information from other studies that the variable was associated with ART initiation and also if the p-value was less than or equal to 0.20 in univariate analysis. A Box-Tidwell test was done to check for linearity between the *logit* and all quantitative variables before inclusion in the regression model. Variables were left as quantitative and not categorized if the Box-Tidwell test showed a linear relationship between the *logit* and the quantitative variable ($p>0.05$).[44]

According to Vittinghoff[45], regression models can be used for 3 different purposes: predictive models; evaluate a predictor of primary interest; or to identify the most important predictors of an outcome. In this study, the model was used for the latter i.e. to identify predictors of ART initiation among eligible pregnant women in Swaziland. Manual backwards stepwise logistic regression using Stata version 11 was done on the full model developed. Post regression analysis was done using the Pearson's and Hosmer-Lemeshow goodness of fit tests, area under the ROC curve and M-asymptotic residuals analysis.

3.6.3. Description of variables considered for logistic regression

Table 3 below shows variables that were considered for the regression model and how they were handled:

Table 3: Description of variables considered for model

Variable	Description
Age	This was left as a quantitative variable after the Box-Tidwell test showed a linear relationship between age and the logit *(see annex 3)*
Parity	This was re-coded into a binary variable i.e. non-multiparous women (parity of 0 or 1) vs. multiparous (parity of 2 and above)
Level of education	This was re-coded into a binary variable i.e. primary education and below vs. some secondary education and above
Employment status	This was re-coded into a binary variable i.e. employed vs. non-employed
Religion	This was coded into a binary variable i.e. Zionists and traditionalists vs. other religions. Zionists and traditionalists in Swaziland generally do not believe in western medicines[46]
Baseline CD4 count	This was left as a quantitative variable after the Box-Tidwell test showed a linear relationship between age and the logit *(see annex 3)*
Gestational age at HIV diagnosis	This was left as a quantitative variable after the Box-Tidwell test showed a linear relationship between age and the logit *(see annex 3)*
WHO Clinical stage	This was re-coded into a binary variable i.e. asymptomatic (stage I) vs. symptomatic (stage II-IV)
Perceptions on benefits for ART	Average scores from the set of construct variables were used as quantitative discreet variables
Perceptions on harms of/difficulties with ARVs	Average scores from the set of construct variables were used as quantitative discreet variables
Perceptions on the need for ART	Average scores from the set of construct variables were used as quantitative discreet variables
Fear of stigma and discrimination	Average scores from the set of construct variables were used as quantitative discreet variables
HIV disclosure status	This was left as a binary categorical variable i.e. disclosed vs. not disclosed
Member of a support group	This was left as a binary categorical variable i.e. member vs. non member
Religion supports ARVs	This was left as a binary categorical variable i.e. religion supports ARVs vs. religion does not support ARVs
Knowledge of partner status	This was left as a binary categorical variable i.e. woman knows HIV status of her partner vs. woman does not know HIV status of partner
Partner support for ART	This was left as a binary categorical variable i.e. partner supports ARVs vs. partner does not support ARVs
Perceptions towards access to clinic	Average scores from the set of construct variables were used as quantitative discreet variables
Health care worker attitudes	Average scores from the set of construct variables were used as quantitative discreet variables

4. ETHICAL CONSIDERATIONS

All patients were asked to provide informed consent as a pre-requisite for inclusion into the study. This study was approved by the University of Pretoria Ethics Committee *(see annex 2)* and by the Swaziland Scientific and Ethics Committee *(see annex 1)*. The confidentiality of all participants enrolled in this study was maintained. Study participants were not identified by name on any form or on any other documentation sent from the study site to the Research Office. All study records were kept in a locked file cabinet accessible to the principal investigator. All computer entry and networking programs identified participants with coded identification numbers only. Participants were not and will not be reported by name in any report or publication resulting from data collected in this study. The data capture forms have been sealed in a labelled and dated box and are stored in the strong room of the School of Health Systems and Public Health; where they will be kept for 10 years.

5. STUDY RESULTS

The sample size could not be reached due to fewer eligible women being identified at the maternity units than anticipated. A total of 163 women were enrolled into the study.

5.1. Clients enrolled into study

Figure 2 is a flow chart summarizing how clients were enrolled into the study.

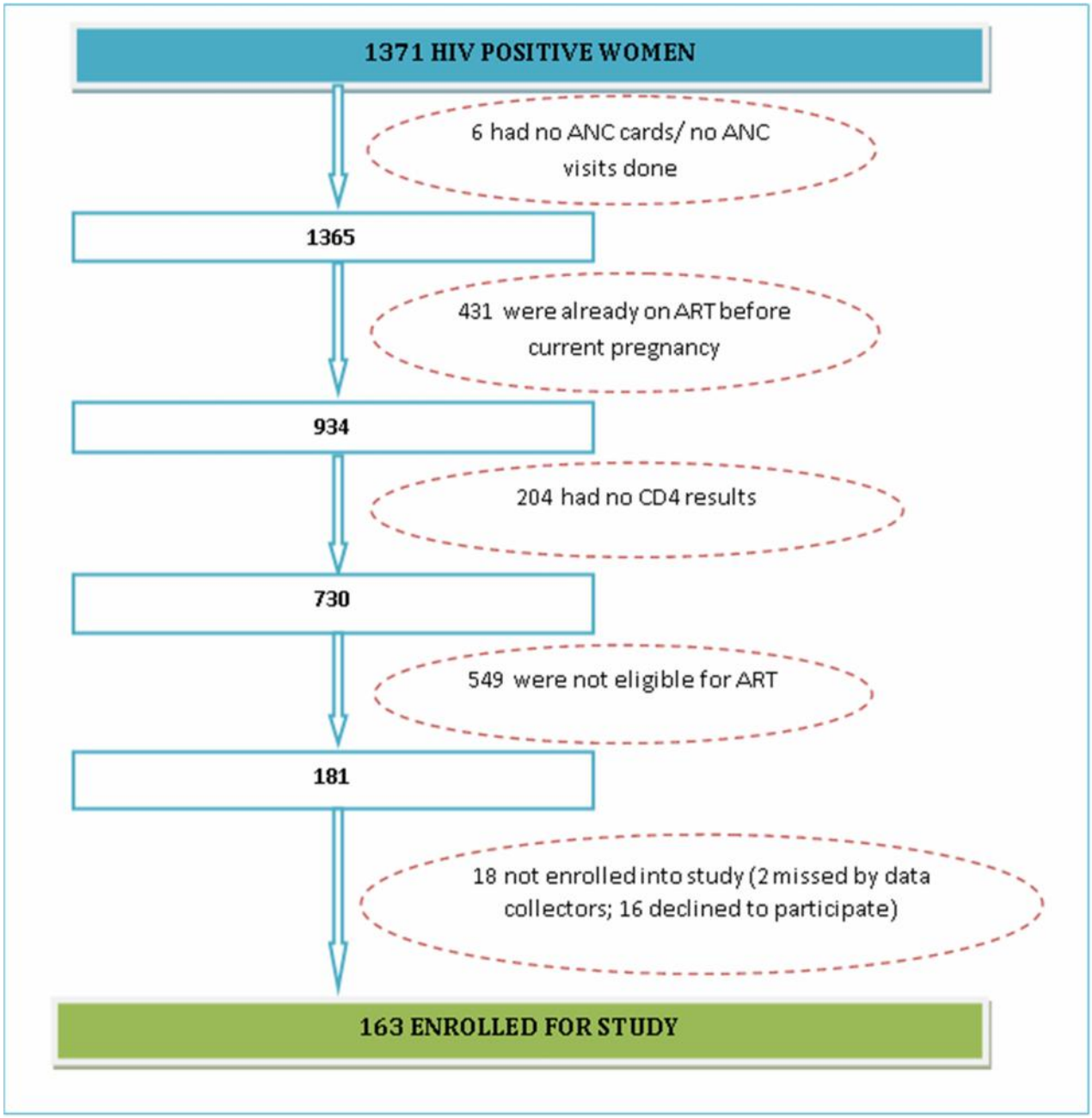

Figure 2: Flow chart for patients enrolled into study

Of the 1371 HIV positive pregnant women delivering at the study sites: 6 had no ANC cards, 431 were already on ART before current pregnancy, 549 were not eligible for ART, 204 had no documented CD4 count results, and 18 could not be enrolled for various reasons. 163 women were therefore enrolled into the study.

5.2. ART initiation

Among the 163 pregnant women who were eligible for ART, 110 (67.5%) were initiated on ART by the time of delivery.

5.3. Descriptive Statistics

5.3.1. Intrapersonal factors

5.3.1.1. Socio-demographic Characteristics

One hundred and sixty three women were enrolled into the study. The median age for the women enrolled was 26 years. The women who did not initiate ART were slightly younger (median age of 25 years) than those who initiated ART (median age of 26 years). Only 4.9% of the women never went to school. The majority of the women, 71.2%, were not employed. A higher proportion of women who initiated ART were unemployed as compared to the women who did not initiate ART.

The median parity for the women was 2 and this was not different between women who initiated ART and those who did not initiate. The most common religion among the women was protestant followed by Zionists. Table 4 summarizes the demographics of the sample.

5.3.1.2. Clinical Characteristics

The median baseline CD4 count for the women under study was 248cells/mm^3 and was slightly higher in women who initiated ART compared to those who did not. Twenty-three percent of the women were already known HIV positive at time of getting pregnant. Excluding women who were already known HIV positive at time of getting pregnant, the median gestational age at HIV diagnosis was 19 weeks and women who did not initiate ART were diagnosed with HIV later in pregnancy compared to women who initiated. More than 90% of the women were either WHO stage I or II. The majority of clients, 88%, were seen at ANC health facilities where ART services were available. There was no difference in ART initiation between women at ANC facilities with ART services (144) and those without with

no ART services (p=0.346). Table 5 shows the clinical characteristics of the sample.

Table 4: Demographic characteristics of the women

Characteristic	**Total** (N=163)		**ART initiated** (N=110)		**ART not initiated** (N=53)	
	n (%)	Median (IQR)	n (%)	Median (IQR)	n (%)	Median (IQR)
Age (yrs.)		26 (23-30)		26 (23-31)		25 (22-29)
Level of education						
Some primary	43 (26.4)		28 (25.5)		15 (28.3)	
Completed primary	10 (6.1)		7 (6.4)		3 (5.7)	
Some secondary	46 (28.2)		32 (29.1)		14 (26.4)	
Completed secondary	52 (31.9)		34 (30.9)		18 (39)	
Tertiary	4 (2.5)		2 (1.8)		2 (3.8)	
Never went to school	8 (4.9)		7 (6.4)		1 (1.9)	
Employment status						
Professional	4 (2.5)		3 (2.7)		1 (1.9)	
Semi-skilled	35 (21.5)		21 (19.1)		14 (26.4)	
Self-employed	8 (5)		4 (3.6)		4 (7.6)	
Not employed	116 (71.2)		82 (74.5)		34 (64.2)	
Parity		2 (1-3)		2 (1-3)		2 (1-3)
Religion						
Catholic	5 (3.1)		2 (1.8)		3 (5.8)	
Muslim	0 (0)		0 (0)		0 (0)	
Traditionalist	3 (1.9)		3 (2.8)		0(0)	
Pentecostal	34 (21.1)		21 (19.3)		13 (25)	
Protestant	67 (41.6)		48 (44)		19 (36.5)	
Seventh Day Adventist	2 (1.2)		1 (0.9)		1 (1.9)	
Zionist	41 (25.5)		27 (24.8)		14 (26.9)	
None	6 (3.7)		5 (4.6)		1 (1.9)	
Other	3 (1.9)		2 (1.8)		1 (1.9)	

5.3.1.3. Perceptions towards ARVs

Perceptions towards ART varied slightly between those initiated on ART and those not initiated. Women who did not initiate ART had a slightly less favourable perception (3.8) on benefits of ART compared to those who initiated ART (4.2). Perceptions of the harms of or difficulties with ARVs were also slightly better on women initiated on ART compared to those not initiated (4.0 versus 3.6). Those who initiated ART had a slightly better

perception towards the need for ART (4.5) than those who did not initiate. There was no difference in perceptions towards stigma and discrimination among the two groups of women as shown in table 6.

Table 5: Clinical characteristics of the women

Characteristic	**Total**		**ART initiated**		**ART not initiated**	
	n/N (%)	Median (IQR)	n/N (%)	Median (IQR)	n/N (%)	Median (IQR)
CD4 count (N=163**)**		248 (190-300)		247 (179-300.5)		254 (199-300)
Known Positive at Entry n/N (%)	38/161 (23.6)			25/108 (23.1)		13/53 (24.5)
Gestational age at HIV diagnosis (N=163)		19 (7-23)		19 (7.5-22)		21 (7-24)
WHO Clinical Stage n/N (%)						
I	117/163 (71.8)		81/110 (73.6)		36/53 (67.9)	
II	35/163 (21.5)		23/110 (20.9)		12/53 (22.6)	
III	10/163 (6.1)		5/110 (4.5)		5/53 (9.4)	
IV	1/163 (0.6)		1/110 (0.9)		0/53 (0)	
Client referred for ART n/N (%)						
Yes	15/163 (9.2)		11/110 (10)		4/53 (7.5)	
No	4/163 (2.5)		0/110 (0)		4/53 (7.5)	
HAART available at site	144/163 (88.3)		99/110 (90)		45/53 (84.9)	

5.3.2. Inter-personal Factors

Interpersonal characteristics of the women are summarized in table 7. More than 90% of the women under study had disclosed their HIV status. However, among those who did not initiate ART, 18.9% had not disclosed their status compared to 2.7% among those who initiated ART. Very few of the women were members of a support group. A higher proportion of women who initiated ART were members of a support group compared with

women who did not initiate ART. The majority of women interviewed, 73%, stated that their religion supported use of ART.

More than 40% of women under study did not know the HIV status of their partner and this proportion was higher among women not initiating ART compared to those who initiated. The majority of women (82.8 %) mentioned that their partners knew the woman's HIV status. However, among women who did not initiate ART, this proportion was lower compared to those who initiated- 69.8% versus 89.1%. Of the 139 women who consulted their partners on ART initiation, 84.2% said their partners supported the decision to start ART. This proportion was low (63.9%) among women who did not initiate ART compared to women who initiated (91.3%).

Table 6: Perceptions towards ARVs of the women

Characteristic	**Total**		**ART initiated**		**ART not initiated**		**Cronbach's alpha**
	N	*Median (IQR)	N	*Median (IQR)	N	*Median (IQR)	
Perceptions on benefits of ART	163	4 (3.6 – 4.6)	110	4.2 (3.8 – 4.8)	53	3.8 (3.6 – 4.2)	0.71
Perceptions on harms of/difficulties with ARVs[2]	162	3.9 (3.4 – 4.4)	109	4 (3.6 – 4.6)	53	3.6 (3.0 – 4.0)	0.63
Perceptions on need for ART[3]	162	4.5 (4.0 – 5.0)	109	4.5 (4.0 – 5.0)	53	4 (3.75 – 4.75)	0.61
Fear of stigma and discrimination[4]	162	4 (3.75 – 4.75)	109	4 (3.75 – 4.75)	53	4 (3.25 – 4.5)	0.54

**maximum score=5 (excellent perception). Scores for harms of ART, stigma and need for ART were reversed so that values closer to 5 indicate that there was perceived less harm, less stigma and more need for ART (see section 3.5.3).*

Table 7: Inter-personal characteristics of the women

Characteristic	Total (N=163)	ART initiated (N=110)	ART not initiated (N=53)
	n (%)	n (%)	n (%)
Disclosed HIV status (N=163)			
Yes	150 (92)	107 (97.3)	43 (81.1)
No	13 (8)	3 (2.7)	10 (18.9)
Member of Support Group (N=163)			
Yes	10 (6.1%)	9 (8.2)	1 (1.9)
No	153 (93.9)	101 (91.8)	52 (98.1)
Religion Supports ART (N=163)			
Yes	120 (73.6)	84 (76.4)	36 (67.9)
No	12 (7.4)	7 (6.4)	5 (9.4)
Don't Know	31 (19)	19 (17.3)	12 (22.6)
Knows HIV Status of Partner (N=163)			
Yes	91 (55.8)	65 (59.1)	26 (49.1)
No	72 (44.2)	45 (40.9)	27 (50.1)
Partner Knows Your HIV Status (N=163)			
Yes	135 (82.8)	98 (89.1)	37 (69.8)
No	28 (17.2)	12 (10.9)	16 (30.2)
Partner supportive of ART (N=139)			
Yes	117 (84.2)	94 (91.3)	23 (63.9)
No	22 (15.8)	9 (8.7)	13 (36.1)

5.3.3. Organizational Factors

5.3.3.1. Travel to clinic

The majority of the study participants used a bus or commuter to travel to the health facility. Close to 70% of the women lived within 10km of the health facility. The median amount of money used to travel to the health facility was four Swaziland emalangeni (SZL) which is almost 0.4 United States (US) dollars. The median amount of money used to travel to the health facility by women who initiated ART was 5 SZL (0.5 US dollars) while those who did not initiate ART used 4 SZL (0.4 US dollars) as shown in table 8.

Table 8: Modes of travel to clinic of the women

Characteristic	**Total** (N=163)		**ART initiated** (N=110)		**ART not initiated** (N=53	
	n (%)	Median (IQR)	n (%)	Median (IQR)	n (%)	Median (IQR)
How do you get to clinic (N=163)						
Walk	36 (22.1)		24 (21.8)		12 (22.6)	
Bus/commuter	124 (76.1)		84 (76.4)		40 (75.5)	
Bicycle	0 (0)		0 (0)		0 (0)	
Hire a taxi	3 (1.8)		2 (1.8)		1 (1.9)	
My own car	0 (0)		0 (0)		0 (0)	
Other	0 (0)		0 (0)		0 (0)	
How far is clinic from home (N=163)						
<5km	55 (33.7)		36 (32.7)		19 (35.9)	
5-10km	59 (36.2)		39 (35.5)		20 (37.7)	
10-20km	23 (14.1)		16 (14.6)		7 (13.2)	
20-30km	14 (8.6)		9 (8.2)		5 (9.4)	
30-50km	10 (6.1)		9 (8.2)		1 (1.9)	
>50km	2 (1.2)		1 (0.9)		1 (1.9)	
Amount of money used to clinic (SZL) (N=163)		4 (3-8)		5 (4-9)		4 (3-5)

5.3.3.2. Perceptions towards access to clinic

Women who initiated ART had better perception scores (i.e. did not perceive access to the health facility as a major barrier) towards access to clinic for ANC services with a median of 4.25 compared to 4.0 among those who did not initiate.

Table 9: Perceptions towards access to clinic by the women

Characteristic	**Total**		**ART initiated**		**ART not initiated**		**Cronbach's alpha**
	N	*Median (IQR)	N	*Median (IQR)	N	*Median (IQR)	
Perceptions towards access to clinic[1]	159	4.25 (4.0 – 5.0)	107	4.5 (4.0 – 5.0)	52	4.0 (3.88 – 5.0)	0.77

**maximum score=5 (excellent perception)*

5.3.3.3. Health Care Workers' Attitude

Women who did not initiate ART experienced less favourable attitude from health care workers with a median score of 3.5 compared to those who did not initiate ART with a median score of 3.61

Table 10: Health care workers' attitude towards pregnant women

Characteristic	Total		ART initiated		ART not initiated		Cronbach's alpha
	N	*Median (IQR)	N	*Median (IQR)	N	*Median (IQR)	
HCWs attitudes towards pregnant women[1]	108	3.57 (3.16 – 3.86)	78	3.61 (3.27 – 3.88)	30	3.5 (2.98 – 3.73)	0.8570

**maximum score=4 (excellent attitude)*

5.3.4. Reasons for ART non-initiation

The most common reason cited for not initiating ART by the 53 women were: not yet ready to commit for lifelong treatment (24.5%); delayed by clinic procedures like baseline laboratory tests, counselling sessions (17%); refusal by partner or family members (13.2%); limited ANC visits because of late booking (13.2%); and nurses not offering ART to the patient (13.2%). Table 11 shows the reasons cited by women who did not initiate ART.

Table 11: Reasons for non-ART initiation

Reason for not initiating ART	n	(%)
Not ready	13	24.5
Delayed by clinic procedures	9	17.0
Partner/family refused	7	13.2
Limited ANC visits	7	13.2
Not offered ART by nurses	7	13.2
Lack of food/finances	4	7.6
Fear of ARVs	3	5.7
Feel healthy	2	3.8
Work challenges	1	1.9

5.4. Analytical Statistics

5.4.1. Univariate Analysis

Univariate analysis was conducted for all the variables listed in table 3 *(section 3.6.3)* to select the ones to be included in the multivariate logistic regression model. Variables were only included into the model if:

i. They had p-value less than 0.25 in univariate analysis. This is recommended by Hosmer and Lemeshow based on work done by Mickey and Greenland[47]

ii. The Cronbach alpha score was above 0.70 for the set of construct variables
iii. The variable has been shown in literature to be a significant factor in ART initiation among pregnant women

Table 12 below shows the univariate analysis of the listed variables.

Based on the univariate analysis and the selection criteria mentioned above, the following variables were included in the initial regression model: employment status; perceptions on benefits of ART; HIV disclosure status; member of a support group; partner support for ART; and knowledge of partner status

Table 12: Univariate analysis of variables considered for the multivariate model

Variable	N	Odds Ratio	p-value	Cronbach alpha	Decision
Age	163	1.04	0.278	n/a	Excluded from model due to p-value>0.25
Parity	163	1.44	0.317	n/a	Excluded from model due to p-value>0.25
Level of education	163	0.90	0.773	n/a	Excluded from model due to p-value>0.25
Employment status	163	0.61	0.172	n/a	Included in initial model
Religion	161	1.03	0.936	n/a	Excluded from model due to p-value>0.25
Baseline CD4 count	161	0.999	0.559	n/a	Excluded from model due to p-value>0.25
Gestational age at HIV diagnosis	161	0.99	0.552	n/a	Excluded from model due to p-value>0.25
WHO Clinical stage	163	0.76	0.449	n/a	Excluded from model due to p-value>0.25
Perceptions on benefits for ART	162	3.49	<0.001	0.71	Included in initial model
Perceptions on harms of/difficulties with ARVs	162	2.14	0.002	0.63	Excluded from model due to Cronbach alpha <0.70
Perceptions on the need for ART	162	1.94	0.011	0.61	Excluded from model due to Cronbach alpha <0.70
Fear of stigma and discrimination	162	1.70	0.011	0.54	Excluded from model due to Cronbach alpha <0.70
HIV status disclosure	163	8.29	0.002	n/a	Included in initial model
Member of a support group	163	4.63	0.151	n/a	Included in initial model
Religion supports ARVs	163	1.53	0.254	n/a	Excluded from model due to Cronbach alpha <0.70
Knowledge of partner status	163	1.50	0.228	n/a	Included in initial model
Partner support for ART	163	7.66	<0.001	n/a	Included in initial model
Perceptions towards access to clinic	159	1.68	0.032	0.67	Excluded from model due to Cronbach alpha <0.70
Health care worker attitudes	108	3.21	0.007	0.857	Excluded due to missing data

5.4.2. Logistic Regression

Backwards stepwise logistic regression was conducted on the initial model using Stata 11 and variables with the largest p-values were dropped at each step. Table 13 below shows the odds ratios (OR) and the 95% confidence intervals (95% CI) for the initial model.

Table 13: Logistic regression results for the initial model

Variable	N	OR	p-value	95% CI
Employment status	162	0.63	0.274	0.27 – 1.45
Perceptions on benefits of ART	162	2.62	0.005	1.33 – 5.16
HIV disclosure status	162	1.84	0.439	0.40 – 8.34
Member of support group	162	4.05	0.227	0.42 – 39.37
Partner support for ART	162	6.84	<0.001	2.44 – 19.11
Knowledge of partner HIV status	162	0.54	0.197	0.21 – 1.38

A Likelihood-ratio test (LR test) was conducted each time a variable was dropped to check if the dropped variable was necessary for the model. *(See annex 4)*

The final model had two variables as predictors of ART initiation among pregnant women: partner support and perceptions towards benefits of ARVs. However, initial post regression analysis of this model showed outlier points with high leverage on the model coefficients. This involved only 5 of the 162 study participants. *(See annex 5)*. Data for these 5 participants were dropped from the data set and regression analysis was done again *(see annex 6)*. Table 14 below shows the final predictors:

Table 14: Regression results for the retained model explanatory variables

Variable	Initial model			Final model		
	OR	p-value	95% CI	OR	p-value	95% CI
Perceptions on benefits for ART	2.62	0.005	1.33 – 5.16	3.04	0.001	1.55 – 5.96
Partner support for ART	6.84	<0.001	2.44 – 19.11	4.75	<0.001	2.11 – 10.67

5.4.3. Post-Regression Analysis

Post-regression analysis was conducted using the area under the ROC curve analysis, goodness of fit tests and M-asymptotic residuals analysis *(see annex 7)*

Area under curve

The area under curve for the final model was 0.7680 showing that the model has a good discriminatory power for this data set.

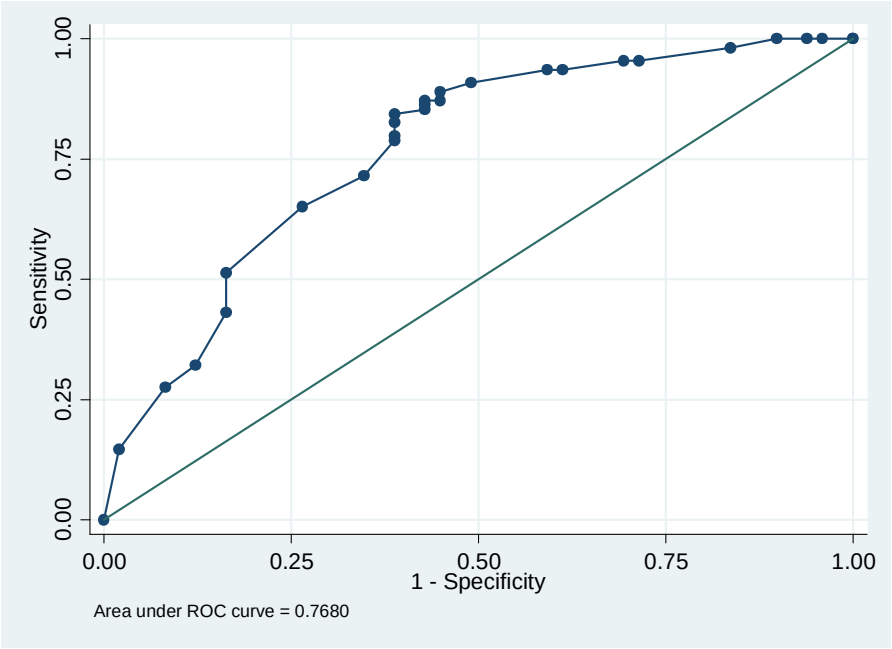

Figure 3: Area under ROC curve for the final model

Goodness-of-fit

The Pearson's goodness-of-fit test yielded a p-value of 0.556. However the number of covariate groups (26 groups for 162 participants) resulted in a large number of expected cell values less than 5. As a result the Hosmer-Lemeshow goodness-of-fit test was carried out with 8, 10 and 12 groups used as a sensitivity analysis. The p values for the 8, 10 and 12 groupings were 0.470, 0.535 and 0.709 respectively, which are all >0.05. The model predictions, therefore, have good agreement with the observed ART initiation outcomes.

M-asymptotic residuals analysis

The final model did not have any high leverage outlier points after removing the 5 outliers detected through residuals analysis.

5.4.4. Interpretation of the final model

Perceptions on benefits for ART

The odds of initiating ART among eligible pregnant women in Swaziland increase 3.04 fold for every one unit score increase in the perceptions of women towards the benefits of ART (p=0.001)

Partner Support

The odds of initiating ART among eligible pregnant women in Swaziland are 4.75 times higher in women whose partners support ART initiation compared to those women whose partners do not support ART initiation (p<0.001)

6. DISCUSSION OF STUDY RESULTS

ART initiation among pregnant women is critical both for their own health and for PMTCT purposes. In this study, conducted in 2013, we determined factors associated with ART initiation among eligible pregnant women through a cross-sectional survey among women at the postnatal wards in all the eleven public hospitals and health centres in Swaziland.

6.1. ART initiation

In this study, it was found that 67.5% of eligible pregnant women were initiated on ART before they deliver. This percentage is comparable to the ones reported in other studies and global reports. According to the Joint United Nations Program on HIV/AIDS (UNAIDS) report, 71% of eligible pregnant women initiated ART in Swaziland in 2011.[48] In another review done in Swaziland in 2010 ART initiation uptake among eligible pregnant women was estimated at 50%.[29] Despite slight improvements over the years, ART initiation uptake among pregnant women remain low in Swaziland compared to the non-pregnant population in which is estimated to be 94% of those eligible.[49] Pregnancy has been identified as a risk factor for lower uptake of ART.[32]

The ART initiation proportion found in this study is within the same range as reported from other countries in the region. According to the Inter Agency Task Team (IATT) on prevention and treatment of HIV infection in pregnant women, mothers and children, 59% of eligible pregnant women initiated ART in the 22 PMTCT priority countries.[50] In one study in South Africa, 51% of eligible pregnant women initiated ART.[31] In another study in Zambia, only 32.9% pregnant women were started on ART.[30] A study done in Botswana[51] showed that 37% of pregnant women initiated ART. In a prospective cohort analysis done in Malawi from 2006-2009, initiation rates among eligible pregnant women were reported to be 47%.[52] This study showed slightly higher initiation on ART which might be due to improvements over years as most of the studies were done much earlier than our study. Initiation proportions among pregnant women in the region and in Swaziland remain below the WHO recommended universal coverage rate of 80%.[53] Exploring barriers and facilitating factors to ART initiation was therefore important in an effort to improve uptake of ART among pregnant women.

6.2. Factors associated with ART initiation

Few studies have been conducted to explore barriers and facilitating factors to ART initiation among pregnant women. Most of these studies were qualitative in design. Factors such as late first presentation, denial of an HIV diagnosis, fear of disclosure, enrolment into a support group, lower level of education, higher age, advanced AIDS disease and fear of treatment side effects were identified as barriers or facilitators to ART initiation among pregnant women.[32,33,34,35,36,37,38] Most quantitative studies done on barriers to uptake of ARVs in pregnant women were mainly looking at short course prophylaxis as opposed to lifelong ART that was investigated in this study.

The major advantage of this study is that it used the socio-ecological model to quantitatively investigate intrapersonal, interpersonal and organizational factors associated with ART initiation among pregnant women.

6.2.1. Intrapersonal factors

The intrapersonal factors investigated in this study included socio-demographic status (age, parity, level of education, employment status and religion), disease/clinical factors (CD4 count, WHO clinical staging, gestational age and duration of being HIV positive) and women's perceptions towards ARVs *(see questionnaire in annex 9)*. None of the socio-demographic or disease/clinical factors were associated with ART initiation in pregnant women investigated in this study, both from the univariate and multivariate regression analyses. Only perceptions of women towards ARVs were associated with ART uptake.

Socio-demographic factors and uptake of ARVs for PMTCT

Several studies have shown different results on the effect of socio-demographic factors on ART initiation and short term ARV prophylaxis, with some showing an association while others showed no association. The most commonly investigated socio-demographic factors are education and age. A study done in Uganda[54] showed that women who had completed at least 7 years of education had 10 times the odds of collecting the ARVs for PMTCT compared to women with less or no education. In Tanzania and Uganda, maternal secondary education was associated with high uptake of ARVs.[55] Kuonza et al[56] showed that lack of maternal education was associated with poor adherence to ARVs for PMTCT in

Zimbabwe. On the other hand, quantitative studies done in Kenya and Zimbabwe[38,57] found no association between maternal education and uptake of PMTCT services. This study also showed no association between maternal education and ART initiation (p=0.773) on univariate analysis.

Similarly with age, some studies have shown an association with uptake of ARVs while some have showed no association. In Malawi, eligible people older than 35 years were more likely to initiate ART than those below 35 years.[58] In Tanzania, age of 23 years and below was associated with lower ARV uptake for PMTCT.[59] However, no such association between age and PMTCT ARV uptake was found in Kenya and Zimbabwe.[38,57] This study also found no association between age and ART initiation among the eligible women (univariate regression p=0.278).

Employment status, religion and parity are the other socio-demographic factors which have been investigated for association with uptake of ARVs for PMTCT. Kuonza[56] found that maternal employment status and parity were not associated with uptake and adherence of ARVs while Kinuthia[57] found that employment status, religion and parity were not associated with ARV use among pregnant women in Kenya. Similar findings were noted in Zambia for parity and maternal employment status.[60] This study concurred with other studies that showed that maternal employment status, religion and parity were not associated with ART uptake among the eligible women (p=0.172, p=0.936 and p=0.317 respectively on univariate analysis).

Though this study found no association on any of the socio-demographic factors, these factors need to be considered as they may have an impact on ART uptake in other settings different from Swaziland.

Disease/clinical factors and uptake of ARVs for PMTCT

This study also investigated the effect of CD4 level, gestational age at HIV diagnosis and WHO clinical stage on ART uptake among the eligible women. A study done in Malawi[58] showed that the odds of ART initiation were higher among individuals with WHO stage 3 or 4 and CD4 count less than 250copies/mm^3. In Uganda, pregnant women with no HIV symptoms did not see the need for ART.[37] On the contrary, CD4 count level was not

associated with ARV uptake and adherence in Zambia[60,61] and Tanzania[59]. Albrecht et al[60] also showed that gestational age at time of diagnosis or ANC enrolment was not associated with ARVs uptake or adherence. Once again, the effects of CD4 level, gestational age and WHO clinical stage on ARVs uptake for PMTCT vary from setting to setting. In Swaziland, our study showed no association between all these factors with ART initiation (CD4 level: p=0.559; gestational age at HIV diagnosis: p=0.552; WHO Clinical stage: p=0.449 on univariate analysis).

Women's perceptions towards ARVs and uptake of ARVs for PMTCT

This study also investigated if women's perceptions on ARVs were associated with uptake of ART. The perceptions were divided into four main categories: perceptions on benefits of ART, perceptions on harms of/difficulties with ARVs, perceptions on the need for ART and perceived stigma and discrimination while taking ARVs. On univariate analysis, all perception scores from all the factors were associated with ART uptake among the women (p=0.000, p=0.002, p=0.011 and p=0.011 respectively). However, perceptions on harms of/difficulties with ARVs, perceptions on the need for ART and perceived stigma and discrimination while taking ARVs were not included in the logistic regression due to a Cronbach alpha value less than 0.70. Following multiple logistic regression, our study showed that the odds of initiating ART among eligible pregnant women in Swaziland increase as the perception of women towards the benefits of ART increases(p=0.001) while controlling for employment status, HIV disclosure status, being a member of a support group, partner support for ART, and knowledge of partner status.

Several studies have shown that poor knowledge on and perceptions towards ARVs hinders uptake.[62,63,64,65] Some studies showed that women declined to take ARVs for PMTCT because they doubted their efficacy or they feared ARVs could harm the unborn child. Most of these studies were qualitative in design. Very few quantitative studies to our knowledge have actually looked at the association of perception scores with uptake of ART among eligible pregnant women.

Perceptions on stigma have also been shown to be barriers to uptake of ARVs for PMTCT in both qualitative[36,62,64,66] and quantitative studies[57].

6.2.2. Interpersonal factors

This study also investigated any associations between interpersonal factors (partner support, disclosure of HIV status, being a member of a support group and knowledge of partner status) and ART uptake among pregnant women.

Partner Support

Partner support is one of the factors that was strongly associated with ART initiation among eligible pregnant women in this study. On univariate analysis, the odds of ART initiation among women who expressed partner support were higher than those of women with no such support ($p<0.001$). On the multiple logistic regression, this study showed that the odds of initiating ART among eligible pregnant women in Swaziland was higher in women whose partners support ART initiation than in those whose partners do not support ART initiation ($p<0.001$) after controlling for employment status, HIV disclosure status, being a member of a support group, perceptions on benefit of ARVs, and knowledge of partner's HIV status.

Male involvement has been one of the barriers to PMTCT in most countries and WHO identified male involvement as a priority for PMTCT programs.[67] Male involvement is critical in PMTCT as it has been shown to independently reduce mother to child transmission of HIV. In a study conducted in Kenya, the combined risk of HIV acquisition or infant mortality was lower with male ANC attendance (aHR = 0.55; p = 0.012).[68]

Our study contributes to the body of literature that has shown that men influence women's decision to accept ARVs for PMTCT purposes. In Tanzania, women whose partners provided support and attended ANC were three times more likely to use ARVs for PMTCT compared to those whose partners did not attend.[69] In South Africa, multivariate analysis showed that male involvement was associated with better uptake and adherence for ARVs for PMTCT.[70] Similar findings were seen in Malawi where male involvement was significantly associated with uptake of PMTCT services including completion of follow up in the program (AOR=16.8, $p<0.0001$).[71] In Kenya, women who came with their partners for HIV testing and counselling were three times more likely to uptake and administer ARVs for PMTCT.[72] A number of qualitative studies have also identified male support as a

facilitating factor to uptake of PMTCT services by pregnant women.[73,74,75]

Disclosure of HIV status and knowledge of partner's HIV status

On univariate analysis, the odds of ART initiation among women who had disclosed their HIV status were higher than those of women who had not disclosed (p=0.002). However, following multiple logistic regression, disclosure of HIV status was not associated with ART uptake when controlling for employment status, presence of male support, being a member of a support group, perceptions on benefit of ARVs, and knowledge of partner's HIV status. Women's knowledge of the HIV status of their partners was not associated with ART initiation both in univariate analysis and multivariate logistic regression.

Univariate analysis in studies conducted in South Africa showed that administration of ARVs for PMTCT was significantly associated with HIV status disclosure by pregnant women.[70,76] In Zimbabwe, non-adherence to PMTCT ARVs was associated with maternal non-disclosure of HIV status to sexual partner (POR=2.75; 95% CI: 1.04-7.32 through logistic regression).[56] Some qualitative studies have also identified fear of disclosure as a barrier to women receiving PMTCT services.[36,64,77]

Support group membership

In this study, being a member of a support group was not significantly associated with ART initiation both in univariate analysis (p=0.151) and multiple logistic regression. Only 10/163 (6%) of women from this study were members of a support group during pregnancy. This might be attributed to the fact that pregnancy has a limited period and women might not get the time to join a support group before they deliver. To our knowledge not many studies have looked at the association of being support membership and ART initiation among pregnant women. However, in Zimbabwe women who were members of an HIV support group were twice as likely to access HIV care and treatment as those who did not belong to any group (OR=2.39; 95% CI: 2.07- 14.89 on univariate analysis).[38]

6.2.3. Organisational factors

The present study also examined the association between organisational factors and ART initiation among the pregnant women. Analysis of organizational factors in our study mainly focused on health care providers' attitudes towards pregnant women and women's perceptions towards health facility access. Both factors were associated with ART initiation among pregnant women on univariate analysis. Women with higher perceptions scores towards health facility access were more likely to initiate ART than those with lower scores (p=0.032). Pregnant women who received positive attitudes (scores) from health care workers were more likely to initiate ART than those receiving negative attitudes (p=0.007). However, both these variables were excluded from the multiple logistic regression model due to many missing variables.

Organisational factors have been widely studied to determine their effects on PMTCT services uptake for pregnant women. In a qualitative study in Uganda, negative interactions between health care staff and pregnant women were cited as a barrier to women initiating ART.[37] Several other studies (mainly qualitative) have cited negative staff attitudes and poor access to ART services as barriers to uptake or adherence of PMTCT services by pregnant women.[33,37,62,64,78,79]

6.2.4. Limitations of the study

The limitations from this study were as follows:

i. The study only focused on women who were delivering at the health facilities. This might have introduced some bias as women delivering at health facilities might be motivated and committed people who are also likely to initiate ART.

ii. Interviews were conducted by health care workers and this might have introduced bias especially on questions asking about health workers' attitude towards pregnant women. However, efforts were made through training and supervision of health care workers to minimize this.

iii. Women were interviewed about attitudes regarding benefits or harms of ART after they had initiated ART. Therefore their responses could have been influenced by their experiences with ART: i.e. if a woman got better because of ART, then her perceptions of the benefits will become more favourable.

iv. The sample is only representative of women who had a CD4 count. A relatively large proportion (15% of the total HIV positive women identified for the study- see figure 2) of the women were excluded from analysis, because researchers could not establish whether they were eligible for ART

v. The planned sample size could not be reached. As a result many of the statistically non-significant factors may also be of importance but this study might have been underpowered to detect them as such.

vi. Two variables, perceptions towards access to clinic and health care worker attitudes, were excluded from the regression model due to missing data

7. CONCLUSION AND RECOMMENDATIONS

Conclusion

ART initiation is very important for HIV positive women both for their own health and for prevention of HIV transmission to their children. However, not all women initiate ART due to a number of reasons. In this study, 32.5% of the eligible pregnant women did not initiate ART. This study investigated which factors are associated with ART initiation among eligible women in Swaziland. On univariate analysis, the factors that were associated with ART initiation were: perceptions on benefits of ART, perceptions on the harms of/difficulties with ARVs, perceptions on the need for ART, fear of stigma and discrimination, HIV status disclosure, partner support for ART, perceptions towards access to clinic, and health care work attitudes towards the pregnant women. Following multiple logistic regression, only perceptions on benefits of ART and presence of partner support were significantly associated with ART initiation. The present study contributes to the body of literature that has identified factors associated with ART initiation among pregnant women.

Momentum has gathered globally to eliminate paediatric HIV by 2015. However, if ART uptake of women remains unsatisfactory, this goal may not be achieved. Therefore, efforts should be intensified to ensure that eligible pregnant women are initiated on ART treatment. In 2013, WHO released new guidelines for PMTCT[16] that now recommend antiretroviral therapy either for life or for the course of pregnancy for all HIV positive women regardless of their CD4 count or WHO stage popularly known as option B or option B+. Although this study was conducted before the release of these new guidelines, the factors that have been identified here need to be seriously considered for uptake of ART among pregnant women to be improved.

Recommendations:

Based on these findings it is recommended that:

i. There is need to strengthen counselling and education of pregnant women on ART. This will address the issues of poor perception towards ARVs by the women. Clear guiding documents and counselling materials need to be provided to all health care

workers to ensure they provide proper and adequate information to the women. Information provided to the women should aim at dispelling myths and misconceptions on ART; and ensuring women understand benefits of ART.

ii. Male involvement strategies need to be developed to ensure pregnant women receive support from their partners. In 2012, WHO released a document which discusses male involvement in depth and identifies some strategies to promote male involvement that have been proven to work in some countries.[80] Some of the strategies include behaviour change communication, community engagement, and establishing male friendly services. Countries have to adopt strategies that work in their different settings.

iii. Stigma and discrimination against people living with HIV needs to be addressed. According to the Department of International Development[81], some of the promising interventions against HIV stigma and discrimination include: identification of drivers of stigma in a country (through research) and development of a comprehensive strategy to address the drivers; engaging public figures who are leaders in their communities to be champions in changing attitudes towards people living with HIV; and reducing stigma at health facilities through establishment of friendly services for people living with HIV.

iv. Women should be empowered on how they can disclose their HIV results to their partners or family members. This can be done through promoting couples HIV testing and counselling; establishment of support groups for people living with HIV; improving interpersonal communication skills for women living with HIV through training; and strengthening ongoing counselling for women living with HIV to promote HIV status disclosure.[82]

v. Any negative attitudes from health care workers toward pregnant women need to be addressed. This can be done through training and workshops with the health providers; and establishment of recognition schemes (certificates of appreciation or non-monetary incentives) for health care workers performing well.

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9. ANNEXES

Annex 1: Swaziland Ethics Committee approval letter

Telegrams:
Telex:
Telephone: (+268 404 2431)
Fax: (+268 404 2092

MINISTRY OF HEALTH
P.O. BOX 5
MBABANE
SWAZILAND

THE KINGDOM OF SWAZILAND

FROM: The Chairman
Scientific and Ethics Committee
Ministry of Health
P. O. Box 5
Mbabane

TO: Caspian Chouraya

DATE: 31st May 2012

REF: MH/599C

RE: Factors associated with antiretroviral treatment initiation among eligible HIV positive pregnant women in Swaziland

The committee thanks you for your submission to the Scientific and Ethics Committee and the clarity on responses to the protocol amendment

In view of the responses submitted after concerns raised and the fact that the study is in accordance with ethical and scientific standards, the committee therefore grants you authority to conduct the study. You are requested to adhere to the specific topic and inform the committee through the chairperson of any changes that might occur in the duration of the study which are not in this present arrangement.

The committee wishes you the best and is eagerly awaiting findings of the study to inform proper planning and programming to use for analysis

Yours Sincerely,

DIRECTOR OF HEALTH SERVICES
MINISTRY OF HEALTH
28
P.O. BOX 5 MBABANE
SWAZILAND

Dr S.M.Zwane
DIRECTOR OF HEALTH SERVICES
(THE CHAIRMAN)
cc: SEC members

Annex 2: University of Pretoria Academic Advisory Committee approval letter

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

* **FWA** 00002567, Approved dd 22 May 2002 and Expires 20 Oct 2016.
* **IRB** 0000 2235 IORG0001762 Approved dd 13/04/2011 and Expires 13/04/2014.

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences Research Ethics Committee
Fakulteit Gesondheidswetenskappe Navorsingsetiekkomitee

DATE: 28/11 /2011

NUMBER	**217/2011**
TITLE OF THE PROTOCOL	Factors associated with antiretroviral treatment initiation among eligible HIV positive pregnant women in Swaziland
PRINCIPAL INVESTIGATOR	Dr Caspian Chouraya **Dept:** SHSPH; Steve Biko Academic Hospital;University of Pretoria. **Cell:** +268 7 641 9892 **E-Mail:** cchouraya@pedaids.org
SUB INVESTIGATOR	Not Applicable
STUDY COORDINATOR	Dr Caspian Chouraya
SUPERVISOR (ONLY STUDENTS)	**Name & Surname:** Dr Louwagie Goedele **E-Mail:** goedele.louwagie@up.ac.za
STUDY DEGREE	MSc Epidemiology
SPONSOR COMPANY	Self
MEETING DATE	23/11/2011

The Protocol was approved on 23/11/2011 by a properly constituted meeting of the Ethics Committee subject to the following conditions:

1. The approval is valid for 2 years period [till the end of December 2013] , and
2. The approval is conditional on the receipt of 6 monthly written Progress Reports, and
3. The approval is conditional on the research being conducted as stipulated by the details of the documents submitted to and approved by the Committee. In the event that a need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

Members of the Research Ethics Committee:

Prof M J Bester	(female)BSc (Chemistry and Biochemistry); BSc (Hons)(Biochemistry); MSc(Biochemistry); PhD (Medical Biochemistry)
Prof R Delport	(female)BA et Scien, B Curationis (Hons) (Intensive care Nursing), M Sc (Physiology), PhD (Medicine), M Ed Computer Assisted Education
Prof JA Ker	MBChB; MMed(Int); MD – Vice-Dean (ex officio)
Dr NK Likibi	MBB HM – Representing Gauteng Department of Health) MPH
Dr MP Mathebula	(female)Deputy CEO: Steve Biko Academic Hospital; MBCHB, PDM, HM
Prof A Nienaber	(female) BA(Hons)(Wits); LLB; LLM; LLD(UP); PhD; Dipl.Datametrics(UNISA) – Legal advisor
Mrs MC Nzeku	(female) BSc(NUL); MSc(Biochem)(UCL, UK) – Community representative
Prof L M Ntlhe	MbChB (Natal) FCS (SA)
Snr Sr J Phatoli	(female) BCur(Eet.A); BTec(Oncology Nursing Science) – Nursing representative
Dr R Reynders	MBChB (Prët), FCPaed (CMSA) MRCPCH (Lon) Cert Med. Onc (CMSA)
Dr T Rossouw	(female) MBChB (cum laude); M.Phil (Applied Ethics) (cum laude), MPH (Biostatistics and Epidemiology (cum laude), D.Phil
Dr L Schoeman	(female) B.Pharm, BA(Hons)(Psych), PhD – Chairperson: Subcommittee for students' research
Mr Y Sikweyiya	MPH; SARETI Fellowship in Research Ethics; SARETI ERCTP; BSc(Health Promotion)Postgraduate Dip (Health Promotion) – Community representative
Dr R Sommers	(female) MBChB; MMed(Int); MPharmMed – **Deputy Chairperson**
Prof TJP Swart	BChD, MSc (Odont), MChD (Oral Path), PGCHE – School of Dentistry representative
Prof C W van Staden	MBChB; MMed (Psych); MD; FCPsych; FTCL; UPLM - **Chairperson**

DR R SOMMERS; MBChB; MMed(Int); MPharmMed.
Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria

◆Tel:012-3541330 ◆Fax:012-3541367 / 0866515924 ◆E-Mail: manda@med.up.ac.za
◆Web: //www.healthethics-up.co.za ◆H W Snyman Bld (South) Level 2-34 ◆ Private Bag x 323, Arcadia, Pta, S.A., 0007

Annex 3: Box Tidwell Test for Quantitative Variables

Variable	p-value	Conclusion
Age	0.571	Age has a linear relationship with the Logit therefore was left as a quantitative variable in logistic regression
CD4 count	0.654	CD4 has a linear relationship with the Logit therefore was left as a quantitative variable in logistic regression
Gestational age	0.722	Age has a linear relationship with the Logit therefore was left as a quantitative variable in logistic regression
Perceptions towards benefit of ART	0.912	Scores for benefits have a linear relationship with the Logit therefore was left as a quantitative variable in logistic regression
Perceptions towards harms of ARVs	0.383	Scores for harms have a linear relationship with the Logit therefore was left as a quantitative variable in logistic regression
Perceptions on need for ART	0.785	Scores for needs have a linear relationship with the Logit therefore was left as a quantitative variable in logistic regression
Fear of stigma and discrimination	0.862	Scores for fears of stigma and discrimination have a linear relationship with the Logit therefore was left as a quantitative variable in logistic regression
Access to clinic	0.156	Scores for access to the clinic have a linear relationship with the Logit therefore was left as a quantitative variable in logistic regression
HCW attitudes	0.245	Scores for HCW attitudes have a linear relationship with the Logit therefore was left as a quantitative variable in logistic regression

Annex 4: Stata output for regression analysis of initial model

```
. logistic outcome employment benefits disclosure supportgrp ptsupport knowptstatus

Logistic regression                                     Number of obs   =        162
                                                        LR chi2(6)      =      44.44
                                                        Prob > chi2     =     0.0000
Log likelihood = -80.188679                             Pseudo R2       =     0.2170

------------------------------------------------------------------------------
     outcome | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
  employment |    .626517   .2676943    -1.09   0.274     .2711669    1.447535
    benefits |   2.623065   .9045465     2.80   0.005     1.334375    5.156325
  disclosure |   1.835351   1.439383     0.77   0.439     .3946028    8.536464
  supportgrp |   4.054392   4.702554     1.21   0.227     .4174894    39.37368
   ptsupport |   6.836957   3.585062     3.67   0.000     2.446371    19.10748
knowptstatus |    .535399   .2591771    -1.29   0.197     .2073128    1.382703
------------------------------------------------------------------------------

. est store a

.
. logistic outcome employment benefits supportgrp ptsupport knowptstatus

Logistic regression                                     Number of obs   =        162
                                                        LR chi2(5)      =      43.81
                                                        Prob > chi2     =     0.0000
Log likelihood = -80.502364                             Pseudo R2       =     0.2139

------------------------------------------------------------------------------
     outcome | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
  employment |   .6241575   .2661745    -1.11   0.269     .2705801    1.439768
    benefits |   2.668708   .9122122     2.87   0.004     1.365668    5.215032
  supportgrp |   4.246713    4.93756     1.24   0.214       .43489    41.46927
   ptsupport |   7.845501   3.903945     4.14   0.000     2.958423    20.80564
knowptstatus |   .5443091   .2628571    -1.26   0.208      .211244    1.402513
------------------------------------------------------------------------------

. lrtest a

Likelihood-ratio test                                 LR chi2(1)  =      0.63
(Assumption: . nested in a)                           Prob > chi2 =    0.4283

. est store b

.
. logistic outcome benefits supportgrp ptsupport knowptstatus

Logistic regression                                     Number of obs   =        162
                                                        LR chi2(4)      =      42.60
                                                        Prob > chi2     =     0.0000
Log likelihood = -81.108686                             Pseudo R2       =     0.2080

------------------------------------------------------------------------------
     outcome | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
    benefits |   2.693058    .917101     2.91   0.004     1.381578    5.249478
  supportgrp |   3.888764   4.48306     1.18   0.239     .4060001    37.24749
   ptsupport |   7.707816   3.813303     4.13   0.000     2.922905    20.32582
knowptstatus |   .5808304   .2770539    -1.14   0.255     .2280497    1.479344
------------------------------------------------------------------------------

. lrtest b

Likelihood-ratio test                                 LR chi2(1)  =      1.21
(Assumption: . nested in b)                           Prob > chi2 =    0.2708

. est store c
```

Annex 4: Stata output for regression analysis of initial model (continued)

```
.
. logistic outcome benefits ptsupport knowptstatus

Logistic regression                             Number of obs   =        162
                                                LR chi2(3)      =      40.83
                                                Prob > chi2     =     0.0000
Log likelihood = -81.991255                     Pseudo R2       =     0.1994

------------------------------------------------------------------------------
     outcome | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
    benefits |   2.603123   .8687089     2.87   0.004     1.353423     5.00675
   ptsupport |   8.148528     4.0124     4.26   0.000     3.104136    21.39034
knowptstatus |   .5661417    .268892    -1.20   0.231     .2231734    1.436177
------------------------------------------------------------------------------

. lrtest c

Likelihood-ratio test                           LR chi2(1)  =      1.77
(Assumption: . nested in c)                     Prob > chi2 =    0.1840

. est store d

.
. logistic outcome benefits ptsupport

Logistic regression                             Number of obs   =        162
                                                LR chi2(2)      =      39.31
                                                Prob > chi2     =     0.0000
Log likelihood = -82.753723                     Pseudo R2       =     0.1919

------------------------------------------------------------------------------
     outcome | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
    benefits |   2.693723   .8968775     2.98   0.003     1.402635    5.173224
   ptsupport |   5.973698   2.395509     4.46   0.000     2.722096    13.10941
------------------------------------------------------------------------------

. lrtest d

Likelihood-ratio test                           LR chi2(1)  =      1.52
(Assumption: . nested in d)                     Prob > chi2 =    0.2169

. est store e
```

Annex 5: Stata output for post-regression analysis of initial model

```
. *AREA UNDER CURVE
. lroc

Logistic model for outcome

number of observations =      162
area under ROC curve   =   0.7748

.
. *GOODNESS OF FIT
. estat gof

Logistic model for outcome, goodness-of-fit test

       number of observations =       162
 number of covariate patterns =        26
             Pearson chi2(23) =        21.42
                  Prob > chi2 =         0.5556

. estat gof, group(8)

Logistic model for outcome, goodness-of-fit test

  (Table collapsed on quantiles of estimated probabilities)

       number of observations =       162
             number of groups =         8
     Hosmer-Lemeshow chi2(6) =         9.05
                  Prob > chi2 =         0.1707

. estat gof, group(10)

Logistic model for outcome, goodness-of-fit test

  (Table collapsed on quantiles of estimated probabilities)
  (There are only 8 distinct quantiles because of ties)

       number of observations =       162
             number of groups =         8
     Hosmer-Lemeshow chi2(6) =         4.88
                  Prob > chi2 =         0.5593

. estat gof, group(12)

Logistic model for outcome, goodness-of-fit test

  (Table collapsed on quantiles of estimated probabilities)
  (There are only 10 distinct quantiles because of ties)

       number of observations =       162
             number of groups =        10
     Hosmer-Lemeshow chi2(8) =         8.81
                  Prob > chi2 =         0.3582

.
. *RESIDUAL ANALYSIS
. predict mu, p
(1 missing values generated)

. predict dx2, dx2
(1 missing value generated)

. predict db, dbeta
(1 missing value generated)

. summ dx2 if dx2>4 & db>1
```

Variable	Obs	Mean	Std. Dev.	Min	Max
dx2	5	5.350941	0	5.350941	5.350941

Annex 6: Stata output for regression analysis of final model (without high-leverage points)

```
. *NEW REGRESSION MODEL WITH DROPPED HIGH LEVERAGE POINTS
. logistic outcome benefits ptsupport

Logistic regression                                     Number of obs   =        158
                                                        LR chi2(2)      =      35.82
                                                        Prob > chi2     =     0.0000
Log likelihood = -79.925471                             Pseudo R2       =     0.1830

------------------------------------------------------------------------------
     outcome | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
    benefits |    3.04082   1.044192     3.24   0.001     1.551298    5.960548
  ptsupport |   4.748461    1.96216     3.77   0.000     2.112609      10.673
------------------------------------------------------------------------------
```

Annex 7: Stata output for post-regression analysis of final model (without high-leverage points)

```
.
. *POST-REGRESSION ANALYSIS ON NEW MODEL
. drop mu dx2 db

.
. *AREA UNDER CURVE
. lroc

Logistic model for outcome

number of observations =      158
area under ROC curve   =   0.7680

.
. *GOODNESS OF FIT
. estat gof

Logistic model for outcome, goodness-of-fit test

       number of observations =       158
 number of covariate patterns =        26
             Pearson chi2(23) =        17.55
                  Prob > chi2 =         0.7817

. estat gof, group(8)

Logistic model for outcome, goodness-of-fit test

  (Table collapsed on quantiles of estimated probabilities)

       number of observations =       158
             number of groups =         8
     Hosmer-Lemeshow chi2(6) =         5.59
                  Prob > chi2 =         0.4701

. estat gof, group(10)

Logistic model for outcome, goodness-of-fit test

  (Table collapsed on quantiles of estimated probabilities)
  (There are only 9 distinct quantiles because of ties)

       number of observations =       158
             number of groups =         9
     Hosmer-Lemeshow chi2(7) =         6.04
                  Prob > chi2 =         0.5349

. estat gof, group(12)

Logistic model for outcome, goodness-of-fit test

  (Table collapsed on quantiles of estimated probabilities)
  (There are only 10 distinct quantiles because of ties)

       number of observations =       158
             number of groups =        10
     Hosmer-Lemeshow chi2(8) =         5.45
                  Prob > chi2 =         0.7089

.
. *RESIDUAL ANALYSIS
. predict mu, p

. predict dx2, dx2

. predict db, dbeta

. summ dx2 if dx2>4 & db>1

    Variable |        Obs        Mean    Std. Dev.       Min        Max
-------------+---------------------------------------------------------
         dx2 |          0
```

Annex 8: Informed Consent Form

I, the undersigned, have read and fully explained the participant information leaflet, which explains the nature, process, risks, discomforts and benefits of the study to the participant whom I have asked to participate in the study.
The participant indicates that she understands that the results of the study, including personal details regarding the interview will be anonymously processed into a research report. The participant indicates that she has no objections to participate in the study. She understands that there is no penalty should she wish to discontinue with the study and her withdrawal will not affect her care at this facility in any way. I hereby certify that the client has agreed to participate in this study.

Participant's name _____
(Please print)
Name of person seeking consent _____
(Please print)
Signature _____ Date _____

Witness's name _____
(Please print)
Witness's signature _____ Date _____

Annex 9: Study Questionnaire

FACILITY INFORMATION

Name of study site: _____

Health provider's name: _____

Date: _____

INTRAPERSONAL FACTORS

SOCIO-DEMOGRAPHIC *(collect information from ANC or ask patient if information is not in the card)*

1. Age (yrs): _____ 2. Parity _____

3. Level of education: ☐Some primary ☐Completed primary ☐Some secondary ☐ Completed secondary ☐ Tertiary ☐Never went to school

4. Employment status: ☐Professional ☐Semi-skilled ☐Self Employed ☐Not Employed

5. Religion: ☐Catholic ☐Muslim ☐Traditionalist ☐Pentecostal ☐Protestant ☐Seventh Day Adventist ☐Zionist ☐None ☐Other (specify)_____

6. Place of residence: _____

DISEASE/CLINICAL INFORMATION *(collect information from ANC or ask patient if information is not in the card)*

7. Date tested HIV positive: _____ 8. Date blood for baseline CD4 collected: _____

9. Date baseline CD4 results received: _____ 10. Baseline CD4 Count Result: _____

11. Gestational Age at HIV Diagnosis (wk)_____

12. WHO clinical stage ☐ I ☐II ☐III ☐IV

13. Was client referred for HAART initiation? ☐Yes ☐No ☐HAART available on site

14. HAART initiated? ☐Yes ☐No

15. Date HAART initiated (if yes to 14) _____

16. If HAART not initiated, ask client to explain what happened for her to end up not initiating HAART

.....
.....
.....
.....
.....

PERCEPTIONS ON ARVs *(ask from patient and tick appropriately)*

We will now ask you some questions about your perceptions on ARVs. Please rate the degree to which each statement is true to you.

No.	Statement	Strongly Agree	Agree	Uncertain	Disagree	Strongly disagree
Perceptions on benefits of ART						
17	ART makes one feel better/stop being sick					
18	ART makes one to be happier					
19	ART makes a person to be able to take care of my family					
20	If a person does not start ART he/she will die					
21	ART will protect a baby in the womb from getting HIV					
Perceptions on harms of/difficulties with ARVs						
22	ART makes a person feel sick					
23	If a person does not have enough food, they cannot start taking ART					
24	ART is bad					
25	If a person starts ART they will die					
26	It is difficult for one to take the ARVs for the rest of my life					
Perceptions on need for ART						
27	I do not want to take any medicine					
28	If a person is not yet sick, there is no need for them to start ART					
29	It would be better to take traditional medicine than ART					
30	I do not understand why I need ART					
Fear of stigma and discrimination						
31	If a person starts ART people will not like him/her					
32	I am afraid to go to the clinic for ART					
33	My family doesn't want me to start ART					
34	I am afraid of being stigmatized if I start ART					

Adapted from Fox PM et al. Barriers to initiation of antiretroviral treatment in rural and urban areas of Zambia: a cross-sectional study of cost, stigma, and perceptions about ART. Journal of the International AIDS Society 2010;13(8):1-11

INTERPERSONAL FACTORS

(Ask from patient)

35. Have you disclosed your HIV Status? ☐No ☐Yes *(specify to who?)*_____

36. Are you a member of a support group? ☐No ☐Yes

37. Does your religion support use of ARVs? ☐No ☐Yes ☐ I don't know

38. Who did you have to consult to make a decision to start ART?

☐Your Father/mother	☐Husband
☐Pastor	☐Friend(s)
☐Your husband's family	☐PLWHA volunteer/counsellor
☐Children	☐Siblings
☐No One	☐Other (specify) _____

39. Do you know the HIV status of your partner? ☐Yes ☐No

40. Does your partner know your HIV status? ☐Yes ☐No

41. Was your partner supportive when you told him your need to take ARVs? ☐Yes ☐No

---

ORGANIZATIONAL FACTORS

(Ask from patient)

42. At which facility did you receive your ANC services? _____

43. How do you get to the ANC facility?

☐ Walk	☐ By bus/commuter omnibus
☐ Bicycle	☐ Taxi
☐ My own car	☐ Other *(specify)* _____

44. How far is the ANC clinic from your home?

☐ Less than 5km	☐ 5-10km	☐ 10-20km
☐ 20-30km	☐ 30-50km	☐ more than 50km

45. How much do you use to get to the ANC clinic? *(In Emalangeni)*_____

46. Which facility did you receive/were referred/were offered for ART? _____

47. How do you get to the ART clinic?

☐ Walk	☐ By bus/commuter omnibus
☐ Bicycle	☐ Taxi
☐ My own car	☐ Other *(specify)* _____

48. How far is the ART clinic from your home?

☐ Less than 5km	☐ 5-10km	☐ 10-20km
☐ 20-30km	☐ 30-50km	☐ more than 50km

49. How much do you use to get to the ART clinic? *(In Emalangeni)*_____

Please rate the degree to which each statement is true to you.

No.	Statement	Strongly Agree	Agree	Uncertain	Disagree	Strongly disagree
50	It is very difficult to get to the ANC clinic					
51	I can't leave my work to go to the ANC clinic					
52	I do not have time to go to the ANC clinic					
53	The ANC clinic is too far for me to travel to					
54	It is very difficult to get to the ART clinic					
55	I can't leave my work to go to the ART clinic					
56	I do not have time to go to the ART clinic					
57	The ART clinic is too far for me to travel to					
58	The fact that I had to be referred to another clinic for ART prevented me from starting the ART					

We will now ask you some questions about your experience of the clinic visits during pregnancy and the relationships with your healthcare providers at the ANC clinic. Based on your experience of the clinic visits during pregnancy, please rate the degree to which each statement is true for you

No.	Statement	Always	Most times	Sometimes	Never	No experience
The clinic staff/health care providers:						
59	Listened to me					
60	Cared about me					
61	Answered my questions					
62	Spent enough time with me					
63	Respected my choices					
64	Helped to solve my problems					
65	Talked to me about my problems					
66	Explained to me what choices I had					
67	Treated me with respect					
68	Supported my decisions					
69	Made me wait too long					
70	Referred me to the right people if they could not help me					
71	Spoke to me rudely					
72	Scared me so I did not speak to them about my problems					

Adapted from the questionnaire on patient satisfaction developed by the research team of Mother and Child Health Unit of the MRC, South Africa

End of questionnaire: Thank client for their time and cooperation