

**ACCEPTANCE OF AND ADHERENCE TO FULL ANTI-RETROVIRAL
THERAPY FOR PREVENTION OF MOTHER TO CHILD TRANSMISSION IN
HIV INFECTED PREGNANT WOMEN WITH CD4 COUNT ABOVE 350 AT
NHLANGANO HEALTH CENTRE, SWAZILAND.**

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Declaration:

I, **Dr Manighuli Kambasu Ndakit** the undersigned, hereby declare that the work contained in this assignment is my original work and that I have not previously submitted it, in its entirety or in part, at any university for a degree. I also declare that ethical approval of the study was obtained from the Health Research Ethics Committee of Stellenbosch University (Reference number: S13/08/152).

Signature:

Date:

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ACRONYMS

AIDS:	Acquired Immune Deficiency Syndrome
ANC:	Antenatal Care
ART:	Anti-Retroviral Therapy
ARV:	Anti-Retroviral
FP:	Family Planning
H AART:	Highly Active Anti-Retroviral Treatment
HIV:	Human Immunodeficiency Virus
MSF:	Medecins Sans Frontiers
MTCT:	Mother to Child Transmission
NHC:	Nhlangano Health Centre
OVC:	Orphaned and Vulnerable Children
PMTCT:	Prevention of Mother to Child Transmission of HIV
STIs:	Sexually Transmitted Infections
TB:	Tuberculosis
WHO:	World Health Organisation

PROJECT TITLE

Acceptance of and adherence to full anti-retroviral therapy for prevention of mother to child transmission in HIV infected pregnant women with CD4 count above 350 at Nhlanguano Health Centre, Swaziland.

ABSTRACT

Epidemic of HIV infection is hitting Swaziland where the prevalence is among the highest in the world. Nhlanguano Health Centre (NHC) in collaboration with Medecins Sans Frontiers Switzerland (MSF Switzerland) opted to hit early by starting Highly Active Anti-retroviral Therapy (HAART) among HIV infected pregnant women with CD4 count cells above 350. This new intervention raised concerns on acceptability and adherence which needed to be assessed.

Study design:

This was a descriptive study which explored the acceptance of and adherence of pregnant women to full anti-retroviral therapy at Nhlanguano Health Centre in the period from 24th June 2014 to 23rd June 2015. The level of adherence was assessed by announced pill counts on subsequent visits. Then, 6 months after initiation, the viral load and a second CD4 count were determined.

Results:

98 participants were recruited and initiated; one later died. 80.6% resided in the rural area. 80.6% attended secondary school. Majority were single (79.6%). Mean age was 25.4 years. 64.3% booked at 2nd trimester. Most were multiparous (75.5%). Mean haemoglobin was 11.1g/dl. After 6 months, mean CD4 count was 709.4 up from 554.4 (initial) and 66 (95.6%) had undetectable viral load risen from 14 (20.2%) at initiation. 69 participants (70.4%) were adherent to treatment; 3 (3.1%) of them failed to suppress completely the viral loads. 13 pregnant women refused HAART; of these 12 were interviewed and one declined. The rate of acceptance was 88.3%.

Conclusion:

Most of the HIV infected pregnant women who visited the clinic accepted the treatment, their CD4 count increased and had undetectable viral loads after 6 months. Anti-retroviral therapy is effective and can be successfully initiated in pregnant women with CD4 count above 350 but should be monitored closely to avoid loss to follow-up.

INTRODUCTION

Highly active antiretroviral therapy (HAART) has dramatically changed HIV-related morbidity and mortality and has improved the quality of life of HIV-infected individuals. Of recent, a lot of effort is being put in to expand access to HIV treatment in resource-limited settings.¹

Swaziland is a developing sub-Saharan country with limited medical resources. In 2009, it had the highest adult HIV prevalence in the world. An estimated 25.9% (24.9% - 27%) of people in the country were living with HIV. Nationally, all women have heard about HIV but only 59% of women and 55% of men have a comprehensive knowledge about HIV prevention according to the final report of multiple indicator cluster survey MICS, 2010. In 2007, Swaziland had 56, 000 orphans (aged 0 - 17) as a result of AIDS.²

A majority of pregnant women living with HIV in the world are from sub-Saharan Africa; an estimated 68% of them received antiretroviral therapy prophylaxis during pregnancy and delivery in 2013.³ Nationally, the proportion of Orphaned and Vulnerable Children (OVC) is 45%, 24% are single or double orphans and the prevalence of orphaned underage with at least one dead parent is 26.6%.⁴ This constitutes a social burden for the extended family, which has the traditional responsibility to care for orphans.

The challenges associated with effective prevention of mother-to-child transmission of HIV (PMTCT) and measuring its impact are numerous and multi-factorial³. It is well known that most of HIV infected infants in Africa acquire the disease from their mothers during pregnancy, at the time of delivery or post-natal through breast-feeding and the risk of transmission for a child born to an HIV infected mother without PMTCT interventions is high. In South Africa, with 5.6 million people living with HIV, 330 000 of these were paediatric infections largely due to mother to child transmission. Out of 38 000 as at mid-2006; 26 000 subsequently got HIV-infected through breast-feeding.⁵ Routine testing is a crucial step and precedes initiation of ART. The objective is to achieve universal access to focused antenatal health care and also promote healthy neonatal and maternal outcomes.³ In the mother to child HIV prevention care, pregnant women also face challenges like fears of knowing one's own HIV status, infant feeding distribution, stigma, discrimination, lack of male partners' support and negative attitude of health workers.⁶

Furthermore, in Uganda, most pregnant women emphasized the importance of their partners in decision making and the access of antiretroviral therapy.⁷

Between 2000 and 2009, there was a 24% reduction in the estimated annual number of new child infections in 25 African countries of which about one third occurred in 2009 alone by providing PMTCT interventions⁸. Antiretroviral therapy (ART) has saved many lives by transforming HIV infection from a fatal into a chronic disease⁹.

Currently, a short course of antiretroviral therapy is being offered by all ANC government services in Swaziland.

Despite availability of free antiretroviral therapy, in Malawi, they noted a progressive loss to follow up of HIV infected women by the postnatal visits which challenged the PMTC programme¹⁰. Good adherence to treatment reduces the risk of mother to child transmission.

ART has been proven safe and effective in reducing rates of MTCT by providing maternal viral suppression and decreasing infant mortality.^{11,12}

Furthermore, more than 6 in 10 pregnant HIV positive women with CD4 cell count of $> 350/\text{mm}^3$ may require triple antiretroviral for prophylaxis of MTCT¹³

Two basic approaches to the use of ART for PMTCT are recommended in government health institutions; HAART and ART prophylaxis. HAART is for HIV positive pregnant women in need of treatment; their CD4 count is below 350 or in stage 3 or in stage 4 by WHO clinical stage. Whereas, ART Prophylaxis is for those who don't need the treatment for their own health; it's a short course of anti-retroviral therapy given from 14 weeks of gestation or as soon as possible thereafter.

Mother-to-child transmission (MTCT) is estimated to be the cause of at least 90% of paediatric HIV infections. WHO guidelines for the prevention of perinatal transmission in low-resource settings recommend using HAART for pregnant women in need of ART for their own health¹⁴. In 2013, a new regimen in our program of prevention of mother to child HIV transmission (MTCT) in collaboration with MSF was launched in NHC in Swaziland where all pregnant women found positive despite their CD4 count cells level will be started on lifelong triple therapy (TDF-3TC-EFV) and 6 weeks of nevirapine will be given to the baby. This regimen reduces the number of women eligible for ART who don't receive ART, avoids the use of nevirapine for a long period and protects infants from an early stage. Concerns over acceptance of initiation and adherence are being portrayed in healthy pregnant women with high CD4 count¹⁵.

Adherence to ART is critical for achieving therapeutic success in the treatment of HIV infection. There is no widely acceptable professional consensus for measuring adherence. Several methods have been used with varying success. The indirect methods of self-report and pill counts are quick and inexpensive¹⁶

Aim

The aim of this study was to explore the acceptability of and adherence to full antiretroviral therapy to HIV infected pregnant women with high CD4 count cells in order to prevent mother-to-child transmission.

Objectives

To assess the acceptance level of HAART among pregnant women with CD4 count above 350 in NHC

To assess the adherence level of HAART among pregnant women with CD4 count above 350 in NHC

To find and list the main reasons for refusal of full antiretroviral therapy among pregnant women with CD4 count above 350.

METHODS

Study design

This was a prospective observational cohort study carried out in the period from 24th June, 2014 to 23rd June, 2015.

Setting

Swaziland is a small country located in south east Africa with Mozambique to the east and South Africa on all other borders. The total land area is 17 364.50km² with a population of 1 018 449 people who primarily reside in rural areas.¹⁷ The birth rate is 3.7 and HIV prevalence is 26%. Nationally, 80% of deliveries occur in health facilities and 82 per cent of pregnant women are delivered babies with the assistance of skilled personnel.

The health care programmes in Swaziland are co-ordinated at the central level by the ministry of health and at regional level by the Regional health management team. The government health care system is divided into 3 levels

namely clinics, the first level of primary healthcare, health centres (HC) and public health units, the second level and hospitals, the last level.

The country is divided into 4 administrative regions which include Shiselweni in the South. The main town in the Shiselweni region is Nhlango. The study was conducted in Nhlango Health Centre where I am a practising doctor.

It is a health centre 35km away from the regional referral hospital with 70 beds. It has a maternity ward with 700 deliveries per annum, female/male ward, children ward, and outpatient department, TB/MDR ward and a public health unit which runs immunizations, family planning (FP), antenatal and postnatal care activities.

The health centre also serves as a secondary referral centre for 7 clinics in this region and has been very helpful to the community of Nhlango and surroundings. The catchment area of the centre is estimated at 1,558 square km for a population of 9 017.

Study population

It was a restricted population with only ART-naive HIV-infected pregnant women with CD4 count above 350 seen at the public health unit of NHC.

The sample population was of those who attended the ante-natal clinic between 24th June 2014 and 23rd June 2015; a time period of one year. In this period, 277 HIV infected pregnant women with CD4 count above 350 were seen; 111 (40.1%) met the inclusion criteria. The 111 pregnant women who met the criteria were approached to participate in the study; 98 accepted and 13 declined.

Inclusion criteria: ART-naive HIV infected pregnant women with CD4 count above 350.

Exclusion criteria: Women already on HAART with CD4 count above 350 who fell pregnant. Women who took short course of antiretroviral prophylaxis during their previous pregnancy. Women who had renal failure and CD4 count above 350.

Data collection

All pregnant women who agreed to test after counselling were screened for HIV antibodies. When a positive result was confirmed after the screening test, a CD4 count, a liver function test (ALT and AST) and a renal function test (Creatinine and Urea) were requested by the nurses at the NHC. Thereafter,

the nurses at NHC initiated HAART or ART prophylaxis. All those who had an initial CD4 count above 350 and with no renal failure were approached for their consent to participate in this research. Thereafter, the patient was expected to visit the clinic on a monthly basis up to 6 months after initiation. The patients were tested for CD4 count at baseline and 6 months, viral load at baseline and 6 months, full blood count at baseline, one month and 6 months, both liver function tests and renal function tests at baseline, one month, 3 months and 6 months. During the study, adherence was assessed on the basis of announced pill count on the monthly review visit days. At 6 months after initiation, all the participants in the study were tested for viral load and CD4 count to evaluate their adherence level. All the costs for the tests were borne by MSF and government.

Socio-economic and demographic data was collected at baseline; on the date of treatment initiation. Data required for the study such as viral load and CD4 count was routinely collected during the regular ante-natal and post-natal visits. So, at the end of the study, routine data from ANC, post-natal, ART and laboratory registers was reviewed. At the end of the day, the number of patients attended to was equal to the number of files which appeared and the details of therapy were counter-checked by nurses in the patient files and the ART register to avoid omissions and disparities. The researcher cross-checked this on a monthly basis; this was to ensure that the cross-checking which was done by nurses was accurate and up to expectations.

Patients who refused on the offer of HAART were interviewed by nurses who had been trained prior to research initiation; to ensure standardisation. A structured interviewer administered questionnaire was completed.

The questionnaire had two parts. The first part had questions on socio-economic and demographic factors like age, marital status, education level, religion and employment status; to be completed for all participants. The second part had a series of open-ended questions categorised according to PMTCT programme knowledge, counselling experience, barriers to participation in the PMTCT programme and possible ways to overcome them.

Data analysis

The analysis focused on evaluation of the acceptance and adherence level to the medication based on announced pill counts. Individual adherence level was evaluated in the manner indicated below (Table 1).

Table1: Adherence level by percentage.

Category	%
Missed one day	95
Missed 3 days	90
Missed one week	80
Missed 10 days	70
Missed 2 weeks	50
Missed 3 weeks	20

Analysis between viral load results, progression of CD4 count results and reported adherence level was done and summary statistics were reported as frequencies and percentages. Total adherence to ARV regimen increases CD4 count and suboptimal adherence leads to incomplete viral suppression and delays immune recovery. A significant drop in viral load and a substantial increase in CD4 count were and are associated with a high level of adherence.

The reasons given by patients for refusal of HAART were categorised and tabulated.

The patients who refused HAART underwent individual semi-structured interviews which were recorded in siswati. The interviews were transcribed and translated into English. Due to the need for confidentiality, no names were used. The transcripts were re-read and coded. The codes were manually sorted into categories using cells in MS excel and the main themes emerged.

Ethical considerations

This study obtained the permission of Health Research Ethics Committee of Stellenbosch University (Ethics reference number S13/08/152) and the Swaziland Ethics Committee (MH/599C/FWA0001526). Informed consent was given prior to participation.

RESULTS

Patients' characteristics

A total of 98 ART-naive HIV-infected pregnant women were recruited and followed up for 6 months between 24th June, 2014 and 23rd June, 2015. 78 (79.6%) of the participants were single and 20 (20.4%) were married (Table 5). Most of the effected pregnant women were Christians 96 (98%), only 2% were not Christians (Table 6). Their other socioeconomic and demographic factors such as age, education level, employment status are detailed below.

Residence

Nhlangano (NHO) is composed of NHO CBD and urban residential areas administered by NHO town council (Figure 1) and 14 Tinkhundla (surrounding areas); Zombodze, Maseyisini, Sigwe, Mtsambama, Shiselweni 1, Shiselweni 2, Hosea, Sandleni, Kubuta, Matsanjeni, Gege, Ngudzeni, Nkwene and Somtongo administered by the traditional government.

The map below shows the position of Nhlangano town and its surrounding rural and hinterland with boundaries: Gege, Mahamba, Mhlosheni and Hlathikhulu.



Figure 1: Shiselweni Region

Source: Swaziland's Official Tourist Guide 2013/4 (Swaziland Discovery)

Table 2 : Percentage distribution of participants by residence.

Residence	Frequency	Percentage (%)
NHO Town	19	19.4
Maseyisini	42	42.9
Shiselweni1	3	3.1
Shiselweni2	22	22.4
Zombodze	8	8.2
Hosea	1	1
Sandleni	1	1
Matsanjeni	1	1
Other region(Manzini)	1	1
Total	98	100

Most of the infected pregnant women reside outside NHO town; in the rural areas (81.6%). Only 19.4% reside in NHO residential areas (Table 2).

Employment

Table 3 : Percentage distribution of participants by status of employment.

Status of employment	Frequency	Percentage (%)
Unemployment	47	48
Employment	51	52
Total	98	100

Nhlangano is a semi-urban area offering employment mainly in textile firms. Of the 51 (52.0%) employed (Table 3), 39 (76.5%) were employed in the textile firms (machinists, dressmakers and trimmers), 9 (17.6%) were employed as either labourers or housekeepers, the rest (5.9%) were: one cashier, one police officer and one self-employed in a small-scale business. Apart from the police officer, the rest were employed in low income earning jobs. Female unemployment rate in Swaziland is 25.60% (World Bank, 2013).¹⁸

Education

Table 4 : Percentage distribution by level of education.

Level of education	Frequency	Percentage (%)
None	1	1
Primary school	13	13.3
Secondary School	79	80.6
Tertiary	5	5.1
Total	98	100

The majority of the infected pregnant women had at least attended secondary school (85.7%).¹⁹ Only 1% never attended school. The transition rate to secondary school of 85.5% is reported for Swaziland (Swaziland Multiple Indicator Cluster Survey 2014).²⁰

Marital Status

Table 5 : Percentage distribution by marital status.

Marital status	Frequency	Percentage (%)
Single	78	79.6
Married	20	20.4
Total	98	100

Religion

Table 6 : Percentage distribution by religion.

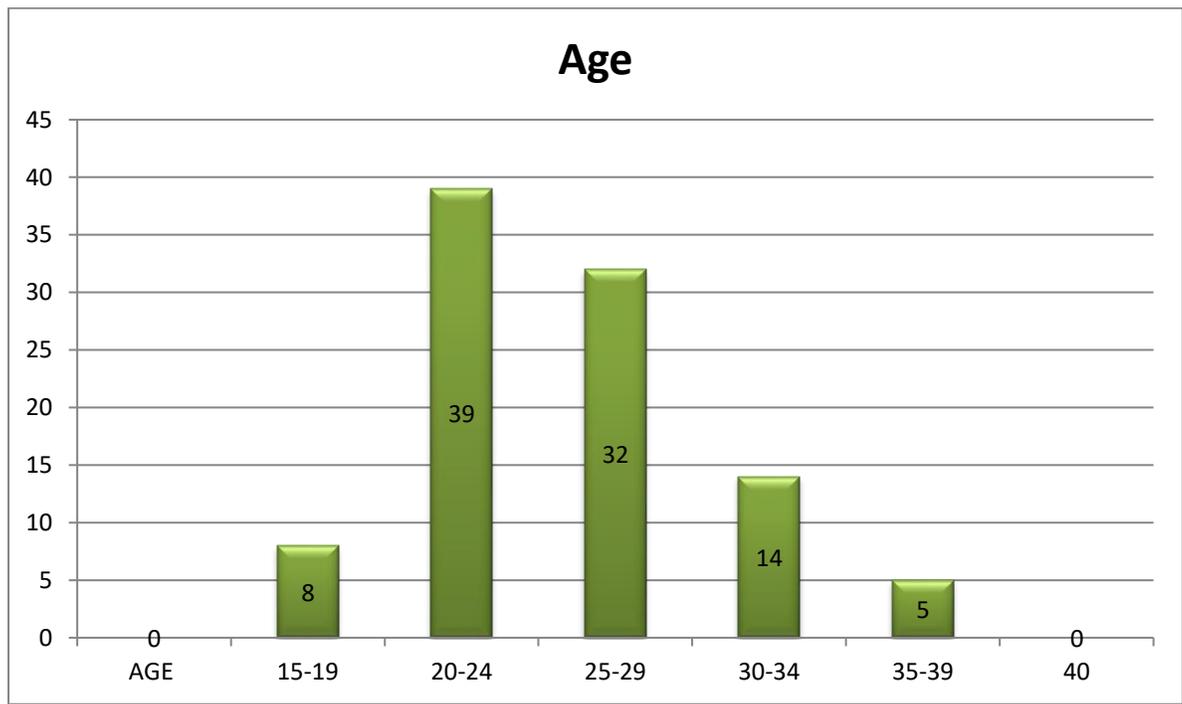
Religion	Frequency	Percentage
Christian	96	98
Non-Christian	2	2
Total	98	100

Age

The 98 infected pregnant women had ages ranging from 17 to 38 years with a mean age of 25.4 years. The majority of the infected pregnant women fell in this age bracket so most interventions should be focused on this group. This age group needs more close follow up during prevention.

Table 7 : Percentage distribution by age.

Age	Frequency	Percentage (%)
15-19	8	8.1
20-24	39	39.8
25-29	32	32.7
30-34	14	14.3
35-39	5	5.1
≥40	0	0
Total	98	100

**Figure 2** : Proportion of participants by age

Gestational age at presentation at NHC

Table 8 : Percentage distribution by gestational age.

Trimester	Frequency	Percentage
First trimester	9	9.2
Second trimester	63	64.3
Third trimester	26	26.3
Total	98	100

63 (64.3%) of infected pregnant women had the first visit during the second trimester. Only 9.2% attended in their first trimester (Table 8). This is in accordance with WHO Survey data from sub-Saharan Africa which indicated that women initiated antenatal care after the first trimester despite the guideline of Swazi Ministry of Health which advises to start ANC as soon as the woman knows that she is pregnant^{21,22}.

Gravidity

Table 9 : Percentage distribution of participants by gravidity.

Gravidity	Frequency	Percentage (%)
1	21	21.4
2-4	74	75.5
≥5	3	3.1
Total	98	100

Most of the participants were multiparous 77(78.6%). Parity and past pregnancy experiences affect ANC initiation. In general, multiparous women attend ANC later compared to primigravida 21(21.4%). Multiparous tend to delay ANC initiation to avoid multiple clinic visits.

Haemoglobin

Table 10 : Percentage distribution by haemoglobin level.

Haemoglobin	Frequency	Percentage
>11 g/dl	59	60.2
10.0-10.9 g/dl	17	17.3
7.0- 9.9 g/dl	22	22.5
<7.0 g/dl	0	0
Total	98	100

Anaemia in pregnancy is defined as haemoglobin reading below 7.0 g/dl (grams per decilitre). According to the World Health Organization, anaemia is classified as mild (10.0-10.9g/d), moderate (7.0-9.9g/dl) and severe (less than 7 g/dl).

The haemoglobin of the participants varied between 7g/dl and 15.2g/dl with an estimated mean haemoglobin of 11.1 g/dl. 39(39.8%) were anaemic but no one had severe anaemia. This might have given them a false impression that they were well.

Follow up visits

Attendance

Table 11 : Attendance of participants.

	Attendance
At initiation	98
First month after initiation	79
Six months later	69

One month after initiation 79 (80.6%) participants attended the first appointment, 19 (19.4%) didn't. Six months later:

- 69 (70.4%) infected pregnant women were still in attendance for refill monthly. Pill counts were conducted at each visit (Table 11).
- 29 (29.6%) were not. Of these, 16 (16.3%) never completed the 6 monthly visits (loss to follow up), 12 (12.2%) patients were referred (3 formally, 9 self-referred to other facilities) and 1 (1.0%) patient died.

All of the remaining 69 (70.4%) were adherent; adherence level was above 95%

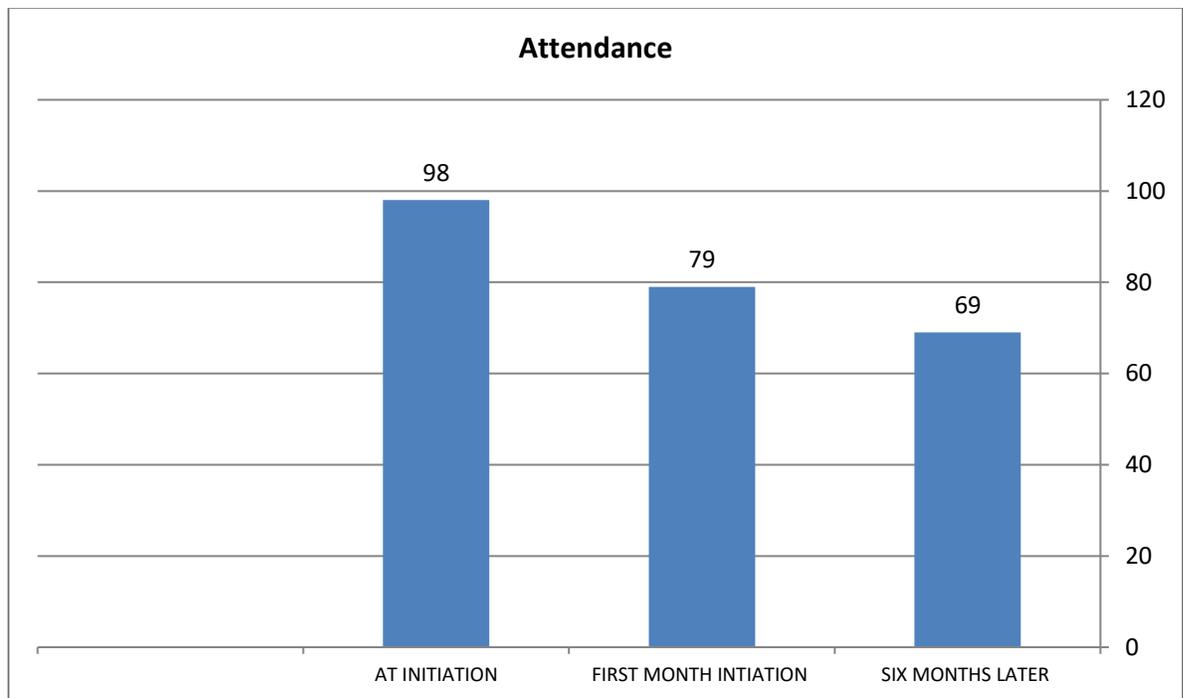


Figure 3 : Proportion distribution by attendance.

CD4 Count

The initial mean CD4 Count of adherent pregnant women was 554.4. After 6 months, the mean CD4 Count was 709.4.

Viral load

Viral load is undetectable if viral load is equal to or less than 100 copies per ml.

Table 12 : Comparison of viral load; at base and final of the 69 adherent pregnant women.

	Detectable Viral Load	Undetectable Viral load
Initial	55	14
After 6 months	3	66

At initiation, of the 69 adherent pregnant women, 14 (20.2%) had undetectable viral load and 55 (79.8%) had detectable viral load. After 6 months, 66 (95.6%) of the adherent pregnant women had undetectable viral load; 3 (4.4%) had detectable viral load (Table12).

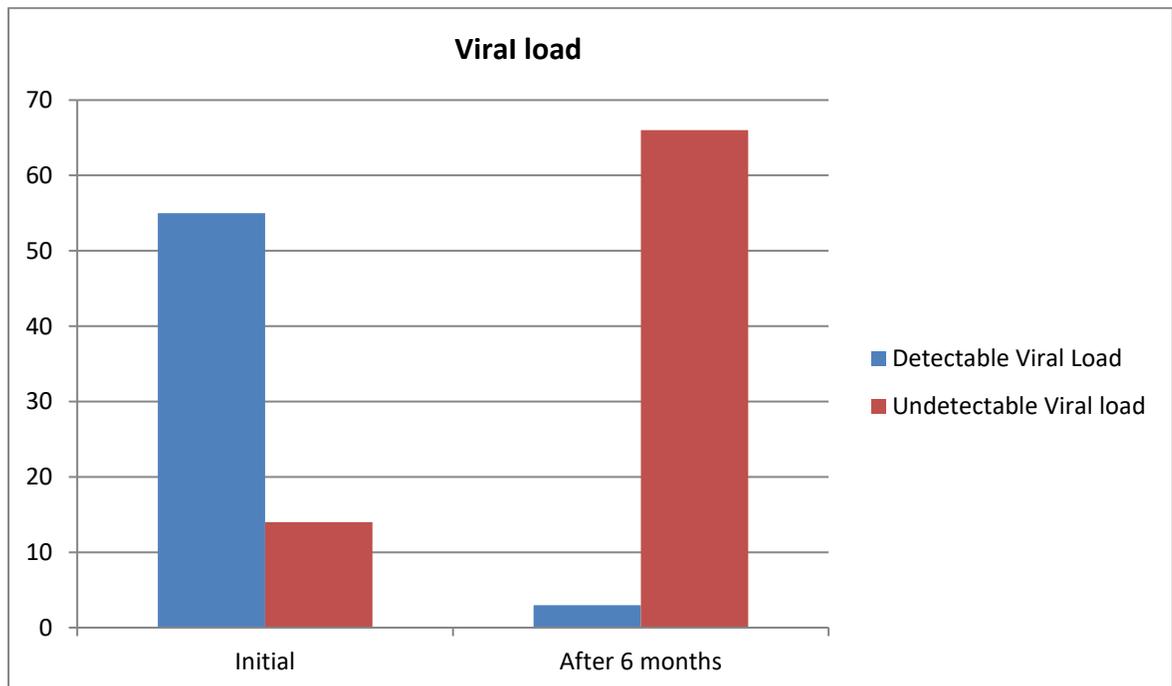


Figure 4 : Comparison of viral load at baseline and after 6 months for the 69 adherent pregnant women.

Acceptance rate

In our study, 98 participants agreed to be on HAART and were initiated. 13 pregnant women refused the treatment; 12 of these were interviewed and one declined. The rate of acceptance was 88.3 %.

Reasons for refusal

Characteristics of respondents

They had similar characteristics to the group that had accepted treatment. Their ages ranged between 18-35 years. Most of them were single and Christians. They had limited education as none had completed high school. They were also unemployed; dependent on partners and family for financial support. A number of the women were familiar with the ANC services as they had in the past repeatedly visited the health facility to seek ANC services. One of the respondents had been living with HIV for 11 years, but still refused to enroll on ART for PMTCT.

"In 2004, I was told I had it (HIV virus). I had just come to get tested (001)".

Knowledge on HIV transmission and treatment (care)

HIV transmission

A number of respondents said that HIV was transmitted through intercourse. A few went further to specify that it was transmitted through sexual intercourse with an infected person.

"I know that it is transmitted through sexual intercourse. Having intercourse with someone who already has it (001)"

"Getting into bed...sex...when the fluids mix and one of them is positive (010)".

"By having intercourse and by...what can I say...through blood (012). "

Another factor that was mentioned was touching someone else's blood who is hurt or bleeding with unprotected hands.

"When you touch someone else's blood, an injured and bleeding person; touching the person with bare hands (010)".

Mother to child transmission (MTC)

The most prominently discussed modes of HIV transmission from mother to child are during delivery and breast feeding. Of note is that these factors were only mentioned when specifically probed on mother to child HIV transmission.

“When he is being delivered...or when breast feeding...or giving complimentary feeding. It’s that... when the baby gets hurt while still trying to breast feed. And then...he (baby) gets infected (001)”.

The women displayed lack of understanding of HIV transmission from mother to child during pregnancy.

“While pregnant, I think the baby gets infected when not using a condom (001) “

Importance and benefits of ART/PMTCT

Most of the women reported that they didn’t know the importance and benefits of ART when pregnant or lactating. However, the benefits that were mentioned included the ability of ART to suppress viral load.

“No. I don’t. I know that it (HIV) is curable, not curable but it is suppress pills are taken (011)”.

“They help me in that they prevent me from infecting the child with the virus. From the time they are in the womb till I give birth (004)”.

“When taking the pills... the soldiers (CD4 count) increase (006)”.

“I benefit in the sense that he (baby) might come out negative and I will live, secondly, you find that you die because of not taking the pills or not (sound of opening door) getting the right treatment (009)”.

Lack of counseling on ART

A majority of the women indicated that they had received no counselling or received little counselling on ART. The ones who indicated to have received counselling said they were only told that enrolling on ART will protect the baby from being infected with HIV. A few mentioned having been told about the importance of adhering to taking ARVs at the same time every day lest they become resistant and also the importance of eating healthy.

“They never explained much to me, they just said that I should go take pills and I refused to take them, I just refused, (silence). I refused. They never said much to me (010)”.

“From South Africa, I had gone for check-ups. They wrote the pills in the card. They said they are for protecting the baby. My CD4 was still ok (004)”.

“Yes. I asked them in the caravan since we were in a caravan, why my CD4 has increased in the period and I never got any response. They then said they can’t deal with me because of the questions that I ask. Ok...I let go just like that. I then asked them (health workers) at what level should the CD4 be to be considered to be at a healthy state and I was not answered on that one. They never answered me. I then listened to the AIDS programmes from radios where they mentioned that some people have a low CD4 count and others have a high CD4count (001)”.

Barriers to ART uptake

Fear of side effects

Another barrier that was raised by the women was fear of ART side effects and these were issues which they had heard from other people such as relatives. The most cited side effect was not feeling well or getting sicker when taking ART.

“There are some instances where people say that sometimes one can be requested to change (switch) them. I have a cousin who tried to switch them and got sick; sickness re-occurred until she was bedridden (002)”.

“In general, the pills make one feel not well all the time (002)”.

“Some people, I hear, say that the pills make them more sick (002)”.

“They say it doesn’t treat others well, you find that when they take it, they throw-up (009)”.

Use of alternative traditional medicine

Some of the women didn’t enroll on ART because they were taking traditional medicine (*Timbita*) which they believe functions in a similar way as ART.

“I think that it will help in general; in the same way that the pills do (002)”.

“I was going to talk to my partner first. He told me that there was some traditional brew that he was going to give me so I shouldn’t take them (pills) (004)”.

"I am not refusing it's just that I live with people and they are still taking me to places with this sickness that I have. I don't know if it will work well with the pills, because they (family) are taking me places. (012)".

Challenges in accepting HIV Status

There was also evidence that some of the women refused enrolling on ART because they were struggling to accept their HIV status; some still needed to confirm if they were HIV positive.

"In fact I still want to be sure ...from here...I will go back to test. If I still get the same result then I will take them (001)".

Seeking approval from spouses and other relatives

Other women cited that they needed to go home and inform their partners or any other relatives first for approval. The other relatives were usually their mothers' in law and grandmothers.

"I was going to talk to my partner first. ...he told me that there was some traditional brew that he was going to give me I shouldn't take them (004)".

"I want to go and tell them at home...My Grandmother (005)."

DISCUSSIONS

At Nhlngano public health Unit, HIV-infected pregnant woman are initiated the same day of booking. 64.3% HIV-infected pregnant women in our study population were booked and initiated during the second trimester. Most were single (79.6%), multiparous (75.5%) and attended secondary school (80.6%). The mean age was 25.4 years and 52% were employed. These findings are similar to antenatal care studies which were carried out in Nigeria²³, Cape Town²⁴ and Uganda²⁵ where a large proportion of pregnant women in a similar age-group booked after the first trimester.

In countries with a high prevalence of HIV infection, there is need for early booking of antenatal care; as soon as the woman knows that she is pregnant. This is of paramount importance and should be emphasized for early initiation so as to increase the duration of antiretroviral therapy given before delivery in order to reduce further maternofetal HIV transmission.

69 participants (70.4%) were adherent to treatment. This result is similar to the studies conducted in Ivory coast²⁶ and India²⁷ which revealed 74.3% and 73% respectively among HIV-infected patients; both with a reported adherence level of $\geq 95\%$.

The regimen TDF-3TC-EFZ is effective. It increased the mean CD4 Count from 554 to 709 with 95.6% of adherent participants in our study having undetectable viral load after 6 months. Studies over the effectiveness of highly active antiretroviral therapy among adults conducted in India²¹, sub-Saharan Africa²⁸, a developing Caribbean country²⁹ and Uganda³⁰, mentioned viral suppression of 63.5 %, 78%, 82% and 85.2% respectively after 6 months.

Also, some studies in a developing caribbean country²⁹ and Uganda^{30, 31} have indicated increment / improvement in CD4 count.

Poor knowledge on HIV transmission, mother-to-child transmission and treatment, lack of effective counseling on ART, fear of side effects, use of alternative traditional medicine, challenges in accepting HIV status, seeking approval from spouses and other relatives are emerging themes for refusal of being initiated for treatment among HIV-infected pregnant women. These motives for refusal of initiation among HIV-infected pregnant women were also revealed in studies conducted in Zambia^{32, 33}, Malawi³⁴ and in Sub-sahara³⁵.

This study reveals and gives an indication of acceptance level, short term adherence and proportion of defaulter to the combined antiretroviral therapy among initiated HIV-infected pregnant women. It has also highlighted that good adherence is required for viral suppression.

Furthermore, it gives us a better understanding of reasons for declining offers of initiation among HIV-infected pregnant women. Those findings can be transferred to similar context.

This study has its limitations. We had a small size of patients. This may raise doubts if it's used to generalize the findings. Some of the loss to follow-up patients could not be reached telephonically (either changed phone numbers or left the region). We couldn't get more information. Quality of counseling before initiation was not explored so as to improve acceptance level. Our Viral load machine was only able to detect more than 100 copies although the chance of resistance to occur below this level in our setting is low. Our study only included treatment of naive patients. These results cannot, however, be extrapolated to treatment of experienced patients to nevirapine or AZT-3TC.

RECOMMENDATIONS

ANC initiation for all HIV-infected pregnant women should be treated as medically urgent. According to Swaziland and integrated HIV management guidelines (2015) and WHO (2010), every pregnant mother should start ANC during the first trimester of pregnancy.^{21,22} In the study, 63.9% booked at 2nd trimester. Programmes to improve health awareness and public enlightenment on right time for ANC enrolment should be implemented.

To improve the acceptance rate, the Ministry of health should implement programs addressing barriers encountered by the HIV infected pregnant women. Initiatives to reduce prevailing stigma, educate the community on HIV related issues and empower women to take their own decisions should be taken.

To improve patient retention, programs to improve service delivery and confidentiality should be implemented. For instance, pill count and provision of re-fills should be done at the same point by the same nurse. This saves on time and limits exposure on the long lines at the pharmacy and hence stigmatization.

Also, outreach programs should be strengthened. Community health workers should be used to track and provide on-going counseling of the HIV-infected pregnant women starting from the positive diagnosis at antenatal care until after delivery.

Furthermore, to improve the uptake of triple antiretroviral therapy and adherence to treatment, all HIV-infected pregnant women with CD4 Count above 350 should be given a comprehensive initial session of education on HIV, care and their health. Policy makers should strengthen the monitoring system of follow up visits of initiated pregnant women; the system should monitor clinical attendance or clinical appointment and ART adherence. In order to reduce the defaulter rate, there should be continuous adherence counseling and an effective system of tracing (phone calls or home visits).

Before the expansion of option B⁺ programs, the provision of life long ARV treatment to HIV-infected pregnant women, the ministry of Health needs to address the mobility of patients with respect to self-transfers to minimize loss to follow-up.

CONCLUSION

Most of the HIV infected pregnant women who visited the clinic accepted the treatment. After 6 months, more than two-third of the initiated participants were adherent and had undetectable viral loads. Antiretroviral therapy is effective and can be successfully initiated in pregnant women with CD4 count above 350 but should be monitored closely to avoid loss to follow-up. Initiatives to reduce prevailing stigma, empower women and educate the community on HIV related issues should be implemented to realise the full potential of this program.

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List of Appendices

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT: Acceptance of and adherence to full antiretroviral therapy for prevention of mother to child transmission in HIV infected pregnant women with CD4 count above 350 at Nhlangano Health Centre, Swaziland.

PRINCIPAL INVESTIGATOR: DR MANIGHULI KAMBASU NDAKIT

ADDRESS: Nhlangano Health Centre

P.O.BOX 29

Nhlangano

Ngwane Corner Street

S400

Swaziland

CONTACT NUMBER: +26876360461

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff or doctor any questions about any part of this project so that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the **Health Research Ethics Committee at Stellenbosch University (South Africa)** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

Please read this document carefully and sign below if you agree to participate in the study.

Setting, Participants and Responsibility

A selection of Ministry of Health facilities are offering lifelong combined

antiretroviral therapy to all HIV positive pregnant women to prevent transmission of HIV infection from mother to child. This document is to help you understand the difference in your care that you will experience because of this.

CD4 cells are a type of white blood cells that fight infection. CD4 count measures the number of CD4 cells in a sample of your blood; normal between 500 and 1500 cells. Your CD4 count is a measure of the strength of your immune system and indicates the stage of your HIV disease and guides treatment. It also predicts your HIV disease progression; high CD4 count reduces complications of HIV disease and extends your life.

When the CD4 count goes down, it means that HIV disease is progressing and the immune system is weakening and you are likely to fall sick.

According to current national guidelines in Swaziland, if you have been diagnosed HIV positive and you are pregnant, you will be enrolled in the prevention from mother to child transmission (PMTCT) programme. In other health facilities, if your CD4 count is below 350, you would be offered combined anti-retroviral therapy as this provides the best protection for you and your baby. However if your CD4 is above 350, you would not be eligible for combined anti-retroviral therapy but would instead be offered preventive therapy to protect your baby from being infected with HIV. This preventive therapy involves a single anti-retroviral drug (AZT) for the mother during pregnancy, and a single anti-retroviral drug (nevirapine) for the infant until the end of breast feeding.

The purpose of the study is to learn about how HIV positive pregnant women are taking the treatment to prevent HIV transmission to the child, to ensure that the treatment is protecting the baby from HIV.

We recommend all HIV+ pregnant women to start combined anti-retroviral therapy because it has several benefits compared to preventive therapy with AZT. Our duty and your rights regarding your participation are stated below.

Benefits

Benefits of a life-long combined antiretroviral therapy compared to preventive therapy with AZT:

- Treatment with ART regimen is simple and consists of one pill a day for you. Your baby will need to receive nevirapine syrup only for 6 weeks after delivery (compared to up to 18 months with preventive therapy)
- Taking life-long ART reduces the risk of transmitting HIV to your sexual partner, if your partner is not infected with HIV. However, you should continue to use a condom during sexual intercourse for full protection.
- Life-long ART started early in pregnancy might reduce the risk of infant

mortality (death of children less than one year) compared to preventive treatment with AZT, if your CD4 count is above 350.

- ART started early in pregnancy might lower the risk of stillbirths (deaths of babies in the womb), prematurity (pre-term baby births) and maternal mortality (death of expecting mother) compared to preventive treatment with AZT.
- Taking life-long ART reduces the risk of HIV transmission to the child of the next pregnancy.
- The ART regimen provided is not known to cause anaemia (deficiency in quality of red blood cells), whilst preventive treatment with AZT, therapy carries a risk of inducing anaemia.
- The ART regimen provided treats active hepatitis B (liver disease) infection.

By participating to this study, you will benefit from a closer follow-up. Additional tests will be performed to assess HIV infection. CD4 count at the start and 6 months, viral load at the start and 6 months, liver function tests at the start, one month, 3 months, 6 months, renal function at the start, one month, 3 months and 6 months. These tests will assist to identify problems with your treatment earlier.

Risks

Challenges/drawbacks of the life-long ART compared to preventive treatment:

- Combined ART should be a life-long treatment that should preferably not be stopped.
- Nightmares or dizziness may occur during the first two weeks but disappear in most of the cases.
- The ART combination can rarely cause kidney and liver problems. You will be closely monitored in order to detect any problems as early as possible. If signs of toxicity are appearing the treatment will be changed.

If you have any questions about PMTCT, please ask one of the nurses.

Participating in this study does not require any treatment or intervention other than that you would normally undergo in the course of medical care as an HIV infected patient. You will have more regular blood tests; renal function tests, liver function tests, CD4 count test and viral load tests. These tests will have no anticipated negative effects on your health.

Confidentiality

The data collected will remain anonymous, no name and addresses will be collected in the database and neither will be published in articles nor thesis. The personal information will only be accessible to individuals who are directly involved in your treatment (the staff of the health facility). These individuals are all under an oath of professional secrecy. To ensure complete and accurate transfer of your scientifically relevant data, selected researchers from the ministry of health, who are also under the oath of professional secrecy, may compare the collected data with your medical file. The members of the ethics commission may see medical data, but this data will be anonymised. Confidentiality will be strictly maintained during the entire study and beyond.

If you accept to enter the study, your information will be collected and put in a database with no names; it is anonymous. We will collect information about the antenatal care you receive, the birth of your baby, your postnatal care, your HIV follow-up care and information about your child up to 6 weeks after birth. You are eligible to be included in the study because you are attending Nhlanguano Health Centre. Data collection will be carried out predominantly in this centre only. Decision to participate or not in the study will have no influence on the treatment you are offered.

Most of the information required for the study is routinely collected for HIV pregnant women during the ante-natal and post-natal visits. We may ask for your opinion on the treatment you are taking. All information will be kept confidential and used only for purposes of the study.

As mentioned earlier your participation in this study is voluntary. You may withdraw from the study at any time without giving a reason. Your decision will not result in any loss of benefits regarding medical treatment – you will still have access to the full range of normal treatments.

You will be informed of the results of the study through general information provided to health facilities and community leaders.

Further information

You should inform your family practitioner or usual doctor that you are taking part in a research study

You should also inform your medical insurance company that you are participating in a research study

You can contact **Dr Manighuli Ndakit** at **76360461** if you have any further queries or encounter any problems.

You can contact the **Health Research Ethics Committee (South Africa)** at **+27 219 389 207** if you have any concerns or complaints that have not been adequately addressed by your study doctor.

You will receive a copy of this information and consent form for your own records

Declaration by participant

By signing below, Iagree to take part in a research study entitled Acceptance of and adherence to full antiretroviral therapy for prevention of mother to child transmission in HIV infected pregnant women with CD4 count above 350 at Nhlanguano Health Centre, Swaziland.

I declare that:

- I have read or had read to me this information in the consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished if the study doctor or researcher feels it is in my best interests or if I do not follow the study plan as agreed to.

Signed at (place).....on (date).....2014.

Signature of participant

.....

Signature of witness

.....

This is to be signed by patients who refuse the offer of HAART (PMTCT programme).

Consent to an interview.

Iagree to an interview about why I do not want HAART. This is for a research study entitled Acceptance and adherence to full antiretroviral therapy for prevention of mother to child transmission in HIV infected pregnant women with CD4 count above 350 at Nhlngano Health centre, Swaziland.

I declare that:

- I have read or had read to me this information in this consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I refuse the offer of HAART.
- I agree to an interview about why I do not want HAART.
- This is voluntary; I have not been pressurised to take part.

Signed at(place).....on(date).....2014

Signature of participant

Signature of witness

.....

.....

Declaration by investigator

I (name)..... declare that:

- I explained the information in this document to.....
- I encouraged her to ask questions and took adequate time to answer them.

- I am satisfied that he/she adequately understands all aspects of the research as discussed above
- I did/did not use an interpreter.(if an interpreter must sign the declaration below)

Signed at(place).....on(date).....'2014

Signature of investigator

Signature of witness

.....

.....

Declaration by interpreter

I (name).....declare that:

- I assisted the investigator (name).....to explain the information in this document to (name of participant)..... using the language medium of Siswati.
- We encouraged her to ask questions and took adequate time to answer them.
- I am satisfied that the participant fully understands the content of this informed consent document and has had all her questions satisfactorily answered.

Signedat(place).....on(date).....2014

Signature of interpreter

Signature of witness

.....

.....

- Separated
- Divorced
- Widowed

EDUCATION LEVEL

- None
- Primary
- Secondary/High school
- Tertiary/University

PART 2

1. Are you aware about how HIV is transmitted?

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2. Do you know the benefits of taking ARVs while pregnant?

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3. What do you think about the PMTC campaign?

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4. Before being tested, you were counselled? In the counselling process, were all your concerns addressed on PMTCT?

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5. What do you feel about participating in the PMTCT programme?

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6. Why are you not accepting the offer of medication for the rest of your life?

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