Antiretroviral therapy initiation of pregnant women before and during the implementation of Nurse Initiated and Management of Antiretroviral Therapy in eThekwini District Community Health Centres

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DECLARATION

I, Nomonde Nozulu declare that:

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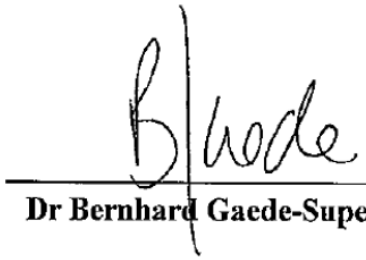

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ACRONYMS AND ABBREVIATIONS

ANC Antenatal Care

ART Antiretroviral Therapy

AZT Zidovudine

CHC Community Health Centre

DoH Department of Health

FY Financial Year

HIV Human Immunodeficiency Virus

KZN KwaZulu-Natal

NIMART Nurse Initiated Management of Antiretroviral Treatment

PMTCT Prevention of Mother to Child Transmission

PN Professional Nurse

STRETCH Streamlining Tasks and Roles to Expand Treatment and Care for HIV

Tier.Net Three Interlinked Electronic Register.net

WHO World Health Organisation

ABSTRACT

When the Prevention of Mother to Child Transmission of HIV programme was introduced in South Africa in 2002, doctors were the health professionals tasked with Antiretroviral Therapy (ART) initiation and management of patients. In a country with a known shortage of doctors and in which about 80% of the healthcare workers are nurses, the dependency on doctors negatively affected management of patients needing ART. The introduction of the Nurse Initiated Management of ART (NIMART) programme expanded the healthcare skill set necessary for ART initiation. With the implementation of NIMART, pregnant women who are regarded as a priority group in the country's ART programme would have ART initiation services offered as part of the antenatal care package.

Aim

The aim of this study was to evaluate ART initiation of pregnant women attending antenatal care in eThekwini district Community Health Centres (CHCs) between the Financial Years (FY) 10/11 (when NIMART was newly introduced) and FY13/14 (when NIMART was in full implementation).

Methods

An observational descriptive retrospective chart review study was conducted in 2015 at four eThekwini district CHCs. From these CHCs, records of pregnant women living with HIV that initiated ART in FY10/11 and FY13/14 were evaluated and compared.

Results

Approximately, 2749 pregnant women who attended antenatal care at the study sites during the two years were eligible for ART. Of the eligible women, 49% (N = 1334) attended antenatal care in FY10/11 while, 51% (N = 1414) attended in FY13/14. In FY10/11, 46% (n = 610) of the eligible women were initiated while 60 % (n = 855) of the1414 eligible in FY13/14 started ART during pregnancy. All women seen in FY10/11 were initiated at ART clinics. In FY13/14, 97% (n=826) of women initiated ART within the antenatal care clinics. ART in FY10/11 was started within 38 days after antenatal care booking while in FY13/14 initiations were within 4.12 days. Antenatal care booking before 20 weeks was found to have improved between the two years from 39 % to 58%.

Conclusion

This study noted a shift in point of care for ART initiation of pregnant women from ART clinics to nurse managed antenatal clinics. This shift resulted in reduced number of waiting days before ART initiations from 38 days to 4 days. The proportion of women found to have been initiated in this study was below the South African national target of 96% set in 2013. Antenatal care booking before 20 weeks was found to have improved, however most women booked after the first trimester.

CHAPTER 1 : INTRODUCTION

According to Statistics South Africa's Mid-year population report for 2015, an estimated one fifth of women between the ages of 15-49 are living with Human Immunodeficiency Virus (HIV) and the national HIV prevalence in this group is reported to be 18.99 % (1). The 2013 National Antenatal Sentinel HIV Prevalence survey reported the country's HIV prevalence for women attending Antenatal Care (ANC) to be 29, 7 % and this figure is higher than the 18.99 % presented by Statistics South Africa (2).

The 2013 sentinel survey indicated KwaZulu-Natal (KZN) to be the leading province with 40.1% of pregnant women attending ANC reported to be living with HIV. The provincial prevalence for 2013 increased by 2.70% from the 37.4 reported in 2012 (2, 3). Within KZN, eThekwini district was reported to be in the top five districts in the country with HIV prevalence above 40% (2). According to the sentinel report, 41.1% of women attending ANC were living with HIV (2).

The current HIV prevalence in ANC necessitates strengthening of efforts to ensure universal Antiretroviral Therapy (ART) access for pregnant women. Such strengthening would have a positive effect in improving the countries maternal and child health outcomes. As part of the Prevention of Mother to Child Transmission (PMTCT) of HIV; South Africa has over the years implemented reforms that would assist in reducing HIV related maternal and child health morbidity and mortality.

Different guideline reforms over the years are a testament to the efforts the South African Department of Health (DoH) is making to ensure coverage of ART in line with PMTCT goals. These guideline reforms can be traced back from 2002 when the country implemented PMTCT pilot projects across eighteen sites in the country; where single dose Nevirapine prophylaxis was introduced (4, 5). The 2008 guidelines introduced Zidovudine which was started at 28 weeks gestation and the single dose Nevirapine was taken at the onset of labour (6). More reforms based on the World Health Organisation (WHO) recommendations were introduced in 2010 (WHO option A) and in 2013 (WHO option B); both options called for the prescription of life long ART for all pregnant women with CD4 count < 350 cells/mm^3 (7).

The implementation of the above mentioned reforms required strong Human Resources for Health if the set targets were to be achieved. The shortage of doctors in South Africa is well known thus as part of the ART management reforms the DoH introduced nurses as ideal health professionals to prescribe ART and also manage patients on ART (8, 9). The introduction of Professional Nurses (PN) in prescribing ART was announced by the country's President in December 2009 (8)

This chapter will present a brief background on South Africa's 2009 PMTCT guideline changes which included the introduction of the Nurse Initiated Management of ART (NIMART). With this background the rationale behind the development of this study will be presented.

1.1 Background to this research

On the 1st of December 2009, The South African president pronounced reforms to the country's ART programme (the reforms became part of the 2010 ART guidelines) (8, 10). Amongst the specific objectives of the new programme was the initiation of pregnant women living with HIV who had a CD 4 count of less than 350 cells/mm^3 to lifelong ART (8, 10). From 2008 to 2009, the CD4 cell count threshold for ART initiation of pregnant women was less than 200 cells/mm^3 (11). These reforms implied that more patients than before would be eligible for ART and the available human recourses would not be adequate to manage the increased demand. The country's ART programme, which had been doctor run since inception, needed a human resource adjustment to ensure successful ART initiation of the 1.6 million people estimated to have been eligible in 2010 (12).

The 2010 ART guidelines also called for the implementation of the NIMART programme. NIMART is a task-shifting programme that utilises PNs to initiate and manage patients on ART. The WHO defines task-shifting as the process of moving tasks to other categories of health workers (13). Task shifting has been reported to be cost effective , offering good quality care to more patients compared to doctor centred care (14). Since the 2010 guidelines were released; the South African DoH has collaborated with various non-governmental organisations to provide NIMART training in the country.

1.1.1 What is the problem?

Pregnant women living with HIV are one of the priority groups in South Africa's HIV management strategy. Optimum management of this group would result in positive outcomes for maternal and child health. In the past, pregnant women living with HIV have experienced delays in ART initiation due to amongst other things, the doctor centred ART programme in South Africa. Initiating ART in pregnancy is linked to a lesser risk of vertical transmission and maternal mortality. Delays to ART initiation could result in morbidity and mortality for mothers who need the treatment to optimise their health and thus putting their unborn babies at risk of vertical transmission. The NIMART programme was introduce to shift the ART programme from being doctor dependent, ensure the decentralisation of ART initiation and thus contribute towards reduced waiting times.

1.1.2 What is known so far

Women of reproductive age are reported to be the most affected by HIV, with the ANC HIV prevalence for 2013 reported to be 29.7 % nationally and 40.1 % in KZN's eThekwini district (2). The SA DoH has introduced reforms to ensure that pregnant women living with HIV receive ART at the right time.

However since the introduction of the PMTCT, the programme has relied on doctor for its implementation. The dependency on doctors in ART management has posed challenges because there are not enough doctors practising in the public sector in South Africa. This meant that pregnant women that needed ART initiation would be referred to ART clinics for the attention of the doctor and this further resulted in delays as patients would be put on waiting lists. Nurses form 80% of health care professionals practicing in South Africa and have been working independent of doctors within the Primary Health setting (9). With the introduction of NIMART, the ART services would be decentralised allowing nurses to initiate ART within the ANC clinics instead of referring to the ART clinic (8).

1.1.3 What needs to be known

Before the implementation of NIMART pregnant women living with HIV who needed ART initiation were referred to ART clinics to be seen by a doctor either in a CHC or hospital and that resulted in some of the women experiencing delays in starting the treatment. The proposed study will investigate whether the implementation of NIMART has reduced the

waiting times towards initiation and whether the programme resulted in an increase in the number of women starting ART during pregnancy?

1.1.4 What is the importance of this study?

The effectiveness of NIMART in managing pregnant women living with HIV would result in positive outcomes for the country, and contribute towards efforts to reduce vertical transmission of HIV and maternal mortality.

1.1.5 How will the study solve the problem?

The study evaluated if NIMART has reduced the waiting times previously experienced by women requiring ART during pregnancy. The study results would be used to improve the NIMART programme and other maternal health related services in the district.

1.2 Statement of the problem

NIMART as a task shifting programme would ensure the decentralisation of ART services. Pregnant women as a group that is managed by nurses during ANC would gain from the decentralisation brought by the introduction of NIMART. The programme has a role to play in ensuring that more eligible pregnant women commence ART with minimum delays.

1.2.1 Hypothesis

The main hypothesis of the study was that NIMART had resulted in an increase in the proportion of pregnant women who initiated ART during pregnancy while attending ANC. The following hypotheses in relation to ANC booking were made:

- Previous exposure to PMTCT would result in women booking for ANC early ; before 20 weeks gestation
- Women who knew their HIV status at the time of getting pregnant would results in those women booking for ANC before 20 weeks gestation.

1.2.2 Aim/Purpose of the study

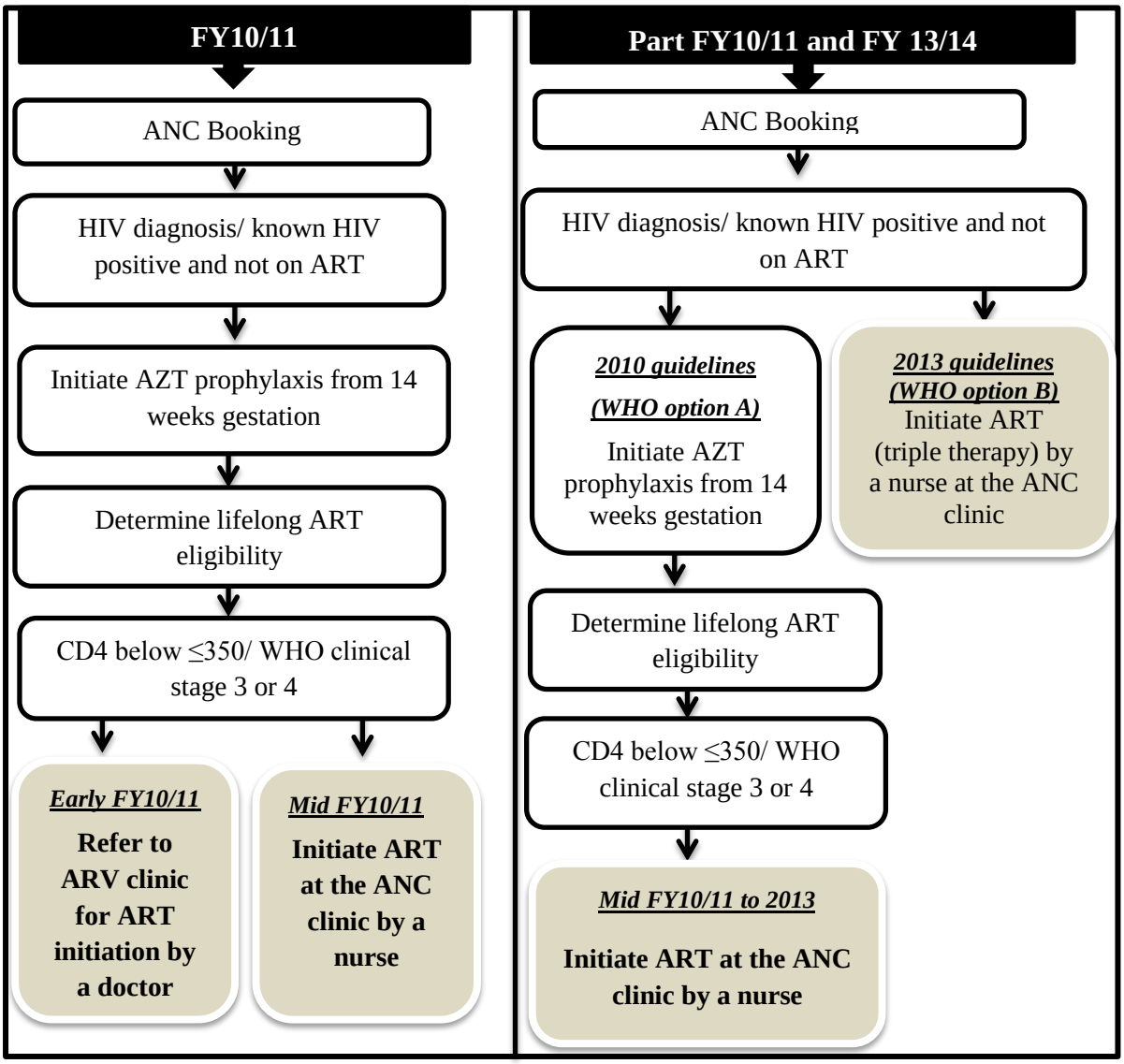
The purpose of the study was to compare ART initiation of pregnant women attending ANC in Community Health Centres of eThekwini district in Financial Year (FY) 10/11 and 13/14.

1.2.3 Specific objectives

- To compare the proportion of women initiated on ART during FY10/11 (before NIMART) and FY13/14 (during NIMART).
- To compare characteristic differences between those initiated in FY10/11 and FY13/14
- To measure the waiting time from ANC booking to ART initiation between groups initiated before and during NIMART.
- To compare the proportion of initiations in the ARV clinic (doctor driven) against those taking place in the nurse run ANC clinics during the two financial years
- Identify ANC attendance practices between the two groups

1.3 PMTCT contextual framework in FY10/11 and FY13/14

The differences in ART initiation between the two timeframes were determined by the country's ART guidelines. The framework for the 2010 and 2013 guidelines is outlined in figure 1 below.



[1]

Figure 1 Differences in ART management between FY10/11 and FY13/14 in eThekwini district CHCs

The points of ART initiation are depicted by grey shaded boxes. During early FY10/11, after the announcement of the 2010 guidelines, pregnant women eligible for ART were referred to the ART clinics for initiation by the doctor. Nurses started to receive NIMART training and

[1] Figure 1 was developed using information from the SA PMTCT of 2010 and 2013, supplemented by the WHO Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection of 2013.

by the middle of FY10/11. The period between mid FY10/11 to 2013 was marked by an increase in NIMART training resulting in more patients being initiated at ANC clinics by nurses.

1.4 Definitions

- **FY10/11**: The period from 1st April 2010 to 31 March 2011,(The South African DoH financial year cycle begins on the 1st of April and completes on the 31 March of the following year).
- **FY13/14**: The period from 1st April 2013 to 31 March 2014.
- **Nurse:** in this study, nurse is used in reference to PNs who are the target group for NIMART training. The two terms (nurse and PN) are used interchangeably in this report.
- **Delay in ART initiation** - ART initiation after seven days from first ANC visit (According to the ART management guidelines pregnant women should be initiated on ART within seven days after booking).
- **Before NIMART** – The period between April 2010 and March 2011 (FY10/11), this represents the early stages of the NIMART programme and this period was followed by NIMART training which intensified in 2011 and 2012.
- **During NIMART** - The period between April 2013 and March 2014 (FY13/14); the period represents a stage when NIMART training and ART initiation at the DOH institutions was occurring.

1.5 Organisation of the report

The report is divided into the following chapters:

- **Chapter 1**: This is the introductory chapter and gives a background to the study and its objectives.
- **Chapter 2**: This chapter presents reviewed literature on the study subjects. Existing information on ART management in respect to pregnant women as well as the role of task shifting is presented.
- **Chapter 3**: The study methodology and related ethical considerations will be tabled in this chapter.

- **Chapter 4**: The study results with be presented in this section
- **Chapter 5**: This chapter contains the discussion of the results as presented in chapter 4
- **Chapter 6:** The chapter presents conclusions and study recommendations.

1.6 Summary

This introduction chapter provided the background to South Africa's PMTCT programme and related human resource challenges with regards to ART initiation. Also outlined in the chapter is the context for ART initiation of pregnant women in FY10/11 and FY13/14. The reasoning behind the development of this study has also been presented. Reviewed literature on the subject under study is presented in chapter 2.

CHAPTER 2 : LITERATURE REVIEW

The effectiveness and success of the PMTCT programme requires collaborative efforts from all stakeholders. This entails legislative processes in the form of protocols and guidelines to direct the programme's activities. These processes have resulted in PMTCT guideline reviews which then necessitated changes in terms of staff functions, allocation of resources and adaptation of health services to ensure that pregnant women living with HIV receive ART timeously.

The changes effected by South Africa in its ART management guidelines are based on PMTCT and maternal health related studies and clinical trials, surveys and recommendations from organisations such as the WHO and UNICEF.

In this chapter evidence based and legislative information from various sources in respect of the maternal health programme, in particular PMTCT and task shifting will be presented.

2.1 Scope of the literature review

Information presented in this section has been sought from different sources namely: South African DoH guidelines, WHO guidelines and reports from similar organisations as well as journal articles on the subject of the study.

2.2 Human resources for health in ART management

The number of people needing lifelong ART has increased over the years. According the Statistics South Africa's mid-year population estimates for 2015; between 2002 and 2015; the number of people living with HIV in the country increased by 2.17 million to an estimated 6.19 million (1). The WHO global report for 2006 , found that of the 3 million people targeted for ART initiation in 2005 , 1.3 million received the required treatment (15). The 1.7 million deficit was attributed to low income countries that were reported to have the lowest human resource for health base (15, 16).

According to Van Damme *et al*, the countries with low human resource for health base (these include South Africa) needed to review and strengthen their ART delivery models in order to meet the set targets (16). Task shifting is entailed in one of the suggested scenarios for ensuring universal coverage mentioned in Van Damme's paper (16). In light of the shortage

of doctors in South Africa; the increased number of people living with HIV necessitates a shift in how human resources are utilised in ART management.

2.3 Task shifting in HIV management

The 2010 ART guideline reforms would benefit countless South Africans in need of ART, however the number of the country's health workers in ART management needed to be adjusted to meet the demand (17). The WHO recommends task shifting as means to address the human resource shortage in health care and especially in HIV management (13). By 2010, South Africa's health services depended largely on nursing personnel which forms 80% of the country's health care professionals (9). Task shifting of some of the doctor's responsibilities to nurses would reduce the patient load attended by doctors (18).

Studies on task shifting have described the process as cost and time effective as well as yielding positive clinical outcomes (14). The role of task shifting in ART management was explored in South Africa in a cluster randomised trial known as Streamlining Tasks and Roles to Expand Treatment and Care for HIV (STRETCH) in the Free State province between 2007 and 2010 (19, 20). The STRETCH trial was intended to give nurses an opportunity to expand their role by adding aspects of HIV management that were previously only performed by doctors (20). The study results found that NIMART implementation in South Africa was feasible and that the success of the programme required some reorganisation of the health system as well as support (20).

2.4 Outcomes of nurse driven HIV management projects

Studies comparing the outcomes of ART services managed jointly by nurses and doctors as well as those where each practitioner functions on their own have been conducted in South Africa. The outcomes of such studies are presented below.

2.4.1 Doctor initiations and nurse follow-up

Before NIMART, nurses effectively managed stable patients on ART through the down–referral model (21). Long *et al.* reported good retention to care (90% after month 12) of patients down -referred to nurse management when compared to patients who remained in hospital care; with relative risk of loss to follow up of 0.27, (95% CI 0.15–0.49) (21). A study conducted by the Centre for the Aids Programme of Research in South Africa between 2005

and 2009 revealed similar outcomes when comparing nurse managed ART programmes with those managed by doctors (22). At the time of the study, NIMART was not part of ART guidelines and thus the comparison of nurses and doctors was only in respect of monitoring patients after initiation.

2.4.2 Nurse initiations

In Khayelitsha South Africa, the task shifting mentorship programme on ART initiations that was implemented by *Medecins Sans Frontieres* (also known as Doctors Without Borders) resulted in up to 77% of eligible patients being started on treatment (23). Over and above the improved proportion of initiated patients, Green et al reported further improvements in variables such as blood draw, adherence assessment and WHO clinical staging (23). The cross sectional study (before and after) study by Green *et al* also reported that the involvement of nurses in ART initiation reduced the work load on doctors allowing them to focus on patients with complex presentation (23).

During the years 2004 to 2006, *Medecins Sans Frontieres* implemented a Primary Health Care and community based task shifting programme to facilitate ART initiation in the area of Lusikisiki which is situated in the Eastern Cape province of South Africa (24). At the time, the area was reported to have a hospital based ART management programme and a population of 150,000 depended on one hospital and twelve clinics (24). Nurses were introduced to provide ART initiation at a Primary Health Care level and this resulted in a 95% ART coverage in Lusikisiki.

An evaluation of a nurse-centred ART pilot programme in Rwanda conducted between 2005 and 2008 showed that with support; nurses can prescribe ARVs and manage patients successfully (25). The Rwanda retrospective medical record review study showed positive outcomes for CD4 cell count improvement, body mass index, and retention to care (92% at month 12 and 91% at month 24) (25).

2.5 NIMART implementation in South Africa

Following the inclusion of NIMART in the 2010 ART management guidelines; training of nurses to initiate eligible patients on ART was started by several NGOs. Studies were conducted to determine the perception of nurses about NIMART, experiences of nurses as well as challenges with the programme.

In a qualitative study by Davies *et al* on the perceptions of nurses about the implementation of NIMART; participants welcomed the expanded roles and found being part of the programme to have been empowering (26). A similar finding was reported by nurses and managers who participated in the STRETCH trial ; this group found the programme to have given them confidence to successfully initiate and manage patients on ART (20). Both these studies revealed acceptability of the NIMART programme by nursing personnel.

Even though the nurses welcomed the extended role brought by NIMART; they also reported the workload to be overwhelming at times (26). The additional pressure to perform was perceived by some managers and nurses as an abuse of the nursing role (26).

Between 2010 and 2011, Cameron *et al*. conducted a survey to determine if NIMART trained nurses were initiating patients after the training (27). The results of the survey revealed that 62% of those trained started initiating patients within 2 months. The study also identified health system barriers to successful implementation of the programme (27). Among the identified barriers and challenges reported by the group were the lack of consultation space, lack of mentorship and the shortage of nurses at their site which took time away from focusing on NIMART (27).

In a study on health care workers' responses to HIV and AIDS care and treatment, Orner *et al* learnt that differences in ART management guidelines among the province and slow authorisation by the South African Nursing Council for nurses were some of the reasons for slow implementation of the NIMART programme (27, 28). Mentorship was reported as integral to the success of the programme however this was found to be weak or lacking. To ensure the sustainability of NIMART; priority should be given to strengthening mentorship (29).

2.5.1 NIMART Mentorship

When task shifting was introduced in South Africa it was driven by the Clinical Mentorship programme. In the Clinical Mentorship Manual for Integrated Services; Clinical Mentorship is defined as a, *"Clinical mentorship is a system of practical training and consultation that fosters on-going professional development of mentees to deliver sustainable high-quality clinical care" (30)*. In NIMART, the ultimate aim of the mentorship process is to create competent nurses who will be able to initiate patients with relative independence from the doctor.

Following the five day didactic NIMART training, the nurses are required to undergo onsite mentorship under the guidance of a doctor or a nurse who is already certified to be competent in ART initiation. During NIMART mentorship the mentees must initiate a set number of patients in different categories and these include paediatrics, pregnant women, adult men, women of child bearing age as well as HIV/TB confected patients (31).

In 2011 *Medecins Sans Frontieres* (Doctors without Borders) implemented; a doctor supported mentorship task shifting programme in Khayelitsha South Africa to assist nurses towards competent ART initiation (23, 32). The implementation of this programme did not only result in increased ART initiation of eligible patients but also improved the confidence of the nurses in managing patients on ART (23).

Trained NIMART nurses have also been found to be valuable in providing post training mentorship. The use of nurses as mentors has been found to be cost effective and convenient as it utilises nurses already present at the facilities and external staff is not always necessary (33). A mentorship programme implemented by the Columbia University's International Center for AIDS Care and Treatment Programs (ICAP) in South Africa's Eastern Cape province in 2006 resulted in confident nurses who were able to provide effective mentorship to their colleagues at a clinic level (33).

Studies attest to the benefits of task shifting in mitigating the Human Resource shortage in ART services; but also of importance is the training and support offered to the nurses in this process. In a 2013 cross sectional study on identifying gaps in nurses training with regards to NIMART in Kenya, Smith *et al* found that of the 165 nurses , 53% (n=87) of the those trained did not feel competent post training (34). Of the group surveyed, 58% (n=96)were trained on PMTCT and only 38% (n=36) o(34)f this group reported feeling competent in initiating pregnant women on ART (34). This study identified lack of NIMART mentorship as a gap and the results from this survey led to the establishment of a NIMART mentorship programme in Kenya (34).

2.6 ART initiation in pregnancy

Initiating life-long ART during pregnancy is an effective strategy in improving the health of the mother and reducing chances of vertical transmission of HIV. Though initiating ART during pregnancy has been linked to low birth weight , studies have also reported significant

benefits for women with advanced disease while also reducing vertical transmission (35). Ekouevi *et al.* compared two groups of pregnant women on ARTs; the first group being on prophylaxis while the second group was on full ART (triple therapy). At 12 months the vertical transmission in the prophylaxis group was reported to be 16.1% which was higher than the 2.3 % in the group that was on full ART (35). Early initiation of ART for eligible pregnant women is favoured as being more effective in improving immunological and viral responses when compared to post-partum initiation when measured 6 months after initiation (36). According to Melekhin *et al.* , possible reasons for the positive responses to ART in pregnancy can be linked to the close monitoring that pregnant women undergo during ANC (36).

2.7 Delays in ART initiation

During the 2008 guideline era, women requiring ART initiated Zidovudine prophylaxis on the day of HIV diagnosis, which was the first ANC visit. A 2010 study conducted in South Africa at the Prince Mshiyeni Memorial hospital confirmed that 96.8% of women living with HIV start ART prophylaxis during the first ANC visits (37). The delay tends to be in initiating lifelong ART as patients were required to wait for the return of CD4 cell count results to determine eligibility for ART. Waiting for the CD4 cell count results affected women who needed ART for their own health getting delayed care and with some starting the treatment during the post-partum period (37, 38).

2.7.1 Laboratory results

CD4 cell count blood collection on the same day as the diagnosis of HIV as well as the period the results take to process impacts on the timing of ART initiation (39). According to Hussain *et al.* in the Prince Mshiyeni Memorial hospital study, of the women who had blood drawn for CD4 count; 31% delivered without receiving the results. Furthermore, the same study found that only 29% of those eligible for ART were put on treatment during pregnancy (37). In a 2005 study, Stinson *et al*. reported that 51% of women eligible for ART initiated the treatment during pregnancy while the rest continued on prophylactic management till delivery (38).

In a 2008-2009 qualitative study on the health system's constraints on PMTCT access; Sprague *et al* reported the challenge of CD4 cell count results as a delaying factor in ART

initiation of pregnant women (40). Sprague also found that women started ART just before delivery while others were only initiated post-delivery (40).

The return of CD4 cell count results from the laboratory influences the timing of treatment initiation. In a Zambian study conducted in 2007-2008, the return of results within seven days was associated with 73% of eligible pregnant women initiating ART (39). The difference in the number of initiated eligible women in the three studies is noticeable with 73% initiated in the Zambian study, 51% in Cape Town and 29% in the Prince Mshiyeni Memorial hospital study. Contrary to the low ART initiation in pregnancy reported by the two South African studies, the Health System Trust data for 2011/2012 depicted higher initiation figures at 80% nationally and 96% for the eThekwini district (41) The Health System Trust however, cautions that the reported figures might be as a result of over estimation due to poor CD4 cell count result data quality.

2.7.2 ANC booking

The 2015 Guidelines for Maternity Care in South Africa recommend that women should start ANC as earliest as possible and this is preferred to be during the first trimester (≤ 12 weeks gestation) (42). The recommended booking gestational age was also pronounced in the Basic Antenatal Care guidelines of 2007 as an appropriate time for a full obstetric assessment and early referral for management where risk factors are identified (43). HIV diagnosis is one of the assessments that pregnant women undergo during the first ANC visit and according to the South African guidelines on maternal care, all HIV positive women should be started on ART as soon as an HIV positive status is determined (42, 44, 45).

In South Africa the gestational age for ANC booking is monitored through two indicators namely; Antenatal first visit before 20 weeks rate and Antenatal first visit after 20 weeks rate and the denominator of which is the total number of women attending first ANC visit. The 2014/15 District Health Barometer reported the national ANC booking before 20 weeks to be 53% ; while this figure fell below the set target of 65% it showed great improvement compared to the previous years (46). For KZN the proportion of women who booked before 20 weeks was reported to be 57% with eThekwini reported to be at 54% (46).

2.7.2.1 Late booking

Even though guidelines recommend that ANC should be started immediately after the diagnosis of pregnancy; the challenge of late booking still continues. In South Africa

Muhwava *et al* investigated ANC booking with regards to related psychosocial factors between rural and urban settings (47). The result from the Muhwava *et al*, survey found aspects such as being religious, married and having a planned pregnancy to be related to early booking.

In a cross sectional study that included women who booked for ANC after 20 week in Uganda ; Kisuule *et al* found that 72% of the study participants were not aware of the correct gestational age for starting ANC (48). The women in the study presented at a mean gestational age of 27.7 weeks and mentioned having no problems with the pregnancy as the reason for not presenting early for ANC (48). Similar findings in Nigeria were reported by Ndidi *et al* with 65% of the 348 women citing lack of knowledge on the benefits of first trimester booking as the reason for late ANC presentation (49). In this Nigerian study they also found that about 80% of women who had been pregnant before had booked late in previous pregnancies (49).

The results on late booking and previous pregnancies are contrary to those found in an Ethiopia cross-sectional study by Belayneh *et al* where previous ANC utilisation was found to be associated with early booking (50). In another area of Ethiopia, Addis Ababa, a cross sectional study by Tariku *et al* reported that women with planned pregnancies and those pregnant for the first time as most likely to present early for ANC (51). However as in Ndidi *et al* study; the Addis Ababa study found no association between previous pregnancies and early ANC booking (49, 51).

In South Africa women have reported presenting early for ANC but were discouraged when told by health workers to come back on another day, to the extent of delaying ANC booking by up three months (52). In descriptive cross-sectional study by Solaris and Black in Johannesburg South Africa ; women indicated not being aware on time of the pregnancy and lack of time to attend the clinic as some of the reasons for presenting late (52). Those who did present early were reported to have not received the required assessment necessary during the first ANC visit (52).

2.7.2.2 ANC booking and PMTCT

Early ART initiation in pregnancy is associated with less vertical transmission. Black *et al* found that more than seven weeks of ART exposure before delivery resulted in an HIV transmission rate of 0.3% (53). This means that late booking after 20 weeks contributes

negatively to the achievement of PMTCT targets. In a retrospective cohort study (data from 2003 -2010) that was conducted in Gugulethu, Cape Town , South Africa by Myer et al, women who presented early for ANC were likely to be on ART by the time of delivery and thus had reduced vertical transmission chances (54). Eligible women who did not initiate ART during pregnancy were found to have booked for ANC at a median gestational age of 31 weeks, compared to 27 weeks of those that started treatment (54).

In an observational cohort study, Fitzgerald *et al* established that women presented for first ANC visit at a median gestational age of 28 weeks and with 25% of women presenting after 31 weeks. According to this PMTCT study late ANC booking reduced the amount of time on ART necessary for effective reduction of vertical transmission (55).

2.8 Summary

The literature review explored human resource challenges in HIV management as well as the role of task shifting, particularly the allocation of nurses to mitigate these challenges. The reviewed studies and guidelines all recommended ART initiation of pregnant women at an earlier gestational age and thus early booking is also suggested. Some challenges in respect of delays in accessing ART timeously have also been highlighted

CHAPTER 3 : METHODS

An observational descriptive retrospective chart review study was conducted to compare the initiation of pregnant women on ART before and after the implementation of NIMART. ANC and ART related data of women who initiated ART in FY10/11 and FY13/14 was collected for comparison. This retrospective chart review study was conducted in four eThekwini district CHCs.

3.1 Type of research

The study can be classified under health system research. The subject under study relates to health policy and its implementation at a facility level. In this case the HIV/PMTCT management guidelines and the introduction of NIMART are the health policy matters whose implementation was evaluated through this study.

3.2 Study Setting

The study took place at four eThekwini district CHCs. Cullinan defined CHC as,

"*A Community Health Centre is defined as a facility that, in addition to a range of other PHC services, normally provides 24 hour maternity and accident and emergency services, and up to 30 beds w here patients can be observed for a maximum of 48 hours" (56).*

The setting was selected because unlike Primary Health Care facilities, CHCs had full time doctors who manned ART clinics before NIMART was introduced and thus would be an ideal setting for comparing ART initiation differences between the two periods under comparison.

Since the inception of the ART programme, CHCs have been providing ART to eligible pregnant women but before NIMART patients were referred to the ART clinic (within the CHC) to be initiated and managed by the doctor. The implementation of NIMART allowed for the decentralisation of ART initiation for pregnant women to the ANC clinic. Based on this context this setting was deemed suitable for the study.

3.3 Research population

Pregnant women living with HIV who initiated ART while attending ANC was the research population for this study.

3.3.1 Selection of research population

The eThekwini health district is divided into three sub districts namely; South, North and West .The district has eight CHC and five of these are in the North, two in the west with one in the South. The sub districts represented clusters from which participating sites were selected. To ensure that each sub district was represented, the one CHC in the South would automatically be part participating sites. CHCs for the North and West were selected through simple random sampling. From the two CHCs in the West one was selected while the North was represented by two from its five facilities. Within the selected sites consecutive records of women that initiated ART during the study period were included in the study.

3.3.1.1 Inclusion criteria

Records of the following patients were included in the study.

- Those attending antenatal care at a CHC
- Living with HIV and initiated ART during pregnancy
- The participating facilities must have NIMART trained nurses who are already initiating patients.

3.3.1.2 Exclusion criteria

Records of the following patients were excluded from the study.

- Pregnant women living with HIV who initiated ART before the pregnancy.
- Pregnant women living with HIV who are not eligible for lifelong ART according to the guidelines of the two timelines.

3.3.2 Size of sample

The sample size was calculated using the Intercooled Stata version 13. To demonstrate the difference in ART initiation between the before and after NIMART eras; the statistical power was set at 80% with a two sided alpha of 0.05. The selection of the sample size was informed by the District Health Information System data for the two

study financial years. According to the district data, 71% (n=942) of eligible pregnant women initiated ART during FY10/11, while 77% (n=2782) started in FY13/14 (57). Data from the two years was used to provide guidance on the extent of ART initiation that had taken place at the selected sites during the study periods. The difference between the initiation proportions presented by the district data was considered in calculating the sample size for the study. A sample of 850 records for each of the two study periods was proposed.

3.3.2.1 Sample size formula

The estimated sample size for two-sample comparison of proportions:
Test Ho: p1 = p2, where p1 is the proportion in population 1and p2 is the proportion in population 2. Assumptions: alpha=0.0500 (two-sided) power =0.8000, p1=.7200, p2 =.7800, n2/n1=1.00

3.4 Data sources

Study data was extracted from the following data sources:

- Antenatal Clinic Register
- Three Interlinked Electronic Register (TIER. net)
- HIV ,AIDS ,Sexually Transmitted Infections and Tuberculosis (HAST) clinical chart
- HIV Counselling and Testing (HCT) register

The DHIS data was also used at baseline to get information on pregnant women eligible for ART during the study timelines.

3.4.1 Measurement instruments / Data collection techniques

A data collection tool covering all variables required to answer the study objectives was designed by the researcher. The design of the data collection tool was informed by the DOH ART management data collection tools mainly the HAST clinical chart. The variables from the HAST clinical chart were adapted for this study. The DoH tools on which the data collection tool is based already have established validity and reliability and are used to collect programme monitoring data.

Study numbers were allocated to each participating CHC, ranging from CHC 1 to CHC 4 and within those facilities; each data collection tool was allocated a unique study numbers.

Information from the data collection tools was captured to the 2010 Microsoft Excel programme for cleaning and exported to SPSS 23 for analysis.

3.4.2 Variables

- Patients age
- Patients parity status
- Previous PMTCT exposure
- Gestational age at starting ANC
- Gestational age at starting ART
- Date of HIV testing
- Cd4 cell count results
- Date of ART initiation
- Comorbidity
- Initiation of prophylaxis
- Delay in ART initiation from the first ART ANC visit
- ART/ANC clinic initiations

3.4.3 Measures to ensure validity

3.4.3.1 Reduction of bias

Simple random sampling in the two sub-districts with more than one CHC was employed to give each CHC in those areas an equal chance of being selected for the study. When it came to selecting the sample of records for each financial year of the study, the records of all women who initiated ART during the study timelines were selected conservatively thus further reducing selection bias.

To reduce information bias, a structured data collection tool was used in all the participating study facilities. The variables were the same for before and during NIMART implementation groups.

3.4.4 Pilot study

On receipt of permission to conduct the study, the data collection tool was tested at CHC 4 (one of the participating sites) using a sample of ten records. Data from the ten files was entered into the data collection form to allow for review and revision. Variable whose information was noted to be consistently missing were removed from the tool. The following adaptations of the collection form were made:

- Year of HIV diagnosis was replaced with Known HIV status and new diagnosis
- Year of previous PMTCT exposure was removed, as records only contained information on whether the patient had previous exposure without specifying the year or years.
- Date of CD4 collection was also not necessary as all records reflected the first ANC visit day as the date on which the blood was collected.
- The date at which the results reach the site was also found missing.
- Nutritional status: Patient height measurements which are required for body mass index calculation were found missing in most files.

3.5 Data collection

Study data was collected in September and October 2015. Information on the number of nurses trained on NIMART and mentored at each CHC was received from the site Operational Managers. The review of patient's records started with data from the ANC clinic where all obstetric information and ART preparation data was collected. Information relating to the preparation of the women for ART was not always available on the ANC registers and thus other sources were consulted. The Three Interlinked Electronic Register (commonly referred to a Tier.net) gave information as to the date of initiation as well as blood results. The HAST clinical chart was consulted for further information on the patient's history, baseline immunology, physical assessment, ART regimen and follow up care.

3.5.1 Data handling/processing

After data collection, each data collection tool was checked for completeness before capturing into Microsoft excel. The capturing was followed by a process of data cleaning. Data codes were allocated to categorical variables for easy analysis once exported to the statistic programme for analysis, (e.g. FY10/11=1 while FY13/14=2, Yes=2, No=1). The cleaned data was then transferred for analysis to the SPSS 23 statistic programme

3.6 Statistical analysis

The data was analysed by applying general descriptive and analytical statistics. The confidence interval for both groups under comparison was set at 95%. The mean and the standard deviation were used to measure the location and distribution of numerical variables between the two study timelines. Difference between the means of the tow study timelines variables were tested using the independent sample t-test. Association between categorical variable were tested using the chi square test.

3.6.1.1 List of possible confounders

- Lack of confidence to initiate on the part of the NIMART trained nurses might result in more cases being pushed to the ART clinics.
- Patients presenting with adverse events for which nurse initiation and management is contraindicated might result in patients being referred to the doctor.

3.6.1.2 List of associations

The following associations were measured between variables:

- Known HIV status and ANC booking
- Previous PMTCT exposure and booking practices
- Number of initiations in a facility and the number of NIMART trained nurses

3.7 Ethics

Permissions to conduct the study were obtained as follows.

3.7.1 From Institutional Ethical Review Board

Ethical approval for the study was obtained from the Biomedical Ethics Research Ethics Committee (BREC) of the University of KwaZulu-Natal. The approval letter from the committee is attached in **appendix 2** of this document.

3.7.2 Permissions from various concerned authorities

Permission for the study was obtained from the KwaZulu-Natal DOH-provincial research office, the eThekwini District DOH office and from the managers of the selected CHCs. The permission letters from the various authorities are attached in **appendix 3** of this report.

3.7.3 Confidentiality

The managers of the participating CHCs were assured that facility names would not be linked to the data and the site confidentiality would be maintained by allocating a numbers to each participating CHC. The names CHC1 to CHC4 were used to code each site. Patient's personal information was also protected as their personal details were not captured to the data collection form.

3.7.4 Data storage

After data collection and capturing was completed data tools were stored in a lockable cupboard that is only accessible to the researcher. The data will be stored in safe storage for five years after all reporting and publishing is completed. The electronic database has been stored in an encrypted, password protected file in the researcher's computer. A back-up file has also been stored in a web based data storage (cloud) system.

3.8 Summary

The chapter gave details of the processes that were followed from deciding on the study design to data collection. Statistical tests employed to investigate differences and associations between the variables have been presented. Ethical requirements such as permissions to conduct the study from relevant sources were also observed.

CHAPTER 4 : RESULTS

This section presents a summary of the analysis of the study results. General characteristic of the study sample as well as related descriptive statistics will be presented. The section will conclude with a brief presentation of NIMART training in the eThekwini district in relation to the four study CHCs.

4.1 ART initiation of eligible pregnant women in FY10/11 and FY13/14

According to the DHIS data, approximately 2749 women that attended ANC at the four CHCs were eligible for ART. Of the eligible women 49% (N=1334) attended ANC in FY10/11 while, 51% (N=1414) attended in FY13/14. In FY10/11, 46% (n=610) of the eligible women were initiated while 60 % (n=855) of the1414 eligible in FY13/14 started ART during pregnancy.

The data for the number of women and eligible for ART initiated in each financial year is reflected in table 1 according to each CHC.

Table 1ART initiation of eligible pregnant women in FY10/11 and FY13/14 according to CHC in the eThekwini district (N=2749)

	FY10/11			FY13/14		
Site	**Eligible**	**Initiated**	**% Initiated**	**Eligible**	**Initiated**	**% Initiated**
CHC1	226	146	65%	242	132	55%
CHC2	277	215	78%	297	220	74%
CHC3	486	190	39%	521	334	64%
CHC4	346	59	17%	354	169	48%
Total	**1334**	**610**	**46%**	**1414**	**855**	**60%**

CHC 3 had the highest number of eligible women in both financial years 486 of which started ART in FY10/11 while 521 were initiated in FY13/14. When it came to ART initiation in CHC 3, 39% (n=190) of 521 eligible women in FY10/11 were initiated, while 64% (n=334) of the 486 eligible in FY 13/14 started ART during pregnancy.

In both financial years CHC 2 had the highest proportion of pregnant women initiated on ART with 78% (n=215) of 277 initiated in FY 10/11 and 74% (n=220) of the 297 eligible women.

CHC 4 reflected the least proportion of women initiated across the four sites in both financial years. During FY10/11, 17 % (n=59) of the 346 eligible women were started ART at this site while 48 % (n=169) of 354 were initiated in FY13/14.

4.1.1 Sample initiated on ART

Of the 1465 pregnant women that started ART during the two study periods, 42% (n=610) were put on treatment in FY10/11 while a larger 58% (n=855) initiated in FY13/14. The proportion of pregnant women initiated on ART in the two study periods differs within each CHC. Figure 2 below shows the spread of ART initiation in percentages within each site according to financial year.

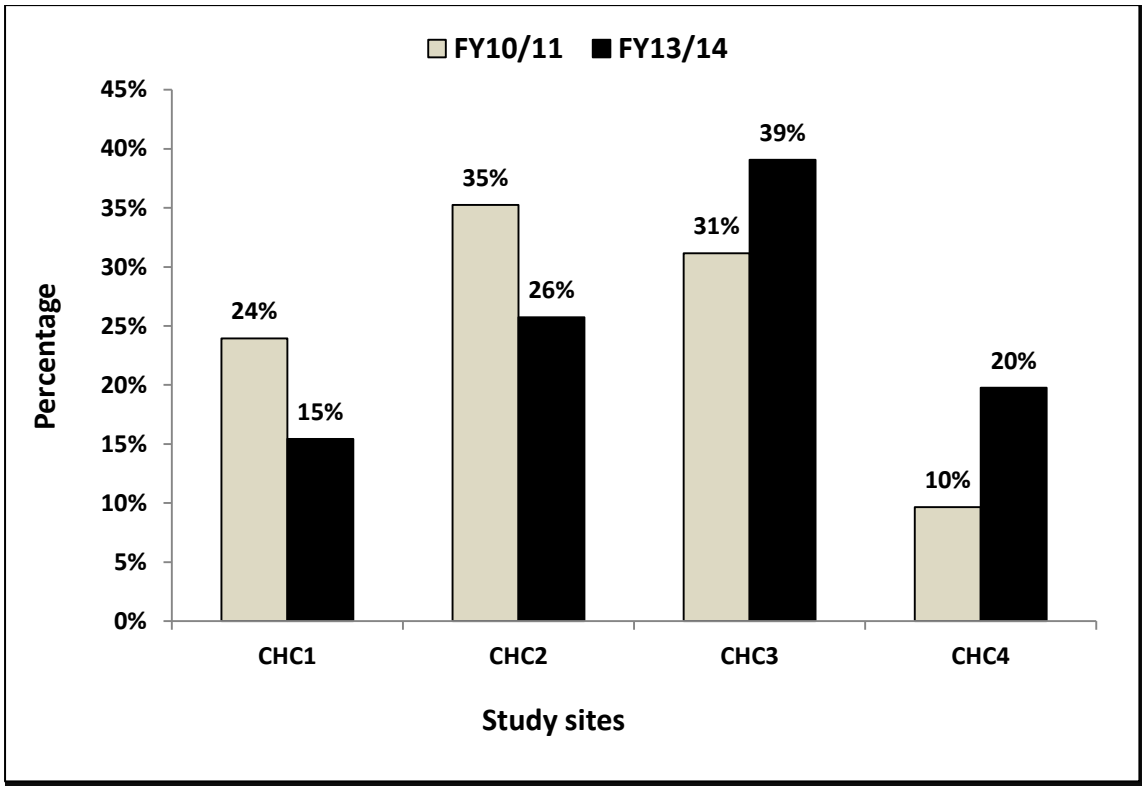


Figure 2: ART initiation of pregnant women at four CHCs in the eThekwini district during FY10/11 (n=610) and FY13/14 (n=855)

During FY10/11, CHC 2 had the highest proportion of those initiated during this period with 35% (n=215) of women having had their lifelong ART at this site. For the same financial year CHC4 had the least proportion of women initiated with 10% (n=59) of those started on treatment being from this site. There is a 25% difference between the two sites with the highest proportion initiated (CHC 2) and the one with the least (CHC 4)

In FY 13/14, 39 % (n=334) of the 855 initiated pregnant women were from CHC 3, with the least proportion from CHC 1 at 15% (n=132). There is a 25% difference between the sites with the least and highest proportion initiated.

A comparison of the two financial years shows 58% (n=855) women as having been initiated in FY13/14. CHC 1 and CHC 2 appear to have more women initiated in FY10/11 with 24% (n=146) and 35 % (n=215) respectively of the women coming from these sites compared to the 15% (n=132) and 26% (n=220) for FY13/14.

4.2 Characteristics of pregnant women initiated on ART

In September 2015 data from records of pregnant women that started ART at the study CHCs was collected. The demographic, obstetric, immunological and ART initiation characteristics of 610 and 855 initiated women are displayed in table according to the two financial years.

Table 2: Characteristics of women initiated on ART during pregnancy at four eThekwini district CHCs during FY10/11 (n=610) and FY13/14 (n=855)

	FY10/11		FY13/14	
Variable	**Frequency**	**%**	**Frequency**	**%**
Age at 1st ANC Visit				
< 18 years	14	2%	19	2%
18-24 years	146	24%	231	27%
25 - 29 years	220	36%	281	33%
30 - 34 years	154	25%	204	24%
≥ 35 years	76	12%	120	14%
Gravid state				
First pregnancy	159	26%	185	22%
Two pregnancies or more	451	74%	670	78%

	FY10/11		FY13/14	
Variable	**Frequency**	**%**	**Frequency**	**%**
Gestational during 1st ANC visit				
Before 20 weeks	235	39%	494	58%
After 20 weeks	375	61%	361	42%
CD4 cell count		0%		0%
< 200	248	41%	205	24%
200–350	361	59%	623	73%
>350	1	0%	27	3%
Clinical staging				
Stage1	44	7%	333	39%
Stage 2	485	80%	404	47%
Stage3&4	81	13%	118	14%
Previous PMTCT				
Yes	104	17%	268	31%
No	506	83%	587	69%
Known HIV Status at ANC booking				
Yes	152	25%	360	42%
No	458	75%	495	58%
Days from 1st ANC booking to ART initiation				
< 7days	4	1%	642	75%
7-14 days	70	11%	155	18%
15-30 days	231	38%	37	4%
31-90 days	280	46%	21	2%
> 90 days	25	4%	0	0%
Gestational age at ART initiation				
1st trimester	2	0%	137	16%
2nd trimester	404	66%	640	75%
3rd trimester	204	33%	78	9%

	FY10/11		FY13/14	
Variable	**Frequency**	**%**	**Frequency**	**%**
Point of ART initiation				
ART clinic	610	100%	29	3%
ANC clinic	0	0%	826	97%

In both financial years the proportion of women initiated on ART during pregnancy in the age group under 18 years was the least represented at 2 % (n=14 in FY10/11, n=19 in FU13/14). The majority of initiated women were age between 25 -29 and in this group 36% (n=220) started ART in FY10/11 while 33% (n=281) in FY13/14 fell in this age range.

With respect to gravid state of women, the majority were found to be in their second and more pregnancy; 74% (n=451) and 78% (n=670) of these women were initiated in FY10/11 and FY13/14 respectively.

Differences in gestational age during the first ANC visit when it came to booking before or after 20 weeks were noted between the two financial years. In FY10/11; 61% (n=375) of initiated women booked after 20 weeks while 58% (n= 494) in FY13/14 booked before 20 weeks.

The majority of women were found to have initiated ART at a CD 4 cell count of between 200-350 cell/ mm^3 with 73% (n=623) initiated in FY13/14 and 59% (n=361) in FY 10/11. The second immunological characteristic observed was the WHO clinical staging and in both financial years the larger proportion of women were initiated at clinical stage 2. Of those initiated in FY 10/11, 80% (n=485) were in WHO clinical stage 2. In FY13/14, women in the WHO clinical stage 2 represented the majority at 47% (n= 404); but also to be noted was that women initiated during WHO stage 1 accounted for 39% (n=333).

Also observed in the women was history of PMTCT exposure in previous pregnancies and whether those initiated knew their HIV positive status during ANC booking. In both financial years a lesser proportion of women reported to have had previous exposure to PMCTC; 17% (n=104) of them initiated ART in FY10/11 and 31% (n=268) in FY13/14. More women in FY13/14 were found to have been aware of their HIV positive status at booking at 42% (n=36) compared to 25% (n=152) reported in FY 10/11.

The ART initiation practices were measured in three variables namely, Days from 1st ANC booking to ART initiation, Gestational age at ART initiation and Point of ART initiation. In FY10/11, the larger proportion of women started ART between 31-90 days after booking 46% (n=280) while in FY13/14, 75% (n=642) of women were initiated within 7 days. In both financial years women started ART during the second trimester, 66% (n=404) in FY10/11 and 75% (n=640) in FY13/14. Of those initiated during the third trimester, 33% (n=204) were seen on FY10/11 compared to 9% (n=78) in FY 13/14. The point of ART initiation was either ANC clinic or ART clinic. The FY10/11; data showed 100% (n=610) of women to have started ART within the ART clinic while in FY13/14; 97% (n=826) were initiated in the ANC clinic and the remaining 3% (n=29) reported to have been initiated at the ART clinics.

4.3 Descriptive statistics

The obstetric, immunological and ART initiation characteristic of the initiated women were analysed using descriptive statistics. The mean, standard deviation and range (minimum and maximum) were used to give an indication as to the spread of these numerical variables. The descriptive statistics for variable under investigations are displayed in table 3.

Table 3: Descriptive statistics in relation to women initiated on ART in four eThekwini district CHCs during FY10/11 (n=610) and FY13/14 (n=855)

	FY10/11				FY13/14			
Variable	Min	Max	Mean	Std. Deviation	Min	Max	Mean	Std. Deviation
Age at first ANC Visit	14	41	27.86	5.27	14	44	27.9	5.82
Gravid state	1	5	2.14	0.86	0	6	2.32	1.02
Gestational age	8	36	20.88	5.63	6	39	18.4	6.3
CD4 cell count	47	416	214.63	78.05	49	584	256.97	82.65
Clinical stage	1	3	2.06	0.45	1	3	1.75	0.68

Days from 1st ANC booking to ART initiation	0	174	37.95	28.72	0	136	4.12	9.65
Gestational age at ART initiation	12	38	26.3	6.02	6	36	19.06	6.86

4.3.1 Age at first ANC visit

The mean age at first ANC visit for FY10/11 was 27.86 (SD=5.27) years while the average age for FY13/14 was 27.90 (SD=5.82). The difference between the two means was tested using the independent samples t test. The results of the test statistics showed a means no significant difference between the two means; t=0.135, p=.898).

The distribution of age at first ANC visit between the study financial years is depicted in the figure 3 below according to percentage for each age group.

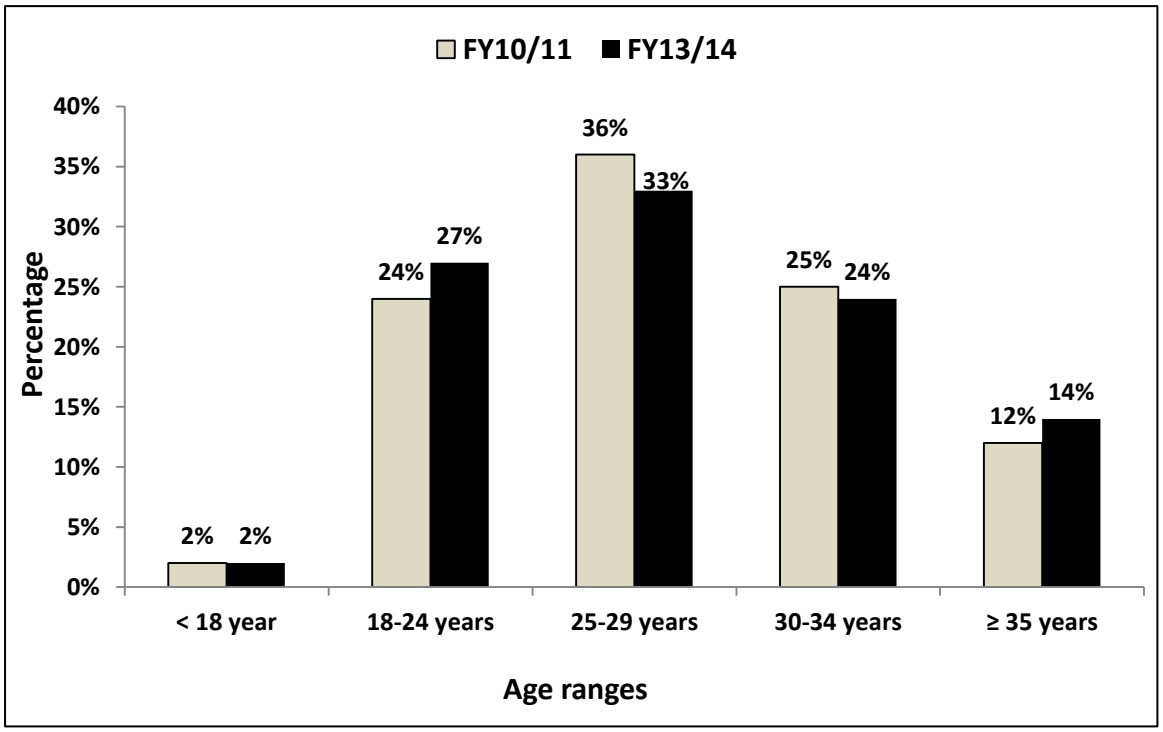


Figure 3: Distribution of age during the first ANC visit in women that initiated ART at four eThekwini district CHCs in FY10/11 (n=610) and FY13/14 (n=855)

The majority of women in both study periods were aged between 25-29 years. Within this group the mean age was 27 years for both financial years.

4.3.2 Gravid state

The gravid state of women that initiated ART at the four participating CHCs showed a mean of 2.14 (SD=0.86) for FY10/11 and 2.32 (SD=1.02) for FY13/14. The difference between the two means was found to be -0.85was tested with the independent samples t test. According to the test statistic the difference between the two means was statistically significant (t=3.55, p=<. 0001).

The distribution of the gravid state variable between the two study periods is displayed in figure 4. The figure shows the proportion of the women that started ART at the research sites according to their gravid state.

In line with the mean for this variable, the majority of women initiated on ART during the study timelines were on their second pregnancy.

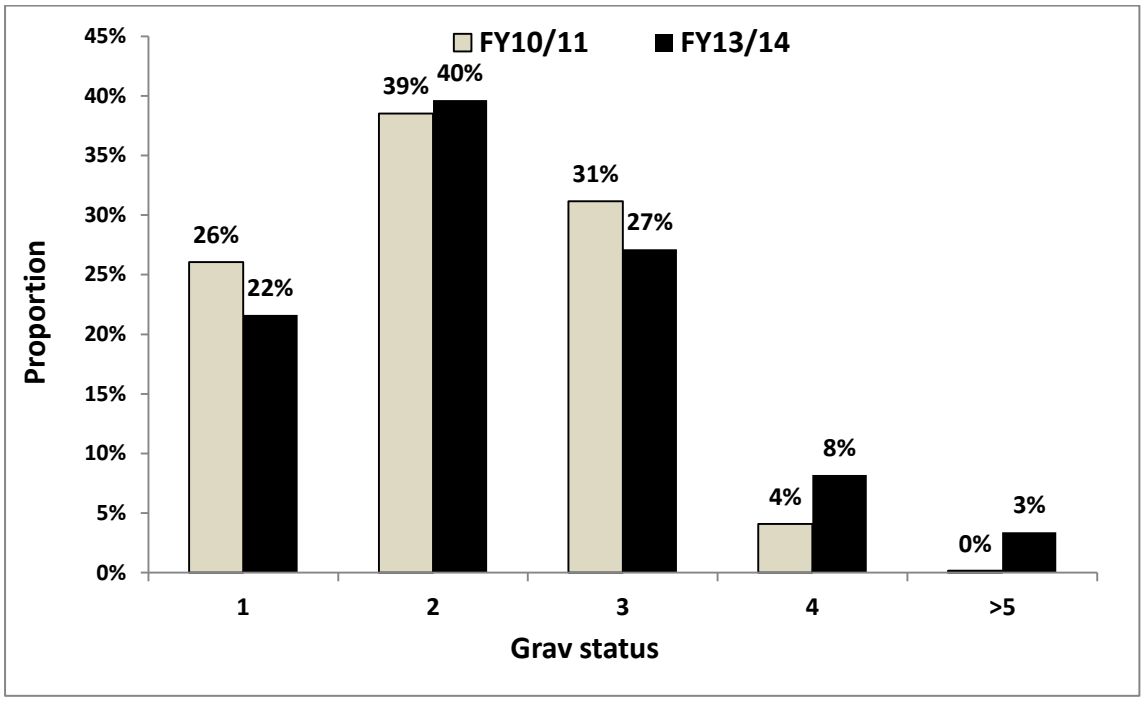


Figure 4: The distribution of gravid state of women initiated on ART in four CHCs in eThekwini district during FY10/11(n=610) and FY13/14 (n=855)

The difference between the two financial years for gravida 2 was 1% (n=104) with FY10/11 represented by 39% (n=235) and 40% (n=339) of gravida 2 women initiated in FY13/14.

The second gravid state with the most proportion of women was gravida 3. This gravid state was second highest in both financial years with 31% (n=190) of women in FY10/11 and 27 % (n=232) in FY13/14 falling under this category.

Women who were recorded as being pregnant for the first time (gravida 1) were 24% (n=344) of all those initiated in both timelines. In FY10/11, this category showed a proportion of 26% (n=159) and 22% (n=185) for FY13/14 as having initiated ART during their first pregnancy.

Fewer women were initiated during their 4th and above 5 pregnancies. In this category 4% (n=25) of women were on the 4th pregnancy during FY10/11 with 8 % (n=70) initiated in FY13/14. In FY10/11 no women were above gravida 5 while 3% (n=29) in FY13/14 were in this category.

4.3.3 Gestational during first ANC visit

The mean gestational for FY10/11 was 20.88 (SD=5.6) while that for FY13/14 was found to be 18.40 (SD= 6.2). The mean difference for the two study timelines was 2.4. The difference between the two means was found to be statistical significant (t =7.759, p = <. 0001).

The distribution of the gestational age at first ANC visit between the two financial years is shown in figure according to booking before and after 20 weeks.

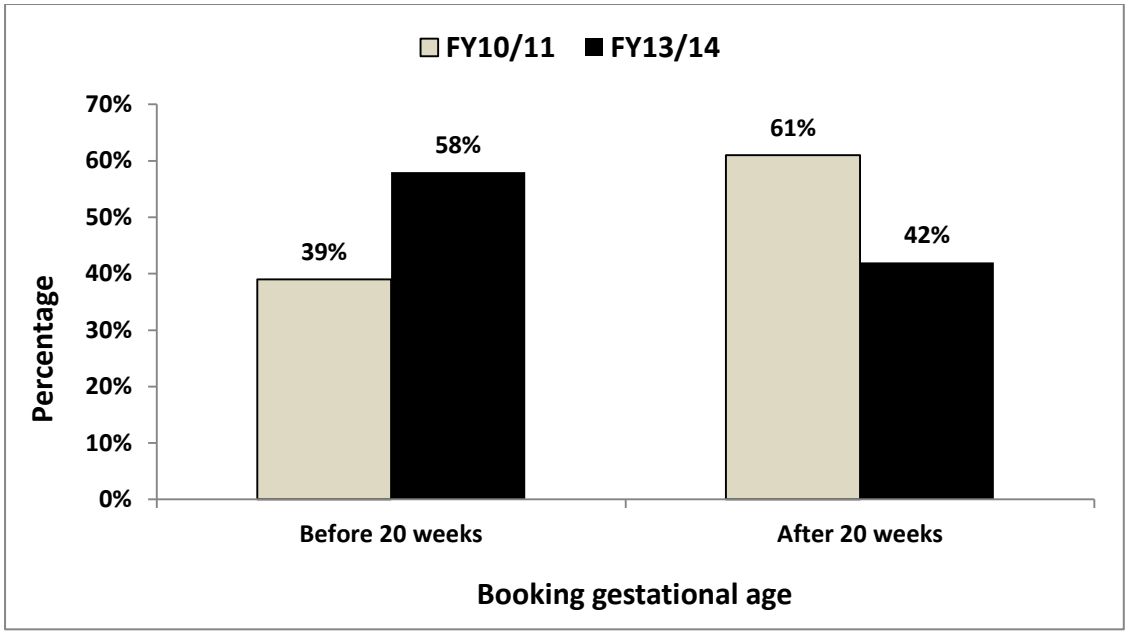


Figure 5: ANC booking of women initiated on ART at four eThekwini district CHCs in FY10/11 (n=610) and FY13/14 (n =855)

The figure 5 shows a slight change in booking practices between the two financial years with 58% (n=494) more women in FY 13/14 booking before 20 weeks compared to 42% (n=361) in FY10/11.

4.3.4 CD4 cell count

The 1456 women that presented at the participating sites had a mean CD4 cell count of 239 cells. The mean for FY10/11 was 214.6 (SD=78.05) while that for FY13/14 was 256.97 (SD=82.65). The difference between two means on an independent t test was found to be -42.340. The t test reflected a statistically significant difference between the two means (t=9.98, p = <. 0001).

The CD4 cell count of women who initiated ART at participating CHCs for both financial years is displayed in figure 12, ranging from less than 100 to above 350.

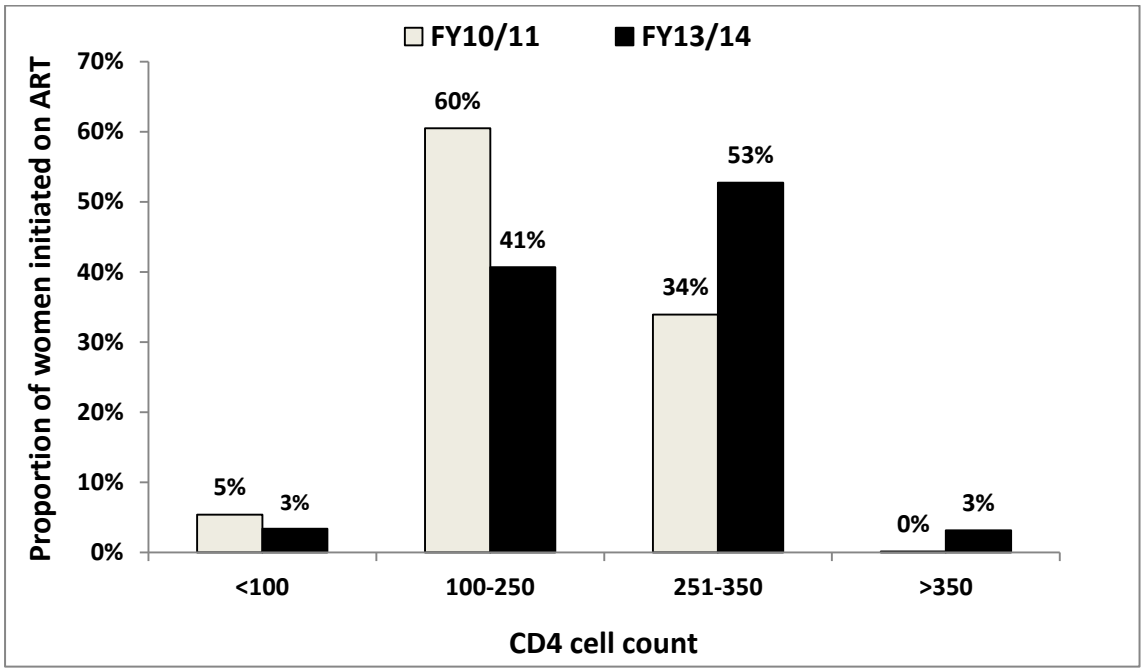


Figure 6:CD4 cell count distribution of women initiated on ART in four eThekwini district CHC in during FY10/11 (n=610) and FY13/14 (n=855)

During FY10/11, 60% (n =369) of women were initiated with a CD4 cell count of 100 to 250 while 34% (n=207) were found to have values between 251 to 350 cells. Fewer women were initiated with a CD4 below 5% (n =33) while no women in FY10/11 had CD4 values above 350.

In FY13/14, 53% (n=451) of women started ART with CD4 cell count values of 251 to 350 while 41% (n=348) were situated in the 100 to 250 range. A lesser proportion of women, 3% (n=29) had CD4 cell count results less than 100 and the same proportion was observed for the above 350 category.

4.3.5 WHO Clinical Stage

The mean WHO clinical stage for women initiated in FY10/11 was 2.06 (SD=0.449) and the value for FY13/14 was 1.75 (SD=0.682). The difference between the two means was 0.312. The difference between the two mean was found to be statistical significance on an independent t-test (t=9.827, p = < .0001)

The distribution of WHO clinical stage from 1 to 3 for the two financial years is reflected in figure 7.

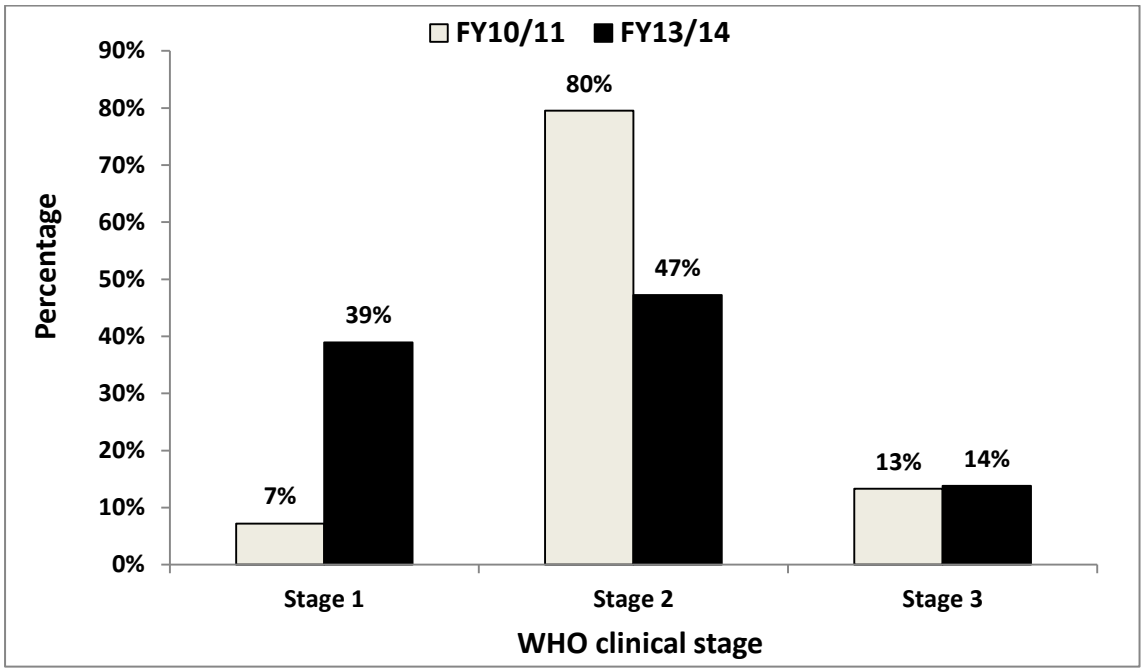


Figure 7: Distribution of WHO clinical stage of women initiated on ART in four eThekwini district CHCs in FY10/11 (n=610) and FY13/14 (n=855)

During FY10/11 80% (n=485) of pregnant women were started on ART at WHO clinical stage 2 while 7% (n=44) and 13% (n=81) were initiated while at stage 1 and 3 respectively.

In FY13/14, 47% (n=404) of women were initiated on ART while at WHO clinical stage 2 and 39% (n=333) were at stage 1 when treatment was started. A proportion of 14 % (n=118) of women commenced ART while at WHO stage 3.

4.3.6 Days from first ANC booking to ART initiation

The delay in the number of days from first ANC visit to the date of ART initiation for FY10/11 was 37.95 (SD=28.71) while that for FY13/14 was 4.12 (SD=9.64). The difference between the two means calculated with an independent t-test was 33.830, the test also revealed a statistically significant difference between the two means (t=32.08, p = <. 0001).

The number of days that the patients waited before initiating ART was divided into six categories of days ranging from less than 7 to more than 180 days. The results of this breakdown between the two financial years are displayed in figure 8.

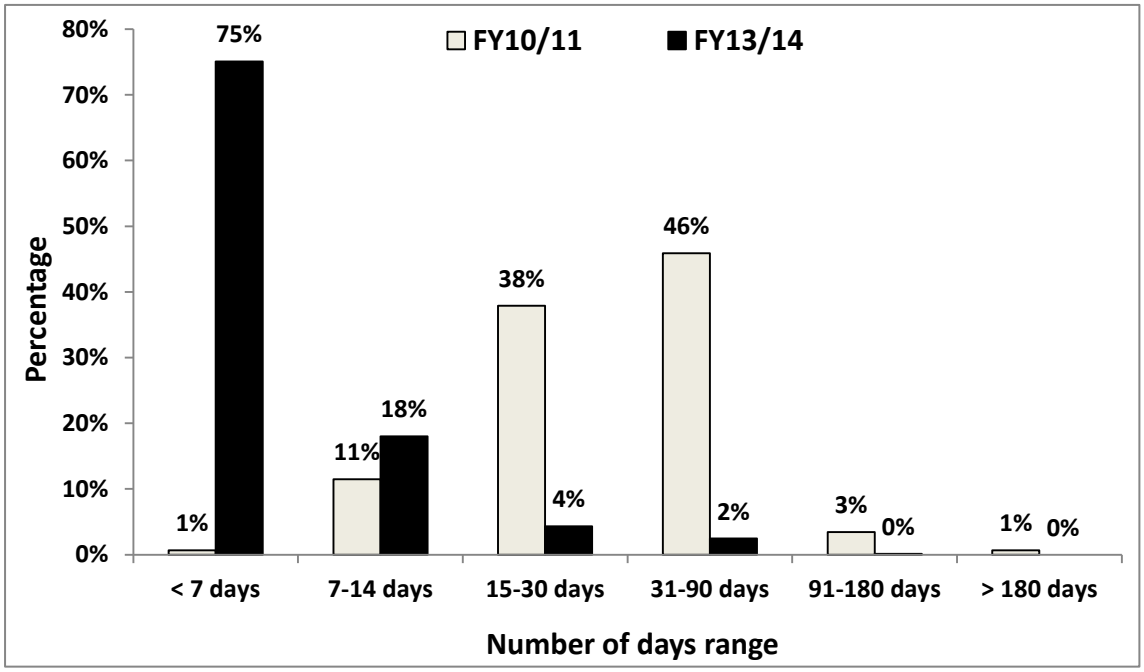


Figure 8: Distribution of days from first ANC visit to ART initiation of women attending ANC in four eThekwini district CHC during FY10/11(n=610) and FY13/14 (n=855)

In FY13/14, 75% (n= 642) of women who started ART during pregnancy did so within 7 days compared to 1 % (n=4) who were initiated in FY10/11. In FY10/11 data shows 46% (n=280) initiated ART within 31 to 90 days after their first ANC visit compared to 2% (n=21) of the FY13/14 who started ART during same time bracket. All women in FY13/14 started ART within 90 days of starting ANC while in FY10/11; a few women were initiated above 180 days.

4.3.7 Gestational age at ART initiation

The mean gestational age at ART initiation for women that initiated ART in FY10/11 was 26.30 (SD=6.02) while on average in FY13/14 the women started ART at 19.06 (SD=6.86) gestational age. An independent t-test showed a mean difference of 7.2 as well as a statistical significance difference between the two means (t=20.94, p = <. 0001).

The distribution of gestational age at ART initiation for both financial years is reflected in figure 9 according to trimester.

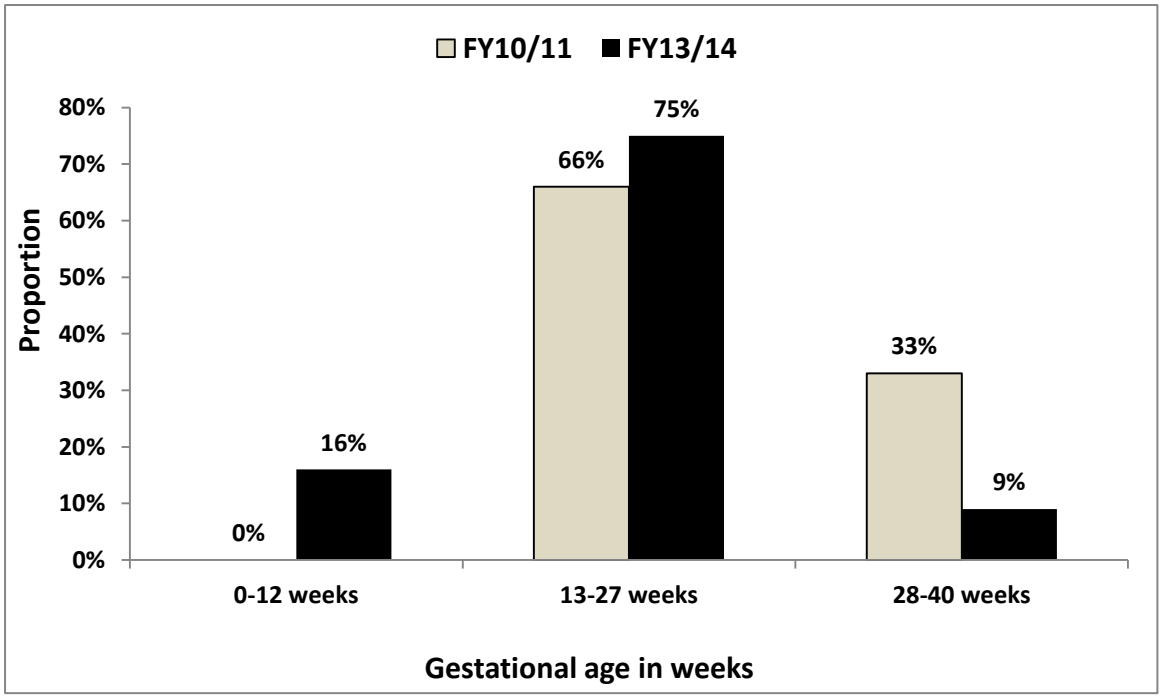


Figure 9: Distribution of gestational age at ART initiation according to trimester of women initiated on ART during pregnancy at four eThekwini district CHC in FY10/11(n=610) and FY13/14 (n=855)

In both financial years the gestational age at ART initiation clustered between 13-27 weeks gestation. Within the second trimester; the mean gestational age was 20 weeks for FY10/11, while those in FY13/14 initiated ART at a mean of 19 weeks.

4.3.8 Point of ART initiation

The ART initiation of pregnant women took place at two service points namely: the ARV where ARV initiations are shared between the nurses and doctors or the ANC clinic where ARV initiations are managed by nurses. The distribution of the women initiated in the two study periods according to service point is reflected in figure 10.

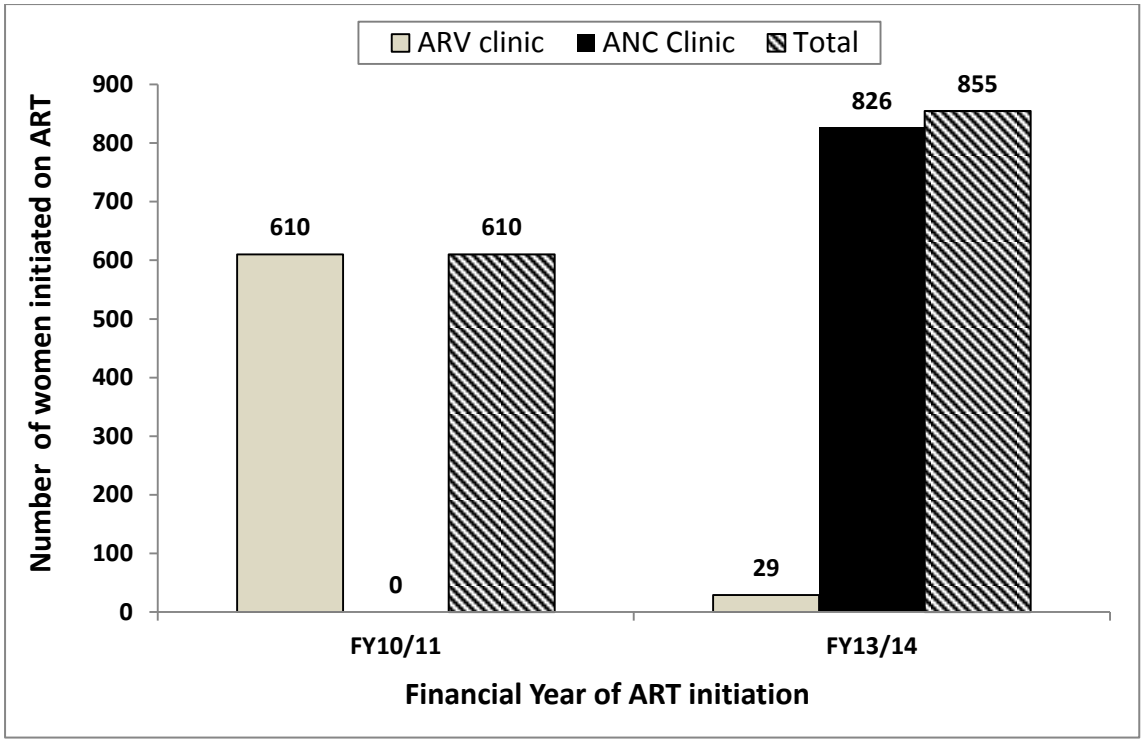


Figure 10: The distribution of women initiated on ART in four eThekwini district CHC according to service point in FY10/11 (n-610) and FY13/14 (n=855)

In FY10/11 100% (n=610) of the pregnant women started ART at the ARV clinic. On the other hand in FY13/14, more women started ART at an ANC clinic with 97% (n=826) compared to the 29 (3%) women that started therapy at and ARV clinic.

4.4 Hypothesis Testing

Associations between variables were tested using the Chi Square test statistic with the level of significance set at .05. The relationship between the following variables was tested.

- Previous PMTCT exposure and ANC booking practices
- Known HIV positive status (at first ANC visit) and ANC booking practices

4.4.1 Previous PMTCT and ANC booking

A total of 372 women that started ART at the study CHCs were recorded to have had some exposure to PMTCT in the past. Of this number 104 initiated ART in FY10/11 while 268 were seen in FY 13/14.

The data on the ANC booking practices of this group is reflected in figure 11 divided between FY10/11 and FY13/14.

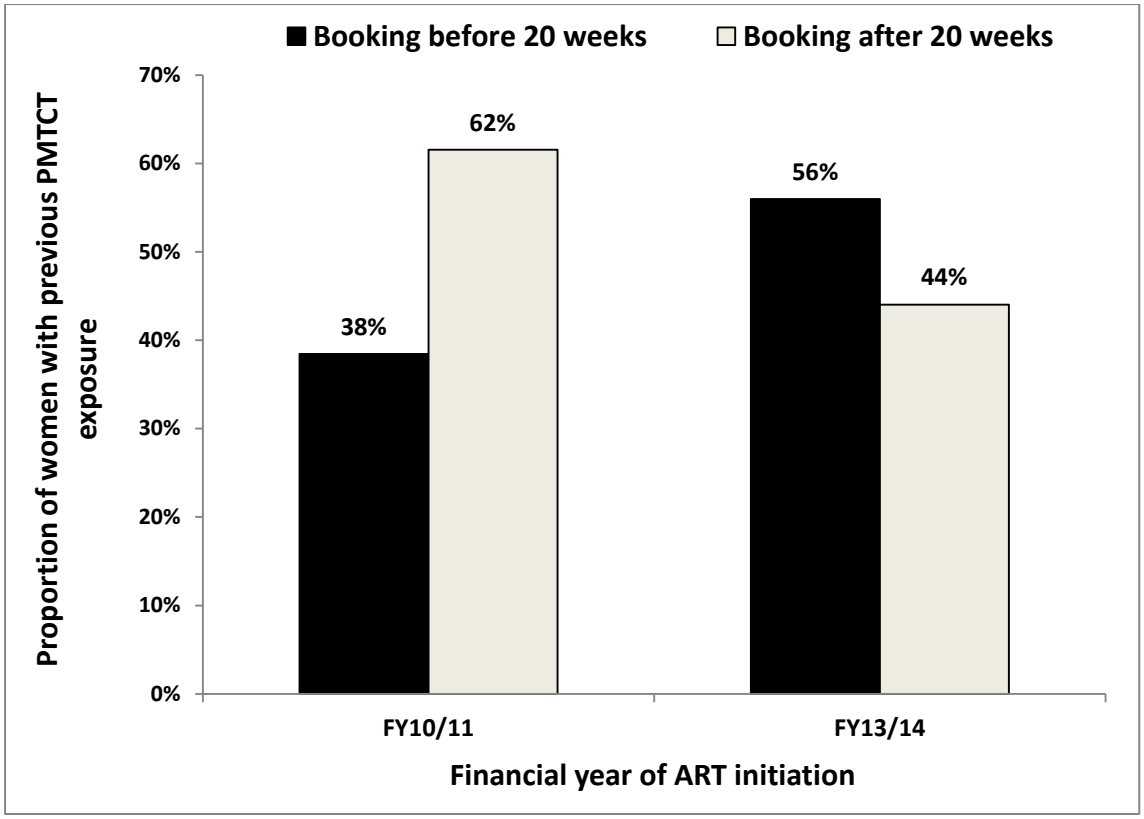


Figure 11: Previous PMCTC exposure and ANC booking practices of women initiated on ART in eThekwini district in FY10/11(n=104) and FY3/14 (n=268)

Of the 104 women with a history of PMTCT exposure 62% (n= 64) booked for ANC after 20 weeks gestation while the remaining 38% (n=40) presented before 20 weeks. In FY 13/14 56% (n=150) of the 268 women with previous PMTCT exposure started ANC before 20 weeks gestation while a lessee 44% (n=118) booked after 20 weeks.

The association between previous exposure to PMTCT and booking before 20 weeks was tested using a chi square test. The hypothesis was that women with previous PMTCT exposure would book for ANC before 20 weeks. For FY 10/11 the observed relationship between the variable was non-significant (X^2 = 0.210, p =.988). The relationship was also found to be non-significant in the FY13/14 data (X^2= 0.523, p=.470). Therefore for both financial years under observation; previous exposure to PMTCT was not associated with early ANC booking.

4.4.2 Known HIV Status at ANC booking

Approximately 512 women that initiated ART at the four CHCs already knew they were living with HIV when they booked for ANC. The distribution of the data for booking before

20 weeks and after 20 weeks for those that knew their status is reflected in figure 12 according to FY10/11 and FY13/14.

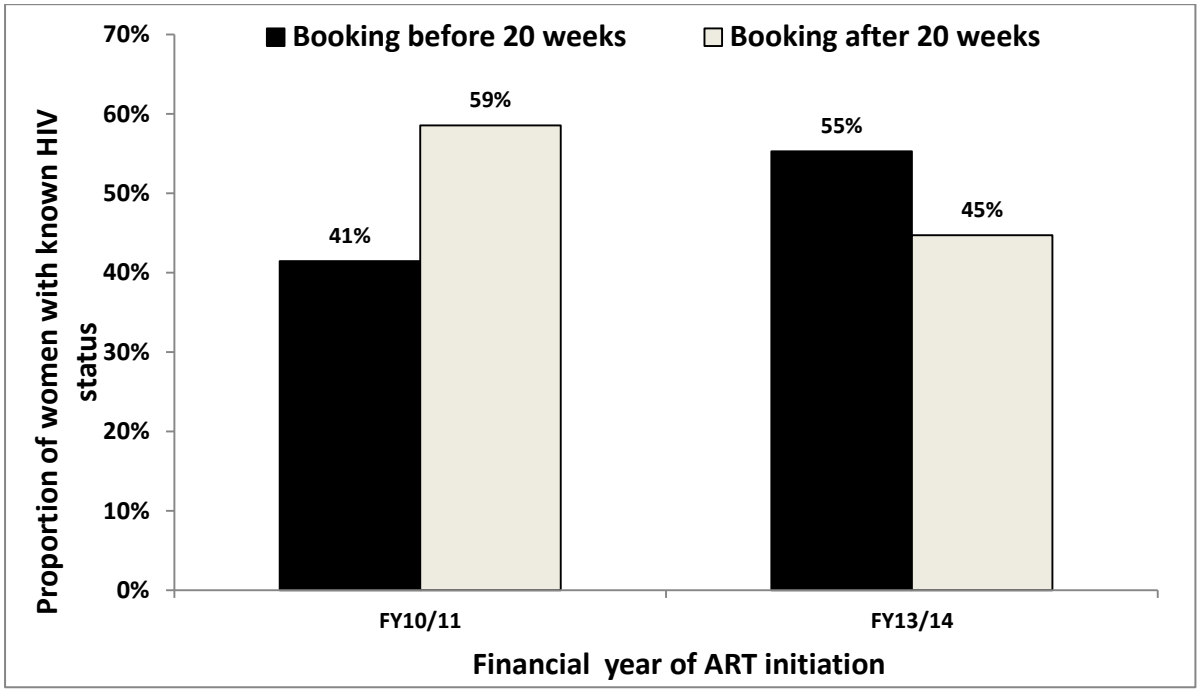


Figure 12: HIV status knowledge at first ANC visit and booking practices of women initiated on ART in eThekwini district during FY10/11 (n=152) and FY13/14 (n=360)

A total of 512 women were reported to have been living with HIV at the time of ANC booking, 30 % (n=152) of which were seen in FY10/11 while the remaining 70 % (n=360) attended ANC in FY13/14. In FY 10/11, 59% (n=89) of women with known HIV status at booking started ANC after 20 weeks while 41% (n=63) presented before 20 weeks. Data from FY13/14 showed 55% (n=199) of women with known status to have booked before 20 weeks.

The association between known HIV status at booking and ANC booking before 20 weeks was tested using the chi square statistic. The hypothesis was that knowing one's HIV status before ANC booking would result in women booking before 20 weeks. For both financial years the relationship was found to be statistically non-significant. For FY 10/11 chi square test for the observed relationship was X^2 = 0.730, p= .393. The chi square test for FY13/14 was X^2=1.59, p= .207.

4.5 NIMART training

Between the years 2011 and 2014 approximately 90 PNs from the four study CHCs attended the five days NIMART training provided by the eThekwini district DOH. Of 90 PNs that attended the training 82% (n=74) completed the required mentorship process necessary for certification. The distribution of the NIMART training numbers is depicted in figure 13 below.

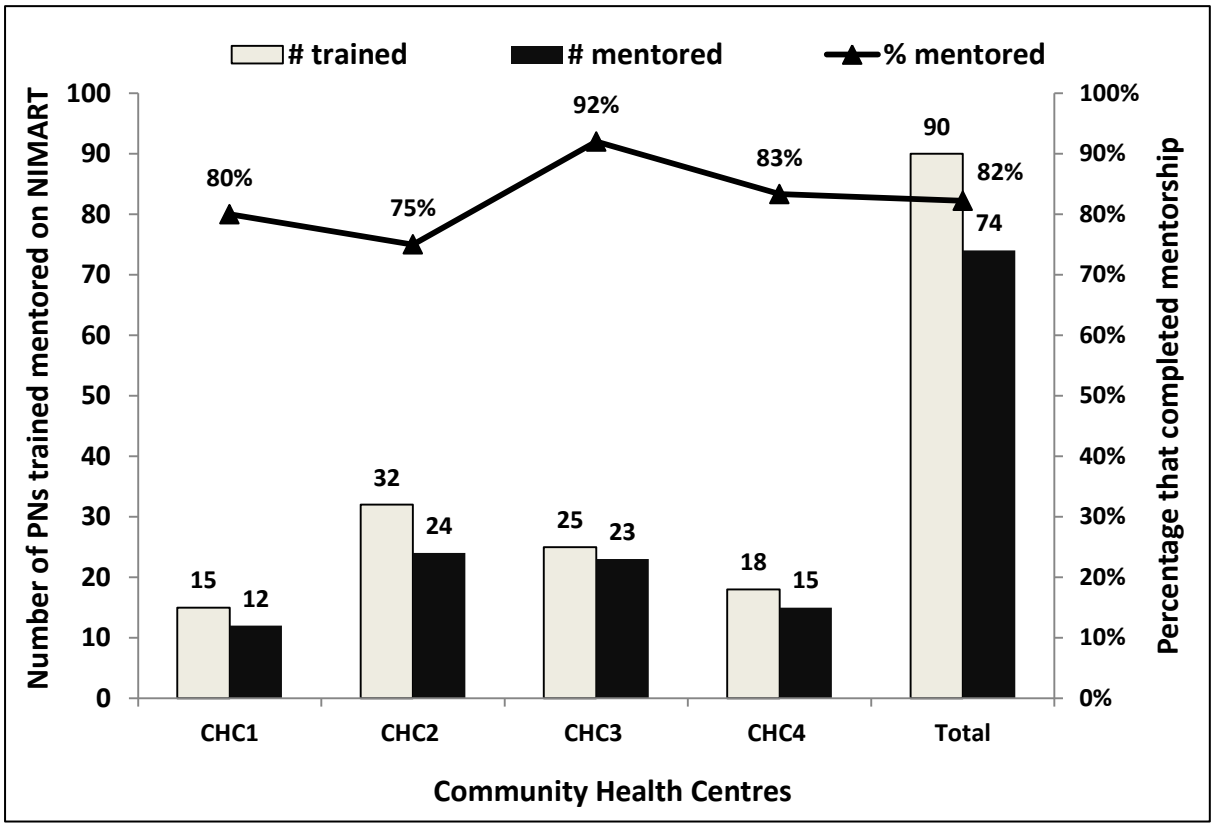


Figure 13: NIMART Training in eThekwini district CHCs from 2011 to 2014, n=90

CHC 1 was reported to have a total number 15 PN to have attended the didactic part of NIMART training with 12 (80%) of these completing mentorship. From CHC 2, PNs attended the training with, 24 (75%) of them reported to have completed mentorship. Despite having the most number of PNs trained, CHC2 also had the least percentage (75%, n=24) that completed the mentorship.

CHC3 was reported to have 25 PNs that attended NIMART training with 92% (n=23) of these completing mentorship. Figure 2 also shows a 17% difference between the sites that had the most proportion of PNs mentored (92%, n=23) and the one with the least (75%, n=24) mentored PNs.

4.6 Summary

In this chapter, variables relating to ART initiation of the study group have been described and compared between the two study timelines. Also presented is a report on the extent of NIMART training in the four district CHCs. A full analysis and discussion of the results follows in chapter 5.

CHAPTER 5 : DISCUSSION

The introduction of task shifting through the implementation of NIMART in South Africa aimed to facilitate the decentralisation of ART services while also facilitating timeously ART initiation of eligible patients. This study sought to establish if pregnant women benefited from the programme by getting initiated on ART within ANC clinics in minimum time. Through this study other maternal health variables that have an impact in health outcomes were explored.

The study results revealed a shift from ART initiation in ART clinics to the ANC clinic for eligible pregnant women. With this shift the waiting times before ART initiation appear to have been reduced. Areas that need more attention in maternal health services have also been revealed and in particular the ANC booking practices of women whose files were reviewed in this study.

In this section an analysis of the study's key results will be presented according to the study objectives also in relation to the literature review. Study limitation will also be covered in the last section of the chapter

5.1 Data Analysis

5.1.1 Comparison of ART initiation between FY10/11 and FY13/14

The study sought to determine if ART initiation had improved between the two financial years under comparison.

The results of this study showed that during FY10/11 out of the 1334 women eligible for ART at the participating CHCs, 49 %(n=610) initiated ART during pregnancy compared to the 60% (n=855, N=1414,) that started ART in FY13/14. This result shows a 14 % improvement in ART initiation of pregnant women between the two years. Also to be noted is that the number that was eligible for initiation in FY10/11 represented as lesser proportion of women (49%, N=1334) compared to 51% (N=1414) for FY13/14. Despite having slightly more to initiate in FY13/14; the sites were able to surpass the numbers initiated in FY10/11. Based on these results one can determine that an improvement in the number of women initiated on ART during pregnancy occurred in FY13/14.

In the Strategic Plan for Maternal, Newborn, Child and Women's Health and Nutrition in South Africa 2012 - 2016, the national target for ART initiation of the pregnant women for 2013 was set at 96% from a baseline of 92% in 2012 (44). The 51% ART initiation improvements achieved in this study for FY13/14 is 41% below the set target. In KZN 95% is the target for ART initiation of pregnant women according to the KZN DOH Strategic Plan for 2010 – 2014 (58). The targets according to the DoH strategic plan 2015/16 - 2019/20 are a little different at national level, the percentage of eligible women that should be initiated on ART by 2020 is set at 98% with a baseline of 76% (59). The percentage initiated at the study sites is also below the national DoH baseline of 76%. Both the national and provincial targets for ART initiation of pregnant women are aimed at scaling up PMTCT access and this would in turn assist in the country achieving the 90, 90, 90 targets for ART initiation (60). From the results of this study more effort is needed to increase PMTCT coverage in line with the set targets.

5.1.2 Differences between variables

Some differences in general characteristics in the women were identified. Age at first ANC visit was the only variable that showed a statistically non- significant difference between the two study timelines. When tested using the independent t test statistics the difference between the groups in terms of age was found to be non-significant (t=0.1348, p = .898). The rest of the variable revealed statistically significant differences and these are discussed in more detail below.

5.1.2.1 CD cell count and WHO clinical stage

The PMTCT guidelines for both 2010 and 2013 recommend that pregnant women be initiated on ART at a cd4 cell count of 350 as well as clinical stage 3 or 4 (8, 45). In this study the women that initiated ART in FY10/11 did so at a mean CD4 cell count of 215 and this appears slightly lower than 257 for FY13/14. On appearance the difference does not look significant; however when this difference was statistically tested a significant difference was revealed (t=9.891, p=.0001).

Despite the identified difference; this variable revealed that on average in both years pregnant women initiated ART at a lower CD4 cell count of 239 which is 110 points below the recommended threshold. The CD4 cell count reported at ART initiation in this study are slightly higher compared to the median value of 208 cells or 2010 presented by Van

Schalkwyk *et al* in their retrospective file review study which compared ART initiation of pregnant women between 2008 and 2010 (61). The median CD4 cell count for this study was 240 cells for both years.

When it came to the WHO clinical stage majority of women in FY13/14 started ART at a mean of 1.75 compared to 2.06 in FY10/11. This result shows that the women were initiated while relatively healthier with only 13 % (n=81) and 13% (n=118) reported to be WHO clinical stage 3 in FY10/11 and FY13/14 respectively. None of the women in both years were identified as being in WHO stage 4.

5.1.2.2 Days from 1st ANC booking to ART initiation

As a priority group in HIV management; the South African guidelines recommend that pregnant women be fast tracked for ART initiation (8, 45). Some delays from ANC booking to initiation were identified in both financial years under investigation.

The delay in ART initiation was measured in days from the first ANC visit (booking) to the date of ART initiation. The number of days waited ranged from less than 7 days to more than 180 days. More differences in the number of days waited by the women between the two study timelines were identified. On average women that initiated ART in FY10/11 waited approximately 38 days before receiving ART compared to 4 days for the FY13/14 group which is a difference of 34 days. Statistically being initiated in FY13/14 was significantly associated with early ART initiation within 4 days (t=32.007, p=<. 001). Though these results show some improvements; they fall short of the guideline recommendations which stipulate ART initiation at the point of diagnosis (45).

In the Van Schalkwyk *et al* comparative study , the duration between booking and ART initiation was measured in weeks and the median weeks for 2010 was 5.1 , which translates to 35 days of waiting (61). This waiting time is similar to the 38 days delay presented in this study for FY10/11. In their observational cohort study conducted in August 2012 to February 2013 on PMTCT related delays, Schnippel *et al* reported that about 21% of initiated ART within 60 days while only 3% were initiated within 30 days.(62).

5.1.2.3 Gestational age at ANC booking

Booking gestational age can predict the timing of ART initiation. The earlier one starts ANC the higher the likelihood of them being initiated on ART as earlier compared to someone who

might present in later pregnancy. Also in the South African context; early booking before 20 weeks is recommended for several other maternal health assessments and these include ART initiation if needed (42, 43). In the Strategic Plan for Maternal, Newborn, Child and Women's Health and Nutrition in South Africa2012 – 2016; the target for women who book for ANC before 20 weeks for 2013 was 55% and this was set from a baseline of 34% (44).

The results from this study showed an inclination to start ANC after the first trimester but still before 20 weeks. In FY10/11; the women booked for ANC at a range of 8-36 weeks gestation compared to 6-39 found in FY13/14. The mean gestational age for women in FY10/11 was 20.88 compared to 18.4 in FY13/14. When one looks at this indicator in terms of booking before or after 20 weeks the results show a 29% improvement in booking before 20 weeks between the two years. In FY 10/11 39% (n=235) of women were reported to have booked before 20 weeks while 58% (n=494) in FY13/14 booked within this time frame.

Previous studies have reported booking gestational ages after 20 weeks. For instance in a study on ART initiation during Stinson *et al* reported the median gestational age at booking to be 26 weeks gestation with a range of 21-31 weeks (38). This Cape Town study was conducted between 2005 and 2008 but it's interesting to note that challenge of booking after the first trimester still exist as shown in the current study. In another Cape Town study by Myer *et al* a median booking gestation age of 28 weeks was reported (54). A much lower booking gestational age of 17 weeks was reported by Van Schalkwyk *et al*, for 2010 and this is comparable to booking gestational ages of 18 and 20 weeks presented in this study (61).

According to the District Health Barometer 2014/15, The South African average for booking before 20 weeks was 53% and this fell below the target of 65% (46). The results from this study for FY13/14 revealed a 5% improvement in ANC booking before 20 weeks above the national average of 53%. The performance in this indicator for FY13/14 is also above the 2013 target of 55% set in the Strategic Plan for Maternal, Newborn, Child and Women's Health (MNCWH) and Nutrition in South Africa 2012–2016.

5.1.2.4 Gestational age at ART initiation

In this study, the mean gestational age for ART initiation in FY10/11 was 26 weeks while lower at 19 weeks for FY13/14. The study results show a trend of relative late ANC booking resulting in women starting ART after the first trimester. Studies have suggested the first

trimester as the ideal time to commence ART so as to derive maximum benefits from the treatment for optimising health and prevention of vertical transmission (53, 55).

The 26 weeks gestation for ART initiations is similar to other studies on with 25 weeks reported by Van Schalkwyk *et al* for the 2010 data and Schnippel *et a*l reporting 27 weeks (61, 62). The gestational ages for ART initiations in the second trimester mentioned in these studies and FY10/11 of this study show an improvement from the median gestational age of 32 weeks reported by Stinson *et al* (38).

Most improved in this study is the gestational age at ART initiation between the two financial years from a mean of 26 weeks in FY10/11 to 19 weeks in FY13/14 which though is in the second trimester is still in the time frame of before 20 weeks. Also to be note is that even though the women in this started therapy after the first trimester, they would have been on more than 8 weeks of ART by the time of delivery (as stated by Black *et al*) and thus would have reduced chances of vertical transmission (53).

5.1.3 ANC booking practices in relation to history of HIV

South African guidelines on maternal health recommend that ANC be started during the first trimester or as soon as the pregnancy is diagnosed (43, 44, 63). The first trimester is seen as the ideal time to identify risk factors, provide comprehensive assessments and management. However reports of late booking continue to be reported in both DoH reports and research papers. Late booking has also been found to negatively affect PMTCT outcomes. Booking at advanced gestational age for women living with HIV means that they would have a shorter time of ART exposure and thus increasing the chances for vertical transmission (53, 55).

In this study ANC booking was explored in relation to women who were reported to have been known HIV positive at first ANC visit as well as those with previous history of PMTCT.

5.1.3.1 Known HIV status

HIV testing and counselling is available at very point of care in South African health facilities through the Provider Initiated Counselling and Testing programme (64). According to this programme, all patients seeking health care must be given an opportunity to test for HIV. This is aimed at increasing the number of people who know their HIV status and this

would further facilitate early interventions. This also means that women starting ANC would have gone through HIV testing at some point if they had attended a health facility in the past.

For this study known HIV status was defined as being aware of ones HIV positive status at the time of ANC booking. The results show 512 women (for both timelines) as having been aware of their HIV positive status at the time of booking and 49% (n =250) of these presented for ANC after 20 weeks gestation while the remaining 51% (n=262) started ANC before 20 weeks. When looking at the two financial years separately; 55% (n=199) in FY13/14 booked before 20 weeks compared to 41% in FY10/11. These results show a 14% improvement in ANC booking of women with known HIV status. Also, the booking results for this group are comparable to the 58% achieved by the rest of the study population. These improvement are encouraging and if sustained could result in positive maternal health outcomes. As mentioned above, early booking ensures early assessments, diagnosis as well interventions.

5.1.3.2 Previous PMTCT exposure

When looking at previous PMTCT exposure one might hypothesise that such experience would have created more awareness and thus one would present early on subsequent pregnancies to received adequate management.

Of the 1465 women that initiated ART in FY10/11 and FY13/14, 25% (n=372) were aware of were recorded to have been part of the PMTCT programme in previous pregnancies. In FY10/11, 62 % (n=64) of women in this group booked after 20 weeks compared to 44 % (n=118) of women seen in FY13/14 who booked during this time frame. The also results show an 18 % improvement in booking before 20 weeks in this group from 38 % (n=40) in FY10/11 to 56% (n=150) in FY13/14. As with known HIV status these results are comparable to the rest of the study population.

5.1.4 ART initiation service points

During FY10/11, 610 women initiated on ART were recorded to have been referred to the ART clinic. Of the 855 women initiated in FY13/14 across the four CHCs; 97% (n=826) were found to have started treatment within the ANC clinic while 3% (n=29) had been referred to the ARV clinic.

The study demonstrated more ART initiation as having taken place in the ANC clinics in FY13/14. It must also be noted as well that even though doctors are allocated in ART clinics;

NIMART trained PNs were also available in the department and initiated patients independent of the doctor.

5.2 The relationship between NIMART training and ART initiation

The number of PNs trained varied per CHC and these differences were also observed in the proportion that completed mentorship. CHC 3 had the second number (25) of PNs trained and 92% (n=23) of these completed mentorship and this was the highest mentorship proportion overall. In this site training, mentorship and ART initiation appear to show a positive relationship. When comparing the two FYs, one finds that in FY13/14, 39% (n=334) more women were initiated in CHC 3 which is still the highest proportion compared to the other three sites. The site was second highest in FY10/11 with 31% (n=190) of women initiated on ART. The positive relationship identified between, mentorship and ART initiation for CHC3 is more noted with the FY13/14 data.

Even though more PNs were trained in CHC2 (total of 32), 75 % (n=24) completed the mentorship and this is the lowest proportion overall. In spite of having the least mentored PNs, the site had the second highest proportion of women initiated at 30% (n=435) when both FYs are considered. This high initiation rate was observed in FY10/11 where 35% (n=215) of women initiated ART compared to the other participating sites. What is of concern with this site is the lesser number of PNs who completed NIMART mentorship which could explain the drop to 26% (n=220) initiated in FY13/14.

The drop in ART initiations from FY10/11 to FY13/14 was also identified in CHC 1 where 25% (n=146) was initiated in FY10/11 compared to 15% (n=132) initiated in the next time period. The site had 80% (n=12) of trained PNs having completed the mentorship. Also with this site the positive relationship between mentorship and ART initiation was not observed.

CHC 4 had the least number initiated for both FYs compared to the other three sites, with 16% (n=228) of women having started ART at this site. However, the site also showed a 10% improvement from FY10/11 to FY13/14. CHC4 had 85% (n=15) PNs that completed the mentorship making the site the second highest overall compared to the other CHCs. The positive relationship between mentorship completion and an increase in ART initiation between the two FYs was observed at this site. The number initiated increased from 59 in FY10/11 to 169 in FY13/14, showing an increase of 110 women.

5.2.1 Mentorship

The 2011 Clinical Mentorship Manual for Integrated Services describes the processes necessary for NIMART training and mentorship (30). Studies that have explored NIMART, describe mentorship as integral to the success of the programme however this has been reported to be underprovided (29). Between 2011 and 2014, the current study found that within the four participating CHCs 90 nurses attended the training and 82 % (n=74) of these were reported to have completed the required mentorship process. In previous studies, nurses who have gone through the mentorship have reported feeling confident to manage patients on ART compared to those who were not exposed to this support process (23, 32, 34). This study did not investigate the area of confidence levels of the trained nurses and this area need to be explored in future studies.

In FY10/11, CHC 4 had 10% (n=59) women initiated on ART compared to other sites and this improved to 20 % (n=169) in FY13/14. This site also had the second most (83%, n=15) nurses reported to have completed NIMART mentorship. It's not clear if the mentorship process had any influence in the improved ART initiation figures observed in FY13/14. The relationship between mentorship and ART initiation is one of the areas that need to be investigated in future studies.

5.3 Study limitations

Study limitation in relation to selection and information bias are presented in the following sub headings

5.3.1 Selection bias

Study sites were selected according to geographical position thus other factors such as the patient headcount per site, site related staff shortages and the socio economic conditions of the communities served were not considered. These differences between the participating sites can be considered to infer a selection bias and make the generalisability of the results to all District CHCs not possible.

When it came to the study sample, all women that initiated ART at the participating sites were to be selected conservatively until the prescribed sample size was reached. However, some information which was important for the study objectives was found missing in some

records and resulting in some variable being removed from the tool. These commonly missing variables were removed after the pilot study review.

5.3.2 Information bias

Incomplete data and missing records posed information bias. This was first noted during the pilot study where some study variables had to be refined to accommodate available data. This was observed mostly with laboratory results which were inconsistently recorded. One would have to go through several data sources in search of one patient's information and this made the data collection process difficult. The challenge of poor recoding was consistent across all CHCs with some sites being poorer than others.

5.4 Summary

Chapter 5 provided a discussion and analysis of the results in relation to reviewed literature and the country's maternal health guidelines. The main areas discussed were on the differences between the characteristics of the research population in the two timelines under comparison. The discussion revealed some improvements in the management of pregnant women living with HIV as well the role played by NIMART nurses in the decentralisation of ART services.

CHAPTER 6 : CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusion

The study has revealed a shift from ART clinic initiation of pregnant women to ANC clinic which is not only convenient for the women but ensures positive benefits for the mothers and their unborn babies. In this study more women in FY13/14 were recorded to have accessed ART in the ANC clinic compared to FY10/11 where all women were found to have been initiated at the ART clinic.

The numbers of women eligible for ART between the two FYs were found to be closer with 1414 women eligible in FY13/14 compared to 1334 in FY10/11 giving a difference of 80. When it came to ART initiation an increase was noted in FY13/14 where 855 compared to 610 in FY10/11 women were initiated. However though improvement between the study timelines were observed; these still fell below the set targets at both National and Provincial level for ART initiation of pregnant women.

The early timing of ART initiation in pregnancy is associated with reduced vertical transmission. The benefits of early ART initiation are observed when treatment is started at an earlier gestational age. An improvement was noted in terms of ART initiation gestational age with those in FY13/14 starting treatment earlier at an average of 19 weeks compared to 26 weeks in FY10/11. The study showed an improvement in the timing of ART initiation after booking between the two timelines with those initiated on FY13/14 starting ART at an average of 4 days after ANC booking compared to 38 days in FY10/11. This is an encouraging result and infers improvements in the management of pregnant women living with HIV.

Booking during the first of pregnancy is recommended in the country's guidelines. The women in this study booked at mean gestational ages of 19 and 20 weeks for FY11/1 and FY13/14 respectively. However, when one looks at the booking in terms of the country monitoring indicator for this variable; an improvement in the proportion of women that booked before 20 weeks has been observed in this study; from 38% in FY10/11 to 58% in FY13/14.

6.2 Recommendations

The recommendations presented below emanated from the challenges experienced during study data collection as well as from the study results.

6.2.1 Record keeping

One of the challenges encountered during data collection for this study was incomplete and missing data records. This affected some of the study objectives and but beyond this project, quality recording and record keeping interferes with programme evaluation. Data informs decision making at all levels of the health system and without it, correct and targeted actions cannot be instituted.

Monitoring and evaluation is part of almost every training programme that health workers attend. However with all this training good quality data continues to be a challenge. Most of the training done is usually in a lecture format with a few cases studies but the basic principles learned tend not to be implemented in the practical situation. One therefore recommends taking the training away from the formal venue to the real work situation.

The implementation mentorship as a strategy to improve data collection and record keeping could go a long way in sustaining an appreciation for good data. Personnel in facilities that are doing relatively well on some aspects of data managements can be identified and groomed to be mentors in their facilities. This group of people should be tasked with leading by example while also being given time and support to slowly effect quality improvement.

6.2.2 ANC booking

The study showed improved ANC booking before 20 weeks however, the majority of the women still booked after the first trimester. ANC booking after the first trimester has featured as on-going challenge that needs attention if positive maternal health outcomes are to be realised. Guidelines are very clear about the importance of starting ANC early especially in the context of PMTCT. There appear to be a gap between what is prescribed in the guidelines and what is practiced in the community.

Community awareness programmes that detail the exact health benefits of early booking should be implemented. This can be in the form of posters in public places. The role of Community Care Givers already entails some health education on ANC. The messages can be

strengthen and made clearer to include research based information on the impact of HIV to an unborn child if the mother delays ANC.

Within health facilities, family planning clinic can be an ideal environment to spread awareness on the importance of early booking. Early booking and HIV management can be added to the health education component of the family planning clinic as part of the preconception module. To implement this, in-service education for the nurses would be required.

Qualitative studies on ANC booking would also assist in generating more knowledge on factors associated with late booking. The studies can be conducted to elucidate, knowledge, belief and attitudes on the ANC from the general population. This knowledge would assist in creating targeted interventions.

6.2.3 NIMART training

Nurses are continuously being trained on NIMART but not all nurses who receive the training end up initiating patients on treatment. There have been reports of nurses who go back to the facilities after the training only to be allocated in departments where there would be no exposure to practising. In some cases the nurses might be eager to practice but the absence of mentors to guide them through the process can be a hurdle. Before sending candidates for NIMART training, availability of a willing site mentor should be confirmed. In addition, plans should be made to ensure that those trained are given practice time by being allocated in departments where enough ART initiation occurs. This would go a long way in boosting the morale and confidence of the trainees and ultimately result in competent practitioners.

6.2.4 Decentralisation of ART services

Decentralisation of services ensures that patients receive convenient medical attention with minimum movement from department to another. The decentralisation of services observed in the case of ANC clients can be extended to other departments in health facilities. Having ART services available in chronic care, under-fives, family planning etc., would also aid in mitigating losses to follow-up and unhonoured referrals. Implementing the decentralisation approach would yield positive results for health care outputs.

6.2.5 Possible or future studies

Qualitative studies on ANC booking would also assist in generating more knowledge on factors associated with late booking. The studies can be conducted to elucidate, knowledge, belief and attitudes on the ANC from the general population. This knowledge would assist in creating targeted interventions.

Studies on nurse experiences and challenges with task shifting are recommended, both qualitative and quantitative study would be useful in this regard. In addition, studies should be extended to include doctors to gauge their knowledge, attitude and belief understanding about task shifting.

6.3 Summary

The study revealed a shift in ART initiation point of care for pregnant women from the ART clinics to the nurse run ANC clinics. With this shift, the waiting time from booking to ART initiating was observed to have been reduced. Though ANC booking during the first trimester was noted to be a challenge, booking after 20 weeks showed improvements. More studies that will provide more understanding of the knowledge, attitudes and beliefs of health workers and communities on the processes necessary to better manage pregnant women living with HIV are recommended.

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APPENDIXES

Appendix 1: Data collection tool

Tool #:_____

CHC #: ☐☐

Patient Study #: _____

1. Period of ART initiation

April 2010-March 2011 ☐ April 2013-March 2014 ☐

2. Baseline information

Date of 1st ANC visit: (day) _____/ (Month) _____/ (Year) _____ Age: ☐☐

Gravid state ☐☐ Parity ☐☐ Gestational age 1st at ANC visit ☐☐

- **HIV diagnosis**: New HIV Diagnosis ☐, Known HIV Status ☐
- **Previous exposure to PMTCT** Yes ☐No ☐

3. ART Eligibility

- CD4 cell count results _____
- Opportunistic infections (OIs): Yes ☐ No ☐ Clinical stage_____

If presenting with OIs indicate presenting clinical stage condition/s:

- _____
- _____
- _____
- Co-morbidity (chronic conditions): Yes ☐ No ☐
- *If yes, indicate presenting condition/s:*
- _____
- _____

4. Prophylaxis

- AZT: Yes ☐ No ☐ NA ☐
- IPT: Yes ☐ No ☐ NA ☐
- CPT: Yes ☐ No ☐ NA ☐

- Other _____ indicate date of initiation____/_____/_____

5. ART preparation

- Other Baseline investigations

Type of investigation	Date	Results
• **Onsite TB screening**		
• **Creatinine**		
• **Haemoglobin**		
• **AFB**		
• **X-ray**		
• **Other**		

6. ART initiation

- Was ART eligibility based on?

  -CD4 cell count ☐

  -Clinical staging ☐

  -Both CD4 cell count and Clinical staging ☐

- Date of ART initiation ____/____/_____
- Gestational Age at ART initiation ☐☐
- ART regimen _____

7. ART initiation service point : ARV clinic ☐ ANC clinic ☐

8. Notes

_____

_____

_____

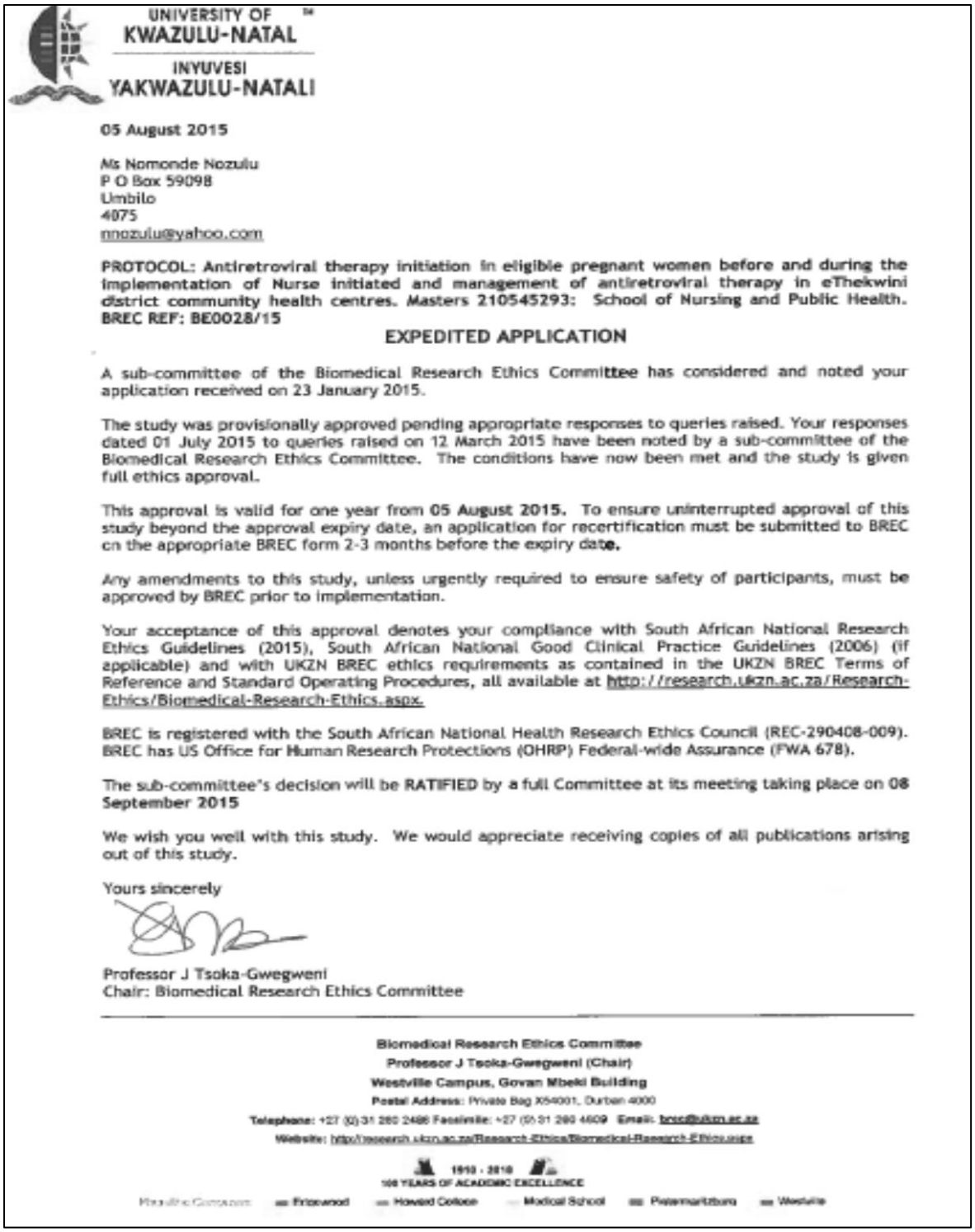
_____

_____

Date of data capture_____

Appendix 2: Ethics letter

BREC Approval letter



UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

05 August 2015

Ms Nomonde Nozulu
P O Box 59098
Umbilo
4075
nnozulu@yahoo.com

PROTOCOL: Antiretroviral therapy initiation in eligible pregnant women before and during the implementation of Nurse initiated and management of antiretroviral therapy in eThekwini district community health centres. Masters 210545293: School of Nursing and Public Health. BREC REF: BE0028/15

EXPEDITED APPLICATION

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application received on 23 January 2015.

The study was provisionally approved pending appropriate responses to queries raised. Your responses dated 01 July 2015 to queries raised on 12 March 2015 have been noted by a sub-committee of the Biomedical Research Ethics Committee. The conditions have now been met and the study is given full ethics approval.

This approval is valid for one year from **05 August 2015.** To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2015), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

The sub-committee's decision will be **RATIFIED** by a full Committee at its meeting taking place on **08 September 2015**

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

Yours sincerely

Professor J Tsoka-Gwegweni
Chair: Biomedical Research Ethics Committee

Biomedical Research Ethics Committee
Professor J Tsoka-Gwegweni (Chair)
Westville Campus, Govan Mbeki Building
Postal Address: Private Bag X54001, Durban 4000
Telephone: +27 (0) 31 260 2486 **Facsimile:** +27 (0) 31 260 4609 **Email:** brec@ukzn.ac.za
Website: http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx

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Appendix 3: DOH permission letters

1. KZN DOH Approval letter

health
Department:
Health
PROVINCE OF KWAZULU-NATAL

Health Research & Knowledge Management sub-component
10 – 103 Natalia Building, 330 Langalibalele Street
Private Bag x9051
Pietermaritzburg
3200
Tel.: 033 – 3953189
Fax.: 033 – 394 3782
Email.: hrkm@kznhealth.gov.za
www.kznhealth.gov.za

Reference : HRKM78/15
NHRD Ref.: KZ_2015RP7_554
Enquiries : Ms G Khumalo
Telephone : 033 – 395 3189

Dear Ms N Nozulu

Subject: Approval of a Research Proposal

1. The research proposal titled **'Antiretroviral therapy initiation in eligible pregnant women before and during the implementation of Nurse Initiated and Management of Antiretroviral Therapy in eThekwini Health District Community Health Centres'** was reviewed by the KwaZulu-Natal Department of Health (KZN-DoH).

The proposal is hereby **approved** for research to be undertaken at Cator Manor, KwaDabeka , KwaMashu & Tongaat Community Health Centres.

2. You are requested to take note of the following:
   a. Make the necessary arrangement with the identified facility before commencing with your research project.
   b. Provide an interim progress report and final report (electronic and hard copies) when your research is complete.

3. Your final report must be posted to **HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200** and e-mail an electronic copy to hrkm@kznhealth.gov.za

For any additional information please contact Ms G Khumalo on 033-395 3189.

Yours Sincerely

Dr E Lutge
Chairperson, Health Research Committee
Date: 07/05/15

2. EThekwini District DOH permission

health

Department:
Health
PROVINCE OF KWAZULU-NATAL

Postal Address: Private Bag X54318 Durban 4000
Physical Address: 83 King Cetshwayo Highway,
Mayville, Durban 4001
Tel.031 2405455: Fax. 031 2405500
Email: henry.sunpath@kznhealth.gov.za
www.kznhealth.gov.za
Enquiries: Dr H Sunpath

19 June 2015

Dear Ms. Nomonde Nozulu,

Re : Title of research : Antiretroviral therapy initiation in eligible pregnant women before and during the implementation of nurse initiated and management of antiretroviral therapy in eThekwini district community centres

Thanks for submitting the documents in support of the above research

Ethics approval –ethics committee date and approval number ; BE 0028/15

Letter of permission from Provincial DOH :dated and reference : 05/05/15HRKM -078/15

Protocol and methodology for reference –received/ not received

Approval is hereby granted to conduct this research in the following health care facilities located in Ethekwini district under the provincial and district management teams.

1. Kwa Mashu Polyclinic
2. Kwa Dabeka CHC
3. Cato Manor CHC
4. Tongaat CHC

Proposed start date :2015 and Proposed completion date:to be updated

Please note that all research activities in the health care facility must be conducted in a way that does not interrupt clinical care.This letter serves only to support the project ,however the logistical details are subject to approval by the CEO/Medical Manager /Nursing services manager.

Wishing you success in this important and relevant research.

Yours faithfully

Dr.Henry Sunpath :MBBS; MFam Med; Dip HIV Man,MPH (UKZN)

Chief Technical Advisor –Clinical Governance; **Ethekwini District Health Office**

3. CHC permission letters

3.1 Cato Manor

health

Department:
Health
PROVINCE OF KWAZULU-NATAL

CATO MANOR COMMUNITY HEALTH CENTRE
25 Kalenden Road, Cato Manor 4091
P.O.Box 2443, Durban 4001
Tel.:031 261 4260, Fax.:031 261 4746
Email.:gloria.mkhize@kznhealth.gov.za
www.kznhealth.gov.za

Reference:
Enquiries: Mrs.G.N. Mkhize
Ext: 4201
Date: 19/03/2015

ATTENTION: Ms. N Nozulu
School of Nursing and Public Health

RE- PERMISSION TO CONDUCT RESEARCH AT CATO MANOR CHC

I have a pleasure in informing you that permission has been granted to you by Cato Manor CHC to conduct research on **ANTIRETROVIRAL THERAPY INITIATION IN ELIGIBLE PREGNANT WOMEN BEFORE AND DURING THE IMPLEMENTATION OF NURSE INITIATED AND MANAGEMENT OF ANTIRETROVIRAL THERAPY IN ETHEKWINI HEALTH DISTRICT COMMUNITY HEALTH CENTRES**
Please note the following:

1. Ensure that you adhere to all the policies, procedures, protocols and guidelines of the Department of Health with regards to this research.
2. This research will only commence once this office (facility) has received confirmation from the Provincial Health Research Committee in the KZN Department of Health, as you have already submitted
3. Please ensure that the facility is informed before you commence your research.
4. The facility will not provide any resources for this research.
5. You will be expected to provide feedback on your findings to the facility

Yours Faithfully
Mrs. P.N. Ngcobo
Acting for Mrs G.N.Mkhize DMN Acting Facility Manager

Signature: _____ Date: 20/3/15

3.2. KwaDabeka

HEALTH
KwaZulu-Natal

KWADABEKA COMMUNITY HEALTH CENTRE
Postal Address: P O BOX 371, CLERNAVILLE 3602
Physical Address: 4 spine Road, Clernaville, Durban
Tel.031 7143704:, Fax 031 7143710

Monjurul.hoque@kznhealth.gov.za:
www.kznhealth.gov.za

08 May 2015
Enquiry: Dr. Hoque

Nomonde Nozulu

Principal Investigaton
School of Nursing and Public Health
University of UKZN

RE: PERMISSION TO CONDUCT RESEARCH AT OUR FACILITY

I have pleasure in informing you that permission has been granted to you by Kwadabeka CHC to conduct research on "Antiretroviral therapy initiation in eligiblepregnant women before and during the implementation of Nurse Initiated and Management of Antiretroviral Therapy in eThekwini Health District Community Health Centres".

Please note the following:

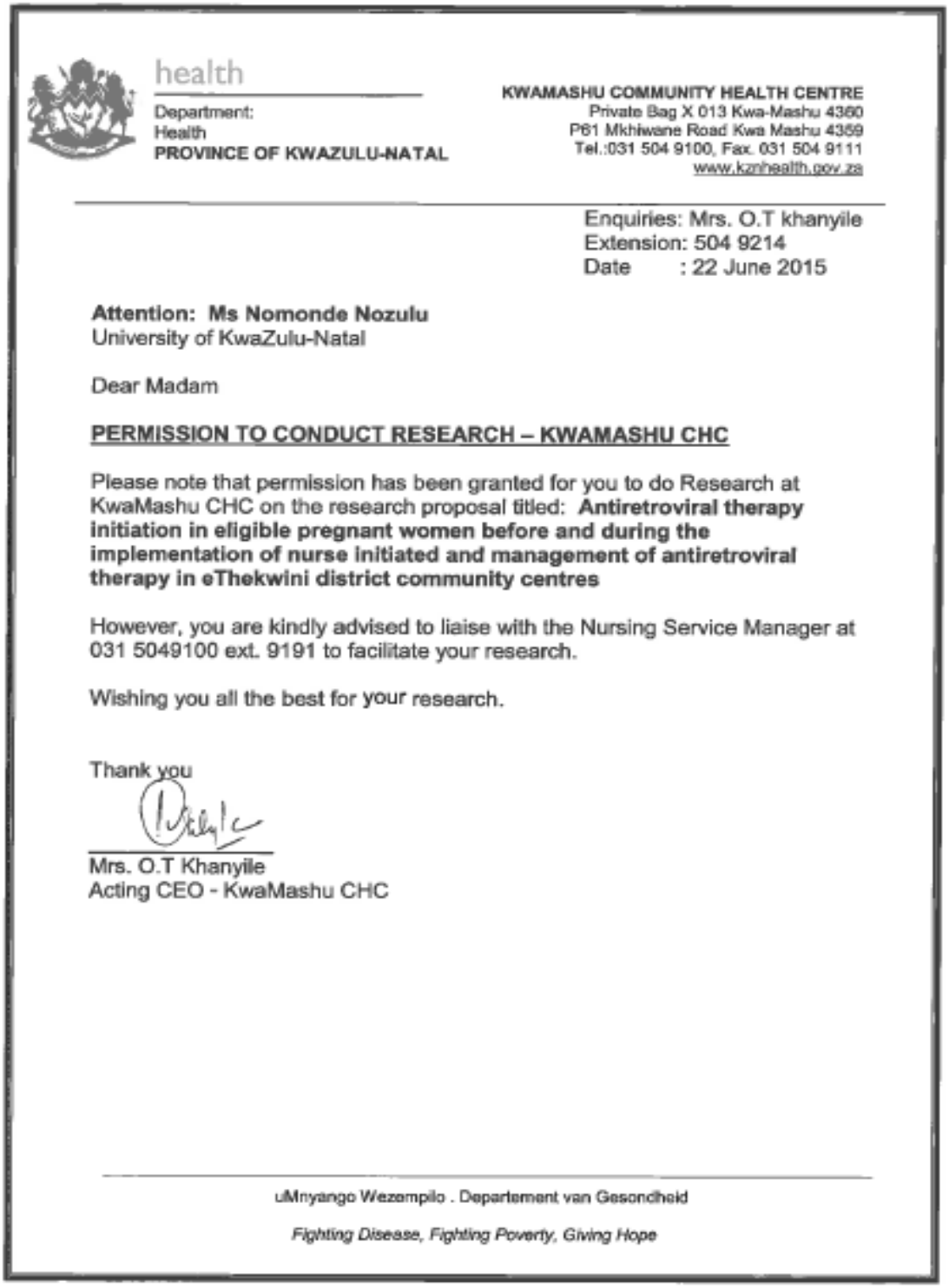
1. Please ensure that you adhere to all the policies, procedures, protocols and guidelines of the Department of Health with regards to this research.
2. This research will only commence once YOU PROVIDE THE FINAL ETHICAL CLEARANCE FROM THE UKZN ETICS COMMITTEE.
3. Please ensure this office is informed before you commence your research.
4. The Kwadabeka CHC (Facility) will not provide any resources for this research.
5. You will be expected to provide feedback on your findings to the Facility.

Thanking you

Sincerely

Acting CEO

3.3 KwaMashu



health

Department:
Health
PROVINCE OF KWAZULU-NATAL

KWAMASHU COMMUNITY HEALTH CENTRE
Private Bag X 013 Kwa-Mashu 4360
P61 Mkhiwane Road Kwa Mashu 4359
Tel.:031 504 9100, Fax. 031 504 9111
www.kznhealth.gov.za

Enquiries: Mrs. O.T khanyile
Extension: 504 9214
Date : 22 June 2015

Attention: Ms Nomonde Nozulu
University of KwaZulu-Natal

Dear Madam

PERMISSION TO CONDUCT RESEARCH – KWAMASHU CHC

Please note that permission has been granted for you to do Research at KwaMashu CHC on the research proposal titled: **Antiretroviral therapy initiation in eligible pregnant women before and during the implementation of nurse initiated and management of antiretroviral therapy in eThekwini district community centres**

However, you are kindly advised to liaise with the Nursing Service Manager at 031 5049100 ext. 9191 to facilitate your research.

Wishing you all the best for your research.

Thank you

Mrs. O.T Khanyile
Acting CEO - KwaMashu CHC

uMnyango Wezempilo . Departement van Gesondheid

Fighting Disease, Fighting Poverty, Giving Hope

3.4 Tongaat

health

Department:
Health
PROVINCE OF KWAZULU-NATAL

TONGAAT COMMUNITY HEALTH CENTRE
Private Bag X06 TONGAAT 4400
SANELE NXUMALO LANE
TONGAAT
Tel.: 032 9445054, Fax: 032 9454058
Email.:boodhi.roopsingh@kznhealth.gov.za
www.kznhealth.gov.za

Date: 08/05/2015

Ms Nomonde Nozulu

RE: PERMISSION TO CONDUCT A RESEARCH PROJECT

1. The above matter refers.
2. Kindly be advised that permission is granted to conduct the research at our institution.

Thank you

DR BM ROOPSINGH
MANAGER : MEDICAL SERVICES (NON CLINICAL)