AN IMPLEMENTATION EVALUATION STUDY OF A NURSE INITIATED AND MANAGED ANTIRETROVIRAL THERAPY (NIMART) PROGRAM IN PRIMARY HEALTH CARE CLINICS IN THE UGU DISTRICT OF KWAZULU-NATAL

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BY

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DECEMBER 2016

DECLARATION

I, Pearl Xaba, hereby declare that this dissertation is my own original work and I am the sole author. This work has not been submitted for any other degree or at any other University. All the literature that I have cited in this study has been given absolute acknowledgement by proper referencing of the source.

Signature _____ _____

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Supervisor: Dr Jane Kerr Date

DEDICATION

I dedicate this dissertation to my dear mother, Sizakele MaSiwela Gama, for her prayers and for being my pillar of strength and also to my late dad and my late parents-in-law for their love.

I also dedicate this dissertation to my loving husband, Philani for his continuous love, tremendous support, patience and encouragement throughout my studies. I wouldn't have made it without him.

Lastly, to my three daughters: Aphiwe, Aphelele and Anelisa for your understanding when mommy couldn't spend precious moments with you, I did it for you my princesses. I hope and pray that I inspire you and you'll follow on mommy's footsteps.

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ABSTRACT

AIM

The purpose of this study was to conduct an implementation evaluation study of Nurse Initiated and Managed Antiretroviral Therapy (NIMART) program in Primary Health Care (PHC) clinics in the Ugu district of KwaZulu-Natal.

METHOD

A quantitative non-experimental descriptive approach and evaluative design consisting of self-administered questionnaires was used to conduct the study to evaluate the availability of the latest Antiretroviral Therapy Guidelines, to evaluate the implementation of the Nurse Initiated and Managed Antiretroviral Therapy (NIMART) program and to evaluate the knowledge and practice of professional nurses towards the NIMART program in the 56 clinics of the Ugu district. Information leaflets were given to the participants and informed consent was obtained from each participant. The number of participants that were enrolled in the study was 52 because they met the inclusion criteria of working in the PHC clinics in the Ugu district and were trained in the NIMART course. The other 4 participants were not trained in the NIMART course and were excluded according to the exclusion criteria.

RESULTS

The study revealed that in 98% (n=51) of the clinics in the Ugu district, nurses were initiating adults on ART and only 2% (n=1) were still being initiated by the doctor. Furthermore, the majority of respondents indicated that children were initiated on ART in their clinics, while some respondents reported that in their clinics children are still initiated by the clinic visiting doctor or hospital doctor. The findings indicated that 98% (n=51) of clinics have the latest ART Guidelines available, while only 2% (n=1) of clinics indicated that they have outdated ART Guidelines available in the clinic. The study revealed that most respondents knew the correct ART regimens, ART eligibility criteria and when blood for CD4 count and viral load is taken, while there were still some respondents who did not know.

CONCLUSIONS AND RECOMMENDATIONS

The District HAST Manager and clinics' Operational Managers must ensure that the latest 2015 National Consolidated Guidelines for PMTCT are available in all the PHC clinics. More nurses should be trained in NIMART. All the nurses that are NIMART trained should receive mentorship after the training so that they become competent and confident in initiating and managing HIV-positive patients on ART.

The findings of this study revealed that there were some gaps in nurse's knowledge around ART regimens, blood tests and eligibility criteria. This study can be used as a baseline to evaluate all the professional nurses trained in NIMART in Ugu district.

The District Training Coordinator must arrange a workshop regarding the 2015 National Consolidated Guidelines to refresh NIMART nurses about ART regimens, about blood tests to be done and about the ART eligibility criteria.

KEY TERMS: NIMART, ART, Evaluation, Implementation

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DEFINITION OF ACRONYMS

ACRONYMS	DEFINITION
AIDS	Acquired Immune Deficiency Syndrome (AIDS) is the clinical definition given to a life-threatening infection in persons whose immune systems have ceased to function properly as a result of infection with HIV.
ARV / ART	Antiretroviral (ARV) drugs inhibit the reproduction of retroviruses. The best known of this group is Human Immunodeficiency Virus (HIV), the causative agent of AIDS. Antiretroviral drugs are virustatic agents which block steps in the replication of the virus. The drugs are not curative. However, the continued use of these drugs, particularly in multi-drug regimens, significantly slows disease progression. ARV drugs are also referred to as Antiretroviral Therapy (ART).
ELIGIBLE FOR ART	Refers to people living with HIV for whom ART is indicated.
HAART	Highly Active Antiretroviral Therapy (HAART) is the combination of several antiretroviral drugs used to slow the rate at which HIV multiplies in the body. A combination of three or more antiretroviral drugs is more effective than using just one drug (monotherapy) to treat HIV.
HAST	HIV/AIDS, Sexually Transmitted Infection and Tuberculosis (HAST) is the program in the Department of Health that deals with HIV/AIDS and the drug management with Antiretroviral Therapy.

HCT	HIV Counselling and Testing (HCT) is an umbrella term used to describe services that combine both HIV counselling and testing.
HIV	Human Immunodeficiency Virus (HIV) which attacks and may ultimately destroys the body's natural immune system.
NIMART	Nurse Initiated Management of Antiretroviral Therapy (NIMART) is the decentralisation of ART initiation to primary health centres (PHCs) by professional nurses, from being doctor-led at hospitals, to reduce workload and the burden of managing uncomplicated cases at referral hospitals.
PICT	Provider Initiated Counselling and Testing (PICT) is HIV counselling and testing recommended by a health care provider in a clinical setting.
PMTCT	Prevention of Mother-to-Child Transmission of HIV program (PMTCT) aims at reducing the transmission of HIV/AIDS from HIV-positive women to their children to improve child and maternal survival.

ABBREVIATIONS

ABBREVIATION	TERM
3TC	Lamuvidine
ABC	Abacavir
AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
CD4	T-lymphocyte cell bearing CD4 receptors
CHC	Community Health Centre
CPT	Cotrimoxazole Preventive Therapy
EFV	Efavirenz
FDC	Fixed Dose Combination
FTC	Emtricitabine
HCT	HIV Counselling and Testing
HIV	Human Immunodeficiency Virus
INH	Isoniazid
IPT	Isoniazid Preventive Therapy
LPV	Lopinavir
LPV/r	Lopinavir/Ritonavir
PEPFAR	President’s Emergency Plan for AIDS Relief

PHC	Primary Health Care
PICT	Provider Initiated Counselling and Testing
PMTCT	Prevention of Mother-To-Child Transmission
TDF	Tenofovir
WHO	World Health Organization

1. CHAPTER ONE
INTRODUCTION AND BACKGROUND

1.1. INTRODUCTION AND BACKGROUND TO THE STUDY

The first Acquired Immunodeficiency Syndrome (AIDS) case was reported on 5 June 1981, in the Morbidity and Mortality Weekly Report produced by the Center for Disease Control (CDC) in Atlanta in the USA. These conditions initially presented to a defined risk group of young homosexual men as rare diseases of Pneumocystis carinii pneumonia (PCP) and Kaposi's sarcoma (a tumour that normally grows slowly). Later on it was noticed that these illnesses were also occurring in other groups, like haemophiliacs, blood transfusion recipients, and intravenous drug users. By 1982, AIDS cases were also being seen in heterosexual couples among partners and infants of those infected. Hence, the name: Acquired Immunodeficiency Syndrome, acronym AIDS, was agreed upon in July 1982.A working definition for AIDS was also formed in the very same year by the CDC based on clinical signs. The name AIDS described the disease accurately since people acquire the condition; it results in a deficiency within the immune system; and it is a syndrome not a single disease. Although the syndrome had been identified and named, the cause remained unknown and how it spread or which drugs were effective or should be formulated (Barlett, Gallant and Conradie, 2008).

In 1983 the virus was identified by Dr. Luc Montagnier and colleagues at the Institute Pasteur in France, and was named Lymphadenopathy Associated Virus. In April 1984, Dr Robert Gallo from the National Cancer Institute in the US isolated the virus and called it Human T-Lymphotropic Virus Type III. It became apparent that the viruses were actually the same. Hence, the Health and Human Services then pronounced to the entire universe that both the French and USA had discovered what causes AIDS. Furthermore, the International Committee on Taxonomy of Viruses declared the name for the virus to be Human Immunodeficiency Virus (HIV) in 1987 (Whiteside, 2008).

Over the three decades of the disease, many developments as well as mistakes have taken place. The AIDS epidemic has stimulated huge amounts of

international and foreign aid. Of particular interest has been the development of a new antiretroviral (ARV) treatment that is capable of transforming HIV infection into a chronic but manageable health condition (Lopez-Aldeguera, Aguirrebengoab, Arribasc, Ested and Kindelane, 2005). Mortality rates due to AIDS have fallen throughout the developed world, and even in some of the more privileged developing countries (UNAIDS, 2010).

El-Sadr, Morrison, Quinn and Volberding (2012) declare that it was hard to recall the world as it existed in 2003 when the President's Emergency Plan for AIDS Relief (PEPFAR) was first announced by President George W. Bush during his state of the Union Address. Millions of men, women and children around the world simply had no access to HIV care or treatment. Then, seemingly overnight, the world changed. No longer were health care workers standing by in dilapidated facilities bemoaning the lack of medicines and laboratory supplies. Instead, in many of the PEPFAR-focus countries, there was palpable vibrancy and unbounded excitement. Millions of persons living with HIV now had access to care and treatment. Millions of pregnant women could prevent transmission of HIV to their babies, millions were aware of their HIV status and had access to methods to protect themselves from acquiring or transmitting HIV.

UNAIDS (2012) reported that despite recent advances in treatment and care available in most developed countries, the HIV/AIDS pandemic continued to spread throughout the developing world. The UNAIDS report on the global AIDS epidemic dated 2013 indicated that an estimated 35.3 million people were living with HIV/AIDS in 2012 globally. This was a decrease from previous years as more people were receiving the life-saving Antiretroviral Therapy. There were 2.3 million new HIV infections globally, showing a 33% decline in the number of new infections from 3.4 million in 2001. At the same time the number of AIDS deaths was also declining, with 1.6 million AIDS deaths in 2012, down from 2.3 million in 2005 (UNAIDS, 2013).

1.1.1. SOUTH AFRICAN HIV PREVALENCE AND INCIDENCE

For 2013, Statistics South Africa (Stats SA) estimated the mid-year population as 52.98 million (Stats SA, 2013). In 2010 there were approximately 5.5 million

people living with HIV in South Africa. New HIV infections have been decreasing. The incidence rate actually reduced by half from 2.6% in 1997 to 1.2% in 2009(SANAC, 2011).

There is an extensive epidemic of HIV in South Africa which is mostly transmitted sexually. In 2009 approximately 17.9% of adult population was living with HIV, of which 3.3 million were women and 334, 000 were children (National Strategic Plan, 2012-2016). KwaZulu-Natal is one of the most affected regions, with about a third of people living with HIV in South Africa living in this province (UNAIDS, 2014).

This epidemic drastically decreased the life expectancy of South Africans by 13 years. In 1990 the life expectancy was 64 years and was reduced to 51 years in 2005 (SANAC, 2011).

1.1.2. SOUTH AFRICA VERSUS THE ENTIRE UNIVERSE

The bulk of world's population of people living with HIV are South Africans. One of every six people living with HIV in the whole world lives in South Africa (SANAC, 2011). Although South Africa makes up only 0.7% of the world population, it carried 17% of the global HIV/AIDS burden in 2010 (UNICEF, 2011).

The UNAIDS report indicates that in Sub-Saharan Africa, 25.0 million adults and children are living with HIV, 1.6 million adults and children are newly infected with HIV, with an adult prevalence of 4.7% and 1.2 million adult and child deaths are due to AIDS (UNAIDS, 2012).

1.1.3. NUMBER OF AIDS-RELATED DEATHS IN SOUTH AFRICA

The total number of deaths due to AIDS in South Africa has declined from 257 000 in 2005 to 194000 in 2012 (UNAIDS, 2011).

Former President Thabo Mbeki and senior politicians in his administration had adopted a widely publicised stance generally understood to mean that HIV does not cause AIDS. Dr. Manto Tshabalala-Msimang who was a Minister of Health then promoted alternative nutritional approaches such as immune boosters. The

minister under Zuma's predecessor distrusted drugs developed to keep patients alive, instead promoting garlic treatments. A Harvard study of the years under President Thabo Mbeki, who questioned the link between HIV and AIDS, concluded that more than 300 000 premature deaths in South Africa could have been prevented had officials here acted sooner to provide drug treatments to AIDS patients and to prevent HIV-positive pregnant women from passing the virus to their children (Bryson, 2009).

1.1.4. ARV COVERAGE IN SOUTH AFRICA

In 2003, under intense political pressure, the government began to increase spending on HIV treatment and in 2009/2010 they spent R11.4 billion or approximately 13% of the R87 billion allocated to health in the 2009/2010 budget (Mukotsanjera, Mwenge and Giya, 2009). The National Department of Health (NDoH) set a goal, in its 2007 HIV Plan, of treating 80% of those in need of ARVs by 2011(Department of Health, 2007).

South Africa has the largest antiretroviral program in the world. Despite this, in 2011, almost half the people in need of the antiretroviral treatment were not receiving it and 48% did not have access to ARVs. Given the late rollout of antiretrovirals in the public health system, South Africa has made impressive progress in scaling up access to treatment: 52% of those who need ARVs received them. More effort is still needed to provide for universal, reliable treatment (UNAIDS, 2011).

1.1.5. PRESIDENT JACOB ZUMA'S SPEECH ON 1 DECEMBER 2009

On 1st December 2009, President Zuma announced that South Africa was to embark on a massive effort to expand antiretroviral care for both adults and children to the primary health care facility level to ensure that all health institutions in the country were ready to receive and assist patients and not just a few accredited ARV centres. South Africa followed in the footsteps of many other countries, particularly those addressing a generalised HIV epidemic, which had begun to decentralise HIV treatment to primary health care centres with the ultimate goal of universal access to HIV treatment. Nurse Initiated and Managed

Antiretroviral Therapy (NIMART) was identified as a key strategy to obtain this goal (Smith, Matshikwe and Letsoalo, 2011).

The South African National AIDS Council (SANAC, 2010) stated that on World AIDS day, 1st December 2009, the President announced that the following directives to address the HIV epidemic in South Africa would be launched on the 1st April 2010:

1. A massive campaign to mobilise all South Africans to get tested for HIV and to ensure that every South African knows their HIV status.

2. Increased access to treatment for children under one year of age that test positive for HIV. This would contribute significantly towards the quality of life for infected children and would reduce infant mortality.

3. Patients presenting with both TB and HIV infection would be initiated on Antiretroviral Therapy (ART) if their CD4 count is 350 or less, shifting from the old guidelines of initiating treatment when CD4 count was less than 200. TB and HIV would be treated under one roof. While 1% of the population has TB, 73% have co-infection with TB and HIV. The policy change would support programs to reduce deaths arising from undetected TB infection among those living with HIV.

4. All pregnant HIV-positive women with a CD4 count of 350 or with symptoms regardless of CD4 count would have access to treatment - a shift from eligibility for treatment when CD4 count was less than 200.

5. All other HIV-positive, pregnant women with higher CD4 counts would be put on treatment at fourteen weeks of pregnancy to prevent Mother-to-Child transmission of HIV.

6. All the health institutions in the country should be able to provide HIV counselling, testing and treatment.

1.1.6. TASK SHIFTING

Task shifting refers to the practice of delegating tasks to health workers with subordinate qualifications. Tasks can be passed on from one group of professionals to another, or to workers with less training (Philips, Zachariah and Venis, 2008). This form of restructuring and decentralisation of health care systems according to task shifting can be seen to alleviate the shortage of health workers, especially in jurisdictions with high HIV incidence (WHO, 2007).The guidelines further state that it is instructive to note that task shifting is not advocated as a sole solution to human resource deficits, as it is universally emphasised that other methods to address this issue need to be deployed in addition to task shifting.

The World Health Organization, together with UNAIDS and President's Emergency Plan for AIDS Relief (PEPFAR) formulated recommendations and guidelines on task shifting with a view to enhancing access to HIV treatment. The National Department of Health's policy response will be set out hereunder, together with the WHO guidelines, as a means to analyse the response to such recommendations and to depict the local response to task shifting (El-Khatib and Richter, 2009). Since then, task shifting has proven to reinforce maintaining patients on ARVs, as well as to reduce the burden of managing uncomplicated cases at hospitals (Nyasulu, Muchiri, Mazwi and Rasetshefola, 2013).

The Department of Health indicated that it recognised the weaknesses in the healthcare system, and devised a ten point plan as part of its strategy to improve healthcare delivery. Aspects of the plan include improving the management of resources and human resource development and management (Department of Health, 2010). Furthermore, in order to remedy the misdistribution of health workers between urban and rural areas and between the private and public sectors, health professionals such as doctors, pharmacists and dieticians are required to engage in one year of community service in a designated area (Health Professions Act, 1974).

1.1.7. NURSE INITIATED AND MANAGED ANTIRETROVIRAL THERAPY – NIMART

In December 2009, the South African government set ambitious goals of testing 15 million people for HIV and expanding ART initiation to 2000 PHC facilities that previously could not offer this service. This required a drastic increase in the number of nurses trained in Nurse Initiated and Managed Antiretroviral Therapy (NIMART). A policy designed to expand HIV treatment and care through task shifting from the sparse quantity of physicians to the stronger cadre of nurses (Istre, 2011). By the end of 2009, it was estimated that about 1.2 million people would need to be initiated on ART over the following two years, which would have exceeded the capacity of the health care system if treatment were to be managed by the cadre of doctors only (Nyasulu et al., 2013). Hence, task shifting to nurse-managed care in primary care settings was essential. From April 2010, nurses began initiating ARVs to patients after they had received NIMART training, in order to bridge the gap between knowledge and practice (Erasmus, 2013). According to Nyasulu et al. (2013), patients had the advantage of fetching ARVs at their local clinics due to NIMART, thus saving time and transport expenses.

The World Health Organization has encouraged the task of primary health care and community-driven care in the distribution of ARVs in remote areas(WHO, 2006). Lesotho has authorised nurses to initiate ARVs since 2006 and it was incorporated officially into the Lesotho Treatment Guidelines in 2008. However many countries in Southern Africa have been hesitant to endorse nurse initiation of Antiretroviral Therapy regardless of the fact that it is recommended by the World Health Organization (Ministry of Health and Social Welfare, 2008).

1.2. **PROBLEM STATEMENT**

The 2013UNAIDS report on the global AIDS epidemic (UNAIDS, 2013) indicated that more people living with HIV/AIDS were accessing the antiretroviral treatment. UNAIDS (2013) reported that, as of December 2012, approximately 9.7 million people in low- and middle-income countries were receiving Antiretroviral Therapy, which was an increase of 1.6 million from 2011. That brought the world nearly two thirds of the way towards the 2015 target of 15 million people accessing Antiretroviral Therapy. However, there were others who should have been receiving the treatment but did not have access to ARVs due to an inadequate number of doctors in the public sector. As a result some patients were initiated on

ARVs late and others died prematurely before they could even access the treatment. Hence, there was a great need for expanding the antiretroviral treatment to the primary health care level.

Bryson (2009) states that President Jacob Zuma said in his speech people would live longer, more fulfilling and healthy lives. The new steps included treatment for all HIV-positive children under one year old; earlier treatment for patients infected with both viruses that cause AIDS and tuberculosis; and earlier treatment for women who are pregnant and HIV-positive. He said all health institutions, not just specialist centres, would provide counselling, testing and treatment.

Hence, the doctor-driven distribution of ART was identified as inappropriate in developing countries with a high HIV burden and restricted healthcare personnel. Consequently, the implementation of HIV treatment policies had been hindered (Erasmus, 2013). In 2010, there was a presidential mandate that public health facilities should make ARVs available and that nurses should be trained to prescribe and manage patients on these drugs. By April 2011, 2552 health facilities were initiating patients on ART (Nyasulu et al. 2013). The implementation of NIMART thus enhanced access to ART and has been incredibly worthwhile (Erasmus, 2013).

1.3. **AIM**

The aim of the study was to evaluate the implementation of the 2010 HIV/AIDS Guidelines in the Primary Health Care clinics in Ugu district to ensure the provision of HIV counselling, testing and treatment to HIV-positive patients, and to ensure the availability of the current guidelines on Antiretroviral Therapy.

1.4. **STUDY OBJECTIVES**

The study objectives were as follows:

1. To evaluate the availability of latest Antiretroviral Therapy Guidelines in the Primary Health Care clinics in the Ugu district.

2. To evaluate the implementation of Nurse Initiated and Managed Antiretroviral Therapy (NIMART) program at the clinics in the Ugu district.
3. To evaluate the knowledge and practice of professional nurses towards the NIMART program in the clinics in the Ugu district.

1.5. RESEARCH QUESTIONS

The three research questions were as follows:

1. What guidelines are available at Primary Health Care clinics in the Ugu district to provide Antiretroviral Therapy for HIV-positive patients?
2. How are the Primary Health Care facilities in the Ugu district equipped to provide HIV counselling, testing and treatment?
3. What is the level of knowledge and practice of professional nurses in the clinics in the Ugu District towards the NIMART program?

1.6. SIGNIFICANCE OF THE STUDY

Nyasulu et al. (2013) pointed out that South Africa was facing a high burden of HIV/AIDS and millions of people living with HIV needed to be initiated on antiretrovirals. However, there was a gross shortage of doctors to initiate them and hospitals were overcrowded. Hospitals could not cope with the volume of HIV-positive patients. A solution to this challenge was to decentralise antiretroviral care to Primary Health Care, so as to increase access of patients to antiretrovirals. By April 2011, 2552 health facilities were initiating patients on ART. Hence, decentralisation of services to primary health centres (PHCs) has strengthened retention of patients on ART, and reduced the burden of managing uncomplicated cases at referral hospitals (Nyasulu et al. 2013).

This study will give an indication as to whether the Ugu district is complying with the presidential mandate. The information from this study can be used to strengthen access to antiretrovirals at PHC, thus saving patients transport costs and reaching more patients who are eligible for ART initiation. This information can also be used in the training of nurses since the district Training coordinator will

be able to establish the total number of nurses that are NIMART trained and the district training needs. Moreover, the district Training coordinator will be able to ascertain if NIMART trained nurses need further mentoring in order to be more confident in initiating patients on Antiretroviral Therapy.

Furthermore, this information can be used by district manager for HIV/AIDS, Sexually Transmitted Infection and Tuberculosis (HAST) to monitor the district performance and improve the programme's indicators. Lastly, the findings of this study will improve service delivery and the health of people.

1.7. THEORETICAL FRAMEWORK

1.7.1. LOGICFRAMEWORK

A logic framework or logic model presents a linear and logical interpretation of the relationship between inputs, activities, outputs, outcomes and impacts with respect to objectives and goals. It also shows the causal relationship between inputs, activities, outputs, outcomes and impact. A logic framework outlines the specific inputs needed to carry out the activities and processes to produce specific outputs which will result in specific outcomes and impacts. A logic framework is also used for monitoring and evaluating activities throughout the stages of the program (Gage and Dunn, 2009).

Gage and Dunn (2009) further state that a logic framework is presented as diagrams connecting program inputs to processes, outputs, outcome and impact as they relate to a specific problem or situation. A logic framework show what resources the program will need in order to accomplish its goals, what the program will do, and what it hopes to achieve, emphasising links between these aspects. A series of "if-then" relationships connects the components of the logic framework, if resources are available to the program, then program activities can be implemented. If program activities are implemented successfully, then certain outputs and outcomes can be expected.

Unlike a conceptual framework, the logic framework does not try to account for all the factors that may influence a program's operation and results. Instead, the logic framework focuses on the program's inputs, activities, and results. This narrow

focus assists program managers as well as monitoring and evaluating planners as they clarify the direct relationships among elements of particular interest within a specific program (Gage and Dunn, 2009).

1.7.2. HOW LOGIC FRAMEWORK RELATES TO THIS STUDY

The logic framework given below represents a simple outlook of a plan intended to develop a health provider's knowledge, attitudes, and practices. It is also intended to enhance access to comprehensive HIV counselling, testing, care and treatment services at community level, and hence decrease the workload at the district hospitals.

Input refers to the human resources and financial resources required to develop the training materials and to implement the training program.

Process in this study refers to identifying service providers who will conduct NIMART training and conduct mentorship training for mentors who will support the nurses who will be the implementers. Process also refers to conducting training for nurses who will be rolling out ARV's at the PHC setting.

Output refers to nurses trained in NIMART, and improved attitudes of NIMART nurses. Output also refers to the increased ability of NIMART nurses to initiate adult and paediatric patients to antiretroviral therapy. Furthermore, output refers to increased understanding and acceptance of task shifting by nurses.

Outcome refers to competent and confident NIMART nurses, increased knowledge of HIV counselling, testing, care and treatment services. Output also refers to the decentralisation of ART and improved access to ART.

Impact in this study refers to improved health and longevity for all. It also refers to compliance with ART since patients will be saving on transport costs.

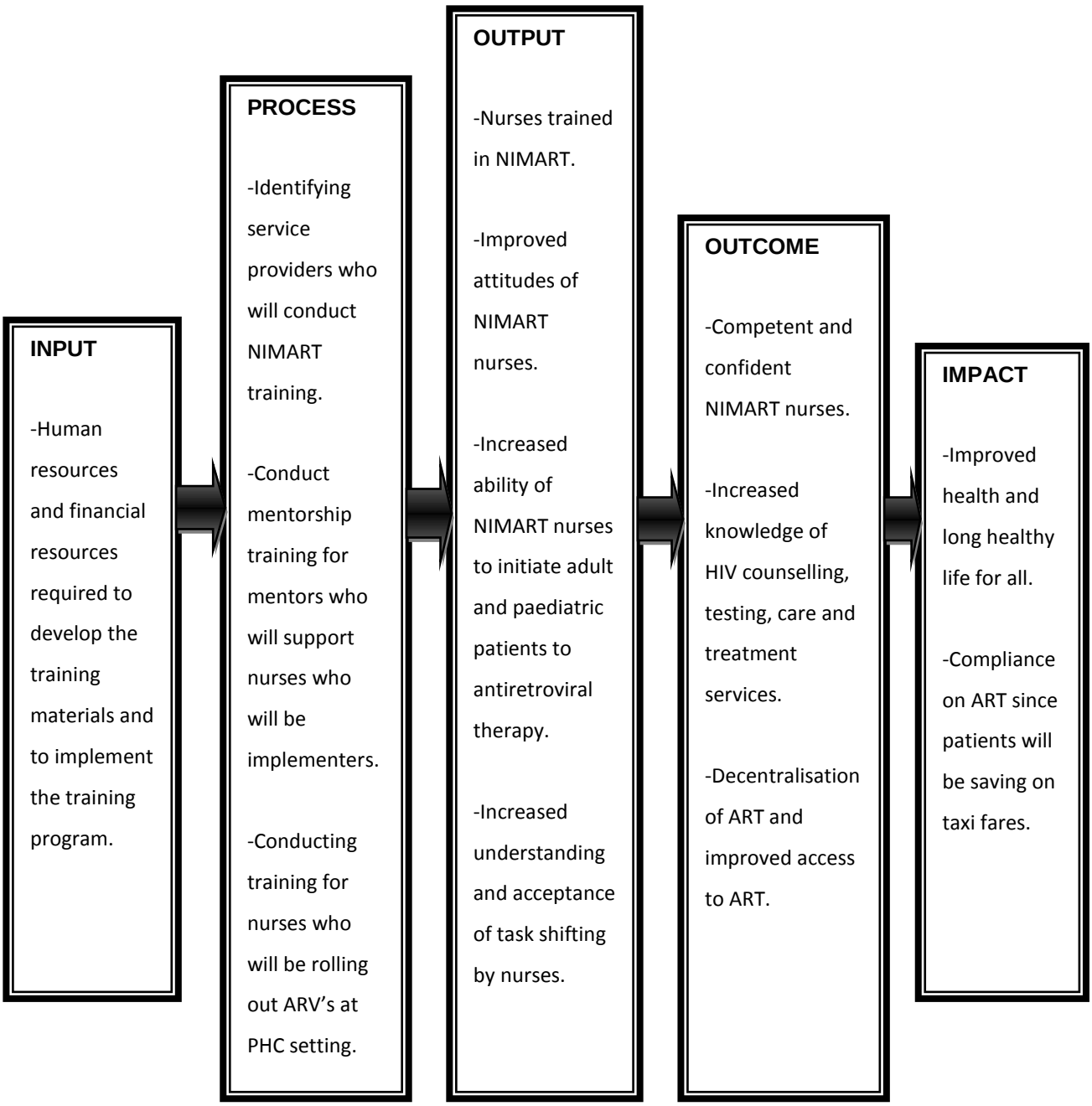

Figure 1. Logic Framework for a Health Provider Training Programme (Gage and Dunn, 2009)

1.8. CONCLUSION

The first chapter introduced the study and provided its background. The aim, study objectives, research questions were outlined. Significance of the study was discussed as well as theoretical framework, which is logic framework in relation to the study.

2. CHAPTER TWO:
LITERATURE REVIEW

2.1. INTRODUCTION

This chapter reviews literature on Nurse Initiated Antiretroviral Therapy (NIMART). The first part of this literature review will analyse the epidemiology of HIV in South Africa. This will be followed by the second part which will focus on how NIMART was established and how it was going to be implemented in Primary Health Care clinics, and also what impact NIMART is going to have on improving patient care of people living with HIV.

The third part of this literature review will then focus on an overview of primary health care. This part will review the literature on the role of nurses in primary health care and in the provision of Antiretroviral Therapy.

The fourth part of this literature review will focus on the decentralisation of Antiretroviral Therapy and task shifting of antiretroviral initiation from being doctor-led to nurse driven. The review will also focus on the challenges nurses have been facing with the task shifting.

The fifth part of this literature review will discuss HIV counselling and testing (HCT) and provider initiated counselling and testing (PICT). This is followed by the sixth part which focuses on Prevention of Mother-to-Child Transmission of Human Immunodeficiency Virus (PMTCT).

The seventh section of this literature review focuses on the NIMART training, followed by the clinical mentorship of the NIMART trained nurses. Lastly, the literature looks at whether the clinical pathway until competency in NIMART has been achieved.

2.2. THE EPIDEMIOLOGY OF HIV IN SOUTH AFRICA

South Africa has the highest number of people living with HIV in the world. Despite the availability of voluntary counselling and testing (VCT) services since 2000, many South Africans have never tested for HIV and the uptake of voluntary counselling and testing (VCT) has been suboptimal. HIV-infected patients who consult their family practitioners are still being missed as opportunities to test and put on care (Makhunga-Ramfolo, Chidarkikire, Farirai and Matji, 2011). In a mid-term review of the National Strategic Plan 2007– 2011, the Human Sciences Research Council (HSRC) reported that the HIV epidemic in South Africa appeared to have stabilised, although a significant number of South Africans did not know their HIV status and testing was still primarily client initiated(World Health Organization, 2007).

SANAC reported in 2010 that in recent years there had been important changes in the management of HIV and TB, provided by the government of South Africa (SANAC, 201O). In 2007 the Deputy President had taken steps to revitalise SANAC, including the review of its terms of reference and membership. A revamped multi-sectoral National Strategic Plan on AIDS and STIs (2007–2011), the NSP, was developed with all key stakeholders in government, civil society and the private sector. It had ambitious targets of reaching 80% of those who needed to be on ARVs by 2011and a 50% reduction in new infections by the same time.

2.3. NIMART

Antiretroviral Therapy and the management of HIV-positive patients was initially a doctor-led program. However, as the incidence increased (that is, the amount of newly diagnosed HIV infections every year), the number of patients that needed to be initiated on antiretroviral drugs also increased. As a result, doctors became overloaded and could no longer cope with the work load. Hence, NIMART was invented to relieve the doctors' workload and of course to increase access to ART. The UNAIDS report of 2008, pointed out that in recent years there had been a tremendous global push to enhance HIV/AIDS prevention and treatment efforts, with a specific focus on increasing the access of low income countries to Anti-Retroviral Therapies (ART) (UNAIDS, 2008). As a result, generic ART has

become cheaper and more widely available across Sub-Saharan Africa, but huge inequality still exist in access to services, with only 30% of those needing treatment currently able to obtain it.

Brennan, Long, Maskew, Sanne, Jaffray, Macphail and Fox (2011) state that the utilisation of nurse managed Primary Health Care clinics (PHCs) for the treatment continuation of stable patients could reduce the load of HIV-positive patients that need to be seen at the hospitals and only the specialised doctor-managed ART patients would remain at the hospitals. According to Smith, Diergaardt, Fourie, Matshikwe and Letsoalo (2011), there was evidence for successful non-physician provided ART in Africa and particularly in South Africa, with equivalent ART treatment outcomes in terms of viral load suppression, mortality and retention in care, being reported. Hence, nurse initiation and management of patients on ART (NIMART) was identified as a key strategy to obtain this goal. Colvin, Fairall, Lewin, Georgen, Zwarenstew, Bachmann, Liebel and Bateman (2010), also stated that field reports from programs that had utilised cadres other than physicians to distribute ART in remote areas of South Africa, were more abundant and reported equally positive results for both ART outcomes and improved access.

Due to the long waiting list of patients awaiting ART initiation and the inadequate number of doctors available, some patients died prematurely while waiting to be initiated on ARV's. Georgeu, Colvin, Lewyn, Bachmann, Uebel, Zwarenstein, Draper and Bateman (2010) stated that PALSA (Practical Approach to Lung Health in South Africa) PLUS had been well accepted and successful in the Free State. However, health managers were still worried about the constantly high mortality of ART-eligible patients awaiting treatment initiation, and were worried about the persistent shortage of physicians available to supply and initiate ART. According to Cameron, Gerber, Mbatha, Mtyabule and Swart (2012), further motivation to rapidly improve access was evidence showing that more than 80% of deaths during the first year after diagnosis of HIV infection occurred before these patients could be started on ART. Therefore, nurse initiation and maintenance of Antiretroviral Therapy (NIMART) improves access, is cost effective, is not inferior to doctor-managed ART, and achieves similar outcomes of viral suppression, adherence, toxicity and death (Cameron et al. 2012).

Nurses in the Free State in 2010 accepted the extensive raise in workload with NIMART since they believed they were well equipped and supported, and had responsibility to save the lives of patients who would have died before being initiated on treatment (Colvin et al., 2010).

Georgeu et al. (2012) pointed out that NIMART appears to be possible and suitable in the primary health care system in South Africa. NIMART was generally well accepted by nurses. Furthermore, nurses were keen and excited to be offered an opportunity to be hands-on in supplying treatment that saves lives. Although the Lesotho Ministry of Health and Social Welfare stated that Lesotho had permitted nurse initiation since 2006 and it had been incorporated formally into the Lesotho National Treatment Guidelines, many countries in Southern Africa have been reluctant to endorse nurse initiation of ART despite the fact that it is recommended by the World Health Organization.

When the ambassador Eric Goosby delivered a key lesson from a decade of action on Global AIDS, and discussed the way forward, at the International AIDS Conference in 2012, he mentioned in his speech that in the United States having access to this treatment has transformed HIV/AIDS into a long chronic condition, cared for largely in an outpatient setting. It had saved many, many lives, but this access to treatment was not universal. “About thirteen years ago, I turned my attention to the global pandemic, and I will never forget what those early years showed us. AIDS was wiping out a generation and reversing health gains in Africa (International AIDS Conference, 2012).”

In conclusion, the good news is that a study conducted by Georgeu et al. (2012) indicated that NIMART was highly acceptable among nurses, doctors and patients. It also revealed that managers and nurses expressed confidence in their ability to apply the guidelines and deliver ART successfully.

2.4. PRIMARY HEALTH CARE (PHC) AND ROLE OF NURSES IN PHC

2.4.1. PRIMARY HEALTH CARE

Wentzel (2008) defines Primary Health Care (PHC) as the cornerstone of health services in South Africa as this is a patient's first level of contact with a health service. The policy of the National Health System in South Africa also states that Primary Health Care services form the basis of health service delivery in South Africa. These services are rendered by primary health care clinics, which have to implement the PHC package. Wentzel (2008) further mentions that PHC was the key element in the South African government's plan to transform health services in South Africa to ensure availability of a comprehensive and integrated package of essential health services for the entire population and in providing a solid foundation for a single unified health system. PHC would be the driving force in promoting equity in health care.

Moreover, Wentzel (2008) points out that PHC services should address the leading cause of mortality and morbidity in the country, so these services had to be accessible to the broader community throughout South Africa. Professional nurses in the clinics do referrals to the next level of services, where necessary. The vehicle for the delivery of the PHC package is the district health system (DHS). The DHS comprises of both fixed and mobile clinics, Community Health Centres (CHC's) and district hospitals (where access to clinics and CHC's is limited). All provinces indicated the need to link the PHC package more clearly with the district hospital (Wentzel, 2008).

The World Health Organization supports the role of PHC and community–led care in the delivery of Antiretroviral Therapy in the remote areas with limited resources (World Health Organization, 2006). Bedelu, Ford, Hilderbrand and Reuter (2007) state that the outcome data in a Lusikisiki survey illustrate that ART can be initiated at the primary health care level with very acceptable outcomes, and also that ART initiation at primary health care enables quicker enrolment than does initiation done only at the hospital.

However, there were no new additional nurses to PHC clinics with the introduction of NIMART and the nurses became overwhelmed. Wentzel (2008) pointed out that

more programs were still being introduced to primary health care facilities, irrespective of inadequate staff establishment which was causing stress and burnout of PHC nurses.

2.4.2. ROLE OF NURSES IN PRIMARY HEALTH CARE

Nurses are the backbone of health care systems across the world. Nurses have always been in the forefront of patient care, providing holistic healthcare to patients from clinic level to bed-side. A lack of doctors and the traditional role played by the nurses, means that they will continue to have a central role to play in not only ensuring universal access to ART for patients in need, but also in the primary prevention and the timely identification of HIV infection (Smith et al., 2011).

The Standard Treatment Guidelines and Essential Medicines List (2014), was implemented in primary health care clinics and professional nurses were allowed to issue Level 1 and 2 medicines, depending on the grading of the clinic. Level 1 medicines can be prescribed by a professional nurse according to the Standard Treatment Guidelines, and Level 2 medicines can only be prescribed by a doctor. The PHC approach requires professional nurses to have comprehensive skills in order to render these services in PHC clinics. South Africa has various categories of training for professional nurses, regulated by the Nursing Act, 50 of 1978, as amended, now replaced by the Nursing Act, 33 of 2005, resulting in different skill levels (Wentzel, 2008).

Smith et al. (2011) stated that the health system in South Africa is reliant on nurse-led services to deal with the burden of HIV/AIDS epidemic facing South Africa. According to Cameron et al. (2012), Dr. K. Chetty, the Acting Director–General of Health, authorised professional nurses who had undergone NIMART training and were mentored to initiate ART on HIV-infected patients as from 1 April 2010. Dohrn, Nzama and Murrman (2009) pointed out that the urgent need for nurses to engage in greater clinical responsibilities in the care of patients with HIV/AIDS has encouraged the practice of task shifting in South Africa. According to Brennan et al. (2011), nurse-managed care has also been estimated to be cost effective.

2.5. DECENTRALISATION OF ANTIRETROVIRAL THERAPY AND TASK SHIFTING

2.5.1. DECENTRALISATION OF ANTIRETROVIRAL THERAPY

The increase in the number of patients eligible to access care and the World Health Organization recommendation to treat patients at higher CD4 cell counts has put pressure on health systems and forced governments to seek new models of treatment delivery. Models of care adapted from industrialised countries typically have a large doctor–patient ratio with increasing demand, a shortage of trained medical staff and limited finances. To attend to these concerns, a proposal of decentralising care to smaller health facilities along with task shifting care from doctors to clinical officers, nurses and community health workers was recommended (Brennan, 2011). Bedelu et al. (2007) suggest that integration and task shifting assisted the work load among the staff, whereas decentralisation assisted to distribute the hospital's work load among different clinics.

Decentralisation involves the implementation of comprehensive HIV counselling and testing, care and treatment services at the first levels of health care (Smith et al., 2011). To implement decentralisation, the following must be in place: policies allowing non-physicians to initiate and monitor treatment and the development of a healthy workforce comfortable with and skilled in initiating and monitoring treatment, including treatment services for pregnant woman, infants and children. Colvin et al. (2010) suggest that decentralising ART to all clinics throughout the country would necessitate a major reshuffle of workloads and relationships among various levels of care. Decentralisation of ART to PHC clinics allows increased access, equity and better support of adherence to ART.

Health care workers are the main role players to scaling up Antiretroviral Therapy (ART), particularly in rural areas, like in Lusikisiki. Medecins Sans Frontiers has been supporting a program to deliver HIV services through decentralisation to PHC clinics, task shifting and community support. This approach has allowed for a rapid scale up of treatment with satisfactory outcomes, and the delivery of HIV services in Lusikisiki was achieved (Bedelu et al., 2007).

Brennan et al. (2011) stated that South Africa's National Department of Health commenced decentralising the care of patients that were stable on ART or who were initiated and managed by doctors at hospitals, to clinics using nurse-managed care. Furthermore, several studies have supported the decentralisation of HIV treatment and have also proved that retention in care and clinical outcomes were improved.

2.5.2. TASK SHIFTING

Georgeu et al. (2012) claimed that the Antiretroviral Therapy (ART) programme for HIV/AIDS in Southern Africa was increasing in the public sector and this has created additional workload, organisational challenges and great concerns about the ongoing shortage of human resources for health. While most programs in South Africa have used a model of physician-initiated and managed ART, yet there are insufficient physicians in the public sector.

In South Africa there are 69 doctors and 388 nurses per 100 000 population. Therefore, task shifting for initiating and maintaining ART from doctors to nurses is a reasonable solution to meet the need of increased access (Cameron et al., 2012).

Georgeu et al. (2012) suggested that due to the insufficient numbers of personnel of physicians mainly in low and middle – income countries with extensive ART programs, there has been an agreement that some ART would be supplied by other non-physicians in order to achieve ART coverage. Task shifting from physicians to nurses has been proposed as one response to the challenge of large scale, sustainable, and effective ART programs in resource constrained contexts.

Furthermore, task shifting of roles and responsibilities for HIV care and treatment in this context can take a number of forms depending on how services are structured. In the context of HIV/AIDS care, the term 'Nurse-Initiation and Management of ART – NIMART' is proposed. In its fullest sense, NIMART involves nurse–initiation of patients into ART, re-prescription for patients stable on ART, and appropriate referral to physicians as needed (Georgeu et al. 2012). As

nursing responsibilities with regard to HIV care have risen, tasks have been shifted to other categories of staff, necessitating the reshuffling of health teams and the formation of new abilities at numerous levels. Task shifting has been recognised by the World Health Organization as an essential and justifiable means to meet the critical health needs which are the consequences of the HIV pandemic (Dohrn et al. 2009).

NIMART is a comprehensive intervention for health systems that aimed to improve access to ART by moving assessment and treatment to primary health care clinics closer to the patient's homes. The intervention developed clinical responsibility for ART from physicians to nurses for stable patients (task shifting), and other aspects of HIV and ART care were integrated into primary health care services (Mann and Lin, 2012).

Colvin et al. (2010) argue that even though task shifting is commonly approved as an answer to expanding ART access, evidence shows that non-physician care in providing ART in Africa is restricted. Moreover, in these studies non-physician care is limited to the monitoring of patients who are already on treatment, with initiation usually being done by study physicians under these conditions. All studies reported equivalent ART treatment outcomes, including viral load suppression, mortality and retention in care. Unlike South Africa, Cohen et al. (2009) state that the Lesotho health authorities promoted task shifting to enable every category of nurses to have diagnosing, prescribing and dispensing authority. This model was gladly accepted by the Ministry of Health and Social Welfare for replication throughout the country.

2.6. HIV COUNSELLING AND TESTING (HCT) AND PROVIDER INITIATED COUNSELLING AND TESTING (PICT)

2.6.1. BACKGROUND

The South African National AIDS Council (SANAC) (2010) states that with the introduction of new guidelines in February 2010, South Africa's policy on voluntary counselling and testing was expanded to incorporate a number of new components. These components include a revision of counselling protocols as well as a shift for HIV Counselling and Testing (HCT) to be offered by health

providers during patients' consultation to any health facility for any ailment. SANAC (2010) points out that provider-initiated HIV counselling and testing remains voluntary but the health care worker has a responsibility to give the patient information about the importance of knowing one's HIV status and of testing regularly for HIV as part of a normal health seeking behaviour. The shift towards provider-initiated HCT comes as one of the measures derived from the 10-point plan of the National Department of Health – particularly the intention of point 1: 'Providing Strategic Leadership for better health outcomes' and of point 7: 'Accelerating implementation of the HIV & AIDS and Sexually Transmitted Infections National Strategic Plan 2007–11' (SANAC, 2010).

Makhunga-Ramfolo et al. (2011) declare that in 2007 WHO made recommendations to launch provider-initiated counselling and testing (PICT) on top of client-initiated counselling and testing also known as voluntary counselling and testing (VCT), as an efficient public health intervention to enhance access to HIV counselling and testing (HCT) and to decrease missed opportunities for testing. Makhunga-Ramfolo et al. (2011) further state that the recent HCT policy guidelines from the National Department of Health (2010) put emphasis on the need to complement VCT through the implementation of PICT by all health care providers in both the public and private sectors. This strategy aims to assist health care providers to expand access to HCT for their clients, and thus the burden of disease in communities will ultimately be reduced.

2.6.2. HIV COUNSELLING AND TESTING (HCT)

The Department of Health (2010) mentions that the National HCT Program aimed to provide universal access to good quality, effective HIV counselling and testing and become an effective referral system to all South African citizens. The aims of the HIV counselling and testing program are to:

- Create an enabling environment that promotes universal access to a safe, effective and good quality HCT service;
- Encourage individuals, couples, families and communities to test for HIV in the interests of their own health;
- Promote support for positive living, healthy lifestyles and good nutrition;

- Encourage and support the voluntary disclosure of HIV status and to minimise stigma;
- Facilitate and promote the integration of HCT with family planning (FP), tuberculosis (TB), sexually transmitted infections (STIs), and other communicable and non-communicable diseases; and
- Integrate affordable, feasible, accessible, safe and sustainable HCT services into the health system.

Furthermore, the DOH (2010) stated that the government's 'new' HIV Counselling and Testing (HCT) campaign had set a target to test a total of 15 million people who had been at risk throughout South Africa by the end of June 2011. Expanding access to HIV counselling and testing is seen as an essential gateway to HIV prevention as well as providing appropriate treatment and care for people who are already infected. With the introduction of new guidelines in February 2010, the government's policy on voluntary counselling and testing (VCT) has been expanded to include provider-initiated HCT. Previously healthcare workers recommended testing only if HIV disease was suspected. Now regular HIV testing, while still voluntary, was to be routinely recommended to everyone as an important part of normal health-seeking behaviour. Objectives of the campaign were as follows:

1. To mobilise people to know their status.
2. To provide key prevention messaging to encourage healthy lifestyle practices irrespective of HIV status.
3. To increase incidence of health-seeking behaviour.
4. To increase the access to treatment, care and support (DOH, 2010).

Makhunga-Ramfolo et al. (2011) pointed out that in clinical settings lots of patients were not offered HIV counselling and testing (HCT) and become missed opportunities for HIV diagnosis.

SANAC (2010) considered HCT to be a starting point of HIV prevention, by knowing one's status and knowing what to do thereafter and by facilitating initiation to antiretroviral treatment. HCT incorporates prevention and treatment,

which both strengthen the National Strategic Plan for HIV and AIDS and STIs, 2007–2011 (NSP). Most often HCT is significant, determined and action-oriented, which makes extensive social mobilisation feasible. It is hard to measure the effectiveness of HCT in primary prevention for HIV-negative patients. However, various supporting studies revealed that the effectiveness of HCT in secondary prevention for HIV-positive patients is significant. Studies have publicised the evidence of behaviour change and reduced viral loads by treatment initiation. Unknown HCT status also gives a restricted picture of who tested and who did not. These assist in discovering which populations were most-at-risk that were not reached.

The National Strategic Plan for HIV and AIDS and STIs, 2007–2011 (NSP) was an intensive and coordinated response to the epidemic in South Africa (DOH, 2010). The NSP had two primary goals which were to reduce the incidence of new HIV infections in South Africa by half, and to ensure that at least 80% of those who were already HIV-positive had access to treatment by 2011.The common factor for both these goals was knowledge of HIV status. Specifically, key strategies in the NSP were to increase access to and uptake of voluntary counselling and testing (VCT), and to increase the geographic coverage of VCT services in medical and non-medical settings by 2011. In addition, the Plan sought to increase the proportion of people between the ages of 15 and49 years who accessed VCT services from 25% to 70%.

Furthermore, the DOH in 2010 stated that HCT had turned out to be progressively more accessible in South Africa in previous years (DOH, 2010). More than 4500 public health facilities were routinely offering HIV testing and client-initiated counselling and testing. With the escalating accessibility of HCT in numerous public health facilities in South Africa, the uptake of counselling and testing had been increasing as well. The ratio of people who had tested for HIV and knew their status had improved from 21% in 2002, to 30% in 2005, and to 50% in 2008 (Shisana and Simbayi, 2012). However, Kalichman and Simbayi (2003) stated that in 2002, out of five South Africans who knew about the services, only one had actually used them.

2.6.3. PROVIDER-INITIATED COUNSELLING AND TESTING (PICT)

Provider-initiated counselling and testing (PICT) was launched to make sure that HCT turns out to be the standard of care in all consultations with health providers. According to Makhunga-Ramfolo et al. (2011), PICT encourages general access to prevention, care and treatment services for all clients by maximising the use and acceptance of HCT services. With PICT the health care provider regularly suggests and recommends an HIV test to all clients, regardless of the medical diagnosis. The core objectives are to incorporate HIV testing into routine medical care, and in so doing, facilitating early diagnosis. Furthermore, Makhunga-Ramfolo et al. (2011), point out that by implementing PICT, family practitioners would not only discover the client's HIV status, permitting for proper clinical decisions to be made, but would also allow all clients to be aware of their status. Early diagnosis improves health outcomes of those who are HIV-positive, at the same time making sure that they are supplied with information to decrease transmission.

The DOH (2010), refers to PICT as HIV counselling and testing which is initiated and recommended by health care providers to all clients attending health care facilities as a standard component of medical care. PICT and other options of testing should be offered at all points of care including trauma, casualty and specialist clinics. PICT is also recommended in all health services dealing with domestic or gender–based violence, child abuse and sexual violence. In addition, the DOH (2010) mentioned that PICT aimed at identifying early high risk clients for whom there may be a strong likelihood of HIV infection, either because of their symptoms, or because of high risk sexual behaviour, or in transmission areas.

Makhunga-Ramfolo et al. (2011) further stated that the accessibility of HIV rapid tests and same-day results has increased access to accurate, trustworthy and cost effective diagnoses. HIV rapid tests enable medical practitioners to test their clients and give results within a short space of time. The relationship between medical practitioners and their patients puts them in a better state to give patient-centred care, allowing for better decisions to be made. For patients consulting medical practitioners, PICT is a vital and efficient model that forms part of the

bigger prevention approach and acts as the door-way for accessing care, support and treatment services (Makhunga-Ramfolo et al., 2011).

2.6.4. BENEFITS OF PICT

Knowing the client's HIV status can have advantages for the person concerned, the provider and the community. For HIV-negative people, knowing their status allows them to protect themselves from getting infected with HIV. It empowers them with necessary information on how to stay negative by assessing their own behaviour and offering solutions for behaviour change. For HIV-positive people, knowing their status ensures that they can be supplied with the suitable treatment, care and support services and helps them in living positively. Couples who know their HIV status are empowered to make safe choices with regards to sexual behaviour, e.g. condom use in discordant couples, practising a positive living approach, and accessing treatment for the prevention of mother-to-child transmission of HIV (Makhunga-Ramfolo et al., 2011).

Furthermore, Makhunga-Ramfolo et al. (2011) point out that PICT allowed medical practitioners to treat their clients properly by prioritising those who required treatment and/or wellness programmes early on. This assisted health care providers to enhance the quality of medical care provided to their clients and to decrease morbidity and mortality. PICT helps in decreasing the stigma in the community by making HIV testing the norm. It resulted in the increasing of care and support services to deal with the demand for services.

2.6.5. PRINCIPLES OF PICT

PICT does not mean that people are forced to test, nor does it consist of compulsory or mandatory testing. There are three principles that should guide medical practitioners when applying PICT, which are: consent, counselling and confidentiality, also known as the three C's. Improper use of PICT reduces trust in health care providers and can result in poor adherence to treatment and insufficient uptake of referrals (Makhunga-Ramfolo et al., 2011).

The DOH (2010), states that PICT is initiated by the health-care provider or worker to support the uptake of HIV testing. The patient's right to autonomy and dignity

should always be taken into consideration when HCT is being offered, while recognising the obligation of health-care providers to protect the right to life and access to health services. Furthermore, pre-test and post-test counselling should always form a part of PICT and the client should give an informed consent for testing in the language that he / she understands.

(a) INFORMED CONSENT

Medical practitioners should only perform HIV testing when the client or his or her parent or legal guardian has given informed consent. The client must be provided with information in his or her language. One must also consider disability and the level of literacy of the client when providing information. The client must also understand what the test consists of and its consequences. Furthermore, the client should understand the rationale of the exchange of information as being in the best interest of his or her own health, that of the partner, and the foetus (if the woman is pregnant), or the infant being breastfed (Makhunga-Ramfolo et al., 2011).

(b) COUNSELLING

Pre-test counselling

Makhunga-Ramfolo et al. (2011) declare that all HIV testing must follow the individual pre-test counselling. PICT does not need a lengthy counselling session, but the medical practitioner should be guided by the client's knowledge and requirements. The following are some of the key points that should be covered during the pre-test counselling in adults:

- Assessing the client's understanding of information provided and reinforcing messages and concepts.
- Assisting the client to determine and assess their risk based on the information provided.
- Assessing the client's readiness for testing and possible results.
- Obtaining informed consent.
- In the case of refusal, ascertaining reasons and responding to misconception.

Post-test counselling

All clients who are offered HCT and agree to a test should also get post–test counselling, regardless of HIV results. The content of post-test counselling will depend on the HIV test results (Makhunga-Ramfolo et al., 2011).

(c) TESTING

It is very simple to do the HIV rapid test, with good training. Results are available within 10 – 15 minutes during consultation with the client and are as reliable and accurate as enzyme immunoassays. A prescribed quality assurance programme should be followed by all persons performing HIV rapid testing in order to ensure that results are accurate and reliable. The prescribed national HIV testing algorithm should be used when performing HIV testing using both a screening and a confirmatory test (Makhunga-Ramfolo et al., 2011).The differences between HCT / VCT and PICT are outlined in Table 1 below.

Table 1. Differences between PICT and HCT / VCT (Makhunga-Ramfolo et al., 2011)

PICT	HCT / VCT
Individual is seeking medical care and HCT is recommended and performed by medical practitioner as part of the consultation	Individual chooses to seek HCT
Services provided are confidential and documented in medical record to ensure continuity of care	Anonymous or confidential services may be offered
Primary focus is on identifying HIV-infected people and linking them with prevention, care and treatment services	Primary focus is on preventing HIV acquisition through risk assessment, risk reduction and testing
Verbal consent is required and should be documented in the patient record	Written consent or thumb print for illiterate clients is required
First user of the test result is the health care worker to make a correct diagnosis and provide appropriate treatment	First user of the best result is the client, who uses the information to make personal life decisions

2.6.6. CONFIDENTIALITY AND DISCLOSURE

Makhunga-Ramfolo et al. (2011) argue that although confidentiality needs to be maintained in HCT, clients should be persuaded to disclose their results to their sexual partners. Health care workers should talk about the issue of shared confidentiality with the client. That is, health care workers who are directly involved with care of a patient may have access to his or her results. Medical practitioners can also suggest assisting clients to disclose their HIV status to their partners. Makhunga-Ramfolo et al. (2011) further state that medical practitioners must be warned against disclosing HIV status to third parties without either the client's written consent or a court order. Medical practitioners should consult with senior consultants for a second opinion if not sure about patient management.

The view of South African Nursing Council (2014) is that the ethical problems with the nursing of HIV/AIDS patients arise mainly from faulty perceptions.

These patients have the right to:

- confidentiality;
- non-judgemental, effective nursing according to personal needs;
- empathy for the social dilemma of AIDS and HIV-positive patients;
- expert accompaniment for themselves, their families and communities, in order to continue a normal, responsible life; and
- protection and life, in the case of the unborn child.

The South African Nursing Council condemns:

- Discrimination against HIV/AIDS-infected patients; and
- Violation of confidentiality.

2.6.7. HIV COUNSELLING PROCESS

The diagram below illustrates the counselling process for PICT and HCT that must be conducted in all public health facilities. It should be conducted in the language that the client prefers and understands (DOH, 2010). There are different ways at which pre-test information sharing sessions may be conducted, either with groups, couples or individuals. Thereafter a brief individual session that address individual HIV risk must follow. See Figure 2 below:

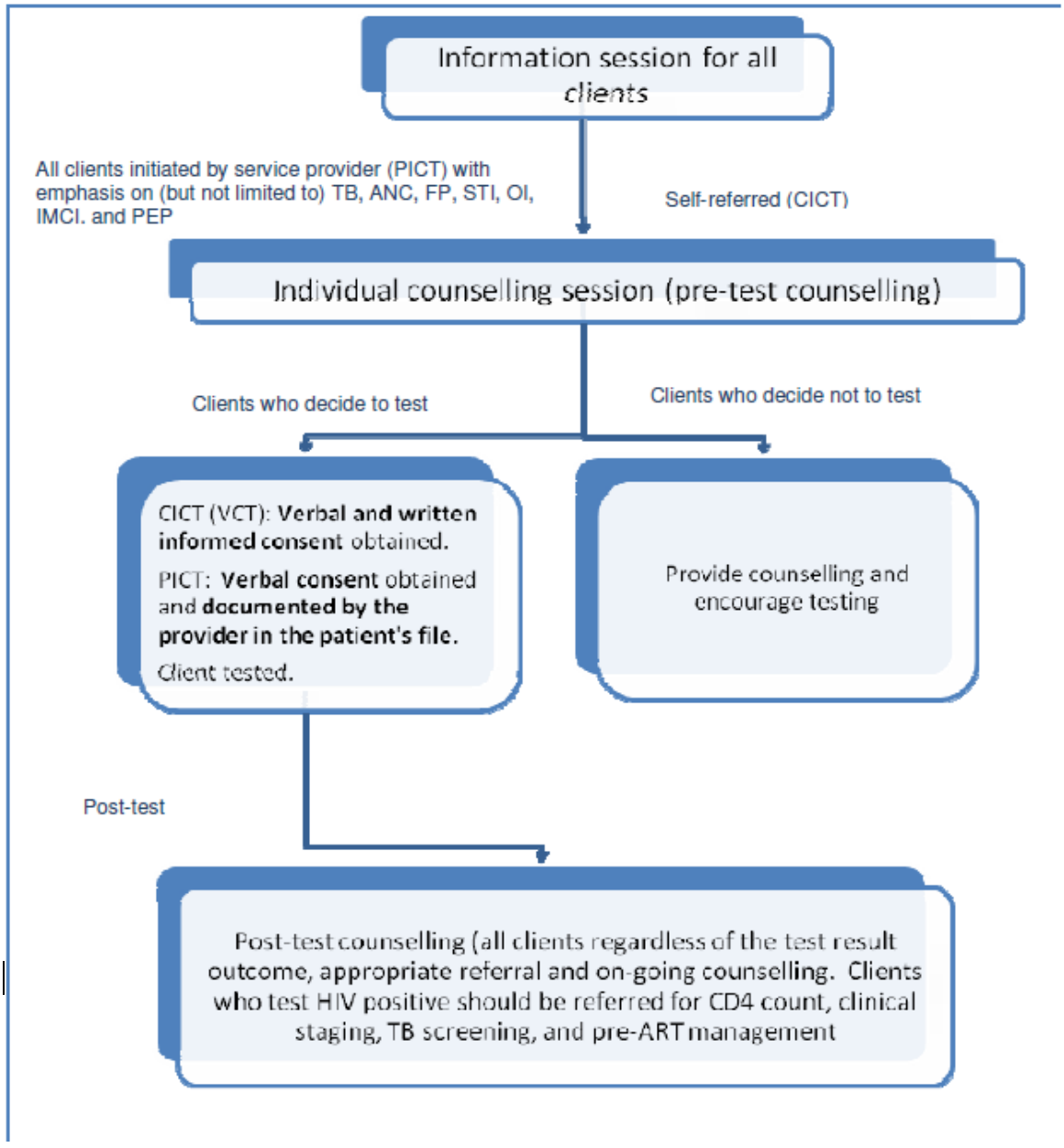

Figure 2. The HIV Counselling and Testing Process (Department of Health, 2010)

2.6.8. HIV TESTING

HIV testing must be ethical, based on human rights, conducted within a supportive environment and be performed where there is adequate health care infrastructure (DOH, 2010). A trained healthcare professional (registered nurse, doctor, dentist and oral therapist or oral hygienist) is responsible for administering the HIV test in terms of current legislation (Human Tissue Act No. 65 of 1983 section 23).

The task shifting / sharing policy was finalised and being implemented for trained HIV counsellors. This policy resulted in the following changes:

- A trained health care worker, enrolled nurse, community health worker or counsellor may then be authorised, in terms of the task shifting policy, to administer the HIV test.
- All healthcare workers who administer the test will receive required training to ensure adherence to the standard operating procedures, utilisation of approved testing kits, and quality assurance of HIV testing.
- HIV testing conducted by a healthcare worker, should be under the supervision of a healthcare professional (i.e. registered nurse, doctor, dentist, oral therapist or oral hygienist).
- A trained healthcare worker / counsellor will be responsible for performing the test, interpreting and confirming the results of the test, as well as informing the client of the results.
- A trained registered nurse will supervise the quality assurance processes for HIV testing (DOH, 2010).

2.6.9. FREQUENCY OFTESTING

The DOH (2010) states that health facilities are also intended for including a culture of HIV testing for individuals. A patient's exposure needs to be considered to determine the correct frequency of repeat HIV testing. Patients who are sexually active must be motivated to test at least annually and this should be encouraged as part of the culture of proactive self-care that all health providers must adopt. Nevertheless, patients who are at high risk of exposure can have repeat testing done more frequently.

2.6.10. TESTING ALGORITHM

The HIV testing algorithm that is approved in SA is serial testing. This means that a screening test is performed first, and then a confirmatory test is performed latter depending on the result of the screening test. If the screening test is positive a confirmatory test is performed. If the results are discordant, then whole blood is taken and sent to the laboratory for ELISA test. Professional nurses were authorised to perform HIV rapid testing and lay counsellors were not supported by legislation to perform the test back then (SANAC, 2010). According to the DOH (2010), the HIV testing algorithm that must be used for all HIV testing is the serial testing algorithm as illustrated in Figure 3 below:

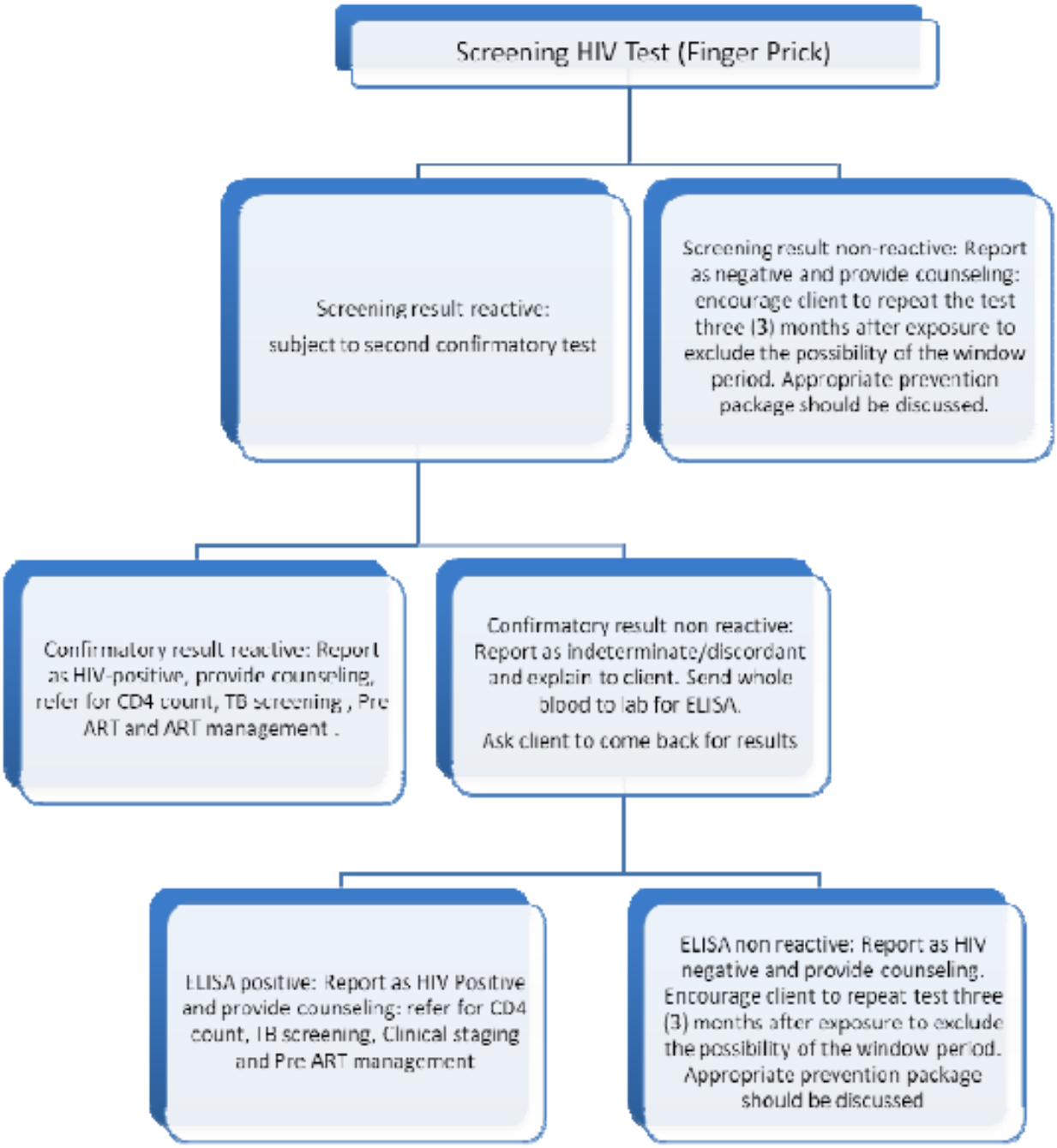

Figure 3. Recommended Serial HIV Testing (Department of Health, 2010)

2.7. PMTCT

2.7.1. PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF HIV (PMTCT) PROGRAMME IN SOUTH AFRICA

The Prevention of Mother-to-Child Transmission of Human Immunodeficiency Virus is abbreviated as PMTCT and was introduced in 2001 in South Africa in the Province of KwaZulu-Natal at King Edward Regional Hospital which is situated in Durban. The aim of this programme was to reduce the number of HIV-infected babies born to HIV-positive mothers (Ngidi, 2011).

Mother-to-Child Transmission of HIV can occur through HIV-positive women passing on infection to their unborn babies (vertical transmission), or through breastfeeding, according to Ngidi (2011). South Africa was experiencing an overwhelming HIV/AIDS pandemic, it was estimated that maternal mortality in KwaZulu-Natal was 192.3 per 100, 000 live births due to HIV epidemic (Ngidi, 2011).

The Prevention of Mother-to-Child Transmission of Human Immunodeficiency Virus (PMTCT), was aiming amongst other things, at reducing the number of infected babies born to HIV-positive mothers (Ngidi, 2011). PMTCT involves methods that reduce HIV transmission during pregnancy, labour and delivery, and through breastfeeding.

Initially, the programme had only one drug, this being the single dose Nevirapine (sd NVP), which was considered by the World Health Organization (WHO) as the minimum standard of care for pregnant mothers living with HIV, and which was recommended by the WHO. This was to be taken by the mother when in active labour, and given to the infants within 72 hours of their delivery. The current transmission rate with sd NVP is 21%, high above the expected 12%, which was the target for single dose Nevirapine in the PMTCT Program (Ngidi, 2011).

Ngidi (2011) states the implementation of the program in 2001 did not transpire without controversy. The Treatment Action Campaign (the activists in support of the provision of antiretroviral treatment) was pushing the National Department of Health to commence the PMTCT Programme. The National Health Department

started by piloting the PMTCT programme consisting of monotherapy (sd NVP). The Treatment Action Campaign (TAC) felt that the pilot studies in the 18 sites, done by the NDOH, should be converted to a roll-out, not only to the 18 sites, but to all state facilities that could dispense it.

Following a court order, the Department of Health had no choice but to implement the program. The TAC won the court order in 2003; therefore the sd NVP PMTCT was spread across all the state facilities, not only the piloted sites. The Minister of Health at the time was Minister Manto Tshabalala-Msimang. She was publicly criticised for delaying revising the sd NVP to dual therapy, which according to the TAC spokesperson (Nathan Geffen in 2003), was a scientifically proven method of reducing Mother-to-Child Transmission. On 25 January 2008, the DOH announced a new national protocol for the PMTCT, namely the introduction to Dual Antiretroviral prophylaxis, which consisted of sd NVP plus Zidovudine (AZT). Though the TAC welcomed the revised program, they felt it should have included Lamivudine (3TC), as recommended by the World Health Organization for the PMTCT of HIV, and not just the abovementioned two drugs. For the TAC, another shortfall of the NDOH was that pregnant mothers were to be initiated on Antiretroviral Therapy once their CD4 was 200 cells/mm^3 or below. The TAC felt this was outside the current international best practice, because the WHO recommended a CD4 count of 350 cells/mm^3 and below (Ngidi, 2011).

Ngidi (2011) stated that according to scientific evidence, there was an advantage to be gained in initiating ART at a CD4 count of350 cells/mm^3 and not 200 cells/mm^3.The United States and European treatment guidelines recommend that all patients including pregnant mothers start Anti-HIV treatment at a CD4 count of 350 cells/mm^3. This was not the case in South Africa at the time of Ngidi's study. In 2007 alone, 330 000 HIV-positive pregnant women gave birth in South Africa, with the estimate that 70 000 of their infants were born HIV-positive. WHO recommended that the full implementation of the revised protocol would have reduced the numbers significantly.

Resistance has developed with the use of single dose Nevirapine for the PMTCT programs, which can compromise the success of the subsequent treatment of

mother and child with ARV. The study by Ngidi (2011) on the prevalence of resistance to NVP in mothers and children after single dose NVP exposure to prevent vertical transmission of HIV-1, revealed that there was a high burden of viral resistance in both women and children. The single dose NVP is considered a minimum standard of care for women living with HIV who are pregnant. The dual therapy revised new PMTCT programme, which consists of Zidovudine (AZT) and Nevirapine (NVP), which is the recommendation by the World Health Organization, is considered more effective than the single dose NVP. Initially the WHO had recommended the single dose NVP, but new evidence became available which supported the effectiveness of the Antiretroviral Treatment (ART) in the prevention of Mother-to-Child Transmission (Ngidi, 2011).

This was supported by a study done in Khayelitsha, Cape Town, South Africa, which aimed at estimating the efficacy of the PMTCT program in Khayelitsha, and at providing details of the antiretroviral regimens received by mothers and infants. The results revealed that the majority of pregnant women in Khayelitsha accepted HIV testing during pregnancy, and were prepared to join the program. This acceptance of testing was the key to the effectiveness of the PMTCT program (Ngidi, 2011). According to Ngidi (2011), in developing countries like South Africa, on average, less than 10% of women received even the most basic PMTCT services, and, therefore, access to the PMTCT services remained low.

2.7.2. HIV COUNSELLING AND TESTING OF PREGNANT WOMAN FOR THE PMTCT PROGRAMME

In order for the PMTCT programme to be successful, it is important that pregnant HIV-infected women are identified (DOH, 2010). All pregnant women must be screened for HIV routinely and be aligned with basic Antenatal Care (ANC), Rhesus factor, haemoglobin, and syphilis. HIV testing should be implemented during ANC as follows:

- PICT (opt out approach) should be offered to all pregnant women and if they choose to opt out, a refusal or opt out form should be signed and this should be captured in their files.

- Women who decline HIV testing need to be counselled and convinced to do the test, by explaining the advantages of testing.

HIV-NEGATIVE: Women who test HIV-negative should get post-test counselling on how to sustain their HIV-negative status and on risk reduction interventions, while they continue to receive routine antenatal care. Furthermore, they should be retested for HIV at or around 32 – 34 weeks to identify late seroconversion, and if they test positive, PMTCT prophylaxis should be immediately initiated.

UNKNOWN STATUS: Unbooked women and women of unknown status presenting in labour must have HCT done in the latent phase of labour, and if possible in the first stage of labour. If they test positive for HIV, a PMTCT intervention should be offered and their babies must be given Post Exposure Prophylaxis (PEP).

HIV-POSITIVE: All HIV-positive pregnant women should have the CD4 count recorded on the same day that HIV-positive status was diagnosed, and if possible at the first ANC visit, and should be classified as clinical stage according to WHO staging. These women should also:

- Be screened for TB, as well as all basic ANC procedures.
- Be initiated on ARV regimens prescribed by a registered health professional in line with the latest PMTCT guidelines, either PMTCT prophylaxis or highly active antiretroviral therapy (HAART).

Women attending the postnatal care clinic at six weeks, whose status is unknown and who tested negative during pregnancy, may have acquired HIV infection recently and need to be offered a repeat HIV test to screen herself and her baby for HIV infection and exposure (DOH, 2010).

2.8. NIMART TRAINING, FOLLOWED BY THE CLINICAL MENTORSHIP OF THE NIMART TRAINED NURSES

2.8.1. NIMART TRAINING

Istre (2011) stated that NIMART Training started sincerely in March 2010. However, training only was proved insufficient to produce competent and confident nurses in initiating ART. Hence, the Clinical Mentorship component became extremely important. However, Cameron et al. (2012) mention that in October 2010, saturation NIMART training for nurses was rolled out in 7 provinces. By the end of March 2011, 1736 nurses had attended at least one of the 39 NIMART Courses facilitated by the Foundation for Professional Development (FDP). Furthermore, Istre (2011) states that ARV therapy changes more frequently, which calls for nurses to be updated now and again of new developments in the treatment and care of HIV/AIDS.

Department of Health (2010) states under the new guidelines that NIMART-trained nurses were allowed to administer ARVs, but some did not feel confident enough to implement their training without clinical support from a more experienced nurse or doctor. Hence, nurses who had received NIMART training required onsite supportive supervision in order to become competent and confident in their ability to provide high quality treatment for clients requiring ART.

Georgeu et al. (2012) also stated that speeding up the rollout of ART in sub-Saharan Africa has emphasised the necessity for capacity building at both the clinical and health system levels, and also for the integration of comprehensive HIV/AIDS care with primary healthcare. Hence, Istre (2011) suggested that nurses should first undergo a10-day theory training course and then go back to the facility to manage certain cases of HIV-positive patients who are on ART. A manual was then developed and a logbook to record the 54 clinical competencies or tasks. These have been of the utmost importance to clinicians nationwide as they form the basis for determining if a provider, irrespective of cadre, is clinically competent to manage and initiate patients on ART (Istre, 2011).

Comprehensive in-service theoretical and practical training on the management of HIV-related conditions and ART was provided to nurses, in order to equip them with the skills to cope with these new responsibilities. This comprised of quarterly “out of service” trainings, taking one week each, which were clinical trainings adapted from the World Health Organization’s (WHO’s) Integrated Management of

Adolescent and Adult Illnesses (World Health Organization, 2004).According to Dohrn et al. (2009), the South African Nursing Council was taking into consideration a review of nursing curricula to approve new specialised degrees in HIV care and was also considering approving an amendment in nursing scope of practice to include NIMART.

2.8.2. CLINICAL MENTORSHIP

The Department of Health (2011) defines clinical mentorship as a system of practical training and consultation that fosters ongoing professional development of mentees to deliver sustainable high-quality clinical care. Clinical mentoring should be seen as part of the continued professional development required to create competent care providers. Following initial theoretical teaching, which conveys knowledge on a particular subject, the clinician responsible for providing quality care and treatment is mentored at the facility level to put into practice clinical standards (guidelines), to concentrate on knowledge, attitudes and behaviour, and thus to improve competency.

In September 2011, Global Medic Force and the Foundation for Professional Development (FDP) deployed to South Africa a nurse with 25 years' experience in HIV clinics in the UK for a 3 month volunteer mentorship in the Central Karoo town of Graaff-Reinet, Cacadu District, Eastern Cape. This mentorship assignment was to support primary care nurses trained in Nurse Initiation and Maintenance of Antiretroviral Therapy (NIMART). By the end of a 3 month mentorship period nurses were competent and had confidence to initiate ART.

Nurses working in primary healthcare clinics throughout South Africa have shared the duty of initiating ART and subsequently patient management, due to the urgent need to expand ART access to 80% of eligible HIV-positive people. In addition to training, nurses have required regular support and mentoring to perform this task competently (Jones, Stander, van Zyl and Cameron, 2012).

Muller (2012) pointed out that initially managing the ART program has been felt to be simply another burden and the nurse mentor has been seen as the instigator of this additional pressure, until nurses felt the benefit of her support.

Cameron et al. (2012) suggested that the spreading out of clinical mentorship was required immediately if the target of initiating1.2 million HIV-positive patients on ART by 2012, was to be reached. In response to this need, the National Department of Health has been working to introduce a comprehensive program for ART Clinical Mentoring throughout South Africa (Department of Health, 2010).

National clinical mentorship guidelines were finalised in January 2011, at a time when 7492 nurses had undergone NIMART training nationally, with 23% (1745) initiating ART after training. The clinical mentorship guidelines were published to provide guidance for provinces, districts, and sub-district management teams to develop and integrate clinical mentoring within the district health system (Medecins Sans Frontiers, 2012).

The DOH (2011) stipulated thatNIMART mentorship is guided by the national guidelines for Clinical Mentorship for Integrated Services. The NIMART mentorship is provided directly and indirectly through telephone access to mentors. Mentorship has become an essential element in ensuring equitable access to quality care and competent clinical providers. Figure 4 below shows the stages of mentorship. Clinical mentors must ensure that mentees examine and treat a broad range of patients, across the lifespan, from infants to older adults. The mentees must be deemed competent in all aspects of the speciality area in which they are being mentored. The mentee must provide care for adults and children in Pre-ART care, ART initiation, TB/HIV co-infection, HIV-infected pregnant women, etc., and must be in consultation with the mentor to assure all patient types are included in the logbook evaluation. Log books are used by the mentees to record 80 completed cases as laid down in the Clinical Mentorship Manual for Integrated Services. Log book and proof of competencies completed by the mentor form a Portfolio of Evidence (POE). The completed log books are kept by districts for record purposes and names are forwarded to provincial offices for certification. The certificate is issued and signed by the provincial Regional Training Centre (RTC) and co-signed by the mentor, district Training Coordinator or training partner.

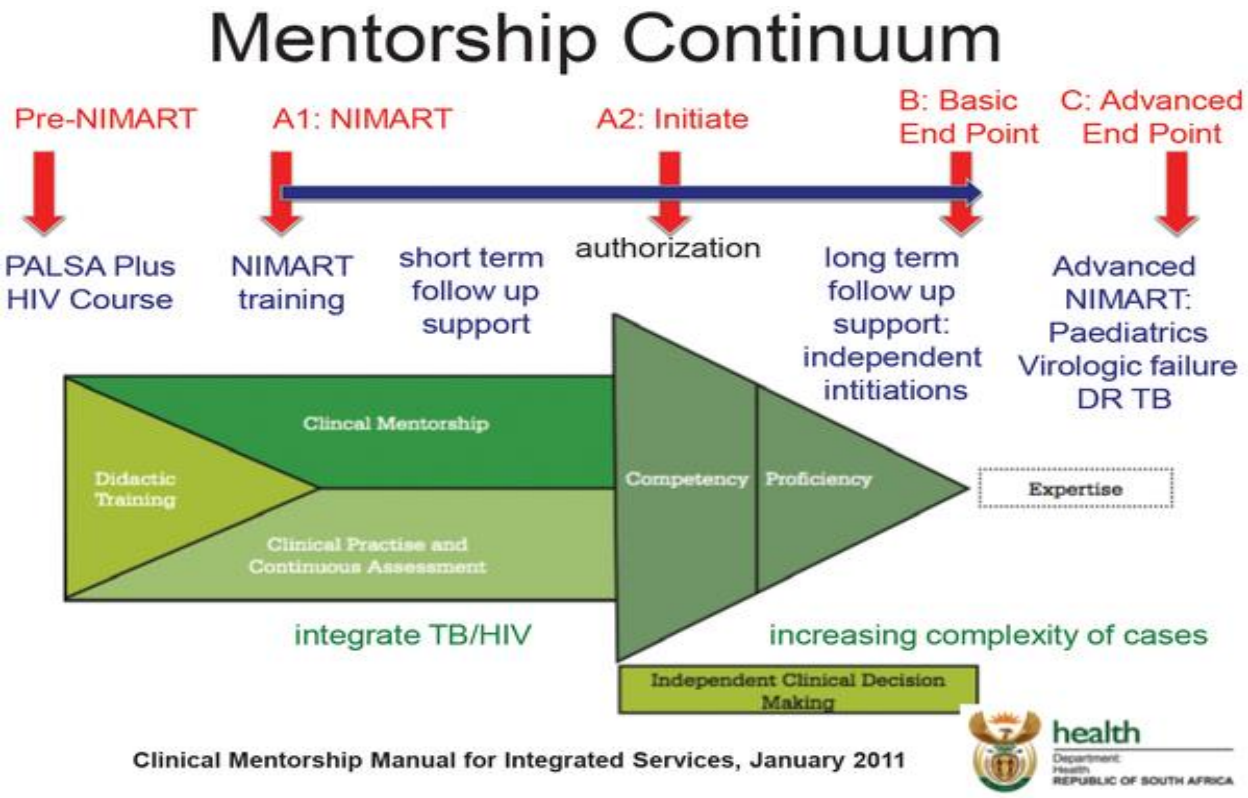

Figure 4. Clinical Mentorship Framework NIMART Clinical Mentorship Model for Integrated Services.

Pre-NIMART: PALSA Plus HIV course training on the use of South Africa's approved algorithmic tool for diagnosis and treatment of common opportunistic infections; A1: NIMART training based on South African Ministry of Health guidelines; A2: Authorisation to initiate is granted based on three required criteria: completion of basic HIV course, PALSA Plus HIV training, and 40 hours of one-on-one mentorship; B: Basic End Point is reached where the authorised nurse is conducting independent initiations; C:Advanced End Point is reached when skill level is expanded to include management of pediatric patients, virologic failure, and drug-resistant TB.

(Green, de Azevedo, Patten, Davies, Ibeto, and Cox, 2014)

2.9. **CONCLUSION**

This chapter analysed the epidemiology of HIV in South Africa. Then it focused on how NIMART was established and how it was going to be implemented in Primary Health Care clinics and what impact NIMART was going to have on improving patient care of people living with HIV. An overview of primary healthcare was also discussed as was the task of nurses in primary healthcare in the provision of antiretroviral therapy. This chapter also focused on the decentralisation of Antiretroviral Therapy and task shifting of antiretroviral initiation from being doctor-led to now nurse driven, and also the challenges nurses have been facing with the task shifting. Differences between HIV Counselling and Testing (HCT) and Provider-Initiated Counselling and Testing (PICT) were also discussed. Prevention of Mother-to-Child Transmission of Human Immunodeficiency Virus (PMTCT) was also discussed at length. Lastly, this chapter focused on the NIMART training, and clinical mentorship of the NIMART trained nurses, followed by the clinical pathway until competency in NIMART is reached.

3. CHAPTER THREE:
RESEARCH DESIGN AND METHODOLOGY

3.1. INTRODUCTION

A quantitative approach was used for the reason that a positivistic paradigm systematises the process of knowledge generation. Quantitative research involves the collection of measurable data using structured data collection instruments (Polit and Beck, 2004).

3.2. RESEARCH PARADIGM

A positivistic paradigm was used because it is allied with the quantitative approach. According to Polit and Beck (2004), the positivist paradigm is the traditional paradigm underlying the scientific approach, which assumes that there is a fixed, orderly reality that can be objectively studied, and it is often associated with quantitative research.

3.3. RESEARCH DESIGN

A quantitative non- experimental descriptive approach and evaluative design was used to evaluate the implementation of the Nurse Initiated and Managed Antiretroviral Therapy (NIMART) Programme in primary health care clinics in the Ugu district of KwaZulu-Natal. A quantitative, non-experimental, descriptive design involves a clear description of a phenomenon (Johnson and Christensen, 2000). This study's design consists of a survey which allows for standardised questions to be asked. Johnson and Christensen (2000) describe a survey as a form of non-experimental research in which data are collected from the respondents in order to understand certain characteristics of a population. Non-experimental designs exclude the manipulation of variables and the random assignment to groups (Johnson and Christensen 2000). According to Polit and Beck (2004), in a descriptive study, the description of phenomena is another important purpose of research and researchers observe, count, define and classify. Quantitative description focuses on prevalence, incidence, size, and measurable attributes of phenomena. In this study the quantitative design was used to ensure the high reliability of the information that was collected and also

that similar questions were asked of all the respondents in the form of a questionnaire.

3.4. POPULATION

In this study the population consisted of PHC nurses trained on NIMART that were working in the 56 (54 fixed clinics and 2 CHC's) primary health care clinics in Ugu district. All the 56 clinics in Ugu district were involved in the study.

Inclusion Criteria: All NIMART trained nurses working in primary health care clinics in Ugu district that attended the NIMART Mentorship meeting.

Exclusion Criteria: PHC Nurses that were not trained on NIMART.

3.5. DATA SOURCES

An assessment was conducted to determine whether PHC clinics in Ugu district were adequately equipped to implement the NIMART Program. The source document was a questionnaire with five parts, namely: demographics, availability of latest Antiretroviral Treatment guidelines, implementation of NIMART program, knowledge of NIMART and practice of NIMART.

3.6. DATA COLLECTION TECHNIQUES

A structured data-collection approach was used. According to Polit and Beck (2004), research data for quantitative studies are often collected according to a structured plan that indicates what information is to be gathered and how to gather it. Most self-administered questionnaires are highly structured. This approach was chosen because data were collected from a large sample over a short time. The same questions were asked of all the respondents so that there was less chance of bias. The researcher designed the questionnaire, which addressed the three objectives of the study, after a comprehensive literature review was conducted on NIMART. The researcher selected four research assistants to collect data due to the large group of participants. The researcher trained the research assistants because they did not have prior experience of collecting data. They were trained

on how to administer questionnaires and also about the content of the tools, in order to be familiar with the research tools.

Data were collected after the NIMART mentorship meeting that was held on 5th September 2016. Invitations were sent to all 56 clinics, inviting NIMART nurses to attend the meeting, and each professional nurse represented a single clinic in Ugu district. The research assistants administered the research tools to eliminate bias since the researcher was involved in the NIMART training, and since the research assistants were not biased. All 56 professional nurses from the 56 clinics were issued with the questionnaire, informed consent and the information sheet explaining the purpose of the study as well as requesting them to participate in the study.

3.7. ISSUES OF RELIABILITY AND VALIDITY

Burns and Groove (2009) mention that the reliability of a measure denotes the consistency of measures obtained in the use of a particular instrument and indicates the extent of random error in the measurement method. The instrument is said to be reliable if it is administered to the same group of respondents at two different times, but still yields the same responses. Burns and Groove (2009), state that the validity of an instrument determines the extent to which it actually reflects the abstract construct being examined.

Burns and Groove (2009) point out that equivalence reliability compares two versions of the same paper-and-pencil instrument or two observers measuring the same event. A test re-test can be done by the pilot study sample group to ensure that the same results are yielded after some time. Homogeneity testing examines the extent to which all the items in the instrument consistently measure the construct. It is a test of internal consistency (Burns and Grooves, 2009). All the questionnaires were consistent in asking the same questions and measuring the same variables. Administration of the questionnaires was consistent as well. Questionnaires were administered to PHC nurses by the research assistants in a group setting after the NIMART mentorship meeting.

Burns and Groove (2009) state that face validity verifies what the instrument looked like, or gives the appearance of measuring the content desired for a study. The instrument was pre-tested by the five doctors who were family physicians and HAST clinical managers, so as to assess the clarity of the questions, and they all recommended that the time taken to administer the instrument was acceptable. According to Burns and Groove (2009), content-related validity examines the extent to which the method of measurement includes all the major elements relevant to the construct being measured, and this evidence is obtained from the literature. The researcher designed the instruments from the literature review using the literature on NIMART.

Criterion-reference testing is a comparison of a subject's score with a criterion of achievement that includes the definition of target behaviours. Inclusion criteria were the professional nurses from the primary health care clinic who were trained in NIMART, because they were initiating patients on Antiretroviral Therapy. Exclusion criteria were the professional nurses from the primary health care clinics that are not trained in NIMART. Construct validity examines the fit between conceptual and operational definitions of variables and determines whether the instrument actually measures the theoretical construct that it purports to measure (Burns and Groove, 2009). The variables change from one participant to another, such as NIMART knowledge and the practice of NIMART program. For the purpose of this study the variables are the knowledge and practice of PHC nurses that are NIMART trained.

3.8. **SAMPLING TECHNIQUES**

The sample size was one NIMART trained nurse per clinic that was participating, amounting to 56 nurses. Convenient sampling was used to recruit the nurses who attended the NIMART mentorship meeting at a central location. All 56 clinics were represented. However, nurses from 4 clinics did not meet the study's inclusion criteria which was NIMART training. Hence, they were excluded from the study. Initially there were 56 nurses, each one representing a clinic. But only 52 nurses met the inclusion criteria out of 56 nurses.

Everybody that came to attend the meeting was recruited to represent the clinics. The researcher used the advantage that 56 PHC nurses from all 56 PHC clinics were attending the second quarter NIMART mentorship meeting and conveniently recruited them, provided they complied with the inclusion criteria of being NIMART trained.

Even though all 56 clinics were represented, the minimum sample size was calculated using a sample size calculator tool called G-Power to determine the minimum number of participants required for the study. The following parameters were used:

a) Effect size = 0,5 (Effect size quantifies the magnitude of the difference between population or relationship between population or relationship between explanatory and response variables. It is the ratio of population standard deviation.)
b) Type 1 Error = 0,05 (Recommended for observational study design)
c) Type 2 Error = 0,2 (Recommended for observational study design)
d) Statistical power of 1-Type 2 (1-0,2) = 0,8 = 80%

Therefore, on the basis of the above parameters, a minimum sample size of 32 professional nurses was determined. The response rate was 100%, but only 92% of the respondents complied with the inclusion criteria.

The table below illustrates the number of PHC clinics and CHCs in the Ugu district per sub-district.

Table 2. Sample Size

Sub-district	Number of Clinics
1. Umdoni / Vulamehlo sub-district	10
2. Umzumbe North sub-district	7 + 1 CHC
3. Umzumbe South sub-district	7
4. Hibiscus sub-district	13 + 1 CHC
5. Ezinqoleni sub-district	6
6. Umuziwabantu sub-district	11
Total	**56**

3.9. DATA ANALYSIS AND INTERPRETATION

The data collected were captured and subsequently analysed using the Statistical Package for Social Sciences (SPSS version 21). Descriptive statistics such as frequencies, percentages, mean and standard deviation were used to summarise results. Responses relating to the knowledge and practice of the NIMART program were aggregated to calculate knowledge and practice scores. Tables, bar graphs and pie charts were used to present results.

3.10. ETHICAL CONSIDERATIONS

The researcher calculated the risk-benefit ratio and concluded that benefits to respondents were greater than the risk. There was no risk of harm to respondents anticipated in this research project as the questionnaire was assessing knowledge of the NIMART programme and the respondents' identity remained anonymous. Respondents benefitted in participating in the study because they were able to identify their gaps in the NIMART program, with a quality improvement plan then being formulated to breach those gaps. Hence, they were able to improve their knowledge and performance. Respondents were not reimbursed for transport while participating in this research project because they were already coming to attend a planned activity which was the NIMART Mentorship meeting using the employer's transport. The researcher took the advantage of the existing meeting to interview the participants. The research results were later shared with the

respondents. The researcher's details were made available to the respondents for any further information regarding the study. Respondents were given the information leaflet with the researcher's address and the University of KwaZulu-Natal Biomedical Research Ethics Committee (UKZN BREC) details, namely, the Ethics Committee names, contact numbers, and addresses. If they had any concerns or complaints regarding ethics issues, respondents could contact the Ethics Committee.

Application letters for permission to conduct the research study in Ugu district were written to the District Manager and the Ugu District Health Ethics Committee. Other application letters for permission to conduct the research study in primary healthcare clinics in Ugu district were written to the gatekeeper, Clinical and Programmes Manager, and lastly to the additional gatekeeper, the HAST Manager to collect data during the NIMART mentorship meeting. Final permission was granted by the KwaZulu-Natal Department of Health Provincial Health Research Committee. Ethical clearance to conduct this research study was obtained from the UKZN BREC.

3.10.1. CONFIDENTIALITY

A disclaimer was written in the information leaflet stating that all information would be kept confidential. Participant's personal data will be kept in a safe place, questionnaires will be archived for five years in the supervisor's office at the University of KwaZulu-Natal (UKZN) and personal information will be stored in a database. Confidentiality of data will be maintained by ensuring that no-one other than the researcher and statistician will access the participants' information. There will be no linkage of the research data with the respondents as the questionnaires were anonymous and the names of respondents were not captured. The purpose for which the data will be used is limited to this research project. Respondents' data will not be reused in the future after the completion of this research project. After the questionnaires are locked in the supervisor's office at UKZN for 5 years, they will be disposed of following the correct procedures for the disposal of legal documents.

3.10.2. INFORMED CONSENT

Respondents who took part in this research project were professional nurses who were mentally capable and competent individuals who would understand the information given about the research project, as well as the objectives. The information leaflet was administered to the respondents to read and keep. Respondents were provided with all the information they needed to know about the research project in order for them to make an informed consent. The research assistants also provided additional information by answering all the questions that the potential respondents had.

The respondents that were interested in participating gave their informed consent to participate in the study and were then enrolled to be the study respondents. Consent was voluntary, respondents were at liberty to decide if they wanted to participate in this research project or not, and they also had a right to withdraw their consent at any time. The research assistants signed as witnesses. Important elements about the research project were disclosed to prospective respondents, such as the aims and methods of the research project as well as the researcher's identity.

3.10.3. DATA DISSEMINATION

Plans to inform the respondents of the research results were as follows. The researcher shared the findings of the research project with all relevant stakeholders who were going benefit from it. Firstly, the findings were shared with the District Manager, Deputy District Manager, District HAST Manager and all other Programme Managers. Lessons learned with regard to the progress of the NIMART Program in the Ugu district were shared with stakeholders. Thereafter, the findings were shared with the respondents and clinic Operational Managers during the NIMART mentorship meeting in 2017. Lessons learned have helped the respondents and Operational Managers in identifying their gaps in the NIMART program. Findings of this research project assisted the District Training Coordinator to plan for the trainings, which will enhance the participants' skills and knowledge of the NIMART program and hence improve the participants' performance and health outcomes.

3.11. **PRE-TEST OR PILOT STUDY**

Burns and Groove (2009) state that a pilot study is a smaller version of a proposed study conducted to develop or refine the methodology, such as the treatment, instrument, or data collection process. The purpose of the pilot study is to identify errors in the research instruments. A pilot study was conducted on a small sample of 5 respondents who were not part of the study sample. The research instrument was pretested on 5 doctors who are District Family Physicians and HAST Clinical Managers, to ensure that the instructions were clear and the questions asked were relevant and unambiguous. They all recommended that the time taken to administer the instrument was acceptable. A test retest could have been performed at any time to ensure that the same responses were yielded.

3.12. **CONCLUSION**

This chapter described the research design and methodology, including the study population and the sampling technique. Data sources and data collection techniques were also discussed as well as issues of the reliability and validity of the data collection instrument and the pretesting of it. Ethical considerations including confidentiality, informed consents and the plan for data dissemination were also described in this chapter.

4. CHAPTER FOUR:
DATA PRESENTATION AND ANALYSIS

4.1. INTRODUCTION

This chapter presents the findings of the study in the form of data. In addition, it presents the data analysis. The study sought to answer the following research questions:

1. What Antiretroviral Therapy guidelines are available at the primary healthcare clinics in Ugu district?
2. What is the status of Ugu district facilities in providing HIV counselling, testing and treatment?
3. What is the level of knowledge and practice of professional nurses towards NIMART program?

A sample size of 56 participants from the 56 PHC clinics was invited to participate in the study. All PHC clinics in Ugu district were represented. However, four professional nurses were excluded according to the exclusion criteria, they did not meet the inclusion criteria of being trained on the NIMART course. Hence, only 52 participants were enrolled in the study. The research questionnaire was administered to the 52 professional nurses who are NIMART trained. All 52 respondents completed the questionnaire.

4.2. DATA CAPTURE TECHNIQUES

The data collected were captured and subsequently analysed using the Statistical Package for Social Sciences (SPSS version 21). Descriptive statistics such as frequencies, percentages, mean and standard deviation were used to summarise the results. The data are presented by means of frequency tables, bar graphs and pie charts and are organised below according to the five parts of the questionnaire: Part 1 –Demographics, Part 2 –Availability of latest Antiretroviral Treatment guidelines, Part 3 –Implementation of NIMART programme, Part 4 –Knowledge of NIMART and Part 5 –Practice of NIMART. Data analysis from the questionnaire was as follows.

4.3. PART 1: DEMOGRAPHICS

4.3.1. ARE YOU A PROFESSIONAL NURSE?

Table 3. Frequencies per Professional Category

Professional Nurse	N	Frequency	Percentage
YES	56	56	100%
NO	56	0	0%

Of the respondents that consented to participate in the study, 100% (n=56) were professional nurses working in primary healthcare clinics.

4.3.2. ARE YOU TRAINED IN THE NIMART COURSE?

Table 4. Frequencies of Professional Nurses trained in the NIMART Course

NIMART Training	N	Frequency	Percentage
YES	56	52	93%
NO	56	4	7%

Of the respondents who work at PHC clinics, 93% (n=52) were trained in the NIMART course, as compared to 7% (n=4), who were not trained in the NIMART course and were excluded according to the exclusion criteria. A total of 52 respondents met the inclusion criteria, and were then enrolled to participate in the study.

4.3.3. CURRENT POSITION

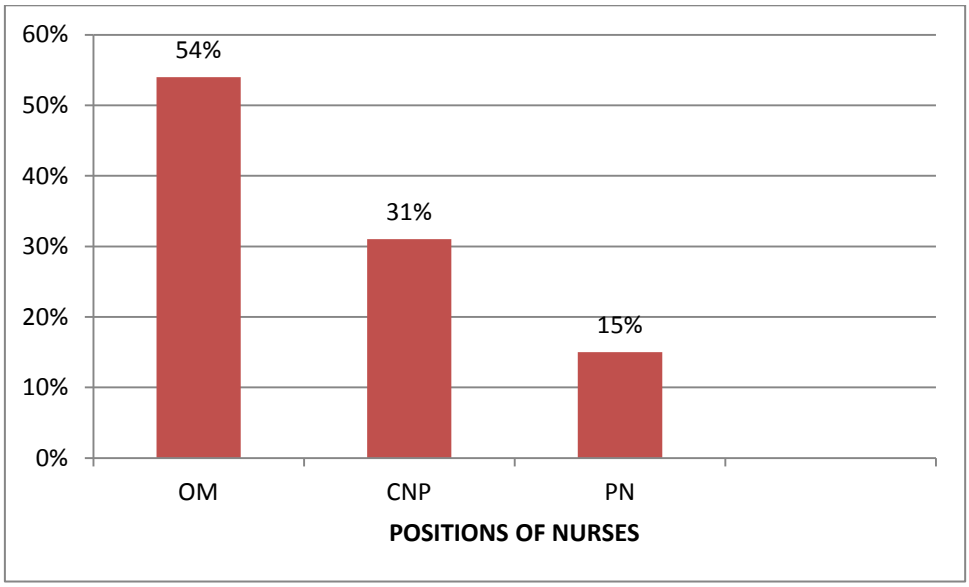

Figure 5. Designations of Respondents

The sample (n=52) of NIMART trained Nurses consisted of PHC Operational Managers, 54% (n=28); Clinical Nurse Practitioners, 31% (n=16) and Professional Nurses, 15% (n=8).

4.3.4. NUMBER OF PROFESSIONAL NURSES IN YOUR CLINIC

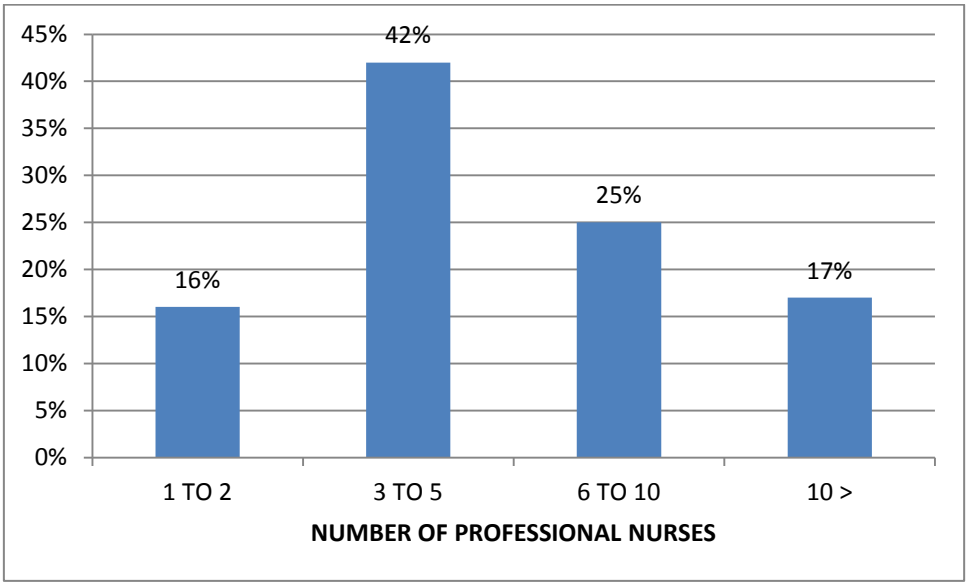

Figure 6. Number of Professional Nurses working in PHC clinics

The findings of the study represented in the bar graph above indicate that in the total sample (n=52) of PHC clinics represented, 16% (n=8) consisted of one to two Professional Nurses; 42% (n=22) consisted of three to five Professional Nurses; 25% (n=13) consisted of six to 10 Professional Nurses and 17% (n=9) consisted of more than 10 Professional Nurses.

4.3.5. NUMBER OF NIMART TRAINED NURSES IN YOUR CLINIC

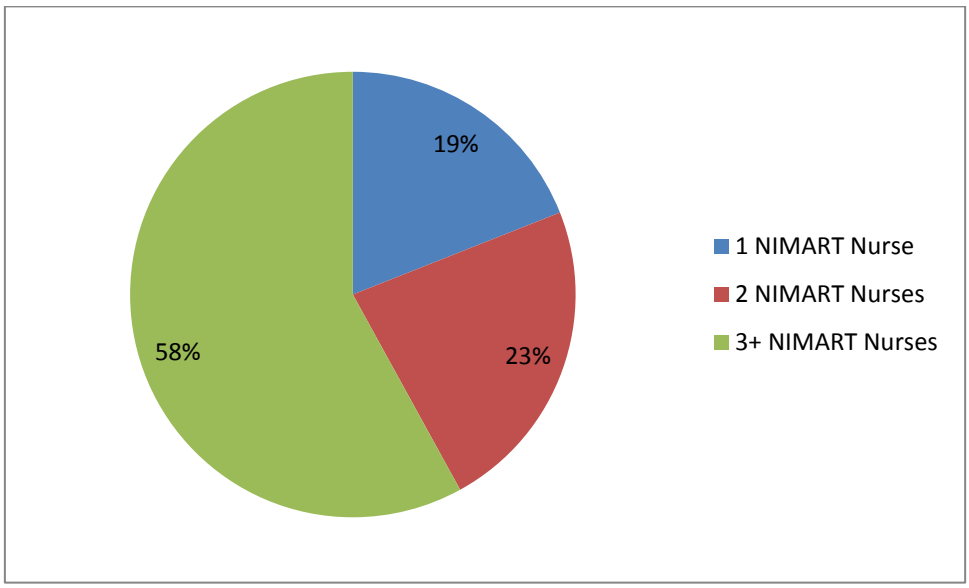

Figure 7. Number of NIMART trained Nurses in each clinic

The findings of the study represented in the pie chart above indicate that in the total sample (n=52) of PHC clinics represented, 19% (n=10) consisted of one NIMART Nurse; 23% (n=12) consisted of two NIMART Nurses; 58% (n=30) consisted of three NIMART Nurses or more.

4.4. PART 2: AVAILABILITY OF LATEST ANTIRETROVIRAL TREATMENT GUIDELINES

4.4.1. ARE ANTIRETROVIRAL THERAPY GUIDELINES AVAILABLE IN YOUR CLINIC?

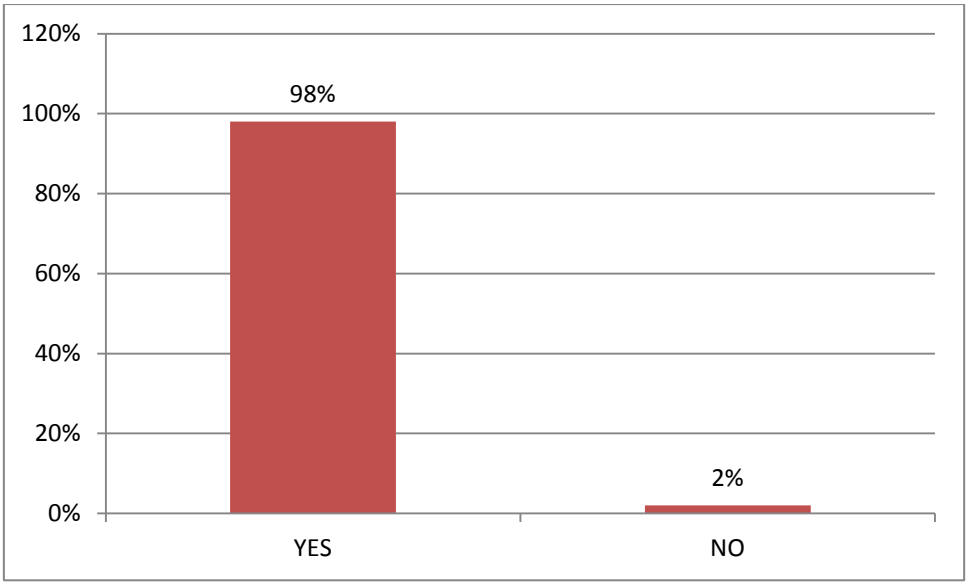

Figure 8. Frequencies of Availability of ART Guidelines

This bar graph presents the availability of ART guidelines in PHC clinics: 98% (n=51) reported that ART guidelines were available in their clinics, and only 2% (n=1) reported that ART guidelines were not available in their clinic.

4.4.2. WHICH ART GUIDELINES ARE AVAILABLE IN YOUR CLINIC?

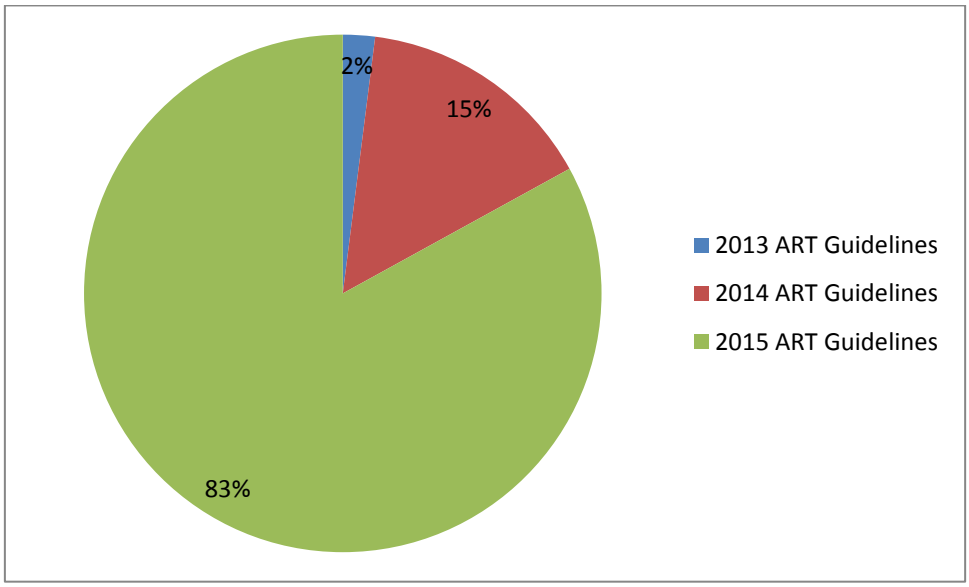

Figure 9. Version of ART guidelines available in PHC clinics

This pie chart above presents the version of ART guidelines that were available in PHC clinics: 2% (n=1) reported that 2013 ART guidelines were available in their clinics; 15%

(n=8) reported that 2014 ART guidelines were available in their clinic and 83% (n=43) reported that the latest 2015 ART guidelines were available in their clinics.

4.5. PART 3: IMPLEMENTATION OF NIMART

4.5.1. DO PROFESSIONAL NURSES INITIATE ADULTS AND MANAGE ART IN THEIR CLINIC?

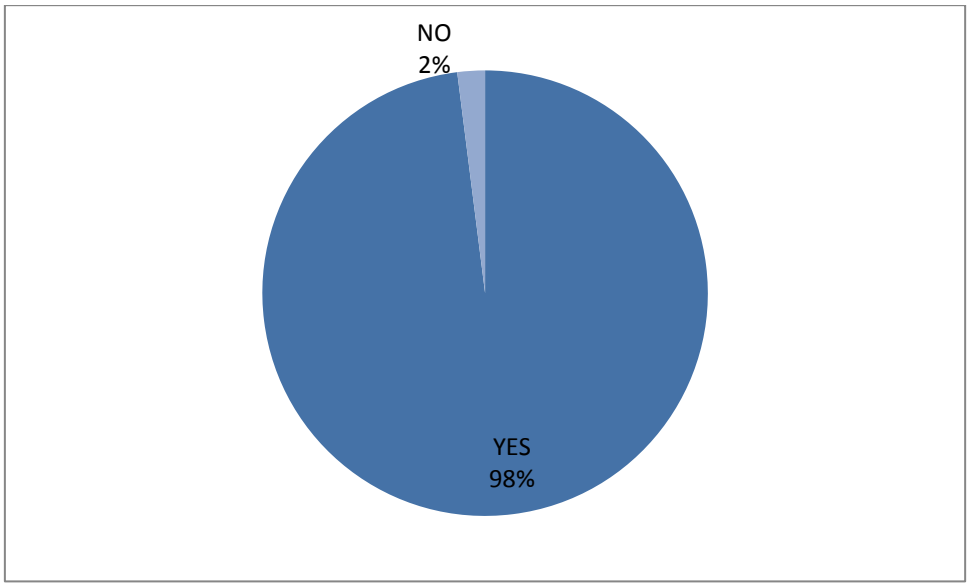

Figure 10. Clinics that initiate adults on ART

Of the respondents who were initiating Antiretroviral Therapy in their clinics, 98% (n=51) of the clinics were initiating adults on ART, as compared to 2% (n=1) of the clinics who were not initiating adults on ART.

4.5.2. ARE CHILDREN INITIATED ON ART IN YOUR CLINIC?

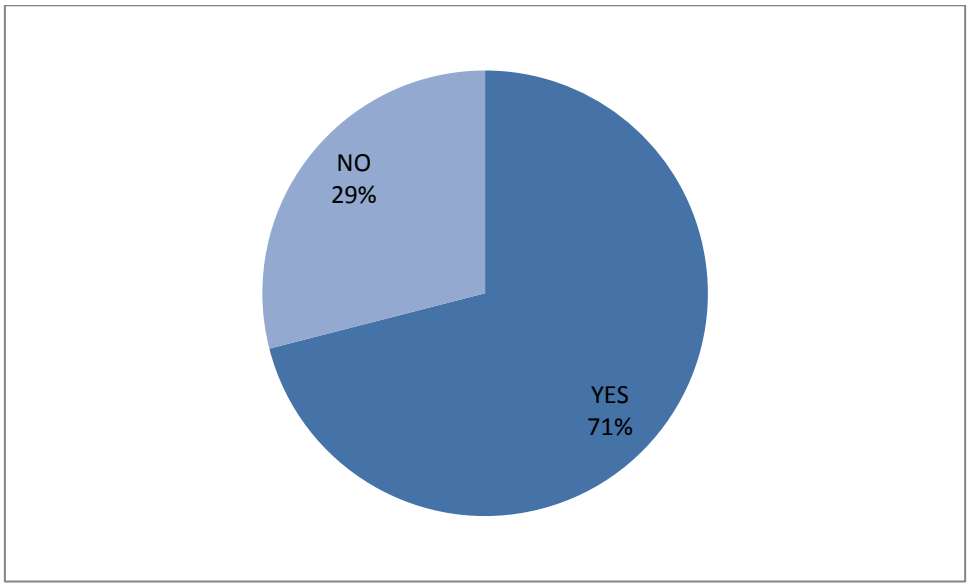

Figure 11. Clinics that initiate Children on ART

Of the respondents who were initiating Antiretroviral Therapy in their clinics, 71% (n=37) of the clinics were initiating children on ART, as compared to 29% (n=15) of the clinics who were not initiating children on ART.

4.5.3. WHO INITIATES CHILDREN ON ART IN YOUR CLINIC?

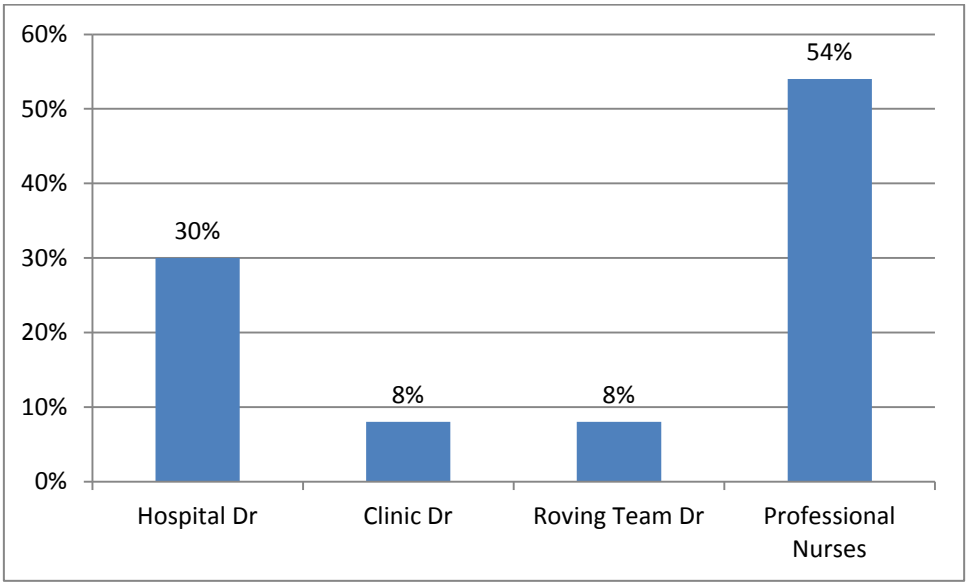

Figure 12. Initiator of children on ART

Of the respondents who were initiating children on Antiretroviral Therapy in their clinics, 30% (n=16) of the clinics children were initiated by a hospital doctor, 8%

(n=4) of the clinic's children were initiated by the clinic's visiting doctor, 8% (n=4) of the clinics children were initiated by the roving team doctor and 54% (n=28) of the clinics children were initiated by professional nurses.

4.6. PART 4: KNOWLEDGE OF NIMART – ART REGIMENS

4.6.1. WHAT IS THE FIRST LINE ART REGIMEN FOR CHILDREN < 3YEARS OR 10KG?

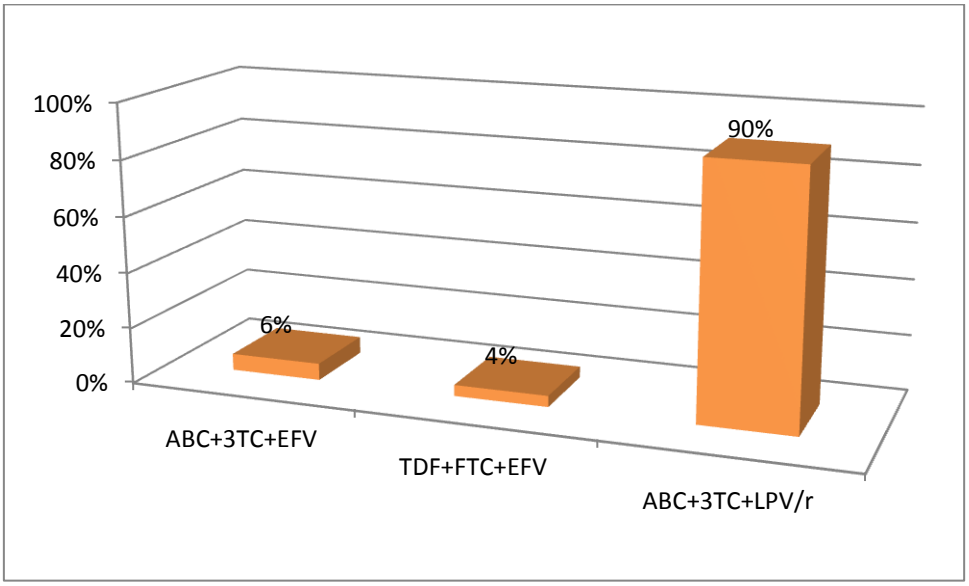

Figure 13. First Line ART regimen for children < 3yrs

This bar graph above presents the first line ART regimen for children under three years: 90% (n=47) knew the correct ART regimen and the other 10% (n=5) did not know the correct regimen. The results indicated a gap in the nurse's knowledge of First Line ART regimen for children under three years.

4.6.2. WHAT IS THE FIRST LINE ART REGIMEN FOR CHILDREN >3 YEARS OR 10KG UP TO ADOLESCENTS <15 YEARS OR <40KG?

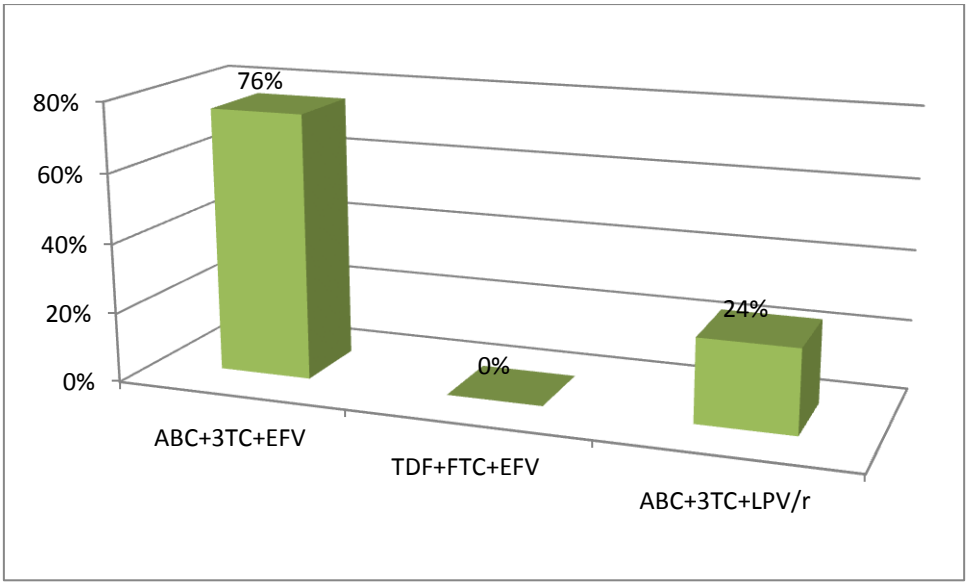

Figure 14. First Line ART regimen for children > 3yrs up to adolescents <15 years or <40kg?

This bar graph above presents the first line ART regimen for children three years and older up to adolescents less than 15 years, 76% (n=39) knew the correct ART regimen; the other 24% (n=13) did not know the correct regimen for children three years and older, which is an area of concern.

4.6.3. WHAT IS THE FIRST LINE ART REGIMEN FOR ADOLESCENTS AND ADULTS?

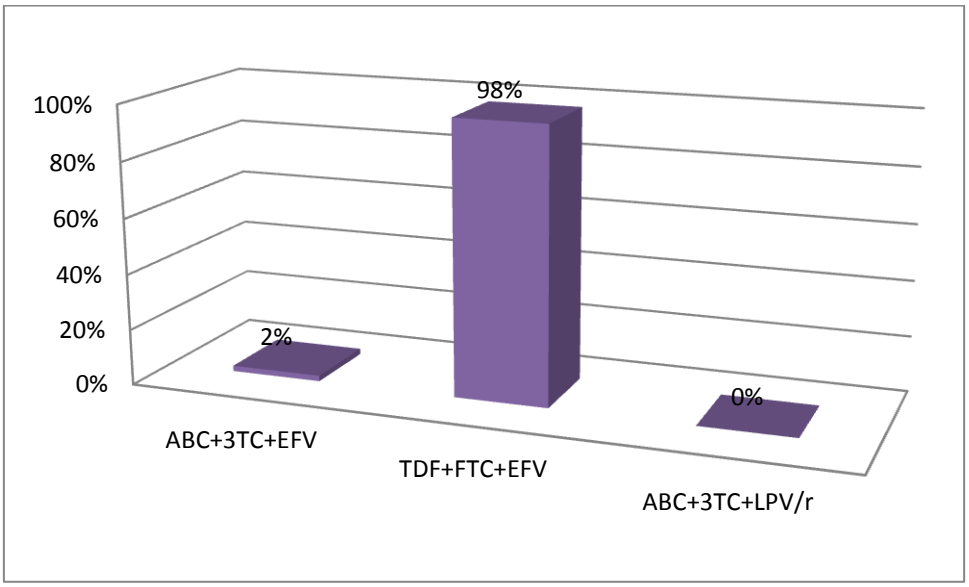

Figure 15. First Line ART regimen for adolescents and adults

This bar graph above presents the first line ART regimen for adolescents and adults: a total of 98% (n=51) knew the correct ART regimen, which is TDF + FTC + EFV, as compared to 2% (n=1) who did not know the correct regimen.

4.6.4. WHAT IS THE ISONIAZID PREVENTIVE THERAPY REGIMEN FOR ADULTS?

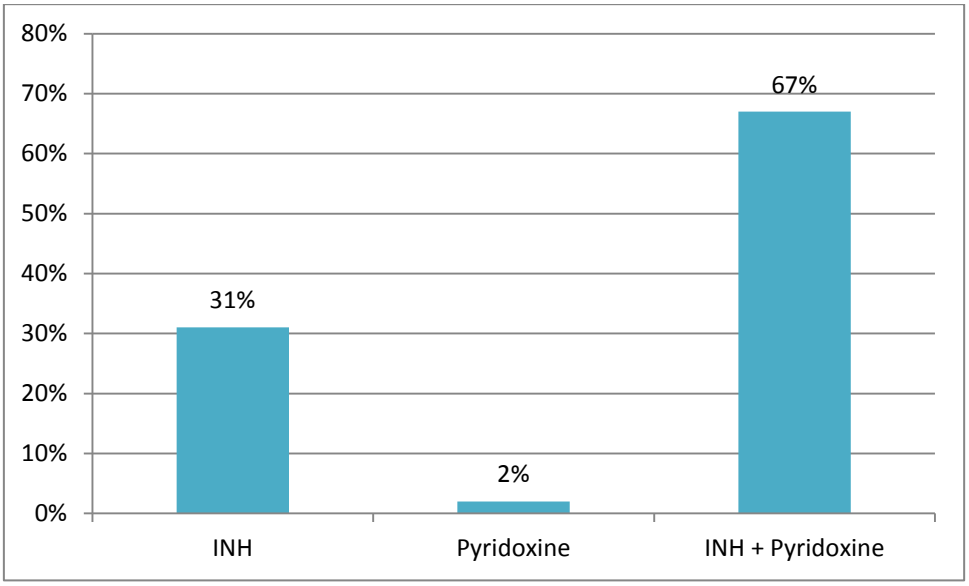

Figure 16. Adults Isoniazid Preventive Therapy regimen

Of the respondents, 67% (n=35) knew about the adults Isoniazid Preventive Therapy, which is administering Isoniazid 5mg/kg/day and Pyridoxine 25mg/day; while 31% (n=16) did not know the correct IPT regimen and reported using Isoniazid only; and 2% (n=1) also did not know the correct regimen, and reported using Pyridoxine only.

4.6.5. WHAT ARE THE CRITERIA FOR STARTING COTRIMOXAZOLE PREVENTIVE THERAPY?

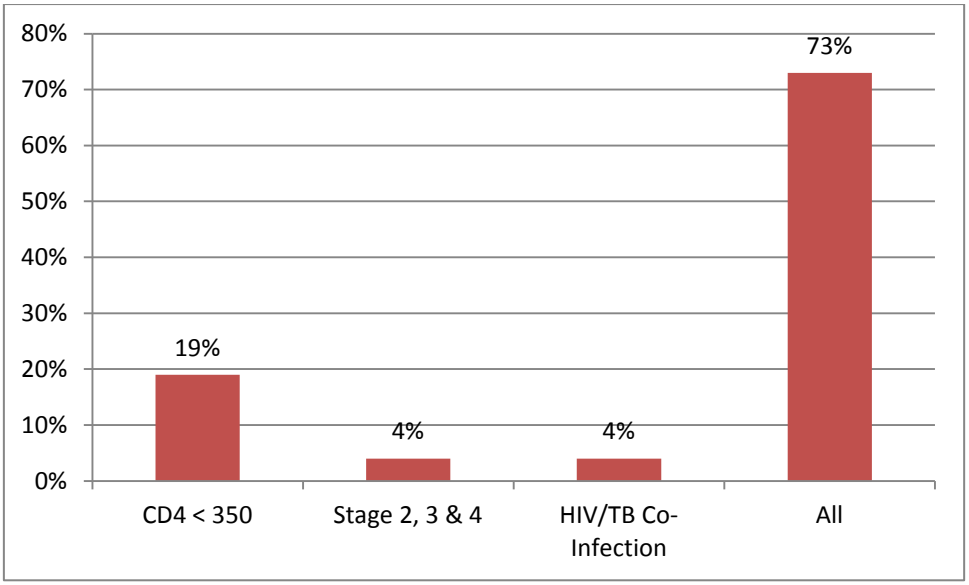

Figure 17. Criteria for Cotrimoxazole Preventive Therapy

Of the respondents, 73% (n=38) knew the criteria for initiating Cotrimoxazole Preventive Therapy which is at a CD4 count < 350; WHO clinical Stage 2, 3, &4 and HIV/TB co-infection. 19% (n=10) did not know the correct criteria, and reported CD4 count < 350 only; 4% (n=2) also did not know the correct criteria, and reported WHO clinical stage 2, 3 and 4 only; and 4% (n=2) did not know the correct regimen either, and reported HIV/TB co-infection only.

4.7. PART 5: PRACTICE OF NIMART – ART ELIGIBILITY CRITERIA AND LABORATORY BLOOD TESTS

4.7.1. PATIENTS WITH WHO CLINICAL STAGES 3 & 4 ARE ELIGIBLE FOR ART INITIATION REGARDLESS OF THEIR CD4 COUNT

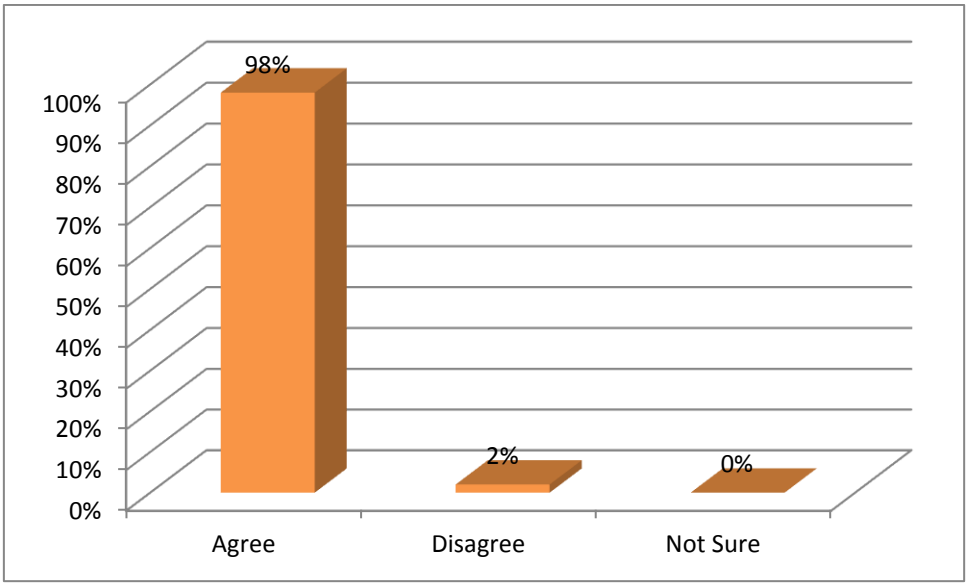

Figure 18. ART Eligibility Criteria: WHO stages 3 & 4 eligible

Of the respondents, 98% (n=51) agreed with the statement that patients with WHO clinical stages 3 & 4 are eligible for Antiretroviral Therapy initiation regardless of their CD4 count; 2% (n=1) disagreed and 0% (n=0) were unsure.

4.7.2. PATIENTS WITH CD4 COUNTS OF OR LESS THAN 500 CELLS/MM^3 ARE NOT ELIGIBLE FOR ART INITIATION

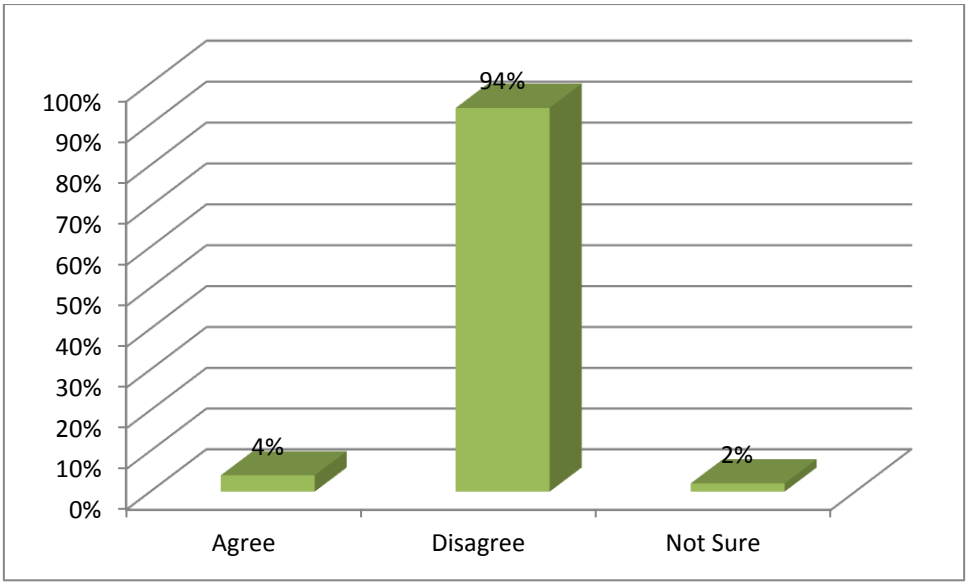

Figure 19. ART Eligibility Criteria: CD4 count < 500 not eligible

Of the respondents, 98% (n=51) disagreed with the statement that patients with a CD4 count of or less than 500 cells/mm^3 are not eligible for Antiretroviral Therapy initiation; 4% (n=2) did not know and 2% (n=1) were unsure.

4.7.3. CHILDREN LESS THAN 5 YEARS OLD ARE ELIGIBLE FOR ART INITIATION REGARDLESS OF THEIR CD4 COUNT OR WHO CLINICAL STAGING

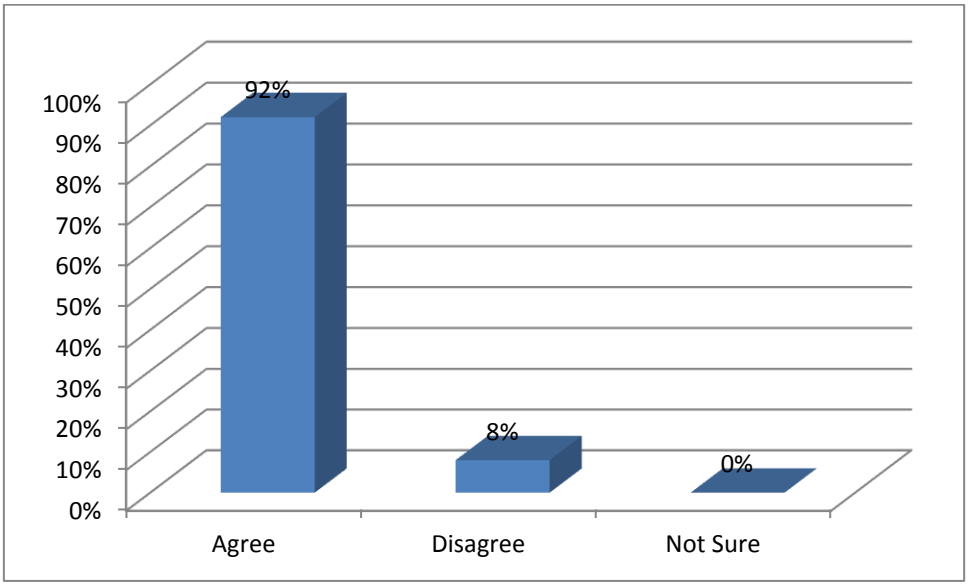

Figure 20. ART Eligibility Criteria: Children < 5 years eligible

Of the respondents, 92% (n=48) agreed with the statement that children less than five years old are eligible for Antiretroviral Therapy initiation regardless of their CD4 count or WHO clinical staging; 8% (n=4) disagreed and 0% (n=0) were unsure.

4.7.4. PREGNANT OR BREASTFEEDING MOTHERS ARE NOTELIGIBLE FOR IMMEDIATE ART INITIATION

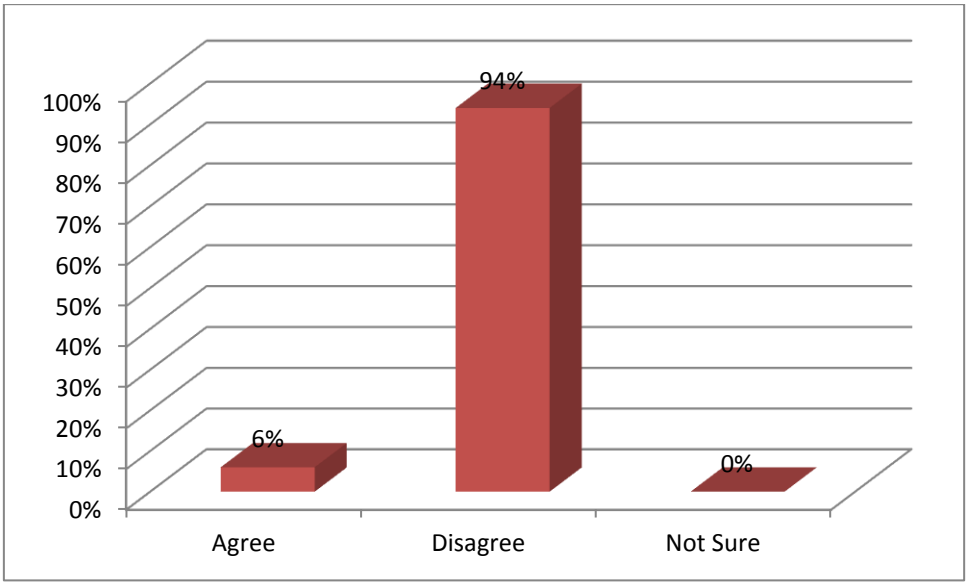

Figure 21. ART Eligibility Criteria: Pregnant &breastfeeding mothers not eligible

Of the respondents, 94% (n=49) disagreed with the statement that pregnant or breastfeeding mothers are not eligible for immediate Antiretroviral Therapy initiation; 6% (n=3) did not know and 0% (n=0) were unsure.

4.7.5. PATIENTS WHO ARE TB / HIV CO-INFECTED SHOULD BE INITIATED ON ANTI-TB DRUGS FIRST, THEN INITIATED ON ART WITHIN 8 WEEKS OR 2 WEEKS IF THEIR CD4 COUNT IS LESS THAN 50 CELLS/MM^3

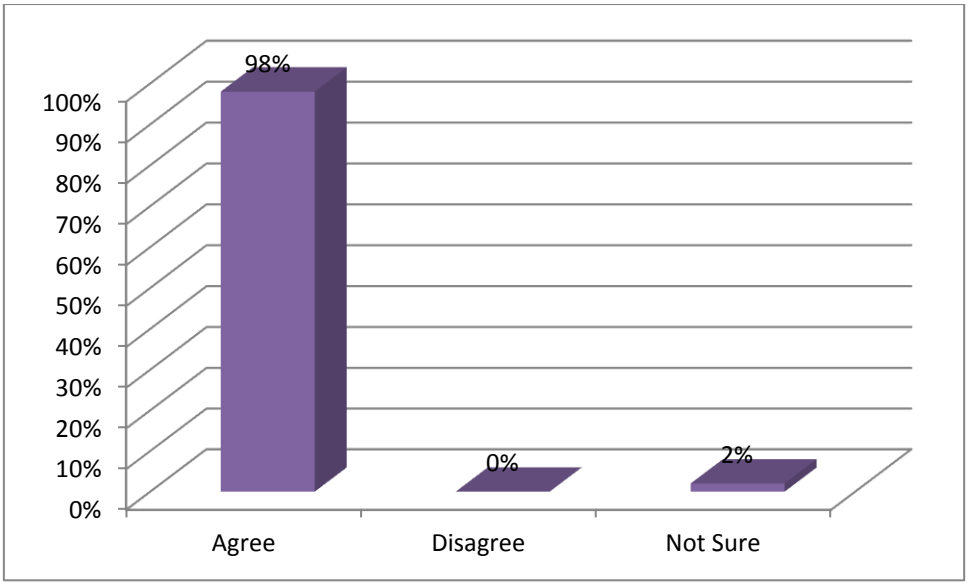

Figure 22. ART Eligibility Criteria: TB / HIV Co-Infected Eligible

Of the respondents, 98% (n=51) agreed with the statement that patients who are TB / HIV co-infected should be initiated on Anti-TB drugs first, then initiated on Antiretroviral Therapy within eight weeks or two weeks if their CD4 count is less than 50 cells/mm^3; 0% (n=0) disagreed and 2% (n=1) were unsure.

4.7.6. WHEN WOULD YOU TAKE BLOOD FOR DETERMINING THE CD4 COUNT?

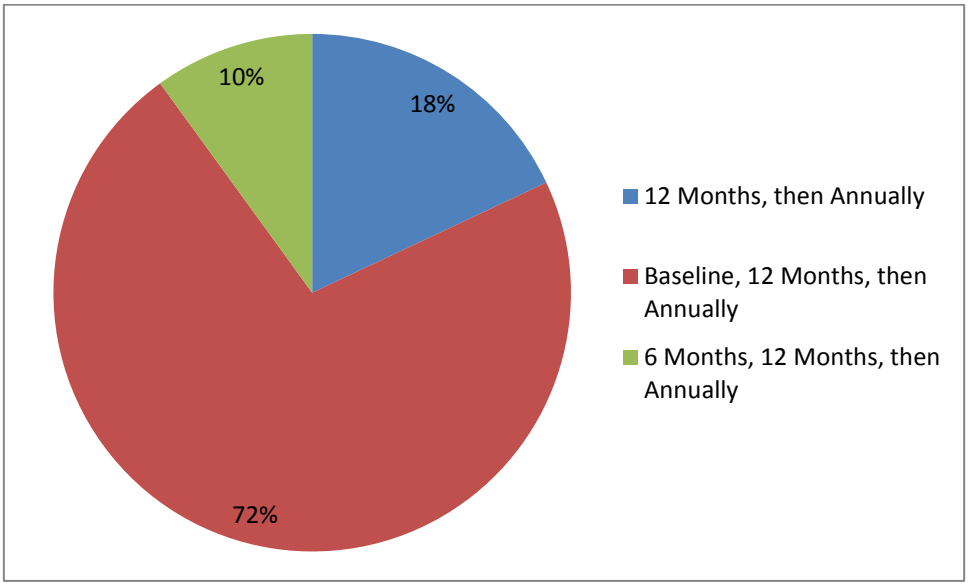

Figure 23. CD4 count blood test

The above pie chart represents the frequencies of the responses to when CD4 count blood tests should be taken. 72% (n=37) reported that CD4 count blood tests are taken at baseline, 12 months then annually; 18% (n=9) reported that CD4 count blood tests are taken at 12 months then annually; and 10% (n=5) reported that CD4 count blood tests are taken at six months, 12 months then annually. In summary, the majority of the participants 72% (n=37) knew when blood for CD4 count tests should be taken, whereas 18% (n=9) and 10% (n=5) did not know.

4.7.7. WHEN WOULD YOU TAKE BLOOD FOR DETERMINING VIRAL LOAD?

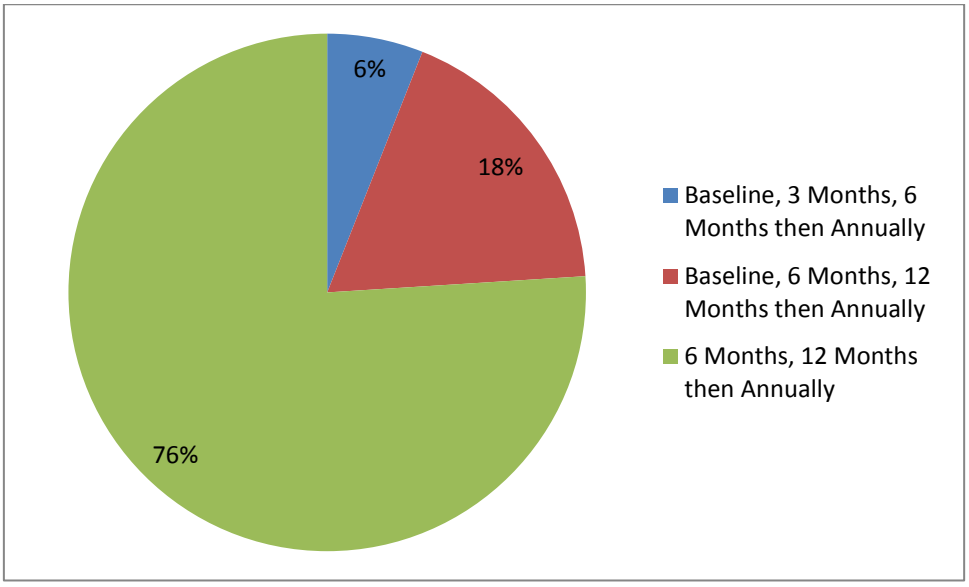

Figure 24. Viral Load blood test

The above pie chart represents the frequencies of the responses to when viral load blood tests should be taken. 76% (n=39) reported that viral load blood tests are taken at six months, 12 months, then annually; 18% (n=9) reported that viral load blood tests are taken at baseline, six months, 12 months then annually; and 6% (n=3) reported that viral load blood tests are taken at baseline, at three months, six months and then annually. In summary, the majority of the participants 76% (n=39) knew when blood for viral load tests should be taken, whereas 18% (n=9) and 6% (n=3) did not know.

4.8. CONCLUSION

This chapter presented the data obtained from the study. The data were analysed and presented in the form of tables, bar graphs and pie charts. In an attempt to answer the research questions, the findings of the study presented that 98% (n=51) reported that ART guidelines were available in their clinics, and only 2% (n=1) reported that ART guidelines were not available in their clinic.83% (n=43) reported that the latest 2015 ART guidelines were available in their clinics. With regard to NIMART implementation, 98% (n=51) of the clinics were initiating adults on ART, as compared to 2% (n=1) of the clinics that were not initiating adults on ART. Chapter Five will discuss the findings, make recommendations, and give the limitations and conclusions of the study.

5. CHAPTER FIVE:
DISCUSSION OF FINDINGS, AND RECOMMENDATIONS, LIMITATIONS AND CONCLUSIONS

5.1. INTRODUCTION

This chapter discusses the summary of the study findings with regard to the availability of the latest ART guidelines, implementation of NIMART and knowledge of the NIMART program. It also discusses the recommendations, limitations and conclusions of the study.

The purpose of this study was to conduct an Implementation Evaluation Study of the Nurse Initiated and Managed Antiretroviral Therapy (NIMART) program in primary healthcare clinics in the Ugu district of KwaZulu-Natal. The objectives were to evaluate the availability of the latest Antiretroviral Therapy guidelines, to evaluate the implementation of the Nurse Initiated and Managed Antiretroviral Therapy (NIMART) program and to evaluate the knowledge and practice of professional nurses towards the NIMART program in the clinics of the Ugu district.

The researcher selected four research assistants to collect data and to eliminate bias, as the researcher was the Training Coordinator in the Ugu district. The researcher trained the research assistants, because they did not have prior experience on data collection, to use the questionnaires and to administer it. Furthermore, the researcher trained the research assistants on the information leaflet and informed consent. The research assistants provided the information about the research study and also assisted in obtaining informed consent.

Data were collected after the NIMART mentorship meeting that was held on the 5th of September 2016. The research assistants administered the research tools to eliminate bias as they were neutral. NIMART nurses from all 56 clinics were invited to attend the meeting. Each professional nurse represented a single clinic in the Ugu district.

5.2. DISCUSSION OF THE FINDINGS

The findings of this study revealed that the majority of Primary Health Care clinics in the Ugu district were implementing the guidelines on NIMART by shifting the task of initiating ARVs to the nurses and by decentralising the services of HIV counselling, testing and treating to the clinics. There is a great need to train more nurses on NIMART, as it was also evidenced by the findings of this study that HIV-positive people in the Ugu district benefited by accessing ARV's in good time because the nurses were also providing treatment. That Quality HIV care was being provided in the Ugu district was shown by the results of this study indicating that guidelines on NIMART were available on almost all the clinics in the district and that the nurses had knowledge of ARV regimens, blood tests for CD4 and viral load and preventive therapy.

The findings of the study are discussed below in relation to the demographics of nurses and the three research questions.

5.2.1. DEMOGRAPHICS OF NURSES

The results of this study revealed that professional nurses from all the primary health care clinics in the Ugu district participated in the study. However, not all 56 professional nurses were trained in NIMART. Four professional nurses were not trained in NIMART and were excluded from the study due to the exclusion criteria. Hence, out of 56 professional nurses only 52 were enrolled in the study. Respondents that were trained in NIMART consisted of different nursing categories namely: PHC Operational Managers, Clinical Nurse Practitioners and Professional Nurses. All these categories are however professional nurses.

Primary healthcare clinics had staffing challenges, operating with only two professional nurses. Other clinics, which were mainly the 24 hour clinics and the CHCs, had more than 10 professional nurses. All the clinics had at least one NIMART trained nurse and some clinics had more than one. If there is an adequate number of nurses and the nurse-patient ratio is maintained, quality comprehensive health care will be rendered (Padarath, Ntuli and Berthiaume, 2003/2004).

5.2.2. WHAT ANTIRETROVIRAL THERAPY GUIDELINES ARE AVAILABLE AT THE PRIMARY HEALTHCARE CLINICS IN THE UGU DISTRICT?

With regard to the availability of ART guidelines in PHC clinics, they were available in all PHC clinics in the Ugu district, although one respondent reported that the clinic had the outdated 2013 ART guidelines. The research that was conducted confirmed what Colvin (2010) had found: that nurses, patients and doctors highly accepted NIMART, and also that managers and nurses expressed confidence in their ability to apply the guidelines and deliver ART successfully.

There are different versions of ART guidelines that are available in PHC clinics in the Ugu district. New developments have been added in the latest guidelines. A few clinics reported that the 2014 ART guidelines were available in their clinics, which is still good enough since the 2014 guidelines were a draft of the latest guidelines of 2015. A majority of clinics reported that the current and latest 2015 ART guidelines were available in their clinics with the title of National Consolidated Guidelines for the Prevention of Mother-to-Child Transmission of HIV (PMTCT) and the Management of HIV in Children, Adolescents and Adults (April 2015).

5.2.3. WHAT IS THE STATUS OF UGU DISTRICT FACILITIES IN PROVIDING HIV COUNSELLING, TESTING AND TREATMENT?

The majority of the professional nurses who work at the Primary Health Care clinics in the Ugu district are trained in NIMART. Only 4 clinics had nurses that were not trained in NIMART. Hence, 52 PHC clinics in the Ugu district are compliant with the presidential mandate that was announced on the 1st December 2009 that all PHC clinics should provide Antiretroviral Therapy and nurses must be trained in NIMART. In2010, there was a presidential mandate that ARVs should be made available in all public health facilities and nurses should be trained to prescribe and manage patients on these drugs (Nyasulu et al., 2013).

Professional nurses in all primary healthcare clinics in the Ugu district, except one, were initiating adults and children on Antiretroviral Therapy, although in half of the

clinics paediatric ART initiation is still done by the hospital or roving teams of doctors and professional nurses who continue with the management.

5.2.4. WHAT IS THE LEVEL OF KNOWLEDGE AND PRACTICE OF PROFESSIONAL NURSES TOWARDS THE NIMART PROGRAM?

KNOWLEDGE OF NIMART–ART REGIMENS

The majority of NIMART nurses, 90% (n=47), knew the correct first line ART regimen for children under three years old according to the Department of Health (2015). The other 10% (n=5) did not know the correct regimen. The results indicated a gap in the nurse's knowledge of the first line ART regimen for children under three years old. Even fewer NIMART nurses, 76% (n=39), knew the correct first line ART regimen for children three years and older. This includes ages up to and including adolescents 15 years old (DOH, 2015). 24% (n=13) did not know the correct first line ART regimen for children three years and older, including adolescents below 15 years, which is an area of concern. The majority of NIMART nurses, 98% (n=51), were knowledgeable about the correct first line ART regimen for adolescents and adults which is provided in the form of Fixed-dose Combination (FDC) (DOH, 2015). Only 2% (n=1) did not know the correct regimen. A large number of NIMART nurses were knowledgeable about the Isoniazid preventive therapy and the criteria for initiating Cotrimoxazole preventive therapy. There were, however, nurses who were not knowledgeable about the two preventive therapies namely, Isoniazid preventive therapy and Cotrimoxazole preventive therapy.

PRACTICE OF NIMART - ART ELIGIBILITY CRITERIA

The NIMART nurses in the Ugu district were knowledgeable about the ART eligibility criteria according to the National Consolidated Guidelines for PMTCT (2015), but there were still nurses trained in NIMART who were unsure or did not know the ART eligibility criteria.

PRACTICE OF NIMART - LABORATORY BLOOD TESTS

Lastly, the study evaluated the knowledge of professional nurses trained in NIMART with regards to the CD4 count and viral load blood tests. NIMART trained

nurses in the Ugu district know when the CD4 count and viral load blood test should be done. According to the DOH (2015), baseline and routine clinical and laboratory assessment for late adolescents and adults: CD4 counts should be taken at diagnosis to identify eligibility for ART and patients on ART, CD4 counts should be checked at 12 months, then annually (if clinically indicated), in order to monitor immune response to ART. Viral load should be checked once the patient is already on ART at month 6, and month 12 on ART and then every 12 months, to identify treatment failures and problems with adherence.

5.3. LIMITATIONS TO THE STUDY

Not all NIMART nurses were assessed: only one per clinic was. More accurate results of the nurses' knowledge on the NIMART program could have been obtained if all NIMART trained nurses had been assessed.

Four clinics were excluded from the study because they had sent nurses to attend the NIMART mentorship meeting that were not NIMART trained and so they did not meet the inclusion criteria. Hence, there was a discrepancy with the sample size because initially it was 56 clinics, yet 52 clinics were evaluated. Nurses from clinics in only one district were included in the study sample which will limit the generalisability of the findings to other districts.

Assessing the availability of guidelines for NIMART using the reported results, the researcher could not verify this response by physically looking at the guidelines since she did not visit the clinics, but had to accept the information that was provided in the questionnaires.

5.4. RECOMMENDATIONS

In view of the findings of the study, the researcher made the following recommendations for the implementation of NIMART.

5.4.1. RECOMMENDATIONS FOR MANAGEMENT

Motivation for the creation of professional nurses' posts must be done by the District Human Resource Manager and the clinics' Operational Managers. This will

ensure the even distribution of staff in PHC clinics and improve the shortage of staff.

The District HAST Manager and clinics' Operational Managers must ensure that the latest 2015 National Consolidated Guidelines for PMTCT are available in all the PHC clinics.

5.4.2. RECOMMENDATIONS FOR EDUCATION

NIMART course should continue and more nurses must be trained in NIMART so that the target of 15 million HIV positive people accessing Antiretroviral Therapy is reached, and also for health facilities to cope with the universal access to treatment.

All the nurses that are NIMART trained should receive mentorship after the training so that they become competent and confident in initiating and managing HIV-positive patients on ART.

The District Training Coordinator must arrange a workshop fthe2015 National Consolidated Guidelines to refresh NIMART nurses about ART regimens and blood tests to be done, as well as learning the ART eligibility criteria.

5.4.3. RECOMMENDATIONS FOR RESEARCH

The findings of this study revealed that there were some gaps in the nurses' knowledge around ART regimens, blood tests and eligibility criteria. This study can be used as a baseline to evaluate all the professional nurses trained in NIMART in the Ugu district.

5.5. CONCLUSION

The study was conducted in the Ugu district of KwaZulu-Natal to evaluate the implementation of the NIMART program. The study revealed that in 98% (n=51) of the clinics in Ugu district nurses are initiating adults on ART and only 2% (n=1) are still being initiated by a doctor. Furthermore, the majority of respondents indicated that children are initiated on ART in their clinics, while some respondents reported

that in their clinics children are still initiated by the clinic visiting doctor or hospital doctor. The findings indicated that 98% (n=51) clinics have the latest ART guidelines available, while only 2% (n=1) of clinics indicated that they have outdated ART guidelines available in the clinic. The study revealed that most respondents knew the correct ART regimens, ART eligibility criteria and when bloods for CD4 count and viral load should be taken, while there are still some respondents who did not know.

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APPENDICES

APPENDIX 1: RESEARCH TOOLS

Instrument 1: Questionnaire

AN IMPLEMENTATION EVALUATION STUDY OF NURSE INITIATED AND MANAGED ANTIRETROVIRAL THERAPY (NIMART) PROGRAM IN PRIMARY HEALTH CARE CLINICS IN THE UGU DISTRICT OF KWAZULU-NATAL.

PART 1: DEMOGRAPHICS

---

1. Are you a Professional Nurse?

☐ Yes ☐ No

2. Are you trained on NIMART Course?

☐ Yes No ☐

3. Current Position

☐ PHC Coordinator ☐ Clinical Nurse Practitioner

☐ Operational Manager ☐ Professional Nurse

4. Number of Professional Nurses in your clinic

☐ 1 - 2 ☐ 6 - 10

☐ 3 - 5 ☐ 10 +

5. Number of NIMART trained Professional Nurses in your clinic

☐	None	☐	2
☐	1	☐	3 +

PART 2: AVAILABILITY OF LATEST ANTIRETROVIRALTREATMENT GUIDELINES

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1. Are Antiretroviral Treatment Guidelines available in your clinic?

☐	Yes	☐	No

2. Which Antiretroviral Therapy Guidelines are available in your clinic?

☐	None	☐	2014
☐	2013	☐	2015

PART 3: IMPLEMENTATION OF NIMART

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1. Do Professional Nurses initiate adults and manage Antiretroviral Treatment in your clinic?

☐	Yes	☐	No

2. Are children initiated on Antiretroviral Treatment in your clinic?

☐ Yes ☐ No

3. Children in your clinic are initiated on Antiretroviral Treatment by

☐ Doctor at hospital ☐ Clinic visiting Doctor

☐ Roving Team Doctor ☐ Professional Nurse

PART 4: KNOWLEDGE OF NIMART – ART REGIMENS

Please choose the best correct answer of the following:

1. What is First Line ART Regimen to start all infants and children under 3 yrs or 10kg on?
   (a) ABC + 3TC + EFV
   (b) TDF + FTC + EFV
   (c) ABC + 3TC + LPV/r

2. What is First Line ART Regimen to start all infants and children over 3 yrs or 10kg on?
   (a) ABC + 3TC + EFV
   (b) TDF + FTC + EFV
   (c) ABC + 3TC + LPV/r

3. What is First Line ART Regimen to start all adults on?
   (a) ABC + 3TC + EFV
   (b) TDF + FTC + EFV
   (c) ABC + 3TC + LPV/r

4. What is the Isoniazid Preventive Therapy (IPT) Regimen for adults?
   (a) INH 5mg/kg/day (max 300mg/day)
   (b) Pyridoxine 25mg/day
   (c) All of the above

5. When would you start Cotrimoxazole Preventive Therapy (CPT)?
   (a) CD4 count is less than 350 cells/mm^3
   (b) WHO Clinical Stage 2, 3 and 4
   (c) HIV/TB co-infection
   (d) All of the above

PART 5: PRACTICE OF NIMART – ART ELIGIBILITY CRITERIA &LABORATORY BLOOD TESTS

ART ELIGIBILITY CRITERIA

Please state how you agree or disagree with each of the following:

	Agree	Disagree	Not Sure
1. Patient with WHO Clinical Stage 3 & 4 is eligible for ART initiation regardless of CD4 count.			
2.Patient with CD4 count of or less than 500 cells/mm^3 is not eligible for ART initiation.			
3.Children less than 5 years are eligible for ART initiation regardless of CD4 count or WHO Clinical Staging.			
4.Pregnant or breastfeeding mothers are not eligible for immediate ART initiation.			
5.Patients who are TB / HIV co-infected should be initiated on Anti-TB drugs first, then initiated on ART within 8 weeks or 2 weeks if CD4 count is less than 50 cells/mm^3.			

LABORATORY BLOOD TESTS

Please choose the best correct answer of the following:

1. When would you take bloods for CD4 count?
   (a) At 12 months then annually
   (b) At baseline; 12 months then annually
   (c) At 6 months; 12 months then annually

2. When would you take bloods for Viral load?
   (a)At baseline; 3 months and 6 months then annually
   (b)At baseline; 6 months; 12 months then annually
   (c)At 6 months; 12 months then annually

THANK YOU FOR YOUR PARTICIPATION

APPENDIX 2: UKZN BREC APPROVAL LETTER

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

17 August 2016

Ms P Xaba (952059855)
Discipline of Public Health
School of Nursing and Public Health Medicine
Pearl.xaba8@gmail.com

Title: An implementation evaluation study of nurse initiated and managed antiretroviral therapy (NIMART) programme in Primary Health Care Clinics in the UGu District of KwaZulu-Natal.
Degree: Master of Nursing (Administration)
BREC REF NO: BE364/16

EXPEDITED APPLICATION

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application received on 08 June 2016.

The study was provisionally approved pending appropriate responses to queries raised. Your response dated 02 August 2016 to queries raised on 20 July 2016 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 and may begin as from 17 August 2016.

This approval is valid for one year from **17 August 2016.** 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 (2004), 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 next meeting taking place on **13 September 2016.**

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

cc supervisor: kerri@ukzn.ac.za
cc postgraduate office: Dhanraic@ukzn.ac.za

APPENDIX 3: DEPARTMENT OF HEALTH KZN PROVINCE APPROVAL LETTER

health
Department:
Health
PROVINCE OF KWAZULU-NATAL

Physical Address: 330 Langalibalele Street, Pietermaritburg
Postal Address: Private Bag X9051
Tel: 033 395 2805/ 3189/ 3123 Fax: 033 394 3782
Email: hrkm@kznhealth.gov.za
www.kznhealth.gov.za

DIRECTORATE:
Health Research & Knowledge Management

HRKM Ref: 247/16
NHRD Ref: KZ_2016RP0_643

Date: 17 August 2016
Dear Ms P. Xaba
UKZN

Approval of research

1. The research proposal titled **'An implementation evaluation study of nurse initiated and managed antiretroviral therapy (NIMART) program in Primary Health Care clinics in the Ugu District of KwaZulu Natal'** was reviewed by the KwaZulu-Natal Department of Health.

   The proposal is hereby **approved** for research to be undertaken at all Primary Health Care clinics and Community Health Centres in Ugu District.

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 Mr X. Xaba on 033-395 2805.

Yours Sincerely

Dr E Lutge
Chairperson, Health Research Committee
Date: 17/08/16.

APPENDIX 4: DEPARTMENT OF HEALTH UGU DISTRICT APPROVAL LETTER

HEALTH
KwaZulu-Natal

UGU HEALTH DISTRICT OFFICE
Private Bag X 735, Port Shepstone, 4240
41 Bissett Street, via Main Entrance of Nelson Mandela Drive
Tel.:039 688 3000,
Fax.:039 682 6296
Email.:comfort.nguza@kznhealth.gov.za

www.kznhealth.gov.za

Enquiries: Mr C Nguza
Ref: UGUDHO research
Date: 30 June 2015

Principal Investigator: Mrs Pearl Xaba

Re: PERMISSION TO CONDUCT RESEARCH AT DISTRICT/FACILITY

I have pleasure in informing you that permission has been granted to you by the District Office/Facility to conduct research on **"An Implementation Evaluation Study of Nurse Initiated and Managed Antiretroviral Therapy (Nimart) Program in Primary Health Care Clinics in the Ugu District in Kwa-Zulu Natal."**

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 this office has received confirmation from the Provincial Health Research Committee in the KZN Department of Health.
3. Please ensure this office is informed before you commence with your research.
4. The District Office/Facility will not provide any resources for this research.
5. You will be expected to provide feedback on your findings to the District Office/Facility.

Thanking you.
Sincerely

Mr Comfort Nguza
Acting District Manager
Ugu Health District Office

HEALTH DISTRICT
OFFICE (DC21)
DISTRICT MANAGER
2015 -06- 30
P/BAG X 735
PORT SHEPSTONE 4240

APPENDIX 5: GATEKEEPER'S PERMISSION LETTER

health
Department:
Health
PROVINCE OF KWAZULU-NATAL

UGU HEALTH DISTRICT OFFICE
Physical Address: 41 Bisset Street, Port Shepstone
Postal Address: P/Bag X735, Port Shepstone, 4240
Tel: 039-6883000/36
Fax: 039-6826296
Email : Thoko.Ntuli@kznhealth.gov.za
Website: www.kznhealth.gov.za

ENQUIRIES : Mrs T.M.M. Ntuli
27 October 2015

Mrs P. Xaba
7 Weaver Road
Yellowwood Park
4004

RE: Gatekeeper's Permission to conduct Research at

Primary Health Care Clinics in Ugu District

Dear Mrs P. Xaba,

Please be informed that permission has been granted to conduct Research on "An implementation Evaluation Study of Nurse Initiated and Managed Antiretroviral Therapy (NIMART) Program" at Primary Health Care Clinics in Ugu District in KwaZulu-Natal.

We wish you best of luck with your Research.

Kind Regards,

Thoko Ntuli
Deputy District Manager: Clinical and Programmes
Telephone no: 0396883000 {ext 3003}
Cellphone no: 0734869577
Email Thoko.Ntuli@kznhealth.gov.za
Fax no: 0396826296
Deprtment Of Health
Ugu District Office

UGU HEALTH DISTRICT
OFFICE (DC 21)

2015 -10- 27

PRIVATE BAG X735
PORT SHEPSTONE 4240

APPENDIX 6: ADDITIONAL GATEKEEPER'S PERMISSION LETTER

health
Department:
Health
PROVINCE OF KWAZULU-NATAL

Physical Address : 41 Bisset Street , Port Shepstone, 4241
Postal Address: P/Bag X735, Port Shepstone, 4240
Tel: 039 - 6883036 Fax: 039 - 6826296 Email:babongile.cele@kznhealth.gov.za
www.kznhealth.gov.za

DIRECTORATE:
UGU HEALTH DISTRICT OFFICE

ENQUIRIES: Mrs B E Cele
29 July 2016

Mrs P. Xaba
7 Weaver Road
Yellowwood Park
4004

RE: Additional Gatekeeper's Permission to collect Data at NIMART Mentorship Meeting for Primary Health Care Clinics in Ugu District

Dear Mrs P. Xaba,

I am pleased to inform you that permission has been granted to collect Data during the NIMART Mentorship Meeting for the Research Study on "An implementation Evaluation Study of Nurse Initiated and Managed Antiretroviral Therapy (NIMART) Program" at Primary Health Care Clinics in Ugu District in KwaZulu-Natal.

I wish you all the best with your Research Study.

Kind Regards,

Mrs B E Cele
Operational Manager : HIV/AIDS
Ugu Health District Office
Tel : 039 688 3048
Fax : 039 682 6296
Cell : 073 134 5872
Email : babongile.cele@kznhelath.gov.za

HEALTH DISTRICT OFFICE (DC 21)
2016 -07- 2 9
P/BAG X735
PORT SHEPSTONE 4240

Fighting Disease, Fighting Poverty, Giving Hope

APPENDIX 7: LETTER REQUESTING PERMISSION TO CONDUCT A RESEARCH STUDY FROM UGU HEALTH DISTRICT OFFICE

7 Weaver Road
Yellowwood Park
4004
27 March 2015

The District Manager
Ugu Health District Office
Private Bag X735
Port Shepstone
4240

Dear Mr Nguza,

APPLICATION FOR PERMISSION TO CONDUCT A RESEARCH STUDY IN UGU DISTRICT

Research Topic: An Implementation Evaluation Study of A Nurse Initiated and Managed Antiretroviral Therapy (NIMART) Program In Primary Health Care Clinics in the Ugu district of KwaZulu-Natal.

I hereby kindly request permission to conduct a research study in Ugu district. I'm a lady of 38 years, currently studying Masters in Nursing Management – Coursework in the School of Nursing at the University of KwaZulu-Natal. Part of the requirements for the Masters Degree is to conduct a Research Project. The study of my interest is an Implementation Evaluation Study of Nurse Initiated and Managed Antiretroviral Therapy (NIMART) Program in Primary Health Care Clinics in the Ugu district of KwaZulu-Natal. Background of this research study is based on the presidential mandate announced by President Jacob Zuma during the World AIDS day celebration on 1 December 2009. That is, to decentralize HIV treatment to primary health care centres with the ultimate goal of universal access to HIV treatment, through the Nurse Initiated and Managed Antiretroviral Therapy (NIMART) strategy.

Objectives of this research study seek to:

1. Evaluate the availability of latest Antiretroviral Therapy Guidelines in the Primary Health Care clinics at Ugu district.
2. Evaluate the implementation of Nurse Initiated and Managed Antiretroviral Therapy (NIMART) program at the clinics in Ugu district.
3. Evaluate the knowledge and practice of Professional nurses towards NIMART program in the clinics at Ugu district.

Method

Ugu district Primary Health Care clinics from all six Sub-districts and two CHC's will be used as the population of this study. All 54 clinics and two CHC's will be evaluated. Professional Nurses that are NIMART trained will be randomly selected from each clinic and CHC in all sub-districts. A total of 56 nurses will be participating in this research study.

This research study does not intend to disturb the service deliveryas the participants will be completing a Questionnaire with five parts namely: Demographics, Availability of latest Antiretroviral Treatment Guidelines, Implementation of NIMART Program, Knowledge of NIMART and Practice of NIMART. Completion of the Questionnaire can take only 30 minutes after the NIMART mentorship meeting. Questionnaire attached please refer to Appendix 5.

I declare that this research project is not sponsored, it is self-funded by the researcher.

Permission to conduct this research study will be obtained from University of KwaZulu-Natal Biomedical Research Ethics Committee (UKZN BREC). If you have any concerns or complaints regarding ethics issues please contact Ethics Committee (UKZN BREC) at (031) 260 4769.

Please find attached the following:

A copy of the research proposal including Participant's information sheet, Informed Consent; and a Questionnaire.

Your kind consideration of the application will be highly appreciated.

Thank you.
Kind Regards,

Researcher : Mrs Pearl Xaba
Work : (039) 688 3000
Cell : 083 350 3620
Email :pearl.xaba8@gmail.com / pearl.xaba@kznhealth.gov.za

Research Supervisor : Dr J. Kerr
Work : (031) 260 1432
Email :kerrj@ukzn.ac.za

UKZN BREC Committee :
Tel: 031 260 4769
Fax: 031 260 4609
Email: BREC@ukzn.ac.za

APPENDIX 8: LETTER REQUESTING PERMISSION TO CONDUCT A RESEARCH STUDY FROM THE GATEKEEPER

7 Weaver Road
Yellowwood Park
4004
23 October 2015

The Clinical and Programmes Manager
Ugu Health District Office
Private Bag X735
Port Shepstone
4240

Dear Mrs Ntuli,

APPLICATION FOR PERMISSION TO CONDUCT A RESEARCH STUDY IN UGU DISTRICT

Research Topic :An Implementation Evaluation Study of A Nurse Initiated and Managed Antiretroviral Therapy (NIMART) Program In Primary Health Care Clinics in the Ugu district of KwaZulu-Natal.

I hereby kindly request permission to conduct a research study in Ugu district. I'm a lady of 38 years, currently studying Masters in Nursing Management – Coursework in the School of Nursing at the University of KwaZulu-Natal. Part of the requirements for the Masters Degree is to conduct a Research Project. The study of my interest is an Implementation Evaluation Study of Nurse Initiated and Managed Antiretroviral Therapy (NIMART) Program in Primary Health Care Clinics in the Ugu district of KwaZulu-Natal. Background of this research study is based on the presidential mandate announced by President Jacob Zuma during the World AIDS day celebration on 1 December 2009. That is, to decentralize HIV treatment to primary health care centres with the ultimate goal of universal access to HIV treatment, through the Nurse Initiated and Managed Antiretroviral Therapy (NIMART) strategy.

Objectives of this research study seek to:

1. Evaluate the availability of latest Antiretroviral Therapy Guidelines in the Primary Health Care clinics at Ugu district.
2. Evaluate the implementation of Nurse Initiated and Managed Antiretroviral Therapy (NIMART) program at the clinics in Ugu district.
3. Evaluate the knowledge and practice of Professional nurses towards NIMART program in the clinics at Ugu district.

Method

Ugu district Primary Health Care clinics from all six Sub-districts and two CHC's will be used as the population of this study. All 54 clinics and 2 CHC's will be evaluated. Professional Nurses that are NIMART trained will be randomly selected from each clinic and CHC in all sub-districts. A total of 56 nurses will be participating in this research study.

This research study does not intend to disturb the service deliveryas the participants will be completing a Questionnaire with five parts namely: Demographics, Availability of latest Antiretroviral Treatment Guidelines, Implementation of NIMART Program, Knowledge of NIMART and Practice of NIMART. Completion of the Questionnaire can take only 30 minutes after the NIMART mentorship meeting. Questionnaire attached please refer to Appendix 5.

I declare that this research project is not sponsored, it is self-funded by the researcher.

Permission to conduct this research study will be obtained from University of KwaZulu-Natal Biomedical Research Ethics Committee (UKZN BREC). If you have any concerns or complaints regarding ethics issues please contact Ethics Committee (UKZN BREC) at (031) 260 4769.

Please find attached the following:

A copy of the research proposal including Participant's information sheet, Informed Consent and a Questionnaire.

Your kind consideration of the application will be highly appreciated.

Thank you.

Kind Regards,

Researcher : Mrs Pearl Xaba
Work : (039) 688 3000
Cell : 083 350 3620
Email :pearl.xaba8@gmail.com / pearl.xaba@kznhealth.gov.za

Research Supervisor : Dr J. Kerr
Work : (031) 260 1432
Email :kerrj@ukzn.ac.za

UKZN BREC Committee :
Tel: 031 260 4769
Fax: 031 260 4609
Email: BREC@ukzn.ac.za

APPENDIX 9: LETTER REQUESTING PERMISSION TO COLLECT DATA ATTHE NIMART MENTORSHIP MEETING FROM THE ADDITIONAL GATEKEEPER

7 Weaver Road
Yellowwood Park
4004
28 July 2016

The HIV/AIDS, STI's and TB (HAST) Manager
Ugu Health District Office
Private Bag X735
Port Shepstone
4240

Dear Mrs Cele,

APPLICATION FOR PERMISSION TO CONDUCT A RESEARCH STUDY IN UGU DISTRICT

Research Topic: An Implementation Evaluation Study of A Nurse Initiated and Managed Antiretroviral Therapy (Nimart) Program In Primary Health Care Clinics in the Ugu district of KwaZulu – Natal.

I would like to apply for a permission to collect data from the NIMART nurses during the Second Quarter NIMART Mentorship Meeting. I'm a lady of 38 years, currently studying Masters in Nursing Management – Coursework in the School of Nursing at the University of KwaZulu-Natal. Part of the requirements for the Masters Degree is to conduct a Research Project. The study of my interest is an Implementation Evaluation Study of Nurse Initiated and Managed Antiretroviral Therapy (NIMART) Program in Primary Health Care Clinics in the Ugu district of KwaZulu-Natal. Background of this research study is based on the presidential mandate announced by President Jacob Zuma during the World AIDS day celebration on 1 December 2009. That is, to decentralize HIV treatment to primary health care centres with the ultimate goal of universal access to HIV treatment, through the Nurse Initiated and Managed Antiretroviral Therapy (NIMART) strategy.

Objectives of this research study seek to:

1. Evaluate the availability of latest Antiretroviral Therapy Guidelines in the Primary Health Care clinics at Ugu district.
2. Evaluate the implementation of Nurse Initiated and Managed Antiretroviral Therapy (NIMART) program at the clinics in Ugu district.
3. Evaluate the knowledge and practice of Professional nurses towards NIMART program in the clinics at Ugu district.

Method

Ugu district Primary Health Care clinics from all six sub-districts and two CHC's will be used as the population of this study. All 54 clinics and two CHC's will be evaluated. Professional Nurses that are NIMART trained will be randomly selected from each clinic and CHC in all sub-districts. A total of 56 nurses will be participating in this research study.

This research study does not intend to disturb the service deliveryas the participants will be completing a Questionnaire with five parts namely: Demographics, Availability of latest Antiretroviral Treatment Guidelines, Implementation of NIMART Program, Knowledge of NIMART and Practice of NIMART. Completion of the Questionnaire can take only 30 minutes after the NIMART mentorship meeting. Questionnaire attached please refer to Appendix 5.

I declare that this research project is not sponsored, it is self-funded by the researcher.

Permission to conduct this research study will be obtained from University of KwaZulu-Natal Biomedical Research Ethics Committee (UKZN BREC). If you have any concerns or complaints regarding ethics issues please contact Ethics Committee (UKZN BREC) at (031) 260 4769.

Please find attached the following:

A copy of the research proposal including Participant's information sheet, Informed Consent and a Questionnaire.

Your kind consideration of the application will be highly appreciated.

Thank you.

Kind Regards,

Researcher : Mrs Pearl Xaba
Work : (039) 688 3000
Cell : 083 350 3620
Email :pearl.xaba8@gmail.com / pearl.xaba@kznhealth.gov.za

Research Supervisor : Dr J. Kerr
Work : (031) 260 1432
Email :kerrj@ukzn.ac.za

UKZN BREC Committee :
Tel: 031 260 4769
Fax: 031 260 4609
Email: BREC@ukzn.ac.za

APPENDIX 10: PARTICIPANT'S INFORMATION SHEET

Date: 1 April 2016

Dear Participant,

My name is Pearl Xaba, a Masters student from the School of Nursing at the University of KwaZulu-Natal, cell: 0833503620 and email address: pearl.xaba8@gmail.com

You are being invited to consider participating in a study that involves research on an Implementation Evaluation Study of Nurse Initiated and Managed Antiretroviral Therapy (NIMART) Program in Primary Health Care Clinics in the Ugu district of KwaZulu-Natal. The aim of this research is to ensure HIV treatment is decentralized to primary health care centres with the ultimate goal of universal access to HIV treatment, through the Nurse Initiated and Managed Antiretroviral Therapy (NIMART) strategy. The study is expected to enrol 56 participants in total, which are NIMART trained Professional Nurses from all the 54 clinics and 2 CHC's in Ugu district. It will involve the following procedures, completion of a Questionnaire. The duration of your participation if you choose to enrol and remain in the study is expected to be one day. The study is self-funded by the Researcher.

There is no risk of harm to you anticipated in this study as the questionnaire will be assessing knowledge of the NIMART Programme and your identity will be anonymous. We hope that the study will create the following benefits, identify your gaps in the NIMART programme, and action will then be planned to breach those gaps. Hence, improve your knowledge and performance. There will be no alternative procedures and treatment that may serve as possible alternate options to study participation.

This study has been ethically reviewed and approved by the UKZN Biomedical research Ethics Committee (approval number BE364/16).

In the event of any problems or concerns/questions you may contact the researcher at 083 3503620 or the UKZN Biomedical Research Ethics Committee, contact details as follows:

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION
Research Office, Westville Campus
Govan Mbeki Building
Private Bag X 54001
Durban
4000
KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2604769 - Fax: 27 31 2604609
Email: BREC@ukzn.ac.za

Participation in this research is voluntary and you may withdraw participation at any point, and that in the event of refusal/withdrawal of participation the participants will not incur penalty or other benefit to which they are normally entitled.

There are no costs that might be incurred by participants as a result of participation in the study. Participants will not be compensated for participating in this study, since the study is not sponsored.

Participant's identity will be anonymous to protect confidentiality of personal/clinical information. Questionnaires will be kept in supervisor's office at UKZN to safeguard the confidentiality of records and will be restricted to the researcher and statistician.

You are entitled to keep this copy of the Participant's Information Sheet.

Thank you for your time in considering participating in this research study.

APPENDIX 11: INFORMED CONSENT

I …….. have been informed about the study entitled “An Implementation Evaluation Study of Nurse Initiated and Managed Antiretroviral Therapy (NIMART) Program in Primary Health Care Clinics in the Ugu district of KwaZulu-Natal” by the research assistant.

I understand the purpose and procedures of the study which is completing a questionnaire.

I have been given an opportunity to ask questions about the study and have had answers to my satisfaction.

I declare that my participation in this study is entirely voluntary and that I may withdraw at any time without affecting any of the benefits that I usually am entitled to.

I have been informed that there is no compensation available.

If I have any further questions/concerns or queries related to the study I understand that I may contact the researcher at (039) 6883000 or Cell: 083 3503620 and email address: pearl.xaba8@gmail.com

If I have any questions or concerns about my rights as a study participant, or if I am concerned about an aspect of the study or the researchers then I may contact:

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION
Research Office, Westville Campus
Govan Mbeki Building
Private Bag X 54001
Durban
4000
KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2604769 - Fax: 27 31 2604609
Email: BREC@ukzn.ac.za

_____ _____
Signature of Participant **Date**

_____ _____
Signature of Witness **Date**
(Where applicable)