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IMPLEMENTATION OF THE DUAL THERAPY PREVENTION OF MOTHER-TO-CHILD-TRANSMISSION PROTOCOL

by

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DECLARATION

I declare that IMPLEMENTATION OF THE DUAL THERAPY PREVENTION OF MOTHER-TO-CHILD-TRANSMISSION PROTOCOL is my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references and that this work has not been submitted before for any other degree at any other institution.

_____ _____

V. Singh **Date**

ABSTRACT

Antiretroviral drugs taken during pregnancy, reduce the rates of mother-to-child transmission from 35% to as low as 1 to 2% (UNAIDS, 2009). In 2002, the Prevention of Mother-to-Child Transmission (PMTCT) programme was implemented in South Africa. Studies on the implementation of the PMTCT programme have shown that understaffed and under-developed health care facilities were key barriers to the provision of PMTCT services (Health Systems Trust, 2002: 6; Skinner *et al.,* 2003).

The aim of this study was to assess the challenges experienced by health care workers working in public sector facilities in the Nelson Mandela Metropole after implementation of the dual therapy PMTCT programme. Four areas were investigated: Infrastructure; Drug Supply Management; Clinic Procedures and Staffing.

A quantitative descriptive study was conducted in August 2009 at nine public health care facilities in the Nelson Mandela Metropole, South Africa. Questionnaires were issued to 81 nurses and 41 pharmacy personnel (pharmacists and pharmacist assistants). Checklist audit forms were issued to the Facility Manager of each facility and completed with the researcher.

The key findings for Infrastructure were lack of space at patient waiting rooms (9; 100% n=9), counselling area (5; 55.5%; n=9), nurse consultation rooms (6; 66.6%; n=9), storage areas (5; 55.5%; n=9) and filing areas (7; 77.7%; n=9). The key findings for Drug Supply Management were none of the dispensaries (0%; n=10) were fully compliant with Good Pharmacy Practice, pharmacy personnel indicated that there were no stock cards for medication (13; 31.7%; n=41); there was less than two weeks supply of buffer stock kept for zidovudine and nevirapine (13; 35.1%; n=37) and medication orders were placed without any reference to minimum and maximum levels of medication (15; 36.5%; n=41) . The key findings for Clinic Procedures were only two facilities followed up on patients that had missed appointments (22.2%; n=9) and four facilities (44.4%; n=9) had a tracking system for patients that had defaulted. Of the nine facilities only three (33.3%; n=9) updated patient demographic details regularly. The key findings for Staffing were a shortage of doctors, nurses, counsellors and pharmacists at the facilities. One of the major challenges identified was the lack of training offered on new PMTCT protocols with 56.2% (45; n=80) of the nurses stating that no training was provided on the dual PMTCT protocol. Only 54.3% (44; n=81) of nurses stated that they knew the criteria to start the mother on dual PMTCT therapy.

In conclusion there is an urgent need for barriers such as lack of staff, lack of space, lack of training on PMTCT and standard procedures for follow up of patients to be addressed in order to ensure the successful scaling up of PMTCT.

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LIST OF ABBREVIATIONS

AIDS	-	Acquired Immunodeficiency Syndrome
ART	-	Antiretroviral treatment
ARV	-	Antiretroviral therapy
CPD	-	Continuing Professional Development
FTE	-	Full Time Equivalent
GPP	-	Good Pharmacy Practice
HAART	-	Highly Active Antiretroviral Therapy
HIV	-	Human Immune Deficiency Virus
ICAP	-	International centre for AIDS Care and Treatment Programs
MTCT	-	Mother-to-Child Transmission
NACOSA	-	National AIDS Coordinating Committee of South Africa
NGO	-	Non Governmental Organisation
NMB	-	Nelson Mandela Bay Municipality
NSP	-	National Strategic Plan
PACTG	-	Paediatric AIDS Clinical Trials Group
PMTCT	-	Prevention of Mother-to-Child Transmission
SANAC	-	South African National AIDS Council
sd-NVP	-	Single dose Nevirapine
SOP	-	Standard Operating Procedure
STI	-	Sexually Transmitted Infections
UNGASS	-	United Nations General Assembly Special Session
WHO	-	World Health Organisation

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CHAPTER ONE

INTRODUCTION

1.1 CHALLENGES FACING IMPLEMENTATION OF THE DUAL THERAPY PREVENTION OF MOTHER-TO-CHILD TRANSMISSION PROTOCOL

It is estimated that 5.6 million people in South Africa are living with Human Immune Deficiency Virus (HIV). The HIV prevalence among pregnant women in public health facilities was 30.2% in 2005, and had decreased to 29.1% in 2006 (Department of Health, South Africa, 2008a: 21). The overall HIV prevalence among antenatal care attendees for the Eastern Cape had risen from 15% in 1998 to 29% in 2008 (World Health Organisation, 2008: 17). This has resulted in about 300,000 babies born exposed to HIV every year (Human Science Research Council, 2008). In 2008, the total number of babies infected with HIV either perinatally or via breast milk was 64000 (ASSA: 2003). It has been estimated that around 2.5% of children aged 2 to 14 years were living with HIV. (Human Science Research Council, 2008). Mother-to-child transmission (MTCT) is the primary cause of HIV infection in children under 10 years of age. Without antiretroviral drugs during pregnancy, rates of mother-to-child transmission range from 30 to 35%, however, Prevention of Mother-to-Child Transmission (PMTCT) reduces the risk of transmission to as low as 1 to 2% (UNAIDS, 2009).

In April 2002, nevirapine monotherapy was implemented nationally in South Africa. During 2007, the Department of Health revised the PMTCT protocol and in 2008, published PMTCT guidelines which included dual prophylaxis with zidovudine and single dose nevirapine (Department of Health, South Africa, 2008a). The 2008 PMTCT protocol was used from 2008 to mid 2010 when the 2010 PMTCT guideline was published (Department of Health, South Africa, 2010a). Although the 2010 PMTCT guideline was published mid 2010 it has not been fully implemented to date as the tenders for the required pharmaceuticals have not yet been awarded.

Preventing new HIV infections remains a significant public health challenge for South Africa. The high HIV infection and mortality rates of under-five-year-olds due to mother-to-child transmission of HIV, together with the continuing need that pregnant HIV-positive women have for antiretroviral drugs and PMTCT interventions, underscore the urgent need for renewed efforts to offer quality PMTCT services in South Africa (Solomon *et al.,* 2009: 1). Implementation of PMTCT remains a challenge. In the Eastern Cape studies undertaken by the Health Systems Trust (Health Systems Trust, 2002: 6) and the Health Sciences Research Council (Skinner *et al.,* 2003) investigated barriers to implementation of PMTCT. These studies reported that

understaffed and under-developed health care facilities were key barriers to the provision of PMTCT services. Solomon *et al.* (2009: 1) reported poor healthcare infrastructure, shortages of staff, poor referral links, and a lack of communication between different health services and within the healthcare system as some of the barriers to implementation of PMTCT.

The HIV epidemic has led to deterioration in the health status of the population and has resulted in an increased health care need (Lehmann, 2008: 164). This has increased the workload and responsibilities for staff. In South Africa significant shortages of professional nurses, pharmacists, medical officers, lay counsellors and administrative personnel existed in 2003 and were still present in 2008. (Padarath *et al.,* 2003: 300; Lehmann, 2008: 163) On average one third of posts for doctors and nurses at public health care facilities were vacant (Lehmann, 2008: 165). Staff shortages are problematic and unless appropriately managed, a large new public sector programme such as HIV and PMTCT could undermine the rest of the health system (Stewart and Loveday, 2005: 233).

Another challenge reported by the Health Systems Trust (2002) was extensive training for the pilot programme had taken place but not all staff had been trained and organising training would, therefore, be a major challenge as the programme expanded. Many provinces had a high staff turnover which made training a key challenge. There was insufficient on-site training and not enough focus on skills development and problem solving. The training of counsellors varied according to provinces and was sometimes not culturally appropriate, provided too much theory and not enough practice and did not deal adequately with the attitudes and prejudices of the trainees themselves. Doctors play an important role in clinical leadership, quality control and training, however, some sites had doctors showing little interest and these sites experienced problems. (Health Systems Trust, 2002: 13)

The HIV epidemic resulted in new infrastructure needs that had not previously been envisaged, such as private consulting rooms for counselling and testing, and space for the additional staff (Lutge and Mbatha, 2007: 9). In a 2006 keynote address the South African Minister of Health mentioned that strengthening physical infrastructure of both hospitals and Primary Health Care facilities were super-priorities (Department of Health, South Africa, 2006a). The state of the physical infrastructure of health facilities in many areas of South Africa was poor and inadequate for the needs of clinic catchment populations (Lutge and Mbatha, 2007: 4). Furthermore, specialised projects and HIV programmes had not achieved their targets due to poor infrastructure (Mandal *et al.,* 2006: 175). Poor infrastructure has been shown to significantly affect a patient's perception of quality of care (Rao *et al.,* 2006: 414) and in South Africa, had a significant negative effect on health professionals' satisfaction with their working conditions (Kotzee and Couper, 2007: 581; King and McInerney, 2006: 74).

In addition to challenges with regard to space and storage of antiretrovirals, challenges with procurement of antiretrovirals, ensuring a reliable supply of medicines at all levels of distribution to avoid out of stock situations and inadequate inventory management procedures remained a problem (Lutge and Mbatha, 2007: 9; Management Sciences for Health, 2008: 6; El-Khatib and Richter, 2009: 412). In November 2008, the Free State Department of Health experienced shortages of antiretroviral (ARV) medication and stopped the provincial roll out of ARVs with the exception of pregnant mothers and children (El-Khatib and Richter, 2009: 412). In a letter to the Minister of Health, the HIV Clinicians Society indicated that the Free State Province out of stock situation was due to bad planning and that the situation undermined the public health service and made attainment of the National Strategic Plan (NSP) goals more difficult (Venter, 2008).

Effective patient information systems are necessary to ensure that a standardised, effective and efficient system for data collection, collation, monitoring and feedback is in place to facilitate programme implementation, ensure good quality care, and achieve good patient and programme outcomes. Kumalo (2006, 66) found that health service delivery related information systems are weak in many developing countries. Health care workers were overburdened with excessive data and reporting demands due to multiple, poorly coordinated systems which often duplicated collection effort and failed to deliver timely, accurate and complete data. Furthermore, there was inadequate access to information from support systems such as human resources and financial systems and linkages of these to routine health information. The Department of Health, South Africa (2004a) reported that in many areas record keeping systems were inadequate to enable the follow up of HIV infected pregnant women. This served as an additional barrier to the PMTCT programme implementation.

Eight years since the inception of PMTCT, in South Africa, many of the barriers to PMTCT implementation still exist. New scientific discoveries result in changes to existing policies and identifying barriers to implementation of the policies can improve efficiency, effectiveness and sustainability of the PMTCT programme.

1.2 PROBLEM STATEMENT

1.2.1 Problem Definition

The HIV and Acquired Immunodeficiency Syndrome (AIDS) pandemic has increased the demands on the health services and health care workers in South Africa (Lehmann, 2008: 164). Mother-to-child transmission of HIV is preventable and in order to increase the number of women participating in PMTCT programmes, the barriers to women taking up PMTCT must be assessed. Challenges such as drug shortages, shortage of nurses and doctors, lack of space,

knowledge and protocols impact negatively on the efficiency of the PMTCT programme in South Africa.

1.2.2 Research Question

Eight years have passed since the implementation of the PMTCT programme in South Africa. During this time the PMTCT protocol has been changed two times. The question asked for this research was:

What were the challenges facing health care workers when the dual therapy PMTCT protocol was implemented?

1.3 RESEARCH AIMS AND OBJECTIVES

With the research question in mind, the following research aim and objectives were developed.

1.3.1 Research Aim

To assess the challenges experienced by health care workers working in public sector facilities in the Nelson Mandela Metropole upon the implementation of the dual therapy PMTCT programme.

1.3.2 Research Objectives

The following objectives were required to be fulfilled in order to achieve the research aim:

- Determine whether the infrastructure required to support the implementation of the dual therapy PMTCT were present;
- Assess the impact on drug supply management of the implementation of the dual therapy PMTCT;
- Assess whether clinical procedures required for follow up of patients receiving dual therapy PMTCT were present;
- Determine if staff levels required for the implementation of the dual therapy PMTCT were present at the research sites;
- Determine the training required by the nurses at the research sites; and
- Make recommendations to health services management in the Nelson Mandela Bay Municipality (NMB) on ways to minimise the challenges faced by health care workers when PMTCT protocols are implemented.

1.4 RESEARCH SITE AND POPULATION

1.4.1 Research Site

The research was conducted in Port Elizabeth, a city in the Nelson Mandela Bay Municipality (NMB) Eastern Cape Province, South Africa. The public health facilities in NMB are under one of two levels of public service authority managing health services namely provincial government (Nelson Mandela Bay District Health and Port Elizabeth Hospital Complex, Eastern Cape Department of Health) and local government (NMB). The sites for the research study comprised of three tertiary level hospitals (Dora Nginza Hospital, Livingston Hospital and Port Elizabeth Provincial Hospital) which are managed by the Port Elizabeth Hospital Complex, two clinics (Motherwell Clinic and Walmer Clinic) which are managed by Nelson Mandela Bay District Health and four clinics (Chatty Clinic, New Brighton Clinic, Masakhane Clinic and Zwide Clinic) which are managed by the Nelson Mandela Bay Municipality. The sites chosen were a sample of the population and were selected as a convenience sample as the researcher had access to these sites as the researcher was employed by a non-governmental organisation (NGO) assisting with the PMTCT programme in the listed clinics.

1.4.2 Population

The research population consisted of nurses, pharmacists and pharmacists assistants working in the public health facilities selected for the research.

1.5 DEFINITIONS

Guideline: are systematically developed evidence-based statements which assist providers, recipients and other stakeholders to make informed decisions about appropriate health interventions (World Health Organisation, 2003a).

Implementation: is the realisation of an application, or execution of a plan, idea, model, design, specification, standard, algorithm or policy (Answers.Com, 2010)

Mother-to-Child Transmission: Transmission of HIV from an HIV-positive woman during pregnancy, delivery or breastfeeding, to her child. The term is used because the immediate source of the infection is the mother, and does not imply blame on the mother (Department of Health, South Africa, 2008a: 9).

Nelson Mandela Bay Municipality: Refers to the local authority that governs Port Elizabeth, Uitenhage and Despatch. The Public Health Directorate, NMB is the administrative authority for health services in NMB (Nelson Mandela Bay Municipality, 2010).

1.6 RATIONALE FOR THE RESEARCH

Having considered the barriers to PMTCT such as inadequate human resources, lack of trained nurses, poor infrastructure and poor management systems such as inefficient drug inventory systems and follow-up systems, it is important to look at the relevance of this research. This research investigates whether challenges are experienced by health care workers in selected NMB public health care facilities during implementation of the dual therapy PMTCT protocol.

Studies on PMTCT demonstrate the efficacy of various antiretroviral regimens and the national protocol for PMTCT in South Africa has been revised following research and advice from experts. While an evaluation of the process of implementation is important for identifying lessons that can help improve efficiency, effectiveness and sustainability, it is also useful to identify the impact of the programme on improving health status (Health Systems Trust, 2002: 24). Many of the difficulties and constraints to full and effective implementation of monotherapy PMTCT were identified by the Health Systems Trust (2002) as being systemic in nature and related to the poor functioning of the health care system. In order to improve the efficacy and sustainability of PMTCT services, and to ensure the effective expansion of the PMTCT programme, the broader health system issues must be addressed concurrently i.e. human resources, physical infrastructure and management (Health Systems Trust, 2002).

Evaluating the challenges experienced by health care workers to implementation of dual PMTCT protocol will enable lessons to be learnt. Hence, as the PMTCT programme expands and changes, the systemic and infrastructural constraints can be addressed and multiplication of poor service delivery can be avoided. According to the study undertaken by the Health System Trust (2002), the full potential of the PMTCT programme, to reduce the number of HIV infected babies and improve the overall health status, would only be realised if the health system was capable of delivering the service optimally.

1.7 OVERVIEW OF THE RESEARCH

The researcher first reviewed the literature with respect to the background of HIV/AIDS and the introduction of MTCT in South Africa. The HIV/AIDS operational plan in South Africa, challenges experienced worldwide and in South Africa and an overview of guideline implementation. The Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa is discussed with respect to human resource, drugs, infrastructure and follow-up of

patients (Department of Health, South Africa, 2003). It is the proposals made by this plan seven years ago that initiated the researchers interest in the study.

The research was quantitative and descriptive in design. Four areas were investigated: Infrastructure; Drug Supply Management; Clinic Procedure and Staffing. Data was collected using six purpose designed data collection tools:

- Infrastructure Audit Form;
- Dispensary Audit Form;
- Dispensary Staff Questionnaire;
- Clinic Procedure Audit Form;
- Staffing Audit Form; and
- Healthcare Worker Questionnaire.

The Dispensary Staff Questionnaire was issued to the pharmacists and pharmacy assistants and the Healthcare Worker Questionnaire was issued to the nurses in the facilities selected for the research. Checklists in the form of Audit Forms were issued to the Facility Managers, in the facilities selected for the research, and were completed with the researcher.

Empirical data from this research was captured, analysed, presented and interpreted. Conclusions and recommendations were made from the findings of this research.

1.8 PROPOSED DESIGN OF RESEARCH REPORT

The research report is divided into the following chapters:

- Chapter 1: Introduction
- Chapter 2: Literature Review: Prevention of Mother-to-Child Transmission
- Chapter 3: Literature Review: Implementation of Guidelines
- Chapter 4: Plan of Work
- Chapter 5: Methodology
- Chapter 6: Results and Discussion
- Chapter 7: Conclusions and Recommendations

1.9 SUMMARY

This chapter was an introduction to the overall research. A brief introduction with respect to the challenges to PMTCT was provided. The rationale for the research was presented together with the proposed design of the research report. In the following chapters the literature review will be discussed in greater detail.

CHAPTER TWO

PREVENTION OF MOTHER - TO - CHILD TRANSMISSION

2.1 INTRODUCTION

The HIV pandemic is one of the most serious health crises the world faces today. The Acquired Immune Deficiency Syndrome (AIDS) has killed more than 25 million people since 1981 and an estimated 33.4 million people are now living with HIV/AIDS. Globally an estimated 370 000 children younger than 15 years became infected with HIV in 2008 bringing the global total of the number of children younger than 15 years living with HIV in 2008 to two million. (UNAIDS, 2009: 11) An estimated 1.9 million people were newly infected with HIV in Sub-Saharan Africa in 2008. Sub-Saharan Africa accounts for 22.4 million (two thirds) of the global total of 33.4 million people living with HIV/AIDS. Almost 90% of the two million children living with HIV live in Sub-Saharan Africa. (UNAIDS, 2009: 11)

In Southern Africa the average life expectancy at birth is estimated to have declined to levels last seen in the 1950's; it is now below 50 years for the sub-region as a whole (UNAIDS, 2008: 46). Southern Africa continues to bear a disproportionate share of the global burden of HIV with 35% of the 33 million people currently living with HIV/AIDS and 38% of AIDS deaths occurring in this region in 2007. An estimated 5.7 million South Africans live with HIV according to the 2007 statistics making this the largest HIV epidemic in the world. (UNAIDS, 2008: 32-40)

Most children living with HIV acquire the infection through MTCT, which can occur during pregnancy, labour and delivery or during breastfeeding. In the absence of any intervention the risk of such transmission is 15 to 30% in non-breastfeeding populations. Breastfeeding by an infected mother increases the risk by 5 to 20% to a total of 20 to 45%. (De Cock *et al*., 2000: 1176) The risk of MTCT can be reduced to fewer than 2% by interventions that include antiretroviral (ARV) prophylaxis given to the women during pregnancy and labour and to the infant in the first weeks of life, obstetric interventions including elective caesarean delivery and complete avoidance of breastfeeding (Dorenbaum *et al*., 2002: 195). In many resource-constrained settings, elective caesarean delivery is seldom feasible (Stanton and Holtz, 2006: 41-48). Recently, to increase the effectiveness of the PMTCT programmes, many countries with a heavy burden of HIV have adopted more effective ARV regimens (adding zidovudine therapy to perinatal nevirapine therapy beginning in the third trimester of pregnancy), which can reduce the risk of transmission to 2 to 4% (Lallemant *et al*., 2004: 221-223). Even when these regimens are used, however, infants remain at substantial risk of acquiring infection during breastfeeding. In resource-limited settings the majority of HIV-infected women breastfeed due

to cost constraints, cultural norms, stigma, and unsafe water supply. Under these circumstances even with short course peripartum antiretroviral interventions such as zidovudine, zidovudine plus lamivudine, or nevirapine overall transmission at 12 to 24 months ranges from 16 to 23%. (Gaillard *et al*., 2004: 178)

The World Health Organization (WHO) set a target of treating three million individuals in the developing world with Highly Active Antiretroviral Therapy (HAART) by 2005 (World Health Organisation, 2005: 5), and the United Nations General Assembly Special Session (UNGASS) on HIV/AIDS committed countries to reducing, by 20%, the proportion of infants infected with HIV by 2005 (UNGASS, 2001: 21). In this context, the WHO provided guidelines for the prevention of perinatal transmission in low-resource settings (World Health Organisation, 2006a: 12-14).

2.2 HIV AND AIDS INFECTION

2.2.1 HIV routes of transmission

The majority of individuals infected with HIV in sub-Saharan Africa acquired the infection heterosexually. Transmission from mother-to-child accounts for a tragically large number of paediatric cases of HIV infection. Table 2.1 indicates the approximate risk of transmission of HIV. In the absence of antiretroviral therapy the transmission rate for mother-to-child is 20 to 40%, a tragedy since this mode of transmission is largely preventable. Homosexual transmission of HIV remains an important cause of infection among gay and bisexual men, and the number of cases of HIV infection due to intravenous drug abuse is likely to grow over the next decade. The virus can be transmitted from one individual to another through contact with: blood or blood products; semen; vaginal secretions; breast milk; and other body fluids containing blood. (Wilson *et al*., 2002: 61)

Sexual behaviour is the main driver of the HIV epidemic. Most children with HIV infection contract their disease through MTCT. The prevalence of HIV in children will therefore be the largest in countries where the major route of transmission in adults is heterosexual. (Abdool-Karim and Coovadia, 2005: 183) Reducing risky sexual behaviour is the first step to decreasing the spread of the disease. In all the plagues which have swept the world it were often the women and children who were the most affected. However, it is the children who have to carry the promise of new life and the rebirth of nations in any catastrophe that has the potential to wipe out whole civilizations. (Abdool-Karim and Coovadia, 2005: 183)

Table 2.1: **The approximate risk of HIV transmission for a single exposure, except for mother-to-child transmission where exposure occurs in utero, at birth and during breastfeeding.**

Exposure	Approximate risk
Blood transfusion	100%
Mother-to-child	20 to 40%
Anal intercourse	1%
Needle-sharing IVDU#	1%
Percutaneous exposure HCW*	0.3%
Vaginal intercourse	0.1%

*HCW = healthcare worker #IVDU = intravenous drug user
Source: (Royce *et al*., 1997: 1072)

2.2.2 Modes of HIV transmission to children

The commonest route of HIV infection for HIV positive children under five is through MTCT. Preventing MTCT of HIV is, therefore, the main intervention to reduce HIV infection amongst children. Transmission of HIV from a mother to her infant can take place during pregnancy, labour, delivery and after birth via breastfeeding, especially mixed feeding. It is thought that the rate of transmission varies at the different stages with the risk during pregnancy ranging from 5 to 10%, 10 to 20% during labour and delivery and 10 to 20% through mixed feeding. In the absence of any intervention to prevent MTCT, it is estimated that in about thirty percent of cases the virus will pass from the mother to the infant. Transmission of HIV occurs by other routes including sexual abuse (particularly in countries such as South Africa with a high level of child abuse), transmission by blood transfusion (this is rare as long as transfused blood is carefully screened, there is a risk when the blood donor could be in the window period), insufficiently sterilized instruments, traditional scarification (linear cuts made on the body to treat or prevent a disease) and wet-nursing with HIV-contaminated breast milk. (Meyers *et al.*, 2005: 8)

2.3 MOTHER-TO-CHILD-TRANSMISSION

Mother-to-child-transmission is defined as the transmission of HIV from an HIV-positive woman during pregnancy, delivery or breastfeeding to her child. The term is used because the immediate source of the infection is the mother, and does not imply blame on the mother (Department of Health, South Africa, 2008a: 9).

2.3.1 Risk factors for Mother-to-Child Transmission

With regards to MTCT the maternal and infant factors that affect the risk of transmission can be seen in Table 2.2. Re-infection with HIV may be one of the factors responsible for the high viral load in the mother during the perinatal period or subsequently. (Meyers *et al.,* 2005: 8)

Table 2.2: The maternal and infant risk factors for MTCT

Maternal factors	**Infant factors**
High viral load	Prematurity
Low CD4 count	Breastfeeding
Advanced AIDS	Mouth problems
Low Vitamin A level	Invasive foetal monitoring during labour
Prolonged rupture of membranes	
Cracked nipples or other breast condition	

Source: (Meyers *et al.,* 2005: 8).

Identification of the risk factors associated with MTCT of HIV is the first step in developing interventions to interrupt such transmission. High levels of maternal viraemia increase the risk of transmission. The new technique of quantitative Polymerase Chain Reaction testing has shown an increased association between maternal viral load and the risk of transmission from mother to child. Maternal ARV therapy issued during pregnancy and post exposure prophylaxis in the child after birth is thought to decrease transmission by reducing the viral load. (Kartikeyan *et al.,* 2007: 327) A Tanzanian study reported that a viral load of 50,000 copies/ml or more at delivery was associated with a 4-fold increase in the risk of early transmission (Fawzi *et al.,* 2001: 1157). The transmission from mother-to-child is more likely with low CD4 counts in maternal blood. Women with a vitamin A level below 1.4 micromoles per litre have a 4 fold increased risk of transmission. (Semba *et al.,* 1994: 1594) It has being suggested that vitamin A may have immune stimulatory properties and a role in maintaining the integrity of vaginal mucosa or placenta. Obstetric factors are important because the majority of MTCT occurs at the time of labour and delivery. A duration of ruptured membranes of more than 4 hours, is an important risk factor (Zeichner and Read, 2005: 114). The risk of transmission through breast milk depends on factors such as stage of maternal disease, maternal vitamin A levels, pattern of breastfeeding (exclusive or mixed), presence of breast abscesses, mastitis and cracked nipples (Kartikeyan *et al.,* 2007: 327).

Clinical and public health interventions exist or are under investigation for some of the maternal and infant risk factors for MTCT. More specifically efficacy has been demonstrated for interventions which decrease maternal viral load and/or decrease the child's susceptibility to infection by giving ARV PMTCT regimens to the mother and child, caesarean section before rupture of membranes and labour, complete avoidance of breastfeeding and ensuring good nutrition and vitamin A supplementation for the mother and child. A high viral load and low CD4 count in the absence of ARV therapy produces transmission rates ranging from 20% to 40%. (Royce *et al.,* 1997: 1072, Zeichner and Read, 2005: 111-112) Provision of ARV PMTCT regimens can reduce the transmission rate from mother-to-child from 2 to 4% (Lallemant *et al.,* 2004: 221-223). Most MTCT occurs during labour and delivery, hence, ensuring safer delivery techniques such as decreasing instrumental delivery, invasive monitoring procedures and episiotomy will decrease the risk of transmission (Meyers *et al.,* 2005: 11).

2.3.2 Prognostic factors in children

Without interventions most of the children that are infected at the time of birth will develop features of the disease by six months. The disease progresses with opportunistic infections becoming apparent and with a downward course much more rapid than in adults. This rapid progression of the disease is largely determined by the immature immune system. High maternal viral load at birth is one of the factors contributing to the rapid progression. Some of the factors affecting infant prognosis are in-utero infection, signs of infection before the age of four months, maternal high viral load and low CD4 count at time of delivery, rapid downhill course of the mother and maternal death. (Meyers *et al.,* 2005: 9)

2.3.3 Prevention of paediatric HIV infection

Effective methods for prevention of paediatric HIV infection have been well demonstrated both in resource-rich as well as resource-poor countries. Prevention of primary infection can be achieved by reducing heterosexual transmission, ensuring that men are involved in the interventions to reduce the epidemic, preventing infection during pregnancy and lactation by educating men and women about the increase risk of HIV-infection during pregnancy and lactation, keeping adolescent girls and boys in school with appropriate health/sexuality education and comprehensive management of sexually transmitted infections (STI). Equally important is the prevention of unintended pregnancies among HIV-infected women. This can be achieved by integrating family planning with the PMTCT programme and counselling regarding the dual risk of unintended pregnancies and STIs and HIV. (Meyers *et al.,* 2005: 9-10)

2.4 PREVENTION OF MOTHER-TO-CHILD-TRANSMISSION GUIDELINES

2.4.1 Development of the Guidelines

The WHO first issued recommendations for the use of ARV drugs for PMTCT in 2000. These recommendations were revised in 2004 with the adoption of simplified regimens (World Health Organisation, 2004: IV). Since 2004 important evidence has become available on more potent ARV prophylaxis regimens and more experience in implementing programmes to prevent PMTCT has accumulated. In this context WHO convened a Technical Consultation in Geneva, Switzerland in 2005 to review new evidence and programmatic experience and to update guidelines on the use of ARV drugs for treating pregnant mothers and preventing HIV infection in infants. The consultation also considered the need to harmonize these guidelines with the WHO adult and paediatric HIV treatment guidelines. Following the June 2005 consultation, draft guidelines were developed and presented at a consensus meeting held in Geneva in 2006. This meeting reviewed evidence that had accumulated and aligned recommendations that were based on evidence from randomized controlled trials, high-quality scientific studies, observational cohort data, or expert opinion where evidence was lacking or inconclusive (World Health Organisation, 2006a: 9).

2.4.2 A public health approach to increasing access to PMTCT services

The prevention of HIV infection in infants and young children is an evolving area from both a scientific and programmatic standpoint. The public health approach proposed in the WHO guidelines builds on previous and emerging scientific evidence and programmatic experience from low as well as middle and high income countries. The main purpose of adopting a public health approach is to ensure access to high-quality services at the population level, while striking a balance between the best proven standard of care and what is feasible on a large scale in resource-constrained settings. Programmes for PMTCT should aim to deliver antiretroviral therapy (ART) for pregnant women living with HIV who require treatment for their own health or, for those who do not yet require such therapy, to provide highly effective prophylactic treatment to prevent MTCT. To achieve this, recommendations for a public health approach are provided by the WHO to assist countries in developing practical standardised protocols for ensuring the optimal use of scarce human and financial resources, simplified clinical and laboratory monitoring, sustainable programmes and the highest achievable effectiveness within existing constraints. (World Health Organisation, 2006a: 10)

2.4.3 Necessity for highly effective ARV regimens for eliminating HIV infection in infants and young children

If the goal of eliminating HIV infection in infants and young children is to be achieved, all pregnant women eligible for ART must have access to it, and countries must adopt more efficacious ARV regimens for preventing MTCT among pregnant women who do not yet require ART. National programme managers are advised by the WHO to develop their capacity to implement the recommended regimen for preventing MTCT. This consists of: antepartum – zidovudine from 28 weeks of pregnancy; intrapartum – zidovudine plus lamivudine plus single-dose nevirapine (sd-NVP); and postpartum – zidovudine plus lamivudine for seven days for women and sd-NVP and zidovudine for one week for infants (Table 2.3). The WHO indicates that widespread implementation of this regimen will dramatically reduce the number of new HIV infections in infants and young children and result in low levels of HIV viral resistance. Operational contexts vary considerably between countries and even within a country. In settings that do not currently have the capacity to deliver the recommended prophylactic regimen to prevent MTCT, it may be necessary – as an absolute minimum – to implement the single-dose (mother and infant) nevirapine regimen. However in these circumstances, the specific obstacles to delivering more effective regimens should be identified and concrete action taken to overcome them. The expansion of PMTCT programmes using sd-NVP should be considered a short-term interim measure while steps are being taken to enable more effective regimens to be delivered (World Health Organisation, 2006a: 14-15). The WHO recommendations for prophylactic ARV regimens for the prevention of MTCT using the public health approach are shown in Table 2.3.

Table 2.3: WHO recommended prophylactic ARV regimen for pregnant women who are not yet eligible for ART

Mother	**Regimen**
Antepartum	zidovudine starting at 28 weeks of pregnancy or as soon as feasible thereafter
Intrapartum	sd-NVP and zidovudine plus lamivudine
Postpartum	zidovudine plus lamivudine for 7 days
Infant	sd-NVP and zidovudine for 7 days

Source: (World Health Organisation, 2006a: 36-37).

2.4.4 ARV prophylaxis for preventing HIV infection in infants

The World Health Organisation indicated that widespread implementation of the regimens (Table 2.3) would result in a decreased number of new infections in infants and young children and also a low level of HIV viral resistance. However, in settings with inadequate resources to deliver the recommended regimen alternate regimens are recommended. These include antepartum – zidovudine from 28 weeks of labour; intrapartum – sd-NVP only and sd-NVP and zidovudine for one week for the infant (Table 2.4). At the very minimum the mother should receive only sd-NVP with zidovudine plus lamivudine during labour and the infant should receive sd-NVP and zidovudine for one week or only sd-NVP. The regimens, shown in Table 2.4, reduce the risk of MTCT by decreasing viral replication in the mother and through prophylaxis for the foetus and infant during and after exposure to the virus. (World Health Organisation, 2006a: 30-31)

The first major breakthrough in the prevention of MTCT came in 1994 with the three-part Paediatric AIDS Clinical Trials Group (PACTG) 076 trial, which demonstrated that long course zidovudine prophylaxis given early in pregnancy and intravenously to the mother during delivery and for six weeks to the infant dramatically reduced the risk of vertical transmission from 25% to 8% (Conner *et al.,* 1994: 1173-1180). Although the PACTG 076 zidovudine regimen was rapidly introduced into practice in Europe and North America, it was costly and too complex for many parts of the world where there was a high prevalence of HIV. Shorter and simpler ARV regimens were thus evaluated in trials in low- and middle-income countries. (World Health Organisation, 2006a: 26)

Table 2.4: Different approaches to the use of ARV prophylaxis to prevent HIV infection in infants

RANKING	PREGNANCY	LABOUR	POSTPARTUM
Recommended	zidovudine (≥ 28weeks gestation)	sd-NVP + zidovudine plus lamivudine	Mother: zidovudine plus lamivudine x 7days Infant: sd-NVP + zidovudine x 7days
Alternative	zidovudine (≥ 28weeks gestation)	sd-NVP	Infant: sd-NVP + zidovudine x 7days
Minimum	------	sd-NVP + zidovudine plus lamivudine	Mother: zidovudine plus lamivudine x 7days Infant: sd-NVP
Minimum	------	sd-NVP	Infant: sd-NVP

(Source: World Health Organisation, 2006a: 36-37).

The simplest of all PMTCT drug regimens was tested in the HIVNET 012 trial, which took place in Uganda between 1997 and 1999. This study found that a sd-NVP given to the mother at the onset of labour and to the baby after delivery roughly halved the rate of HIV transmission. As it is given only once to the mother and baby, single-dose nevirapine is relatively cheap and easy to administer (Jackson *et al.,* 2003). Since 2000, many thousands of babies in resource-poor countries have benefited from this simple intervention, which has been the mainstay of many PMTCT programmes (Guay *et al.,* 1999: 796-800).

A number of simple regimens have been identified as effective in reducing perinatal transmission in resource-limited countries. Because the studies involved different patient populations residing in different geographic locations, infected with different viral subtypes and having different infant feeding practices, direct comparison of results between trials is difficult. However, some general conclusions can be drawn from the study results that are relevant to understanding the use of ARVs in both resource-limited and rich countries. (Public Health Service Task Force, 2008: 4-6)

Short-term efficacy has been demonstrated for a number of short-course antiretroviral regimens, including those with zidovudine alone; zidovudine plus lamivudine; single-dose nevirapine; and more recently a combination of single-dose nevirapine with either short-course zidovudine or zidovudine plus lamivudine combinations (Shaffer *et al.,* 1999: 773-780; Wiktor *et al.,* 1999: 781-785; Lallemant *et al.,* 2000: 982-991; Leroy *et al.,* 2002: 631-641; Petra Study Team, 2002: 1178-1186; Moodley *et al.,* 2003: 725-735; Taha *et al.,* 2004: 202-209; Dabis *et al.,* 2005: 309-318; Gray *et al.,* 2005: 1289-1297). In general, combination regimens have proven to be more effective than single-drug regimens in reducing perinatal transmission, and when it is feasible and affordable, a longer 3-part regimen given antenatally, intrapartum, and postpartum rather than a shorter 2-part antepartum/intrapartum or intrapartum/postpartum regimen is preferred (Petra Study team, 2002: 1178-1186; Dabis *et al.,* 2005: 309-318; Leroy *et al.,* 2005: 1865-1875). Almost all trials in resource-limited countries have included an oral intrapartum prophylaxis component, with varying durations of maternal antenatal and/or infant postpartum prophylaxis (Table 2.5). Perinatal transmission has also been reduced by regimens with antenatal components starting as late as 36 weeks gestation and lacking an infant prophylaxis component (Shaffer *et al.,* 1999: 773-780; Wiktor *et al.,* 1999: 781-785; Leroy *et al.,* 2002: 631-641). However, a longer duration of antenatal therapy (starting at 28 weeks gestation) has been shown to be more effective than a shorter duration (starting at 36 weeks gestation), suggesting that a significant proportion of in utero transmission occurs between 28 weeks and 36 weeks gestation (Lallemant *et al.,* 2000: 982-991). Some women may lack antenatal care and first present to the health care system during labour, therefore, regimens that do not include maternal therapy during pregnancy have been evaluated in some resource-limited settings.

Table 2.5: Results of major studies on antiretroviral prophylaxis to prevent MTCT

STUDY/LOCATION	DRUGS	ANTENATAL & INTRAPARTUM	POSTPARTUM	MTCT RATE
PACTG 076, United States, France (Conner *et al.,* 1994: 1173-1180)	zidovudine vs placebo	Long (from 14 weeks); intravenous IP	Long (6weeks), infant only	8.3% in zidovudine arm vs 25% in placebo arm
CDC short course zidovudine trial, Thailand (Shaffer *et al.,* 1999: 773-780)	zidovudine vs placebo	Short (from 36 weeks); oral IP	None	9.4% in zidovudine arm vs 18.9% in placebo arm
DITRAME trial,Coted'Ivoire (Dabis *et al.,* 1999: 786-792; Leroy *et al.,* 2002: 631-641)	zidovudine vs placebo	Short (from 36 weeks); oral IP	Short (1 week)	18% in zidovudine arm vs 27.5% in placebo arm
CDC short course zidovudine trial, Cote d' Ivoire (Wiktor *et al.,* 1999: 781-785)	zidovudine vs placebo	Short (from 36 weeks); oral IP	None	16.5% in zidovudine arm vs 26.1% in placebo arm
Petra trial, South Africa, Tanzania, And Uganda (Petra Study Team, 2002: 1178-1186)	antenatal, IP/PP zidovudine plus lamivudine vs IP/PP zidovudine plus lamivudine vs IP-only zidovudine plus lamivudine vs placebo	Short (from 36 weeks); oral IP	Short (1 week), mother and infant	AP/IP/PP 5.7%, IP/PP 8.9%, IP-only 14.2%, placebo 15.3%
HIVNET 012 trial, Uganda (Jackson *et al.,* 2003: 859-868)	sd-NVP vs zidovudine	Oral IP	sd-NVP within72 hours of birth infant only vs zidovudine for 1 week infant	11.8% in sd-NVP vs 20% in zidovudine arm
Saint trial, South Africa (Moodley *et al.,* 2003: 725-735)	sd-NVP vs zidovudine plus lamivudine	Oral IP	sd-NVP within 48 hours of birth mother and infant vs zidovudine + lamivudine for 1 week	12.3% in sd-NVP vs 9.3% in zidovudine plus lamivudine
Perinatal HIV prevention trial, Thialand (Lallemant *et al.,* 2000: 982-991)	zidovudine alone vs zidovudine + maternal and infant sd-NVP vs zidovudine+ maternal sd-NVP	zidovudine from 28 weeks; oral IP: zidovudine alone or zidovudine + sd-NVP	zidovudine for 1 week with or without sd-NVP; infant only	MTCT rate did not differ significantly In maternal sd-NVP arm vs infant rec. sd-NVP or not
DITRAME trial, Cote d'Ivoire (Dabis et al., 2005: 309-318)	zidovudine + sd-NVP	zidovudine from 36 weeks; oral IP	sd-NVP + zidovudine for 1 week; infant only	6.5% vs 12.8%
NVAZ trial, Malawi (Taha *et al.,* 2003: 1171-1177)	neonatal sd-NVP vs sd-NVP + zidovudine	No AP or IP ARV	sd-NVP with/without zidovudine for 1 week, infant only	15.3% in sd-NVP + zidovudine arm; 20.9% in sd-NVP only arm
Post-exposure Infant prophylaxis, South Africa (Gray *et al.,* 2005: 1289-1297)	neonatal sd-NVP vs zidovudine for 6 weeks	No AP or IP ARV	sd-NVP vs zidovudine for 6 weeks	Formula fed: 14.3% in sd-NVP arm and 14.1% in zidovudine arm

IP = intrapartum; AP = antepartum; PP = postpartum

Regimens that included only intrapartum and postpartum drug administration have also been shown to be effective in reducing perinatal transmission (Petra Study Team, 2002: 1178-1186; Moodley *et al.,* 2003: 725-735). However, intrapartum pre-exposure prophylaxis alone with drugs like zidovudine and lamivudine, without continued post-exposure prophylaxis to the infant have not been shown to be effective (Petra Study Team, 2002: 1178-1186).

The SAINT trial demonstrated that two proven effective intrapartum/postpartum regimens (zidovudine plus lamivudine or sd-NVP) were similar in efficacy and safety (Moodley *et al.,* 2003: 725-735). In resource-limited settings, administration of even 6 weeks of infant zidovudine may be difficult and a sd-NVP is used. In a trial, undertaken in South Africa, administration of a sd-NVP given to the infant within 24 hours of delivery was compared to six weeks of infant zidovudine therapy in infants born to mothers who did not receive antenatal or intrapartum therapy. Transmission rates were not significantly different (Gray *et al.,* 2005: 1290-1295). A trial in Malawi compared single-dose nevirapine with a week of zidovudine therapy when no antenatal maternal therapy was received. The addition of one week of zidovudine therapy to infant sd-NVP reduced transmission by 36% compared to infant sd-NVP alone (Taha *et al.,* 2003: 1172-1176). The Perinatal HIV Prevention trial (PHPT)-2 study and the Ditrame study demonstrated that the addition of sd-NVP did significantly increase efficacy when short-course antenatal zidovudine alone or zidovudine plus lamivudine were administered (Dabis *et al.,* 2005: 310-317; Lallemant *et al.,* 2004: 220-225).

Research in high income countries has focused on more complex regimens and has shown that triple-ARV combinations given to women during pregnancy and labour can reduce the risk of transmission to less than 2% (Cooper *et al.,* 2002: 486; Dorenbaum *et al.*, 2002: 189-198; Thorne *et al.,* 2005: 460). Since 1998, triple ARV combinations have increasingly been used to prevent MTCT. Currently the majority of pregnant women living with HIV in Europe and North America receive such regimens (Thorne *et al.,* 2005: 460; Public Health Service Task Force, 2008: 14-15). In these settings and without breastfeeding, HIV infections in infants have nearly been eliminated. More recently, triple-ARV prophylactic regimens to prevent MTCT have been widely recommended and used in Brazil and other South American countries, with levels of effectiveness comparable to those observed in other high income countries (Matida *et al.,* 2005: S39-S40). In a study in Cote d'Ivoire, women who met the WHO criteria for being started on therapy received HAART namely zidovudine, lamivudine and nevirapine and women with less advanced HIV disease received short-course antiretroviral regimens namely zidovudine and lamivudine with sd-NVP at labour. This study resulted in MTCT rates of 2 to 4%. Transmission rates did not significantly differ between the groups. Thus this two-tiered strategy appeared to be safe and highly effective for both short and long course PMTCT treatments in resource-constrained settings (Tonwe-Gold *et al.,* 2005: Abstract 785).

In general combination regimens are more effective than single-drug regimens (World Health Organisation, 2006a: 29). Data collected from several African MTCT-prevention trials indicated that the combination of zidovudine plus lamivudine from 36 weeks of pregnancy had greater efficacy in preventing MTCT than ARV monotherapy with either zidovudine from 36 weeks of pregnancy or single dose nevirapine (Leroy *et al.,* 2005: 1866). Studies in Botswana, Cote d'Ivoire and Thailand have assessed the efficacy of adding single dose nevirapine to a zidovudine regimen given to the mother antepartum for varying durations as well as intrapartum, and postpartum to the infant and have shown that this regimen is highly efficacious and achieves lower rates of MTCT than with zidovudine or single dose nevirapine alone (Lallemant *et al.*, 2004: 225; Dabis *et al.,* 2005: 313; Phanuphak *et al.,* 2006: Abstract 712).

2.4.5 South African PMTCT Guidelines

2.4.5.1 Maternal prevalence of HIV infection

In South Africa, approximately 1,100,000 babies are born every year (Statistics South Africa, 2007). The HIV prevalence among pregnant women in 2006 was 29.1% (Department of Health, South Africa, 2008a: 21). This resulted in about 300,000 babies born exposed to HIV every year and without intervention approximately 30% (around 90,000) of these babies would become infected with HIV. It has been estimated that around 2.5% of children aged 2 to 14 years were living with HIV. (Human Science Research Council, 2008) One of the leading causes of death amongst mothers and children in South Africa is HIV/AIDS, accounting for 20% of maternal deaths (Saving Mothers Report, 2007: 12) and 40% of under-five deaths (South African Medical Research Council, 2003).

Data from the 2008 annual antenatal survey conducted by the Department of Health showed high levels of infection amongst pregnant women attending antenatal clinics in the Eastern Cape. The overall HIV prevalence among antenatal care attendees for the Eastern Cape had risen from 15% in 1998 to 29% in 2006 and 2008 (World Health Organisation, 2008: 17). During the 2005/2006 financial year 70% of the Antenatal Clinic attendees were counselled and tested for HIV of which 26% tested positive. About 60% of pregnant women who tested HIV positive received nevirapine according to the protocol at the time. (Department of Health, South Africa, 2008a: 12)

2.4.5.2 Nevirapine registration and use for PMTCT in South Africa

In April 2001, the Medicines Control Council in South Africa gave conditional approval status to the use of nevirapine as monotherapy for the reduction of MTCT of HIV. Nevirapine

monotherapy was subsequently launched in 18 pilot sites in the country. In a case brought by the Treatment Action Campaign against the government in April 2002, however, the Pretoria High Court ordered that the use of nevirapine monotherapy was to be expanded and made available countrywide. (Fomundam *et al.,* 2005: 5) By 2007, PMTCT services were offered in all public hospitals and in more than 95% of health care facilities (Department of Health, South Africa, 2008a).

2.4.5.3 Dual therapy for PMTCT

During 2007, the National Department of Health, South Africa, revised the PMTCT protocol and in 2008, published PMTCT guidelines which included dual prophylaxis zidovudine with sd-NVP and HAART for eligible mothers and early infant diagnosis for all exposed/symptomatic infants at the six week visit (Department of Health, South Africa, 2008a: 17-18). The 2008 PMTCT protocol was used from 2008 to mid 2010 when the 2010 PMTCT guideline was published (Department of Health, South Africa, 2010a).

According to the 2008 PMTCT guideline women with a CD4 cell count of less than 200 cell/mm^3 were prioritised to initiate HAART at any stage of pregnancy. For pregnant women not requiring HAART a PMTCT regimen was the main strategy to reduce MTCT. The use of dual therapy in the PMTCT treatment strategy was as follows: women presenting at 28 weeks or later, were started on zidovudine prescribed by a registered health professional at that visit, unless clinically anaemic (pale) or laboratory findings indicated that they were severely anaemic (i.e. haemoglobin less than 7g/dl). Women who were HIV positive and who had anaemia were referred for management by a doctor prior to initiation of any ARVs, including zidovudine. During labour the mother received sd-NVP (200mg tablet) and zidovudine 300mg on a 3 hourly basis. Antiretrovirals were given soon after birth to infants born to women who were HIV-positive whether maternal ARVs were received or not. This formed the basis of a post-exposure prophylaxis strategy. The infant received sd-NVP syrup immediately after birth and zidovudine syrup for 7 days. The infant received zidovudine syrup for 28 days if the mother received less than 4 weeks of zidovudine during pregnancy; the mother received less than 4 weeks of HAART; or the mother only received sd-NVP tablet. (Department of Health, South Africa, 2008a: 40-43)

2.4.5.4 PMTCT system performance

In 2008, the number of births in the public sector per annum was approximately 1 million and 85% (850 000) of those births took place in clinics (Department of Health, South Africa, 2008b). The number of women accepting an HIV test was 578 000 (Health Systems Trust, 2008: 130). Given an HIV prevalence rate of 28%, the number of women diagnosed to be HIV positive would be 238 850. By the end of 2007, the number of women receiving single-dose PMTCT was

127 164 and the number of babies born HIV positive was 70 000, with an MTCT rate of 18.8% (Department of Health, South Africa, 2008b).

The NSP (2007-2011) aims to reduce the 2007 MTCT rate from 18.8% to less than 5% by 2011 (Department of Health, South Africa, 2007a: 11). A Round Table Conference, held in Bloemfontein, South Africa during October 2007, on health systems and antiretroviral access, concluded that "from a national perspective, South Africa had largely failed in the prevention of mother to child transmission of HIV." Among the reasons for failure cited in the report was the inability of the programme to "address the many points of fall-out along the PMTCT cascade" (Schneider *et al.,* 2007: 28). A successful PMTCT programme is dependent upon pregnant mothers being tested for HIV. The proportion of antenatal care patients that were tested for HIV in 2007 ranged from 44% to 100% across the country's 52 districts. In 23 districts, less than 50% of pregnant women were tested for HIV (Doherty, 2007: 67). In addition, in 2007, only 66% of the pregnant women known to be HIV positive received single-dose PMTCT (Department of Health, South Africa, 2008b). The low number of pregnant mothers tested for HIV and the low percentage of HIV positive mothers receiving PMTCT both contribute to high levels of mother-to-child transmission.

The dual therapy PMTCT guideline, that was established in 2008, has shown mixed results. Data from the Western Cape (where dual therapy has been in place for a number of years having been implemented prior to 2008) reported that over 95% of pregnant women were being tested for HIV and that close to 95% of HIV positive mothers and their babies were receiving interventions under the PMTCT programme. The result has been that the transmission rate has steadily come down and is by 2008 was around 5%. Associated with this was an improvement, over the last 3 years (2006 to 2008), of the infant mortality rate. (Department of Health, South Africa, 2009a: 6)

By the end of 2008, 91% of health care facilities in South Africa were offering PMTCT services. More than 1060 health professionals had been recruited to support the PMTCT programme and 9107 health care professionals had been trained in the management, care and treatment of HIV and AIDS. The government was also working on conditions to recruit and retain more health professionals. This included providing scarce skills and rural allowances for certain categories of health professionals. (Department of Health, South Africa, 2008c)

However, these results varied between provinces. In the 2008/2009 estimate budget report, the Free State Department of Health reported that 97% of healthcare facilities were providing PMTCT and 181 health care professionals were trained in PMTCT (Department of Health, South Africa, 2008d). The performance target for 2007/2008 for the service delivery measure of the percentage of primary health care facilities with at least one health care provider trained in the Comprehensive HIV/AIDS Care, Management and Treatment Plan was only 50%. Of the 24788

created posts, 9026 posts were not filled, leaving a vacancy rate of 36.4% (Department of Health, South Africa, 2008d).

In a study undertaken by Janse van Rensburg-Bonthuyzen *et al.* (2008: 109) on the resources and infrastructure for the delivery of ART at primary health care facilities in the Free State Province the most frequently reported problem throughout the study was the lack of space for consulting rooms and waiting areas. Despite renovations at many facilities space remained a challenge with the expansion of the programme and the increasing number of patients.

2.5 RECENT UPDATES TO PMTCT DUAL THERAPY PROTOCOLS IN SOUTH AFRICA

On World AIDS Day, 2009, President Jacob Zuma announced new interventions to improve access to ART for priority groups, in order to decrease the disease burden, to address maternal and child mortality, and to improve life expectancy (Department of Health, South Africa, 2010a). Based on the presidential announcement in April 2010, the Department of Health issued new guidelines for PMTCT. All HIV positive pregnant women, with CD4 counts of 350/mm^3 or less or at WHO clinical stage 3 or 4, would receive lifelong ART namely tenofovir, emtricitabine/lamivudine and nevirapine. All HIV positive pregnant women, with a CD4 count of more than 350/mm^3 or WHO clinical stage 1 or 2, would receive zidovudine from week 14 of pregnancy, single-dose nevirapine at initiation of labour and zidovudine three hourly during labour followed by single-dose tenofovir and emtricitabine/lamivudine after delivery of the baby. The infant would receive nevirapine at birth and for six weeks, irrespective of the infant feeding choice, provided the mother was receiving lifelong antiretroviral therapy. If the mother only received PMTCT or did not receive any antiretroviral medication then the infant would receive nevirapine at birth and for six weeks continued for as long as the mother breastfed the infant. Therefore, there would be more patients accessing services for PMTCT as the criteria for treatment access had been broadened. (Department of Health, South Africa, 2010b: 30)

CHAPTER THREE

GUIDELINE IMPLEMENTATION

Literature has demonstrated problems associated with the implementation of PMTCT guidelines. This section explains the steps involved in the implementation of a guideline, the issues that affect the successful implementation of a guideline, South Africa's HIV/AIDS Strategic and Operational Plan and the challenges in the implementation of the PMTCT programme. Thus, this will guide and allow a comparison for proper planning in future to meet the challenges involved in the implementation of PMTCT guidelines.

3.1 OVERVIEW OF GUIDELINE IMPLEMENTATION

There are three stages of guideline use namely adoption, implementation and institutionalisation. Usually the leadership of a health care organisation decides to adopt a clinical practice guideline. The next process is implementation, which ensures that patient care follows the necessary recommendations and flowcharts or algorithms of the required process that is presented in a guideline. Guideline documents can be quite lengthy and detailed. This can make it very difficult to highlight the most important clinical aspects in the guideline. The goal of implementation is to apply recommendations made in the guideline into routine clinical practices. The health care leadership must support guideline implementation and the formation of an implementation action team. In order for the implementation action to start, an "Implementation Action Plan" needs to be developed. This is based on assessments of administrative and clinical processes and procedures. Whilst the action plan is drawn up, any changes noted, must be specified. Implementing change in a health care organisation is a challenging task, however this can be done by testing small-scale changes that can then be extended and adapted for full-scale implementation. Once the implementation process is fully operational, the final stage is to monitor the progress achieved. (Nicholas *et al.,* 2001: 7)

3.2 GUIDELINE IMPLEMENTATION STRATEGIES

Active involvement of leadership together with strong support is necessary to successfully implement practice guidelines. This requires staff time and other resources that are commonly in short supply in health care facilities. The challenges in facilities need to be identified and a list of strategies and actions to decrease the challenges drawn up. (Nicholas *et al.,* 2001: 57)

There are four strategies that can be used for guideline implementation, namely:

- Organise for guideline implementation;

- Support the implementation planning process;
- Facilitate action; and
- Monitor progress.

(Nicholas *et al.,* 2001: 57)

3.2.1 Organise for guideline implementation

Administrative and clinical aspects of health care are stated in clinical practice guidelines. There should be an executive team of administrative and clinical staff in the initial meetings. This will assist with sufficient commitment of time and resources to guideline implementation. The implementation team must report periodically to the clinical and administrative leaders in order to attain continued support. Guideline implementation is a high priority which sends the message to staff that leadership believes in the value of practice guidelines and that guidelines represent 'the way things should be done'. Approaches to prioritising guideline implementation include the following:

- Issuing a directive memorandum – the memorandum should convey the importance of the guideline and request the staff's cooperation in all implementation efforts;
- Using guideline implementation as a public relations tool – the implementation activities can be presented to external customers the facilities' commitment to providing high-quality, cost effective health care to beneficiaries. In order to help ensure that a consistent message is delivered to the public, a patient representative and a public relations officer should be elected; and
- Making guideline implementation a regular agenda item at directive team meetings – these meetings will provide updates on the status of the work and serve as a discussion forum for eliminating barriers to implementation that may arise. (Nicholas *et al.,* 2001: 58)

In addition the formation of an institutional body or committee will support the guideline activities. The committee would coordinate and monitor implementation of all guidelines and forward recommendations to the management regarding staff and resource allocations and other specific guideline-related issues. The members should include primary care physicians, nurses, administrative staff and ancillary support staff. (Nicholas *et al.,* 2001: 58)

3.2.2 Support the implementation planning process

The implementation team will partake in an organised planning process of which the Implementation Action Plan is the final result. This is a vital planning document that is the foundation for all guideline implementation activities and includes:-

- Revision of the implementation action plan as needed – this must be a plan of action to overcome key barriers to guideline implementation identified during the planning process. The directive should review the draft action plan for consistency and acceptability of proposed actions. New or suggested revisions should be incorporated in the plan before it is approved;
- Accountability of the implementation team for the implementation action plan – this can be done by creating expectations for the team's performance and for reporting its progress in implementing the planned actions; and
- Management-level support is needed for the follow up of implementation actions – timely accomplishment by the management on problems that require specific decisions will provide impetus for the implementation team to carry out the action plan effectively. (Nicholas *et al.,* 2001: 59-60)

3.2.3 Facilitate action

It is difficult to implement change in any large organisation. Although the implementation team is accountable for the management of the implementation endeavour, the staff's involvement is of the essence to its success. Obtaining the staff's involvement includes:

- Nurturing a favourable implementation climate – a favourable implementation climate contributes to successful guideline implementation. This is done by ensuring that staff gains all the necessary skills, supporting administrative and clinical processes are in place, and barriers to implementation are removed. Leadership can address the implementation climate by communicating regularly with staff throughout the implementation process (for example, using memoranda, meetings, newsletters, etc), committing the necessary resources so that the implementation team can carry out their duties, and troubleshoot implementation problems by resolving conflicts in the implementation team and ensuring that implementation continues smoothly and steadily; and
- Motivating staff to change – although support strategies are in place to facilitate guideline implementation, some staff will be hesitant about or even resistant to implementation because it disrupts their normal way of doing things. This kind of resistance is common when organisations attempt to implement major changes.

Staff can be motivated by acknowledging and validating any reluctance towards change among staff. Clinicians can be assisted to realise that guidelines are about streamlining systems of care so that medicine can be practiced in the way they already know is best. Clinical guidelines can focus health care organisation on putting the necessary elements of staff, information systems and clinical and administrative processes in place so that patients receive high quality care. (Nicholas *et al.,* 2001: 60-61)

3.2.4 Monitor progress

Monitoring the progress of implementation must be planned from the beginning of the implementation process. It is time consuming to identify appropriate measures for monitoring progress and to put measurement systems in place. This is done by:

- Ensuring that the guideline metrics are in place – for each guideline implemented an expert panel has been tasked with developing a set of indicators for monitoring guideline implementation;
- Providing insight for development of additional guideline metrics – additional metrics are usually developed to suit a particular implementation plan. Some important considerations in choosing metrics include:

  Process, service utilisations and patient outcome measures – process measures (e.g. document form in chart, new patient encounters) are particularly useful in the early stages to assess whether the actions specified in the action plan are taking place. Utilisation measures (e.g. referrals, diagnostics) are helpful for charting changes in access to care and costs of care. Ultimately, changes in patient outcomes (e.g. work days lost, blood pressure levels) are excellent measures of quality;

  Data availability, cost and ease of administration – using data from existing automated information systems or adding new data elements to these systems are the easiest and least costly ways of collecting data. If required data is not available from these sources, chart abstractions, surveys, new administrative forms can be used. However, these are more resource-intensive and are often more exposed to incomplete documentation; and

  Identifiable and measurable denomination – it is important to have complete counts of relevant patient populations to create accurate reports of chosen indicators.

- Accountability for the progress of implementation – just as the implementation team is held accountable for their action plan and choice of metrics, they should also report to the management team frequently about their progress on the metrics, including any data collected and analysed. (Nicholas *et al.,* 2001: 62)

3.3 KEYS TO SUCCESSFUL GUIDELINE IMPLEMENTATION

There are two key issues that contribute to the success of guideline implementation. These are building local ownership and ensuring that clinical and administrative systems are in place.

The staffs responsible for implementing the guideline are essential for building local ownership and support. Staff affected by guideline implementation must be committed to its success. This can be achieved by:-

- Educating staff - the first step on the way to accepting a guideline is to become familiar with it. Trainings, educational seminars or small group discussions among providers can make staff comfortable with the guideline;
- Focusing on local implications – show the implementing staff how the guideline fits into the clinical context of their job. Work with providers and staff to identify what areas of clinical care will be most positively or negatively affected by the guideline;
- Including all levels of staff - education and training should include all levels of staff involved in the implementation; and
- Focusing on improving patient outcomes – try emphasizing and improving the quality of patient care and how the guideline will help achieve that goal. (Nicholas *et al.,* 2001: 11)

By ensuring that clinical and administrative systems are in place to aid staff adherence to the guideline, will increase the success rate of implementation. Clinical guideline implementation requires more than just the enthusiasm and commitment of individual staff members. To achieve lasting improvements in clinical practices and patient outcomes a wide array of staff resources and administrative and clinical systems need to be coordinated. For guideline implementation to be successful, existing systems must be modified and/or new systems must be put into place to facilitate desired practice changes. The following suggestions:

- Simplify the current processes by using flow charts to map out all clinical and administrative processes relevant to the guideline in order to gain a clearer understanding of exactly where the process stands in comparison to the guideline recommendations;
- Identify necessary changes by identifying the system changes that need to be made to accommodate the guidelines;
- Involve a variety of staff members - clinical systems often involve multiple levels of staff and attaining representation from all areas will yield better results as well as building staff support; and
- Using process data to measure change by measuring changes in the care processes targeted by the new guideline to track the progress and to ensure that unexpected results are responded to quickly. (Nicholas *et al.,* 2001: 12-13)

Optimal results are achieved by having both local ownership and systems support. This shows a success of the implementation. System support without local ownership produces providers who are resistant to implementation, despite having clinic procedures and systems equipped to

support the process. Provider ownership without systems support produces willing providers who are frustrated at their inability to overcome barriers in their workplace that leads to their inability to implement changes. Finally with neither local ownership nor systems support implementation will fail. (Nicholas *et al.,* 2001: 12-13)

The Department of Health through the HIV/AIDS and STI cluster is responsible for the development and implementation of policy guidelines (Department of Health, South Africa, 2008a: 68). A number of policies and guidelines have been developed in order to support the implementation of HIV and AIDS strategies in South Africa. In 2000, the Department of Health developed and implemented a South African National Strategic Plan (NSP 2000-2005) for HIV/AIDS and STIs which represented the country's multisectoral response to the challenge with HIV infection and the wide ranging impact of AIDS (Department of Health, South Africa, 2007a: 7).

3.4 BACKGROUND – SOUTH AFRICAN HIV/AIDS GUIDELINES AND STRATEGIC PLANS

In 1992, the National AIDS Coordinating Committee of South Africa (NACOSA) was launched with a mandate to develop a national strategy on HIV and AIDS. A review conducted in 1997, in line with the goals of the NACOSA plan, indicated the strengths and weaknesses of this health sector only, disease-specific approach to HIV and AIDS. Some of the recommendations, from the 1997 review, related to capacity building for implementation agencies, increasing political commitment, increasing involvement of people living with HIV infection and/or AIDS, and strengthening integration. Much was done to implement the recommendations of the 1997 NACOSA plan review. This included the appointment of provincial AIDS coordinators, the establishment of the Inter-Ministerial Committee on AIDS, launch of Partnerships against AIDS by the Deputy President in 1998, development of the Department of Education HIV and AIDS policy for learners and educators, development of other national policies, including the syndromic Management of STIs, the establishment of the National Interdepartmental Committee on HIV and AIDS as well as the development of a Strategic Framework for a South African AIDS Youth Programme (Department of Health, South Africa, 2003: 54).

In 1999, through a consultative process with stakeholders, a National Strategic Plan 2000 to 2005 (NSP 2000-2005) was developed. The aim was to strengthen the implementation of the recommendations of the 1997 NACOSA plan review. The HIV and AIDS care and treatment programme for South Africa aims to integrate care and treatment with prevention efforts and to link existing HIV interventions, such as voluntary counselling and HIV testing, PMTCT, and TB control. (Department of Health, South Africa, 2003: 54)

The 2007-2011 South African National Strategic Plan (NSP 2007-2011) for HIV, AIDS and STI's flowed from the 2000-2005 NSP for HIV, AIDS and STI's as well as the Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment (Department of Health, South Africa, 2003; Department of Health, South Africa, 2007a: 7). The NSP (2007-2011) aims to provide continued guidance to all the government departments and sectors of civil society, building on work done in the past decade and informed by the nature, dynamics and character of the epidemic, as well as developments in medical and scientific knowledge (Department of Health, South Africa, 2007a: 6). The primary aims of the NSP (2007-2011) were to:

- Reduce the number of new HIV infections by 50%; and
- Reduce the impact of HIV and AIDS on individuals, families, communities and society by expanding access to appropriate treatment, care and support to 80% of all people diagnosed with HIV. (Department of Health, South Africa, 2007a: 10)

One of the interventions that were needed to reach the NSP's goals was to reduce MTCT of HIV. The NSP (2007-2011) aimed to do this by expanding existing MTCT services to include contraception and fertility services, reducing unwanted pregnancies, involving men in decision-making and providing HIV prevention services to uninfected pregnant women. In addition, the coverage of PMTCT was to be scaled up in order to reduce MTCT to less than 5%. (Department of Health, South Africa, 2007a: 9)

In 2006 the Department of Health assessed the extent of the implementation of the 2000-2005 NSP with regards to PMTCT. The assessment indicated that the number of PMTCT sites in the country increased during 2000 to 2008 (Department of Health, South Africa, 2007a: 44). The Department of Health had provided skilled personnel, medicines and other commodities to ensure that the access to PMTCT increased. The training of health care providers on PMTCT was, however, lagging behind the expansion of the PMTCT services. Fertility options for women known to be HIV-positive were still lacking and the effectiveness of the programme had still to be established. (Department of Health, South Africa, 2007a: 44)

In order for the effective implementation of the 2007-2011 NSP for South Africa to be achieved several practical and policy issues would have to be addressed by the Department of Health such as adoption of the 2007-2011 NSP by the South African National Aids Council (SANAC). This would ensure the use of the NSP 2007-2011 in developing national, provincial and district operational plans and the establishment and improvement of structures for delivery, policy and legal issues and human resources. In order to establish and improve structures for delivery the Department of Health would duplicate national structures such as SANAC at provincial and local levels. Such structures should include all role players in the field of HIV and AIDS within the community. (Department of Health, South Africa, 2007a: 95)

3.5 THE OPERATIONAL PLAN FOR COMPREHENSIVE HIV AND AIDS CARE, MANAGEMENT AND TREATMENT FOR SOUTH AFRICA

In 2003 the Minister of Health appointed a National Task Team to develop a detailed operational plan for an ART programme (Department of Health, South Africa, 2003: 2). The aim of the plan was to achieve two interrelated goals: to provide comprehensive care and treatment for people living with HIV and AIDS; and to facilitate the strengthening of the national health system in South Africa. The strengthening of the national health system would be accomplished by:

- Improving human resources;
- Training – upgrading the skills base and competencies of health care workers within the public health sector;
- Upgrading the national drug distribution system;
- Improving physical infrastructure in line with current capital programmes; and
- Upgrading patient and health information systems.
  (Department of Health, South Africa, 2003: 29)

3.5.1 Human resources

In 2008, in the South African Health Review, Lehmann reported that the HIV and AIDS crisis, in conjunction with other diseases and health threats has led to deteriorations in the health status of the population and a resultant increase in health care needs. Neither the private sector nor the public health sector had been able to adequately respond to those needs. On the contrary, the public health sector continued to be under-funded and was faced with a serious human resources crisis. (Lehmann, 2008: 166) More than one third of public sector posts remained vacant, and health professionals were not renewing their registration with the Health Professions Council (Day and Gray, 2007: 309-310).

Matching workforce capacity with skilled human resource needs represented a significant challenge for programme implementation. In South Africa significant shortages of professional nurses, pharmacists, medical officers, lay counsellors and administrative personnel existed in 2003 and were still present in 2008 (Padarath *et al.,* 2003: 300; Lehmann, 2008: 163). At the time of the launch of the Operational Plan for Comprehensive HIV/AIDS Care, Management and Treatment in 2003, the retention of trained personnel was a challenge throughout the public health system as health care workers moved from one province to another for family and career opportunities, other countries actively recruited personnel offering attractive incentives and financial packages to relocate abroad and rural areas faced even bigger challenges for attracting and retaining qualified staff. In addition, the impact of HIV and AIDS on the health

sector had strained an already overburdened system. (Department of Health, South Africa, 2003: 103)

Four years after the implementation of the Operational Plan for Comprehensive HIV/AIDS Care, Management and Treatment, the biggest threat to the implementation of the subsequent 2007-2011 NSP was still the unavailability of skilled personnel. However, the Department of Health was determined to ensure that human resource shortages were not a pretext for paralysis. Innovative methods were used to mobilise local communities for the provision of services. These strategies were successful in promoting greater access to services. Some examples included the use of community development workers, community care givers and lay counsellors in health facilities. Task shifting involved the delegation of activities to less qualified cadres. This included: lay counsellors (rather than nurses) "pricking" patients for rapid HIV tests; lay counsellors (instead of social workers) for orphan support activities; and training of primary health care nurses (rather than doctors) to initiate ART. The regulatory and policy barriers to achieving this needed to be removed and the processes initiated to provide the necessary training. Such policy decisions required a supportive systemic environment, in order to minimise the risk of compromising quality of services. (Department of Health, South Africa, 2007a: 97) Although international and national experiences with nurses prescribing ARVs had been overwhelming positive, and the practice was well established in many African countries, legislative provisions in the new Nursing Act remained ambivalent (World Health Organisation, 2007a: 21). There was no doubt that this ambivalence together with slow accreditation processes created one of the major bottlenecks, particularly in HIV and AIDS treatment and care (Lehmann, 2008: 172).

In order to meet the goals of the Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment training of staff workers, targeted recruitment, private sector participation, retention strategies, and the adjustment of roles and responsibilities of the available health care workers to best match the needs of the programme would have to occur. To implement the programme, provinces would require additional funding to upgrade their human resources for provision of health services. Within recommended guidelines for minimum personnel requirements for each service site, the provincial health managers would be able to utilise the additional funding to hire additional personnel, contract with private sector personnel or put in place incentives to retain workers. Additional funds would also be required for training of existing clinicians, nurses, pharmacists, counsellors and affiliated health care workers. (Department of Health, South Africa, 2003: 102)

In the 2009 budget speech for the Northern Province it was reported that over the next three years, the Department of Health would spend R185 million on bursaries for matriculants, unemployed youth and serving employees in order to ensure that the quest for the production

of appropriately qualified health professionals and workers was realised (Department of Health, South Africa, 2009b).

In 2002 the Department of Health established a Task Team to determine the level of human resources needed for implementation of a Comprehensive HIV and AIDS Care, Management and Treatment programme. Provinces submitted proposals on their requirements for additional staffing needs. The proposals were reviewed and adjusted by the Department of Health to allow for a standardised approach for estimating staff requirements. Estimates of the underlying demand for AIDS care and treatment were drawn from the ASSA2000 model (ASSA, 2000). Based on the epidemiological estimates, ranges for patient demand and achievable treatment coverage were discussed with provinces to form the basis for provincial planning. The midpoint of the range is shown in Table 3.1. (Department of Health, South Africa, 2003: 105)

Table 3.1: The midpoint of the range of the projected total number of patients, using the ASSA2000 model, requiring CD4 tests and ARV treatment by year

YEAR	PATIENTS REQUIRING CD4 TESTS	NUMBER OF ARV PATIENTS	TOTAL
2003/04	212,000	53,000	265,000
2004/05	628,705	188,665	817,370
2005/06	1,078,446	381,177	1,459,623
2006/07	1,497,580	645,740	2,143,320
2007/08	2,167,834	1,001,534	3,169,368

Source: (Department of Health, South Africa, 2003: 105).

The projected number of patients who would require ARV medication by 2007/2008 was over 1 million and the number of patients requiring CD4 tests was over 2 million (Table 3.1). The patient demand was then translated into projected total patient visits (Table 3.2). The projected number of patients for 2007/2008 was 3,169,368 and this would translate to over seventeen and a half million patient visits for that year. (Department of Health, South Africa, 2003: 105)

Table 3.2: Projected patient visits per year, using the ASSA2000 model

YEAR	PATIENT VISITS
2003/04*	265,353
2004/05	3,592,428
2005/06	7,088,948
2006/07	11,661,119
2007/08	17,848,642

*Three month period
Source: (Department of Health, South Africa, 2003: 105).

The Department of Health, in 2003, determined the estimates of core staffing requirements per service site (Table 3.3). This was reported as the number of staff that would be required to treat 500 patients with antiretrovirals. The core staffing estimates were used to determine the total number of full-time equivalent (FTE) personnel that would be required in order to support the Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment (Department of Health, South Africa, 2003a: 104).

Table 3.3: Core staffing requirements, using the ASSA2000 model, per service site to treat 500 patients with antiretrovirals

CATEGORY OF STAFF	MINIMUM FTE*
Medical officers	1
Professional nurses	2
Pharmacists	1
Dieticians	1
Social workers	0.5
Lay counsellors	5
Administrative clerks	1
Data capturers	1
TOTAL	**12.5**

*FTE – Fulltime equivalent

Source: (Department of Health, South Africa, 2003: 106)

Therefore, it can be seen that in order to treat 500 patients with ARV's a site would require one medical officer and two professional nurses. Based on the estimated number of persons with

HIV and AIDS the Department of Health was able to estimate the number of staff required for the following five years from 2004 to 2008 (Table 3.4).

These estimates assumed no diminution of work for health professionals in the short-term. It was anticipated that patients, once initiated on ART, would visit their health professional less frequently for infections and complications associated with their HIV status. This recruitment model assumed all ARV-related treatment as additional workload for health professionals in the system, but a great deal of this work was likely to replace existing time spent with the same patients. However, longer term, ARV treatment would require a substantial increase in human resources due to HIV being treated as a chronic condition and the number of AIDS patients would increase significantly. (Department of Health, South Africa, 2003: 107)

Table 3.4: The numbers of additional staff, using the ASSA2000 model, required by professional category over a period of 5 years to implement the Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment

CATEGORY STAFF	THROUGH MARCH 2004 (*FTE)	APRIL 2004 – MARCH 2005 (*FTE)	APRIL 2005 – MARCH 2008 (*FTE)
Medical officers	76	271	628
Professional nurses	228	813	1,883
Enrolled nurses	152	542	1,255
Assistant nurses	152	542	1,255
Pharmacists	76	271	314
Pharmacist assistants	76	271	314
Dieticians	76	136	314
Social workers	38	136	314
Lay counsellors	760	2,710	6,275
Administrative clerks	152	542	1,255
TOTAL	**1,776**	**6,233**	**13,805**

*FTE – Full time Equivalent
Source: (Department of Health, South Africa, 2003: 108).

The projected number of pharmacists and pharmacist assistants required in order to implement the government's Operational Plan for Comprehensive HIV/AIDS Care, Management and Treatment during the time period April 2005 to March 2008 was, 314 full-time additional

pharmacists and 314 pharmacist's assistants (Department of Health, South Africa, 2003: 108). However, South Africa is currently only producing 457 pharmacists per year and the majority of these pharmacists do not work in the public sector (Lehmann, 2008: 167). In 2005 the total number of pharmacists working in the public health care sector was 1617 and in 2007 the total number of pharmacists working in the public health sector was 1830. Thus in three years there was only an increase of 877 pharmacists employed in the public health sector. (Day and Gray, 2007: 309)

By the end of 2007, the percentage of nurses employed in the public sector was only 42% and the number of nurses per population was 1.1 per 1000 (Lehmann, 1008: 166). The nursing vacancy rate in the public sector was 37.3% (Schneider *et al*., 2007: 22). This is probably due to the migration of nurses to other countries and a shift of nurses working in the public sector to the private sector (Lehmann, 2008: 166). Thus, according to Lehmann (2008: 166), due to the shortage of nurses in the public sector there will continue to be clinics with vast attachment areas staffed only by one or two nurses, making health care inaccessible for many.

The problems faced by nurses are compounded by high vacancy rates in all other areas of health care. The dramatic shortage across the health system - from auxiliary workers to doctors is loading nurses with a greater burden of the work. The result according to the South African National AIDS Council (2008: 22) is that the "shortage, distribution, management and supervision of skilled personnel in the public health sector pose serious impediments to efficient ART provision and expansion".

In the 2006 Progress Report on Global Access to HIV Antiretroviral Therapy the WHO acknowledged that the lack of human resource capacity, including management capacity, was a recurring problem in health systems in many low income countries, a weakness that was highlighted by the scaling up of HIV treatment. Lack of trained personnel, poor capacity in educational systems and the loss of trained health care workers to the private sector or to high income countries as well as to the epidemic was taking a toll. In sub-Saharan Africa, the general shortage of health workers was estimated to be one million. (World Health Organisation, 2006b: 61)

3.5.2 Training

To begin delivering HIV and AIDS care and treatment at the outset of implementation, in 2004, designated service points utilised existing experienced personnel with additional human resources to fill the gaps. The first priority for the initial phase of the implementation of the plan was to establish a comprehensive training programme with a wide geographic coverage for all categories of health care workers and support personnel required for the provision of HIV and AIDS treatment and care. Accreditation of sites for the provision of HIV/AIDS care was

tied to certification of the core team of health care workers. Certification was achieved through the completion of the didactic portion of training followed by a programme of clinical mentoring, by the medical officer, to be completed once provision of ART had commenced at the service point. The Department of Health also required all academic health institutions to develop and implement a strategy to ensure that all students, who graduated from the end of 2003, received a short, intensive course on providing a comprehensive package of care for HIV and AIDS. (Department of Health, South Africa, 2003: 109)

3.5.2.1 Training needs

The Operational Plan for Comprehensive HIV/AIDS Care, Management and Treatment developed approaches for the training of staff for the short term as well as for the long term. Standardised training programmes for health care workers were to be developed on a national basis and implemented locally. The initial focus of this effort was to develop basic competencies required of all health care workers that would directly deliver the comprehensive services for HIV and AIDS care and treatment. Thereafter, the emphasis was to be broadened to support ongoing HIV training and clinical support for health care workers, including continuing professional development (CPD) programmes that would upgrade the training of health professionals on the latest developments in HIV and AIDS care and treatment. (Department of Health, South Africa, 2003: 110-116)

The Comprehensive HIV/AIDS Care, Management and Treatment Plan indicated that each province was to appoint a training coordinator from existing personnel to take responsibility for ensuring that training needs were identified and staff were fully prepared for the launch of the Operational Plan for Comprehensive HIV/AIDS Care, Management and Treatment. The medical advisor with the provincial training coordinator was responsible for delivering the nationally defined curriculum to the site staff, especially clinicians and nurses. Medical officers, nurses, pharmacists and lay counsellors at initial service points were to complete training on a priority basis. Long term professional training was to be an expansion of the short-term process and was to focus not only on the comprehensive approach to HIV and AIDS prevention, treatment and care, but also on other diseases. (Department of Health, South Africa, 2003: 110-116)

Healthcare practitioners have a responsibility to continually update their professional knowledge and skills for the end benefit of the patient. Continuing Professional Development is another initiative introduced by the Health Professions Council of South Africa in order to address the training and continuous development of health care workers. (Health Professions Council, South Africa, 2010) The legislation pertaining to CPD for pharmacists is awaiting publication, in the Government Gazette, by the Department of Health.

3.5.2.2 Recruitment of health personnel

Dramatic inequities, but also insufficient absolute numbers of health personnel have been identified as one of the key impediments in the improvement of health systems performance worldwide (World Health Organisation, 2006a: 15). However, in South Africa, great strides had been made in the past decade to formulate policies aimed at attaining the goal of a unified functional health system (Lehmann, 2008: 166). Some of the policy initiatives suggested in the Comprehensive HIV/AIDS Care, Management and Treatment Plan for the recruitment of health care workers included:

- Targeting healthcare workers who have completed community service;
- Recruitment from the pool of new nursing graduates;
- Introduction of community service for nurses;
- Establishment of targeted bursaries;
- Creation of preferential registration of qualified foreign workers who have committed to working in designated government facilities;
- Recruitment of retired health care professionals;
- Extension of over-time hours;
- Review of the policy of rotation for nurses;
- Increase in retention of existing health care workers;
- Support of non-governmental organisations, faith-based organisations and community-based organisations; and
- Establishment of public-private partnerships.
  (Department of Health, South Africa, 2003: 116-118)

3.5.3 Drug distribution

An efficient and secure process for storage, distribution and appropriate utilisation of ARV medication was planned, by the Department of Health, for the public health system to ensure a reliable supply of medicines at all levels of distribution to avoid “stock-outs”, prevent shrinkage and the return of medicines back to the drug depot (Department of Health, South Africa, 2003: 155-156). At the time of the launch of the Comprehensive HIV/AIDS Care, Management and Treatment Plan each province operated its own drug depot that provided drug storage and distribution services to the public health centres in the province. Some drug depots had strong security mechanisms and inventory-tracking information management systems in place, while others did not. Those that did not have these systems experienced higher rates of theft and stock-outs. In the public sector a significant volume of pharmaceutical products were lost during the process of distribution and storage and the majority of loss was attributed to theft. (Department of Health, South Africa, 2003: 155-156)

The Operational Plan for Comprehensive HIV/AIDS Management, Care and Treatment drafted an approach to ensure proper drug distribution. This included:

- Inventory management including secure storage facilities at the central, provincial and local levels;
- Efficient and secure transport of medicines between central warehouse facilities, provincial pharmaceutical depots and public health service points;
- Training of pharmacy personnel to implement inventory management practices;
- Improving packaging to support inventory control and to improve patient adherence;
- Ensuring patient prescription data is recorded; and
- Maintaining financial management systems at national, provincial and local levels. (Department of Health, South Africa, 2003: 155)

As part of inventory management provincial depots were required to process and ship an order within two days of receipt to ensure the proper supply of ARVs to the public health service points. In order to minimise potential disruptions to the ARV programme implementation, a contingency stock plan was considered by the Operational plan for Comprehensive HIV/AIDS Care, Management and Treatment. Drug manufacturers were required to keep a two month supply of stock on hand in their local warehouses. This requirement would help to minimise the chance of stock-outs in the country while at the same time lessening the storage demands on the provincial depots and public health pharmaceutical facilities. (Department of Health, South Africa, 2003: 155-159). In 2006, the Department of Health established a new buffer stock system for HIV/AIDS. This system was funded by a Dutch Non-governmental agency called IDA Solutions. In the event of South Africa being out of stock of antiretroviral drugs this service would ensure that antiretroviral medication was mobilised within 24 hours and reached 80% of sub-Saharan Africa within one week. (Health Systems Trust, 2006) However, out of stock situations are occurring and in 2008, the Free State Department of Health experienced shortages of ARV medication and stopped the provincial roll out of ARVs with the exception of pregnant mothers and children (El-Khatib and Richter, 2009: 412).

One of the major problems in stock management was the theft of medicines from the public sector especially when dealing with expensive medicines such as ARV drugs that had a high value in both developed and developing countries. The Operational Plan for Comprehensive HIV/AIDS Care, Management and Treatment proposed major investments in the improvement of the distribution and secure storage of medicines as well as increasing dramatically the number of pharmacists in the public sector. (Department of Health, South Africa, 2003: 155-159)

Due to the volume of medicines that were likely to be ordered, electronic tracking would be required in order to ensure proper drug distribution. Information technology systems in each

provincial depot were to be updated but there would still be paper based tracking systems in facilities that did not have computer systems or reliable access to electricity. (Department of Health, South Africa, 2003: 157)

The provincial depots were to be involved in the packaging of ARVs to improve overall drug adherence. A system that was already in place in a few provincial depots namely packaging of all the separate ARVs for a single regimen into one box, would greatly improve the dispensing and administration of the ARVs. (Department of Health, South Africa, 2003: 159)

The 2006 Progress Report on Global Access to HIV Antiretroviral Therapy also noted that the constraints in the procurement and supply of drugs continued to present a critical barrier to the scaling up of ARV programmes in that procurement and supply management systems were weak, inefficient or poorly managed in many countries. It was worrying to note that the lack of secure funding for most national ARV therapy programmes beyond 2008 remained a concern. (World Health Organisation, 2006b: 59)

3.5.4 Infrastructure

Delivering complex health care, in resource limited facilities, is difficult in the absence of good infrastructure. Shelter for patients and staff, water and a source of electricity for refrigeration of vaccinations are fundamental for the safe provision of health care. A working communication mechanism is also vital for the functioning of a referral system, as well as to enable the provision of support services (such as laboratory services) to the facility. A road that is traversable is necessary to enable patients to attend the facility (Lutge and Mbatha, 2007: 4).

In a 2006 keynote address the South African Minister of Health mentioned that the vision for the country was an accessible, caring and high quality health system and the strengthening of the physical infrastructure of both hospitals and primary health care facilities (Department of Health, South Africa, 2006a). Lutge and Mbatha, (2007: 4) reported that the state of the physical infrastructure at health facilities in many areas of South Africa was poor and inadequate for the needs of the clinic catchment populations. Poor infrastructure has been shown to significantly affect a patient's perception of quality of care (Rao *et al.,* 2006: 414-418) and in South Africa has had a significant negative effect on health professionals' satisfaction with their working conditions (Kotzee and Couper, 2007: 581; King and McInerney, 2006: 70-81).

The HIV and AIDS epidemic resulted in new infrastructural needs that had not previously been envisaged, such as private consulting rooms for counselling and testing, and space for the additional staff (Lutge and Mbatha, 2007: 9). According to the Comprehensive HIV/AIDS Care, Management and Treatment Plan the pharmacies in most public health facilities needed to be

upgrade in order to cope with the demands of storing and dispensing large volumes of ARVs. Site upgrades were to include an expansion of storage facilities for schedule 5 medicines and investments in the information technology required for online order placement and prescription information collection and management. In addition, pharmacies needed adequate space for patient counselling. This should strengthen pharmaceutical care in all services rendered. (Department of Health, South Africa, 2003: 158)

3.5.5 Patient information systems

Effective patient information systems are necessary to ensure that a standardised, effective and efficient system for data collection, collation, monitoring and feedback is in place to facilitate programme implementation, ensure good quality care, and achieve good patient/programme outcomes. The specific functions that a patient information system required for the Comprehensive HIV/AIDS Care, Management and Treatment Plan were the ability to:

- Register patients utilising a standard patient record;
- Collect relevant clinical care information at baseline and subsequent follow-up visits to monitor progress of patients;
- Monitor adherence to treatment;
- Monitor adverse drug events; and
- Collect other clinical, laboratory, and non-clinical data that would be useful for programme monitoring at local, provincial and national levels.
  (Department of Health, South Africa, 2003: 185)

A significant portion of the population moves between homes and a separate place of work. To ensure uninterrupted access to medications, it would be important for individuals to be able to get prescriptions filled as they moved throughout the country. Therefore, in South Africa, a system was required that could track prescriptions throughout the country (Department of Health, South Africa, 2003: 158). Kumalo (2006: 66) found that health service delivery related information systems were weak in many developing countries. Health care workers were overburdened with excessive data and reporting demands due to multiple, poorly coordinated systems which often duplicated collection effort and failed to deliver timely, accurate and complete data. Furthermore, there was inadequate access to information from support systems such as human resources and financial systems and linkages of these to routine health information.

By 2006, there were still a number of challenges facing the availability of reliable health and management information in South Africa including a shortage of dedicated health information personnel, insufficient skills in understanding computer software, a need for training of staff and technology infrastructure and support was inadequate (Kumalo, 2006: 71). There was still

a lack of an information culture in the public health sector, possibly due to a generation of managers who had insufficient training or experience in the Health Management Information System. There was also evidence that there was inadequate use of the available information by managers. (Burn and Shongwe, 2004: 38) Furthermore, clear policies and procedures were needed to guide data management processes and to standardise practice at all levels of the system (Kumalo, 2006: 72). Due to the increase in demand for public health there has been an unprecedented increase in demand for an accessible, accurate and integrated health information system. This information would enable managers to monitor and evaluate programme implementation and progress. (Kumalo, 2006: 75)

3.6 CHALLENGES ENCOUNTED DURING THE IMPLEMENTATION OF THE MONOTHERAPY PREVENTION OF MOTHER-TO-CHILD TRANSMISSION PROGRAMME IN SOUTH AFRICA

Short course ARV regimens for PMTCT are cost effective, easy to administer, and for those reasons, have been scaled up in many developing countries including South Africa (Bajunirwe and Muzoora, 2005). Despite the low cost of these short course regimens, the implementation of programmes for PMTCT have faced many challenges and consequently the success of the programme implementation as a whole had varied. Since the introduction of nevirapine mono-therapy for PMTCT in South Africa, few studies had been done on the challenges faced by the programme. The Health Systems Trust, in 2002, undertook a study on the 18 PMTCT pilot sites (Health Systems Trust, 2002: 1). The findings concluded that, many of the difficulties identified were systemic in nature, and related to the poor functioning of the healthcare system in general. The report highlighted challenges regarding human resources, management and physical infrastructure. Furthermore tremendous differences in implementation and uptake rates between provinces and sites were found. At the core of these differences were the inequalities in healthcare infrastructure within the country. The following issues and challenges were identified by the 2002 Health Systems Trust report:

- Start-up difficulties;
- Staff shortages;
- Training;
- Space and Privacy;
- Quality of Counselling; and
- Follow-up care.

(Health Systems Trust, 2002: 1-23)

Some of the difficulties experienced were linked to the fact that the health system was still undergoing transformation. On-going structural changes, inefficiency and bureaucracy were some of the factors preventing the rapid implementation of the new programme as well as

poor health facilities, low morale and motivation amongst staff, denial and stigma within communities. The difficulty of working with nine different provincial Departments of Health was another factor. (Health Systems Trust, 2002: 6)

The review indicated the PMTCT programme had resulted in an increase in the workload and responsibilities for staff. In a few sites there had been no additional staff appointed and there were concerns that the increase in workload would lead to poor quality of care in other areas and to stress and burn-out. The recruitment and training of lay counsellors to work with professional staff was a very positive aspect of the PMTCT programme, however, some provinces (in 2002) were still not employing lay counsellors. Finally provinces differed widely in the way that they recruited, trained, managed and paid lay counsellors. Some provinces had contracted NGO's to be responsible for this and payment varied while some lay counsellors did not receive any payment. All these inequalities caused problems that ultimately affected the rate of women taking up PMTCT services. (Health Systems Trust, 2002: 13)

In terms of training the Health Systems Trust, in 2002, review reported that extensive training for the pilot programme had taken place but not all staff had been trained. Organising training would, therefore, be a major challenge if the programme was expanded further. Many provinces had a high staff turnover which made training a key challenge. There was insufficient on-site training and not enough focus on skills development and problem solving. The training of counsellors varied according to provinces and was sometimes not culturally appropriate, providing too much theory and not enough practice and did not deal adequately with the attitudes and prejudices of the trainees themselves. Doctors played an important role in clinical leadership, quality control and training, however, some sites had doctors who showed little interest and these sites experienced problems. (Health Systems Trust, 2002: 13)

Counselling and testing requires privacy and additional space. Wide differences occurred in the PMTCT pilot sites. Where testing and counselling occurred in inappropriate places this had a negative effect on the number of people making use of the services. However, where rooms for HIV counselling and testing were obviously demarcated for HIV counselling and testing, this could have acted as a deterrent as people did not want to be seen going into one of these rooms. (Health Systems Trust, 2002: 15)

The PMTCT programme required a pro-active approach whereby all pregnant women were actively encouraged to gain from the benefits of HIV testing. However, quality of counselling was a serious problem in facilities where morale and motivation were low or where there was a denial towards HIV amongst the staff. A pointer to the poor quality of encouragement and counselling was the fact that few pregnant women had disclosed their status to their partners or families. (Health Systems Trust, 2002: 15)

The policy guideline indicated that babies of HIV positive women should receive follow-up visits weekly during the first month of life, monthly thereafter until 12months of age then every three months until two years of age. Providing this on-going care was an enormous task as long distances and the cost of transport to health facilities made follow-up visits difficult, long waiting times and queues discouraged visits, and poor patient records and patient mobility made it difficult to maintain continuity of care. (Health Systems Trust, 2002: 22)

The Health Systems Trust, in their 2003 report on PMTCT implementation, indicated that in order to reach the objectives of reduced child morbidity and mortality, care for HIV positive mothers and a better understanding and response to HIV in general together with a fundamental re-thinking of PMTCT implementation was required. Universal coverage was essential but it was unrealistic to do this with a whole basket of interventions simultaneously. The report showed that it was feasible to implement PMTCT in all provinces, in rural and urban settings and at hospital and primary care levels, however, real constraints existed in many settings and difficulties had been experienced at every level in the planning and implementation of the programme. (Health Systems Trust, 2003: 72)

Similar challenges were identified by a study undertaken by the Human Sciences Research Council (HSRC) in 2003 on the barriers to the implementation of the PMTCT programme in the District of Flagstaff, part of Region E in the Eastern Cape Province. The clinics that were part of Region E were Xhopozo Clinic, Bala Clinic, Holy Cross Gateway Clinic, Flagstaff Clinic, Nkozo Clinic and Mkhambati Clinic. (Skinner *et al.,* 2003: 1-28) Some of the key areas investigated by Skinner and colleagues (2003) that could have influenced the provision of the PMTCT programme included:

- Staffing of health services;
- Infrastructure and space;
- Roads and transportation;
- Telecommunication; and
- Problems raised by volunteers.

The shortage of staff in clinics affected PMTCT services. Although the posts were advertised there were few nurses that were prepared to work in the remote areas. The shortage of staff raised the concern about the capacity of the clinical staff, overstretched on their existing tasks, to take on the PMTCT functions without another service being reduced. There was no comprehensive PMTCT team in those clinics. (Skinner *et al.,* 2003: 21)

In most of the clinics there was insufficient infrastructure to offer PMTCT services, especially in terms of offering counselling services. Counselling took place in treatment rooms and there

was little confidentiality. There were only two treatment rooms and one small waiting room in all clinics that were studied in the Flagstaff district of the Eastern Cape. (Skinner *et al.,* 2003: 14)

At the time of the study, in 2003, there was only one main road and the other roads were gravel or dirt, some in poor condition. The villages and clinics were also very scattered and that made it demanding to travel from one place to another. Many stretches of roads were not maintained, while in other cases there were no roads at all. The number of small communities and the lack of signposting made finding destinations even more complicated, especially at night. This impacted on access to the clinics and transfer of patients to hospitals in the case of emergencies. Most people travelled on public transport, either taxis or buses. In most areas buses were only available in the early mornings and again in the afternoon to return home. Taxis were expensive and old and would often be full. The problem of over flowing rivers also posed a problem in terms of access to clinics. (Skinner *et al.,* 2003: 20)

Communication was one of the major problems mentioned by staff in all clinics studied. Virtually no patients had landline phones in their homes and network coverage for cell phones was problematic. Furthermore the clinics had no phones and communication between clinics was extremely difficult. (Skinner *et al.,* 2003: 19)

Finally, due to understaffing, all the clinics relied heavily on volunteer workers, including the PMTCT programme, in that counselling and education programmes were dependent on the volunteer workers. However, a problem existed in that volunteers complained about lack of financial incentives to support them in doing their work in that they had to use their own money to travel and buy the food that they often had to give to sick patients. Another group complained about the lack of gloves. (Skinner *et al.,* 2003: 19)

3.7 CHALLENGES ENCOUNTED DURING THE IMPLEMENTATION OF THE PREVENTION OF MOTHER-TO-CHILD PROGRAMME IN OTHER COUNTRIES

Prevention of mother to child transmission of HIV has continued to gain immense significance in the fields of HIV prevention and care, mostly in the last 10 years. This significance has come about due to the growing recognition that HIV is not only found in blood and sexual fluids but also in breast milk. The fact that over 90% of all infections in South Africa are found among women of reproductive age (15 to 24 years) makes PMTCT a life and death subject (UNAIDS, 2008). In order to achieve comprehensive care for mothers living with HIV and AIDS the capacity of the health system needs to be strengthened in many developing countries. In most high-income countries the wide implementation of an evidence based package of interventions built around the use of antiretroviral drugs, the avoidance of breastfeeding and elective caesarean section has virtually eliminated new HIV infections among children. In contrast, resource

constrained settings have made little progress in scaling up services for the PMTCT. (World Health Organisation, 2007b: 5) In many African countries, the uneven distribution and infrastructural inadequacies that exist within the PMTCT service make the PMTCT services ineffective and unattractive to many patients. Access to PMTCT services and community knowledge around mother to child transmission (MTCT) remain low (Onyango, 2008). According to the World Health Organisation (2003b: 9) an effective HIV and AIDS treatment programme is defined by its capacity to quickly and effectively treat a substantial number of people living with HIV and AIDS. However, many rural countries, South Africa included, lacked this capacity and this could be attributed to the constraints in the health care system human resources and infrastructure. In 2007 Schneider *et al*. (2007: 9) summarised this by stating that the main systemic constraints to scaling up was the inadequate supply of human resources and infrastructure.

The AIDS pandemic had become a leading cause of illness and death among women of reproductive age in countries with a high burden of HIV infection and the burden of this was taking a toll on the health care systems of many developing countries. The antiretroviral regimens for the PMTCT in constrained settings were cost effective and the need for the scaling up of the programme in order to achieve national coverage and universal access was urgent. However, despite the low cost for short course PMTCT regimens, implementation of programmes for the PMTCT of HIV faced many challenges as services expanded to remote or rural areas. (Wilfert 2002: 863-865) In many developing countries, the population was predominantly rural and the majority of women sought care at their rural health units. There are significant differences in the socio-demographic structure of populations that lived in urban versus rural areas in most of Africa with urban populations being more educated and economically advantaged compared to the rural population. (Painter *et al*., 2005: 237-242) However, a study in Uganda, demonstrated that there were no major differences in terms of the potential barriers that might hinder the successful implementation of PMTCT programs in rural areas as compared to urban areas since there were no major differences in terms of attitudes towards acceptance of interventions for PMTCT. This indicated that experiences learnt from programs in the urban area would apply to rural PMTCT programs. (Bajunirwe and Muzoora, 2005)

A study of the challenges of PMTCT programme implementation in rural Zambia, in 2004, indicated that over half of the 28 clinics studied had only one trained staff member, district clinical staffing was at 50%, with 100% shortfall at the highest level of medical staff and there was a 35% shortfall of nurses. Only 9 clinics had electricity and 22 of the 28 clinics needed delivery beds. In rural areas in Zambia the PMTCT programme required more fundamental infrastructure, administrative and training support than similar projects in urban clinics. (Kolsky e*t al.,* 2004: Abstract E6778)

Similarly scaling up of the PMTCT programme in Uganda entailed providing in-service training to health workers using standardized locally developed training manuals, voluntary counselling and testing for pregnant women and their partners, comprehensive package of antenatal, intra-partum and post-partum care to mothers and their children, ARVs to HIV positive mothers and their infants, advocacy for male involvement and integration of PMTCT into existing health services. The challenges identified in this study also indicated that inaccessibility of services for the majority of the rural population was a problem and that poor infrastructure and limited human resources hindered programme expansion to lower health facilities. Programme expansion was resource intensive requiring training of in-service health workers, uptake of PMTCT services was still low and only 40% of deliveries took place in health facilities in spite of over 90% antenatal clinic attendance (Ojera *et al.,* 2004: Abstract B7083). A Tanzanian study on barriers to PMTCT services indicated similar challenges such as many service providers possessing inadequate skills in core PMTCT interventions, HIV counselling and testing were not integrated into antenatal clinic services and ARV drugs were not available in the health facilities surveyed (Ntabaye and Lusiola: 2004: Abstract B11396).

In a study done in 2008, in Vietnam, it was found that operational guidelines on PMTCT were still not available, however, it was state policy to provide prophylactic sd-NVP free of charge to all HIV positive pregnant women. These services were not available everywhere, partly because of the weakness of the health system. Among the HIV positive women that were detected, as few as 20% received the sd-NVP. In the rural areas, the health services were not yet strong enough to deliver adequate PMTCT services. But even in the best funded and equipped urban settings, women had to find their way through a maze of fragmented services, with the result that many women who needed PMTCT did not receive it. Reasons for unsatisfying performance in the PMTCT programs included ARV medication not available, there was inappropriate counselling on ARV use and adherence, there was a lack of knowledge and education, and a fragmented health system especially weak referral systems which did not provide integrated case management between hospitals. (Nguyen *et al*., 2008)

In a study from the Republic of Congo, published in 2009, the challenges experienced in the implementation of integrated HIV and AIDS programs included convincing staff of the need and capability to introduce HIV care when faced with other medical priorities, low resources, heavy workloads and avoiding the development of excessive secrecy around HIV management that could be created in an attempt to maintain confidentiality and overcoming the concern of staff over the risk versus benefits of introducing HIV counselling and testing in conflict settings (O'Brien *et al.,* 2009). Similar challenges were found in a Zambian experience in the scaling up of PMTCT in resource limited settings. The programme also experienced constraints such as human resource deficit, inadequate infrastructure especially in rural areas, insufficient systems

of care for the HIV exposed child, insufficient male involvement and mainstreaming data collection. (Bweupe, 2006)

3.8 SUMMARY

The review of the literature suggests that a number of barriers continue to hinder the successful implementation of PMTCT programmes. The South African government has committed to allocating more resources towards HIV prevention and to ensuring that the number of infants receiving ARVs for PMTCT and the number of pregnant women tested for HIV increases by 2012 (Motsoaledi, 2010). As more scientific evidence becomes available indicating more efficient antiretroviral regimens, it is expected for new PMTCT guidelines to be developed. Since 2004 and the implementation of PMTCT in South Africa, there have been several changes to PMTCT policies and guidelines. However, the initial challenges of human resource shortages, training, infrastructure and drug distribution that affected the implementation of PMTCT in 2002 still exist eight years later. The South African Health Care System in general would need to be strengthened in order for PMTCT to succeed.

CHAPTER FOUR

PLAN OF WORK

4.1 INTRODUCTION

In South Africa, approximately 1,100,000 babies are born every year (Statistics, South Africa, 2007). The HIV prevalence among pregnant women in public health facilities was 28% in 2007 (Department of Health, South Africa, 2009a: 6). This resulted in about 300,000 babies born exposed to HIV, and without intervention approximately 30% (around 90,000) of these babies would have become infected with HIV (Human Science Research Council, 2008). The HIV/AIDS and STI Strategic Plan for South Africa (NSP 2007-2011), set an ambitious target of reducing mother-to-child transmission of HIV to less than 5% by 2011 (Department of Health, South Africa, 2007a: 11). According to the World Health Organisation (2003b: 9) an effective HIV and AIDS treatment programme is defined by the capacity to quickly and effectively treat a substantial number of people living with HIV and AIDS. However, many third world countries including South Africa, lack this capacity and this could be attributed to the constraints in the health care system, human resources and infrastructure (Health Systems Trust, 2002: 1). In 2002, a study on the implementation of PMTCT undertaken by the Health Systems Trust concluded that many of the difficulties identified were systemic in nature, and related to the poor functioning of the healthcare system in general (Health Systems Trust, 2002: 1). Eight years have now passed since the implementation of PMTCT in South Africa and in 2008 the Department of Health introduced a new dual therapy PMTCT protocol (Department of Health, South Africa, 2008a). This study will look at the challenges faced by the health care workers at various clinical sites in NMB on implementation of the new dual therapy PMTCT protocol in 2008.

4.2 HYPOTHESIS

The hypothesis for this study is that there is no human resource, infrastructural or training barriers to the effective implementation of the dual therapy PMTCT protocol in the Nelson Mandela Bay.

4.3 RESEARCH PLAN

In order to prove or disprove the hypothesis the following objectives were formulated:

To investigate whether the infrastructure at the clinical sites was in line with the national recommendation for the provision of a PMTCT programme;

To investigate whether the pharmacy and medicine room at the clinical sites was in line with the Good Pharmacy Practice Guidelines of the South African Pharmacy Council;

To investigate whether the staff had received training on the dual therapy PMTCT programme; and

To determine if the human resource complement at the clinical sites was in line with the national recommendations for the provision of a PMTCT programme.

To meet and fulfil the objectives of the study the following approach was adopted:

- A comprehensive literature review on the subject was undertaken to gain an understanding of the challenges that exist regarding HIV and implementation of policies.
- Appropriate sites and population were selected.
- Ethical approval was requested from the Faculty Research Technology and Innovation (FRTI) Committee and Research Ethics Committee (Human) (REC-H) at Nelson Mandela Metropolitan University , permission from the Port Elizabeth Hospital Complex, NMB, Eastern Cape Department of Health and the International Centre for AIDS Care and Treatment Programme (ICAP) was obtained.
- To investigate Infrastructure, an Infrastructure Audit Form was developed to determine whether the space at the facilities was sufficient.
- To investigate Drug Supply Management, a Pharmacy Audit Tool and a Dispensary Healthcare Questionnaire were developed to allow for a fast and practical way of collecting all the relevant data from the dispensary staff.
- To investigate Clinic Procedures, a Clinic Procedure Audit Form was developed to determine whether follow up procedures for patients were in place.
- To investigate Training, a Staffing Audit Form and a Healthcare Questionnaire were developed that would allow for a fast and practical way of collecting all the relevant data from the health care workers.
- The audit tools and questionnaires were piloted in order to determine the reliability and validity.
- Data collected, using the audit tools and questionnaires, was captured on to an Excel® spreadsheet (Microsoft Limited) and analysed.

CHAPTER FIVE

RESEARCH METHODOLOGY

5.1 INTRODUCTION

In this chapter, the research methodology will be described in detail. Literature has shown that the implementation of the PMTCT programme in South Africa has faced many challenges. Consequently the success of the programme implementation in the different provinces has varied. (Meyers *et al.,* 2006: 235) Since the introduction of nevirapine mono-therapy for PMTCT in South Africa in 2001, not many studies have been done on the challenges faced by the PMTCT programme. In 2002, the Health Systems Trust undertook a study on the 18 PMTCT pilot sites in South Africa. The study highlighted challenges regarding human resources, management and physical infrastructure. Furthermore, there were differences in the implementation of PMTCT and uptake rates of patients between provinces and sites. The Health Systems Trust concluded that at the core of these differences were the inequalities in healthcare infrastructure within the country. (Health Systems Trust, 2002: 1) In 2008, the National PMTCT programme was changed from nevirapine mono-therapy to dual antiretroviral therapy (Department of Health, South Africa, 2008a).

This study focused on investigating the challenges faced at the various study sites on the implementation of the new dual therapy PMTCT policy. The data for the study was collected using purpose designed questionnaires administered to health care workers and purpose designed audit forms.

5.2 STUDY DESIGN

Research design according to Mouton (2001: 55) is described as a plan or blueprint of how one intends conducting the research. Descriptive research deals with the question of what things are like and depends on what we want to discuss (de Vaus: 2002: 18). This research was descriptive since the design assumes that the researcher already had basic knowledge regarding certain variables and circumstances associated with the researched topic (Struwig and Stead, 2001: 16-18). In quantitative studies, description typically refers to the characteristics of a population and a survey design is popular. Survey designs are often of a more quantitative nature requiring a questionnaire as a data collection method. (de Vos, 2002: 110)

Survey methodology is the most widely used approach employed by pharmacy practice researchers. It encompasses a wide range of research objectives in a variety of populations and

is a quick and cost effective method of obtaining information. This study was therefore, an empirical and descriptive survey study since the questionnaires were of the empirical type (explorative, descriptive and causal). (Smith, 2002: 1-2)

5.3 STUDY SITE

The research was conducted in Port Elizabeth, a city in the Nelson Mandela Bay Municipality (NMB), Eastern Cape Province, South Africa. The public health facilities in NMB are under one of two levels of public service authorities managing health services namely provincial government (Nelson Mandela Bay District Health and Port Elizabeth Hospital Complex, Department of Health Eastern Cape Province) and local government (Nelson Mandela Bay Municipality). The sites for the research study comprised of three tertiary hospitals (Dora Nginza Hospital, Livingstone Hospital and Port Elizabeth Provincial Hospital) which are managed by the Port Elizabeth Hospital Complex, two clinics (Motherwell Clinic and Walmer Clinic) which are managed by NMB District Health and four clinics (Chatty Clinic, New Brighton Clinic, Masakhane Clinic and Zwide Clinic) which are managed by the Nelson Mandela Bay Municipality. The sites chosen were a sample of the population and were selected as a convenience sample as the researcher had access to the sites as the researcher was employed by a NGO assisting in the PMTCT programme in the listed clinics.

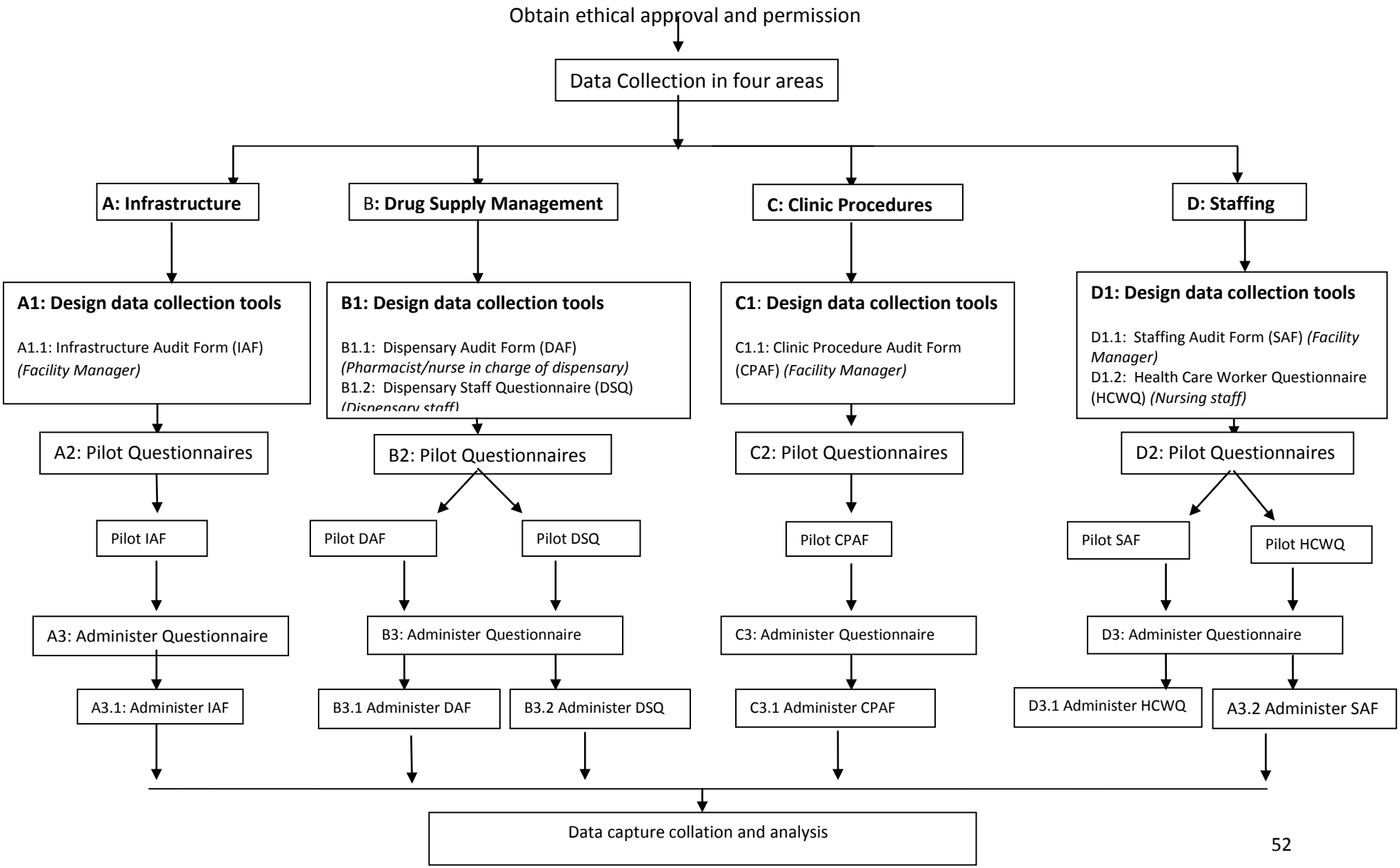
5.4 STUDY POPULATION

For this study data was collected pertaining to four areas Infrastructure; Drug Supply Management; Clinic Procedure and Staffing. Six data collection tools were designed and the study population varied depending on the area under investigation (Figure 5.1).

Infrastructural factors were investigated using a researcher administered, Infrastructure Audit Form (Figure 1: A1.1). The study population for the Infrastructure Audit Form was the Facility Managers at the research sites.

Drug Supply Management practices were assessed using two data collection tools namely a researcher administered Dispensary Audit Form (Figure 1: B1.1) and a respondent administered Dispensary Staff Questionnaire (Figure 1: B1.2). The study population for the Dispensary Audit Form consisted of the responsible pharmacist in charge of the dispensary or the nurse in charge of the medicine room. The study population for the Dispensary Staff Questionnaire was the dispensary staff at the research sites. This included pharmacists, post basic pharmacist

Figure 5.1: Flowchart of Methodology



assistants and basic pharmacist assistants who were on duty on the day the researcher issued the questionnaires at the facility.

Clinic procedures for patient follow up were investigated using a researcher administered Clinic Procedure Audit Form (Figure 1: C.1.1). The study population for the Clinic Procedure Audit Form was the Facility Managers at the research sites.

Human resource availability was investigated using both a Staffing Audit Form (Figure 1: D1.1) which the researcher administered at the research sites with the assistance of the Facility Managers and a respondent administered Health Care Worker Questionnaire (Figure 1: D1.2) which was issued to all clinical nursing staff. The study population for the Staffing Audit Form was the Facility Managers at the research sites. The study population for the Health Care Worker Questionnaire was the nurses at the research sites.

5.5 DATA COLLECTION

Data was collected using six purpose designed data collection tools (Figure 5.1):

- Infrastructure Audit Form;
- Dispensary Audit Form;
- Dispensary Staff Questionnaire;
- Clinic Procedure Audit Form;
- Staffing Audit Form; and
- Health Care Worker Questionnaire.

The data collection will be discussed separately for each of the four areas investigated i.e. Infrastructure; Drug Supply Management; Clinic Procedures and Staffing.

5.5.1 Infrastructure

This section examined the non human resource related aspects of infrastructure and whether there were insufficiencies in equipment and design of the facility that could create a barrier to the proper functioning of the PMTCT programme. Infrastructure in terms of space, shelving and storage areas was investigated using an Infrastructure Audit Form (Figure 5.1: A1.1).

5.5.1.1 Data collection tool design

The Infrastructure Audit Form: The purpose designed audit tool was constructed in the form of a check list (Appendix 1). The Infrastructure Audit Form addressed the topics of space and equipment. Space included sections on patient waiting area, clinical area, dispensary waiting

area and storage area. Equipment included sections on air conditioners and fridge thermometers. The Infrastructure Audit Form was researcher administered.

The Department of Health's Comprehensive HIV/AIDS Care, Management and Treatment Programme for South Africa includes a Facility Service Point Accreditation Form which facilities are required to complete and submit prior to accreditation as service points for the rollout of antiretrovirals (Department of Health, South Africa: 2004b). Physical space and medical waste management are components of this form and the Infrastructure Audit Form designed was based on these components of the Facility Service Point Accreditation Form. In order for confidentiality to be maintained adequate space is required for consultation, treatment and counselling of patients. Space is also required for the correct storage of antiretroviral medication.

5.5.1.2 Piloting of data collection tool

The Infrastructure Audit Form: The audit form was piloted, by the researcher, at a Primary Health Care clinic in the NMB, not involved in the current study. Any area of the audit form that was not clear was noted and amended in the final audit form. The time taken to complete the infrastructure audit form was recorded.

5.5.1.3 Administration of data collection tool

The Infrastructure Audit Form was completed by the researcher. Prior to arriving at the facility, the researcher set up an appointment with the Facility Manager. The Facility Manager accompanied the researcher during the audit and supplied the information required for the audit form.

5.5.2 Drug supply management

This section examined the following areas: procurement of stock; receipt of stock; delivery of stock; out of stock procedures; records maintained; storage conditions; stock levels; stock reconciliation; requirements in a pharmacy; and staff in the dispensary. For Drug Supply Management two data collection tools were designed (Figure 5.1: B1):

- Researcher administered Dispensary Audit Form (Figure 5.1: B1.1);
- Respondent administered Dispensary Staff Questionnaire (Figure 5.1: B1.2).

5.5.2.1 Data collection tool design

The Dispensary Audit Form: This audit form was administered by the researcher with the aid of the pharmacist/pharmacist assistant/nurse in charge of the pharmacy/medicine room (Appendix 2). The researcher physically audited the dispensary prior to completing the audit form. The audit form entailed questions on the presence or absence of requirements for a pharmacy such as stock level cards (bin cards), air conditioners and storage facilities. The audit form was designed in the format of tick boxes with Yes and No answers.

The Dispensary Staff Questionnaire: This questionnaire was respondent administered and consisted of 36 questions (Appendix 3). The pharmacy staff answered by ticking the most appropriate answer, however, the last question was open ended allowing the participant to give their own views. The questions addressed the key areas of: procurement; receipt and delivery of drugs; stock reconciliation and out of stock procedures.

Good Pharmacy Practice (GPP) in South Africa is a guideline issued by the South African Pharmacy Council that governs the practice of pharmacists and pharmacist assistants in South Africa. The GPP contains the standards and norms for pharmacy premises, equipment and services provided in a pharmacy. (South African Pharmacy Council, 2008: i-iii) The GPP was used as a guide in the design of the Dispensary Audit Form and the Dispensary Staff Questionnaire.

5.5.2.2 Piloting of data collection tools

The Dispensary Audit Form: This audit form was piloted by the researcher at a Primary Health Care clinic in the Port Elizabeth Metropole, not involved in the current study. Any areas of the audit form that were not clear were noted and amended in the final audit form. The time taken to complete the audit form was noted. The information recorded during the pilot study was not included in the final study data.

The Dispensary Staff Questionnaire: This questionnaire was piloted using four dispensary staff at a Primary Health Care clinic in the NMB, not involved in the current study. The dispensary staff included a pharmacist, post basic pharmacist assistant and basic pharmacist assistant. Prior to piloting the Dispensary Stock Control Procedure Questionnaire written informed consent was obtained from the dispensary staff involved. The time take to complete the Dispensary Staff Questionnaire was noted. Piloting was used to check that the questionnaire gathered reliable and valid data effectively and efficiently.

5.5.2.3 Administration of data collection tools

The Dispensary Audit Questionnaire: This audit form was completed by the researcher. The researcher set up an appointment with the Facility Manager and person in charge of the pharmacy/medicine room prior to arriving at the clinic or hospital, in order to ensure that the audit could be undertaken. The audit was undertaken by the researcher in the presence of the person in charge of the pharmacy.

The Dispensary Staff Questionnaire: This questionnaire was completed by the dispensary staff. The researcher hand delivered the questionnaires to the relevant staff members. The completed questionnaires were then collected after one week. Confidentiality was maintained at all times and no identifiers linked the staff members to the questionnaire. Permission was obtained from the Executive Director of Environment and Health for the Nelson Mandela Bay.

5.5.3 Clinic procedures for patient follow up

This section examined the following aspects of clinic procedures: referral of patients; patient follow-up and missed patients. A purpose designed data collection tool Clinic Procedure Audit Form was designed (Figure 5.1: C1.1). The Clinic Procedure Audit Form was researcher administered.

5.5.3.1 Data collection tool design

The data collection tool used for this section was a purpose designed audit form. The Clinic Procedure Audit Form (Appendix 4) was designed in the form of a check list. The Clinic Procedure Audit Form consisted of the following areas: procedures for referral of patients between facilities; missed patients (patients who required medication but were overlooked); and management of problem patients such as defaulters and non-adherent patients. The Clinic Procedure Audit Form was researcher administered.

One of the challenges identified in the Comprehensive HIV/AIDS Care, Management and Treatment Plan was the adherence by patients to antiretroviral therapy (Friedland, 2003: 39). Non-adherence and defaulting on ART results in resistance and virological failure. There are many reasons that cause a patient to become non-adherent to their antiretroviral therapy and to miss scheduled appointments at the facility. It is imperative that facilities are able to locate the defaulting patients in order to minimise resistance to antiretrovirals and increase the lifespan of the patient. It is also important for facilities to be able to manage patients that are referred to other facilities. The Standard Operating Procedure for referrals, defaulters and missed to follow ups of patients was used during the development of the Clinic Procedure Audit Form (International Centre for AIDS Care and Treatment Programme, 2009).

5.5.3.2 Piloting of data collection tool

The Clinic Procedure Audit Form: The audit form was piloted, by the researcher, at a Primary Health Care clinic in NMB, not involved in the current study. Any area of the audit form that was not clear was noted and amended in the final audit form. The time taken to complete the audit form was recorded.

5.5.3.3 Administration of data collection tool

The Clinic Procedure Audit Form was administered by the researcher. Prior to arriving at the facility, the researcher set up an appointment with the Facility Manager. During the audit, the Facility Manager supplied the information required to the researcher.

5.5.4 Staffing

This section addressed issues on demographics of staff, qualification of staff, training and problems encounted by staff and human resource shortages. In order to investigate staffing issues two purpose designed data collection tools were designed:

- Staffing Audit Form (Figure 5.1: D1.1); and
- Health Care Worker Questionnaire (Figure 5.1: D1.2).

5.5.4.1 Data collection tool design

The Staffing Audit Form: This audit form completed by the researcher with the assistance of the Facility Manager (Appendix 5). The Staffing Audit Form investigated topics such as staffing numbers, staff per patient ratio and human resource problems.

The increasing shortage of skilled health care professionals such as doctors, nurses, counsellors and pharmacists is one of the key challenges to the rollout of antiretrovirals to patients. The Staffing Audit Form was designed in order to ascertain the number of patients treated at the study facilities and the number of health care workers treating the patients.

The Health Care Worker Questionnaire: This questionnaire was respondent administered and consisted of 56 questions (Appendix 6). The questionnaire consisted of both closed and open ended questions. The questionnaire addressed the following: qualifications of respondent, training received, training required, and the respondents' knowledge about the dual PMTCT policy.

According to Lehmann (2008: 166), South Africa is experiencing a dramatic shortage of skilled professionals including nurses. In 2007, there were only 1.1 nurses to treat every 1000 persons

and only 42% of nurses worked in the public sector. In addition, 40% of the skilled nurses were to retire in the next five to ten years. (Lehmann, 2008: 167) Primary Health Care Facilities are nurse based and research has shown that nurses often feel ill-prepared in terms of the training they receive to render services (Lehmann, 2008: 170). The Health Care Worker Questionnaire was designed in order to determine the percentage of nurses nearing retirement age, the training the nurses had received on HIV, PMTCT and the new dual PMTCT policy.

5.5.4.2 Piloting the data collection tools

The Staffing Audit Form: This audit form was piloted by the researcher at a Primary Health Care clinic in NMB, not involved in the current study. Any areas of the questionnaires that were not clear were noted and amended in the final questionnaire. Piloting was undertaken in order to check that the questionnaire gathered reliable and valid data effectively. The time taken to complete the audit form was noted.

The Health Care Worker Questionnaire: This questionnaire was piloted using five sisters at a Primary Health Care clinic in NMB, not involved in the current study. Prior to piloting the Health Care Worker Questionnaire written informed consent was obtained from the health care workers. The time taken to complete the Health Care Worker Questionnaire was recorded. Piloting was used to check that the questionnaire gathered reliable and valid data effectively and efficiently.

5.5.4.3 Administration of the data collection tools

The Staffing Audit Form: This audit form was completed by the Facility Manager. Prior to arriving at the facility, the researcher set up an appointment with the Facility Manager. The sister completed the audit form by herself. The researcher collected the audit forms one week later from the Facility Manager.

The Health Care Worker Questionnaire: This questionnaire was completed by the nurses at the research sites. The researcher hand delivered the questionnaires to the relevant staff members. The questionnaires were collected after one week. Confidentiality was maintained at all times. No identifiers linked the staff member to the questionnaire. Informed consent was obtained from the respondents.

5.6 DATA ANALYSIS

The data from the completed questionnaires and audit forms was captured on a purpose designed Excel® (Microsoft Limited) spreadsheet and analysed.

5.7 STATISTICAL ANALYSIS

Descriptive statistics were used to quantitatively describe the data in this study. Statistica® Version 9 (Statsoft Incorporated) was used for statistical analysis. Descriptive statistics are used to give a description of the data by determining measures of location and expressing variability (Willis, 2004: 77) i.e. descriptive statistics simply describe what is or what the data shows and are used to present quantitative description in a manageable form, help to simplify large amounts of data in a sensible way and provide a summary that enables comparison across people or other units. Where appropriate the results were presented as mean ± standard deviation. The results were tabulated and reported graphically based on the statistical information compiled. The interpretation of the results was done at the same time as the analysis.

5.8 ETHICAL CONSIDERATIONS

The principles embedded in the Helsinki Declaration (World Medical Association, 2008) were adhered to, the basic principle of which is "first do no harm". Confidentiality and anonymity of participants was maintained at all times. Prior to conducting this research the following steps were followed. Ethical approval was requested from The Faculty of Health Sciences Research Technology and Innovation Committee as well as the Nelson Mandela Metropolitan University Research Ethics Committee (Human). The study then required permission from the Department of Health, Eastern Cape and the Nelson Mandela Bay Municipality Public Health for access to the research sites and statistics. This was requested from the Chief Executive Officer of the Port Elizabeth Hospital Complex, Department of Health Eastern Cape Province, the Director of Health for NMB and the Epidemiological Research and Surveillance Management Department, Bisho. Permission was also requested from International Centre for Aids Care and Treatment Programs (ICAP) for permission to utilise epidemiological statistics. Furthermore informed written consent (Appendix 7) was obtained from each participant, who was involved in the research, prior to participation.

5.9 LIMITATIONS OF THE STUDY

The following limitations were encounted:

- A comprehensive list of all nurses employed was not available at each site. In addition the nurses worked shifts and thus only the nurses who were on duty at the time the researcher administered the Health Care Worker Questionnaires were selected as the study sample;

- Some of the questions on the questionnaire were not answered by the health care workers resulting in missing data; and
- The study was descriptive in nature and assisted in identifying the problem areas requiring further study. It did not provide solutions to these problems, but rather highlighted which areas should be given priority.

CHAPTER SIX

RESULTS AND DISCUSSION

6.1 INTRODUCTION

This chapter will present the results of the research and discuss them according to the research objectives. Statistica® Version 9.0 statistical package was used to analyse the data. The findings will be presented according to the four categories that were investigated: infrastructure, drug supply management, clinic procedure and staffing. Where appropriate the results will be presented as percentages and mean ± standard deviation.

6.2 ETHICAL CONSIDERATIONS

Ethical approval for this study was granted by the Faculty of Health Sciences Research Technology and Innovation Committee NMMU and the NMMU Research Ethics Commitee (Human): Reference Number H09HeaPHA002 (Appendix 8). Approval for the study was also granted by the Chief Executive Officer of the Port Elizabeth Hospital Complex (Appendix 9), the Executive Director for Health and Environmental Sciences in the Nelson Mandela Bay Municipality (Appendix 10) and the Epidemiological Research and Surveillance Management Department in the Department of Health, Eastern Cape Province (Appendix 11). Permission was also granted by the International Centre for Aids Care and Treatment Programs (ICAP) to utilise epidemiological statistics (Appendix 12). The study was undertaken in accordance with the principles embedded in the Helsinki Declaration (World Medical Association, 2008).

6.3 INFRASTRUCTURE

6.3.1 Introduction

A suitable infrastructure is essential for the delivery of any form of health care. In order for an antiretroviral facility to be accredited by the Comprehensive HIV/AIDS Care, Management and Treatment Programme, at the Department of Health, certain criteria have to be met. The Facility Service Point Accreditation Form provided by the Department of Health provides the criteria that each facility has to meet (Department of Health, South Africa, 2004b). Physical space and medical waste management form part of the criteria. Sufficient space is required for consultation, counselling, treatment and storage of clinical equipment and medication. Sufficiency was addressed by the healthcare personnel at the study facilities in terms of their needs. The Infrastructure Audit Form was designed using the Facility Service Point Accreditation Form as a guideline against which the criteria for the audit form was selected.

The physical condition of facilities deteriorates over time and the volume of patient's seen at the clinics changes over time. Data relating to facility infrastructure should, therefore, be collected on a regular basis. The data for this study was collected only once and the results are therefore, for the facility at a particular time period.

6.3.2 Study population and site

The study population included all nine facilities (n=9). The data was collected by the researcher using the researcher administered Infrastructure Audit Form. The Facility Manager accompanied the researcher during the audit and provided the information required for the Infrastructure Audit Form. As the researcher collected the information the response rate was 100% (9; n=9).

The Infrastructure Audit Form was piloted by the researcher at a Primary Health Care Clinic in NMB, not involved in the current study. No amendments were made to the Audit Form. The time taken to complete the audit form was one hour.

6.3.3 Infrastructure availability

Sufficiency was defined by the Facility Manager in terms of the needs of the facility based on the number of patients serviced by the clinic. Infrastructural availability was investigated with regards to: waiting areas; patient consultation, treatment and counselling areas; administrative areas; staff facilities; storage areas and waste management.

6.3.3.1 Waiting areas

All the facilities (9; 100%; n=9) studied had waiting areas for their patients, however, all the respondents (9; 100%; n=9) indicated that the space in the waiting area was not sufficient for the volume of patients seen at the facility (Figure 6.1). Only 22.2% (2; n=9) of the facilities stated that the waiting area at the pharmacy was adequate (Figure 6.1). Due to the increasing patient load at the various clinics, the space for waiting areas was no longer adequate for the current volumes of patients seen at the clinics.

The Department of Health's Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment indicated, in the projections of patient targets, that there would be an increase by 50-60% in patient numbers each year (Department of Health South Africa, 2003: 105). Mandal *et al.* (2006: 175) reported that due to poor infrastructure specialised projects such as HIV/AIDS programmes had not achieved their targets. In a study, undertaken by Janse van Rensburg-Bonthuyzen *et al.* (2008: 109) on resource and infrastructure for the delivery of antiretroviral therapy at Primary Health Care facilities in the Free State Province, the most frequently reported problem was lack of space especially regarding consulting rooms and

waiting areas for the Comprehensive HIV/AIDS Care, Management and Treatment Programme. Despite renovations to the facilities space was a recurrent problem due to the increase in the number of patients. Thus, although the facilities in the current study had waiting areas for patients, the space for the patients was not adequate due to increasing patient numbers.

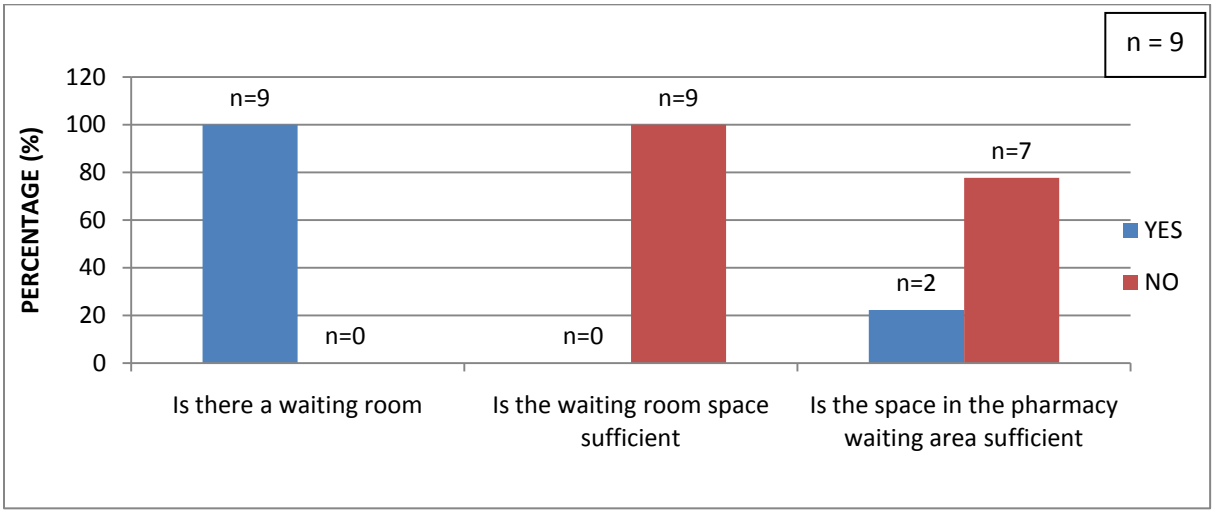


Figure 6.1 Availability of space for patient waiting rooms/areas

A high number of the facilities (7; 77.7%; n=9) indicated that there was no separate waiting area for patients with tuberculosis. Tuberculosis is a highly contagious infection and apart from the HIV positive patients, who are at high risk of contacting opportunistic infections such as tuberculosis, there are also other patients such as paediatric patients, geriatric patients and immune-compromised patients who are also at risk of exposure to tuberculosis. A separate waiting area for patients with tuberculosis is required, or if this is not feasible, methods should be in place to fast track patients to decrease their time spent in the general waiting areas and thus decreasing the exposure of other patients to tuberculosis. One possible method to fast track patients would be to screen and triage patients from the very first point of entry i.e. at reception. In addition, waiting areas in more than half (6; 66.7%; n=9) of the facilities were not well ventilated and only 55.6% (5; n=9) of closed areas such as consulting rooms and counselling rooms were well ventilated.

6.3.3.2 Patient consultation, treatment and counselling areas

Six of the nine facilities (6; 66.6%, n=9) did not have enough space for the nurses to perform their function (Figure 6.2). All patients at the facilities are first screened by a nurse in order to check vital signs such as blood pressure and weight. In addition, only five of the facilities (55.5%; n=9) had an area for patient counselling and six of the facilities (66.6%; n=9) did not have enough space for the lay counsellors to enable confidential counselling (Figure 6.2).

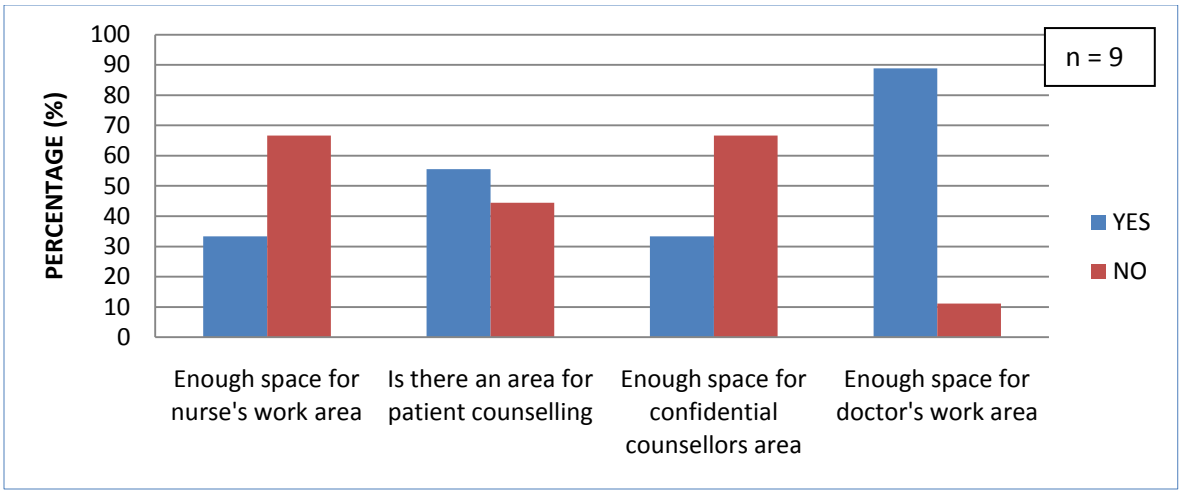


Figure 6.2 Space available for working areas for nurses, counsellors and doctors

Due to the increase in awareness of HIV and AIDS the number of people arriving at the facilities in order to receive voluntary counselling and testing for HIV is also increasing. Hence the numbers of patients seen by the counsellors are increasing each day. The danger of having limited space to perform necessary functions is two-fold. Firstly, the patient might be shunted from area to area when there is not enough space. Poor infrastructure has been shown to significantly affect a patient's perception of quality of care (Rao *et al.,* 2006: 414). Secondly, the moral and frustration levels of the health care workers may be negatively affected as seen in a studies done by Kotzee and Couper (2007: 581) and King and McInerney (2006: 74). The HIV and AIDS epidemic has resulted in new infrastructural needs that had not previously been envisaged, such as private consulting rooms for counselling and testing, and space for the additional staff (Lutge and Mbatha, 2007: 9). One of the barriers to the effective provision of the PMTCT programme is lack of space for consulting and counselling (Phaswana-Mafuya and Kayongo, 2008). Counselling HIV positive patients is an integral part of monitoring adherence to treatment, not only to understand the disease process, complications and disclosure but also the correct drug, dose, and dosage intervals which ultimately benefits the patients. Research conducted by the Health Systems Trust (2002: 15) on the PMTCT pilot sites found that barriers to the implementation of PMTCT included lack of space for counselling of patients. Other studies have shown that inadequate space for confidential counselling and private disclosure inhibits the uptake of PMTCT services (Skinner *et al.,* 2003: 14; World Health Organisation, 2007a). Doherty *et al.* (2005: 217) found that lack of privacy in delivery rooms may prevent women from disclosing their HIV status when asked by a health care worker. Lack of space will impact on the privacy of a counselling session and the quality of counselling offered for PMTCT (Skinner *et al.*, 2003: 14). However, 88.8% (8; n=9) of the facilities had enough space for the doctor to consult (Figure 6.2). This could be due to the fact that the majority of the clinics are nurse driven and the doctors only visit the clinic once or twice per week.

6.3.3.3 Administrative areas

Many (7; 77.7%; n=9) of the facilities did not have sufficient space for filing of patient files and administrative work (Table 6.1). One of the requirements for the accreditation of an ARV site is sufficient space for administrative work and record keeping (Department of Health, South Africa, 2008a: 70). None of the facilities in the study were computerised in terms of filing and physical files for each patient were kept on the premises. As the patient load increases so too does the number of files. In addition, the clinics do not have space for an Archive Department and keep all inactive files (files of deceased patients and defaulter patients) in the same area as the active files thereby leaving less space for the effective storage of active files.

Table 6.1 Availability of space for administrative functions, staff facilities and storage of clinic stock

INFRASTRUCTURE (n = 9)	**YES**		**NO**	
	(No.)	**(%)**	**(No.)**	**(%)**
ADMINISTRATION				
Is there sufficient space for filing	2	*22.2*	7	*77.7*
STAFF FACILITIES				
Is there a staff tea room	8	*88.8*	1	*11.1*
Are there sufficient staff toilets	5	*55.5*	4	*44.4*
Are the sufficient patient toilets	8	*88.8*	1	*11.1*
STOCK				
Is there sufficient space for storage of all stock used by clinic (e.g. syringes)	4	*44.4*	5	*55.6*
Is the storage area secure	6	*66.6*	3	*33.3*
Is the storage area under appropriate conditions	3	*33.3*	6	*66.6*

6.3.3.4 Staff facilities

Eight of the facilities (88.8%; n=9) had a staff tea room (Table 6.1). Five of the facilities (5; 55.6%; n=9) stated that there were sufficient staff toilets and 88.9% (8; n=9) of the facilities had sufficient patient toilets. Sanitation and a healthy and safe environment is an elemental right for all citizens.

6.3.3.5 Storage areas

Four (44.4%; n=9) of the facilities stated that there was sufficient space for the storage of all stock used by the clinic (Table 6.1). Only 33.3% (3; n=9) of the facilities indicated that the storage area was not secure. However, only 33.3% (3; n=9) of the facilities stated that the stock

in the storage area was stored under the appropriate conditions i.e. correct temperature, light and humidity (Table 6.1).

6.3.3.6 Waste management

Five of the facilities (55.5%; n=9) had an area designated for waste management (Figure 6.3). Healthcare waste is defined as the total waste generated in health care facilities and in addition to hospitals and clinics includes waste generated by blood banks, research facilities and laboratories (Pruss *et al.*, 1999: 2). In a study, undertaken by Leonard (2002) approximately 45% of health care waste generated in the province of KwaZulu-Natal was not accounted for. The management of healthcare waste is of great concern as incorrect disposal of the waste or incinerating the waste, with resultant emissions of dangerous chemicals, may threaten public health and the environment (Malkan, 2005: 568).

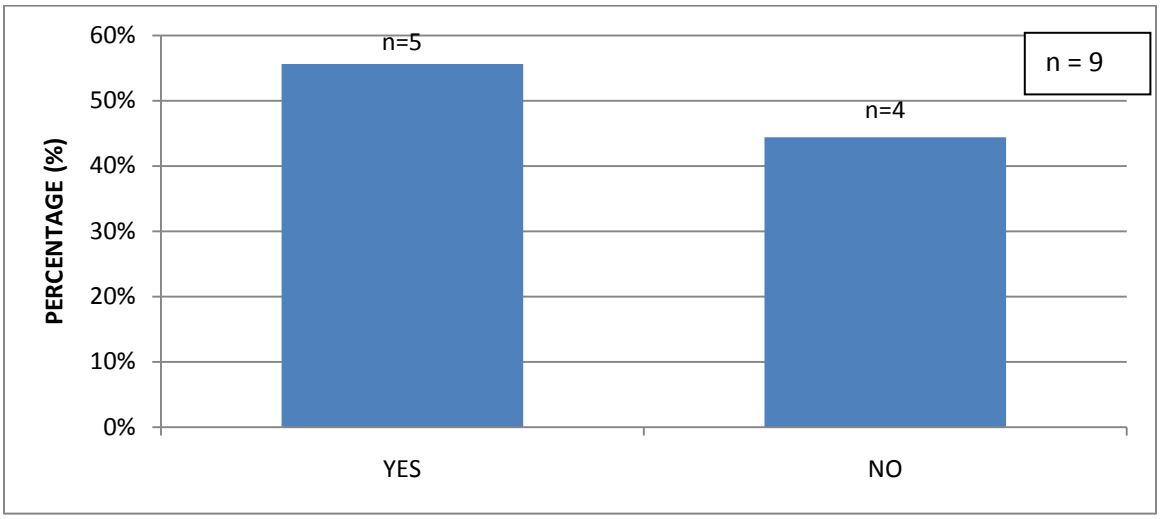


Figure 6.3 Availability of space for an area for waste management at the study facilities

6.3.4 Summary of Infrastructure Audit

The aim of this study is to evaluate the challenges experienced by the health care workers on implementation of the dual therapy PMTCT protocol and to make recommendations to the Department of Health in NMB on ways of minimising the challenges encounted.

In this section the researcher explored the infrastructural challenges with regards to space available for waiting areas for patients; consulting areas for nurses, counsellors and doctors; administrative functions; staff facilities; storage and waste management areas. Some of the key findings in this study were that all the facilities (9; 100%; n=9) reported that there was insufficient space in the general waiting room for patients and in the pharmacy waiting area (7; 77.7%; n=9). Sixty seven percent (6; n=9) of the facilities did not have sufficient work space for

the nurses and counsellors. Seventy eight percent (7; n=9) of the facilities did not have sufficient space for filing. In addition, 44% (4; n=9) of the facilities did not have space available for an area for waste management.

Space was the main problem identified in this section. Lack of space for staff to work will cause demotivation of staff and increase the probability of a high staff turnover. In addition, lack of space will impact the privacy of counselling sessions and the quality of counselling offered for PMTCT. Counselling is an integral part of PMTCT and requires an area that will enable effective counselling. Limited space in waiting rooms for patients will also decrease the uptake rate of patients into the PMTCT programme. The infrastructure of the facilities should be an ongoing priority to enable effective provision of PMTCT.

6.4 DRUG SUPPLY MANAGEMENT

6.4.1 Introduction

A key component of the PMTCT is the reliable provision of ARV medication. The availability of medicines is dependent on the accurate monitoring of stock levels of the medication. Good record keeping systems are crucial for monitoring stock levels. The Department of Health envisaged an efficient and secure process for the storage, distribution and appropriate utilisation of ARV medication for the public health care sector in the Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment (Department of Health, South Africa, 2003: 155-156).

Two data collection tools were designed in order to collect data for this section - the Dispensary Audit Form and a Dispensary Staff Questionnaire. In keeping with the vision of the South African Pharmacy Council, which is to ensure that the best pharmaceutical services are available to meet the healthcare needs of the people, the South African Pharmacy Council developed GPP standards (South African Pharmacy Council, 2008). The aim of the GPP standards is to ensure that high quality pharmaceutical services are provided in both the public and private sector. The Dispensary Audit Form was developed, using the GPP guidelines on maintaining professional standards for premises by adhering to minimum standards for pharmacy facilities and equipment. The audit was completed by the researcher. The Dispensary Staff Questionnaire focused on the aspects from the GPP standards that dealt with maintaining professional standards for services provided in a pharmacy namely storage, procurement and distribution of ARV medication. The questions were completed by the respondents who were pharmacists, post basic pharmacist assistants, basic pharmacist assistants and a nurse.

6.4.2 Dispensary Audit

The dispensary Audit Form was used to investigate whether the premises and equipment were in line with GPP requirements.

6.4.2.1 Study population and site

The study population, for this component of the study, involved nine facilities with a total of nine dispensaries and one medicine room (n=10). The facilities included three hospitals and six clinics. One of the clinics had two dispensaries namely a Primary Health Care dispensary and a dispensary for ARV medication. Both dispensaries were included in the study. The data was collected by the researcher, using the Dispensary Audit Form which was in the form of a checklist. As the researcher collected the information the response rate for the Dispensary Audit Form was 100% (10; n=10).

The Dispensary Audit form was piloted by the researcher at a Primary Health Care clinic in NMB, not involved in the current study. No amendments were made to the Audit Form. The time taken to complete the audit form was 45 minutes.

6.4.2.2 Standards pertaining to the dispensary and the medicine room

According to GPP, the storing, compounding, dispensing or supply of medicines by a pharmacist, pharmacist intern or pharmacist's assistant may only take place in premises which comply with minimum standards relating to premises, facilities and equipment. The premises must be licensed by the Department of Health and recorded in terms of the Pharmacy Act (South African Pharmacy Council, 2008: 9). This study investigated the following minimum standards relating to premises, staffing facilities and equipment: control of access to pharmacy premises, safety of premises, condition and hygiene of premises, storage areas in premises, waiting and counselling areas, equipment and reference material in premises.

(i) Classification and Management of premises

Of the nine facilities, there were nine dispensaries and one medicine room. In a Primary Health Care clinic where the services are provided by a post basic pharmacist's assistant or pharmacist the room used to dispense and store medication is a dispensary whereas if the services are provided by a licensed dispenser such as a nurse then the room used to store medication is called a medicine room (South African Pharmacy Council, 2008: 30). The conditions for premises and equipment are the same for both the dispensary and the medicine room. The data collected from the dispensaries and the medicine room was therefore pooled and analysed as one group.

According to GPP, a pharmacist, pharmacist intern and/or post basic pharmacist assistant working under the indirect supervision of a pharmacist may supply medication in a pharmacy. In cases where the pharmaceutical services in a Primary Health Care facility not provided by a pharmacist they may be provided by a post basic pharmacist working under the indirect supervision of a pharmacist (in a dispensary) or a nurse licensed to dispense medicines (in a medicine room). At Primary Health Care clinics where the service is provided by a post basic pharmacist assistant, indirect supervision may only take place if the pharmacist visits and documents each visit to the clinic once a month and only pre-packed and repackaged medicines are provided to the clinic (South African Pharmacy Council, 2008: 30). In this study, 70% of the facilities (7; n=10) indicated that pre-packed medicines were provided. Only one (10%; n=10) of the facilities indicated that a pharmacist did not visit at least once a month.

Of the 10 dispensaries/medicine room in the study, 60% (6; n=10) of the dispensaries were staffed with basic pharmacist assistants, 80% (8; n=10) of the dispensaries had post basic pharmacist assistants and only one (10%; n=10) had a registered nurse as dispenser (Figure 6.4). None of the dispensaries (0; 0%; n=10) were staffed by a basic pharmacist assistant alone. At three of the dispensaries the pharmacist only worked one day a week and rotated between five or more facilities.

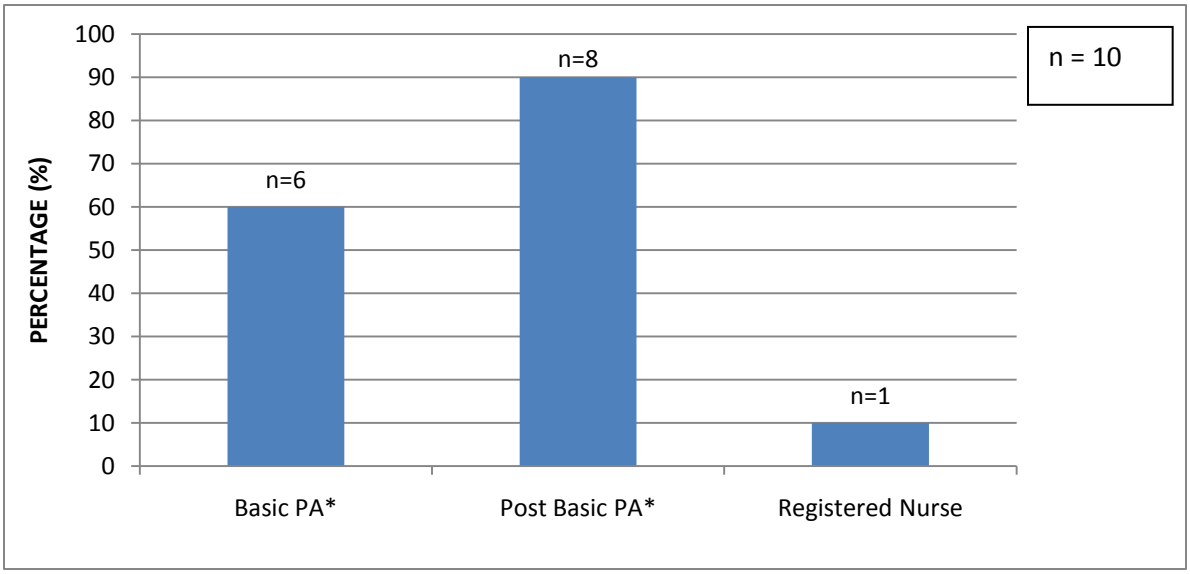


Figure 6.4 The number of facilities that had a basic pharmacist assistant, post basic pharmacist assistant and registered nurse staffing the dispensary/medicine room
*PA = Pharmacist Assistant

Only 50% of the dispensaries (5; n=10) had Standard Operating Procedures (SOPs) available in the dispensaries. One of the requirements for GPP and for the accreditation of a facility as a Comprehensive HIV/AIDS Care, Management and Treatment site is the availability of SOPs in

the pharmacy and the implementation of the SOPs (Department of Health, South Africa, 2004b; South African Pharmacy Council, 2008: 18). To comply with clinical governance requirements, health care professionals including pharmacists are required to put in place strategies for risk management, harm minimisation and to ensure that the systems operating within the premises are safe (Royal Pharmaceutical Society, Great Britain: 2007).

Sixty percent (6; n=10) of the facilities maintained their stock control cards/bin cards. Monitoring stock levels is highly dependent on good record keeping. All the facilities used bin cards as a means to record medication stock levels. The purpose of a bin card as an inventory management system is to obtain the right medication, monitor the medication intake and flow of goods within the system. The bin cards also function as a performance monitoring system in that it can be used to check that the system is operating effectively and assist management with decision making (Management Sciences for Health, 2000: 21). The GPP as well as the SOPs for the facilities requires 100% compliance with regard to inventory management tools such as the bin card system. Without an accurate record of the amount of stock available it is very easy for stock to be stolen, and very difficult to maintain the required amount of stock for the facility. The results showed that not all the dispensaries were compliant with GPP and Department of Health protocols in that only 50% (5; n=10) of the dispensaries had SOPs available in the dispensaries and only 60% (6; n=10) of the dispensaries maintained their bin cards.

(ii) Security of premises

The dispensary in all the facilities studied (10; 100%; n=10) abided by the GPP standards for access control in that the dispensary was locked at all times and the keys of the dispensary were kept on authorised personnel at all times. Security in a pharmacy is of utmost importance to prevent theft of medication.

In South Africa each province operates its own drug Depot that provides drug storage and distribution services to the public health centres in the province. Some Depots had strong security mechanisms and inventory-tracking information management systems in place, while others did not. Those that did not have these systems experienced higher rates of theft and stock-outs. It was estimated that in the public sector a significant amount of pharmaceutical products were lost during the process of distribution and storage and the majority of loss was attributed to theft. (Department of Health, South Africa, 2003: 155-156). One of the major problems in stock management was the theft of medicines from the public sector especially when dealing with expensive medicines such as ARV drugs that have a high value both in developed and developing countries. The Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment proposed major investments in the distribution and secure

storage of medicines as well as increasing dramatically the number of pharmacists in the public sector (Department of Health, South Africa, 2003: 155-159).

(iii) Safety of premises

Of the nine facilities, one facility had a medicine room. According to GPP, in premises where the services are provided by a licensed dispenser, the dispensing must be done in the consulting room and not the medicine room. The medication is stored in the medicine room and transported to the consulting room on a daily basis in a lockable trolley or tray and medicine must not be stored in the consulting room. (South African Pharmacy Council, 2008: 37) In this study, there was no lockable cupboard in the consulting rooms of the nurses dispensing (0; 0%; n=1) and the medicine was not transported in a lockable trolley from the medicine room to the consulting rooms (0; 0%; n=1). The medication was not taken back for storage at the end of the day at the facility with a medicine room (0; 0%; n=1). Thus, there is a possibility of theft occurring.

(iv) Condition of premises

In the majority of the facilities the dispensary (8; 80%; n=10) was easily accessible to the patients i.e. patients could easily find the dispensary and receive their medication and 70% (7; n=10) of the dispensaries were easily accessible to the dispenser. Accessibility of the dispensary for the patient was determined by the dispenser according to the patient's ease of access to the dispensary. This was determined by the closeness of the dispensary to the clinic consulting rooms, the ease of movement in the corridors and the signage indicating the dispensary's location. The accessibility of the dispensary for the dispenser was determined by dispenser according to the dispenser's ease of access to the dispensary. One of the reasons given by the dispensers for the lack of easy accessibility to the dispensary was the high volume of patients in the facility that crowded the corridors.

According to GPP guidelines the patients must have easy access to the dispensaries (South African Pharmacy Council, 2008: 21). This is especially important in facilities that are constrained in terms of space and that have high patient numbers.

In half (5; 50%; n=10) of the facilities studied, the area of the dispensary premises was >20 m^2 leaving 50% of the dispensaries with a space of <20 m^2. The GPP manual indicates that the size of the dispensary must reflect the volume of prescriptions dispensed in order to allow a safe and efficient flow of work and effective communication and supervision for the number of persons working in the dispensary (South African Pharmacy Council, 2008: 15). One of the aims of the NSP (2007-2011) is to scale-up the coverage of PMTCT (Department of Health, South Africa, 2007a: 9), hence the number of patients accessing treatment at Primary Health Care

facilities is likely to increase. Thus, there is a probability that the space in the dispensaries would not be sufficient for effective provision of dispensing services.

The results show that 70% (7; n=10) of the dispensaries indicated that they had enough space to work efficiently in that they had enough space for all the staff to dispense the patient's medication. Of the 10 dispensaries 80% (8; n=10) also had enough countertop space for dispensing the volume of prescriptions. However, space for administrative work and pre-packing was limited in most of the dispensaries. Pre-packing can only be done at facilities were a pharmacist is present (South African Pharmacy Council, 2008: 153). Pharmacists were available at five of the facilities on a full time basis and at three facilities on a rotational basis, hence eight of the facilities could pre-pack medication. Only 50% (5; n=10) and 40% (4, n=10) of the dispensaries had enough space for these functions respectively (Figure 6.5). Thus in the majority of the dispensaries there was enough space to dispense the volume of prescriptions received daily.

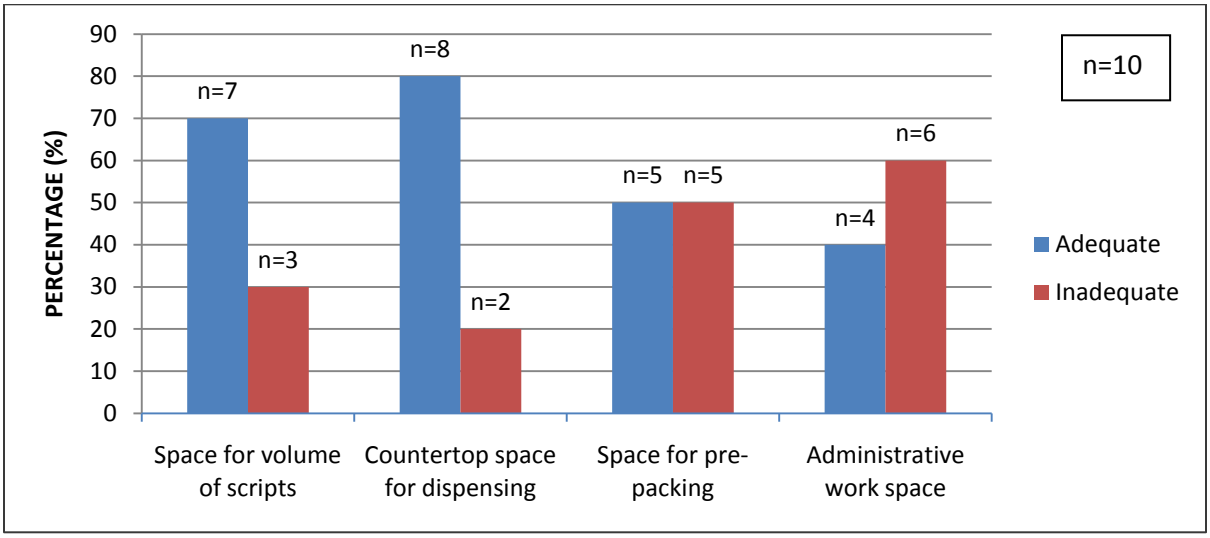


Figure 6.5 Adequacy of space in the dispensaries for the flow of work

The majority of the facility dispensaries (8; 80%; n=10) had a refridgerator that was in good working order and (9; n=10) of the dispensaries had a thermometer in the fridge and recorded the temperature of the refridgerator (Figure 6.6). However, only (7; n=10) of the dispensaries recorded the temperature twice a day. A refridgerator equipped with a suitable thermometer which is capable of storing products at temperatures between 2˚C and 8˚C must be available in a dispensary according to the GPP (South African Pharmacy Council, 2008: 14). Thus two (20%; n=10) dispensaries were not compliant with GPP requirements for functioning as a pharmacy. Recording the temperature of the refridgerator twice a day will ensure that if any problem occurs with the refridgerator it will be noted in good time. The proper storage of thermo-labile medication must be followed at all times to ensure the effectiveness of the medication. This is

especially relevant to certain antiretroviral medication which requires refridgeration and storage between 2˚C and 8˚C (South African Pharmacy Council, 2008: 14). Although the majority (8; 80%; n=10) of the dispensaries complied with GPP requirements for refridgerators the result should have been 100% in order to compliant with GPP.

In all the dispensaries that had refridgerators (8; 80%; n=10) the refridgerators were used only for pharmaceutical products and no food or beverages were stored in the refridgerators. The GPP guideline for refridgerators used for the storage of pharmaceuticals does not allow for the storage of food or beverages. Thus the eight (80%; n=10) facilities in this study abided by GPP.

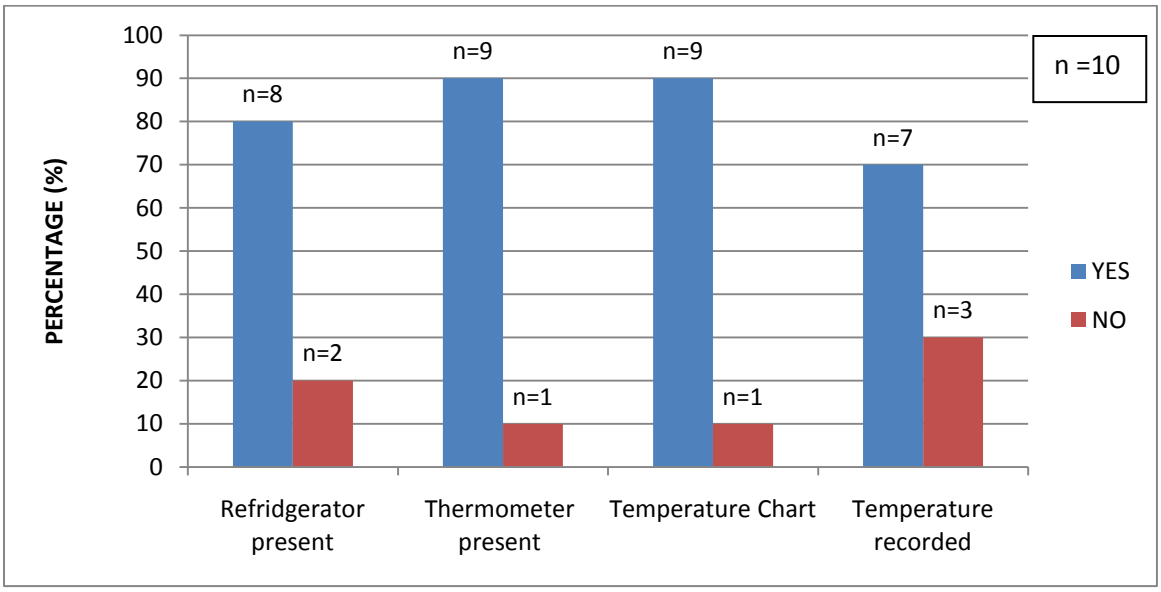


Figure 6.6 Availability of a refridgerator, thermometer and the recording of refridgerator temperature

The results showed that 70% (7; n=10) of the facilities had a computer which was in working order while 30% (3; n=10) of the facilities had a computer which was not functional (Figure 6.6). One of the drug capacity indicators for the Comprehensive HIV/AIDS Care, Management and Treatment accreditation form is a computerised medicine inventory system. During the audit, the researcher found that although 7 (70%; n=10) of dispensaries had a computer only 4 (40%; n=10) used a computerised medicine inventory system. A computerised medicine inventory system decreases errors and increases the accuracy of maintaining stock levels of medicines.

Only 60% (6; n=10) of the facilities had a fire extinguisher present in the dispensaries. All public facilities must have an up dated fire extinguisher on the premises (South African Pharmacy Council, 2008: 15) (Figure 6.7). Thus 40% (4; n=10) of the facility dispensaries did not comply

with GPP. This is a hazard in the case of an emergency that requires a fire extinguisher as dispensaries store flammable substances.

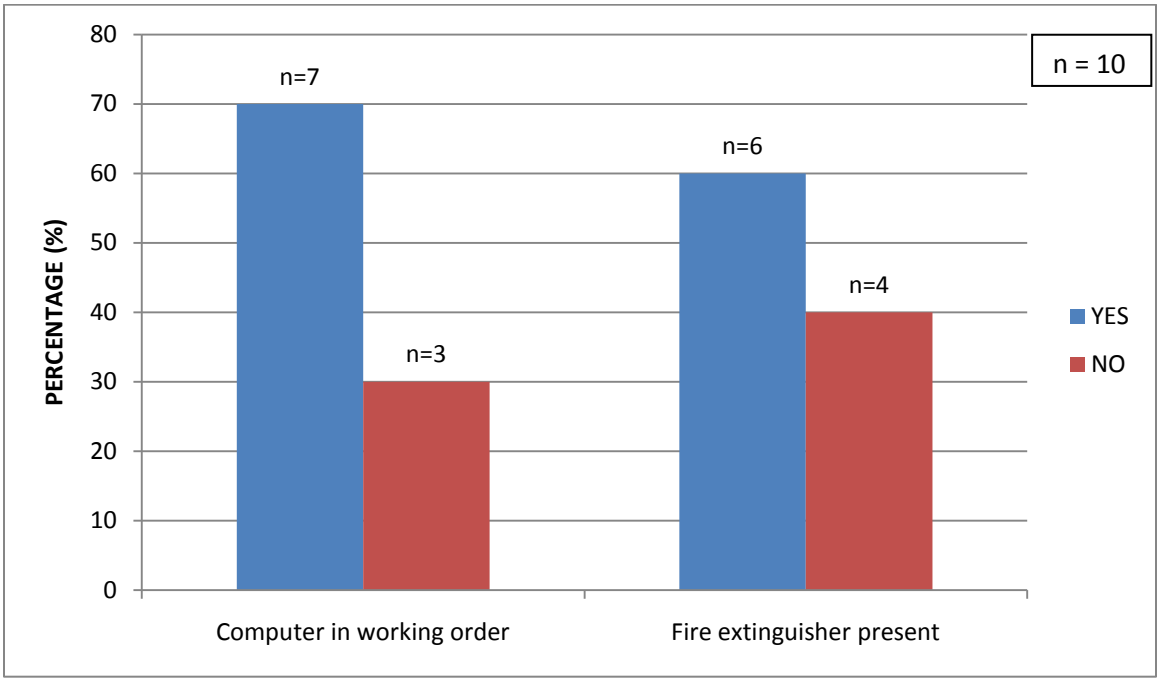


Figure 6.7 Availability of a computer and fire extinguisher

The results show that seven (70%; n=10) of the dispensaries had an air conditioner and of those dispensaries, six (60%; n=10) had air conditioners that were working. Seven (70%; n=10) of the dispensaries had a room thermometer present and only six (60%; n=10) of the dispensaries recorded the room temperature twice a day. (Figure 6.8) The temperature in a dispensary must be less than 25˚C and the premises must be fitted with an air conditioner in good working order (South African Pharmacy Council, 2008: 15). One of the SOPs for the Eastern Cape Department of Health Pharmacies is the recording of room temperatures twice a day (Department of Health, South Africa, 2005). In order to preserve the shelf life of medication the storage conditions must be adhered to (South African Pharmacy Council, 2008: 15). The results indicated that three of the nine facilities did not have an air conditioner present in the dispensary. These dispensaries did not comply with GPP. Medication is, therefore, not stored according to the specified storage conditions recommended by the drug manufacturers.

In 80% (8; n=10) of the dispensaries the walls and floors were clean and in 90% (9; n=10) of the dispensaries the countertops were finished in a smooth, washable and impermeable material. According to GPP the walls, floors, windows, ceilings and woodwork of the premises must be kept clean and in such a good order, repair and condition as to enable them to be effectively

cleaned and to prevent as far as reasonable practicable, any risk of infection (South African Pharmacy Council, 2008: 13). Thus, there was failure to comply with GPP requirements.

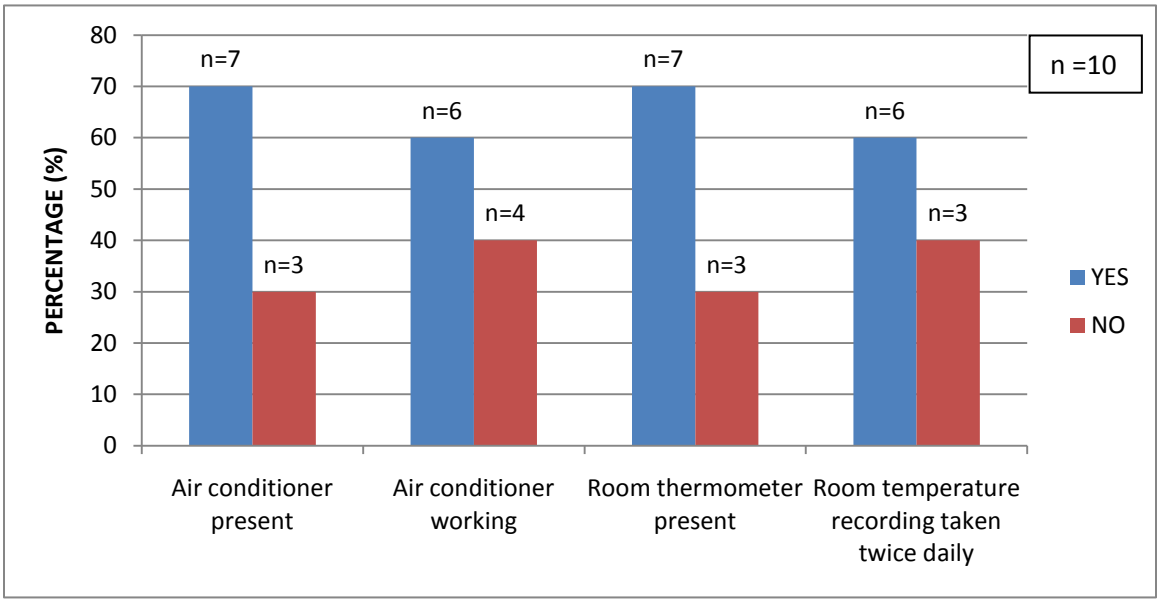


Figure 6.8 Presence of air-conditioning and standard operating procedures for temperature control

Only 60% (6; n=10) of the facilities had a closed receptacle for waste. The GPP guidelines state that waste material must be collected in a suitable covered receptacle for removal. Furthermore, waste material must not be allowed to accumulate and under no circumstances must substances be disposed of down surface water drains. Thus the results show that although a high number of the facilities adhered to GPP with regards to hygienic surface areas, only 40% (4; n=10) of the facilities had the required closed receptacle for waste disposal. Most (8; 80%; n=10) of the facilities had a hot and cold water wash basin in the dispensary. In keeping with the hygiene of a dispensary the GPP states that a suitable clean wash hand basin must have a source of hot and cold tap water to ensure that all equipment and other utensils can be washed. (South African Pharmacy Council, 2008: 14).

(v) Storage areas

Only 60% of the clinics (6; n=10) had sufficient shelving for medication and had storage areas that were large enough to allow for orderly arrangement and proper stock rotation of medication. Sufficiency was determined by the dispenser in charge of the dispensary in terms of the needs of the clinic. The GPP and the Accreditation Form for Comprehensive HIV/AIDS Care, Management and Treatment requires a dispensary to have sufficient shelving for

pharmaceuticals and a large enough storage area to ensure proper and effective functioning (South African Pharmacy Council, 2008: 14; Department of Health, South Africa, 2004b).

(vi) Waiting and Counselling areas

Analysis of the waiting areas in the facilities showed that 80% (8; n=10) of the facilities had a waiting area near the dispensary but in 70% (7; n=10) of the facilities the seating was not adequate for the needs of the dispensary. The GPP states that a waiting area must be situated near the dispensing area and must have adequate seating for the number of patients expected to arrive at the pharmacy at any one time. Most of the dispensaries, 70% (7; n=10) had semi-private areas for counselling patients and the remaining 30% (3; n=10) of the dispensaries had private counselling areas. The facilities that had private counselling areas were the three hospital dispensaries. A minimum standard for pharmacies where medicines are supplied directly to the public is a suitable area for furnishing of advice to patients in a reasonably private environment and with background noise eliminated as far as possible (South African Pharmacy Council, 2008: 14). With the emergence of HIV/AIDS and the stigma attached to disclosure of the disease, the GPP requires all HIV/AIDS patients to be counselled on their medication including side effects, adverse effects, adherence and assessing for opportunistic infections in a private area (South African Pharmacy Council, 2008: 104). The facilities in this study were designed prior to the HIV/AIDS epidemic. Hence, no allowance was made for extra counselling space in the dispensaries. The private counselling rooms in the three hospital dispensaries studied were recently redesigned to comply with the need for private counselling of HIV patients. The rollout of ARV medication for HIV in South Africa is now in its seventh year and the results from this study show that seven of the dispensaries have not yet made any allocation for private counselling.

(vii) Equipment

All the dispensaries (10; 100%; n=10) had counting trays and most (8; 80%; n=10) had graduated measuring cylinders available. Only 60% (6; n=10) of the dispensaries had dispensing labels and 40% (4; n=10) of the dispensaries had an ointment tile with a spatula and a mortar and pestle. (Figure 6.9) The GPP guideline indicates that there must be adequate and suitable dispensing equipment in dispensaries. In addition to labels indicating the directions for use of medication, additional warning labels must be available (South African Pharmacy Council, 2008: 16). The results on dispensing equipment indicated that GPP is not followed by all the facilities.

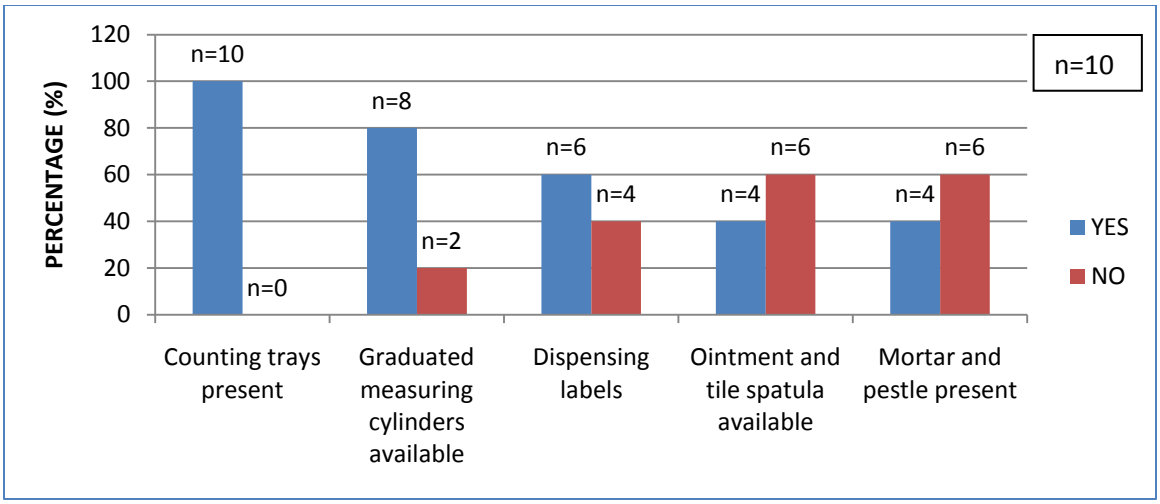


Figure 6.9 Availability of equipment as per Good Pharmacy Practice

(viii) Reference material

According to GPP certain reference books (Table 6.2) must be present in a dispensary (South African Pharmacy Council, 2008: 17). Table 6.2 indicates the percentage of dispensaries that had the required reference books. The reference material must be available in all pharmacies for consultation. The GPP Guideline was only available at only 40% (4; n=10) of the facilities. In order for a pharmacy to be registered with the South African Pharmacy Council one of the requirements is the availability of suitable reference material (South African Pharmacy Council, 2008: 17). Legislation in the form of the Pharmacy Act and its regulations refers to the GPP guidelines as the document to consult, as the GPP guidelines set the norms and standards of the legislation (South African Pharmacy Council, 2008: 18). Thus, not all the facilities were compliant with GPP as the required reference books were not available at all the facilities.

Table 6.2 Availability of reference material at the facilities in the study

REFERENCE BOOK	**AVAILABILITY AT THE FACILITIES (n=10)**	
	No.	%
MIMS	7	70%
Daily Drug Use	6	60%
South African Medicine Formulary (SAMF)	9	90%
Standard Treatment Guideline – Adults	9	90%
Standard Treatment Guideline – Paediatric	9	90%
Standard Treatment Guideline – Primary Health Care	8	80%
Good Pharmacy Practice Guideline	4	40%
Eastern Cape Formulary	7	70%

6.4.2.3 Summary of Dispensary Audit

The Dispensary Audit form was used to investigate whether the premises and equipment were in line with GPP requirements. The results indicate that thirty percent (3; n=10) of the dispensaries did not have the space available to process the volume of prescriptions seen at the facility and sixty percent (6; n=10) did not have space available for administrative functions. Forty percent (4; n=10) of the dispensaries did not have sufficient shelving for storage of medication and for proper stock rotation. The space for patients in the waiting area at seventy percent (7; n=10) of the dispensaries was insufficient. At forty percent (4; n=10) of the dispensaries, the fire extinguisher was not present. Forty percent (4; n=10) did not have an air conditioner.

With regards to equipment and reference material, forty percent (4; n=10) of the dispensaries did not have dispensing labels and sixty percent (6; n=10) did not have the GPP Guideline. Only fifty percent (5; n=10) of the dispensaries had SOPs available.

None of the dispensaries in the study were 100% compliant with GPP. There was insufficient space for pharmacy personnel to perform their jobs as well as lack of space in the patients waiting area. Lack of air conditioners, reference materials and labels will impact the effective provision of PMTCT service by pharmacy personnel. Insufficient space for storage of antiretrovirals will result in less buffer stock being kept and the possibility of out of stock situations occurring. It is the responsibility of every pharmacist and pharmacist assistant to ensure that the standards of pharmacy practice outlined in GPP are adhered to, in the interest of public safety.

6.4.3 Dispensary Staff Questionnaire

The supply of essential medicines and products is critical to the success of any health programme. If the goal of eliminating HIV infection in infants and young children is to be achieved, all pregnant women eligible for ART must have access to the medication. The availability of medicines is dependent on accurate monitoring of the stock levels of the medicines. Good record-keeping systems are crucial for monitoring stock levels. Pharmaceutical services form an integral and crucial part of the broader health care system in which medicines play a key role.

6.4.3.1 Study population and site

For this component of the study the population consisted of the dispensary staff in all the facilities. There were nine facilities in total and there were 41 (n=41) respondents. The Dispensary Staff Questionnaire was completed by all 41 respondents and the response rate was

100% (41; n=41). The respondents consisted of a sample of pharmacists, post basic pharmacist assistants, basic pharmacist assistants and registered nurse in charge of dispensing. The number of respondents differed for each question, therefore, the value (n) for each question may differ according to the number of respondents that answered.

The number of respondents per facility varied. However, the majority of the answers received from the respondents at a facility, differed irrespective of the facility. The replies from the 41 respondents were therefore analysed as one group.

The Dispensary Staff Questionnaire was piloted at a Primary Health Care clinic in NMB, not involved in the current study. The dispensary staff included pharmacists, post basic pharmacist assistants and basic pharmacist assistants. No amendments were made. The time taken to complete the Dispensary Staff Questionnaire was one hour.

6.4.3.2 Inventory Management

The questionnaire investigated the use of SOPs for inventory management tools such as stock cards which are essential for stock control.

The results are divided into four sections: stock cards, stock ordering, receipt of drugs, and out of stock procedures.

(i) Stock Cards

The consequence of clinics and hospitals running out of medicines or other essential items is that patients who need treatment do not receive their medicine or the patients have to seek help at another facility. This facility is often not in the patient's residential area and the patient has to bear the cost of transport to the alternative facility. As a result the patient loses confidence in the ability of the clinic or hospital to meet their needs. This can also lead to health care workers becoming demotivated. For this reason, an effective stock management system for drugs is important at all levels of the health care system. All too often there is some control over stock at higher levels of the distribution chain (Depots and hospitals) but poor control at lower levels such as at the clinics. This lack of control can result in large financial losses. South Africa spends over R3.6 billion per year on ARV medicines in the public sector alone (Khumalo, 2008). An accurate stock control system would ensure reliable statistics on the usage of ARV medicines. This in turn would allow for accurate projections to be made for the planning of ARV budgets.

Only 68.2% (28; n=41) of the respondents indicated that there were stock cards available at the facility (Figure 6.10). Of the facilities studied three of the facilities namely the three hospitals

used a computerised inventory system as well as a stock card system and the remaining six facilities (clinics) used only a stock card system.

The stock cards were kept on the same shelf as the medication in 58.5% (24; n=41) of the facilities and only 58.5% (24; n=41) of the respondents indicated that the stock cards where up to date with current transactions (Figure 6.10).

The respondents (60.9%; 25; n=41) indicated that the stock card was filled out at the time of the medication transaction i.e. medication was either received or issued. However, only 56.1% (23; n=41) of respondents reported that the stock card gave an accurate indication of the transactions. Regular physical checks of the stock card balance and the actual stock on hand were reported to be done by 60.9% (25; n=41) of the respondents (Figure 6.10).

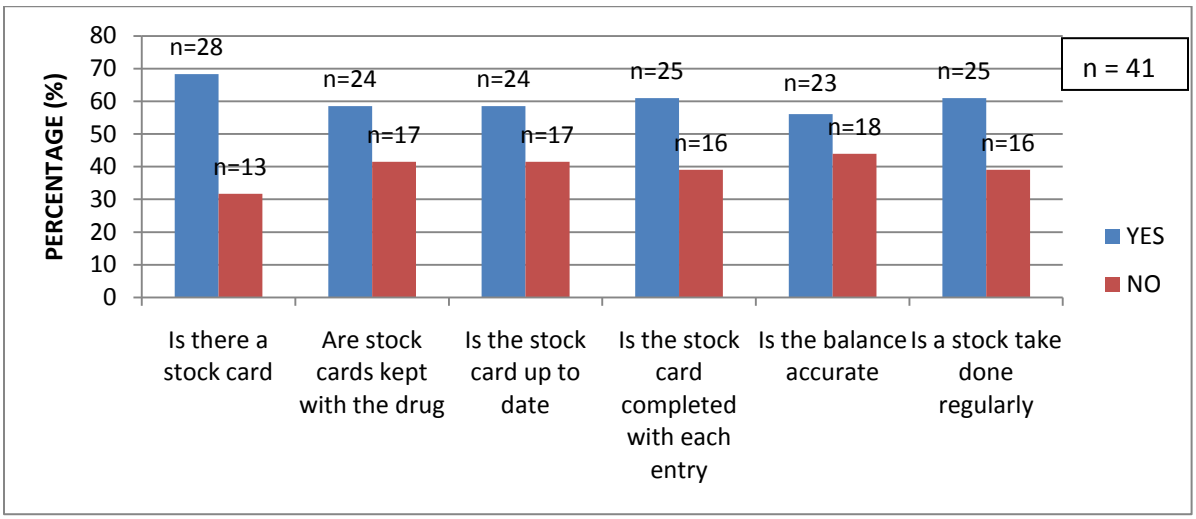


Figure 6.10 Adherence to standard operating procedures for stock cards

Standard operating procedures for inventory management are of utmost importance in ensuring the availability of medicines. Standard operating procedures assist in the process of ordering stock, stock rotation and maintaining adequate levels of stock. The GPP guideline expects all institutions to have available and implement these SOPs (South African Pharmacy Council, 2008: 2). The absence and inaccurate maintenance of the stock card system which serves as a basic inventory management tool could explain why some facilities did not have stock. Analysis of the results regarding emergency orders indicated that 21% of the respondents placed emergency orders when they had no stock of medication. This was due to the facility not ordering correctly. Emergency orders are placed when the facility has run out of stock that is required by the patient. The stock card contains the history of the usage of a medicine and this is used to order further supplies (Department of Health, South Africa, 2005). When stock cards are not up to date with transactions then orders are placed without any reference and there is a risk of medication been out of stock.

In a 2008 study done by Management Sciences for Health on the availability and delivery of pharmaceuticals in the Northern Cape, it was found that only 52% of the 30 facilities studied were using a stock card system. None were using a computerised system. Amongst the facilities studied only 48% had SOPs in place for receiving stock and another 48% had implemented SOPs for ordering, storage and supply of medicines. Ninety three percent of the facilities did not keep records of stock which made it difficult to conclude with certainty if those facilities had stock or not during this study period which was from 1 October 2007 to 25 July 2008. According to the study, orders were placed arbitrarily or based on experience and the reason cited for the lack of inventory management tools was inadequate staff and workload. (Management Sciences for Health, 2008: 6-9) These results are similar to the results obtained in this study in that there was not 100% compliance with the SOPs for stock cards. In keeping with the precepts of The National Strategic Plan for HIV, AIDS and STIs 2007-2011 (NSP), of rapid expansion of the amount of people treated for HIV, there are an increasing number of patients requiring ARVs (Department of Health, South Africa, 2007a: 10). It is the responsibility of the pharmacist to provide an accurate indication of the number of ARVs required. Without a proper inventory management system this cannot be accurately given and the Depots would, as a result not be able to provide reliable quantities of ARV medication (Management Sciences for Health, 2000). In November 2008, the Free State Department of Health experienced shortages of ARV medication and stopped the provincial roll out of ARVs with the exception of pregnant mothers and children (El-Khatib and Richter, 2009: 412). In a letter to the Minister of Health, the HIV Clinicians Society indicated that the out of stock situation was due to bad planning and the situation undermined the public health service and made attainment of the NSP goals more difficult (Venter, 2008).

(ii) Stock ordering:

Orders for medication were placed at different intervals. According to the respondents 50% (20; n=40) placed medication orders once a week; 25% (10; n=40) biweekly; 10% (4; n=40) ordered monthly and 15% (6; n=40) ordered at another time interval that was not specified by the respondents (Figure 6.11). Of the nine facilities studied, five of the facilities ordered medication from the provincial Depot located in Port Elizabeth and the remaining four facilities ordered from the municipal Depot located in Port Elizabeth. The Depots order from the wholesalers once a month and therefore, restrict the hospitals and clinics to certain ordering frequencies, usually once every two weeks. When facilities do not keep to these ordering time frames, there is a risk of medication been out of stock. Four facilities (40%; n=10) reported that they had insufficient space for storage. Medication is ordered more frequently possibly due to the lack of space for storage. (Figure 6.11) The facilities that ordered every two weeks and monthly could have had more storage space available or could have over ordered the previous month thus having sufficient stock for the patients. Analysis of the results on buffer stock indicated that

35% (13; n=37) of the respondents indicated that less than one month buffer stock was kept (See section (iv) Out of stock procedures). One of the reasons cited by the respondents for having less than on month's buffer stock was the limited amount of storage space available for medicines.

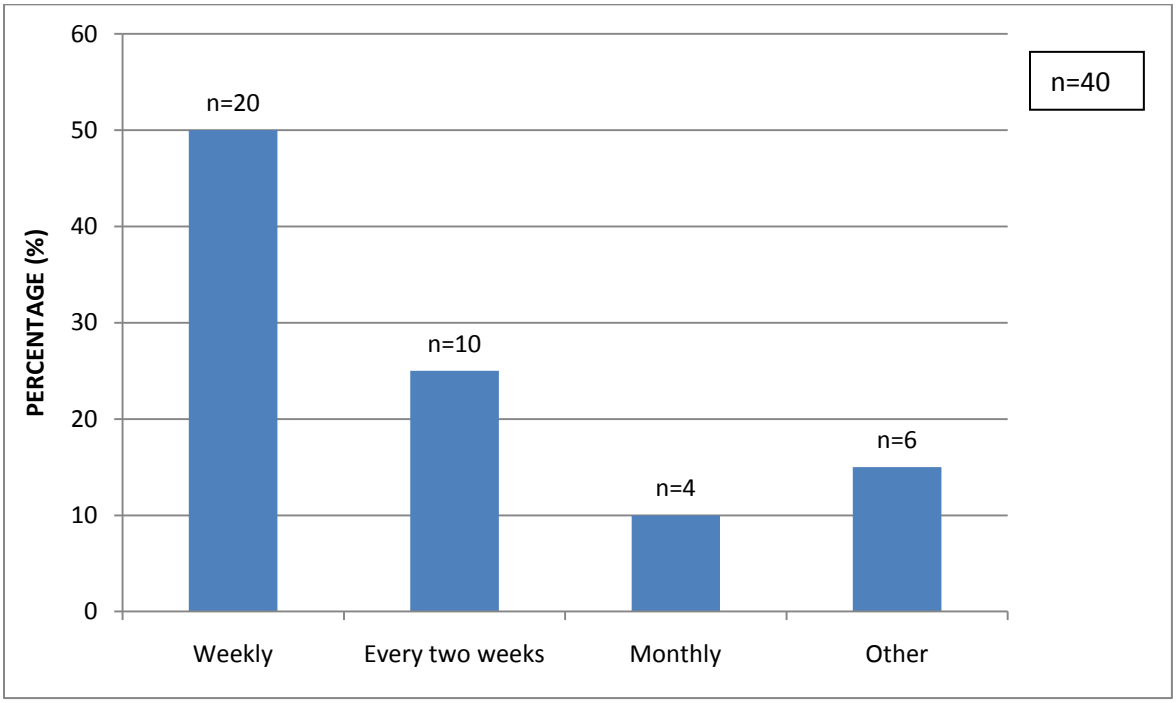


Figure 6.11 Frequency of ordering of medication from the Depot

The orders for medication were forwarded to the Depot by various means, 42.5% (17; n=40) of the respondents indicated that the order was sent by fax; 27.5% (11; n=40) by the facility driver; 7.5% (3; n=40) by e-mail; 7.5% (3; n=40), 10% (4; n=40) and 5% (2; n=40) indicated that the order was sent with the pharmacist, nurse or anyone at work respectively. (Figure 6.12) According to the respondents, in some instances the problem existed that when the order was taken to the Depot by the facility driver, the driver only delivered the order to the Depot a week later citing workload as the reason. Furthermore, clinics that faxed the order through to the Depot reported that often the Depot had not received the fax. Upon querying with the Depot regarding the fax the response was either lack of fax paper, fax machine not working or misplacement of the faxed order. Only 5% (2; n=40) of the respondents indicated that the order was sent by "anyone at work". The risk involved here is that no one is accountable for the order and in certain instances the order never reached the Depot resulting in the Depot not processing the order and the facility not receiving the expected medication. Thus, there is an apparent need for a uniform system to be implemented and used by all the facilities to ensure that medication orders are received timeously by the Depot. This will ensure that orders are processed and delivered on time. Furthermore, if certain items are out of stock at the Depot

the items can be ordered elsewhere (buy-outs of drugs that are not on tender) and delivered timeously to the facilities.

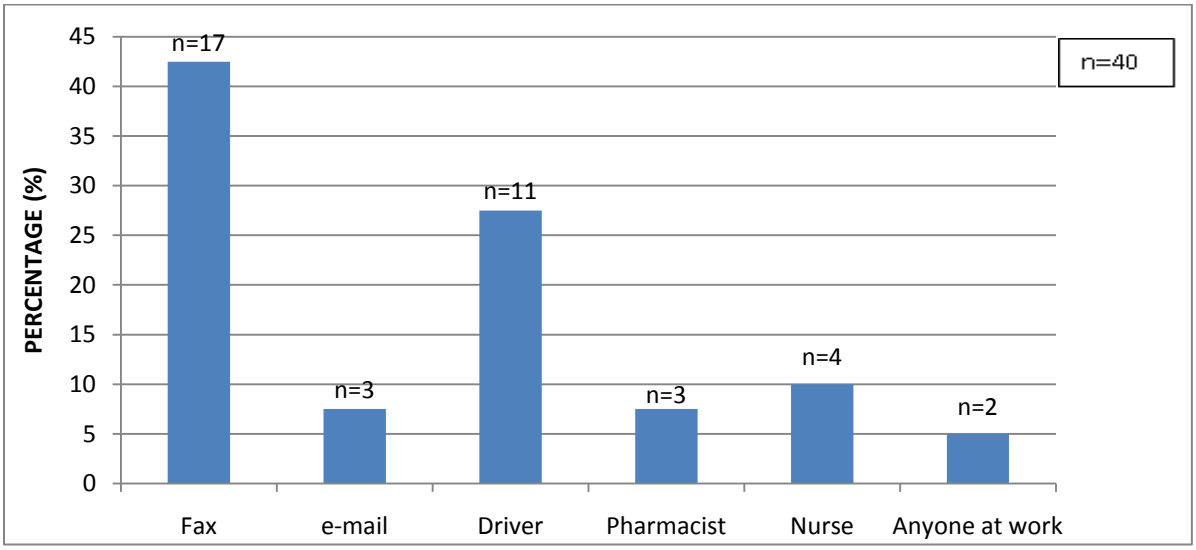


Figure 6.12 Method used to submit the medication order to the Depot

Medication was ordered according to minimum and maximum levels in 63.4% (26; n=41) of cases. (Figure 6.13) Of the 36.5% (15; n=41) that did not order stock according to minimum and maximum levels 8 (66.6%; n=12) ordered according to need and 4 (33.3%; n=12) ordered according to visual inspection. These results are reinforced by the results shown with regards to keeping updated stock cards. Of the respondents 31.7% (13; n=41) did not keep a stock card and 43.9% (18; n=41) of the respondents indicated that the balance on the stock cards was not accurate. This could be one of the reasons for facilities ordering according to need and visual inspection. There are many risks involved when facilities do not have an up dated stock card with all the requirements namely:

- An accurate order for medication cannot be placed;
- Unaccountable loss of medication; and
- Theft of medication.

Although the majority of the facilities (26; 63.4%; n=41) ordered medication according to minimum and maximum stock levels there is still a high percentage (15; 36.5%; n=41) of facilities that order medication with no reference. The ordering of medication without using predetermined minimum and maximum stock levels could result in situations of over ordering medication, under ordering medication and/or out of stock situations.

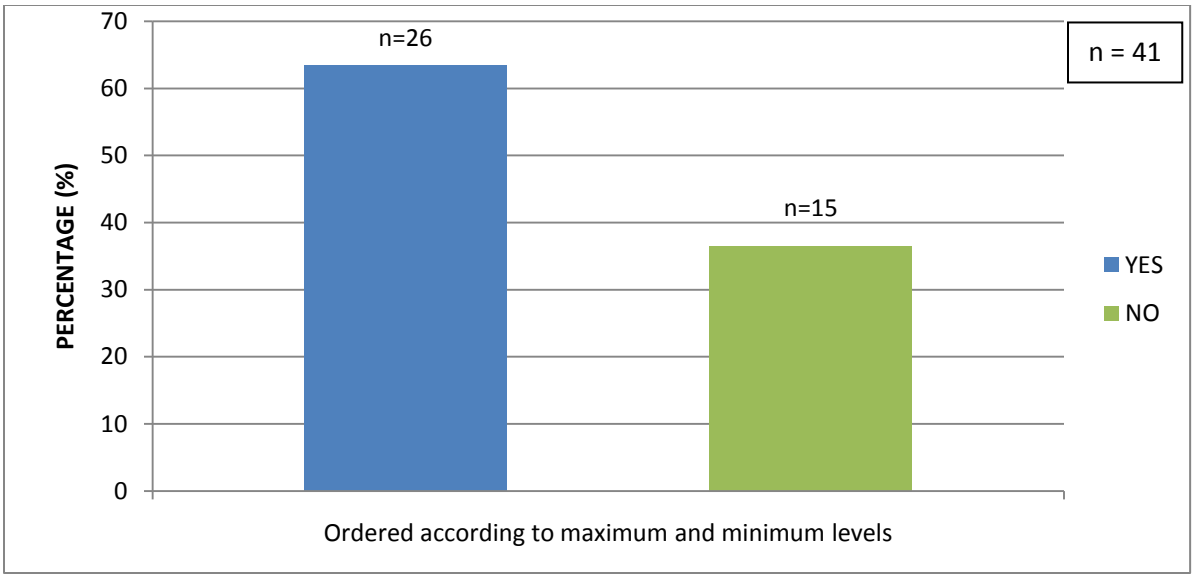


Figure 6.13 Ordering of medication according to maximum and minimum levels

With HIV and AIDS treatment interruption there is a risk of rendering the treatment ineffective. This is caused by the development of resistance in the virus. Not only does this affect the individual concerned but it may allow a resistant virus to spread. Dr Francesca Conradie, Deputy Director of the Clinical HIV Research Unit at the University of Witwatersrand reported to the Mail and Guardian newspaper that drug resistance due to ARV out of stock situations will result in the health systems facing higher medicine costs as a different more expensive cocktail of ARVs with more side effects would be required (ARVs: Hogan Acts, 2008).

Analysis of the results indicated that 6.2% (2; n=32) of the respondents last reviewed the monthly stock level in 2005; 18.7% (6; n=32) in 2008 and 75% (24; n=32) of respondents in 2009. The questionnaire was completed by the respondents in August 2009. In addition, 70% (28; n=40) of the respondents stated in the preceding section of the questionnaire that the stock level for each item was calculated each month. The Eastern Cape Department of Health SOP on ordering medication states that monthly stock levels for all items must be determined at the end of each month and minimum and maximum values should be calculated based on the previous three months monthly stock level (Department of Health, South Africa, 2005). The result of 75% (24; n= 32) of the respondents indicating that the last monthly stock level was calculated in 2009 is an indication that a high number of the facilities were following the SOP regarding stock takes which is to determine the average usage of medication regularly. This could be attributed to the increase in staff members due to collaborations with Non Government Organisations and an increase in training on stock control procedures (International Centre for AIDS, Care and Treatment Programme, 2006).

Only 31.4% (11; n=35) of the respondents reported that there was a separate order book for ordering PMTCT medication and 47.1% (16; n=34) indicated that zidovudine was ordered separately for the PMTCT programme. Of the respondents 80.5% (33; n=41) indicated that general zidovudine stock was used for the PMTCT programme. Half of the facilities in the study ordered from the Provincial Depot in Port Elizabeth and the other half of the facilities ordered from the Municipal Depot. The facilities ordering from the Provincial Depot ordered all antiretroviral medication i.e. medication for both PMTCT programme and for the general HIV programme together. The Municipal Depot, however, required all facilities to order the antiretroviral medication needed for the PMTCT programme using a separate order book and for the general antiretroviral stock not to be used for the PMTCT programme. Thirty three of the respondents (80.5%; n=41) of the respondents used general zidovudine stock for the PMTCT programme and only ten (27%; n=37) of the respondents indicated that there were PMTCT registers for the medication. However, as the study did not distinguish between the number of respondents at each facility, no conclusion can be derived from the above two results. The Provincial and Municipal Depot do, however, need to reinforce their requirements to dispensary staff to ensure that the PMTCT medication is ordered according to protocol.

(iii) Receipt of drugs

Once an order is sent the time taken for the order to be delivered was reported to be 1 day by 10% (4; n=40) of respondents; 1 week by 35% (14; n=40) of respondents; two weeks by 27.5% (11; n=40) of respondents; one month by 17.5% (7; n=40) of respondents and greater than one month by 10% (4; n=40) of respondents (Figure 6.14).

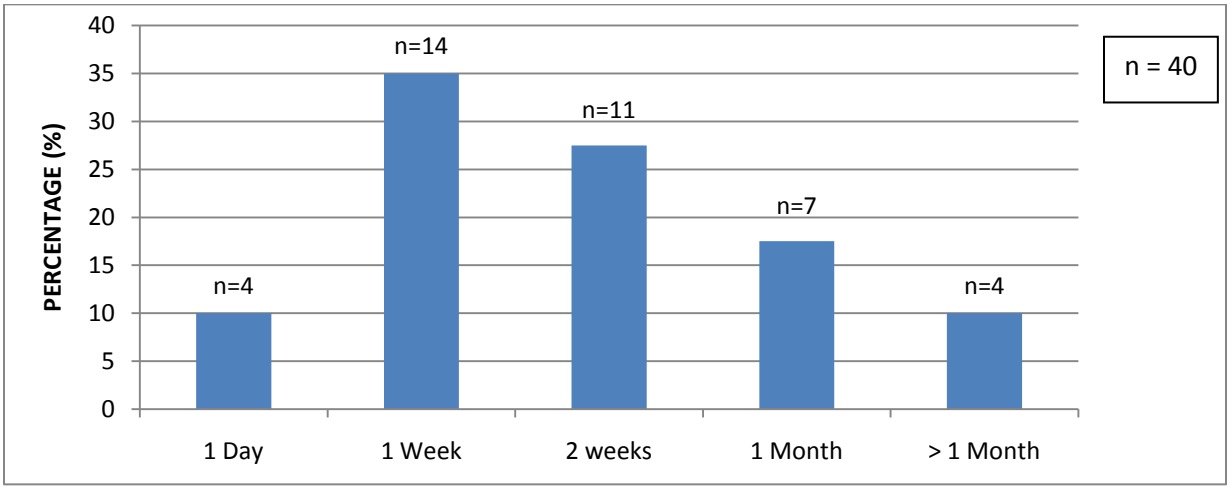


Figure 6.14 Time taken to receive medication orders from the day of ordering to day of receipt

The facilities order medication according to an ordering schedule. The Depots supplying the orders deliver the medication ordered by the facility according to a schedule which is usually

one week after the order was placed (Department of Health, South Africa, 2005). The reason why 10% (4; n=40) of respondents reported delivery after one day could be that the facility had placed an emergency order with the Depot (Figure 6.14). Emergency orders are placed when the facility has no stock of a medication that is required for immediate use by a patient.

The process of receiving stock must be in accordance with the Standard operating procedures for the Eastern Cape. The SOP indicates that when stock is delivered to a facility the delivery slip must be signed by pharmacy personnel and the delivery person. The delivery must be checked for accuracy before acceptance. The expected result should be 100% for the SOPs on receiving stock. The results of this study showed that the delivery was received by dispensary staff according to 95.1% (39; n=41) of respondents and checked before acceptance according to 75.6% (31; n=41) of respondents. Seventy six percent (31; n=41) of the respondents indicated that the delivery person signed the delivery slip before leaving the facility. Some of the reasons given by the respondents for not having 100% compliance were lack of staff, increase in workload, no time and the order arrived close to closing time.

A high number, 88.8% (36; n=41) of the respondents indicated that items had been sent back to the Depot at some time. Items were sent back due to the wrong item been supplied; item was damaged; expired stock was received and/or excess stock was received.

Of the respondents, 56.1% (23; n=41) stated that short dated items were not sent back to the Depot in time. Medications that have a short expiry date are usually sent back to the Depot if the medication cannot be used by the facility prior to the expiry date (Department of Health, South Africa, 2005). The result obtained regarding adherence to SOPs for stock cards indicated that only 60.9% (25; n=41) of the facilities regularly checked the physical stock on hand (Figure 6.10). Therefore, it can be assumed that if the physical stock was not checked regularly then the short dated stock would not have been identified and returned to the Depot to be used by another facility. The resultant risk is that the short dated stock will expire before it is used resulting in a wastage of funds.

A further 68.2% (28; n=41) of the respondents indicated that stock was not entered on the stock card as soon as it was received. The risk of not immediately entering the stock received on to the stock card is that the transaction might be forgotten, resulting in incomplete and inaccurate records.

Of the respondents, 82.9% (34; n=41) stated that when items were received from the Depot discrepancies were encounted. Eighty five percent (35; n=41) of the respondents stated that the fridge items were checked for correct packing, 68.2% (28; n=41) checked for discolouration of drugs, 87.8% (36; n=41) checked whether the containers where broken; 82.9% (34; n=41) checked if the items supplied where soiled by leakage and 82.9% (34; n=41) checked if the item

where sealed and labelled. Only 65.8% (27; n=41) of the respondents stated that the discrepancies encounted when items were received from the Depot were documented. Part of the SOP for the receipt of medication is to check the medication received for any discrepancies such as discolouration of medication, correct packing of vaccines, broken containers of medication, soiling of medication and if the medication is sealed and labelled. The action required by the SOP is to note and report the discrepancies to the Depot (Department of Health, South Africa, 2005).

When the Depot does not deliver the medication to the facility, 34.1% (14; n=41) respondents indicated that the order was picked up from the Depot by the facility driver, 12.1% (5; n=41) stated that a nurse picked up the order, 51.2% (21; n=41) stated that a pharmacist picked up the order and 2.4% (1; n=41) stated that the pharmacist assistants picked up the order.

(iv) Out of stock procedures

In the development of the Operational Plan for Comprehensive HIV and AIDS Management, Treatment and Care an efficient and secure process for storage, distribution and appropriate utilisation of ARV medication was planned by the Department of Health, for the public health system, to ensure a reliable supply of medicines at all levels of distribution to avoid "stock-outs", prevent shrinkage and re-exportation (i.e. sending unused medicines back to the Medicine Depots) of drugs. Included in the plan was the training of pharmacy personnel in Inventory Stock Management. (Department of Health, South Africa, 2003: 155-156).

A high percentage, 70% (28; n=40), of respondents indicated that there were no SOPs at their facilities for scenarios where medication was out of stock. When medication was out of stock at the Depot, 75.6% (28; n=38) of the respondents borrowed from another facility and 26.3% (10; n=38) waited for stock to be available at the Depot.

Most of the respondents (97.5%; 39; n=40) reported that emergency orders were placed. This is a high percentage as emergency orders should only be placed in cases of emergencies such as when items had been out of stock at the Depot and were now back in stock. Of the emergency orders 60.6% (20; n=33) were placed when an item that had been out of stock at the Depot was back in stock; 21.2% (7; n=33) of emergency orders were due to incorrect orders being placed by the facility; 12.1% (4; n=33) of emergency orders were due to buy outs and 6.1% (2; n=33) were placed because the order was not delivered on time by the Depot. (Figure 6.15) Buy outs occured when a facility was required to procure a drug from a source other then the Provincial or Municipal Depot. This usually occured for drugs that were required by the patient, that the Depots did not stock. The Depot requires the doctor, treating the patient requiring the drug, to submit a motivation form indicating the need for the drug (Department of Health, South Africa, 2005). A small percentage of medical conditions require drugs that are not kept at the Depot.

Only 12.1% (4; n=33) of respondents indicated that emergency orders were placed for buy-outs. However, when orders are not placed correctly and the facility runs out of stock then the facility places an emergency order with the Depot in order to procure the medication as seen in Figure 6.15 when 21.2% (7; n=33) of the respondents indicated that emergency orders were placed when orders were not placed correctly. This causes an increase in the work load for the personnel at the Depot due to unscheduled orders being placed. The 6.0% (2; n=33) of respondents who indicated that emegency orders were placed when the Depot did not deliver on time, cited reasons such as lack of staff at the Depot and strike action at the Depot for non-delivery.

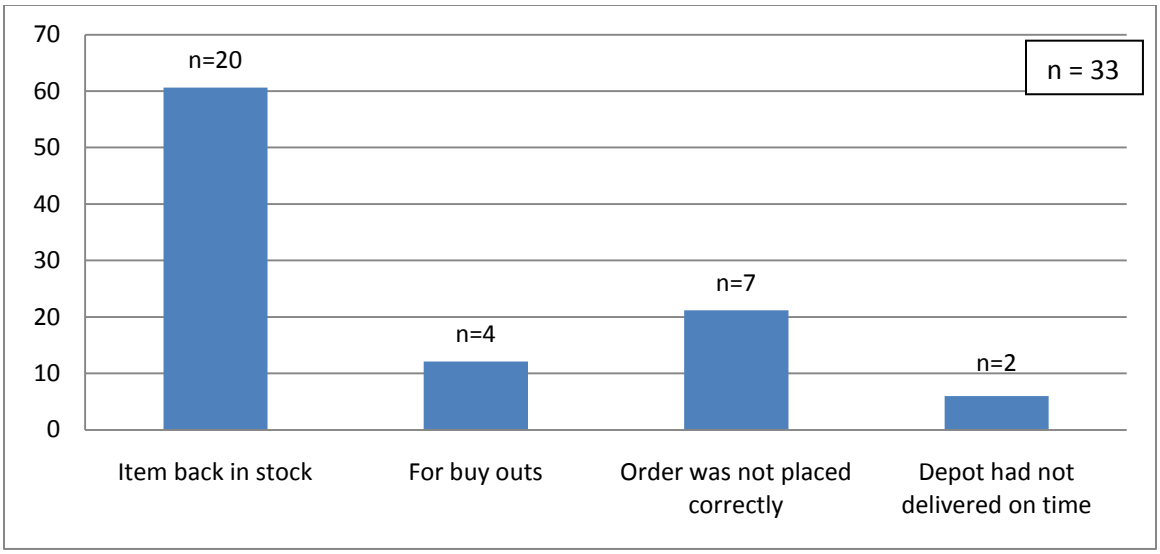


Figure 6.15 Reasons for placing emergency orders for medication

Buffer stock is that amount of medicine that should be kept aside and used in instances when medicine is not available from the supplier so that medical care can be continued with no interruption in treatment (Department of Health, South Africa, 2005). The amount of buffer stock for zidovudine and nevirapine was reported by all respondents to be the same quantity. Only 16.2% (6; n=37) of the respondents indicated that only one week of buffer stock was available; 18.9% (7; n=37) maintained two weeks; 35.1% (13; n=37) had one month of buffer stock and 29.7% (11; n=37) had three months of buffer stock available. One of the reasons given by the respondents for having only one to two weeks of buffer stock on hand was limited space for storage of medication. The risk involved in having only one or two week supply of buffer stock is that if the medication is out of stock at the Depot then it might take the Depot longer than two weeks to procure the stock from the manufacturers. The facility would then be out of stock of the medication until the Depot had re-procured the medication. Commenting on the crisis in the Free State in which the province had no stock of ARVs, in November 2008, Professor Ian Sanne of the Infectious Disease Unit at the University of Witwaterstrand reported that there was a need for buffer stock to be available in all provinces (ARVs: Hogan Acts, 2008).

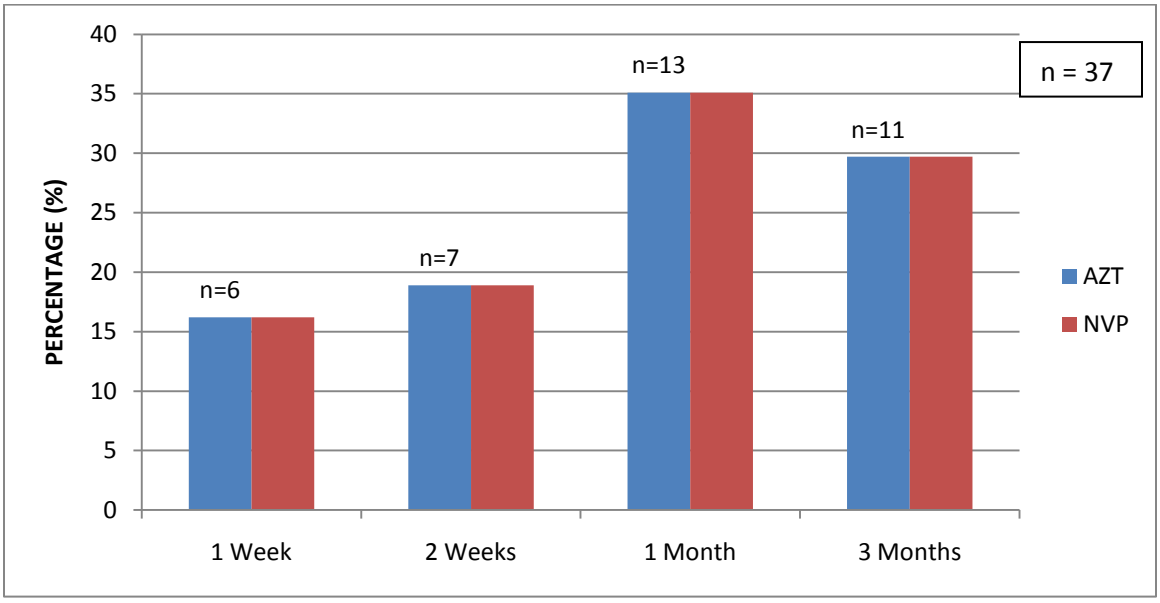


Figure 6.16 The quantity of buffer stock for zidovudine and nevirapine that was kept at the facilities

Of the respondents, 90% (36; n=40) reported that out of stock situations at the Provincial Depots were not reported to them in advance. The respondents indicated that they were made aware of the out of stock situation when an order was not received. Furthermore, respondents indicated that information concerning out of stocks was not passed on to the relevant staff at the facility. This occurred when the Medicine Depot sent faxes to the facility indicating the out of stock situation but the facility did not pass the information on to the dispensary. It would be expected, that, if medications were out of stock then it would be reported to the facilities immediately so that the facilities could implement strategies to ensure that patients did not run out of medication. However, the dispensaries did not have any fax or e-mail facilities. In addition, one of the SOPs for the Depots is to supply the facilities with a list of medication that are not in stock at the Depot each week. This list is called a "dues out" list and gives the facility a list of all drugs that are out of stock at the Depot (Department of Health, South Africa, 2005).

Similar results to this study have been seen in studies done in Tanzania and Vietnam on barriers to PMTCT services. One of the challenges to providing a PMTCT service was ARV drugs not being available at the health facilities surveyed (Ntabaye and Lusiola, 2004: Abstract B11396; Nguyen *et al*., 2008).

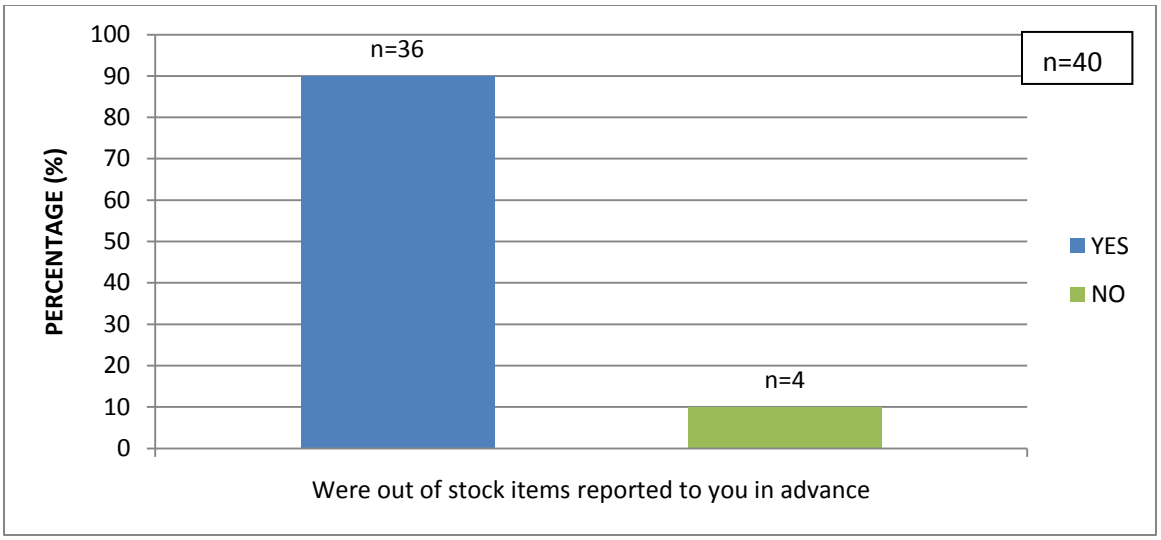


Figure 6.17 Reporting of out of stock items to the dispensaries by the Depot

In September 2009 the Health Minister reported that nationally, there was a R1-billion funding shortfall for ARVs and that the government could not meet its target of providing the life-prolonging treatment to 80% of HIV infected people suffering from advanced infections by 2011 (Govender, 2009). However, according to the 2010 Budget review, the Minister of Finance announced plans for an additional R5.4 billion for the HIV and AIDS programme in order to take on more people and improve the effectiveness of treatment programmes (Gordhan, 2010).

The Free State had the second highest HIV prevalence (33.5%) in the country in 2007. However, in December 2008, the Free State Department of Health stopped initiating new patients on ARVs because of out of stock ARV drugs and a lack of funds. An estimated 30 people living with HIV were dying every day in the province while the hiatus continued, there was a loss of trust in the health system as well as the potential negative impact of the ARV crises on patient adherence. (El-Khatib and Richter, 2009: 412)

6.4.3.3 Summary of Dispensary Staff Questionnaire

This component of the study focused on the minimum standards pertaining to the use of SOPs for inventory management at the research facilities. One of the major barriers, to the provision of an effective service, highlighted in this study, was the lack of adherence to the SOP for stock cards. All the facilities in the study used a manual inventory management tool, the stock card, although three facilities (hospitals) also had a computerised system. The accurate maintenance of the inventory management tool plays an important role in the availability of medicines.

It was observed that 31.7% (13; n=41) of the respondents stated that there were no stock card present and 41.5% (17; n=41) of respondents reported that the stock cards were not up to date. In addition, 43.9% (18; n=41) of respondents indicated that the stock balance on the stock cards

was not correct. Regarding the calculation of a monthly stock level, 25% (8; n=32) of the respondents stated that the monthly stock level was last reviewed at least one year prior to the study. The monthly stock level of medication should be reviewed every quarter (Department of Health, South Africa, 2005).

With regards to the ordering of medication, 50% (20; n=40) of the respondents stated that orders were placed weekly. Thirty five percent (13; n=37) of respondents stated that less than two weeks of buffer stock for zidovudine and nevirapine was kept at the dispensary. Thirty seven percent (15; n=41) of respondents stated that orders were not placed according to minimum and maximum values and 66.6% (8; n=12) of those respondents indicated that orders were placed according to need. Emergency orders were placed with the Depot due to inaccurate orders been placed by the dispensaries according to 21.2% (7; n=33) of the respondents.

The majority (28; 70%; n=41) of the respondents stated that there was no SOP for scenarios when medication was out of stock. With regards to the reporting of out of stock items to the dispensaries, 90% (36; n=40) respondents indicated that out of stocks were not reported to them in advance and were only made aware when an item that was ordered was not received.

Poor inventory management (non existence or poor use of stock cards) at the facilities in the study was evident by the responses received by the pharmacy personnel. Ordering of medication according to visual inspection could lead to insufficient medication being ordered and out of situations occurring. In addition, more emergency orders will be placed, increasing the workload of staff at the Depots. Standard operating procedures should be made available to all pharmacy staff and the implementation of the SOPs should be monitored, to ensure the smooth running of PMTCT services.

6.5 CLINIC PROCEDURE

6.5.1 Introduction

One of the commitments of the Department of Health is to ensure availability and accessibility of essential healthcare to all citizens at all levels of the health care system. Uncertainty with regards to the methodology and procedures involved in fulfilling this commitment together with the increasing number of patients affected with HIV and AIDS has undermined the successful implementation of the policy. Patients requiring higher levels of medical service, patients with chronic medical conditions including HIV/AIDS should be able to collect their monthly medicines at the nearest Primary Health Care clinic and patients relocating elsewhere should be able to continue treatment without any added hindrances (Department of Health, South Africa, 2005). This section of the study assessed whether clinical procedures required for

the referral of patients and follow up of patients receiving dual therapy PMTCT were present. Furthermore, the study also assessed the procedure that was followed when patients missed their appointments.

6.5.2 Study population and site

The study population included all nine facilities (n=9). Three of the facilities were tertiary hospitals and six of the facilities where clinics. The data was collected by means of a researcher administered Clinic Procedure Audit Form. The Clinic Procedure Audit Form was a checklist and the Facility Manager assisted the researcher in the completion of the Clinic Procedure Audit Form. The response rate was 100% (9; n=9).

The audit form was piloted, by the researcher, at a Primary Health Care Clinic in NMB, not involved in the current study. No amendments were made to the Audit Form. The time taken to complete the audit form was one hour.

6.5.3 Clinic Protocols

The Clinic Procedure Audit Form was used to investigate whether protocols involving transferring and tracking HIV positive patients are followed. Updating patient demographic details and protocols for patients missing appointments were also investigated.

6.5.3.1 Transfer forms

Only 77.7% (7; n=9) of the facilities had a transfer form for the referral of patients from the hospital or clinic to another facility (Figure 6.18). However, only 33.3% of the facilities (3; n=9) filled out the referral forms correctly. According to the Facility Manager this could be attributed to the health care workers not knowing that a referral form was required; the facility had run out of referral forms due to the photocopy machine not working; and the health care workers did not know what information to fill out resulting in an incomplete form.

An incomplete transfer form or no transfer form had the following implications on the patient and on the health care facility. When the patient arrives at a facility with no transfer form, some facilities refer the patient back to the referring facility in order to obtain a completed referral form. This could compromise the level of care of the patient as treatment would be delayed and the cost incurred for transport between the sites would be the responsibility of the patient. Some facilities did not refer the patient back to the referring facility when a referral form was not presented but re-assessed the patient clinically. This would result in a duplication of laboratory tests and man power utilisation with subsequent cost implications. Lastly under-diagnosis or misdiagnosis of the patient's ailment could occur due to the referral institution receiving an incomplete clinical history for the patient.

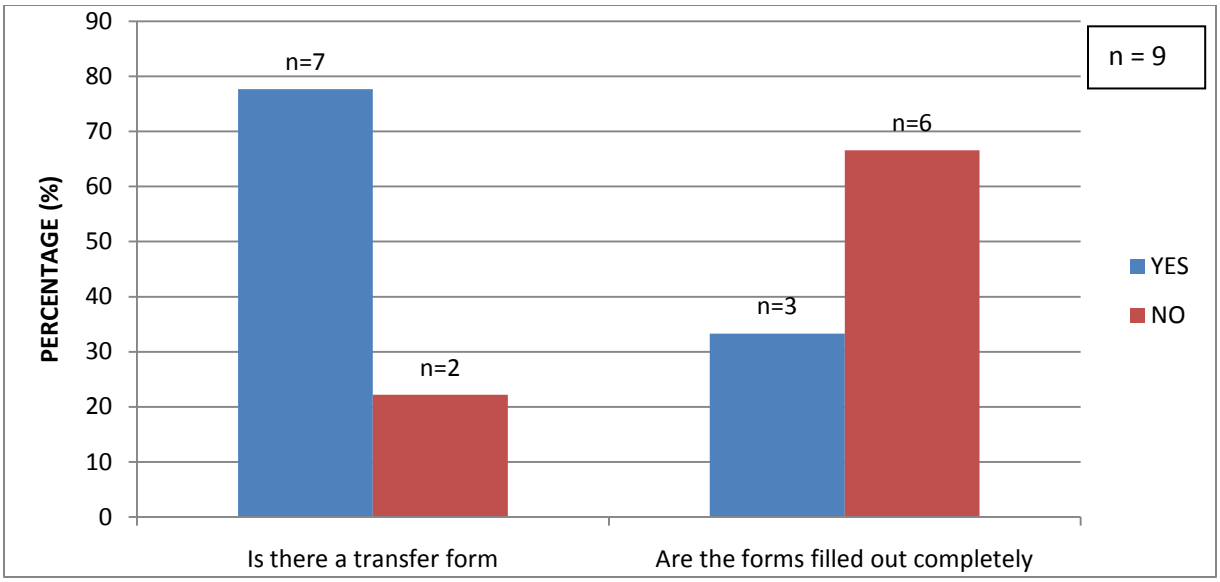


Figure 6.18 Availability and completion of transfer forms by the facilities in the study

6.5.3.2 Follow up of patients

Patients are referred from a higher level of care, such as a hospital, to a lower level of care, such as a clinic when their chronic medical condition has stabilised and can be managed at a lower level of care. Patients may also be referred from a lower level of care (clinic) to a higher level of care (hospital) where hospital level care is required to further investigate and treat the patient. When a patient is referred to another facility it is imperative that the receiving site is notified telephonically. This will ensure continuity of care for the patient and hence improved quality of life.

More than half of the facilities (5; 55.5%; n=9) followed up when the patient was referred to a higher level of care such as a hospital. Only two (22.2%; n=9) of the facilities followed up when the patient was referred to a lower level facility. Three of the nine facilities in the study were tertiary hospitals and could refer to a lower level of care. Thus, the results show that one of the hospitals did not follow up on patients that were referred to a lower level of care. Currently, there is no SOP for follow up of referred patients. Hence, not all the facilities followed a standardised protocol for follow up of patients.

Only 33.3% (3; n=9) of facilities stated that there were procedures in place for those patients who do not arrive at the referral site. There is a possibility that patients who are not followed up do not arrive at the referral site (clinic) or wait until the disease has worsened before attending the referral site. Some patients arrive at the clinic without notification i.e. a referral form or telephonic consultation from another institution and the staff at the clinic have no indication of the patient's history, clinical condition or contact details of the prescriber.

Only 33.3% (3; n=9) of the facilities indicated that there was communication between the two referring sites. Regular communication between referring and referred institutions is imperative in order to facilitate a feasible referral system. Furthermore, it should be the responsibility of the referring institution to consult with the patient and notify the patient about the importance of adherence to therapy.

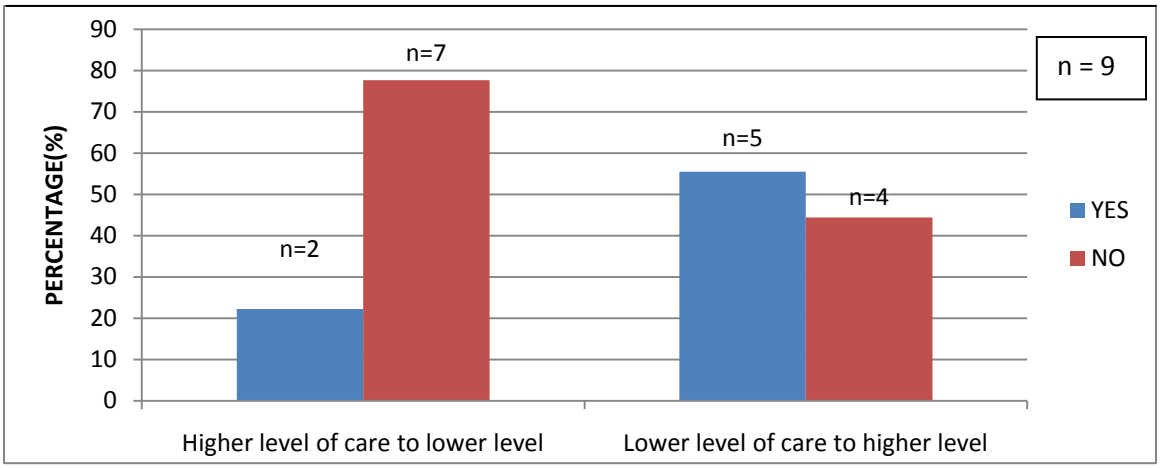


Figure 6.19 Follow up of referred patients to different levels of care

Five of the facilities (55.5%; n=9) had experiences when patients arrived at the facility from a referral site with no medication. The most common example given by the respondents was mothers that gave birth and were discharged with no zidovudine syrup for the baby. This is one of the most serious challenges experienced in the dual therapy PMTCT protocol. The protocol enables all HIV positive pregnant mothers to be started at 28 weeks of pregnancy on the new dual therapy protocol namely zidovudine 300mg 12 hourly and a single dose of nevirapine is given to the mother to keep and take when she is in labour. The baby will be given the single dose of nevirapine syrup at birth and zidovudine syrup 12 hourly based on the weight of the baby. On discharge the mother should receive zidovudine for the baby (Department of Health, South Africa, 2008a: 40)

Some of the respondents indicated cases in which the infant did not receive medication citing reasons such as:

- The health care worker was not adequately trained in the new protocol;
- The health care worker was not sure of the dose;
- The health care worker forgot;
- The mother gave birth at home and did not report to the clinic; and
- Zidovudine syrup was out of stock at the facility.

The repercussions of this are serious as studies have shown that if the baby receives dual therapy after birth the risk of HIV true transmission is reduced to 2 to 4% (Lallemant *et al.*, 2004: 221-223).

However, the researcher noted that zidovudine syrup was in stock during the entire study period, therefore, the reason of zidovudine being out of stock was not possible and the omission was probably due to the health care worker not having been trained on the dual therapy PMTCT policy or that the medication was not ordered timeously by the facility.

6.5.3.3 Patient tracking systems

Only 44.4% (4; n=9) of the facilities used a tracking system for patients (Figure 6.20). Antiretroviral medication adherence refers to taking medication on schedule in the right doses and in the right way (Department of Health, KwaZulu Natal, 2004). With ARVs even a 95% adherence rate is associated with a 21% virological failure rate (Paterson *et al.,* 2000; 21). Failure to adhere to ARV medications can lead to a resistant virus resulting from incomplete suppression of viral replication (Abdool-Karim and Coovadia, 2005). In a 2009 study, done on the factors associated with patients defaulting with medication pick-ups and clinic visits, it was found that of the 638 defaulters only 205 patients were contactable and only 98 patients could be reached (Zulu, 2009: 3). The main reason for tracking patients on ARVs is to be able to reach patients who do not collect their medications on time and/or do not come in for their clinic visits so that possible reasons for impending non-adherence can be picked up immediately.

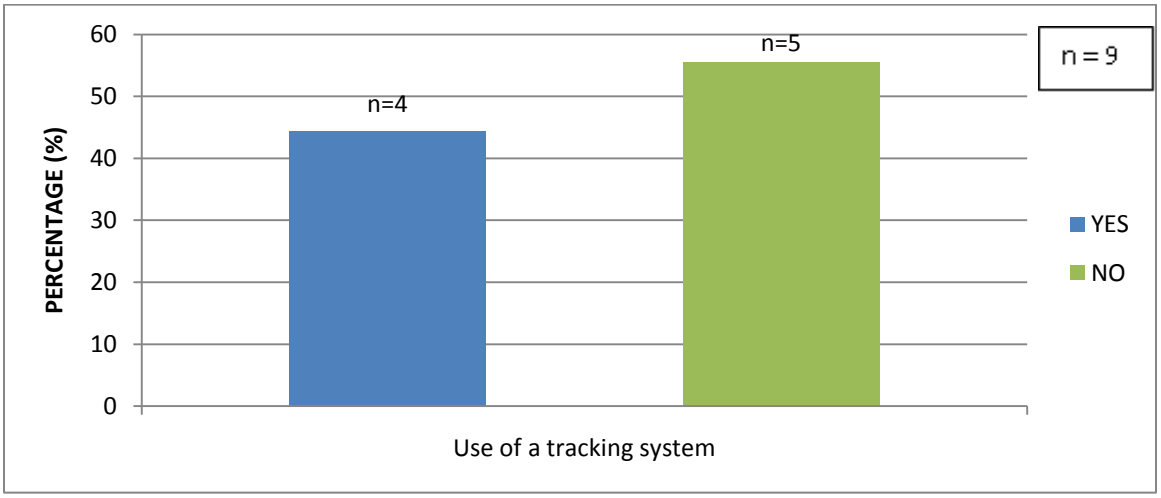


Figure 6.20 Use of a tracking system for patients that miss appointments

According to the Facility Managers, a defaulter is classified as an ARV patient who does not return to the facility after one month. To ensure patients are compliant and adhere to their

medication, tracking systems such as telephones, community care workers, home based carer's and vehicle tracking should be in place. Pill counts, 'to-come-back' dates and visual analogues are used to monitor adherence, however, some patients still do not keep their clinic appointments. Demographic details i.e. patient's name, address and telephone numbers should be recorded. But due to some patients providing incorrect cell phone numbers and addresses some patients cannot be located.

Less than half (4; n=9; 44%) of the facilities updated patient demographic information regularly (Figure 6.21). To ensure that patients can be contacted demographic information pertaining to patients must be updated on a regular basis.

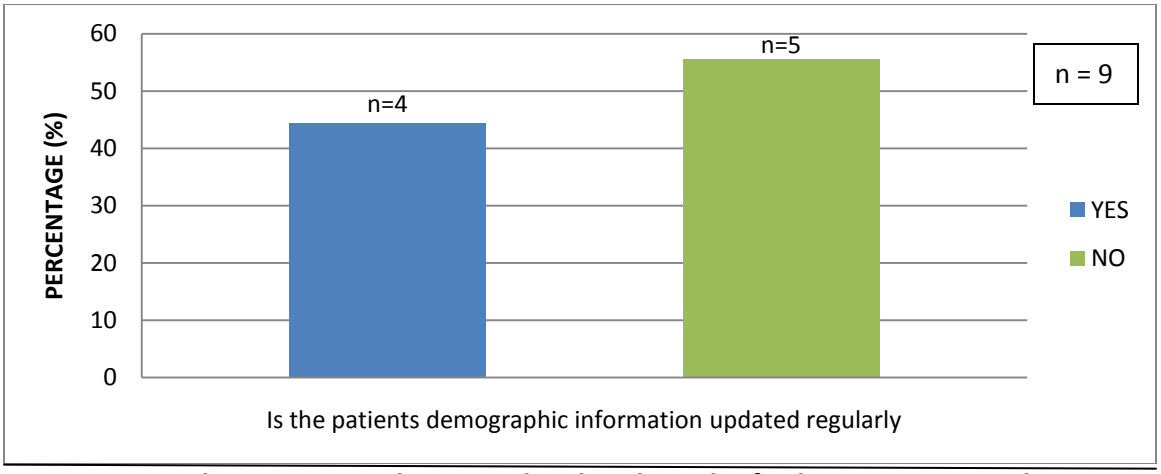


Figure 6.21 Updating patient demographic details at the facilities investigated

Figure 6.22 shows that 44.4% (4; n=9) of the facilities answered "Difficult to say" for the question on how often the demographic details of patients were updated. This could indicate that the facilities did not know the importance of maintaining recent demographic details and or did not have a regular staff member responsible for updating the patient demographic data. Only two (22.2%; n=9) of the facilities updated the patients demographic details at each visit. The results show that the facilities need to be made aware of the importance of obtaining the most recent demographic details of the patients especially contact telephone numbers.

Although the majority of the facilities (7; 77.7%; n=9) had a system in place for tracking patients such as availability of a telephone and community health workers to visit patients at home, only 44.4% (4; n=9) of the facilities had a procedure in place to contact patients that had missed their appointments (Figure 6.23).

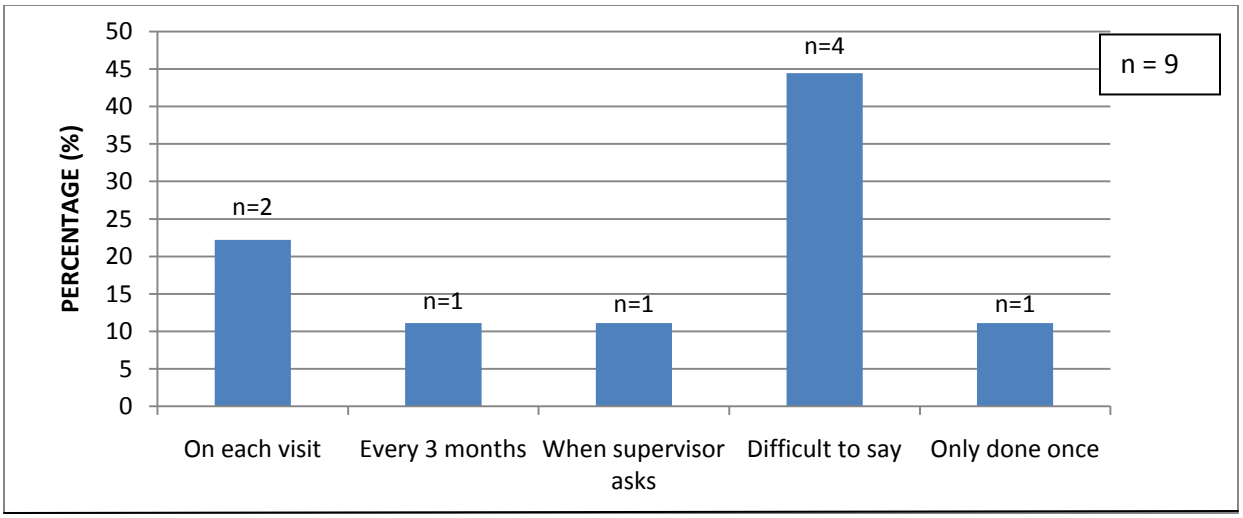


Figure 6.22 Frequency of updating of patient demographic details at the facilities investigated

According to Zulu (2009: 34) failure of a patient to attend scheduled clinic visits could be attributed to death or serious illness of the patient, lack of transport, migration, interpersonal relationships, imprisonment, the preference for traditional medicine and the termination of disability grants. Failure to keep scheduled clinic appointments could result in non-adherence and the development of drug resistance (Department of Health, KwaZulu Natal, 2004). Thus, there needs to be a uniform system in place that all facilities to follow in order to trace patients that have missed their appointment.

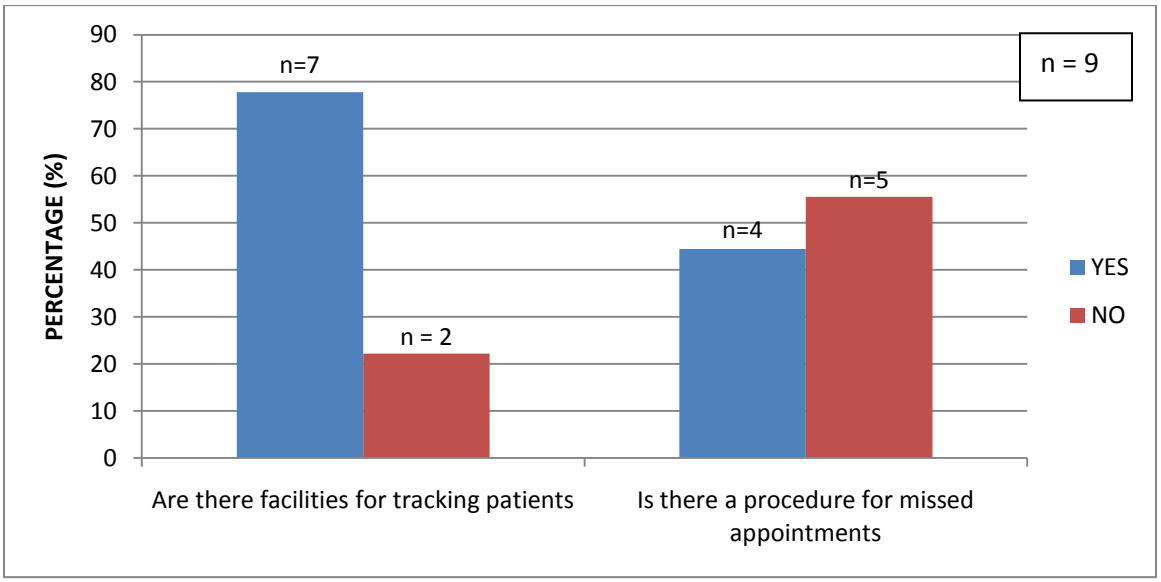


Figure 6.23 Availability of facilities (telephone or community health worker) and procedures for tracking patients that miss appointments

Some of the procedures that were initiated when patients did not arrive for an appointment are shown in Figure 6.24. For the three facilities (33.3%; n=9) that had no procedure in place for patient that missed the scheduled clinic visit the risk involved is that patients will not be located and possible non-adherence and resultant virological failure will occur. Only 55.5% (5; n=9) of the facilities indicated that patients were reminded about their appointments e.g. using an sms system.

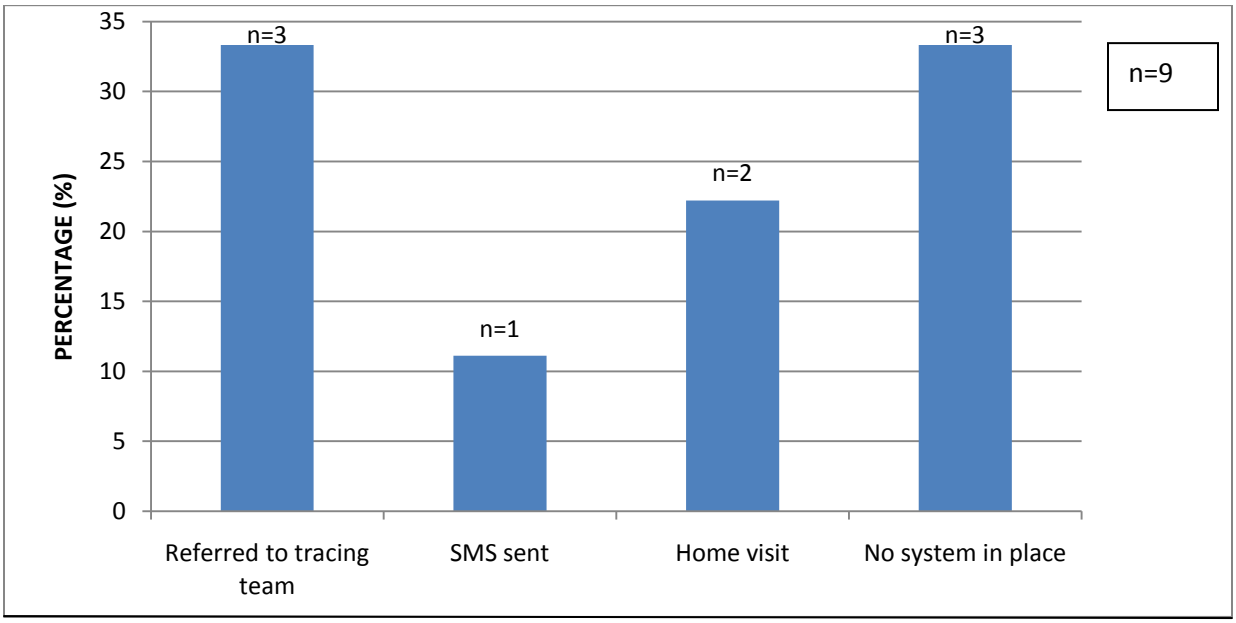


Figure 6.24 Procedures that were used for tracing patients that had missed an appointment

The length of time that it took to follow up on patients that had missed a scheduled clinic visit differed between the clinics. Only 44.4% (4; n=9) of the facilities followed up on patients when the patient was one week late for their appointment; 33.3% (3; n=9) of facilities followed up on patients the day after the patient missed an appointment, 11.1% (1; n=9) of facility followed up on patients the day after the patient missed their second appointment and one (11.1%; n=9) facility did not follow up on patients at all. Although there are no Departmental policies for patients that have missed their appointments, the results showed that most facilities were tracing the patients within one month (7; 77.7%; n=9). According to the Facility Managers the tracing of patients, who have missed appointments was possible due to partnerships with NGOs who provided the required funding and/or manpower.

The minimum requirements needed to track patients who have missed an appointment are a list of defaulters, list of transferred patients and a telephone line. Most, 77.7% (7; n=9) of the facilities had a list of defaulters and 88.8% (8; n=9) had a telephone line allowing the facility to contact patients. All the clinics (9; 100%; n=9) had a record of patients transferred to other facilities. The results showed that eight of the nine facilities had a telephone, therefore, those facilities should have been able to contact the patients if the demographic details were up to

date. Failing this, the home based workers, employed at the facility, could have located the patients by physically visiting the patients at their homes. Figure 6.25 shows that 44.4% (4; n=9) of the facilities traced defaulters using home based workers visiting the patients at home, 33.3% (3; n=9) of the facilities referred the defaulter to a tracing team to locate and 22.2% (2; n=9) of the facilities had no system in place.

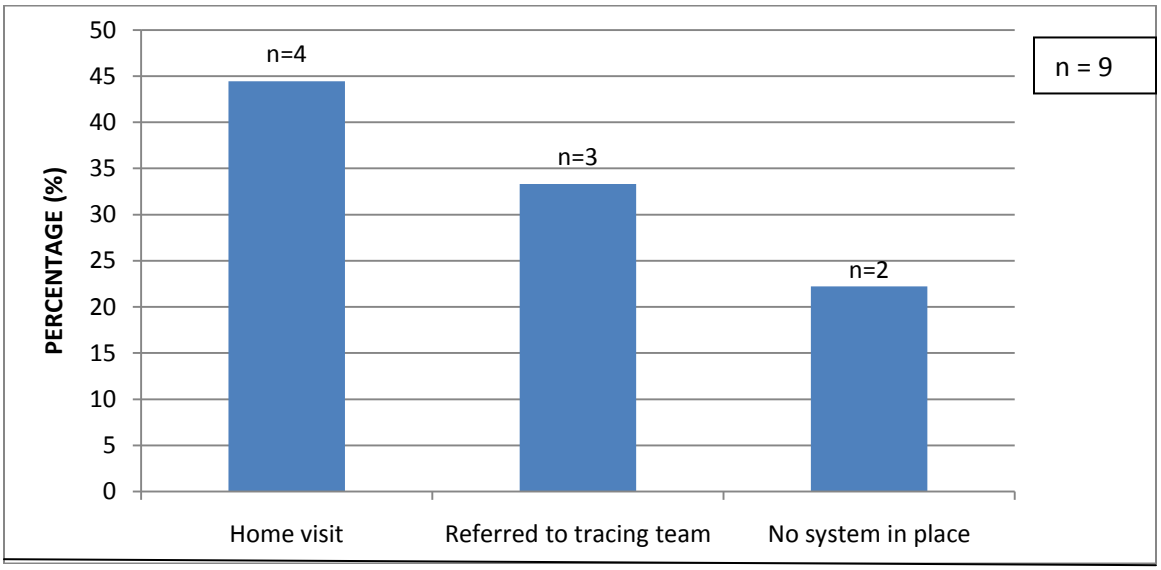


Figure 6.25 Methods used to track patients who had missed their appointments

6.5.4 Summary of the Clinic Procedure Audit

The introduction of HAART has extended and improved the quality of life of patients living with HIV/AIDS by reducing the viral load to nearly undetectable levels. However, strict adherence to antiretroviral medication is essential in order to obtain the desired benefit and to avoid the emergence of drug resistance and clinical failure. Lack of strict adherence to antiretroviral medications is one of the biggest challenges to AIDS care in South Africa (Friedland, 2003: 39). Retaining patients on treatment and following up on defaulters is imperative in order to reduce the resistance to ARVs and minimise treatment failure. In this section the following procedures where discussed: transfer forms for patients, follow up of referred patients, tracking systems for patients, updating patient contact details, missed patients and defaulters.

Two (22.2%; n=9) of the facilities indicated that there were no transfer forms available at the facilities and six (66.6%; n=9) of the facilities stated that the forms were not filled out completely. Seven (77.7%; n=9) of the facilities did not follow up on patients that were referred from a lower level of care such as a clinic to a higher level of care such as a hospital. Only four (44.4%; n=9) of the facilities in this study updated the patient's demographic details regularly. Of the nine facilities, three (33.3%; n=9) did not use a tracking system to locate patients that

had defaulted and five (55.5%; n=9) facilities did not have any procedure in place for missed appointment by patients. (Figure 6.23)

The transfer of patients to a facility nearer to their home reduces the financial burden associated with cost and loss of income for clinic visits. In addition, decentralising treatment to Primary Health Care clinics will enable the expansion of ARV provision. Easy access to treatment is essential to ensure treatment continuity and adherence. It is important that in transferring the patient, the patient's demographic details are obtained in order to track the patient. This study highlighted the lack of standard procedures for transfer of patients. The staff need to be educated on the importance of completing the transfer forms correctly and facilities need to have standard mechanisms in place to track patients.

6.6 STAFFING

6.6.1 Introduction

The HIV and AIDS crisis has led to an increase in health care needs The public health sector continues to be under-funded and is faced with a serious human resources crisis (Lehmann, 2008: 166). More than one third of public sector posts remain vacant (Day and Gray, 2007: 309-310). In South Africa significant shortages of professional nurses, medical officers, lay counsellors and administrative personnel exist (Lehmann, 2008: 170). The biggest threat to the implementation of the 2007-2011 National HIV/AIDS Strategic Plan for South Africa is the unavailability of skilled personnel. This section of the study was conducted to determine the number of staff available at the HIV facilities, training of staff, and the availability of SOPs. The Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa was used to compile the Staffing Audit Form and the Dual therapy PMTCT policy was used to compile the Healthcare Worker Questionnaire (Department of Health, South Africa, 2003: 102-127; Department of Health, South Africa, 2008a).

6.6.2 Study population and site

The study population for the Staffing Audit Form included all nine facilities (n = 9). The Audit Form was completed by the researcher with the aid of the Facility Manager. Prior to arriving at the facility, the researcher made an appointment with the Facility Manager. The response rate was 100% (9; n=9). The audit form was piloted by the researcher at a Primary Health Care clinic in NMB, not involved in the current study. No amendments were made to the Audit Form. The time taken to complete the audit form was one and a half hours.

6.6.3 Analysis of the Staffing Audit Form

The Staffing Audit Form was used to determine the number of nurses, counsellors and doctors at the facilities and with reference to the core staffing requirements calculated in the Operational Plan for South Africa determine the percentage understaffing. The numbers of pharmacists required for the facilities were determined, but, were not included in the tabular comparison of the facilities. (Department of Health, South Africa, 2003: 106)

6.6.3.1 Patient load

The catchment area varied according to the area in which the facility was situated. The population of the catchment areas ranged from 18000 to 1.6 million (mean: 380 146; ±595 491).

The total average number of patients seen at the ART facilities per month during April 2009 to October 2009 was 1920.8 ± 977. The minimum number of patients was 550 per month and the maximum number of patients was 3290 per month during the seven month period (Figure 6.26).

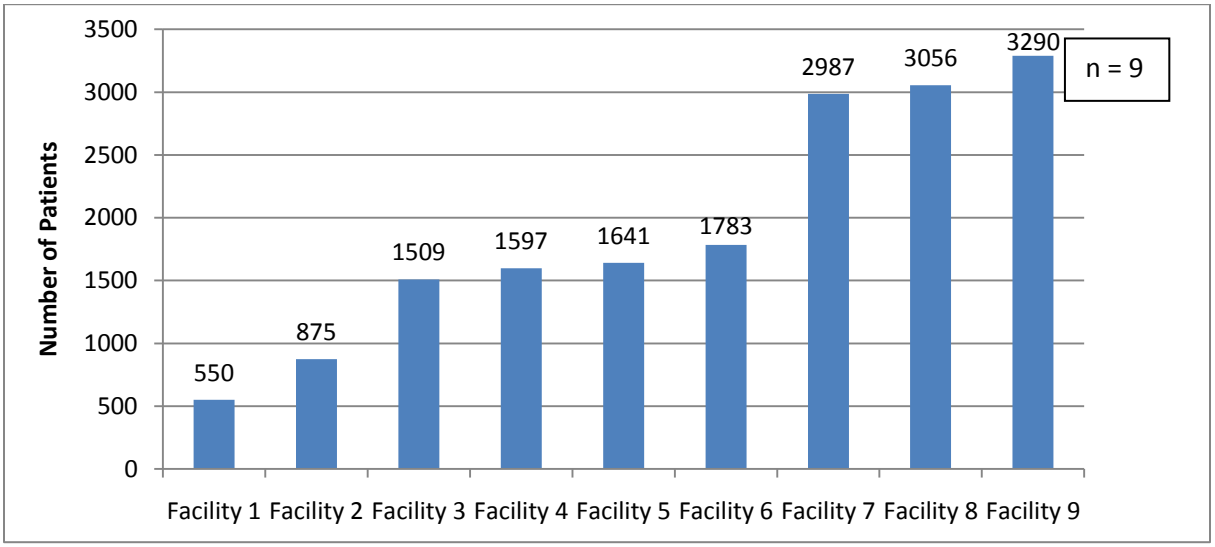


Figure 6.26 The average number of patients seen at the facilities per month from April 2009 to October 2009

6.6.3.2 Staffing levels

The average number of staff at each facility was 25.7 ± 13.2 (min: 9; max: 55; n = 231) and the average number of staff at a wellness clinic was 9.2 ± 3.6 (min: 5; max: 17; n = 83). The average number of nurses at a wellness clinic was 4.1 ± 2.5 (min: 2; max: 10; n = 37); the average number of counsellors at a wellness clinic was 4.1 ± 1.8 (min: 2; max: 6; n = 36) and the average

number of doctors at a wellness clinic was 1.1 ± 0.3 (min: 1; max: 2; n = 10 (Table 6.3). However, as the counsellors were only working five hours per day (5/8 post) the number of Full Time Equivalent (FTE) posts were calculated by multiplying the number of counsellors (36) by 5/8 to give 22 FTEs.

Table 6.3: The number of doctors, nurses and counsellors at each facility

FACILITY	Total no. of staff	Total no. of staff in the wellness clinic	Total no. of nurses in wellness clinic	Total no. of doctors in wellness clinic	Total no. of counsellors in wellness clinic; and FTE*	
					(no.)	(FTE*)
Facility 1	22	9	2	1	6	3.8
Facility 2	9	5	2	1	2	1.3
Facility 3	32	10	4	2	4	2.5
Facility 4	23	17	10	1	6	3.8
Facility 5	27	6	3	1	2	1.3
Facility 6	27	7	3	1	3	1.9
Facility 7	12	12	5	1	6	3.8
Facility 8	55	8	5	1	2	1.3
Facility 9	24	9	3	1	5	3.1
AVERAGE	25.7	9.2	4.1	1.1	4.0	2.5
STANDARD DEVIATION	13.2	3.6	2.5	0.3	1.8	1.1

*FTE = Full Time Equivalent. All counsellors were appointed to 5/8 posts. The number of FTEs was calculated by multiplying the number of counsellors by 5/8.

In the Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa the core staffing requirements per category of health care worker that would be required per facility was estimated. For the treatment of 500 patients the minimum full time equivalent for nurses, doctors and counsellors was 2; 1 and 5 respectively (Department of Health, South Africa, 2003: 106).

Using the number of patients seen at a facility, the number of nurses, doctors and counsellors at the facility and the core staffing requirement to treat 500 patients the staff required at each facility was calculated. The facilities on average required 7.6 nurses; 3.8 doctors and 19 counsellors to treat the average number of patients seen at the facilities. Table 6.4 indicates the actual numbers of nurses, doctors and counsellors at the facilities and the percentage of understaffing at the facilities. At Facility 4, the actual number of nurses was greater than the

proposed number of nurses due to nursing staff from the antenatal clinic, tuberculosis department and immunisation department assisting in the Wellness Clinic at the time of the study (Table 6.4).

Table 6.4: Actual staffing levels compared to the minimum number required according to the proposed norm

		NURSES			DOCTORS			COUNSELLORS			
FACILITY	**Average no. of patients per month**	**Minimum no. of nurses required – proposed norm**	**Number of. nurses – actual**	**Percentage under-staffed (%)**	**Minimum no. of doctors required – proposed norm**	**Number of doctors – actual**	**Percentage under-staffed (%)**	**Minimum no. of counsellors required – proposed norm**	**Number of counsellors – actual**	**Number of FTE* counsellors posts**	**Percentage under-staffed**
Facility 1	550	2	2	0	1	1	0	5	6	3.8	24
Facility 2	874	3.5	2	42.9	2	1	50	10	2	1.3	87
Facility 3	1509	6	4	33.3	3	2	33.3	15	4	2.5	83.3
Facility 4	1597	6	10	-66.7†	3	1	66.7	15	6	3.8	74.7
Facility 5	1641	6.5	3	53.8	3	1	66.7	15	2	1.3	91.3
Facility 6	1783	7	3	57.1	3.5	1	71.4	18	3	1.9	89.4
Facility 7	2987	12	5	58.3	6	1	83.3	30	6	3.8	87.3
Facility 8	3056	12	5	58.3	6	1	83.3	30	2	1.3	95.7
Facility 9	3290	13	3	76.9	6.5	1	84.6	33	5	3.1	90.6
AVERAGE	1920	7.6	4.1	45.6	3.8	1.1	96.0	19	4.0	2.5	78.9
STANDARD DEVIATION	977	3.9	2.5		1.9	0.3		9.8	1.8	1.1	

*FTE = Full Time Equivalent † = A negative percent indicates overstaffing at a facility

The staffing level at the study facilities was drastically below the number of staff that should be at the facilities in order to treat the patient load. The facilities experienced an average understaffing of: nurses at 45.6%; doctors at 96% and counsellors at 78.9% (Table 6.4). The scale-up of HIV/AIDS care poses a challenge for a health system that is already struggling with a shortage of qualified health staff. Some of the reasons for the shortage of skilled workers are

emigration, migration from public facilities to private facilities and increasing number of workers retiring (Lehmann, 2008: 166).

The estimates norms for full time employees required per 500 patients were made in 2003 (Department of Health, South Africa, 2003: 106) and the plan has not been revised since then. Furthermore, the number of patients accessing and requiring treatment in South Africa has increased. As more people have access to treatment they will live longer and continue to present themselves for care thus placing a greater strain on the health care system and a substantial increase in human resources will be required.

6.6.3.3 Availability of pharmacists and pharmacist assistants

Five (55.5%; n=9) of the facilities had a full time pharmacist. At three facilities the pharmacist only worked one day a week and rotated between five or more facilities. Eight of the facilities (88.8%; n=9) had a post basic pharmacist assistant and five of the facilities (55.5%; n=9) had a basic pharmacist assistant. At the ninth facility a registered nurse with no dispensing license provided dispensing services. The Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa estimated that for every 500 patients on ARVs a facility would require one pharmacist, thus for the study facilities 34 pharmacists would be required (Department of Health, South Africa, 2003: 106). The staffing norms for pharmacist assistants for clinics have not been established (Lehmann, 2008: 172).

During the audit, the researcher found that due to the shortage of pharmaceutical personnel at the facilities and the high workload of the post basic pharmacist assistants, the basic pharmacist assistants were dispensing medication to the patients. According to law governing pharmacy personnel, the scope of practice of basic pharmacist assistants does not allow them to dispense medication to patients (South African Pharmacy Council, 2009a: 10).

Table 6.5 indicates the actual staffing levels of pharmacists and post basic pharmacist assistants compared to the minimum number required according to the proposed norm. At Facility 1 and Facility 3 the actual norm of pharmacy personnel was greater than the proposed norm of pharmacy personnel, hence the negative percentage indicates overstaffing of pharmacy personnel at the facility (Table 6.5). One of the aims of the NSP (2007-2011) is to scale-up the provision of PMTCT (Department of Health, South Africa, 2007a: 9). The 2010 dual therapy PMTCT protocol accelerates the provision of PMTCT services by enabling HIV infected pregnant women to commence lifelong ART earlier (Department of Health, South Africa, 2010b: i). Thus, there will be an increase in the number of patients accessing treatment at facilities. This study highlights the shortage of pharmacy personnel (Table 6.5). To ensure continuity of the provision of PMTCT services, this shortage of pharmacy personnel needs to be addressed.

Table 6.5: Actual staffing levels of pharmacists and post basic pharmacist assistants compared to the minimum number required according to the proposed norm.

FACILITY	Pharmacist*	Postbasic Pharmacist Assistant	Total Pharmacy Personnel	Minimum required proposed norm‡	Percentage understaffing
Facility 1	1	1	2	1	-100
Facility 2†	0	0	0	2	0
Facility 3	0.2	3	3.2	3	-6
Facility 4	1	1	2	3	33.3
Facility 5	1	1	2	3	33.3
Facility 6	0.2	2	2.2	3.5	37.1
Facility 7	1	2	3	6	50
Facility 8	1	1	2	6	66.7
Facility 9	0.2	3	3.2	6.5	50.8
AVERAGE	0.7	1.6	2.8	3.8	42.4
STANDARD DEVIATION	0.45	1	1.5	1.9	

*** If the pharmacist was present for 1day per week the clinic was allocated 0.2 of a pharmacist**
† A negative percentage indicates overstaffing at a facility
‡ Staffing norms for pharmacists assistants are not established thus, for the purposes of this study the total number of pharmacy personnel (sum of pharmacists and post basic pharmacist assistants) was compared to the staffing norm for pharmacists

6.6.3.4 Vacant posts

Only four of the nine facilities (44.4%; n=9) had vacant nursing posts. The total number of vacant posts was 14. The vacancy level for as a percentage of all posts was 16.9% for all staff and 37.9% for nursing staff. The vacancy level was calculated by dividing the number of vacant posts by the product of the average number of staff and the number of facilities and multiplying by 100. A vacant post refers to an advertised position for a job that has not been occupied and for which there is funding available. Some of the reasons given by the other five facilities for not having any vacant posts were that a new organogram had been developed and the posts were not advertised as yet; posts were frozen due to budget constraints and the facility was in the interim planning for more staff in the next financial year.

In 2008, in the Eastern Cape the vacancy level for nurses was 53.6% and the vacancy level for doctors was 40% (Health Systems Trust, 2009). The high vacancy level of nurses found in this study further compounds the problems caused by the shortage of health care workers such as patients having to wait for new appointments, delays in treating patients, increased waiting times for patients at the facilities and low motivation amongst health care workers due to the increase in workload. The reduced number of health personnel has been identified as one of the key impediments to providing an effective PMTCT service (Skinner *et al.,* 2003: 14).

6.6.3.5 Nursing staff and counsellors

The patient nurse ratio can be defined as the number of patients seen by the nurse in a clinical work day. The patient-nurse ratios were available for six of the nine facilities wellness clinics. The data regarding the ratio of nurses to patients for the other three facilities was not available at the time the questionnaire was administered. The average ratio of patients to nurses at the facilities investigated was 1:66 (one nurse to 66 patients) with a standard deviation of 46.2. The Health Systems Trust reported in 2006 that the ratio of patients to nurses in South Africa was 1:28 while in the Eastern Cape it was 1:29 (Health Systems Trust, 2009). South Africa is facing a crisis in human health resources due to a critical shortage of health workers. The shortage is compounded by a high burden of infectious diseases, emigration of trained professionals, difficult working conditions and low motivation (Lehmann, 2008; 169; Zachariah *et al*., 2009: 549). Thus the study shows that the shortage of health care workers especially nurses has impacted on the study facilities with the nurses having to work far above the national average ratio of 1:28.

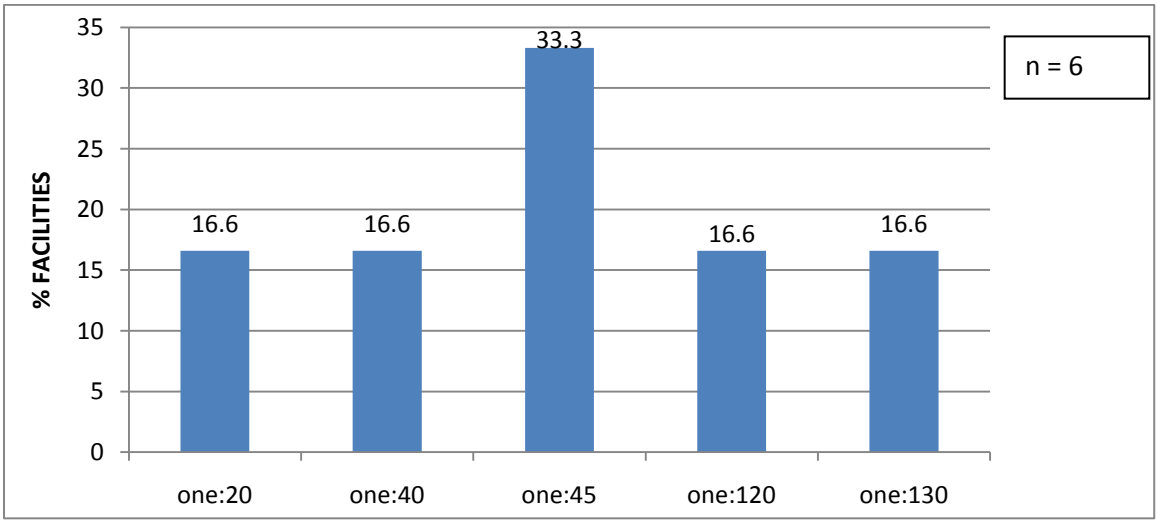


Figure 6.27 The nurse-patient ratio at the facilities (n=6)

All the facilities (9; 100%; n=9) had lay counsellors appointed and all of the lay counsellors (36; 100%; n=36) were renumerated and had been trained. In response to the HIV epidemic the

Department of Health made provision for the appointment of lay counsellors who are paid a stipend by NGOs (Lehmann, 2008: 171). However, although all the facilities had lay counsellors (100%; n=36) the counsellors were appointed to a 5/8 position. One of the main concerns brought up by the Facility Managers was that the lay counsellors at the facilities were employed by different NGOs. Non-governmental organisations support the government with the roll-out of antiretrovirals by employing and training health care workers including counsellors (Lehmann, 2008: 171). The Facility Managers assisting in the completion of the audit form indicated that due to the different training the counsellors received from the various non-governmental agencies the information passed on to the patient regarding HIV was not standardised. According to the Facility Managers this was also in part due to the cultural backgrounds of the counsellors. An additional barrier to patient education was that the counsellors did not speak the same language as the HIV course trainer resulting in the counsellors interpreting the information incorrectly. Therefore, although the results indicated that all the counsellors were trained, a challenge existed in ensuring that all the counsellors passed on uniform information to the patients. The average number of lay counsellors employed at the facilities was 2.5 ± 1.1 due to the counsellors working half a day only (5/8 position). The study found that the average number of patients seen at the facilities was 1920 (Figure 6.1). Based on the Department of Health's Operational Plan for HIV and Aids Care, Management and Treatment estimates the required number of counsellors would be 19, an understaffing of 78.9% (Table 6.2). Thus, the shortage of counsellors in the facilities was highlighted in the study. Community care workers such as lay counsellors have been identified as an important resource for primary health care (Lehmann, 2008: 170).

6.6.3.6 Working conditions

The majority of facilities did not require staff to work shifts or overtime. Only one (11.1%; n=9) facility worked shifts and two (22.2%; n=9) of the facilities worked overtime. According to the Facility Managers, who assisted the researcher in the completion of the audit forms, the results for shift work could be attributed to the maternity wards which are opened after hours and on week-ends. The results for overtime could be attributed to staff members being absent from work, on leave or coming in late for work, thus causing the staff member on duty to work extra hours and claiming for overtime.

All the facilities 100% (9; n=9) had a procedure in place to handle patient complaints about staff members. This is encouraging as according to Batho Pele Principles all patients have the right to complain regarding service delivery (Department of Health, South Africa, 2007b).

6.6.3.7 Job description and performance appraisal for staff

At six (66.6%; n=9) of the facilities there was a job description for the staff and five (55.5%; n=9) of the facilities undertook performance appraisals. A job description outlines the requirements for a specific position and is used by Human Resource Departments to measure an employee's performance thereby determining the relative worth of an employee to an organisation. A performance appraisal is a method by which the job performance of an employee is evaluated and is a part of guiding and managing the career development of the employee. (Heathfield, 2010)

One of the criteria for an effective healthcare system is an efficient Human Resource Department. In order for employees to function at their maximum capabilities the employees need to know the requirements of the job. The results show that three (33.3%; n=9) of the facilities did not have a job description for the employees. Therefore, there is a possibility of employees at those facilities not performing all the required functions of the job. Furthermore, four (44.4%; n=9) of the facilities did not undertake a performance appraisal of their employees and the performance of the employee could, therefore, not be assessed.

6.6.3.8 Staff training

Of the nine facilities studied, eight (88.8%; n=9) of the facilities indicated that there was training was available for staff members. Primary healthcare in South Africa is overwhelmingly driven by nurses. Most clinics are staffed by professional, enrolled and auxiliary nurses who are supported by clerical workers. In the face of a rising demand due to an increased burden of disease and a growing population, the training of sufficient numbers of nurses with appropriate skills must be a human resources priority (Lehmann, 2008: 169). Although eight (88.8%; n=9) of the facilities do provide training for their health care workers, training should be provided at all (100%; n=9) of the facilities.

Only two (22.2%; n=9) of the facilities provided training associated with HIV and AIDS on a monthly basis; four (44.4%; n=9) of the facilities provided training on an annual basis and three (33.3%; n=9) of the facilities only sent their staff for training programs when they had sufficient staff to maintain the functioning of the clinic (Figure 6.28). New guideline recommendations for the treatment of HIV/AIDS are continually being developed and implemented (Department of Health, South Africa, 2010a). Thus it is important that all staff are continuously trained and updated on any new developments. The National Human Resource Plan, finalised in 2006, indicated that the training of health professionals must keep abreast of all trends that impact on health care, especially the changing disease profiles and global human resource trends (Department of Health, South Africa, 2006b).

Five (55.5%; n=9) facilities sent only one staff member for training at any given time, three (33.3%; n=9) facilities sent one to two staff members and one (11.1%; n=9) could only send a staff member for training when sufficient staff were available to run the clinic.

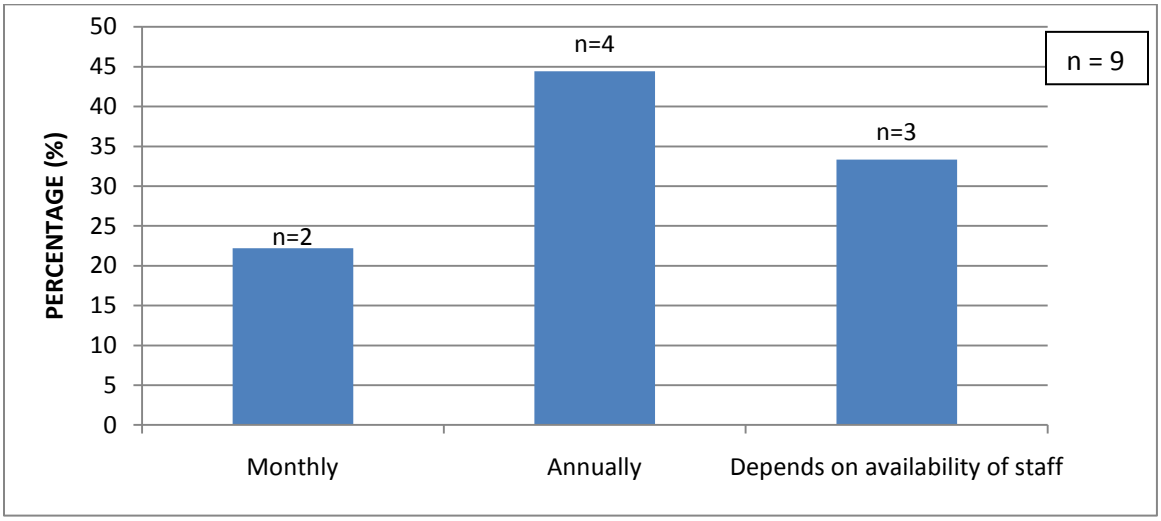


Figure 6.28 Frequency of provision of staff training at the facilities in the study

The average duration of a training course was two days. The results also showed that for five (55.5%; n=9) of the facilities training was done off site.

The significant shortage of medical officers, nurses and lay counsellors in South Africa (Lehmann, 2008: 163) could impact on the training of health care workers. Three (33.3%; n=9) facilities sent health care workers for training depending on the availability of staff at the facility to maintain normal functioning of the clinic. The difficulty incurred in sending staff for training could also be affected by the fact that more than half of the facilities (5; 55.5%; n=9) indicated that training occurred off site. Eight facilities (88.8%; n=9) reported that feedback was received from the training sessions. Thus the information received during the training, that some of the health care workers received, was disseminated to staff at the facility who had not attended the training session.

Of the nine facilities, only eight facilities completed the question on whether doctors, nurses and counsellors were trained. During the study period (April 2009 to October 2009) the Facility Managers who completed the questionnaires with the researcher for each facility indicated that doctors at 75% (6; n=8) of the facilities had been trained on HIV, nurses at all the facilities (8; 100%; n=8) had been trained on HIV and counsellors at 87% (7; n=8) of the facilities had been trained on HIV. (Figure 6.29)

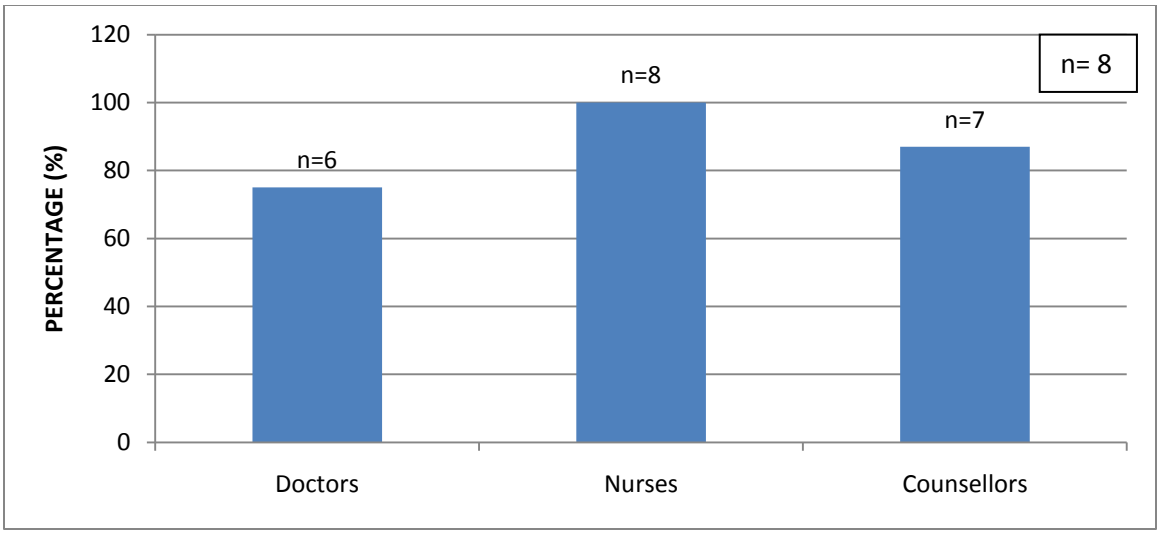


Figure 6.29: The percentage of doctors, nurses and counsellors trained

In 2003 the Department of Health planned to develop the basic competencies required by all health care workers who would directly deliver the comprehensive services for HIV and AIDS care and treatment. This included continuing professional development programmes that updated health professionals on the latest developments and policies pertaining to HIV and AIDS. The Operational Plan for Comprehensive HIV/AIDS Care, Management and Treatment indicated that it was the duty of each province to designate a training coordinator from existing personnel to ensure that training needs were identified and that staff were fully prepared for the launch of any new policies. Doctors, nurses, pharmacists and lay counsellors should complete training on a priority basis. (Department of Health, South Africa, 2003: 110)

6.6.4 Summary of Staffing Audit Form

The aim of this section was to determine the patient load, staffing levels, vacant posts, working conditions, job description and performance appraisals for staff and the training of staff at the facilities in the study. The key conclusions for the Staffing Audit are summarised below:

The key results for patient load and staffing levels were: the average number of patients that attended the study facilities per month was 1920 ± 977; the average number of nurses at the wellness clinic was 4.1 ± 2.5; the average number of doctors at the wellness clinic was 1.1 ± 0.3; the average number of lay counsellors at the wellness clinics was 4.1 ± 1.8. However, the lay counsellors worked only for half a day (5/8 posts), therefore, the average number of lay counsellors based on half day posts was 2.5 ± 1.1. The results show that five (55.5%; n=9) of the facilities had a full time pharmacist. At three facilities the pharmacist only worked one day a week and rotated between five other facilities. Eight of the facilities (88.8%; n=9) had a post

basic pharmacist assistant, five of the facilities (55.5%; n=9) had a basic pharmacist assistant and one (11.1%; n=9) of the facilities had a registered nurse with no dispensing license.

Only four (44.4%; n=9) of the facilities had vacant posts for the employment of health care workers. Three facilities (33.3%; n=9) did not have a job description available for staff and four facilities (44.4%; n=9) did not undertake performance appraisals of staff.

With regards to staff training one facility (11.1%; n=9) stated that no training had been provided to the staff, four facilities (44.4%; n=9) stated that training was provided only once a year and three (33.3%; n=9) that training was provided when there were staff available to maintain the functioning of the facility.

One of the major barriers highlighted in this study was the shortage of nurses, doctors, counsellors and pharmacists at the facilities investigated. The facilities experienced an average understaffing of: nurses at 45.6%; doctors at 96.0% and counsellors at 78.9%. Although posts are advertised the vacancy level is not adequate to meet the needs of the facility. The shortage of staff will affect the provision of PMTCT services and decrease the uptake rate of patients into the PMTCT programme as facilities will not be able to cope with the increasing number of patients.

6.6.5 Healthcare Worker Questionnaire

6.6.5.1 Introduction

The introduction of the PMTCT programme, as with any new health programme, required training of nurses in order for the nurses to acquire and develop HIV knowledge, skills and attitudes. When the PMTCT programme was initiated in April 2001, there was no strategic plan to train health care workers; instead provinces either relied on local academic resources or local non-governmental agencies to train the health care workers. The Eastern Cape Province relied on non-governmental agencies and academic institutions to assist with the training (Tint *et al.,* 2003: 4). The effective organisation and provision of training is possibly the most important function of national and provincial management. Unless the available human resources at site and facility level have the correct and appropriate knowledge, skills and attitudes, the PMTCT programme is only partially effective. Questions need to be asked as to whether health professionals, in general and nurses, in particular, are indeed prepared to address the changing burden of disease, and to function effectively in primary and community care settings.

6.6.5.2 Study population and site

The study sample for the Healthcare Worker Questionnaire consisted of the nursing staff working at the facilities. The response rate was 100% (81; n=81). The number of respondents differed for each question, therefore, the value (n) for each question may differ according to the number of respondents that answered. Due to the rotation of nurses from other departments through the wellness clinic, the study sample included nurses from other departments and not only the wellness clinic staff. The questionnaire was piloted by five nurses at a Primary Health Care clinic in NMB, not involved in the current study. No amendments were made to the questionnaire. The time taken to complete the Healthcare Worker Questionnaire was one hour.

6.6.5.3 Analysis of Healthcare Worker Questionnaire

The Healthcare Worker Questionnaire was used to determine the demographics of the respondents, the training of respondents on HIV/AIDS and PMTCT and the knowledge of the dual therapy PMTCT protocol.

(i) Demographics

Of the respondents 97.5% (78; n=80) were female and 2.5% (2; n=80) were male (Figure 6.30). At the end of 2008, 93% of the registered nurses in South Africa and the Eastern Cape were female and only 7% were male (South African Nursing Council, 2009). Therefore, the study sample follows the same pattern of a greater percentage of females employed in the nursing sector compared to males.

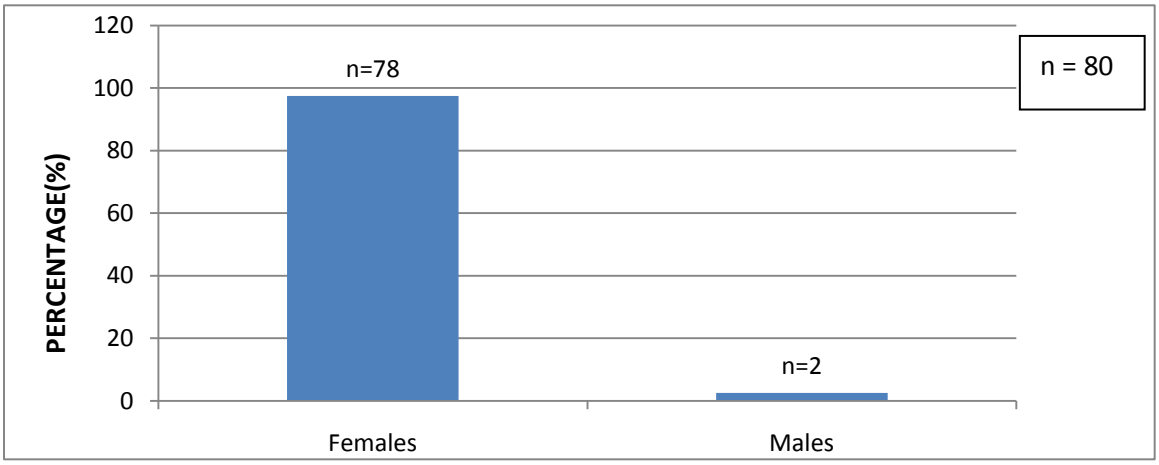


Figure 6.30 The gender demographics of the respondents

Of the respondents 7.6% (6; n=78) were less than 30 years of age, 21.7% (17; n=78) were between 30 to 34 years, 25.6% (20; n=78) were between 35 to 39 years and 44.8% (35; n=78) were over 40 years of age (Figure 6.31). The South African Nursing Council reported at the end of 2008 that 61% of registered nurses in South Africa were over 40 years old and only 3% were under 30 years of age (South African Nursing Council, 2009). Thus a large percentage of qualified nurses will probably be at an age to retire within the next 10 years. This study showed that 44.8% of the nurses were over the age of 40. Thus, it is possible that within the next five to ten years a large percentage of nurses would be of retiring age. According to Lehmann (2008: 168) this could have implications for the training of nurses as training institutions would have to increase the output of trained nurses to maintain current levels not taking into consideration the increased demand due to the HIV/AIDS pandemic.

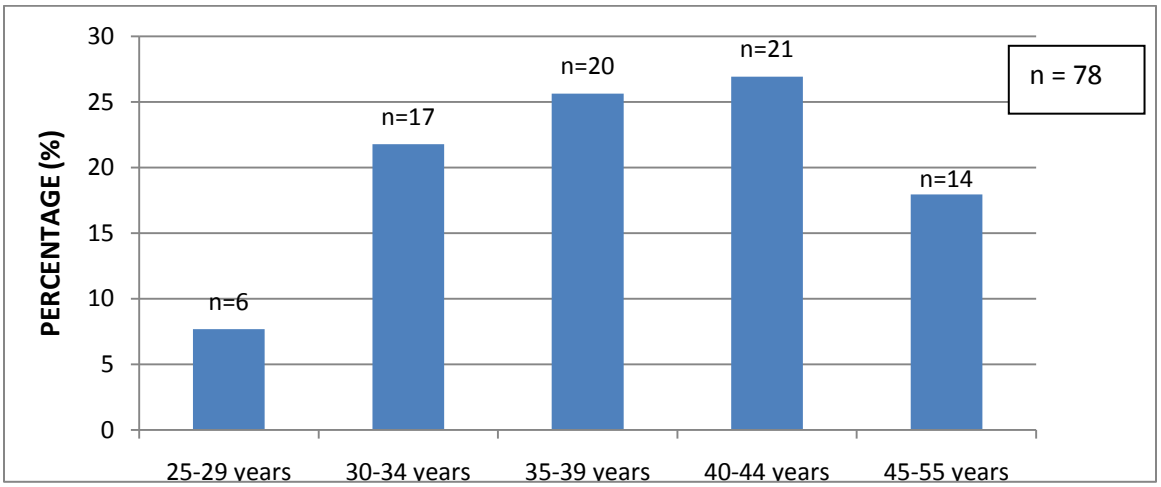


Figure 6.31 Age analysis of the nursing staff

The majority of respondents, 65.7% (48; n=73) had a diploma in nursing; 26.0% (19; n=73) had a bachelor's degree in nursing; 5.4% (4; n=73) had a master's degree in nursing and 2.7% (2; n=73) of respondents were registered midwives (Table 6.5). The provision of PMTCT services requires a professional nurse, hence, the study shows that the majority of the respondents had a tertiary qualification (73, 90.0%; n=81) and the majority were professional nurses (66; 81.4%; n=81).

At the time of the study 83.5% (66; n=79) of the respondents were qualified professional nurses; 8.8% (7; n=79) were enrolled nurses; 3.7% (3; n=79) were staff nurses; 2.5% (2; n=79) were community liaison officers and 1.26% (1; n=79) of the respondents were managers (Table 6.6). Thus the majority of respondents who had a tertiary nursing qualification were employed as professional nurses.

Table 6.6: Qualification of the nursing staff (n=73)

Qualification	Percentage Response	n
Diploma in nursing	65.7	48
Bachelors degree in nursing	26	19
Masters degree in nursing	5.4	4
Registered midwife	2.7	2

Table 6.7: Job description of the nursing staff (n=79)

Job description	Percentage Response	n
Professional nurses	83.5	66
Enrolled nurses	8.8	7
Staff nurses	3.7	3
Community liaison officer	2.5	2
Manager	1.26	1

The majority (73; 90.2%; 81) of the respondents had worked for more than five years since obtaining their tertiary qualification in nursing (Figure 6.32).

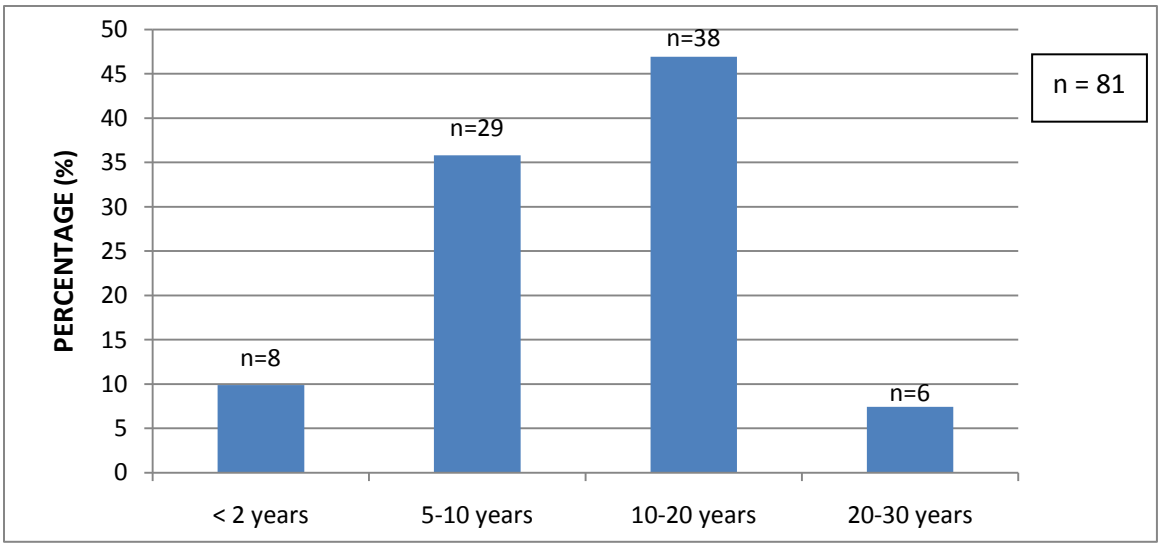


Figure 6.32 The number of years worked by the respondents since obtaining their tertiary qualification in nursing

The majority 73.3% (58; n=79) of the respondents had been in their current position for less than three years. The PMTCT programme has been in operation for ten years and together with the numerous protocol changes with regards to PMTCT, the staff shortages and the increasing workload it can be assumed that the majority of the respondents (58; 73.3%; n=79) working in their current position were not well experienced in terms of the policy for PMTCT, HIV and AIDS.

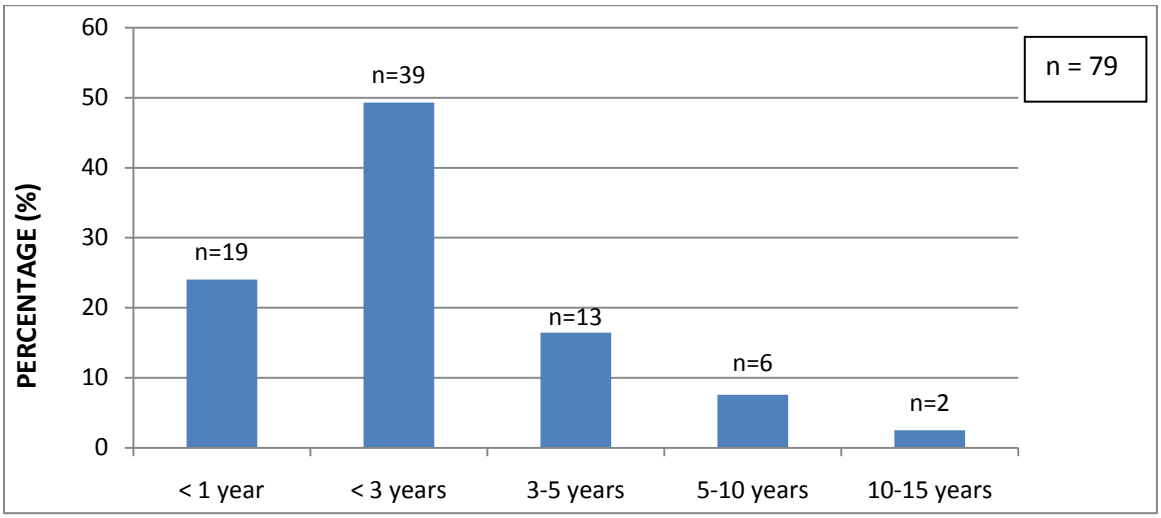


Figure 6.33 Number of years in current position

(ii) HIV/AIDS and PMTCT training received

The majority of nurses 82.7% (67; n=81) had received training on HIV and AIDS, 65.4% (53; n=81) and 54.3% (44; n=81) had received training on PMTCT and dual PMTCT policies respectively (Figure 6.34). The percentage of respondents that had received training on maternal zidovudine dosing was 55.5% (45; n=81). Only 36.2% (29; n=81) and 41.2% (33; n=81) of the respondents had received training on infant zidovudine dosing and infant nevirapine dosing respectively (Figure 6.34).

The dual therapy PMTCT protocol was introduced in NMB in August 2008 (Zweni, 2008). Between January 2008 and June 2008 only 19.5% (8; n=41) of the respondents had received training on the dual PMTCT protocol; between July 2008 and December 2008 only 73.1% (30; n=41) of the respondents received training and during 2009, 4.8% (2; n=41) of the respondents received training. One of the key barriers to the implementation of any new protocol is the training of health care workers.

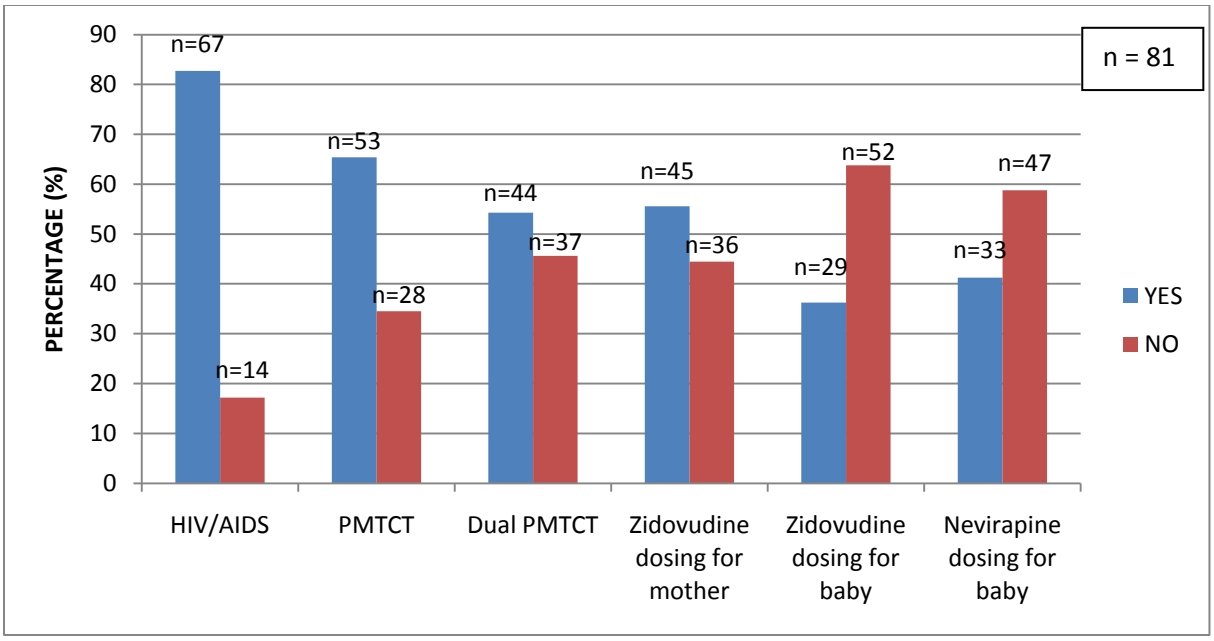


Figure 6.34 Training received by nurses on HIV/AIDS and PMTCT

In a study done, in 2008, it was found that one of the barriers to the PMTCT programme in the Eastern Cape, South Africa was the shortage of nurses at the facilities trained in PMTCT due to high staff turnover and transfer of staff (Phaswana-Mafuya and Kayongo, 2008). In addition, the Human Science Research Council (HSRC) reported, in a 2009 study, that there were many clinics that had staff members that had not yet been trained for any of the PMTCT services thus making it difficult to implement the PMTCT protocol fully. The lack of training had lowered staff morale and thus further impacted on the progress of the implementation of the PMTCT programme (Peltzer *et al.,* 2009: 29). This study highlighted the challenges regarding the training of healthcare workers prior to the implementation of a new protocol, as at the time of the start of the dual therapy PMTCT programme in the facilities only 19.5% (8; n=41) of the respondents had been trained. The shortage of trained nurses in dual therapy PMTCT could affect the effective provision of PMTCT services.

Most of the respondents 80.7% (63; n=78) did not attend CPD courses and 80.2% (65; n=81) of the respondents did not participate in multi-disciplinary team meetings to discuss case studies. Furthermore, 91.3% (74; n=81) of the respondents indicated that updates on new drugs were not provided by pharmaceutical representatives. Prior to the implementation of HIV/AIDS services in South Africa, the Department of Health developed the Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment. Training all relevant health care workers in HIV/AIDS was a priority for effective implementation. The Comprehensive HIV/AIDS Care, Management and Treatment programme also focused on the continuous development of healthcare workers in the form of CPD courses to upgrade training of the healthcare workers on the new developments in the field (Department of Health, South Africa,

2003: 110-116). In a study undertaken by the HSRC, one of the recommendations outlined by the HSCR was that CPD activities for health professionals should be made compulsory so that health care workers were abreast with current policies and treatment guidelines and to ensure that uniform messages were disseminated to the public (Peltzer *et al.,* 2009: 29). It can be seen from this study that the continuous development of nurses was not occurring as most of the respondents had not attended CPD courses, did not participate in multi-disciplinary team meetings and were not provided with updates on new drugs by pharmaceutical representatives.

Only 5.0% (4; n=79) of the respondents had discussions on a weekly basis regarding new developments in HIV/AIDS, while 21.5% (17; n=79) of the respondents had discussions once a month (Figure 6.35). The majority of the respondents had infrequent discussions; 26.5% (21; n=79) indicated once a year; 18.9% (15; n=79) indicated that they never had any meetings to discuss new developments and 16.4% (13; n=79) indicated that the discussions only occurred rarely (Figure 6.35). In addition, 11.3% (9; n=79) of the respondents were made aware of new developments when staff, participated in workshops, reported back to the clinic (Figure 6.35). New developments in the field of HIV/AIDS are continuous, as can be seen by the rapidly changing protocol in South Africa with regard to PMTCT. Therefore, the management team at the facility level must continue to develop the staff in terms of new developments, policies and procedures. The results indicate that only a few of the respondents (17; 21.5%; n=79) had discussions on new developments on a monthly basis.

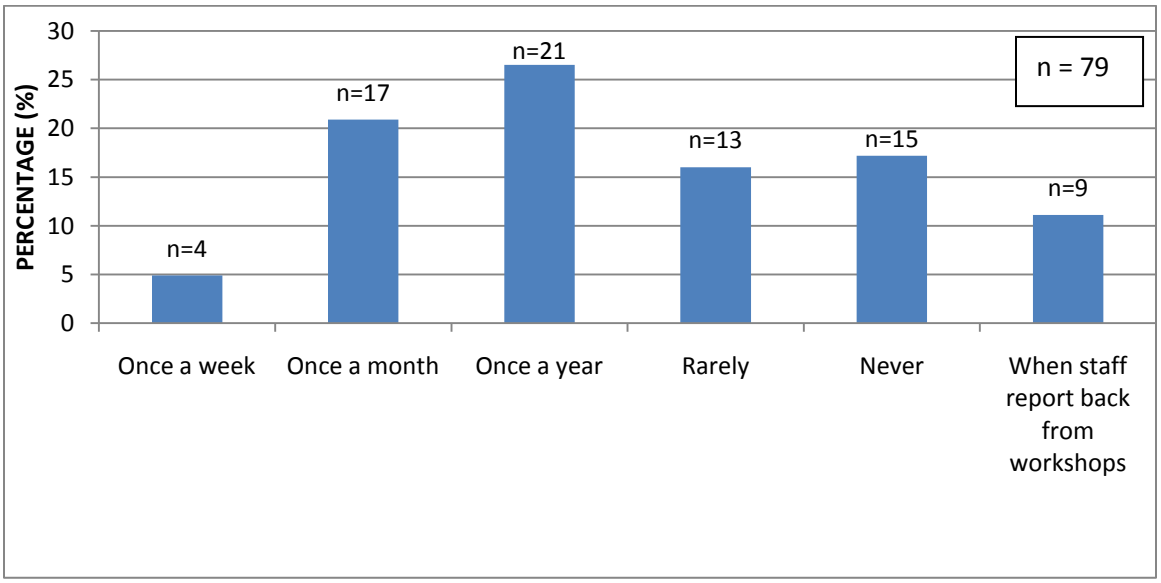


Figure 6.35 Frequency of training on new developments in HIV/AIDS

Of the respondents, 11.5% (9; 78) indicated that training was received once a month and 30.7% (24; 78) of the respondents received training once a year (Figure 6.36). Thirty five percent (27;

34.6%, 78) of the respondents rarely received training and 17.9% (14; n=78) of the respondents only received training when there were sufficient staff available to enable release of some of the respondents for training (Figure 6.36). Four of respondents (5.1%; 78) indicated that no training had been received. Similar results were reported by the HSRC in that the professional nurses could not do their jobs properly due to not being well informed about changing programmes because they were unable to attend meetings and training (Peltzer *et al.,* 2009: 29). The treatment of HIV/AIDS is rapidly changing and regular training of all staff is required to ensure the effective implementation of the PMTCT programme (Department of Health, South Africa, 2008a: 69).

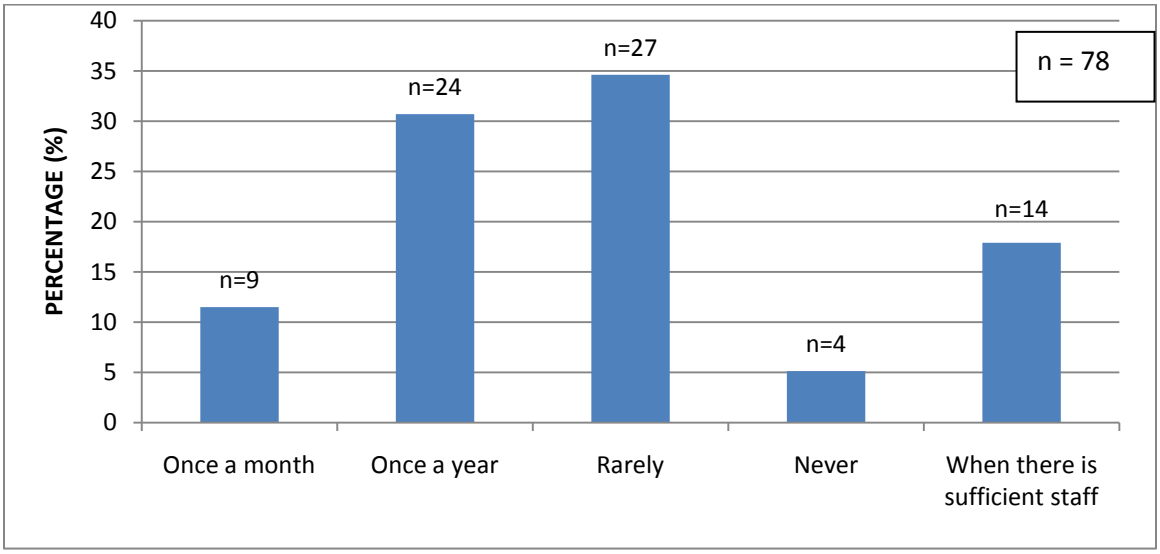


Figure 6.36 Frequency of training received by respondents at the study facilities

According to Table 6.7, 56.2% (45; n=80) of the respondents had not been offered training on current information and policy updates on PMTCT and 70.8% (56; n=79) indicated that not all the staff had received training. Due to the high staff turnover and the vacancy levels at most facilities in South Africa, it is likely that nurses from other departments within the facility would have to "fill in" for nurses at HIV and PMTCT sites (Lehmann, 2008: 169). Eighty respondents (98.7%; n=81) would like to receive more training on HIV and PMTCT. Therefore, facilities have to ensure that they support and train all nurses.

The study showed that 39.7% (31; n=78) of the respondents felt that the training they had received had not prepared them for their job. Research, has shown that doctors and nurses were ill prepared to work in a primary health care setting (Lehmann, 2008: 170). There has been a massive expansion in the needs and service expectations in the primary health care setting due to the HIV/AIDS and TB epidemics (Lehmann, 2008: 169). Even though nurses

received training at their tertiary institutions, 39.7% (21; n=78) of nurses in this study felt that the training was inadequate, thus, the training the nurses had received at the tertiary institutions had not been effective. According to Lehmann (2008: 169) the effectiveness of existing training initiatives needed to be questioned and there was a need for the standardisation of primary health care systems and learning interventions such as mentoring. A study undertaken by Reid (2003: 135) on the evaluation of community service programmes suggested that new graduates continued to feel ill-prepared for service in PHC settings. Many expressed a "*disjuncture between the academic training expectations and the actual conditions in the public service".* Other studies have also suggested that nursing graduates continue to feel ill-prepared for practice (Hlahane *et al*., 2006: 82-94; Makhuvha *et al*., 2007: 61-72). Thus, in addition to the training received by the respondents at the tertiary institutions, extra training on HIV and PMTCT must be provided to health care workers in the work place.

Table 6.8: Training on HIV/AIDS offered, received and required by the nursing staff

	YES (%)	**NO (%)**	**n**
Is training offered on current information and policy updates	43.7	56.2	80
Do all staff receive training	29.1	70.8	79
Do you educate patients on HIV and AIDS	91.3	8.6	81
Would you like to receive more training	98.7	1.2	81
Do you think that the training you have received has prepared you for you for your job	60.2	39.7	78
Do you need training on counselling	71.6	28.3	81
Do you have access to academic and technical experts	25	75	80
Do you receive training on infant feeding	65	35	80

Of the respondents 72.8% (59; n=81) would consult a colleague for any queries on HIV and PMTCT; 22.2% (18; n=81) would consult with the doctor and only 2.4% (2; n=81) would consult the literature and guidelines. During the facility audits it was found that the facilities did not

have copies of the national and provincial guidelines. This could be the reason why only 2.4% (2; n=81) of the respondents would consult the guidelines. In addition, the doctors at most of the clinics were not permanent and worked on a sessional basis. They were not available all the time at the facility and this could account for the low percentage (18; 22.2%; n=81) of consultations between nurses and doctors regarding information required on HIV and PMTCT. As the majority of the respondents (59; 72.8%; 81) would consult their colleague it is imperative that all health care workers receive the necessary and proper training with regards to the HIV and PMTCT guidelines.

Forty four percent of respondents (36; n=81) would like the frequency of the training to be once a month, 32.1% (26; n=81) of the respondents indicated every four to six months; 14.8% (12; n=81) of respondents indicated every week to biweekly and 8.6% (7; n=81) indicated that training should only occur when there was a need.

With regards to who facilitates the training, 60% (48; n=80) of respondents wanted a trained facilitator to present the training rather than senior staff members and doctors, 22.5% (18; n=80) of the respondents wanted the doctor at the facility to present the training and 17.5% (14; n=80) of the respondents wanted the senior staff do the training.

Additional training on drugs, dosing and side effects of the PMTCT medication was required by 28.1% (59; n=81) of respondents, while 22.3% (47; n=81) respondents stated that more training on the new PMTCT guidelines were required and 15.2% (32; n=81) on any new updates regarding policies (Figure 6.37). The dual PMTCT protocol was announced by the Department of Health in January 2008, and was implemented in NMB in August 2008 (Zweni, 2008). However, 67.9% (55; n=81) of the respondents indicated that they had not heard of the dual therapy PMTCT protocol before it was introduced at the facilities in August 2008.

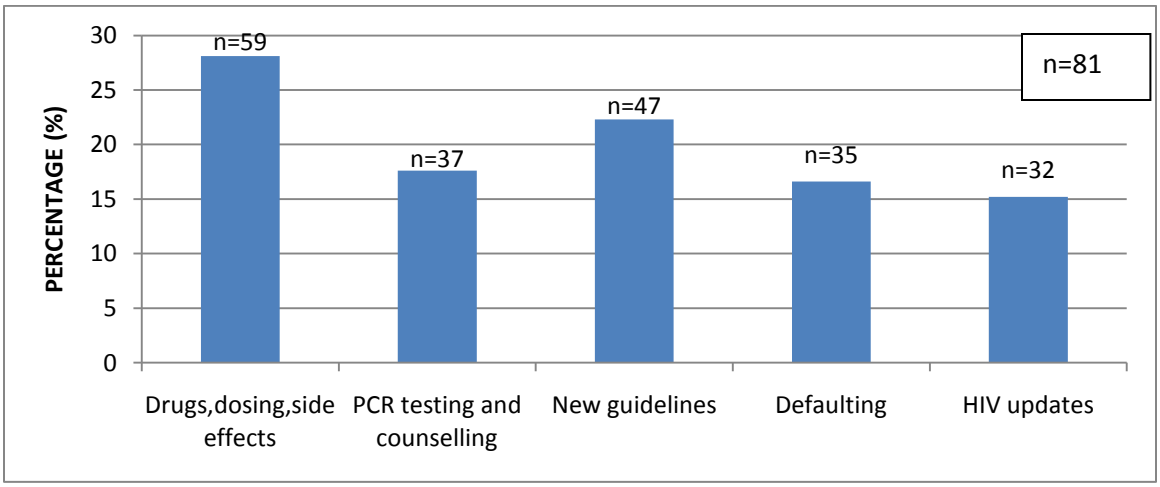


Figure 6.37: Training required by respondents on drugs, PCR testing and counselling, guidelines, defaulters and HIV updates

(iii) Knowledge of the dual therapy PMTCT protocol:

According to the 2008 PMTCT guideline, women with a CD4 cell count of less than 200 cell/mm^3 were prioritised to initiate HAART at any stage of pregnancy. For pregnant women not requiring HAART a PMTCT regimen was the main strategy to reduce MTCT. The use of dual therapy in the PMTCT treatment strategy was as follows: women presenting at 28 weeks or later, were started on zidovudine prescribed by a registered health professional at that visit, unless clinically anaemic (pale) or laboratory findings indicated that they were severely anaemic (i.e. haemoglobin less than 7g/dl). Women who were HIV positive and who had anaemia were referred for management by a doctor prior to initiating any ARVs, including zidovudine. At 28 weeks or later the mother was given a single dose of nevirapine (200mg tablet) to take home. The nevirapine was to be taken when labour started. Zidovudine 300mg was given to the mother on a 3 hourly basis during labour at the clinic. Antiretrovirals were given soon after birth to infants. This formed the basis of a post-exposure prophylaxis strategy. The infant received a single dose of nevirapine syrup immediately after birth and zidovudine syrup for 7 days. The infant received zidovudine syrup for 28 days if the mother received less than 4 weeks of zidovudine during pregnancy. (Department of Health, South Africa, 2008a: 40-43)

Criteria for starting mother on dual therapy: Only 54.3% (44; n=81) of the respondents stated that they knew the criteria for starting the mother on dual therapy. However, when asked what the criteria were only 37.5% (30; n=80) of the respondents knew the correct criteria i.e. 28 weeks pregnant women who are HIV +ve with a CD4 count > 200.

Dosing of zidovudine for mother: Only 62.5% (50; n=80) of the respondents indicated that they knew the dose of zidovudine for the mother, however, only 48.7% (39; n=80) of the respondents indicated that the dose was 300mg twice a day. In addition, 48.7% (39; n=80) of the respondents did not know when to start the mother on zidovudine.

Do you call the mother back in after one week of zidovudine therapy: 77.2% (61; n=79) of the respondents did not call the mother back to the clinic after one week of zidovudine therapy. The Facility Managers at the study facilities indicated, during the facility audits, that the protocol for the follow up of patients differed among the facilities. There was no standard protocol on when to follow up on a patient who had received zidovudine. Patients with a low haemoglobin level and zidovudine prescribed were required to come back to the facility to re-evaluate their haemoglobin levels after one week.

Only 34.2% (26; n=76) of the respondents knew and followed the protocol for low haemoglobin levels and 42.1% (32, n=76) did not know what to do (Figure 6.38). The correct dose of ferrous sulphate was known by only 43.0% (31; n=72) of the respondents. Thus, the nurses needed to receive further training on the protocols regarding the effects of zidovudine on the

haemoglobin levels, the protocol to be followed and the dosing of medication used to treat low haemoglobin levels.

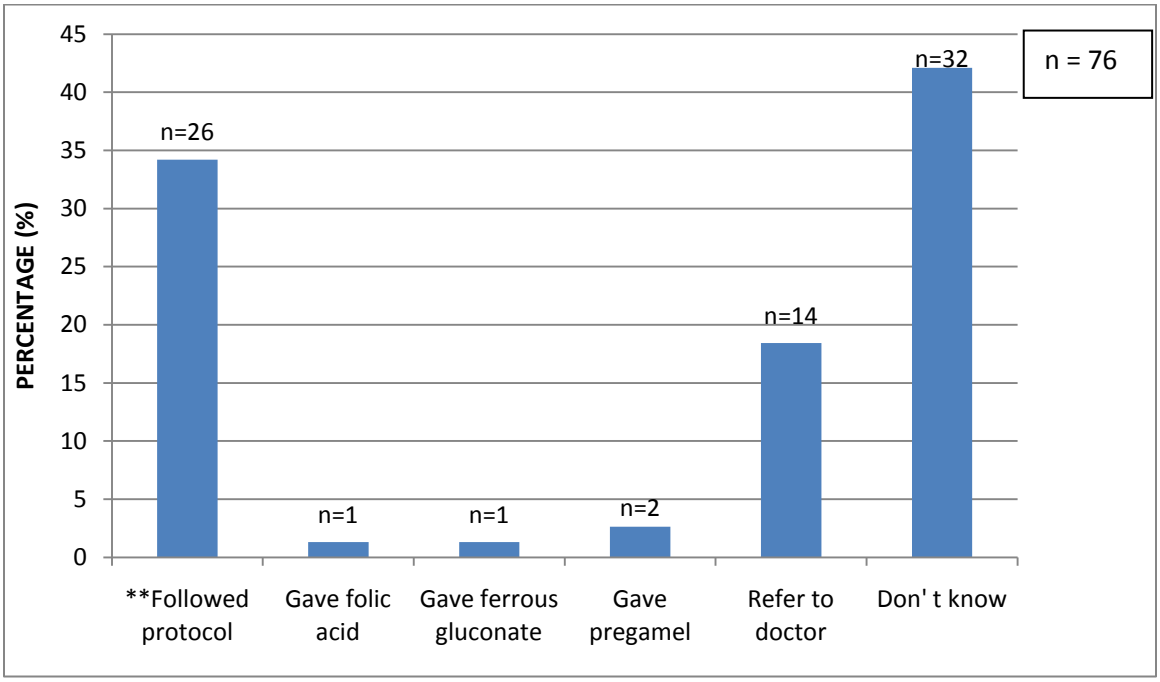


Figure 6.38 Drugs prescribed for low haemoglobin levels at the facilities in the study

** If Haemoglobin value was <7g/dl stop/do not start zidovudine, if Haemoglobin value was>7g/dl and <10g/dl continue zidovudine and give ferrous sulphate 1 three times a day and if the haemoglobin value > 10g/dl continue zidovudine and give ferrous sulphate 1 twice a day.

The question on what action the respondent would undertake when ferrous sulphate was not available at the facility, was answered by all respondents, however some respondents gave more than one answer making the population size (n) 94 for the question. Of the responses obtained, 31.8% (21; n=94) were 'borrow from another facility' and 40.9% (27; n=94) were 'would not give the patient anything but would advise the patient on an appropriate diet'. Thirty two percent (21; n=94) of the responses were 'would ask the patient to buy the medication from the local pharmacy'; 9% (6; n=94) were 'would issue folic acid'; 9% (6; n=94) were 'would issue ferrous gluconate' and 9% (6; n=94) were 'refer to a doctor'. Seven of the responses (10.6%; n=94) were 'did not know what to do'. Thus, not only is it important to train nurses on the clinical aspects regarding medication, it is also important to educate nurses on the procedure to follow with regards to medication being out of stock.

Of the 54.4% (37; n=58) of respondents that encounted patients who experienced nausea and vomiting, 45.9% (17; n=37) of these patients had experienced nausea and vomiting during pregnancy; 37.8% (14; n=37) on starting ARV medication while pregnant and 16.2% (6; n=37) during labour. When asked about the medication prescribed to treat nausea and vomiting, 44.7% (17; n=37) of the respondents indicated that they would issue prochlorperazine, 39.4%

(15; n=37) would issue metoclopramide, 7.8% (3; n=37) would issue domperidone and 5.2% (2; n=37) would issue rehydration solution.

Only 45.2% (33; n=73) of the respondents correctly stated that the dose of zidovudine during labour was every three hours while 54.7% (40; n=73) stated that they did not know the dose. The dual PMTCT protocol states that during labour zidovudine is given every three hours to the mother until the baby is born. Only 20.5% (15; n=73) of respondents knew that when labour stops then zidovudine dosing is stopped. Thus, training the nurses on the dual PMTCT protocol is required.

Zidovudine was ordered on a schedule 5 order book according to 44.9% (31; n=69) of the respondents (Table 6.8). Of the facilities in this study, only four of the clinics ordered medication from the municipal Depot and were required to order zidovudine in a schedule 5 order book. Thus, only some of the respondents (31; 44.9%; n=69) ordered zidovudine in a schedule 5 register.

Table 6.9: PMTCT drug records and patient follow up

	YES	**NO**	**n**
Is zidovudine ordered on a schedule 5 order book	44.9%	55.0%	69
Is there a separate register to record zidovudine and nevirapine transactions	60%	40%	70
Are all patients details recorded	63.8%	36.1%	72
Do you follow up on patients that do not come back for appointment after one week	25.3%	74.6%	71
Do you do pill counts after one week	47.2%	52.7%	72

Forty percent (28; n=70) of respondents stated that there was no separate register to record the zidovudine and nevirapine transactions and only 63.8% (46; n=72) stated that all the patient's details were recorded.

All PMTCT medication that is issued as well as all the details of the mothers (such as name, identity number, contact details) receiving PMTCT treatment must be recorded in a register to ensure that accurate statistics are maintained for the Department of Health and to enable tracking of the patients for follow up. According to Kumalo (2006: 66) information is crucial for

the identification of health needs and priorities, for health systems and service planning, to track progress in implementation and to evaluate the impact of interventions. Thus, nurses need to be educated on the importance of recording all information pertaining to PMTCT.

Patients who did not receive zidovudine three hourly during labour: 50.8% (29; n=57) of respondents stated that there were instances when some mothers did not receive zidovudine during labour. The protocol for dual PMTCT treatment states that even HIV positive mothers who did not receive HAART during pregnancy, should receive zidovudine three hourly during labour (Department of Health, South Africa, 2008a: 40-43).

The reason provided by 35.7% (15; n=42) of respondents for the mother not receiving zidovudine during labour was that the mother arrived too late at the facility and 23.8% (10; 42) of respondents stated that the mother delivered her baby at home (Figure 6.39). Thus, more emphasis should be placed on educating mothers on PMTCT. Other reasons for non administration of zidovudine include staff not trained on PMTCT (7; 16.6%; n=42); patient's HIV status unknown (6; 14.2% n=42) and short staffed (4; 9.5% n=42) (Figure 6.39). Thus, there is a need for an improved communication in the health care system between the healthcare workers and the patients.

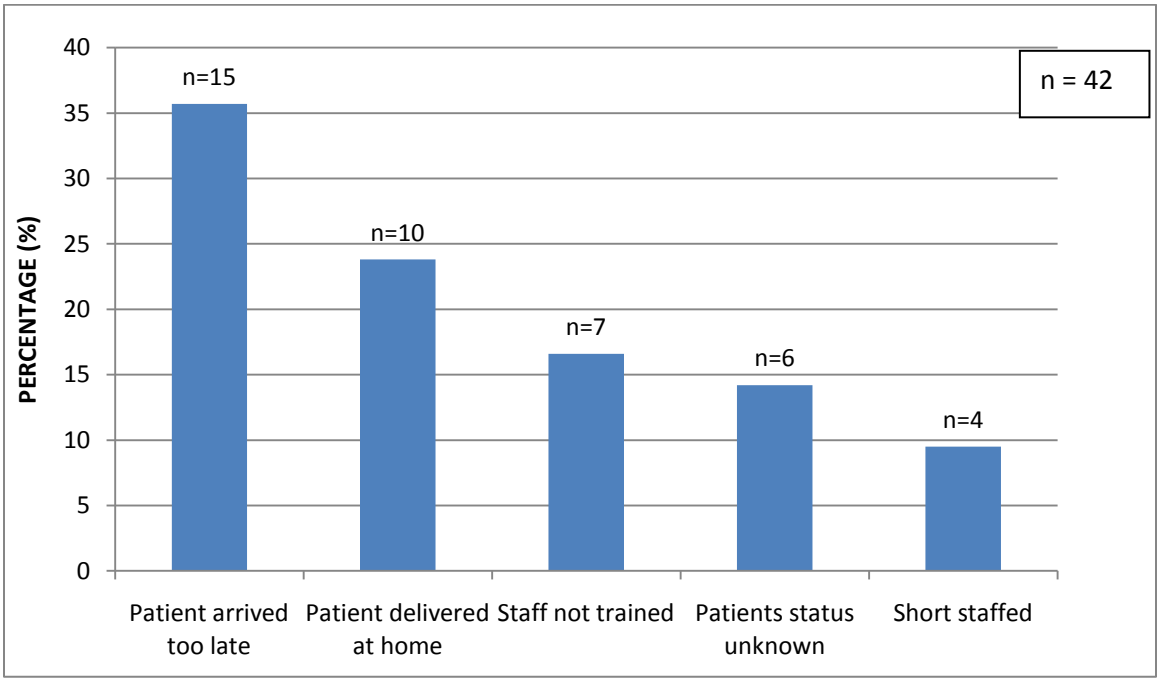


Figure 6.39 Reasons provided for the mother not receiving zidovudine during labour

Patients who did not receive nevirapine at the onset of labour: 65.0% (41; n=63) of respondents stated some patients did not receive nevirapine at the onset of labour. According to the respondents there were many reasons why some mothers did not take their nevirapine at the onset of labour (Figure 6.40). The reasons for this included: mother was afraid of her partner

(14; 19.7%; n=71); mother lost the nevirapine tablet (16; 22.5%; n=71); mother forgot to take the nevirapine tablet (24; 33.8%; n=71); and mother did not know when to take the nevirapine tablet (17; 23.9%; n=71).

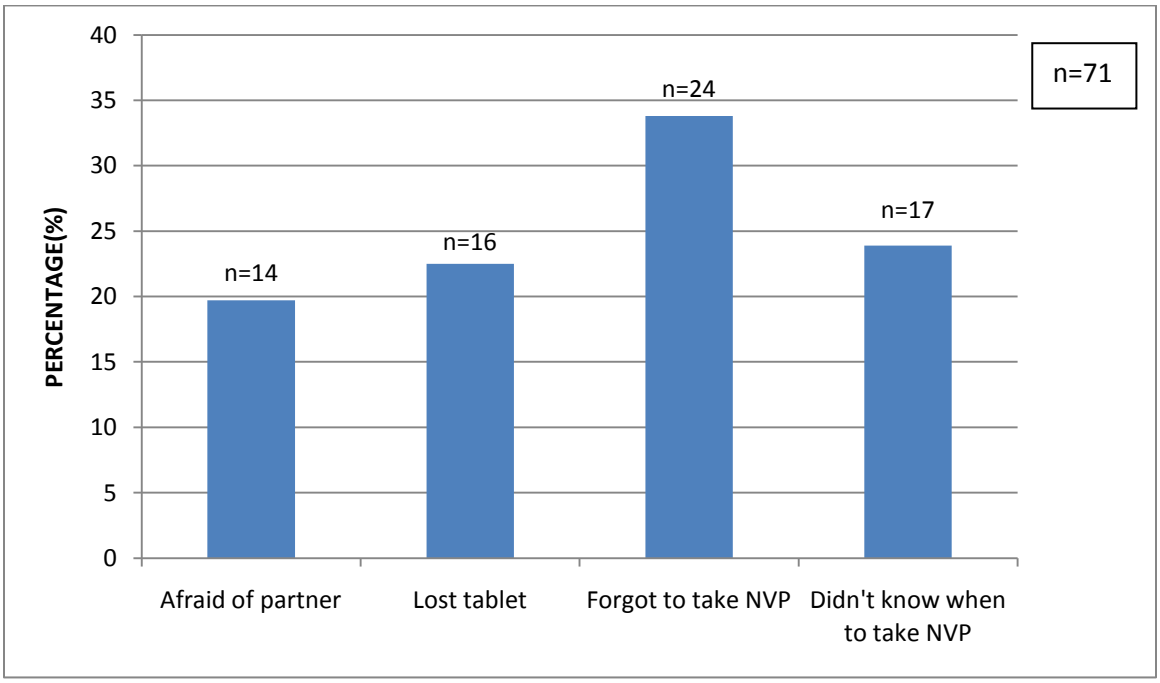


Figure 6.40 Reasons provided for the mother not taking nevirapine at onset of labour

Thus, the results showed that greater emphasis should be placed on counselling the mother when issuing her with nevirapine. The mother should understand the reasons for adhering to the therapy and the steps she should take in the event of losing the tablet or forgetting the dosing instructions.

An open ended question for suggestions and comments yielded the following results and comments (Figure 6.41):

- A high percentage of respondents (73; 66.9%; n=81) stated that they required more training especially on new protocol changes and before any of the changes to protocol were implemented;
- Only 16 (14.6%; n=81) of the respondents indicated that more staff were required;
- More equipment was required for diagnosis e.g. Blood pressure machines, scales, stethoscopes according to 9 (8.2%; n=81) of the respondents;
- Improved communication from head office was required when programmes changes were made (6; 5.5%; n=81); and
- More space was required for the increasing number of patients (5; 4.5%; n=81).

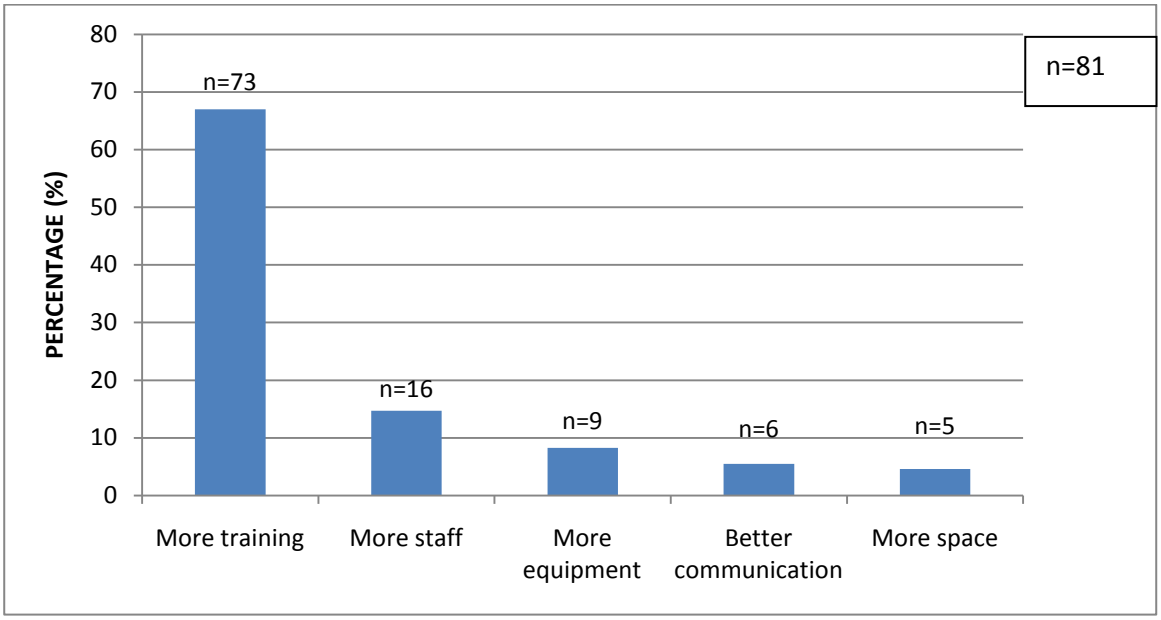


Figure 6.41 Suggestions and comments by the respondents

6.6.5.4 Summary of Healthcare Worker Questionnaire

The aim of this section of the study was to determine the demographics, training received and required and the knowledge of dual therapy PMTCT of the respondents in the study population. The key conclusions found for the Healthcare Worker Questionnaire were as follows:

At the time of the study 83.5% (66; n=79) of the respondents were professional nurses and 73.3% (58; n=78) had been in their current position for less than three years. According to the study, 44.8% (35; n=78) of the population were over the age of 40. At the time of the study and eight months after the implementation of the dual therapy PMTCT programme, twenty eight (34.5% n=81) nurses had not been trained on PMTCT and thirty seven (45.6%; n=81) nurses had not been trained on the dual therapy PMTCT protocol.

Most of the nurses, (63; 80.7%; n=78) did not attend continuous professional development courses and most (80.2%; n=81) did not participate in multi-disciplinary team meetings. In addition, 91.3% (74; n=81) of nurses stated that updates on new ARV drugs were not provided by pharmaceutical representatives. The majority of nurses stated that at the facilities where they worked they rarely had discussions on new developments in the HIV/AIDS field: (21; 26.5%; n=79) once a year and (15; 18.9%; n=79) rarely. Forty four percent of nurses (36; n=81) of nurses would like the frequency of training to be once a month and 60% (48; n=80) preferred the training to be conducted by a trained facilitator rather than the facility staff. Forty five

(56.2%; n=80) nurses stated that no training on policy updates and current information had been offered to them.

Forty percent (31; n=81) of respondents stated that the undergraduate training they had received had not prepared them for their job. Most of the respondents (80; 98.7%; n=81) stated that they would like more training on PMTCT and 28.3% (23; n=81) on counselling of patients. Thirty five percent (28; n=81) of respondents did not receive training on infant feeding, which is a vital part of PMTCT counselling.

Most of the respondents 54.3% (44; n=81) did not know the criteria to start a mother on dual therapy PMTCT and many (39; 48.7%; n=80) did not know the dose of zidovudine for the mother. The majority of the respondents (50; 65.8%; n=76) did not know the protocol for patients with low haemoglobin levels; and 54.7% (40; n=73) did not know the dosing of zidovudine to be given during labour.

Sixty five percent of respondents (41; n=63) stated that some mothers did not receive nevirapine at the onset of labour. According to the respondents, the reasons for a mother not taking nevirapine at the onset of labour included: forgot to take nevirapine (24; 33.8%; n=71); did not know when to take nevirapine (17; 23.9%; n=71); lost tablet (16; 22.5%; n=71) and afraid of partner (14; 19.7%; n=71).

The PMTCT programme is nurse driven. This study highlighted the number of nurses that are nearing retirement age. Strategies will need to be implemented to ensure that sufficient nurses are employed in the facilities to ensure the continuity of the PMTCT programme. The provision of training to nurses on new guidelines prior to the implementation of a protocol and the continuous training of nurses on HIV/AIDS continues to be a challenge. Facilities will need to provide an environment that is conducive for the training of nurses to ensure the effective provision of PMTCT.

CHAPTER SEVEN

CONCLUSIONS AND RECOMMENDATIONS

7.1 CONCLUSIONS

The data presented in this study provided sufficient information in relation to the research question and objectives of the study. The researcher explored the deficiencies at the facilities in the study with respect to Infrastructure; Drug Supply Management; Clinic Procedure and Staffing. It can be seen from the results that many challenges exist at the facilities in the Nelson Mandela Bay. The key findings are listed below:

Infrastructure:

- All the facilities, 9 (100%; n=9) had insufficient waiting room space.
- Six (66.6%; n=9)) facilities did not have sufficient space for nurses and counsellors to work.
- Seven (77.7%; n=9) facilities did not have sufficient space for filing of patient files.
- Four (44.4%; n=9) facilities did not have the space for a designated area for waste management.

Drug Supply Management:

- Four (40%; n=10) of the dispensaries did not have sufficient space for storage of medication and proper stock rotation
- Four (40%; n=10) of the dispensaries did not have a fire extinguisher present.
- Four (40%; n=10) of the dispensaries did not have labels for dispensing available and six (60%; n=10) dispensaries did not have the GPP available.
- Amongst the respondents for the Dispensary Staff Questionnaire, 31.7% (13; n=41) stated that there was no stock card present and 41.5% (17; n=41) that the stock card was not up to date.
- 43.9% (18; n=41) respondents indicated that the stock balance on the stock cards was not correct.

- 35.1% (13; n=37) respondents stated that less than two weeks of buffer stock for zidovudine and nevirapine was kept at the dispensary.

- 36.5% (15; n=41) of respondents stated that medication orders were not placed according to minimum and maximum values and 66.6% (8; n=12) of those respondents indicated that orders were placed according to need.

- 21.2% (7; n=33) of respondents stated that emergency orders were placed with the Depot due to inaccurate orders having been placed by the dispensaries.

- The majority (28; 70%; n=41) of the respondents stated that there was no SOP for scenarios when medication was out of stock.

- With regards to the reporting of out of stock items to the dispensaries, 90% (36; n=40) of respondents indicated that out of stocks situations at the Depot were not reported to them in advance and the dispensary was only made aware when an item that was ordered was not received

Clinic Procedure:

- Two (22.2%; n=9) of the facilities indicated that there were no transfer forms available at the facility and 6 (66.6%; n=9) of the facilities stated that the forms were not filled out completely.

- Seven (77.7%; n=9) of the facilities did not follow up on patients that were referred from a lower level of care such as a clinic to a higher level of care such as a hospital.

- Only four (44.4%; n=9) of the facilities in this study updated the patient's demographic details regularly.

- Of the nine facilities, 5 (55.5%; n=9) did not use a tracking system to locate patients that had defaulted and 5 (55.5%; n=9) facilities did not have any procedure in place for reacting to missed appointment by patients.

Staffing:

- The percentage of nurses understaffed, based on the Operational Plan for Comprehensive Care, Management and Treatment proposed norms, was 45.6%.

- The percentage of doctors understaffed, based on the Operational Plan for Comprehensive Care, Management and Treatment proposed norms was 96%.

- The percentage of counsellors understaffed, based on the Operational Plan for Comprehensive Care, Management and Treatment proposed norms, was 78.9%.
- Only 5 (55.5%; n=9) of the facilities had a full time pharmacist, at three facilities the pharmacist only worked one day of the week and rotated between five other clinics.
- Four (44.4%; n=9) of the facilities did not do a performance appraisal for staff.
- The majority of nurses (65; 80.2%; n=81) did not participate in multi-disciplinary team meetings and 26.5% (21; n=79) of respondents stated that discussions on new developments with regards to HIV/AIDS only occurred once a year.
- 56.2% (45; n=80) stated that no training had been offered to them on policy updates and current information.
- Many (36; 44.4%; n=81) of nurses would like the frequency of training to be once a month and 60% (48; n=80) preferred the training to be conducted by a trained facilitator rather than a member of their staff.
- An important observation was that 40% (31; n=81) of nurses stated that the training they had received had not prepared them for their job.
- 98.7% (80; n=81) nurses indicated that they would like more training on PMTCT.
- Most of the nurses (44; 54.3%; n-81) did not know the criteria to start a mother on dual therapy PMTCT. In addition, 39 (48.7%; n=80) did not know the dose of zidovudine for the mother and 40 (54.7%; n=73) did not know the dosing of zidovudine to be given during labour.

In conclusion, this study has shown potential challenges in implementing PMTCT programmes at the facilities investigated. The challenges include: lack of space; lack of adherence by the dispensaries to GPP and poor inventory control; insufficient and ineffective procedures for follow up of patients; shortage of nurses, doctors, counsellors and pharmacists and insufficient training on new protocols and PMTCT. These challenges will need to be addressed to ensure the effectiveness of the PMTCT programme, especially with the scaling up of ART services.

7.2 RECOMMENDATIONS

Some of the recommendations suggested may be within the local management's control whilst others may require policy changes from the provincial head office. The following recommendation can be made from this research:

- Prior to the implementation of any protocol by the Department of Health, an assessment of the facilities' infrastructure with regards to size, design and the availability of staff needs to be assessed.

- Structured training on new protocols needs to be organised by stakeholders as soon as a National announcement about a new policy has been made.

- Training of healthcare workers, on new protocols, needs to be done across the metro, hospital complex and district.

- Every level of staff needs to be involved in the training on the new protocol.

- A weekly mentorship programme should be devised for the first two to three months of the introduction of a new protocol.

- Monthly updates and changes to the protocol should be communicated to all staff.

- Training on HIV/AIDS should, at least, be done on a quarterly basis as there are rapid new advances and changes. This ensures that staff are made aware of the changes and updated information is available.

- At the Multidisciplinary Team meetings, doctors and non-governmental agencies should also play a role in mentoring and training as often as possible.

- In order to facilitate training of all nursing staff the following is recommended:
  Multiple training sessions should be held, so all staff can attend;
  Part-time or contract staff should be brought in during this period of training to assist at the clinics so permanent staff can attend the training; and
  Provision should be made for staff to be rotated amongst facilities once trained so as to ensure that other staff have an opportunity to attend training sessions.

- The Department of Health, in their estimation of future patient number, needs to consider not only HIV/AIDS but also TB and chronic diseases. The catchment population should be used as a basis when planning a clinic or improving the current space challenge at the facilities. Provision of patient waiting areas, dispensary size and dispensary waiting areas need to accommodate the patient load.

- Drug Supply Management remains a major problem. Drug quantification, availability of space and the projected increase in patient numbers have to be compared to ensure a continuous supply of ARVs.

- Pharmacy managers need to ensure that all pharmacy personnel are trained and mentored on proper inventory control.
- Space for dispensary storage room needs to be readdressed to ensure that at least one month's buffer stock for antiretrovirals can be kept.
- Pharmacy managers need to ensure that the stock cards are maintained and that minimum and maximum values for each medication are calculated each month.
- Pharmacy managers need to develop and implement Standard Operating Procedures for ordering, receiving and out of stock scenarios of medicines.
- There needs to be a reliable delivery system for the medication order from the facilities to the Depot.
- Communication between the Depot and the facilities (telephone; fax; e-mail) needs to be improved.
- As the PMTCT programme has expanded, patient queues and waiting times have increased and the consequence is patients default more frequently. Strategies to decrease loss to follow up need to be strengthened developed and implemented.
- There is an urgent need for the Departments to look at referral and transfer documents. Protocols or Standard Operation Procedures should be standardised and followed by all facilities. Demographic information should be captured at each patient visit. The key area for the updated information to be gathered is when patients are seated at the reception or awaiting the doctor's consultation. The development of an electronic database system is strongly recommended.
- The number of nurses, doctors, counselors and pharmacist need to be increased and brought in line with the norms recommended.
- The results obtained from the research encouraged the researcher to design a Down referral Policy which is currently been implemented in Nelson Mandela Bay (Appendix 13).
- A checklist has been designed and forwarded to one Hospital to pilot, to ensure follow up and continuity of care for both the mother and the baby from labor to birth to follow up at a facility close to home – the demographic information, the mother's status, PMTCT and feeding options as well as the baby's weight and drug dosing (Appendix 14).

- A patient demographic document has been drafted and to be handed to hospital complex to pilot (Appendix 15).
- Finally, dialogue between researchers, policy makers and service providers need to be improved to ensure that discussion and implementation of the recommendations occur.

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APPENDIX 1

Infrastructure Audit Form

(This Audit Form is to be completed by the researcher with the assistance of the Facility Manager)

INFRASTRUCTURE AUDIT FORM			
CLINIC……			**DATE……..**
	YES	**NO**	**COMMENTS**
SPACE			
Is there a waiting area for patients?			
Is there sufficient space for patient waiting room?			
Is there enough space for nurses working station? e.g. for checking Blood Pressure and Glucose reading			
Is there enough space in the doctors room?			
Is there an area to conduct patient counselling?			
Is the area sufficient for counseling?			
Is there space for the ARV pharmacy waiting area?			
Is there enough space for the storage of all stock?			
Is the storage area secure?			
Is the storage area under appropriate conditions? e.g. ventilation			
Is there a staff tea room?			
Are there sufficient staff toilets?			
Are there patient toilets?			

Is there a separate waiting area for TB patients?			
Are the waiting areas well ventilated?			
Are the closed areas such as consulting and counseling rooms well ventilated?			
Is there sufficient space for filing?			
Is there an area for waste management?			
Are there any other comments or suggestions?			

APPENDIX 2

Dispensary Audit Form

(This audit form is to be completed by the researcher)

DISPENSARY AUDIT FORM			
CLINIC……			**DATE…….**
	YES	**NO**	**COMMENT**
DESIGNATION OF FACILITY			
A: Dispensary			
B: Medicine room			
If Dispensary fill in section A, or if Medicine room fill in section B.			
A: DISPENSARY			
Access Control of Dispensary			
Is the door to the pharmacy locked at all times while authorized personnel are absent?			
Are the keys for access to the dispensary kept on the authorized personnel at all times?			
Is the dispenser of medicine a: (also indicate number of people)			
Basic Pharmacist Assistant?			
Post basic Pharmacy Assistant?			
Registered nurse & licensed dispenser?			
Location of dispensary			
Is the pharmacy easily accessible to patients?			
Is the pharmacy easily accessible to dispenser?			
Dispensary – is the size:			
Less than 20 square meters?			
Greater than 20 square meters?			
Space allocated			
Is there sufficient space for dispensing activities and volume of prescriptions dispensed?			
Is there space for pre-packing?			
Is there sufficient office space for administration work?			

Dispensing area			
Is there sufficient countertop space for dispensing (1m per person dispensing)?			
Condition/Hygiene			
Are the walls and floors clean?			
Are the countertops washable?			
Is the refrigerator used only for pharmaceuticals products (no food or beverages stored within)?			
Storage areas			
Is there sufficient shelving (all medicines above floor level)?			
Are the storage areas large enough to allow for orderly arrangement and proper stock rotation?			
Waiting area			
Is the waiting area near the pharmacy?			
Is there sufficient seating?			
Counselling area - does this area provide:			
* No privacy			
* Semi private area			
* Private area			
Equipment			
Is the refrigerator in good working condition?			
Is there a thermometer in the fridge?			
Is there a chart for recording the temperature?			
Is the temperature reading for the refridgerator recorded twice a day?			
Is there an air conditioner?			
Is the computer in working order?			
Is there a washbasin with cold and hot water?			
Is there a fire extinguisher in pharmacy?			
Temperature control			
Is the air conditioner in good working order?			
Is there a room thermometer for recording room temperature?			
Is there a room temperature chart for recording the temperature twice a day?			

Waste disposal			
Are there closed receptacles for waste?			
Dispensing equipment			
Are there counting trays?			
Is there a range of graduated glass or plastic measures?			
Is there a refrigerator?			
Are there sufficient dispensing labels?			
Is there an ointment tile and spatula?			
Is there a mortar and pestle?			
Reference Resources – is there a:			
* MIMS?			
* Daily Drug Use?			
* South African Medicine Formulary (SAMF)?			
* Standard Treatment Guideline and Essential Drugs List: 1. Adults Hospital? 2. Paediatrics Hospital? 3. Primary Health Care?			
* Good Pharmacy Practice Manual?			
* Eastern Cape Formulary?			
MANAGEMENT OF DISPENSARY			
Is there a pharmacist that visits at least once a month?			
GENERAL			
Are the SOP documents available in dispensary?			
Are pre-packed medicine provided to dispensary?			
Are the Bin cards maintained?			
B: MEDICINE ROOM			
ACCESS CONTROL OF MEDICINE ROOM			
Is the door to the medicine room locked at all times while the licensed dispenser in charge is absent?			
Are the keys for access to the medicine room kept on the licensed dispenser in charge at all times?			

World Health Organisation has access to the medicine room?			
Is there a procedure in place to ensure access to the medicine room in an emergency?			
IS THE DISPENSER OF MEDICINE A: (also indicate number of people)			
Registered nurse & licensed dispenser			
Registered nurse			
Designation of medicine room			
Is the dispensing done in the consulting room?			
Is dispensing done from the medicine room?			
Is medicine stored in the consulting room?			
If Yes, is there an air conditioner in the consulting room?			
If Yes, is the temperature controlled?			
How often is medicine issued to the consulting rooms?			
Is the medicine transported in a lockable trolley/tray from the medicine room to the consulting room?			
Condition of medicine room			
Are the walls and floors clean?			
Are the countertops washable?			
Is there an air conditioner?			
Is the air conditioner in good working condition?			
Is there a refridgerator?			
Is the refridgerator used only for pharmaceuticals products (no food or beverages stored within)?			
Storage areas			
Is there sufficient shelving?			
Are there any medicines stored on the floor?			
Are the storage areas large enough to allow for orderly arrangement and proper stock rotation?			
Equipment			
Are there counting trays?			
Is there a range of graduated glass or plastic measures?			
Is there a refrigerator?			

Is there a suitable range of dispensing containers for medicinal products?			
Are there sufficient dispensing labels?			
Is there an ointment tile and spatula?			
Are there closed receptacles for waste?			
Temperature control			
Is the air conditioner in good working order?			
Is there a room thermometer for recording room temperature?			
Is there a room temperature chart for recording the temperature twice a day?			
Reference Resources – is there a:			
* MIMS?			
* Daily Drug Use?			
* MIMS Desk Reference?			
* South African Medicine Formulary (SAMF)?			
* Standard Treatment Guideline and/or Essential Drugs List: 1. Adults? 2. Paediatrics? 3. Primary Health Care?			
* A textbook on Pharmacology?			
* A medical dictionary?			
* Good Pharmacy Practice Manual?			
*****Latest copy of Medicines and Related Substances Act 101 of 1965 As amended?			
MANAGEMENT OF DISPENSARY			
Is there a pharmacist that visits at least once a month?			
Consulting room			
Is there a lockable cupboard in the consulting room?			
Is there an air conditioner in the consulting room?			
Are medicines stored in the consulting room?			
GENERAL			
Are the SOP documents available in the medicine room?			
Are the Bin cards maintained?			
How often is stock take done?			

When stock is received from the depot is it entered into the stock cards immediately?			
If not, when is the stock entered in the stock card?			
When medicine is issued, is the entry made in the stock card immediately?			
Is expired stock removed from the stock card?			
Where is the expired stock kept?			
Is there a register for schedule 5 and 6 items?			
Is the register balanced every quarter?			
Does the quantity on the stock card match the quantity of medication on the shelves?			

APPENDIX 3

Dispensary Staff Questionnaire

(This questionnaire is to be completed by the Dispensary Staff)

DISPENSARY STAFF QUESTIONNAIRE

INSTRUCTIONS:

This questionnaire is directed to the dispensary staff.
Please answer all questions.
Please tick with an (X) in the relevant blocks.
Give comments where necessary.
Please feel free to contact Vikesh Singh, if you have any difficulties or queries, on 0741622907

CLINIC:..... DATE.....

SECTION 1: STOCK CARD

1. Is there a stock card for each item in the store?

yes	no

2. Are the stock cards kept on the same shelf of the item?

yes	no

3. Is all the information on the stock card up to date?

yes	no

4. Is the information recorded on the stock card at the time of movement?

yes	no

5. Is there an accurate running tally kept in the balance column?

yes	no

6. Is a physical count made at regular intervals?

yes	no

SECTION 2: STOCK ORDERING

7. How often is medication ordered?

daily	weekly	Bi-weekly	Monthly	other

If other, please state the frequency of ordering:

_____

8. Is there a separate order book for the PMTCT programme?

yes	no

9. How is the order sent to the depot?

Fax	E-mail	Driver	Other:

If other, please specify how the order is sent?

_____

10. Is ordering done according to minimum and maximum levels?

yes	No

If not, please comment:

_____

_____

11. Has the monthly stock level been calculated for each item?

yes	No

12. When was the monthly stock level last reviewed?

2005	2006	2007	2008	2009

13. Is a standard requisition form used?

yes	no

14. Are all the orders placed in writing using the prescribed forms?

yes	no

15. Is all the information on the order form accurate and clearly written?

yes	no

16. Is AZT ordered separately for the PMTCT programme?

yes	no

17. Has the order ever been rejected by the depot?

yes	no

18. Has the general AZT stock ever been used for PMTCT?

yes	no

SECTION 3: RECEIPT OF DRUGS

19. Once an order is sent, how long does the order take to be delivered?

1 day	1 week	2 weeks	1 month	>1month

Specify, if > 1month

_____

_____

20. Are deliveries received by a dispensary staff?

yes	no

21. Are the deliveries checked before acceptance?

yes	no

22. Does the delivery person sign before leaving?

yes	no

23. Have items ever been sent back to the depot?

yes	no

If yes, please explain:

_____

_____

24. Are short dated items and expired items sent back to the depot in time?

yes	no

25. As soon as stock is received, is it entered on the stock card?

yes	no

26. Are items received checked by the dispensary staff for?

26.1 Poorly packed fridge items?

yes	no

26.2 Discolouration of drugs?

yes	no

26.3 Broken containers?

yes	no

26.4 Supplies soiled by leakage?

yes	no

26.5 Being unsealed and unlabelled?

yes	no

27. Are all discrepancies documented?

yes	no

28. Have discrepancies ever been encountered?

yes	no

If yes, give examples

_____

_____

29. World Health Organisation collects the order if it is not delivered?

Driver	Nurse	Pharmacist	Other:

If other, please state how the order is collected?

_____

30. Are there PMTCT registers for drugs?

yes	No

SECTION 4: OUT OF STOCK PROCEDURES

31. Are there SOPs for out of stock situations?

yes	no

32. When ARVs are out of stock at the depot what does the pharmacy do?

Wait	Borrowed	Other:

If other, please explain:

_____

_____

33. Are emergency orders placed?

yes	No

If yes, please explain why:

_____

34. How much buffer stock is there for AZT?

1 week	2 weeks	1 month	Other :

If other, please state:

_____

_____

35. How much buffer stock is there for NVP?

1 week	2 weeks	1 month	Other :

If other, please state:

_____

_____

36. Is notice received of out of stock situations in advance?

yes	No

THANK YOU FOR YOUR ASSISTANCE IN COMPLETING THIS QUESTIONNAIRE

APPENDIX 4

Clinic Procedure Audit Form

(This Audit Form is to be completed by the researcher with the assistance of the Facility Manager)

CLINIC PROCEDURE AUDIT FORM			
CLINIC……			**DATE…….**
	YES	**NO**	**COMMENTS**
REFERRAL BETWEEN FACILITIES			
Is there a transfer form for referrals?			
Are the forms filled out completely?			
When a patient is referred to a higher level of care is the patient followed up on?			
When a patient is referred from a higher level care facility to a clinic is the patient followed up on?			
Do any patients arrive at your clinic from a referral site with no medication e.g. a mother that gave birth with no AZT for baby?			
Is there a tracking system for patients?			
Is there any communication between the two referring sites?			
What are the reasons for referring patients?			
Is the patient demographic information updated regularly?			
How often do you update the patient's demographic information?			
Are there procedures in place for those patients World Health Organisation do not arrive at the referral site?			
TRACKING PATIENTS			
Is there a system in place for tracking patients?			

Is there a procedure for patients that have missed their appointments?			
What is the procedure for “missed” patients?	[redacted]		
How long is it before “missed” patients are followed up on?			
Are patients reminded about their appointments? e.g. sms system			
Is there a list of defaulters?			
What procedure is there to handle defaulters?	[redacted]		
Is there a telephone line or any other communication allowing the clinic to contact patients?			
Is there a record of transfer out patients?			

APPENDIX 5

Staffing Audit Form

(This form is to be completed by the researcher with the assistance of the Facility Manager)

STAFFING AUDIT FORM			
CLINIC……			**DATE:……**
	YES	**NO**	**COMMENTS**
FACILITY			
What catchment area do you serve?			
What is the approximate population in the catchment area?			
How many patients do you see in the clinic per month?			
STAFFING			
What is the total number of staff in the clinic?			
What is the total number of staff in the wellness clinic?			
How many nurses do you have in the wellness clinic (levels)?			
How many doctors do you have in the wellness clinic?			
How many counselors do you have in the wellness clinic?			
Is there a pharmacist?			
Is there a pharmacist assistant?			
Are there lay counselors at the clinic?			
Are the lay counselors remunerated?			
How many lay counselors do you have?			
How many vacant posts do you have?			
What is the ratio of patients to nurses?			
Are there any staff that work shifts?			
Are there any staff that work overtime?			
Is there a procedure for staff complaints?			
Is there a formalized job description for staff?			

	YES	NO	COMMENT
Are there performance appraisals for staff?			
Is there training for staff?			
How often does the staff receive training?			
What training does the staff receive?			
Is the training on site or off site?			
Are there updated SOPs for the facility?			
When were the SOPs last updated?			
Is there a protocol for referral of patients?			
Are the lay counselors trained?			
How many staff are sent for training at any given time?			
How long are training sessions?			
Is there feedback received from the training?			
Is there training for all levels of staff namely:			
* Doctors?			
* Nurses?			
* Counselors?			

APPENDIX 6

Healthcare Worker Questionnaire

(This questionnaire is to be completed by the nurses at the research facilities)

HEALTH CARE WORKER QUESTIONNAIRE

INSTRUCTIONS:

This questionnaire is directed to the dispensary staff.
Please answer all questions.
Please tick with an (X) in the relevant blocks.
Give comments where necessary.
Please feel free to contact, Vikesh Singh, if you have any difficulties or queries on 0741622907

CLINIC:..... DATE.....

SECTION 1: STAFF DEMOGRAPHICS

1. What is your sex?

male	female

2. What is your age group?

25-30yr	30-35yr	35-40yr	40-45yr	45-55yr

3. Please state your qualification, example B.Curr.

_____

4. What is your designation?

Staff nurse	Enrolled nurse	Professional nurse	Other:

If other, please specify: _____

5. How many years since you qualified?

< 2 years	5-10 years	10-20 years	Other:

If other, please specify: _____

6. What post do you occupy? _____

7. How many years experience you have had in the current post that you occupy?

<1yr	>3yrs	>5yrs	Other

If other, please specify: _____

SECTION 2: TRAINING

1. Have you received training on HIV/AIDS?

Yes	No

2. Have you received training on PMTCT?

Yes	No

3. Have you received training on the dual therapy PMTCT protocol?

Yes	No

4. If yes, when did you receive training on the dual therapy PMTCT protocol?

_____

5. Have you received training on:

5.1 dosing of AZT for mother?

Yes	No

5.2 dosing of AZT for baby?

Yes	No

5.3 dosing of NVP for baby?

Yes	No

6. Do you attend CPD courses?

Yes	No

7. Do you have weekly meetings to discuss case studies?

Yes	No

8. Do pharmaceutical representatives detail you on new drugs?

Yes	No

9. How often do you have discussions on new developments in the HIV/AIDS area?

Once a week	Once a month	Once per year	Other

If other, please explain _____

10. If you have questions regarding patients care where do you go to for answers?

Friend	colleague	Other

If other, please explain _____

11. How often is training done?

Once a month	Once per year	Other

If other, please explain _____

12. Is any training offered on current information and updates?

Yes	No

13. Are all staff receiving training?

Yes	No

14. Do you educate patients on HIV/AIDS?

Yes	No

15. Would you like to receive more training?

Yes	No

16. How often would you like training to occur on site? _____

17. World Health Organisation do you think would be most qualified to do the training on site? _____

18. Do you think that the training you have received has prepared you for your job?

_____

_____

19. In what areas do you feel that you require training regarding to HIV/AIDS?

_____

_____

20. In what areas do you feel that you require training regarding PMTCT?

_____

_____

21. In what areas do you feel that you require training regarding other areas that you are involved with?

_____

_____

22. Do you need training on counselling?

Yes	No

23. Do you have access to academic and technical experts?

Yes	No

24. Do you receive training on infant feeding?

Yes	No

25. Had you heard about the dual therapy PMTCT protocol before it was introduced in August 2008?

Yes	No

26. Have you received training on the new protocol?

Yes	No

27. When did you receive training on the new protocol? _____

28. Do you know the criteria to start the mother on dual therapy?

Yes	No

29. What are the criteria?

_____

_____

30. Do you know the dosing of AZT for the mother?

Yes	No

31. What is the dose of AZT for the mother?

_____

32. At what week do you to initiate the mother on AZT? _____

33. Do you recall (make an appointment with) patients after one week of AZT dosing?

Yes	No

34. How do you do this?

_____

_____

35. Do you perform haemoglobin tests on patients after initiation on AZT?

Yes	No

36. If the haemogloblin is low what do you do?

_____

37. Do you refer patients with extremely low haemoglobin?

Yes	No

38. Do you know the dose of ferrous sulphate for such patients?

Yes	No

39. What is the dose of ferrous sulphate?

_____ tablets _____times a day for _____days

40. If ferrous sulphate is out of stock what did you do?

_____

_____

41. Is AZT ordered on a schedule 5 order book?

Yes	No

42. Is there a separate register to record AZT and NVP?

Yes	No

43. Are all patients details recorded?

Yes	No

44. What details are recorded?

_____

_____

45. Do you follow up patients that did not come back after one week?

Yes	No

46. Are you doing pill counts after one week?

Yes	No

47. Do the doctors initiate dual therapy for pregnant patients after 28weeks?

Yes	No

48. Are there any patients World Health Organisation do not receive the AZT 3 hourly during labour?

Yes	No

49. If so, why not?

_____

_____

50. Do you have any patients World Health Organisation do not take NVP at the onset of labour?

Yes	No

51. If so, why not?

_____

_____

52. Do you encounter patients World Health Organisation experienced extreme nausea and vomiting?

Yes	No

52.1 When do you encounter such patients?

_____

52.2 What is administered/ordered by the doctor for the nausea or vomiting?

_____

_____

53. How often should AZT be given during labour?

_____

54. How do you dose AZT during a prolonged labour?

_____

55. How do you dose AZT if labour stops?

_____

56. Is there any suggestions or comments?

_____

_____

_____

_____

_____

Thank you for your assistance in completing this questionnaire

APPENDIX 7

Written informed consent and preamble letter

1 NELSON MANDELA METROPOLITAN UNIVERSITY

1.1 INFORMATION AND INFORMED CONSENT FORM

(Please delete any information not applicable to your project and complete/expand as deemed appropriate)

Title of the research project	IMPLEMENTATION OF THE DUAL THERAPY PMTCT PROTOCOL
Reference number	
1.1.1.1 Principal investigator	MR VIKESH SINGH
Address **Postal Code**	PO BOX 211245 THE FIG TREE 6033
Contact telephone number **(private numbers not advisable)**	074 1622907

A.1 I HEREBY CONFIRM AS FOLLOWS:

1. I, the participant, was invited to participate in the above-mentioned research project that is being undertaken by: Mr V Singh

of the Department of: Pharmacy

in the Faculty of: Health Sciences

of the Nelson Mandela Metropolitan University.

2. **The following aspects have been explained to me, the participant:** 2.1 **Aim:** The investigators are studying: the challenges faced by health care workers on the Implementation of the new dual therapy PMTCT protocol The information will be used to/for: part of a masters degree	
2.2 **Procedures: I understand that I will be completing a questionnaire and the results of the study will be disseminated to the university and the directors of the Department of Health**	
2.3 **Risks: There will be no risk involved to me as this questionnaire is anonymous and no part of it will identify me**	
2.4 **Possible benefits:** As a result of my participation in this study the status in the clinics upon the implementation of the dual therapy protocol will be highlighted.	
2.5 **Confidentiality:** My identity will not be revealed in any discussion, description or scientific publications by the investigators.	
2.6 **Access to findings:** Any new information/or benefit that develops during the course of the study will be shared as follows: the university , Department of Health Port Elizabeth , and the Nelson Mandela Municipality.	

2.7 **Voluntary participation/refusal/discontinuation:**

My participation is voluntary

	YES		NO

My decision whether or not to participate will in no way affect my present or future care/employment/lifestyle

	TRUE		FALSE

3. The information above was explained to me/the participant by

Mr V Singh

in

Afrikaans		English		Xhosa		Other	

and I am in command of this language

4. No pressure was exerted on me to consent to participation and I understand that I may withdraw at any stage without penalisation.

5. Participation in this study will not result in any additional cost to myself.

A.2 I HEREBY VOLUNTARILY CONSENT TO PARTICIPATE IN THE ABOVE-MENTIONED PROJECT

Signed/confirmed at

	on		20

Signature or right thumb print of participant	Signature of witness
	Full name of witness

B. STATEMENT BY OR ON BEHALF OF INVESTIGATOR(S)

I ,VIKESH SINGH……declare that

- I have explained the information given in this document to

  (name of patient/participant)

  and/or his/her representative

  (name of representative)

- he/she was encouraged and given ample time to ask me any questions;

- this conversation was conducted in

Afrikaans		English		Xhosa		Other	

  and no translator was used

- I have detached Section D and handed it to the participant

	YES		NO

Signed/confirmed at

	on		20

Signature of interviewer	Signature of witness
	Full name of witness

D. IMPORTANT MESSAGE TO PATIENT/REPRESENTATIVE OF PARTICIPANT

Dear participant/representative of the participant

Thank you for your/the participant's participation in this study. Should, at any time during the study:

- you require any further information with regard to the study

Kindly contact Vikesh Singh
at telephone number 0741622907
(it must be a number where help will be available on a 24 hour basis, if the research project warrants it)

APPENDIX 8

Letter of approval from the Faculty Research, Technology and Innovation Committee, Nelson Mandela Metropole University

Nelson Mandela Metropolitan University

for tomorrow

Summerstrand South
Faculty of Health Sciences
Tel +27 (0)41 504 2121 Fax +27 (0)41 504 9483
Nouwaal.ahmed@nmmu.ac.za

Ref: 209032503

Contact person: N Ahmed

20 April 2009

Dear Mr Vikesh Singh

FINAL RESEARCH PROPOSAL: Ethics number

Please be advised that your application for Ethics Approval of your final research proposal was discussed at the Faculty Research, Technology and Innovation Committee.

Ethics approval was granted by the Faculty Research, Technology and Innovation Committee. No further ethics application is required from the University Research Ethics Committee-Human.

The Ethics reference number is **H09HeaPHA002**.

Please contact the writer should you require further information regarding the above-mentioned.

Yours sincerely,

FACULTY OFFICER
FACULTY OF HEALTH SCIENCES

APPENDIX 9

Letter of approval from the Clinical Governance Manager, Port Elizabeth Hospital Complex

EASTERN CAPE DEPARTMENT OF HEALTH

PE HOSPITAL COMPLEX
Private Bag X60572, Greenacres
PORT ELIZABETH, 6057

Tel: 041-391 8002 Fax: 041- 391 8007 E-mail: fred.rank@lmpilo.ecprov.gov.za

To : Mr. Vikesh Singh

From : DR. F. L RANK
HEAD: Clinical Governance Manager

Date : 12 February 2009

RE : APPLICATION TO DO RESEARCH

Your request to interview staff at our hospitals is dated 03 February 2009.

As indicated by you the research has been approved by the university ethics committee and hence your request to interview nurses and Pharmacists is hereby approved.

Kindly note that confidentiality must be observed at all times. We would also appreciate a report on your findings once complete.

.....
DR. F.L RANK
HEAD: CGM
FLR/jhm

BATHO PELE
ABANTU KUQALA, PEOPLE FIRST

APPENDIX 10

Letter of approval from the Executive Director of Environment and Health, Nelson Mandela Municipality

nelson mandela bay
MUNICIPALITY
PORT ELIZABETH | UITENHAGE | DESPATCH

PUBLIC HEALTH DIRECTORATE

OFFICE OF THE EXECUTIVE DIRECTOR

tel: +27(41) 506 1412, fax: +27(41) 506 1247
P.O. Box 283, Port Elizabeth 6000
Republic of South Africa
e-mail: [illegible]@mandelametro.gov.za
Dr/Prof/Mr/Ms/Mrs/Ms: Dr Ebrahim Hoosain
Director: Primary Health Care
Tel (041)506 7406 Fax: (041)5067417

Your Ref:
Our Ref: 8/1/1/R
Date: 20 April 2009

Mr Vikesh Singh

RESEARCH PROPOSAL FOR PERMISSION: "IMPLEMENTATION OF MOTHER-TO-CHILD TRANSMISSION PROTOCOL" – Ref: 209032503 – Ethics Clearance Number HO9HeaPHA002

Your application for permission to conduct the above research study at facilities administered by the Nelson Mandela Bay Metropolitan Municipality (NMBMM) is approved. In terms of your research ethics approval, dated 08 April 2009 and Ethics Clearance Number: **H09HeaPHA002**, permission is hereby granted with the following proviso:

The study may be done at the following Primary Health Care (PHC) facilities within the Nelson Mandela Bay Metropolitan Municipality (NMBMM): West End Clinic (Pilot Clinic);Chatty Clinic, New Brighton Clinic, Masakhane Clinic and Zwide Clinic.

There should be no negative impact on existing health service delivery operations. All required data should be collected by the Researcher or a designated fieldworker (whose name should be forwarded to the relevant municipal Assistant Director prior to data collection). This letter should be presented when visiting the selected clinic facility or when interacting with any of the three municipal Assistant Directors for PHC Services listed below:

Sub District A Mrs Anna Mkosana Telephone: 508 7425, Cell: 079 490 0870,
Sub District B - Mrs Sarah Forbes Telephone: 994 1229, Cell: 079 490 0874.
Sub District C - Mrs Nola Monteith Telephone: 509 7424, Cell: 079 490 0742.

The Nelson Mandela Bay Metropolitan Municipality as the research site, will expect a copy of the final research report when the study is completed. If the duration of the research period or the selection of PHC facility is required to be altered, the NMBMM should be informed accordingly.

We would like to take this opportunity to wish you well for your research study.

APPENDIX 11

Letter of approval from the Epidemiological Research and Surveillance Department, Department of Health, Bisho

Eastern Cape Department of Health

Enquiries: Vuyokazi Poswayo | Tel No: 083 378 1780

Date: 08 April 2009 | Fax No: 043 642 1403

e-mail address: vuyo.poswayo@yahoo.com

Dear Mr Vikesh Singh

Re: THE IMPLEMENTATION OF MOTHER TO CHILD TRANSMISSION PROTOCOL

The Department of Health would like to inform you that your application for conducting a research on the abovementioned topic has been approved based on the following conditions:

1. During your study, you will follow the submitted protocol with ethical approval and can only deviate from it after having a written approval from the Department of Health in writing.
2. You are advised to ensure observe and respect the rights and culture of your research participants and maintain confidentiality of their identities and shall remove or not collect any information which can be used to link the participants. You will not impose or force individuals or possible research participants to participate in you study. Research participants have a right to withdraw anytime they want to. However, you shall be responsible for dealing with any adverse effects following the research treatment provided in your study.
3. The Department of Health expects you to provide a progress on your study every 3 months (from date you received this letter) in writing.
4. At the end of your study, you will be expected to send a full written report with your findings and implementable recommendations to the Epidemiological Research & Surveillance Management. You may be invited to the department to come and present your research findings with your implementable recommendations.
5. Your results on the Eastern Cape will not be presented anywhere unless you have shared them with the Department of Health as indicated above.

Your compliance in this regard will be highly appreciated.

EPIDEMIOLOGICAL RESEARCH & SURVEILLANCE MANAGEMENT

DATE 8/04/09

APPENDIX 12

Letter of approval from the International Center for Aids, Care and Treatment Programs

ICAP
International Center for AIDS Care and Treatment Programs
Mailman School of Public Health
Columbia University

[illegible] Second Floor, Fairview House, Ring Road, [illegible], Port Elizabeth [illegible], South Africa
PO Box [illegible] The Fig Tree [illegible], South Africa
Tel [illegible] • Fax [illegible] • E-mail [illegible]

To: Mr Vikesh Singh
Pharmacy advisor
Port Elizabeth Region

Re: Application to Conduct a Research using ICAP Supported Sites Data and Statistics

Your request to use ICAP data and statistics for your Masters Degree Research/Thesis is hereby granted on pre-condition that you strictly adhere to Columbia Universities (Mailman School of Public Health) and CDC/OGAC guidelines on conducting research using human subjects and confidential patient data elements. Ensure that the pre-conditions are met prior to any data use.

Do not hesitate to contact me if you need any additional information or help, regarding this.

Yours sincerely

[illegible] 30, 2009

Dr. Gregory Jagwer
Deputy Country Director
ICAP South Africa, Mailman School of Public Health, Columbia University

Cc: Mr. Lungi Sontyale
Regional Manager, Port Elizabeth

Dr. Tshiwela Neluheni
Country Director

Ms. Kanchan Reed
Technical advisor, M&E

APPENDIX 13

Down Referral Policy

Draft

PROTOCOL FOR UP & DOWN REFERRAL SYSTEMS AT

HIV CARE AND TREATMENT SITES

UP AND DOWN REFERRAL SYSTEM FOR THE COMPREHENSIVE CARE, MANAGEMENT AND TREATMENT (CCMT) PROGRAME

1. BACKGROUND

The Department of Health (DOH) and the South African National AIDS Council (SANAC) have developed the South African National strategic plan (NSP) for 2007-2011 and the Operational Plan for the Comprehensive HIV&AIDS Care, Management and treatment programme (DOH, Nov 2003).

The NSP 2007-2011 has set itself 2 primary aims:

1. Reduce the number of new HIV infections by 50%
2. Reduce the impact of HIV and AIDS on individuals, families, communities and society by expanding access to an appropriate package of treatment, care and support to 80% of all people diagnosed with HIV

The _____(province) has a population of _____. As of the National ANC Seroprevalence survey 2007, ___% of clients is HIV infected. This prevalence ranges across the __ (n) districts of the province from ___% in, up to ___%. There are currently ___ ART accredited sites in the province, where HIV Treatment is freely available. There is a need to increase the number of these service points to assist in meeting the primary aim number 2 of the NSP 2007-2011.

The purpose of this document is to develop a standardized system for the transfer of clients between the initiation site, and its many feeder sites without compromising on quality of service delivery.

3. REVIEW

This protocol shall be subject to review on an annual basis.

4. OBJECTIVES

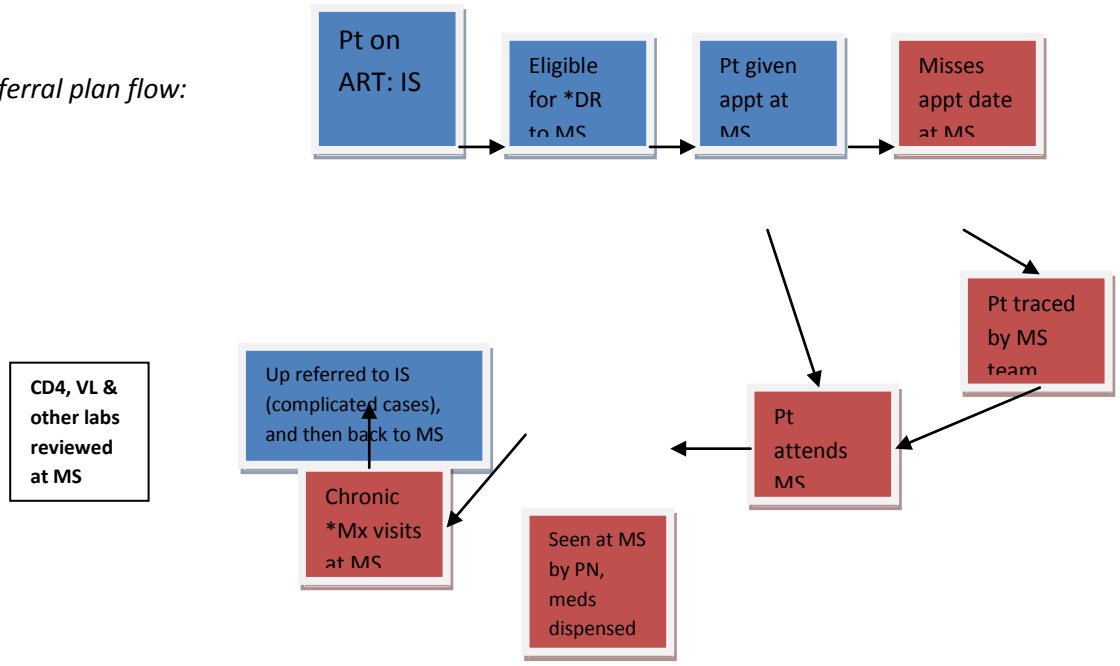
The long term goal is to develop more sites to meet the criteria for HAART accreditation, thus bringing the services closer to eligible clients. Each of the HIV treatment sites is supported by feeder sites, where HIV care is provided.

RATIONALE FOR DOWN-REFERRAL:

There is a need to decentralize the HIV treatment services to feeder sites for a variety of reasons:

- Wider geographical coverage of HIV treatment services, increasing access to HIV Care and Treatment
- Bringing the services closer to the communities most in need
- Decongesting initiation sites
- Improve quality of care at initiation sites
- Decreasing waiting times for initiation of HAART at initiation sites
- To encourage a nurse based model of HIV Care and Treatment services
- To increase community involvement in improving clinical outcomes
- Develop sites for the accreditation process

Down-referral plan flow:



**DR = Down Referred*

**Rx = Treatment*

**Mx = Management*

**IS = Initiation site*

**MS = Maintenance site*

Red = Activities at MS

Blue = activities at IS

ADULT 'DOWN REFERAL' CRITERIA: FROM INITIATION TO MAINTENANCE SITE

All eligible clients will be initiated on HAART at the initiation site. Clients will be followed up for at least 6 months at the initiation site. Clients responding well to treatment will be offered down-referral to the feeder site closest to the clients' home. Clients eligible for down-referral will be referred to the feeder site. This will be a consultative process, starting during the pre-ART phase and continuing during the initial 6 months of treatment.

Eligibility criteria for down referral to feeder site:

- Clinically stable (as determined by the attending clinician)
- Patient has completed at least 6 months of ART
- No current serious side effects and adverse drug reactions
- No serious uncontrolled co-morbid conditions
- Undetectable viral load
- Displays good adherence
- Patient consent

Clients down-referred to the feeder site will be reviewed by a doctor every 6 months, with follow up lab and clinical monitoring as per National ART Guidelines

Staff at IS will assist with capacity development of MS staff to better manage HIV/AIDS. This support will comprise:

- Support in the development of efficient patient flow patterns
- Training and mentoring (staff exchange programs, periodic visits to MS)
- Adaptation and development of relevant site specific tools (checklists, flow charts, IEC materials)
- Developing a Down-Referrals Committee (IS and MS representation), with regular meetings for data review, and to identify and address systematic challenges affecting service delivery

8. DOWN REFERRAL PROCEDURE

Roles and responsibilities:

Initiation site:

ART Nurse

- Identify potential eligible clients for down referrals as per eligibility criteria
- Inform client of eligibility for down referral
- Reinforce counselling on down-referral procedure
- Do a CD4 and Viral Load
- Schedule the client for discussion in the onsite MDT meeting
- Assimilate all lab results and clinical info for the client
- Summarize client history for discussion at MDT meeting

MDT

- Doctor lead
- Final decision on eligibility for down-referral
- Develop management plan for clients not eligible
- Write script for HAART, 5 repeats
- Communicate decision to client
- Complete referral documentation to feeder site

ART Nurse

- Forward a copy of referral form to feeder site, with a date of first appointment at MS included
- Give client original copy
- Store patient folder as per site specific filing practice

Pharmacist

- Dispense one month supply of ART as per script
- File one copy of the prescription as per GPP (quadruplet copy of script: client file at IS, pharmacy record (IS), original with client, one copy in down referral dispensing file)
- ARVs will be pre-packed on a weekly basis, and couriered to the MS in a lockable, temperature controlled case
- Ensure that ARVs are forwarded to MS at least 1 week before scheduled appointment date

Maintenance Site:

ART Nurse

- Receives notification of down-referral from IS
- Record scheduled date of client visit in appointment book
- Inform pharmacy of: patient name, ART regimen, appointment date

Pharmacist/Pharmacist Assistant/Nurse

- Receive notification of down-referral
- Enter client details into appointment book
- Ensure that client specific ART is received at least 1 week after scheduled visit date
- Confirm that ARV packs received are as per distribution control sheet
- Store appropriately

Actively follow up on ART not received at least 1 week before appointment date

ART Nurse: *(MS)*

The appointment book will be reviewed regularly to identify clients defaulting first visit. At the first visit of the client:

- Retrieve client folder (if client was previously on care at the site)
- Make up file for newly down-referred clients
- Record client history (demographics and clinical information on the new Adult Clinical Record)

- Conduct monthly visit activities as per suggested patient flow including all aspects of the treatment programme (vitals screening, clinical examination, identification and management on side effects, pregnancy TB and STI screening, provision of contraceptives and prevention procedures -appendix AA)
- Schedule follow up visits at MS, and arrange 6 monthly review by doctor
- Inform IS of patient arrival (list compiled, and shared with IS weekly)
- Inform IS of deaths

System for Management of Missed visits:

- Clients missing visits at MS will be actively followed up the MS team
- Missed visits will be identified on a daily basis (review appointment book daily)
- When possible, clients will be contacted telephonically to remind them of their visit, and reschedule visit at their earliest convenience
- A list of clients not contactable will be developed regularly, and shared with the onsite tracking team
- The tracking team will conduct a home visit within 3 days of receiving the notification, and feedback outcomes of activities to the ART Nurse
- provides feedback to the onsite Pharmacist
- ART Nurse informs MS Pharmacist and IS ART Nurse of details of clients World Health Organisation have missed visits, and are not traceable
- MS Pharmacist will store uncollected ARVs for a maximum period of 1 week, before returning to the IS

UP- REFERRAL

Clients accessing ART at the feeder sites will have access to higher levels of care at the initiation site, and referral hospital where indicated. These referrals will be facilitated by a referral letter, including all the necessary clinical information. Emergency referrals will be preceded by a telephonic notification and consultation with the doctor at the referral site receiving the client. Eligibility criteria for up-referral:

- Evidence of treatment failure: virological, immunological, or clinical (appendix bb)
- Development of side effects, adverse reactions to HAART, development of OIs or co-morbid conditions beyond the scope of management of the feeder site
- 6 monthly follow-up of clients (in the absence of an onsite doctor at the MS)

Feedback will be provided by the referral site, to ensure continuity of care and prevent any disruptions to treatment.

Monitoring and Evaluation

- Patient files will be stored appropriately with restricted access at both IS and MS
- MS data will be shared with the IS Data Capturer on a monthly basis
- Data analysis and feedback sessions will be conducted quarterly with the down-referral committee (IS and MS staff)

12. BASIC REQUIREMENTS FOR A MAINTENANCE SITE

- Professional nurse (trained in HIV/AIDS Management)
- Ability to conduct clinical follow up visits for clients on ART
- Data support staff
- Functional appointment system
- Psychosocial support: staff and resources to complement clinic activities, and improve treatment outcome by decreasing LTFU, increasing community involvement and providing home based care services
- Storage space for ARV drugs compliant with GPP
- Ability to perform laboratory tests as recommended by the National ART Guidelines (appendix cc)

Strategies for Quality Control of Down-Referral Programme:

- Baseline assessment of Maintenance site with the development of a Needs Analysis and effective workplan
- Regular MS visits by IS clinical staff to improve staff capacity in management of HIV/AIDS (mentoring, training activities)

- Regular review of the Drug Distribution Process by IS Pharmacy Manager
- Regular data quality review to assess and improve data management
- Availability of buffer stock of ARVs at MS for unscheduled visits, and complications that may arise in the treatment programme (not for new clients)
- Development and dissemination of a referrals directory to harmonize referral systems and improve community involvement in clinical activities

Conclusion:

The National Strategic Plan 2007 -2011 has set itself ambitious goals to expand access to HIV care and treatment services. An effective down-referral programme is currently the most effective strategy to meet these aims. There is sufficient evidence to motivate the benefits of this programme, however, there needs to be efficient systems in place to harmonize this process and improve treatment outcomes of clients.

APPENDIX 14

PMTCT Checklist

PMTCT CHECKLIST

	MOTHER'S DATA		
1.	Name of Patient:		
2.	Folder number:		
3.	ID Number:		
4.	Hospital/Clinic:		
5.	Address(Mum/Dad):		
6.	Phone number(Mum): Alternative number:		
7.	Booking status:		
8.	Referred from:		
9.	RVD status: Refused HCT:	Viral Load: TB status:	

	CD4 count:		
10.	**ART:** CD4<350 Current HAART regimen:		
11.	**CD4>350 – Dual Therapy** • Zidovudine issued at 28 weeks or when: • Single dose Nevirapine at delivery • Zidovudine 3(three) hourly during labour • Any other meds during labour e.g. metoclopramide		
12.	**Mode of delivery** • Normal Vaginal Delivery • Caesarean section		
13.	**Feeding option** • Breastfeeding • Formula		
15.	**Labour Ward sister** • Name: • Signature:		
16.	**PMTCT** • Name • Signature		
	BABY'S DATA		
17.	Name:		
18.	Hospital number:		

19.	Weight	
20.	Reason for admission into nursery/ premature unit	
21.	**Mum on lifelong HAART** • Stat dose of nevirapine syrup at birth + • Zidovudine syrup for 7 days only	
22.	**Mum on Dual Therapy PMTCT** • Stat dose of nevirapine syrup at birth + • Zidovudine syrup for 7 days OR 28 days	
23.	**Mum status unknown** (but agrees for baby to test) • HIV antibody test at six weeks (PCR)	
	FOLLOW UP/OUTCOME	
24.	Referral/Peripheral clinic:	
25.	Name of sister:	
26.	Appointment date at six weeks:	
27.	PCR at six weeks:	
	Prophylaxis at six weeks • Cotrimoxazole • TB prophylaxis • 6 weeks immunization	
28.	Mum refused test:	
29.	Mum returned for result:	
30.	Referral to HAART site:	

APPENDIX 15

Patient Demographic Information

PATIENT DEMOGRAPHIC INFORMATION			**DATE:**
Name		Surname	Age
Address:		ID no:	Tel:
Cell:		Contact number of husband/partner:	
Do you work:	YES/NO	Is this your regular clinic	YES/NO
How long are you on treatment:			
Is your partner tested:			YES/NO
How many children do you have:			
Is your child/children being tested:			YES/NO
Do you know the status of your children:			YES/NO
Did you know your status whilst you were pregnant:			YES/NO
Have you received any medication while you were pregnant:			YES/NO
If so, what:			
Do you know your CD4		YES/NO	
Are you on ARVs		YES/NO	
If YES , tick			
Stavudine			
Lamivudine			
Efavirenz			
Nevirapine			
Aluvia			
Zidovudine			
Tenofivir			
Didanosine			