An Assessment of DSP Pharmacy Medication Delivery for HIV Treatment in a Family Practice in KwaZulu-Natal

Submitted to:

SCHOOL OF CLINICAL MEDICINE, NELSON.R.MANDELA CAMPUS

UNIVERSITY OF KWAZULU-NATAL DURBAN

SOUTH AFRICA

For:

Submitted in partial fulfilment of the academic requirements for the degree:

Master of Medical Science (Clinical HIV/AIDS Management)

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Durban 2014

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10 February 2015

ABSTRACT

Background: HIV/AIDS remains a major cause of morbidity and mortality in South Africa, with an adult prevalence rate of 17.9% in 2012. The massive antiretroviral (ARV) rollout has seen many more patients commenced on antiretroviral therapy (ART), and has transformed it into a manageable chronic disease. However, successful treatment is dependent on high rates of adherence to antiretroviral drugs. Recently there has been an increased utilisation of Designated Service Providers (DSP) by Healthcare Funders to manage escalating healthcare costs. This study aims to assess DSP pharmacy medication delivery to patients on antiretroviral therapy.

Method: A retrospective cross-sectional descriptive study was conducted at a general family practice in the private sector, surveying all patients who received ART via DSP pharmacy services. Data was collected via an anonymous, self-administered structured questionnaire and a review of clinical records. A total of 40 patients were registered and initiated on ART at the sampled practice. Although 40 patients were available in the cohort only 34 participated.

Results: A total of 34 patients (97.4%) participated in the study. Females (67.6%) between 30 and 50 years old employed in the public sector (53%) constituted the highest proportion of respondents. Most of the respondents were members of GEMS medical scheme (58.8%) followed by Discovery (14.7%) and Polmed (11.8%). The majority of the respondents (67.6%) have ART delivered to a doctor’s address; 20.6% receive medications from a pharmacy; and 11.3% collect their medications at a post office. Of the respondents, 88% received reminders providing medicine delivery details, with 82.4% receiving short message service (sms) reminders via cellular telephone. However, 23.5% of the respondents reported receiving medication late or never, and 29.4% received incorrect medications. The DSP pharmacy service was rated as poor or satisfactory by 29.4% of respondents, with 70.6% preferring to access ART from

their own doctor; 8.6% from a pharmacy of own choice; 5.9% from a courier pharmacy; and 14.7% from a DSP pharmacy. Significantly, 79.4% of respondents rated their adherence less than “excellent”; 17.6% missed doses; 23.5% took ART > 2 hours late; and 33.4% missed doses in the last week. Of concern 32.4% of patients recorded viral loads > 50cp/ml and 5.9% recorded viral loads > 1000 cp/ml. Over a third of patients (38.3%) recorded CD4 levels < 400.

Conclusion: DSP Pharmacy Services provide an innovative and cost effective method of antiretroviral medicine delivery, however there is scope for service improvement. Although most patients receive regular ARV medicine supplies, a significant number of patients receive incorrect medicines or no medicine at all, which may result in treatment interruptions and treatment failure. Successful ART requires near-perfect ARV adherence levels, however the majority of patients fail to maintain the required adherence levels. Most users of DSP pharmacy services rate the medicine delivery service poorly and the majority of patients prefer to access ART from their own doctor. ARV medicine access factors need to be carefully considered by medical schemes when ART treatment programs are designed, otherwise drug interruptions may result in poor adherence and in treatment failure.

Keywords: HIV, Designated service provider, adherence, antiretrovirals, antiretroviral therapy

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DECLARATION

This Master of Medical Science (Clinical HIV/AIDS Management) dissertation is my own work and all primary and secondary sources have been appropriately acknowledged. The dissertation has not been submitted to any other institution as part of an academic qualification.
This dissertation is prepared in partial fulfilment of the requirement of the Master of Medical Science (Clinical HIV/AIDS Management) degree at the School of Clinical Medicine, Nelson R. Mandela School of Medicine, University of KwaZulu-Natal, Durban, South Africa.

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ACKNOWLEDGEMENTS

I wish to express my sincere gratitude to my supervisor Dr. O. H. Mahomed and Dr. A. Ross for their invaluable support, advice and patience. This study would not have possible without their contribution and encouragement.

My sincere appreciation goes to the Biomedical Research Ethics Committee at the University of KwaZulu-Natal for granting me the permission to conduct the research and to Ms G Wood for her efficient editing service.

I am grateful to the respondents who agreed to participate in this study.

PUBLICATIONS OR PRESENTATIONS

No publications or presentations have arisen from this research report.

ACRONYMS AND ABBREVIATIONS

ARV:	Antiretroviral
DSP:	Designated Service Provider
SEP:	Single Exit Price
HPCSA:	Health Professionals Council of South Africa
NSDA:	Negotiated Service Delivery Agreement
PLHIV:	People Living with HIV
HAART:	Highly Active Antiretroviral Therapy
KZN:	KwaZulu-Natal
DMP:	Disease Management Program
STI:	Sexually Transmitted Infection
PMB:	Prescribed Minimum Benefits
ART:	Antiretroviral Therapy
WHO:	World Health Organisation

TABLE OF CONTENTS Page

LIST OF TABLES

LIST OF FIGURES

CHAPTER I: INTRODUCTION

1.1. Background

South Africa has an estimated population of 52.98 million, with approximately 5.26 million people living with HIV (PLHIV) and an overall HIV prevalence rate of approximately 10% (1). Geographically KwaZulu- Natal has the highest HIV prevalence (16.9%) and the eThekwini metropolitan where Durban is situated has a HIV prevalence rate of 14.5%.(2) An estimated15.9% of the population between the ages 15 and 49 years old were infected by HIV (1). Approximately 17% of South African women of reproductive age are HIV positive. The prevalence of HIV amongst antenatal care patients has reached a plateau below 30.2% in 2010 (3). Although the prevalence of HIV has levelled off, the absolute numbers of PLHIV is increasing by 100 000 per year (3).

The total number of patients receiving antiretroviral therapy increased from 47 500 (95% CI 42 900 - 51 800) to 1.79 million (95% CI 1.65 - 1.93 million) between the middle of 2004 and the end of June, 2011. Of the patients receiving ART, 85% were receiving ART through the public health sector, 11% were receiving ART through disease management programmes in the private sector, and the remaining 4% were receiving ART through community treatment programmes run by non-governmental organisations (NGO's) (4).The adult ART coverage rate based on CD4 counts < 200ul increased from 5.1% (95% CI 4.2 - 6.1%) in the middle of 2004, to 79% (95% CI 80 - 85%) by the middle of 2011. The adult ART coverage using CD4 counts < 350ul was 52% (95% CI 46 - 57%) by the middle of 2011 (4). The incidence of new HIV infections has decreased by 41%, from 2.43% in 2011, to 1.42% in 2011, with the mortality rate of HIV/AIDS decreasing by 27% in 2011. During 2011, there were 1 113 284 persons (15 years and older) and 377 047 children (between 0 and 14 years old) in need of antiretroviral therapy (3).

The private health sector plays a major role in HIV and AIDS care in South Africa, with over 100 000 (mid 2006) patients enrolled in Disease Management Programs (DMPs) (5).The private sector affords patients easier access to

HIV/AIDS care, but concentrates more on HAART with poor collaboration between it and the public health services (5).The private sector role players include Medical Scheme Beneficiaries (15% of population), Workplace Treatment Programs, Community Treatment Programs and Individuals paying for their own treatment. Data from the private sector indicates an 86% survival rate in patients following 12 months of ART. Discovery medical scheme also reported an 8% increase in survival rate of patients on ART, from 76% in 2010 to 84% in 2012 (3).

The Medical Schemes Act 131 of 1998 requires Medical Schemes to provide Prescribed Minimum Benefits (PMBs) in relation to HIV, and prohibits medical schemes from refusing high risk patients and loading premiums. PMBs in relation to HIV include:

- HIV Counseling and testing
- Screening and Prevention of TB
- Diagnosis and Treatment of STIs
- Treatment of Opportunist Infections
- Prevention of Mother to Child Transmission
- Post Exposure Prophylaxis
- Medical Management and medications as prescribed within National Public sector Guidelines

Healthcare Funders (Medical Schemes) have established Disease Management Programs (DMPs) and Designated Service Providers (DSPs) to reduce costs, to improve patient outcomes to and meet legislative requirements.(6)

A study by Johnson to assess the number of patients accessing HAART in the private sector via DMPs, reported that there were 67 600 patients receiving HAART in the private sector in mid-2006. There was over 17 DMPs with 55 900 patients on HAART. The majority of DMP patients on HAART (46 800) were treated by Aids for AIDS (36%), Lifesense (15%), Discovery (11%), Arum Health (11%), Qualsa (11%), respectively. Community Treatment Programs, Right to Care, SA Catholics Bishops Conference and Treatment Action Campaign had 11

600 patients on HAART in mid 2006. The Johnson study estimates a 32% annual growth in patients on HAART in the private sector (7).

1.2. Problem statement

DSP pharmacy services are increasingly being utilised by medical schemes to provide antiretroviral medications to patients. Successful HIV management is dependent on near perfect adherence to ART which is in turn dependant on a reliable supply of antiretroviral medications. Anecdotal evidence suggests the patients experience challenges with DSP pharmacy medicine deliveries. Any factor that may impact on ART adherence warrants concern, therefore an assessment of DSP pharmacy medicine delivery has been undertaken.

1.3. Purpose of Study

This study aims to assess the process of DSP pharmacy medication delivery, patient satisfaction with and adherence to HIV treatment, whilst receiving medication through a DSP at a family practice.

1.4. Specific Objectives

The objectives of the study are:

1. To review clinical and social demographic profile of patients receiving ARVs via DSPs at the general practice.
2. To evaluate the process of medicine delivery to patients from this practice via DSPs
3. To determine patient satisfaction with DSP services
4. To assess patient adherence to ART through the DSP process
5. To make recommendations based on findings of the study

1.5. Structure of Dissertation

This study is presented in 6 chapters:

Chapter I (Introduction) provides an introduction with a discussion of the background of the study, purpose of the study, and specific objectives of the study.
Chapter II (Literature Review) presents a literature review of the current evidence regarding HIV treatment and designated service providers.
Chapter III (Research Methodology) explains the study research design, study population, sample determination, inclusion and exclusion criteria, data collection and data handling and analysis.
Chapter IV (Results and Analysis) describes the interpretation and explanation of the study findings in line with the objectives of the study.
Chapter V (Discussion) presents a discussion in line with the objectives of the study.
Chapter VI (Recommendations and Conclusion) presents a summary of the study and provides recommendations.

CHAPTER II: LITERATURE REVIEW

2.1. Introduction

This chapter reviews existing evidence pertaining to HIV treatment and designated service providers (DSPs'). A literature review was conducted through Pubmed and Google Scholar using the following keywords: HIV, adherence, Antiretroviral, HAART, prevalence, designated service providers, private sector, healthcare funders, South Africa, KwaZulu-Natal and, Ilembe. This was done to provide information on Designated Service Providers and the law pertaining to them, as well as factors that affect adherence to HAART.

2.2. Designated Service Provider Legislation

Regulation 7 of the Medical Schemes Act defines a DSP as a provider or group of providers selected to provide the diagnosis, treatment and care in respect to one or more Prescribed Minimum Benefit (PMB) condition." DSP" within the regulations is only used for the management of PMBs and all other managed health care conditions utilise "participating providers" (8).

The appointment of DSPs is not well regulated within South African law, with only a few legal provisions applicable.(8) Legal provisions that impact on DSP arrangements are found within the Medical Schemes Act 131 of 1998, Health Professionals Council of South Africa (HPCSA) rules in terms of the Health Provisions Act (2006 HPCSA Policy on Undesirable Business Practice), and the Competition law and the Consumer Protection Act 68 of 2008.

Medicine pricing in South Africa is tightly regulated with medicines sold at a regulated Single Exit Prices (SEP). Discounts and incentives are not permitted within the Medicines and Related Substance Amendment Act 72 of 2008 (section 18A).

2.3. Designated Service Providers in Healthcare Provision

DSP arrangements have resulted in both positive and negative effects on healthcare provision. Lower cost of service, security of supply, and service

specific investment have been mentioned as positives, however DSP contracts can have the effect of being anticompetitive and of promoting collusion and reducing patient freedom of choice (6).

A recent survey by Old Mutual Actuarial Consultants found that 60% of medical aid members had a negative attitude towards DSPs (31% wanted freedom of choice, 13% wanted to see their own doctor, and 9% found it inconvenient). The majority of DSP agreements involved general practitioners or pharmacies. Geographic coverage was listed as the biggest problem in appointing DSPs. Eighty percent (80%) of open schemes had DSP contracts with pharmacies. DSP agreements have shown substantial savings with general practitioners (60%) and pharmacies (80%), however medicine savings have been minimal (10%) (9). The minimal savings may be due to the effect of the single exit pricing of medicine.

2.4. Role of Private Sector Doctors

The demand for HIV care has placed a huge demand on healthcare services. Private health sectors doctors, especially primary care doctors, play an important role in providing HIV services. In 2006, the WHO reported that approximately 21% of patients receiving ART in six African countries (SA, Nigeria, Uganda, Namibia, Botswana, and Kenya) were receiving treatment in the private sector. Private sector facilities offer more convenience to patients with shorter waiting times and more flexible schedules, are usually closer to home or work and some patients perceive private sector facilities as offering more confidentiality and sensitivity towards HIV patients. Despite the potential benefits, there have been concerns about quality, training, prescribing standards, testing and monitoring of patients, counselling, and the management of opportunistic infections. Changes in regulation, clinical training and ongoing education have improved clinical HIV management. A recent study in 2010 conducted in the KwaZulu Natal EThekwini region to assess whether private sector doctors manage patients in accordance with international and national guidelines, concluded that the majority of doctors were compliant with current HIV management guidelines, therefore maintaining an acceptable quality of care (10).

2.5. HIV Adherence

Antiretroviral treatment has transformed HIV into a chronic manageable illness with median life expectancy now increased substantially (a 25 yr old on treatment now has an additional 39 years life expectancy in developed countries) (11). However, successful treatment outcomes are dependent on sustained high rates of adherence i.e. appropriate dose, at the appropriate time, in the appropriate manner (viz. with or without food) (12). An antiretroviral adherence rate > 95% is required to ensure treatment success. Studies suggest that antiretroviral adherence rates of between 70% and 89 % are associated with viral rebound and the emergence of drug resistance. Non-adherence to ARVs results in: the emergence of debilitating constitutional symptoms; more opportunistic infections; more damage to vital organs by inflammatory processes; an increased chance of transmitting HIV to others; and substantial financial costs to both individuals; healthcare funders; and general society. Second and third line antiretroviral regimes are more complex; consist of more medications; cost more; are associated with more side effects and toxicities; and require more management and expensive laboratory tests (genotyping, phenotyping) (11).

Maintaining adequate adherence rates remains the greatest challenge for patients on ARVs. Non-adherence rates to treatment range from 33% to 88% in studies, depending on how adherence is defined and assessed. A systematic literature review to examine the factors that affect adherence to treatment showed that factors common to patients in developed and developing counties were:

- fear of disclosure
- forgetfulness
- lack of understanding of treatment benefits
- complicated regimes
- being away from medicines (being away from home, not carrying meds)(13)

In developing countries common factors were:

- Patient related factors (eg. patient beliefs, side effects, addiction, concurrent illness)
- financial constraints
- disruption to access to medication (13).

2.6. Summary

Adherence to antiretroviral medication is one of the most important factors required for HIV viral suppression and treatment success. A secure, reliable, regular supply of antiretrovirals is an important factor for successful outcomes. The recent introduction of legislative changes has empowered healthcare funders to increasingly utilise DSP pharmacy services in order to provide antiretroviral medications to medical aid members. This study aims to assess the delivery of antiretrovirals by DSP pharmacy services to patients in a family practice.

CHAPTER III: METHODOLOGY

3.1. Introduction

The following chapter gives a brief outline of the research design adopted for the study, the study population, the sample size determination, the location in which the research was carried out and the inclusion and exclusion criteria.

3.2. Type of Research

Epidemiological Study

3.3. Research Methodology

3.3.1. Study Setting

The study was conducted at the researcher's general family practice situated in Tongaat, a small coastal town on the KwaZulu-Natal North coast and part of the eThekwini municipality. Tongaat serves as business centre for the surrounding sugar farming industry and other associated small industries. Tongaat is serviced by a public sector primary healthcare facility and a private hospital (Mediclinic Victoria Hospital). The medical practice operates as a general family practice with approximately 5-10 patients on ART seen per day. The racial profile is approximately 70% black and 30% Indian. Almost 80% patients are medical scheme members and 20% are self funded.

3.3.2. Study Design

This study was a retrospective cross-sectional descriptive study was adopted for this study.

3.4. Target Population

All HIV patients receiving ARVs via a DSP pharmacy service in the private sector.

3.5. Study Population

Approximately 150 patients, comprising both self funded and medical scheme funded patients are seen per month at the research site with 40 patients receiving ARV medication via DSP pharmacy services.

3.5.1. Inclusion Criteria

All adult patients at the study site initiated on HAART and contracted to DSPs for delivery of ARVs.

3.5.2. Exclusion Criteria

- Children
- All patients at the study site that receive HAART from the medical practice and not from the DSP pharmacy services.

3.6. Study Sampling

A purposive convenient sampling strategy was used to obtain the sample for the study. All patients who were contracted to DSPs for their ARVs were identified from medical records and contacted by the researcher to participate in the study. No patients were excluded, unless they declined participation. All prospective subjects were provided with a study information sheet and a consent form.

3.6.1. Size of Sample

A cohort of 36 patients accessing ARVs via a DSP pharmacy at the practice was identified. All patients were included in the study. Two patients declined to participate in the study.

3.7. Data Collection

The following data collection tools were designed:

3.7.1. Data Collection Tools

1. Anonymous self-administered questionnaire. The questionnaire consists of 15 questions in 4 broad categories:
   a. Clinical and social demographic profile
   b. Process of Medication delivery
   c. Patient satisfaction
   d. Adherence to ART
   The questionnaire was available in the study participant's choice of language (English or isiZulu).
2. Review of Clinical Patient records: - viral load levels; CD4
3. Pill counts

3.7.2. Application of Data Collection Tools

1. Study participants presented themselves to the medical practice where they were given a study information sheet (Appendix-1) and consent forms (Appendix-2). Once informed consent was obtained, the patient was given a study questionnaire (Appendix-3) to complete independently in a private setting. The researcher and trained research assistant were on hand to explain or clear up any unclear or ambiguous questions. Once completed, the questionnaires were checked for completeness and retained by the researcher.
2. A records review tool was developed to review patient's clinical records. Patients were encouraged to attend the medical practice at least monthly, where they were clinically examined for treatment failure and blood samples were drawn when required as part of their usual care and expenses. Viral load and CD4 counts were done every 3 months.
3. Pill counts of patient ARVs were conducted monthly when patients presented themselves for clinical review, or decided to pick up delivered medication. Patients were requested to bring the previous

month's medication boxes and bottles when visiting the medical practice.

3.7.3. Data Handling

Questionnaires that were filled in were handed over to the researcher, who stored them securely in a locked cabinet, which was only accessed by the researcher. Questionnaires were checked for completeness, factual inaccuracies and inconsistencies, and numbered to facilitate tracking later when data was entered onto a database. The coding scheme for variables was incorporated into the questionnaire design, allowing data to be entered directly into a database. The database was created using the IBM SPSS statistical software package. Data was entered directly into the database without using a separate coding sheet so as to minimise the introduction of data handling errors. All data entries into the database were double checked against the questionnaires for correctness. The completed database was then examined for inconsistencies and outliers. Frequency figures for each question were produced, which quickly showed outliers and inconsistencies. The computer database was password protected and backup copies were securely stored.

3.7.4. Data Analysis

Descriptive statistical analysis was conducted. Means, proportions, percentages and confidence intervals were calculated and the results summarised in tables and graphs. The data within the database was grouped into categories to analyse according to the objectives of the study. The following categories were used:

1. Demographic profile: the gender distribution of patients was summarised using a pie diagram and frequency tables were used to summarise the medical aid membership, level of education and occupation of patients utilising DSP pharmacy services. The age distribution of patients accessing ARV's via pharmacy DSP services was summarised using a bar graph.

2. Clinical profile: a frequency table was used to summarise how long patients have been on ART before participating in the study and a pie diagram was used to summarise where patients first commenced their ART.
3. Medicine delivery process: the number and percentage of patients receiving ARV's at various possible delivery sites was summarised using a frequency table. Data regarding whether ARV's were delivered on time, whether delivery reminders were received and whether correct medications were delivered, was summarised on a frequency table. These questions all required a yes or no response. Data pertaining to the type of reminders received before medicine delivery was summarised on pie diagram showing number and percentage. The data regarding when, if ever, incorrect medicines were delivered was summarised using a bar graph.
4. Patient satisfaction: a frequency table was used to summarise the data regarding how satisfied patients were with the DSP pharmacy's medicine services. Data pertaining to where patients would prefer to access their ARV medication was summarised using a pie graph.
5. Adherence to ARV's: frequency tables were used to summarise data regarding the number of ARV doses missed in the last 7 days, and the number of ARV doses taken > 2hrs late in the last 7 days. A bar graph was used to summarise data pertaining to when last a patient had missed an ARV dose. Bar graphs were used to summarise data regarding patient ARV adherence.

3.8. Ensuring Validity and Reliability

Each stage of the study (data collection, data maintenance, data processing and reporting) was carefully planned to avoid the introduction of error, thereby ensuring validity and reliability.

A self-administered questionnaire was chosen, because it offers some degree of anonymity and is not influenced by the interviewer. The questions were designed to be short, simple, specific, as well as easy to read and understand, thus promoting the greatest number of accurate answers and completed questionnaires. The questionnaire was available in the participant's choice of

language (English or isiZulu). General questions were asked first, followed by more specific questions to encourage a better response rate. To avoid a time memory bias, time frames were kept to < 6 months where possible and wide time scales were used. Wherever possible, closed type questions, questions with fixed answer options, Likert-type scales, and visual analogue scales were used. This makes the questionnaire easier and quicker to complete, encourages respondents to complete the questionnaire, and allows for easier, more accurate coding of data, therefore reducing the introduction of bias. The questionnaire was designed with the coding of the answers built in, so that responses could be entered directly into the software programme, without the need to first code and transcribe. This reduces the risk of introducing bias in the data processing stage and ensures reliability.

All adult patients receiving antiretroviral medications via a DSP pharmacy service at the research site were identified and invited to participate, thereby reducing the risk of introducing a selection bias. Prospective study participants were all telephonically invited to participate. The questionnaire administration process was planned and the research assistant was trained to administer the questionnaire according to strict rules. The researcher or research assistant was always on hand to clarify any unclear or ambiguous questions. Completed questionnaires were immediately received by the researcher, who numbered them and stored them in a secure locker.

In order to ensure study validity questionnaire responses were corroborated with practical observations e.g. delivery of medicines and clinical observations. There is no gold standard measure available for use in this study. However, wherever possible, established instruments were used to ensure validity. A recent study by Chaiyachati et al to assess the validity of a questionnaire with five questions, which assess adherence to antiretrovirals in the public sector, was conducted (14). These questions were included in the study. Various validation strategies were used to triangulate data. The responses received on the questionnaire were verified against clinical data, delivery data records and patient records, thereby ensuring factual validity. Consistency checks were built into the

questionnaire by asking similar questions more than once. In order to ensure face validity, respondents were interviewed by the researcher after the questionnaire was filled out, in order to assess if answers corroborated questionnaire responses. The interview questions were posed differently, however they were based on those of the questionnaire. The questionnaire responses that seemed unusual were also verified during the interview.
The study was conducted in a confined local area; therefore the study outcomes will only be applicable to areas with similar patient profiles, demographics and socio-economic characteristics.

3.9. Ethical Consideration

This study was approved by the University of KwaZulu-Natal Biomedical Research Ethics Committee (ref: BE071/13).The 4 principles of ethics (autonomy, justice, beneficence, non-maleficence) were addressed. It was conducted in the researcher's own medical practice, by means of a self-administered questionnaire. The participants were given full information regarding all risks and benefits, methods and purpose of the study, in the language of their choice, before participating. Study participants were not coerced in any manner and were free to accept or reject participating in the study. The study participants were chosen fairly consistent with the priorities of the study. The questionnaires were anonymous and were handled only by the researcher and research assistant. Participants were guaranteed confidentiality and questionnaires were stored securely .The study was carefully designed to avoid any risk or harm to study participants. This research project aims to enhance current knowledge regarding delivery of antiretroviral medications by DSP pharmacy services which will improve future management of patients.

CHAPTER IV: RESULTS AND DATA ANALYSIS

4.1. Introduction

This chapter describes the interpretation and explanation of the findings of the study, in line with the objectives of the study. The results are discussed under the following subtopics: demographic and clinical profile; medicine delivery process; patient satisfaction; and adherence and clinical outcomes. A total of 34 patients accepted and participated in the study, yielding a response rate of 94.74 percent.

4.2. Demographic Profile

4.2.1. Gender Profile

The majority of the respondents namely 23 of the 34 respondents (67, 6%) who participated in the study were females. Eleven males (32.4%) participated. (Figure 4-1).

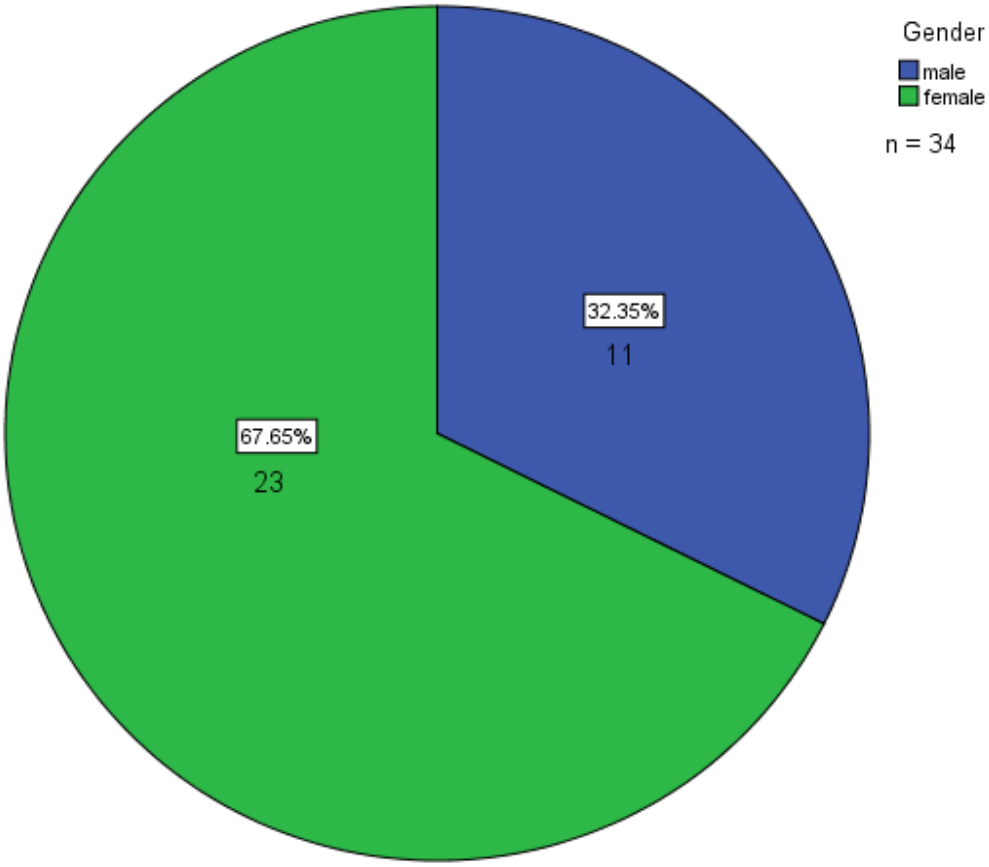

Figure 4-1: Gender profile of patients accessing ART via DSP pharmacy at medical practice in Tongaat, KZN in 2013

4.2.2. Age Profile

The majority of respondents accessing ARV's via DSP pharmacies were aged between 31 and 50 years old, with 38.2% between 31-40 years old and 35.3% of all respondents between 41-50 years old. Patients between 21-30 years of age accounted for 17.6% of all respondents. Only 2.9% of the patients on ARV's were aged over 60 years old. (see Figure 4-2)

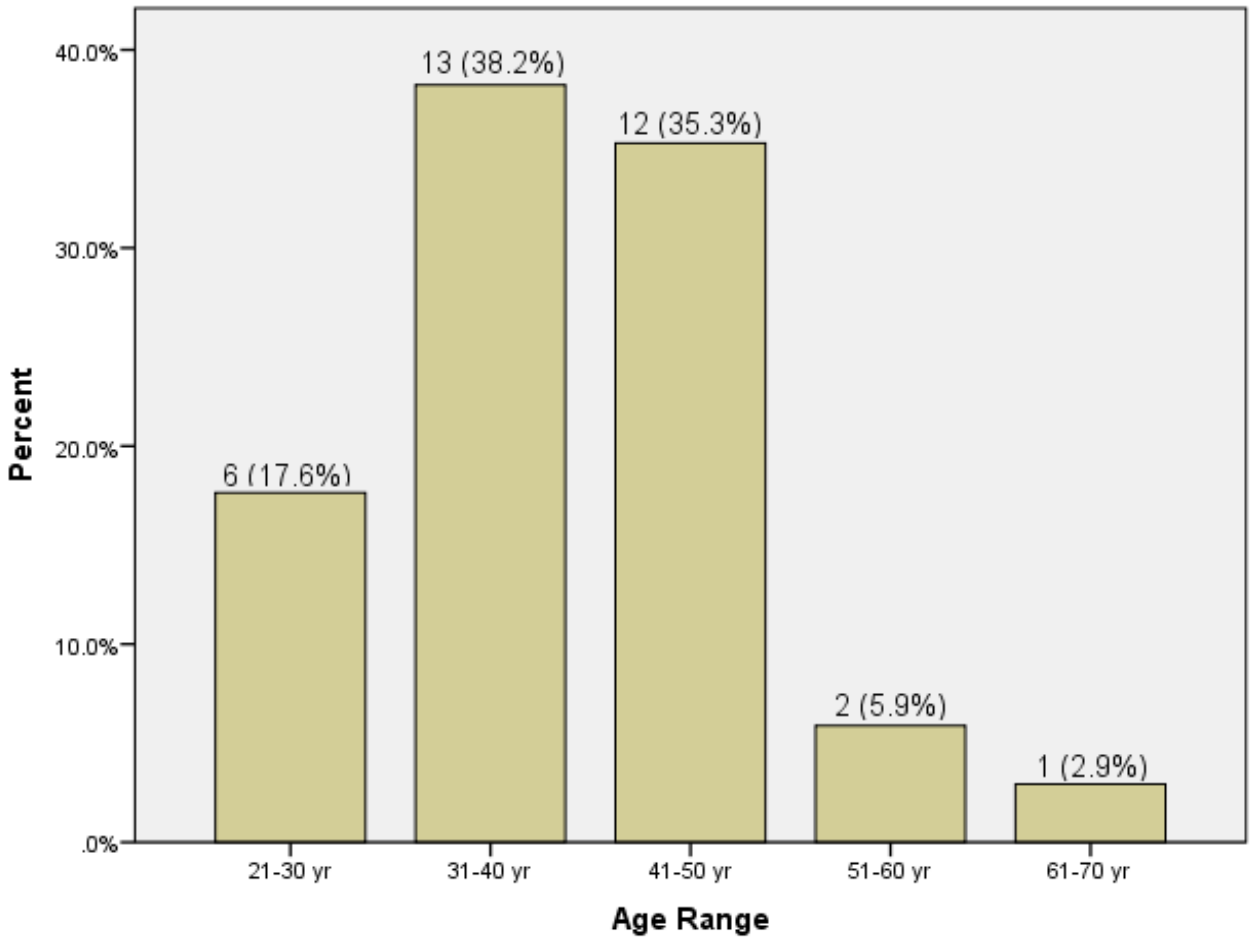

Figure 4-2: Age distribution of patients accessing ART via DSP pharmacy at medical practice in Tongaat, KZN in 2013

4.2.3. Occupation

Public Sector employees account for the majority of patients, with educators numbering 11 respondents (32.4%) of the sample, police personnel accounting for 4 (11.8%) and nurses numbering 3 of 34 respondents (8.8%). The balances of the respondents represent a wide spectrum of occupations, from pensioner, housewife, to local political councillors, reporters and truck drivers etc. (see Table 4-1).

Table 4-1: Frequency distribution of occupation of patients accessing ART via DSP pharmacy at a medical practice in Tongaat, KZN in 2013

Occupation	Number	%
Admin Clerk	2	5.9
Artisan	1	2.9
Assistant	2	5.9
Councillor	2	5.9
Educator	11	32.4
House wife	1	2.9
Manager	1	2.9
Nurse	3	8.8
Pensioner	1	2.9
Police	4	11.8
Receptionist	1	2.9
Reporter	1	2.9
Student	1	2.9
Supervisor	1	2.9
Truck driver	1	2.9
Total	**34**	**100.0 %**

4.2.4. Level of Education

Most patients (88.2%) matriculated from school, with 52.9% of patients (18 of 34 respondents) achieving post matriculation qualifications, with 2.9% (1respondent) that held a technical certificate. There were 12 respondents (35.3%) who matriculated from school with no further tertiary education, and 3 respondents (8.7%) who never matriculated from school. (see Table 4-2).

Table 4-2: Frequency distribution of the level of education of patients who access ART via DSP pharmacy at a medical practice in Tongaat, KZN in 2013

Level of Education	Number	%
Post matric qualification	18	52.9
Matriculation	12	35.3
Secondary education	3	8.9
Technical certificate	1	2.9
Total	**34**	**100.0%**

4.2.5. Medical Scheme

A wide variety of medical schemes offer medical cover to the patients. Government Employees Medical Scheme (GEMS) represent 20 (58.8%) of the study sample, with Discovery Medical Scheme representing 5 (14.7%) and Polmed Medical Scheme representing 4 (11.8%) patients on ARV therapy.

Bonitas Medical Scheme and Medshield Medical Scheme both represent 2 (5.9%) patients each. A single patient (2.9% of sample) is represented by SABC Medical Scheme. (see Table 4-3).

Table 4-3: Frequency distribution of medical scheme membership of patients receiving ART via DSP pharmacy at a medical practice in Tongaat, KZN in 2013

Medical Scheme	Number	%
Bonitas	2	5.9
Discovery	5	14.7
GEMS	20	58.8
Medshield	2	5.9
Polmed	4	11.8
SABC	1	2.9
Total	**34**	**100.0%**

4.3. Clinical Profile

4.3.1. Duration on ART

Patients enrolled in the study have been on ARVs for varying periods of time. The longest a patient from amongst those included in the study has been on

medication is 16 years, having commenced ARV therapy in 1997. Three patients (8.8% of sample) have been on medications for over 10 years. A total of 7 patients (20.6%) were on treatment for 2-3 years, 5 patients (14.7%) were on treatment for 3-4 years, 7 patients (20.6%) were on treatment for 4-5 years and 9 patients (26.5%) were on treatment for > 5years. Only 3 patients (8.8%) of the respondents had commenced ARV's in the current year. (see Table 4-4).

Table 4-4: Frequency distribution of time since commencing ART in Patients who obtain medication via DSP pharmacy at a medical practice in Tongaat, KZN in 2013

Time since Commencing ARV's	Number	%
0-1 year	3	8.8
2-3 years	7	20.6
3-4 years	5	14.7
4-5 years	7	20.6
5-10 years	9	26.5
> 10 years	3	8.8
Total	**34**	**100.0%**

4.3.2. ART Regimen

The largest proportion of patients, 20 (58.8%), were first started on ARV regimen by the General Practitioner (GP). Only 2 (5.9%) were first commenced on ARVs at the Government Clinic, before transferring to private sector GP's. The other

respondents first commenced ARV medication under Specialist medical care and Public Sector Hospitals before transferring to GP's. (see Figure 4-3)

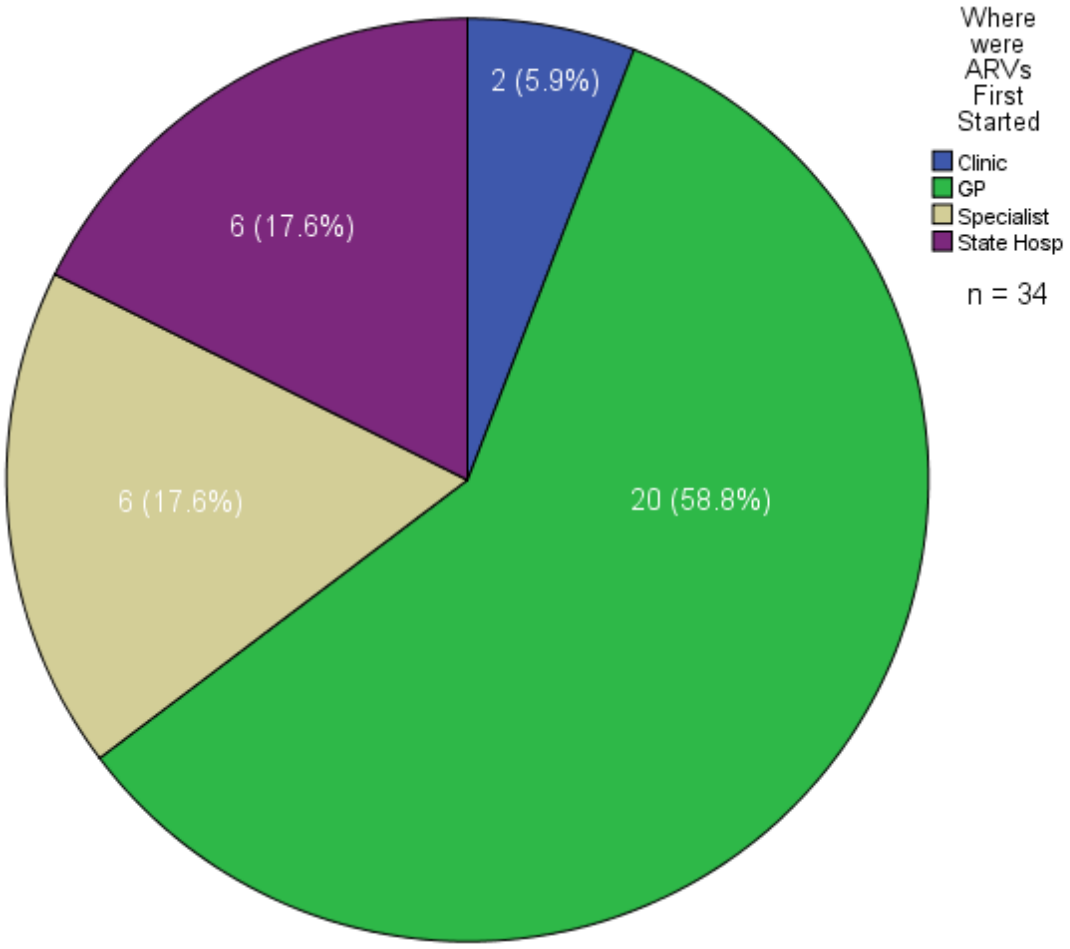

Figure 4-3: Commencement site of ART in patients who receive ART via DSP pharmacy at a medical practice in Tongaat, KZN in 2013

4.4. Medicine Delivery Process

4.4.1. Point of Delivery

Patients who subscribe to DSP Pharmacy Services have their medicines dispensed by a DSP Pharmacy (eg. Medipost, Pharmacy Direct etc.), which are then couriered to a chosen address or post office. A large proportion of 23 (67.6%), chose to have ARV's delivered to the doctor's address for pick-up. A total of 7 (20.6%) of the respondents chose to pick up their ARV's from a pharmacy and 4 (11.8%) preferred their medications delivered to a Post Office. None of the respondents chose to have ARV's delivered to a home address. (see Table 4-5).

Table 4-5: Frequency distribution of delivery address for ART of patients who receive medication via DSP pharmacy at a medical practice in Tongaat, KZN in 2013

Delivery address of ARV's	Number	%
Doctor	23	67.6
Pharmacy	7	20.6
Post Office	4	11.8
Home	0	0
Total	**34**	**100.0%**

4.4.2. Reliability of Medicine Delivery

The majority of patients, 76% (26 of 34 respondents) report receiving ARV medication deliveries on time, with 8 patients (23.5%) not receiving their ARVs on time. In those patients who receive medication deliveries, 30 patients (88.2%) report receiving a reminder before delivery, and 4 patients (11.8%) report receiving no delivery reminders at all. The 26 patients (70.6%) who received regular medicine deliveries report receiving correct medications, whereas 8 patients (23.5%) report receiving incorrect medications. (see Table 4-6).

Table 4-6: Frequency distribution of ARV medication delivery in patients receiving medication via DSP pharmacy at a medical practice in Tongaat, KZN in 2013

Response	Are ARVs Delivered in Time	Delivery Reminders Received	Correct ARVs Delivered
Yes	26(76.5%)	30(88.2%)	26(76.5%)
No	8(23.5%)	4(11.8%)	8(23.5%)
Total	**34(100.0%)**	**34(100.0%)**	**34(100.0%)**

4.4.3. Reminders

SMS messages are the most popular method used to inform patients of an impending medicine delivery. A total of 28 patients (84.4%) of all respondents report receiving SMS messages. Telephone call reminders were received by 4

patients (11.8%) and 2 patients (5.9%) reported receiving no reminder. (see Figure 4-4).

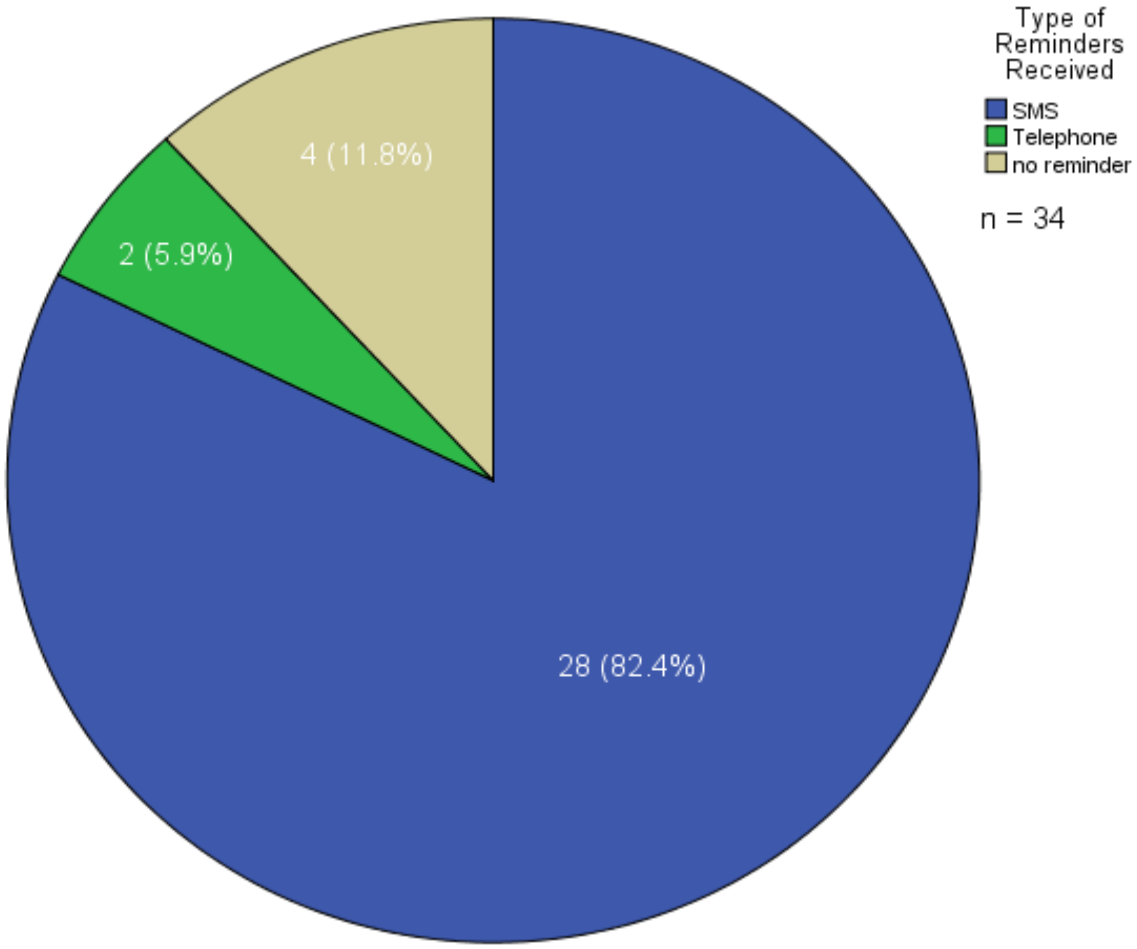

Figure 4-4: Types of reminders patients receive before receiving ARV medication delivery via DSP Pharmacy at a medical practice in Tongaat, KZN in 2013

4.4.4. Incorrect Supply of Medicines

Twenty-four respondents (70.6%) reported always receiving correct medication deliveries; however 10 respondents (29.4%) reported receiving incorrect medication deliveries in the past. (see Figure 4-5).

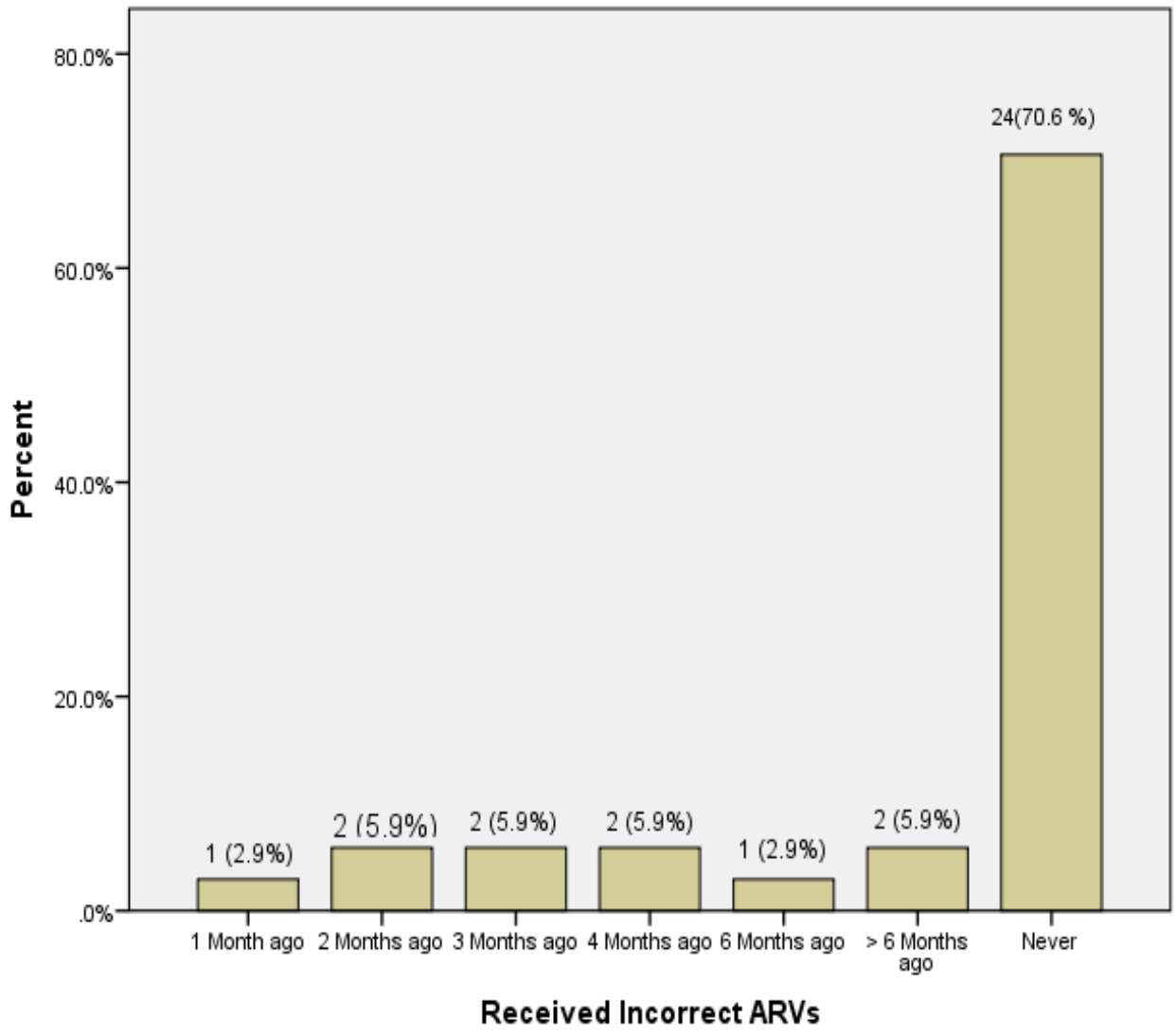

Figure 4-5: Incorrect ARV medication delivery to patients who access ART via DSP pharmacy at a medical practice in Tongaat, KZN in 2013

4.5. Patient Satisfaction

The majority of patients (70.6%) rated their satisfaction with the service between good and excellent. Only 29.4% (10) of patients rated the service satisfactory or poor. (see Table 4-7).

Table 4-7: Frequency distribution of patient satisfaction in patients who receive ART via DSP pharmacy at a medical practice in Tongaat, KZN in 2013

Patient Satisfaction	Number	%
Excellent	11	32.4
Very Good	5	14.7
Good	8	23.5
Satisfactory	6	17.6
Poor	4	11.8
Total	**34**	**100.0**

4.5.1. Patient Preferences

The majority of patients (70.6%) reported that they prefer to access their ARV medications from their own doctor. A group of 5 patients (14.7%) preferred to access ARV medications from DSP pharmacies eg. Dischem, Clicks etc. A small group of 2 patients (5.9%) preferred receiving medications delivered by courier pharmacies eg. Medipost, and 3 respondents (8.8%) preferred to access their ARV medications at a pharmacy of their choice. (see Figure 4-6).

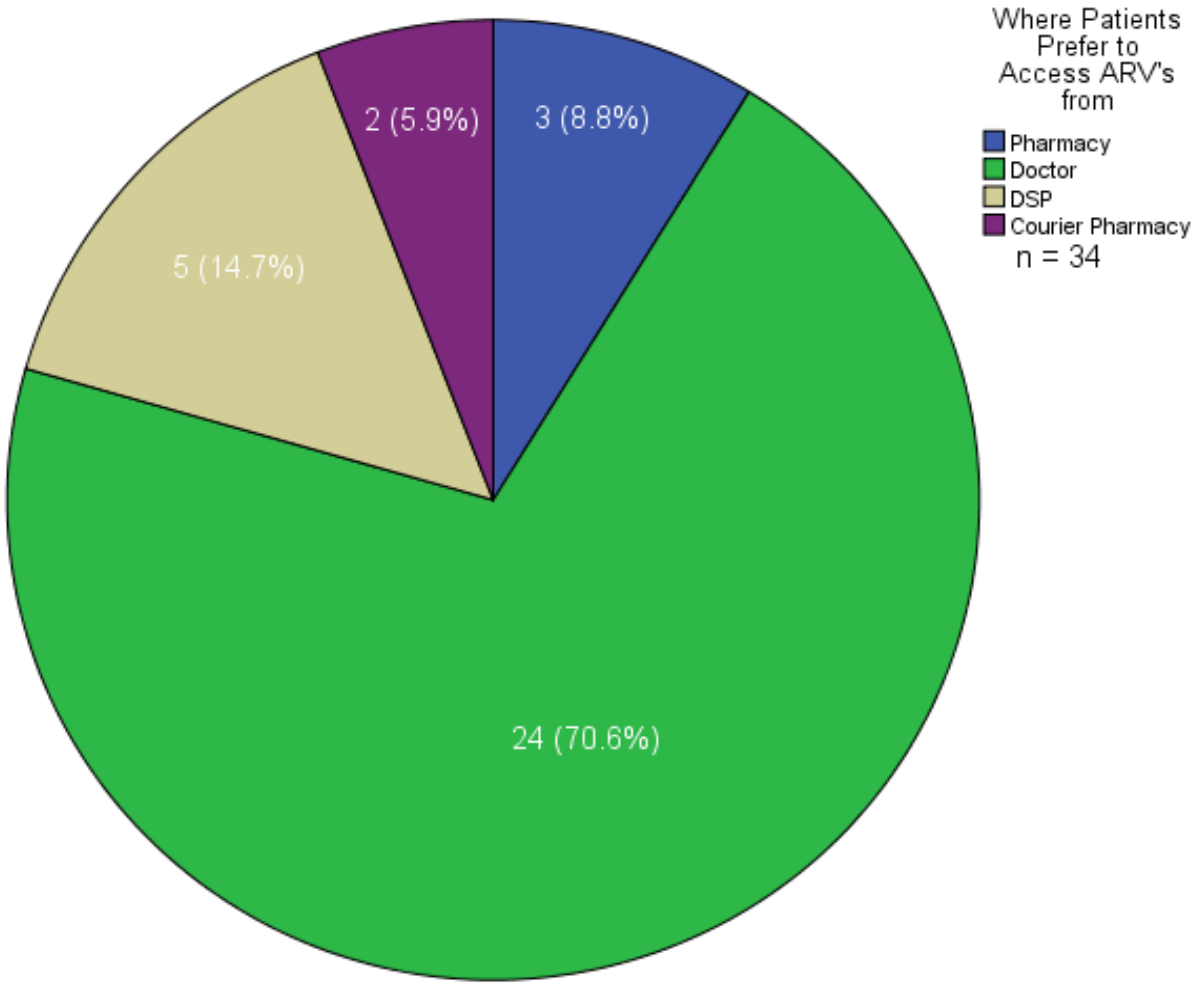

Figure 4-6: Where patients prefer to access their ART from in Patients who access ART via DSP pharmacy at a medical Practice in Tongaat, KZN in 2013

4.6. Adherence to Antiretroviral Therapy

A group of 28 patients (82.4%) reported missing no antiretroviral medication doses in the last 7 days. There was however 3 patients (8.8%) who missed 1 ARV dose in the preceding 7 days, 2 patients (5.9%) who missed 2 doses of

ARV's in the preceding 7 days and 1 patient (2.9%) reported missing 4 ARV doses in the preceding 7 days. (see Table 4-8).

Table 4-8: Frequency distribution of the number of ARV doses missed in the last 7 days in patients who receive medication via DSP pharmacy at a medical practice in Tongaat, KZN in 2013

No. of Doses Missed	Number	%
0	28	82.4%
1	3	8.8%
2	2	5.9%
4	1	2.9%
Total	**34**	**100.0%**

A large proportion of patients sampled, 26 (76.5%) reported taking all ARV doses on time. There were 2 (5.9%) who took 1 ARV dose more than 2 hours late in the previous 7 days. A total of 5 (14.7%) respondents reported taking 2 ARV doses more than 2 hours late. There was 1 patient who reported taking 4 ARV doses more than 2 hours late in the last 7 days. (see Table 4-9).

Table 4-9: Frequency distribution of the number of ARV doses taken > 2 hours late in the last 7 days in patients who receive medication via DSP pharmacy at a medical practice in Tongaat, KZN in 2013

No. of Doses >2 Hrs Late	Number	%
0	26	76.5%
1	2	5.9%
2	5	14.7%
4	1	2.9%
Total	**34**	**100.0%**

Six patients (17.7%) reported missing an ARV dose in the preceding week. It was reported that 2 patients (5.9%) had missed a dose “yesterday” and 4 patients (11.8%) had missed a dose “earlier this week”. There were 23 patients (67.6%) who reported never missing a dose. There were 3 patients (8.8%) who missed a dose “more than a month ago”, 1 patient (2.9%) missed a dose “less than a month ago” and 1 patient (8.8%) who missed an ARV dose “last week”. (see Figure 4-7).

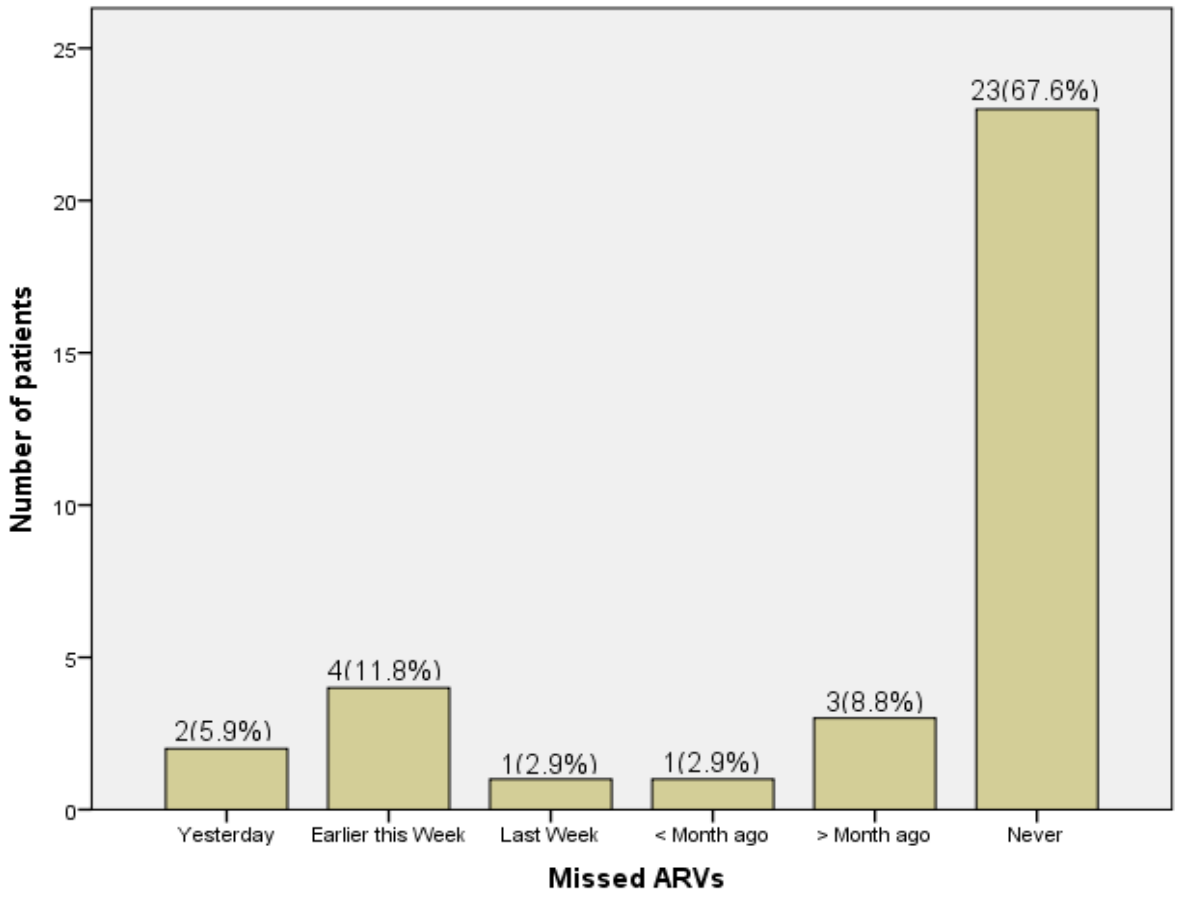

Figure 4-7: Missed ARV doses in patients who receive ART via DSP pharmacy at medical practice in Tongat,KZN in 2013

There were only 7 patients (20.6%) who rated their adherence to have been "excellent". A total of 27 patients (79.4%) reported suboptimal adherence, with 8 patients (23.5%) who rated their adherence as "very good", 16 patients (47.1%) who rated their adherence as "good",1 respondent (2.9%) who reported "very poor",1 respondent (2.9%) who reported "poor", and 1 respondent (2.9%) who reported "fair". (see Figure 4-8).

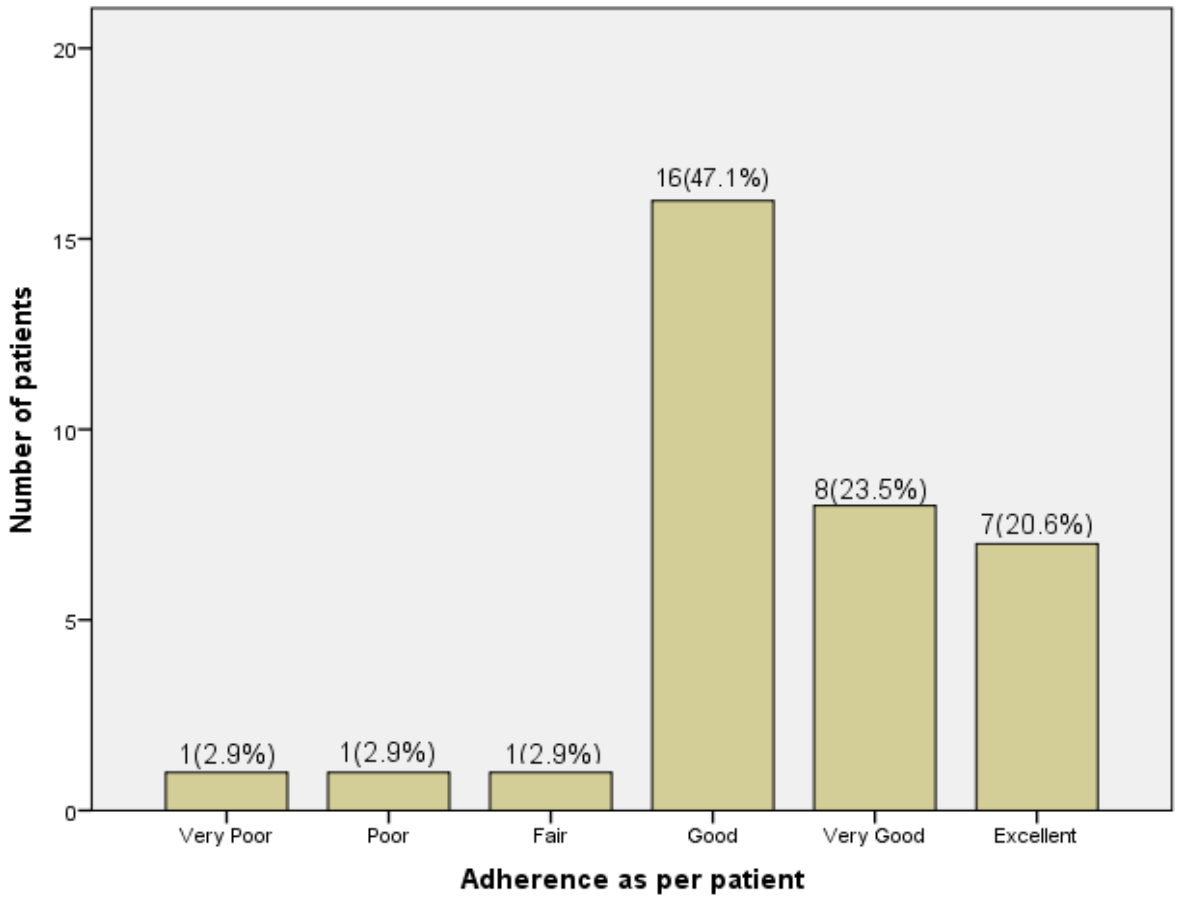

Figure 4-8: Adherence to ART as rated by patients receiving ART via DSP pharmacy at a medical practice in Tongaat, KZN in2013

A total of 25 of 34 patients (73.5%) rate their adherence as having been between 90-100 percent. Nine patients (26.5%) rated their adherence to have been less than 90%, with 7 patients (20.6%) rating their adherence to have been between 80-89%, 1 patient (2.9%) between 70-79% and 1 patient between 40-49 percent. (see Figure 4-9).

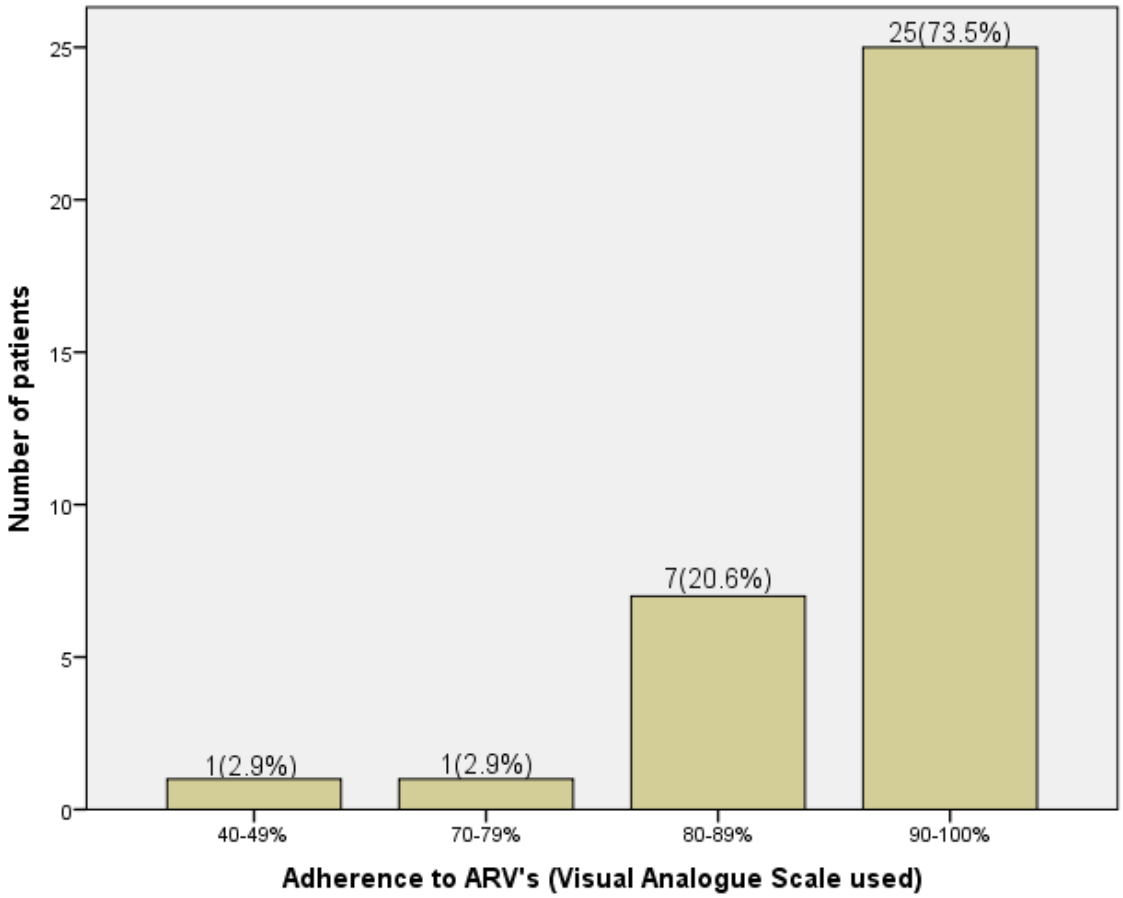

Figure 4-9: Adherence to ART rated on visual analogue scale by patients who receive ART via DSP pharmacy at a medical Practice in Tongaat, KZN in 2013

4.7. Clinical Outcomes

4.7.1. Viral Load

Viral loads measurements conducted revealed that there were 15 patients (44.1%) who recorded undetectable HIV viral loads, and 6 patients (17.6%) who recorded viral load levels between 20-49 copies/ml. A total of 9 patients (26.5%) of the study sample recorded viral load levels between 50-999 copies/ml. There were 2 patients (5.9%) who recorded HIV viral load levels greater than 1000 copies/ml. (see Figure 4-10).

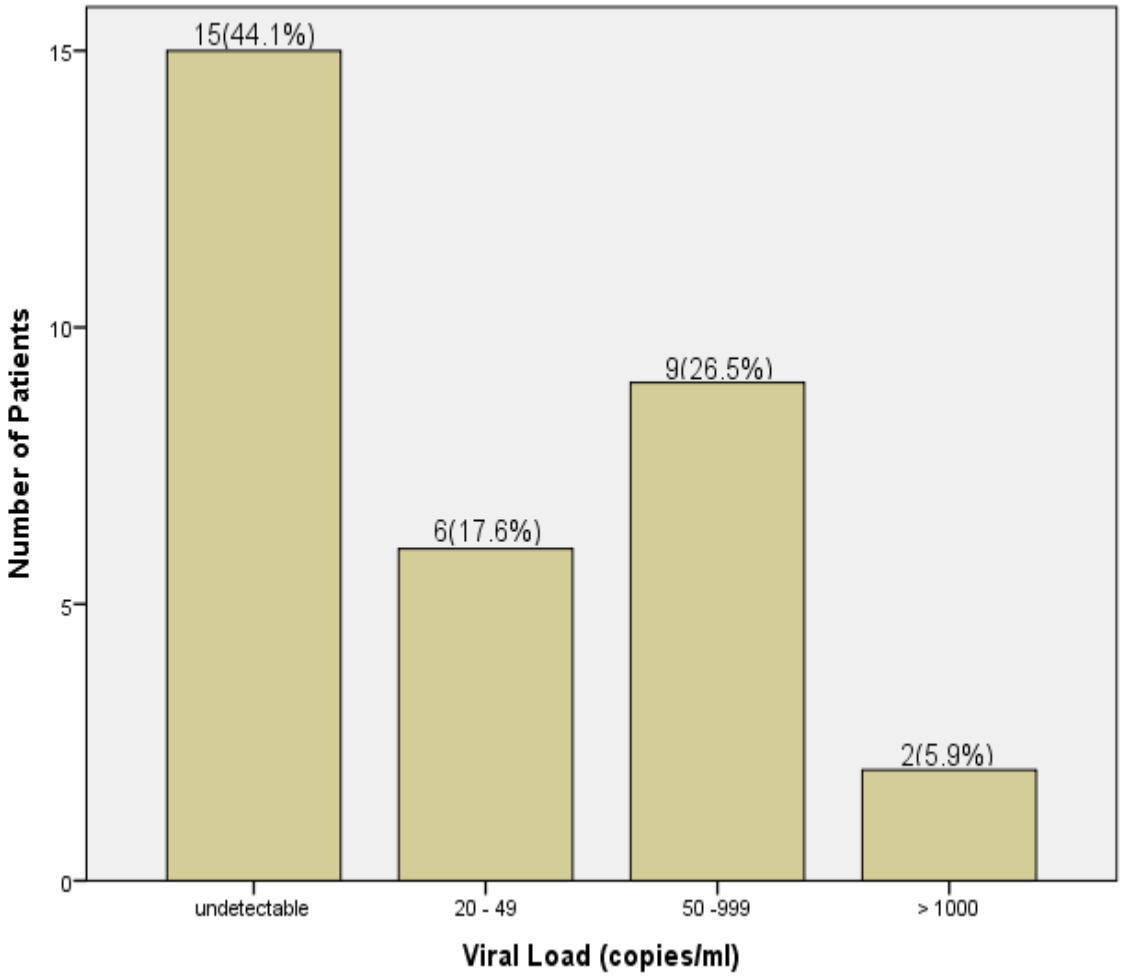

Figure 4-10: Viral load measurements in patients who receive ART via DSP pharmacy at a medical practice in Tongaat, KZN in 2013

4.7.2. CD4 Count

There were 4 patients (11.8%) with severe immune suppression, with CD4 cell counts less than 200 cell/uL, 9 patients (26.5%) recorded CD4 counts between 201-400 cells/uL and 6 patients (17.6%) recorded CD4 cell counts between 401-600/uL. A total of 13 patients (38.2%) recorded normal CD4 cell counts with 5 patients (14.7%) recording CD4 counts between 601-800cell/uL, 6 patients (17.6%) with CD4 counts between 801-1000 cell/uL, and 2 patients (5.9%) recording CD4 counts between 1001-1200cells/uL.(see Figure 4-11).

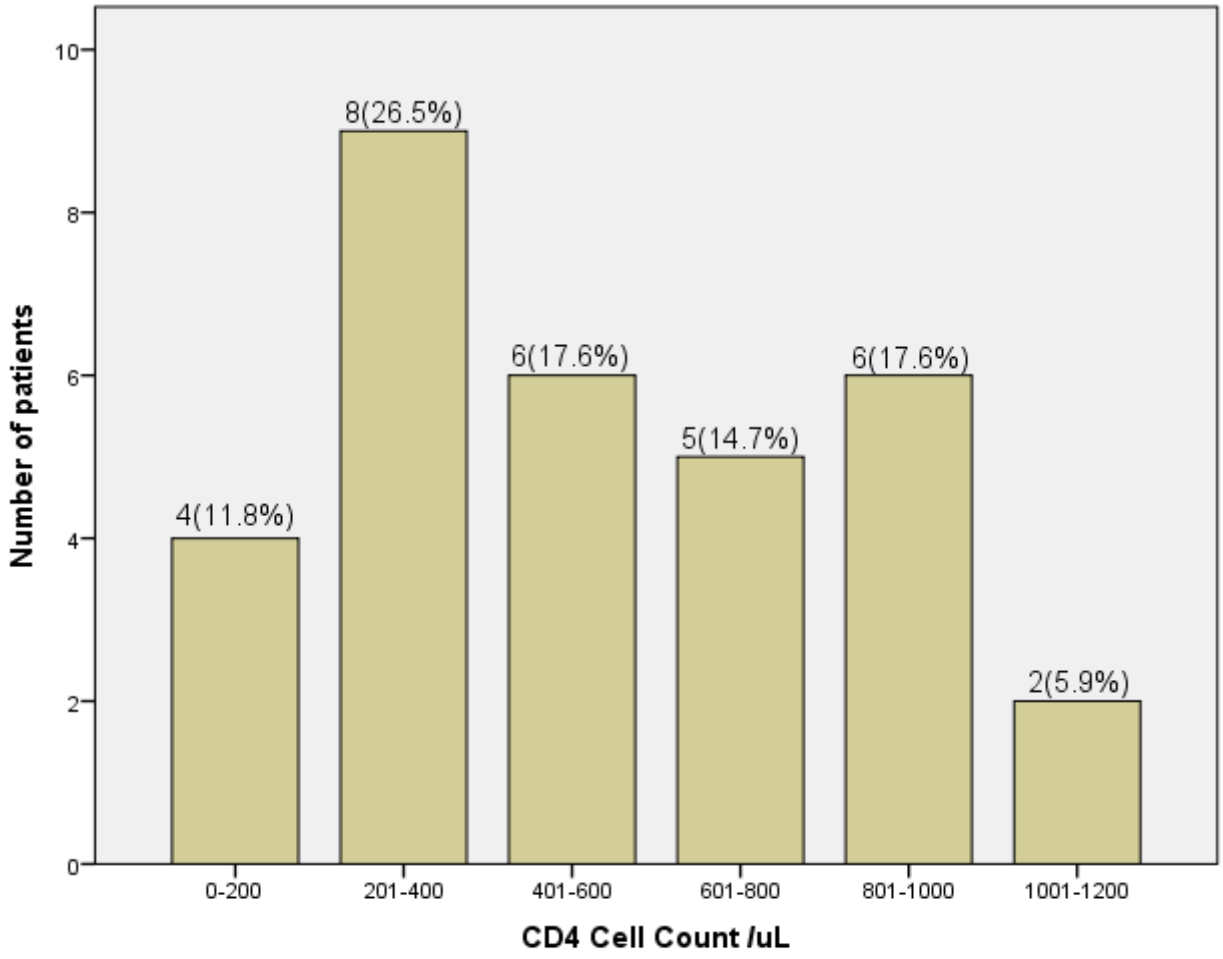

Figure 4-11: CD4 cell counts in patients who receive ART via DSP pharmacy at a medical practice in Tongaat, KZN in 2013

CHAPTER V: DISCUSSION

5.1. Introduction

The unprecedented HIV treatment rollout in South Africa has yielded excellent results, and has dramatically changed the prognosis of HIV, with an 80% (ART eligible at < 200 /ul) adult coverage rate achieved by mid-2011. The life expectancy of patients has doubled since the introduction of HAART. The median survival time from seroconversion to death prior to HAART was 9.8 years and now has been extended to 13.3 years with HAART (4). HIV is therefore increasingly being regarded as a chronic, but manageable condition. Chronic disease management of HIV requires early detection of disease, sustained suppression of the viral load and restoration of immune function resulting in improved quality of life.

5.2. Summary of results

Females (67.7%) outnumber males (32.4%) in this study with 73.5% of respondents aged between 30 and 50 years old. The majority attained school matriculation (88.2%), and 52.9% achieved tertiary qualifications, with over half of all study participants employed in the public sector. In terms of insurance, GEMS represented 58.8% of all study participants, Discovery Medical Scheme 14.7% and Polmed served 11.8 percent.

At the time of study, 55.9% of study participants had been on ART for more than 5 years, with 75.6% having started their treatment at private sector health practitioners.

Although DSP pharmacy users could choose to receive ART via courier services at any delivery address or at a nearby DSP network pharmacy (Clicks, Dischem pharmacy), 67.6% of respondents chose to have ART delivered by courier to their doctors address. No respondents in this study chose to have ART delivered their home address, 20.6% preferred to pick up medication at a nearby DSP network pharmacy and 11.8% preferred to receive ART via the post office. Of the respondents, 88% received reminders providing medicine delivery details, with

82.4% receiving short message service (sms) reminders via cellular telephone. However 23.5% of the respondents reported receiving medication late or never and 29.4% received incorrect medications. DSP pharmacy service was rated as poor or satisfactory by 29.4% of respondents with 70.6% preferring to access ART from their own doctor, 8.6% from a pharmacy of own choice, 5.9% from a courier pharmacy and 14.7% from a DSP pharmacy. It is of significance to note that 79.4% of respondents rated their adherence less than “excellent”, 17.6% missed doses, 23.5% took ART > 2hrs late and 33.4% missed doses in the last week of their medication. Of particular concern was the fact that 32.4% of patients recorded viral loads > 50cp/ml, while 5.9% recorded viral loads >1000 cp/ml. Over a third of patients (38.3%) recorded CD4 levels <400.

5.3. Patient Demographics

The gender distribution of this study, of 67.6% female and 32.4% male is in line with the data from Aid for AIDS which shows 74% of patients in the 25-45 yr age group, with 61% being female (5). This is consistent with a recent study that yielded a similar gender distribution with 61% female and 31% male (4). Several other studies have reported similar results with more women than men accessing HAART in both public and private healthcare sectors. The preponderance of females in HAART programs is partly due to the fact that there is a larger proportion of females than males infected with HIV in South Africa (in 2005 the ratio was1.2 female: male). Antenatal care programs have been very successful with screening, prevention and treatment of HIV. This is a common entry point for women into HAART programs. Women are also primary care givers and therefore interact more frequently with healthcare services. This familiarity with services provided by healthcare facilities may play a role in fostering female access to HIV care, specifically. Moreover, in South Africa most females are infected by their male spouses. It is thought that because men feel stigmatised by acquiring HIV outside of marriage that they don’t access HIV services as freely as women do (15). The gender imbalance in accessing HAART has severe consequences for men, who experience a greater rate of HIV related morbidity

and mortality than women. Although there is significant concern regarding the low uptake of HAART by men, disease management programs and NGO's have not routinely collected and reported on age and sex of patients (4).

The prevalence of HIV in South Africa is highest in the 30 to 34 year age group, with the mean age of patients on HAART in the 33 -38 years old age group (15). This suggests that patients are accessing treatment approximately 10 years after infection, when symptoms are most likely and when CD4 counts are low enough to qualify for HAART. The majority of participants in this study were in the 31 to 40 year old age group (38.2%) and 41-50 year old age group, with 17.6% of study participants in the under 30 years old age group.

HIV management programs and the associated DSP pharmacy services that provide antiretrovirals to patients are complex structures, which patients often struggle to understand. Higher levels of education enable patients to understand the language and terminology used, to read literature provided by treatment programmes and to access services that are provided via complex, often new technology. The inability to understand and interact with these programmes often results in service failure, as well as patients not receiving their HIV treatment on time, which negatively affects adherence. Although the majority of the study participants (88.2%) attained school matriculation, with 52.9% achieving tertiary qualifications, anecdotal evidence suggests that patients struggle to solve DSP pharmacy service problems when they arise for one reason or another.

5.4. Medicine delivery

The closest DSP network pharmacy (Clicks, Dischem) is situated more than 20 kilometres away from the study site. Patients have to access their medications via DSP courier pharmacies (Medipost, Pharmacy Direct) or travel to the DSP network pharmacies (Clicks, Dischem). Courier pharmacies offer patients a choice of whether to receive medicine at a delivery address or at a post office. Patients, who reside in rural or peri-urban areas, as is the case in this study, do not have reliable delivery addresses, and work place addresses are not favoured because of concerns over confidentiality. Courier DSP pharmacies are only

feasible if patients have fixed, reliable, secure personal addresses, otherwise they are inconvenient and may be unreliable and unsecure. DSP pharmacy services fared poorly in this study, with 76.5% of patients reporting antiretrovirals were not delivered on time, and more worryingly, 29.4% reported receiving incorrect medicines. A safe, efficient and reliable antiretroviral supply is an absolute necessity for successful HIV management. Medicine parcels are often collected by others on behalf of the patients, and may not be stored in appropriate conditions on their way to them. Therefore, many patients choose to use their doctors practice address for delivery of DSP courier medicines. This is clearly evident, with 70.6% of the study sample preferring to access their antiretrovirals from their own doctor, and not via a DSP pharmacy service. Furthermore couriers who deliver medicines for DSP pharmacy services are not trained in appropriate medicine handling, therefore medicines are often handled and transported in less than ideal conditions (medicine transported in vehicles with no temperature control, medicine parcels not handled with maximum care, medicines delivered but not picked up by patient left unsecured for long periods of time) which may impact on their effectiveness. The interaction between pharmacist and patient is important, especially so when it comes to antiretrovirals that have important drug interactions, side effects and special precautions. A large percentage of participants (82.4%) reported receiving SMS communication only, and only 5.9% report receiving telephone communication from DSP pharmacy services. Therefore, DSP pharmacy services have inadvertently resulted in a breakdown of the patient pharmacist relationship. Frequent, regular interaction with pharmacists ensures that patients take their medications safely and reliably. Furthermore, with antiretrovirals being delivered directly to patients, many patients feel less of a need to consult with their treating doctors regularly, except when they require repeat prescriptions. HIV is a complex illness to manage and requires frequent interaction with the patient. A breakdown in this healthcare provider patient relationship can result in poor adherence to treatment plans, missed opportunities and ultimately treatment failure.

5.5. Patient Satisfaction

The use of DSP's by healthcare funders may help reduce the cost of healthcare services, but it also removes the patient's freedom of choice, may affect efficiencies in service provision, and lead to diminished competition (6). In a recent OMAC healthcare survey (2010) conducted in south Africa, 60% of patients were negative towards DSP's, with "lack of freedom of choice" cited as the main negative aspect (9). Patient satisfaction is an important ingredient for good adherence and eventual treatment success. Ten patients (29.4%) reported they were not satisfied with DSP pharmacy services, and rated the service as merely "satisfactory", or "poor". Only 14.7% of study respondents prefer to access their medications via DSP pharmacy services.

5.6. HIV Adherence

Although sustained adherence rates > 95% are required for treatment success, only 73.7% of study participants reported adherence rates > 90%, and 79.4% rated adherence as less than excellent. Patient self-report adherence measures are known to overestimate adherence by as much as 20%, but this is still considered the best measure of ARV adherence (16). A large proportion of this study sample exhibits suboptimal adherence to ARV's and therefore is at risk of viral resistance and subsequent treatment failure. Barriers to ARV adherence in South Africa relate to:

- Practical, environmental and service related problems
- Lack of support by healthcare personnel
- Poor HIV knowledge
- Patients perceived lack of control over personal health
- Discrimination (16)

Currently, there is a paucity of information regarding DSP pharmacy services, but anecdotal evidence suggests they create numerous barriers to ART adherence. DSP pharmacy services are complex programmes with many role players, and complex administrative structures, which patients find difficult to understand and interact with. Therefore, patients experience difficulty solving service-related issues, which can result in drug delivery problems and treatment interruptions.

DSP pharmacy programs require patients to have knowledge and access to modern technology (fax, email, telephone) to effectively utilise services. Many areas surrounding the study area is rural, with poor access to modern technology with many patients having no computer literacy. Therefore patients have difficulty faxing or emailing medicine prescriptions to DSP pharmacies, as well as difficulty receiving drug delivery reminders and service messages. As a consequence of receiving ART via couriers, many patients don't consult with medical personal regularly, which can result in suboptimal HIV management. DSP pharmacy courier services rely on patients having a secure delivery addresses. A secure delivery address is critical to ensuring confidentiality and safe drug delivery. Many study respondents live and work in rural areas that have unreliable addresses, therefore these patients have difficulty utilising DSP pharmacy courier services. The study site has network DSP pharmacies located 20km away, therefore study participants don't have a convenient alternative to DSP courier pharmacies. For this reason, patients have to incur excess expenses and are inconvenienced by having to travel large distances, at great effort to access DSP pharmacy services. Patients that are unable to utilise DSP pharmacy services and choose to access ART from non-DSP providers are often charged large co-payments, which blocks easy access to ART. When patients are unable to afford co-payments, they are compelled to only use DSP services. This loss of freedom of choice in access to ART has a negative impact on ART adherence (11).

Successful HIV management programmes need to carefully identify barriers to adherence and design strategies to enhance compliance and to avoid treatment failure. Viral load levels > 50 copies/ml is an indication of virological failure, because drug mutations can occur at these levels (17).Overall 32.4% of the study sample met the criteria for virological failure, with 5.9% recording viral load levels > 1000 copies/ml. Patients with viral loads > 50 copies/ml require urgent intervention (adherence assessment, counselling and retesting) and those with viral load readings > 1000 copies/ml most likely have virological failure and require adherence counselling and a change of treatment regimen. The WHO defines immunological failure as having either:

- CD4 count < 100 cells/uL 6 months after commencing ART's;
- CD4 counts less or equal to the starting CD4 before commencing ART's;
- Or > 50% reduction from peak CD4 count while on ART.

5.7. Study Limitations

Although all prospective study participants were identified from medical practice patient files, and invited to participate in the study, the study relies on voluntary enrolment by participants. The study was conducted with a small sample size and in a confined local area where the study outcomes will only be applicable to areas with similar patient profiles, demographic and socio-economic characteristics. The anonymous self-administered questionnaire although carefully planned to avoid information bias does rely on patient recall. Pill counts and clinical records could not be used to validate patient response to ART because many study respondents did not keep to follow-up appointments.

CHAPTER VI: RECOMMENDATIONS AND CONCLUSION

6.1. Introduction

This chapter presents a summary of the research study, the results and recommendations to policy makers and medical schemes, which can improve the DSP pharmacy medication delivery of ART to patients.

6.2. Conclusion

DSP pharmacy services supply ARV medications to a broad spectrum of medical aid members. Although most patients receive regular ARV medicine supplies, a number of patients receive incorrect medicines or no medicine at all, which may result in treatment interruptions and treatment failure. Successful ART requires near-perfect ARV adherence levels, however the majority of patients fail to maintain the required adherence levels. Most users of DSP pharmacy services rate the medicine delivery service poorly and the majority of patients prefer to access ART from their own doctor. ARV medicine access factors need to be carefully considered by medical schemes when ART treatment programs are designed, otherwise drug interruptions may result in poor adherence and in treatment failure.

6.3. Recommendations

DSP pharmacy services provide an innovative method for the delivery of ARV medication to members of medical schemes, however for the service to be more efficiently utilised, it requires intervention at the patient level and at the DSP provider level. Based on the finding of this study the following recommendations are given:

At the patient level:

1. Appropriate counselling by healthcare personnel about the importance of high levels of adherence needs to be emphasised.

2. Concentrated patient education and marketing needs to be directed at DSP pharmacy users so as to improve knowledge regarding DSP pharmacy services and the various service providers involved in rendering the medicine delivery service.

At the Designated Service Provider level:

1. At a policy level, DSP pharmacy service providers need to address better regulation regarding personnel that are employed for the provision of antiretroviral medicines to patients. Appropriately trained staff are needed to process medication claims and resolve ART queries; couriers ought to be educated on how medicine should be appropriately handled and transported, adequate numbers of properly trained pharmacists and pharmacy assistants are needed to efficiently and appropriately handle the dispensing of medications; and appropriately trained clinical staff is required to address ART related enquiries.
2. The current process of ARV medicine provision needs to be assessed and enhanced so as to improve efficiency of medicine delivery. Creating a single point of contact for patients will streamline service provision and help patients to resolve service-related problems quickly and easily when they occur.
3. Increased use of cellular phone, smart phone and tablet technology and related apps will help improve and simplify DSP pharmacy service access.
4. The current DSP pharmacy networks need to be expanded, with more pharmacies and dispensing doctors so as to improve access to DSP pharmacy services to more patients in all areas.
5. Regular audits of service provision and adherence to good pharmacy practice need to be conducted, and shortcomings quickly resolved.

The researcher recommends a larger study be conducted that examines patient outcomes, with a broader population from across a more expansive area.

Furthermore clinical outcomes from patient charts and pill counts should be utilised so as to validate patient responses.

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Appendix-1

STUDY INFORMATION SHEET

TITLE OF STUDY: An Assessment of DSP Pharmacy Medication Delivery for HIV Treatment in a Family Practice in KwaZulu-Natal

Dear Mr / Mrs / Ms …….Date: …../…../……..

1. PURPOSE OF THE STUDY

I understand that I am being asked to participate in a research study. The aim of the study is to assess Designated Service Provider (DSP) pharmacy medication delivery for HIV treatment, patient satisfaction and adherence to HIV treatment. We wish to identify strengths and challenges and provide recommendations based on the findings of the study.

2 .EXPLANATION OF PROCEEDURE TO BE FOLLOWED

The study involves answering a questionnaire regarding the DSP (eg. Medipost, Direct medicines) that supplies your ARVs.

3 .RISK AND DISCOMFORT INVOLVED

I as a participant in this study will remain anonymous. I will have to fill in a questionnaire that will take 20 – 30 minutes and there is no other risk involved.

4 .POSSIBLE BENEFITS OF THE STUDY

Valuable information and lessons learned from this study will be shared with other Health care professionals.

5. I understand that if I do not want to participate in this study, there are no penalties, and I will not be prejudiced in any way.

6. I may at any time withdraw from this study.

7. HAS THE STUDY RECEIVED ETHICAL APPROVAL

This protocol is to be submitted to the Faculty of Health Sciences Research Ethics Committee, University of KwaZulu-Natal and written approval has to be obtained from that committee. The study has been structured in accordance with the Declaration of Helsinki which guides doctors in biomedical research involving

human subjects. A copy of the Helsinki Declaration can be obtained from the researcher should you wish.

8. INFORMATION

If I have any question you should contact researcher Dr V.V.Reddy: 0329441115 (W) or 0822557272 (cell)

9. CONFIDENTIALITY

All information obtained during this study will be regarded as confidential. Study results will be published/presented in a manner that participants remain anonymous.

10. IF YOU FEEL HARMED

If you feel harmed in any way by participating in this study you can contact my supervisor for this study Dr O Mohamed (0312604382)

Appendix-2

CONSENT FORM

I have read or had read to me in a language that I understand the above information before signing this consent form. The content and meaning of this have been explained to me. I have been given the opportunity to ask questions and am satisfied that they have been answered satisfactorily. I understand that if I do not participate it will not alter my management in any way. I hereby volunteer to take part in this study.

I have received a signed copy of this informed consent agreement.

…….	……..
Participant signature	Date
…….	…….
Person obtaining consent	Date
…….	…….
Witness	Date

VERBAL PARTICIPANT INFORMED CONSENT (If participant cannot read or write)

I, the undersigned, Dr V.V.Reddy or nurse have read and have explained fully to the participant the information leaflet, which has explained the nature and purpose of the study in which I have asked him/her to participate. I have explained the possible risks and benefits of the study. The participant indicates that she/he understands that she/he is free to withdraw from the study at any time without any prejudice.

I hereby certify that the participant has agreed to participate in the study.

Participants name: …….. Signature:
……

Investigators Name:…….. Signature:
……

Witness: …….. Signature:
……

Appendix-3

PATIENT QUESTIONAIRE

Age :

……..

Medical Aid Name :

…….

Occupation :

……..

Highest Level of Education :

……

1 .When did you start ARVs?

…….

2. Where did you start ARVs?

……

3. Currently, where do u receive your ARV medication? (Choose one)

Home pharmacy post office doctor

4. Is your ARV medication delivered on time? Yes No

5. Do you receive reminders when ARV medication is ready for delivery? Yes No

6. What type of reminder do you receive?

SMS email telephone call other

7. Do you receive the correct ARV medication every month? Yes No

8. When did you receive incorrect medicine, short medicine or no medicine?

a. 1 month ago b. 2 months ago c. 3 months ago d. 4 months ago

e. 5 months ago f. 6 months ago g. More than 6 months ago h. Never

9. Rate your satisfaction with the DSP pharmacy delivery service on a scale 1 – 5

Excellent = 5 Very good = 4 Good = 3 Satisfactory = 2 Poor = 1

10. I would prefer to receive my antiretroviral medication from:

a. Pharmacy b. Doctor c. DSP Pharmacy d. Courier Pharmacy

11. During the last 7 days, how many times in total did u miss taking one or more antiretroviral pills.: ……times

12. In the last 7 days, how many times in total did you take your ARV pills more than 2 hours late : ……times

13. How would you rate your adherence over the last month? (choose one)

a..Very poor

b. Poor

c. Fair

e. Good

f. Very good

g. Excellent

14. When was the last time you missed your antiretroviral pill? (multi-choice question)

a .Today b. Yesterday c . Earlier this week

d. Last week e. Less than a month ago f. More than a month ago

g. I have never missed

15. Please put a cross on the line below at the point showing your best guess about how many antiretroviral pills you have taken in the last month. 0% means you have taken none of the pills, 50% means you have taken half your pills and 100% means you have taken every single pill

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

i……i……..i……..i……..i……..i……..i……..i……..i……..i……..i……i

None Half All

Appendix-4

Biomedical Research Ethics Committee Approval

Amended Letter

31 May 2013

Dr VV Reddy
School of Clinical Medicine
Nelson R Mandela School of Medicine
University of KwaZulu-Natal

PROTOCOL: As Assessment of DSP Pharmacy medication delivery for HIV Treatment in a family practice KwaZulu-Natal. REF: BE071/13.

EXPEDITED APPLICATION

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application received on 18 March 2013.

The study was provisionally approved pending appropriate responses to queries raised. Your responses dated 21 May 2013 to queries raised on 17 May 2013 have been noted by a sub-committee of the Biomedical Research Ethics Committee. The conditions have now been met and the study is given full ethics approval and may begin as from 31 May 2013.

This approval is valid for one year from **31 May 2013.** To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

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

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2004), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at

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

The sub-committee's decision will be **RATIFIED** by full Committee at its next meeting taking place on **11 June 2013.**

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

Yours sincerely

Professor D.R Wassenaar
Chair: Biomedical Research Ethics Committee

Biomedical Research Ethics Committee
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