Title of thesis: A descriptive study to evaluate the effect of guidelines used by counsellors to improve adherence to antiretroviral therapy in the private sector.

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ABSTRACT

Background
A problem was identified at Aid for AIDS (AfA) whereby some doctors requested a change in treatment within less than a year after their patients started antiretroviral therapy. The requests were normally based on treatment failure. It appears that in most cases where the desired treatment outcome is not achieved is due to poor adherence to therapy. AfA is a HIV / AIDS disease management company offering access to antiretroviral therapy (ART), prevention of opportunistic infections, treatment and blood results monitoring, treatment support through adherence coordinators and expert clinical support and advice to healthcare providers. They monitor treatment adherence through claims history, CD4 and viral load (VL) results as well as telephonic contact with the client. Factors that could contribute to poor adherence are side-effects, barriers e.g. work environment, non-disclosure, lifestyle, lack of client commitment, limited contact between the client and treatment support counsellor, limited funds, stigmatisation and a lack of clear adherence guidelines to improve treatment outcome.

Method
A comparative study was done to assess the impact of an intervention to improve patient adherence to ART. The researcher postulates that by the implementation of guidelines to counsellors, client adherence to therapy would increase. A
comparative study was used to assess whether structured guidelines can improve client adherence to therapy.

Results
The results have proven that guidelines used by treatment support counsellors does improve adherence to ART.

Recommendations
It is recommended that treatment support counsellors, to improve their clients’ adherence to ART, should apply adherence guidelines.
DECLARATION

I declare that “A comparative study to evaluate the effect of guidelines used by counsellors to improve adherence to antiretroviral therapy in the private sector.” is my own piece of work, that it has not been submitted before for any degree or examination in any other University or college, and that all the sources I have quoted or used have been indicated and acknowledged as complete references.

Melanie Marais

May 2006

Signed..........................
DEDICATION

I dedicate this thesis to my Heavenly Father for strengthening me the past three years; my earthly father, late Alan Joseph Swanson who left us behind on 15 January 2003 “I will always love and miss you” and to all people living with HIV / AIDS.
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I would first of all like to thank my Heavenly Father for making all this possible and for the strength to overcome all the research obstacles the past two years.

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# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Index</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABSTRACT</td>
<td>i</td>
</tr>
<tr>
<td>DECLARATION</td>
<td>iii</td>
</tr>
<tr>
<td>DEDICATION</td>
<td>iv</td>
</tr>
<tr>
<td>ACKNOWLEDGEMENTS</td>
<td>v</td>
</tr>
<tr>
<td>TABLE OF CONTENTS</td>
<td>vi</td>
</tr>
<tr>
<td>LIST OF APPENDICES</td>
<td>xvi</td>
</tr>
<tr>
<td>LIST OF TABLES</td>
<td>xvii</td>
</tr>
<tr>
<td>LIST OF FIGURES</td>
<td>xviii</td>
</tr>
<tr>
<td>LIST OF ABBREVIATIONS</td>
<td>xix</td>
</tr>
<tr>
<td>TITLE</td>
<td>xxi</td>
</tr>
<tr>
<td>KEYWORDS</td>
<td>xxi</td>
</tr>
</tbody>
</table>

## CHAPTER ONE

**INTRODUCTION TO RESEARCH PROJECT**

1.1 AIM.................................................................................1

1.2 OBJECTIVE......................................................................1

1.3 RATIONALE.....................................................................1

1.4 HYPOTHESIS....................................................................2

1.5 DEFINITIONS OF KEY CONCEPTS.......................................2

1.6 BACKGROUND LITERATURE...............................................5

1.6.1 PREVALENCE AND INCIDENCE OF HIV / AIDS.................5
1.6.2 HIV / AIDS PREVALENCE IN AFA

1.6.3 ADHERENCE

1.6.4 PROGRAMMES

1.6.5 RESISTANCE TO ANTIRETROVIRAL THERAPY

1.6.6 CURRENT GUIDELINES AVAILABLE ON ADHERENCE

1.6.7 CURRENT METHODS OF COUNSELING

1.6.8 BEHAVIOUR CHANGES

1.7 RESEARCH PROBLEM

1.8 RESEARCH QUESTION

1.9 NULL HYPOTHESIS

1.10 RESEARCH METHODOLOGY

1.10.1 FORMULATION OF GUIDELINES

1.10.2 POPULATION, SAMPLE AND SAMPLE SIZE

1.10.3 COMPARATIVE SAMPLE GROUP

1.10.4 INTERVENTION GROUP

1.10.5 INSTRUMENT

1.10.6 WORKSHOP

1.10.7 PROCEDURE
<table>
<thead>
<tr>
<th>Section Number</th>
<th>Section Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.10.8</td>
<td>DATA ANALYSIS</td>
<td>16</td>
</tr>
<tr>
<td>1.10.9</td>
<td>VALIDITY AND RELIABILITY</td>
<td>16</td>
</tr>
<tr>
<td>1.11</td>
<td>RELEVANCE OF THE STUDY</td>
<td>17</td>
</tr>
<tr>
<td>1.12</td>
<td>ETHICAL STATEMENT</td>
<td>17</td>
</tr>
<tr>
<td>1.13</td>
<td>CHAPTER OUTLINE</td>
<td>18</td>
</tr>
<tr>
<td>1.14</td>
<td>TIME LINES</td>
<td>18</td>
</tr>
<tr>
<td>1.15</td>
<td>BUDGET</td>
<td>18</td>
</tr>
<tr>
<td>1.16</td>
<td>SUMMARY</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td><strong>CHAPTER TWO</strong></td>
<td>20</td>
</tr>
<tr>
<td>2.1</td>
<td>INTRODUCTION</td>
<td>20</td>
</tr>
<tr>
<td>2.2</td>
<td>THEORETICAL FRAMEWORK</td>
<td>21</td>
</tr>
<tr>
<td>2.2.1</td>
<td>ADAPTED SOCIAL LEARNING THEORY OF ROTTER</td>
<td>22</td>
</tr>
<tr>
<td>2.2.2</td>
<td>ADAPTED COGNITIVE THEORY BY GEORGE KELLY</td>
<td>24</td>
</tr>
<tr>
<td>2.3</td>
<td>HISTORY OF HIV AND AIDS</td>
<td>26</td>
</tr>
<tr>
<td>2.3.1</td>
<td>ORIGIN OF HIV</td>
<td>27</td>
</tr>
<tr>
<td>2.3.2</td>
<td>THEORIES OF THE TRANSMISSION OF SIV TO MAN</td>
<td>28</td>
</tr>
<tr>
<td>2.3.3</td>
<td>FIRST REPORTS ON DEATHS DUE TO HIV / AIDS</td>
<td>28</td>
</tr>
<tr>
<td>2.3.4</td>
<td>GAY – RELATED IMMUNE DEFICIENCY (GRID)</td>
<td>29</td>
</tr>
<tr>
<td>2.3.5</td>
<td>CONTROVERSY ABOUT THE DISCOVERY OF HIV / AIDS</td>
<td>30</td>
</tr>
<tr>
<td>2.3.6</td>
<td>FURTHER DEVELOPMENTS</td>
<td>30</td>
</tr>
<tr>
<td>2.4</td>
<td>ANTIRETROVIRAL TREATMENT PROGRAMMES</td>
<td>31</td>
</tr>
<tr>
<td>2.4.1</td>
<td>INTERNATIONAL APPROACH</td>
<td>31</td>
</tr>
</tbody>
</table>
2.4.2 RESOURCE LIMITED SETTINGS..............................................34
2.4.3 THE SOUTH AFRICAN GOVERNMENT ART PROGRAMME.....37
2.4.3.1 IMPLEMENTING THE HIV / AIDS TREATMENT PROGRAMME.37
2.4.3.2 VOLUNTARY COUNSELLING AND TESTING (VCT)..............38
2.4.3.3 REPORTING ON THE PROGRESS........................................39
2.4.3.4 CHALLENGES FACED BY THE SA DEPARTMENT OF
HEALTH..................................................................................40
2.4.3.5 THE SA GOVERNMENT’S RESPONSE TO CHALLENGES......42
2.4.3.6 CHOICE OF TREATMENT SELECTION..............................43
2.4.3.7 HOW TO IMPROVE ACCESS TO ART IN THE PUBLIC SECTOR
.................................................................................................44
2.4.3.8 SIDE – EFFECTS.................................................................46
2.4.3.9 WESTERN CAPE DEPARTMENT OF HEALTH (WC DOH)....50
2.4.4 SOME PRIVATE FACILITIES OFFERING ART PROGRAMMES
IN SOUTH AFRICA (SA)..............................................................53
2.4.4.1 AID FOR AIDS (AFA).......................................................53
2.4.4.2 QUALSA HEALTH RISK MANAGEMENT SPECIALISTS......54
2.4.4.3 MX GROUP......................................................................55
2.4.4.4 CALIBRE CLINICAL CONSULTANTS.................................55
2.4.4.5 LIFESENSE.....................................................................56
2.5 HIV PREVALENCE.................................................................56
2.5.1 INTERNATIONALLY..............................................................56
2.5.2 NATIONALLY......................................................................58
2.14 MOTHER – TO – CHILD - TRANSMISSION (MTCT)……………..98
2.15 ADAPTING A HEALTHY LIFESTYLE……………………………….99
2.15.1 NUTRITION…………………………………………………………...100
2.15.2 WEIGHT LOSS AND HIV WASTING SYNDROME………………101
2.15.3 MAINTAINING BODY MASS……………………………………….103
2.15.4 EXERCISE AND REST……………………………………………...105
2.15.5 ILLNESS AND STRESS…………………………………………….106
2.16 COPING WITH NEW CIRCUMSTANCES………………………...107
2.17 SUMMARY………………………………………………………………108

CHAPTER THREE…………………………………………………………………..109

METHODOLOGY………………………………………………………………109
3.1 INTRODUCTION...........................................................................109
3.2 RESEARCH APPROACH.............................................................109
3.3 RESEARCH DESIGN.................................................................110
3.4 STUDY POPULATION................................................................111
3.5 INCLUSION CRITERIA.................................................................112
3.6 EXCLUSION CRITERIA.................................................................113
3.7 INTERVENTION GROUP (IG).......................................................113
3.8 COMPARISON GROUP (CG).......................................................114
3.9 RESEARCH INSTRUMENT..........................................................115
3.9.1 ADHERENCE GUIDELINES.....................................................115
3.9.2 INCREASED CONTACT..........................................................116
3.10 DATA GATHERING INSTRUMENT / CRF..............................116
3.11 VALIDITY AND RELIABILITY ..................................................................117
3.11.1 CONTENT VALIDITY ........................................................................117
3.11.2 FACE VALIDITY ..............................................................................117
3.11.3 CONSTRUCT VALIDITY ....................................................................118
3.11.4 RELIABILITY ...................................................................................119
3.12 DATA ANALYSIS AND PROCESSING ..................................................119
3.12 SUMMARY ..........................................................................................120

CHAPTER FOUR ..........................................................................................121

RESULTS ....................................................................................................121

4.1 INTRODUCTION ....................................................................................121
4.2 SAMPLE SIZE ......................................................................................122
4.3 BASELINE BIOGRAPHICAL DATA .......................................................123
4.3.1 AGE ..................................................................................................123
4.3.2 GENDER DISTRIBUTION ..................................................................124
4.3.3 CLIENT DISTRIBUTION PER PROVINCE .........................................125
4.4 BASELINE DATA OF PRIMARY OUTCOMES .......................................127
4.4.1 BASELINE CD4 CELL COUNT ..........................................................127
4.4.2 BASELINE VIRAL LOAD .................................................................128
4.5 PRIMARY OUTCOMES ..........................................................................129
4.5.1 CD4 CELL COUNTS ..........................................................................129
4.5.2 VIRAL LOAD .....................................................................................130
4.5.3 ADHERENCE TO FOLLOW UP BLOOD TESTS .................................131
4.5.4 ART CLAIMS HISTORY ......................................................................133
CHAPTER FIVE
DISCUSSION OF RESULTS

5.1 INTRODUCTION

5.2 RELEVANCE OF A HIV / AIDS PROGRAMME

5.3 THE RELATIONSHIP BETWEEN AGE AND ADHERENCE

5.4 GENDER, A DETERMINING FACTOR TO ART ADHERENCE

5.5 THE BASELINE AND OUTCOME CD4 AND VL

5.6 THE IMPACT OF REGULAR CONTACTS WITH CLIENTS USING HAART

5.7 INCREASE IN ART CLAIMS VS. SIDE – EFFECTS

5.8 DOES REGULAR DOCTOR VISITS LEAD TO INCREASED ADHERENCE?

5.9 CD4 AND VL PREDICTING HOSPITAL ADMISSIONS

5.10 STUDY LIMITATIONS

5.11 CONCLUSION OF THE STUDY
<table>
<thead>
<tr>
<th>APPENDIX</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>APPENDIX I</td>
<td>DATA GATHERING INSTRUMENT</td>
<td>171</td>
</tr>
<tr>
<td>APPENDIX II</td>
<td>RESEARCH INSTRUMENT</td>
<td>174</td>
</tr>
<tr>
<td>APPENDIX III</td>
<td>WHO HIV DISEASE STAGING SYSTEM</td>
<td>180</td>
</tr>
<tr>
<td>APPENDIX IV</td>
<td>LETTER TO AID FOR AIDS</td>
<td>181</td>
</tr>
<tr>
<td>APPENDIX V</td>
<td>APPROVAL LETTER FROM AFA</td>
<td>182</td>
</tr>
</tbody>
</table>
**LIST OF TABLES**

<table>
<thead>
<tr>
<th>Table</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 2.1</td>
<td>Commonly used herbal medicines &amp; side – effects</td>
<td>48</td>
</tr>
<tr>
<td>Table 2.2</td>
<td>Classes of antiretroviral drugs &amp; side - effects</td>
<td>64</td>
</tr>
<tr>
<td>Table 4.1</td>
<td>Sample size</td>
<td>123</td>
</tr>
<tr>
<td>Table 4.2:</td>
<td>Contacts to clients</td>
<td>135</td>
</tr>
</tbody>
</table>
LIST OF FIGURES

Figure 4.1:  Age..........................................................................................124
Figure 4.2:  Gender......................................................................................125
Figure 4.3:  Combined client distribution per province.........................126
Figure 4.4:  Client distribution per province............................................126
Figure 4.5:  Baseline CD4 cell count.................................................................127
Figure 4.6:  Baseline viral load.................................................................129
Figure 4.7:  Mean CD4 cell count...............................................................130
Figure 4.8:  Mean viral load.................................................................131
Figure 4.9:  CD4 follow up blood tests..................................................132
Figure 4.10: Viral load (VL) follow up blood tests...............................133
Figure 4.11: ART claims history of the IG vs. CG.................................134
Figure 4.12: Side - effects on ART...............................................................137
Figure 5.1: Opportunistic disease after HAART..................................150
# LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIDS</td>
<td>AQUIRED IMMUNE DEFICIENCY SYNDROME</td>
</tr>
<tr>
<td>AfA</td>
<td>AID FOR AIDS</td>
</tr>
<tr>
<td>ART</td>
<td>ANTIRETROVIRAL TREATMENT</td>
</tr>
<tr>
<td>ARV</td>
<td>ANTIRETROVIRAL</td>
</tr>
<tr>
<td>CD4</td>
<td>CLUSTERED DESIGNATION 4</td>
</tr>
<tr>
<td>CDC</td>
<td>CENTRE FOR DISEASE CONTROL</td>
</tr>
<tr>
<td>CG</td>
<td>COMPARISON GROUP</td>
</tr>
<tr>
<td>CPZ</td>
<td>CHIMPANZEE</td>
</tr>
<tr>
<td>CRF</td>
<td>CASE REVIEW FILE</td>
</tr>
<tr>
<td>DM</td>
<td>DISEASE MANAGEMENT</td>
</tr>
<tr>
<td>DNA</td>
<td>DEOXYRIBONUCLEIC ACID</td>
</tr>
<tr>
<td>DOT</td>
<td>DIRECT OBSERVED THERAPY</td>
</tr>
<tr>
<td>ELISA</td>
<td>ENZYME LINKED IMMUNOADSORBENT ASSAY</td>
</tr>
<tr>
<td>FI</td>
<td>FUSION INHIBITOR</td>
</tr>
<tr>
<td>FDA</td>
<td>FOOD AND DRUG ASSOCIATION</td>
</tr>
<tr>
<td>GRID</td>
<td>GAY – RELATED IMMUNE DEFICIENCY VIRUS</td>
</tr>
<tr>
<td>HAART</td>
<td>HIGHLY ACTIVE ANTIRETROVIRAL TREATMENT</td>
</tr>
<tr>
<td>HIV</td>
<td>HUMAN IMMUNE DEFICIENCY VIRUS</td>
</tr>
<tr>
<td>HTLV - 111</td>
<td>HUMAN T CELL LYMPHOTROPIC VIRUS TYPE</td>
</tr>
<tr>
<td>IG</td>
<td>INTERVENTION GROUP</td>
</tr>
<tr>
<td>LAV</td>
<td>LYMPHADENOPATHY ASSOCIATED VIRUS</td>
</tr>
<tr>
<td>NNRTI</td>
<td>NON - NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITOR</td>
</tr>
</tbody>
</table>
NRTI  NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITOR
NSP  NUTRITION SUPPLEMENTATION PROGRAM
PCP  PNEUMOCYSTIS CARINII
PI  PROTEASE INHIBITOR
RNA  RIBONUCLEIC ACID
RT  REVERSE TRANSCRIPTASE
SIV  SIMIAN IMMUNODEFICIENCY VIRUS
SOP  STANDARD OPERATING PROCEDURE
TB  TUBERCULOSIS
TSC  TREATMENT SUPPORT COUNSELLOR
UNAIDS  UNITED NATIONS PROGRAMME ON HIV/AIDS
USA  UNITED STATES OF AMERICA
VCT  VOLUNTARY COUNSELLING AND TESTING
VL  VIRAL LOAD
Title

A comparative study to evaluate the effect of guidelines used by counsellors to improve adherence to antiretroviral therapy in the private sector.

Key words

Adherence; treatment support counsellors; disease management; guidelines; antiretroviral therapy; monitoring; CD4; viral load; treatment outcome; client commitment; human immune deficiency syndrome (HIV).
1.1 Aim

The overall aim of this research project is to implement and evaluate guidelines that will be used by treatment support counsellors (tsc) in an attempt to increase client adherence to antiretroviral treatment (ART).

1.2 Objective

- To design a set of guidelines that can assist tsc to improve client adherence.
- To evaluate the effect of these guidelines on client adherence to ART.

1.3 Rationale

AfA (2002) provides their employees and clients with information booklets pertaining to clinical guidelines in the management of human immune deficiency syndrome (HIV). These guidelines concentrate on treating the HIV-infected individual. More emphasis is needed on the importance of adherence to ART. It appears from some client records that optimal viral suppression is not achieved, despite availability of these clinical guidelines. Failure to adhere to prescribed therapy is one of the main causes why optimal viral suppression may not be obtained. From experience as interventionist at AfA, the researcher
found that healthcare providers tend to request change in their patients' current therapies or to include other ART drugs. Based on the researcher's experience, these requests for change of medication usually occur without investigation of their patients' adherence to their current therapy regimen. The concern is that poor adherence may result in an increase of mutations and viral resistance (Richman & Staszewski, 1997: 4, 8; Miller, 2002: 32 - 33). The researcher postulated that adherence guidelines used by counsellors may enhance adherence to therapy and better adherence will result in less frequent change in treatment.

1.4 Hypothesis

Adherence guidelines will reduce viral loads, increase CD4 cell counts and lead to a reduction in frequent changing of ART.

1.5 Definitions of key concepts

Adherence

Adherence is the process whereby clients follow instructions, guidelines, a prescription or recommendations based on a regimen of care (Mosby, 1986:27).
**Human Immune Deficiency Virus (HIV)**

Richman and Staszewski (1997:1) define HIV as a member of the Retroviridae family of viruses with single-stranded (RNA) ribonucleic acid. Van Dyk (2001:7) adds that HIV is a virus that directly attacks the human immune system, by slowly diminishing the total number of CD4 cells in the body, making it ineffective to fight against exterior pathogens.

**Antiretroviral Therapy (ART)**

Antiretroviral medicines are used to treat HIV by inhibiting the two viral enzymes, HIV reverse transcriptase and HIV protease (AfA, 2005:10, 17).

**Acquired Immune Deficiency Syndrome (AIDS)**

AIDS is defined as a combination of many different conditions that manifest in the body after HIV weakened the body’s immune system to such an extend that it can no longer fight the pathogens that entered the body (Van Dyk, 2001: 4 - 5; Evian, 2000:8).

**Regimen**

A regimen is a strictly regulated treatment programme like a diet or exercise schedule (Mosby, 1986: 974). For the purpose of this study a regimen is defined as a set of drugs administered to a client to achieve a required goal.
Disease Management (DM)
Matria healthcare (2003) explain that a disease management programme is there to assist individuals with chronic diseases to better understand and manage their conditions by increasing their knowledge about their illness, potential complications and importance of medication and treatment adherence.

Counselling
Counselling is aimed at assisting people to understand and develop their personality in lieu of existing problems (Baruth and Huber, 1985:15). For the purpose of this project, counselling is defined as helping clients telephonically, to adapt to a major change in their lives and that is to a life-threatening disease and to commit to life-long ART.

Guidelines
The Oxford dictionary (1984:327) defines a guideline as a directing principle. In other words a guideline is a written principle to help us to manage and / or solve a problem.
Chapter one

1.6 Background literature

1.6.1 Prevalence and incidence of HIV / AIDS

Meredith and Horan (2000:798) stated that up to 42 million people became infected with HIV globally thus far. These infections accounted for nine million deaths and 1.1 million orphans. Of an existing 30 million infected people worldwide, 90% reside in developing countries with Sub-Saharan Africa taking the lead followed by Asia. According to Meredith and Horan (2000:798) a total of 641 086 cases of AIDS in the United States of America (USA) have been reported to the Centre for Disease Control (CDC).

The total number of people living with HIV / AIDS at the end of 2001 was 40 million (HIV / AIDS global report). This lead to 14 million children globally orphaned because of the impact of HIV / AIDS. From this global incidence of HIV infections, the highest number of infections was found in Sub-Saharan Africa, presenting with 28 500 000 HIV-infected people. South and South-East Asia followed with 5 600 000 people living with HIV / AIDS in 2001. In contrast to these high infection rates, Australia and New Zealand had the lowest incidence with only 15000 people infected with HIV / AIDS in 2001. There were five million newly infected people and three million AIDS deaths recorded in 2001. UNAIDS (2002:190) state that the number of people living with HIV / AIDS in South Africa was estimated at 5 million by the end of 2001. They indicated that 4 700 000 people were infected with HIV / AIDS between the age of 15 - 49 years of which 2 700 000 were women between the age of
15 - 49 years. Three hundred thousand and six hundred AIDS deaths were recorded at the end of 2001.

1.6.2 HIV / AIDS prevalence in AFA

Michael Hislop, data analyst of AFA stated that AfA managed about 21293 South African (SA) lives on their HIV Disease Management (DM) Programme in 2004. He said AFA is not only contracted with companies and medical schemes within the SA borders but also in Botswana, Swaziland, Namibia, Malawi, Zambia and Zimbabwe. He further on added that the age range with the highest prevalence was between the ages of 30 - 34 years with a percentage of about 3, 2% of all lives covered by AFA. The ages with the lowest incidence were between 10 to 14 years with a percentage of about 0.1% and of all those registered on the AFA programme, about 66% qualified for Highly Active Antiretroviral Therapy (HAART). The province with the highest number of clients registered on the AFA programme was Kwa Zulu Natal (KZN) with a percentage of about 2.5%. The Free State (FS) followed with 1.5%, North West (NW) 1.2%, Eastern Cape (EC) 1%, Mpumalanga (MM) 0.9%, Gauteng 0.8%, Northern Cape 0.6%, Northern Province 0.55% and Western Cape with 0.3%. These were the percentages of all the lives covered under the AFA programme (Hislop, 2004).
1.6.3 Adherence

A concern was raised by UNAIDS about the extensive provision of antiretroviral therapy in all societies. A further concern is whether health systems have the capacity to ensure adherence to multifaceted antiretroviral regimens (UNAIDS, 2002:153). Orrell, Bangsberg, Badri and Wood (2003: 1 - 7) states that adherence cannot be seen as a stumbling block to successful ART in South Africa, but concluded that simpler dose frequency contributed to increased adherence to ART.

Orrell, Bekker, Maclean, Darder, Tinise and Wood (2003: 20, 21) investigated the adherence outcome in resource poor settings in three sites in Cape Town, South Africa. The outcome of their study showed excellent adherence and viral suppression and found that there is a definite benefit of pre - treatment education and communicating the do and don'ts of therapy to the clients. They also suggested that those who encourage adherence to the clients need to have knowledge of ART and do not necessarily have to be a doctor or a nurse.

1.6.4 Programmes

AFA is one of the companies that offer disease management of HIV / AIDS. There are several other companies in South Africa that provide similar disease management programmes to their clients. Examples of these companies are MX Health, Calibre Clinical Consultants, Lifesense and Qualsa (MX Group, 2004: online; Calibre Clinical consultants, 2004: online; Lifesense Disease
McDonald (2001:30) states that the cost of the effects of HIV / AIDS leads medical schemes to the essentiality of offering a DM programme to their clients. He added that a DM programme offers patient assessment, treatment guidelines, the need to know what investigations are required and when it need to be done, client support, counselling, education, health status monitoring and outcome measurement. Meredith and Horan (2000: 810), found that patients on chronic medicine maintain an approximate 70% adherence to their treatment. The concern they raised was that this level of adherence can lead to viral resistance. Adherence to therapy therefore became an integral part of HIV care.

1.6.5 Resistance to antiretroviral therapy

HIV reverse transcriptase (RT) and protease are necessary enzymes in the replication cycle of HIV and by interfering in their processes the replication of HIV is inhibited. They found that viruses survive in altering their surroundings. Poor patient adherence or structured treatment interruption (drug holiday) results in periods of sub optimal dosing which can add to faster materialization of viral resistance (Richman and Staszewski, 1997: 2, 4, 8).

Resistance can be seen as a result of hereditary mutations (changes) that take place where there is an ongoing HIV replication in the presence of sub optimal drug levels. There are specific factors that contribute to sub therapeutic drug
levels. Some of these factors include poor diffusion of composite into certain body sites, poor patient adherence, drug interactions and poor drug absorption etc (Miller, 2002:32, 33).

1.6.6 Current guidelines available on adherence

Due to constant mutations of the virus and the risk of treatment failure, it is important to have guidelines available before people start on treatment such as highly active antiretroviral therapy (HAART). The following methods have been described by Bartlett (2002:38, 39):

- Discuss a plan that the client will understand and be committed to it;
- Take time to ensure readiness to start treatment;
- Obtain support from family, friends, peer and the community;
- Encourage the client to use memory aids to help prevent poor adherence;
- Monitor adherence and ensure availability of stock for the next month;
- Use missed dosages as an opportunity to prevent the same from happening;
- Active drug, alcohol use and mental illness can predict poor adherence to therapy;
- Clients need to be educated about the disease process, ART, side – effects, the effects of food and simple regimens provided.
1.6.7 Current methods of counselling

The HIV epidemic emphasized the need for healthcare workers to have counselling skills (Bekker, 2002:30). Counselling in a health care setting refers to as; consisting of a supportive relationship in a structured environment where one person helps another person to know more about their problem, contain emotions, explore and define feelings, thoughts and actions around the newly diagnosed disease find solutions to the problems and develop coping skills (Bekker, 2002: 30).

1.6.8 Behaviour changes

Kanfer and Saslow in (Phares, 1984:336) state that behaviour changes could be answered by asking the following questions about behaviour assessment:

- Which specific behaviour patterns need change?
- What are the best practical means to change the behaviour? (Do we need to manipulate the environment, the behaviour or self - attitude of the patient?)
- What factors are maintaining this behaviour and under what conditions are this behaviour sustained?
1.7 **Research problem**

A problem was identified by the researcher in the area of client adherence to antiretroviral therapy at AFA. The researcher found during her experience as a treatment support counsellor at AfA that there was a lack of written adherence guidelines. The researcher believes that written adherence guidelines would assist treatment support counsellors to remain focused on adherence issues and be consistent in information given to clients.

1.8 **Research question**

Can a clear documented adherence guideline assist treatment support counsellors to be consistent with information when counselling clients regarding antiretroviral therapy? Can this information improve client adherence to their therapy?

1.9 **Null hypothesis**

The null hypothesis states that the implementation of specific guidelines for counsellors will have no effect on adherence to ART.

The positive hypothesis states that there will be an increase in CD4 cell count, claims history, follow up blood tests and a reduction in viral load and change of treatment.
1.10 Research methodology

The research methodology will be re-discussed in depth in Chapter 3. A quasi-experimental, descriptive study design was used to evaluate the effectiveness of the proposed adherence guideline (McBurney, 2001:333 – 336; Blocher, 1987:383; Sarafino, 1996:380). Thus there will be no randomisation but a comparison group will be used. The design for this study made use of an intervention and comparison group and the purpose of the design is quantitative-descriptive rather than exploratory.

1.10.1 Formulation of guidelines

Guidelines information was drawn from literature and from what AFA required from their clients. Analysis of literature regarding adherence guidelines was used to formulate an adherence guideline tool that was used during this project.

1.10.2 Population, sample and sample size

The overall population for this study were clients who were on ART. The sample for this study was limited to clients who registered on the AfA programme and who started ART for the first time.
1.10.3 Comparative sample group

The assumption is that the overall profile of clientele of AFA stays constant over years. Two groups were selected from the larger population. Retrospective data were obtained for the comparison group and prospective data for the intervention group (detailed discussion of the two groups will be done in chapter 3). Retrospective data was collected from clients’ records that registered at Afa and who started ART from 01 February 2004 to 31 March 2004. All the files and claims that had been processed for these clients from February 2004 – September 2004, were reviewed. The files were audited to observe the adherence history. It also assessed how frequently the counsellors contacted them. Blood results such as CD4 cell counts and viral load baseline results as well as the results after six months on ART were evaluated. The number of records evaluated for the comparison group was those of all the clients that registered as new clients at Afa during the time period of February and March 2004. A total number of 40 clients were identified for the retrospective evaluation. Due to ethical reasons and the impact that abstention of an intervention would have on the patients, the researcher chose to select a historical group and identified them as the comparison group. The researcher did not foresee the difference in seasons to be problematic in the outcomes of the study.
1.10.4 Intervention group

This sample was drawn from the greater population sample that is made up of all registered clients receiving ART at AFA. A systematic sample selection was done and the records of the first 40 SA clients who registered with AFA on the ARV therapy as from 01 October 2004 to 30 November 2004 were used as the study sample. The adherence guidelines were formulated based on literature as well as needs identified by AfA. The guidelines were completed at the end of August 2004 and implemented in September 2004.

1.10.5 Instrument

A newly formulated adherence guideline was going to be presented to counsellors. These counsellors had to apply the guidelines with all the new clients that registered from 01 October 2004 to 30 November 2004.

1.10.6 Workshop

A workshop was held to explain to the counsellors on how to apply these adherence guidelines. Based on the researcher’s experience at AfA, treatment support counsellors are required to have basic background knowledge on HIV / AIDS as well as the current treatments available and the importance of adherence to ART. They also undergo intensive training on all aspects of HIV / AIDS when joining the company. In addition to this, ongoing training and
development is offered by the company on a weekly basis that enable treatment support staff to remain up to date with the latest developments in the area of HIV / AIDS. The researcher was therefore confident to use the assistance of the treatment support staff during the course of the project.

1.10.7 Procedure

A case review file (CRF) was used to gather the data from all the files (see APPENDIX 1). The researcher reviewed the records of the comparison group (CG) and recorded the data in the CRF. The files of the intervention group (IG) were to be analysed once the study population had been identified. Treatment support counsellors were going to contact each of the newly enrolled clients on a monthly basis for six months by applying the adherence guidelines at every contact. At the end of the six months the records of these clients would be drawn, adherence evaluated as well as the CD4 and viral load outcome measured. The results of the two groups would then be compared. All treatment support counsellors signed a confidentiality agreement when they were employed by AfA. Each client that is registered on the AfA programme has a unique identification code (known as patient key number) whereby confidential information of clients is protected. For the purposes of this study, patient key numbers will be used instead of names and medical aid numbers. The identity of clients is therefore protected throughout the study.
1.10.8 Data analysis
A CRF was used to obtain the relevant information from the files of the comparison group and the intervention group. These included the demographics, current ART, baseline CD4, viral load results, contacts made with the clients as well as the CD4 and viral load outcomes. The information were analysed to determine whether the guidelines did assist counsellors to motivate clients to adhere to therapy. Descriptive data were used to give the results.

1.10.9 Validity and reliability
Content and face validity of the instrument were evaluated to determine whether the test seemed on the surface what it intended to test and whether the content of the test included a series of actions that required testing (McBurney, 2001:128). The researcher therefore requested specialist in the field of HIV and counselling to comment on the guidelines before it was implemented. The researcher ensured reliability by giving a workshop to all counsellors to ensure that they know exactly how to use the instrument (adherence guidelines). The researcher further on assisted the counsellors with the first few phone calls to ensure that they all understood what is expected from them. The intention of testing reliability of the instrument was to determine whether the same results were given every time the instrument was tested (McBurney, 2001:127; De Vos, Strydom, Fouche & Delport, 2005:160 -
163). A CRF were used to extract data from client’s files and to record all the needed outcomes that were to be evaluated.

### 1.11 Relevance of the study

The researcher is faced with the fact that disease management companies in the private sector are mostly limited to telephonic contact with clients and depends on claims history to determine client adherence to therapy. It is impossible to substitute directly observed therapy and pill counting to ensure adherence. The researcher hopes that implementing guidelines to support counsellors may assist clients to improve their adherence.

### 1.12 Ethical statement

The proposal was submitted to the Senate Higher Degrees at the University of the Western Cape for ethical approval. The researcher is currently employed by AfA and bound by a confidentiality agreement with the company. The aim of this agreement is to protect the identity of all clients registered on the AfA programme. Written consent was obtained from AfA to perform the study. Client confidentiality remained intact by keeping the collected data under an identification code (patient key number) and no form of identification of clients were added on to the thesis / published.
1.13 Chapter outline

Chapter one will outline the proposal of the project. The next chapter will give a layout of literature that deal with adherence issues. The third chapter will describe the methodology of the thesis as well as the instrument / guidelines. In chapter four the results will be given. Chapter five will deal with the discussion of results and recommendations.

1.14 Time lines

<table>
<thead>
<tr>
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<tr>
<td>Writing of Proposal and guidelines</td>
<td>Feb – July 2004</td>
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<tr>
<td>Submission of proposal to Higher Degree</td>
<td>August 2004</td>
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<tr>
<td>Submission of permission to Aid for AIDS</td>
<td>August 2004</td>
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<tr>
<td>Implementation of guidelines</td>
<td>September 2004</td>
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<tr>
<td>Collecting and analysing data</td>
<td>September – March 2005</td>
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<tr>
<td>Writing of thesis</td>
<td>Feb – April 2005</td>
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<td>Submission of thesis</td>
<td>May 2006</td>
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1.15 Budget

The researcher funded the research project but AfA supported the infrastructure of the study.
1.16 Summary

The aim of this research project is to implement and evaluate guidelines that will be used by treatment support counsellors in an attempt to increase client adherence to ART. From experience as interventionist at AfA, the researcher found that healthcare providers tend to request change in their patients’ current therapies or to include other ART drugs and these requests for change of medication usually occur without proper investigation of their patients’ adherence to their current therapy regimen. The concern raised by the researcher is the problem of premature treatment failure and reduction in future treatment options. Failure to adhere to a prescribed treatment regimen is one of the main causes why optimal viral suppression may not be obtained. The researcher hypothesize that clear adherence guidelines used by treatment support counsellors may enhance adherence to therapy and better adherence to therapy will result in less frequent change in treatment.
2.1 Introduction

A literature review on adherence to treatment was done to gain a background and a more in-depth understanding of all issues that may impact adherence. The researcher took this approach to be able to formulate effective user-friendly adherence guidelines. Literature was searched for in the Google search engine, at AfA, medical journals, PubMed, the National Library and various other resources available. International and national literature was used for this study to give the researcher an indication whether there was some form of common grounds about adherence. It was also done to find out whether there may be similar studies about adherence guidelines elsewhere. Though adherence guidelines are not uncommon nationally and internationally, no literature was found that specifically dealt with studies about adherence where the telephone was the only means of contact between clients and counsellors. Most literature dealt with adherence barriers, which turned out to be very important in assisting the researcher to act proactive in her adherence guidelines approach. A social learning theory and cognitive theory was used as a foundation on which the adherence guidelines were based.
2.2 Theoretical framework

Rotter in Phares (1984:358) stated that personality is an acquired or learned behaviour and the majority of learning occurs in situations involving relationships with other people. It is a social learning theory because “it stresses the fact that the major or basic modes of behaving are learned in social situations and are inextricably fused with needs requiring for their satisfaction…” (Phares, 1984:358). The researcher applied the concepts of Rotter’s theory to the HIV positive client and their behaviour towards adherence to highly active antiretroviral treatment (HAART). In addition was it felt to add aspects of Kelly’s cognitive theory to the theoretical framework because people make cognitive decisions on what is important in situations (Kelly in Kent & Dalgleish, 1983:49 - 50).

Adherence to therapy is perceived as behavioural and it became important for health care professionals to understand the social sciences behind it (Feuerstein, Labbé & Kuczmierczyk, 1987, 259). By understanding the social sciences behind behaviour, adherence problems can be detected and resolved. Feuerstein, et al. (1987:259) further on points out that adherence to treatment in most studies indicated that at least one third of patients failed to adhere to therapy. Many patients do not follow their doctors’ treatment recommendations as they should, therefore behaviour modification methods need to be applied to increase patient adherence to therapy (Sarafino, 1996:53).
Kelly in Kent and Dalgleish (1983:49 - 50) acknowledges that people are unique and can make their own decisions. However, they can still be assisted by the provision of information and reinforcement that would make their decisions more acceptable.

The concepts identified were:

- Potential change in behaviour;
- Expectancy of the effect of the change of behaviour;
- Power of reinforcement;
- Psychological state;
- Predictive formula for behavioural change as well as problem-solving methods.

### 2.2.1 Adapted social learning theory of Rotter

Rotter emphasized that human behaviour is motivated by the persons needs, and is further determined by the expectations that will occur due to the chosen behaviour (Phares, 1984:358; Brannon & Feist, 1992:333 - 334). Thus the person can set his / her own needs (goals) and will then use a certain learned behaviour pattern to achieve these goals. The question that arises is what is the needs of a person living with HIV / AIDS and how will these needs determine the persons behaviour and expectant outcome behaviour towards the adherence to ART. It is hoped that through specific guidelines the counsellors will be able to
assist the clients to do introspection and to prioritize their needs so that the taking of their medications will be a basic need that need to be satisfied. Expectancy refers to the probability that the intervention will assist the client to adhere to the treatment and to which extend this adherence will lead to improvement in the client’s life. In other words adhering to antiretroviral therapy will achieve an undetectable viral load. This expectancy then encourages their behaviour to adhere to therapy. Thus the client will take the information given by the counsellor about adherence to ART and will make their behaviour choice based on what they believe their chances are to survive. This behaviour is then reinforcement when they see on the blood results that their actual viral loads are fully suppressed. The psychological state of the client also needs to be understood and acknowledged. Issues such as depression could contribute to poor adherence due to a negative state of mind (Phares, 1984:358, Bartlett, 2002:38).

Rotter (Phares, 1984:358) refers to the predictive formula. This formula includes the previous mentioned concepts such as: behaviour potential, expectancy, reinforcement and psychological status. This formula is used to predict behaviour whereby the behaviour with the highest potential can be predicted. In other words the behaviour with the highest potential will occur when patients know the value of reinforcements involved and when they are faced with more than one option of behaviour. This factor highlights the fact that clients need to
be made aware of the importance of adhering to ART and what outcome to expect.

Clients further need to be taught skills on problem-solving (Phares, 1984:358). Many side-effects are associated with adherence. Clients must be informed about potential side-effects and strategies must be in place for them on how they will deal with the problems associated with the choice that they have made. Controversial information may also cause conflict and clients need to know how to deal with conflicting advice from caregivers and news reports.

2.2.2 Adapted cognitive theory by George Kelly

Kelly in Kent and Dalgleish (1983:49 - 50) used a repertory grid analyses to cognitively decide what is important in a situation. In other words, if someone believes that ART is ineffective and can shorten life then the predicted behaviour would be poor adherence or no adherence at all. Alternatively, if the client believes that ART is effective and that adherence reinforce the effectiveness he/she may cognitively make the decision to adhere to the therapy and will make additional decisions on how to deal with problems like side-effects. Cognitive therapy is used to assist clients to understand the existing problem and to perceive their current thoughts, beliefs and feelings as actions that can be tested (Sarafino, 1996:447). Sarafino added that clients are encouraged to attempt various observable and concealed behaviours and review the outcome to assess
incorrect beliefs and expectations. In addition, they are taught fresh skills and tactics to manage observable and concealed social, cognitive and emotional behaviour (Sarafino, 1996:447).

While in Wilson – Barnett (1983: 1, 5) reported that health education needs to be promoted within communities in order to change behaviour that might negatively impact on health. She suggested that it is important to communicate behaviour options to patients to enable them to improve their health status through behaviour change.

While (1983:7) furthermore emphasized the importance of sending out a “positive” health message, in other words giving patients the advantages of behaviour that positively impacts health. She argues that a negative message on the other hand, will make a poor impact on behaviour change. Each client therefore has to make a cognitive decision about their choice of behaviour before commencing therapy.

ART in its complexity in the sense of two to three combinations, time, food restriction, potential drug interactions and side - effects make it a difficult task to simply use without full understanding of the disease, medication and everything that impacts the HIV infected individual. Added to these concerns are the mixed messages send out about the safety of ART and alternative treatment like the Dr Rath and vitamins controversy (Bodibe, 2005). A positive reinforcement (increased CD4 and fully suppressed VL) is the consequence of accurately adhering to antiretroviral therapy.
The researcher however suggests that adhering to HAART should be seen as a background to the whole, rather than as a separate element. According to Mukherjee, Farmer, Niyizonkiza, McCorkle, Vanderwarker, Teixeira & Kim (2003), some studies indicated an increase in risky behaviour with the availability of treatment. This has emphasized the importance of HIV education and prevention in correlation to the provision of antiretroviral treatment (Mukherjee, et al. 2003).

A full understanding about the inner self, the disease and ART is needed before the required behaviour can be met. The patient needs to understand why adherence to ART combined with a healthy lifestyle and follow up visits to their doctors and laboratories are important.

2.3 History of HIV and AIDS

The exact origin of HIV will always remain unanswered, but as far as the literature is concerned can one claim that the origin of the HIV occurred around 1931, about 30 years before the first confirmed HIV positive blood sample. Parallel supercomputers were used to analyse the HIV - 1 sequences in order to estimate the timing of the first ancestral sequence of the main HIV – 1 strain. The estimated date of the common ancestor was identified to be 1931 (Korber, Muldoon, Theiler, Gao, Gupta, Lapedes, Hahn, Wolinsky, Bhattacharya, 2000).

As far is known the first infection with HIV might have occurred as far back as 1940 when primates were slaughtered for food. Cefrey (2001:24) states that HIV
is a virus referred to as acquired, because a person has to perform certain behaviour to become infected by this virus. Van Dyk (2001:6) supports the statement about the origin of the HI - virus. She reported that Korber found HIV was transmitted from primates to human beings through butchering these primates for food. Migration, socio economic instability, transportation, multiple sex partners, drug use through injections and blood transfusion contributed to the spread of the virus to all parts of the world (Van Dyk, 2001:6).

2.3.1 Origin of HIV

The simian immunodeficiency virus (SIV) has been identified in Asian monkeys (macaques) as well as in the sooty mangabey monkey found in West Africa. The SIV seems to be harmless to their host. Another SIV has been identified that are mainly carried by the chimpanzees (cpz) and are referred to as SIV cpz. Laboratory analyses found a comparison between the SIV and the HIV - 1 and HIV - 2 strains, but recognised that multiple transgressions had to occur between these viruses to claim the similar ancestor. The question that arises was how a seemingly non - pathogenic virus became so volatile and pathogenic over the time. Various theories tried to address this issue (Moore, [sa]).
2.3.2 Theories of the transmission of SIV to man

One of the thoughts is said that the first human being who became infected with HIV, possibly had contact with SIV infected primates. Some researches believe that these primates were kept as pets or slaughtered for food. The belief of how it reached the United States of America (USA) could be possibly due to the selling of slaves when 10 million African slaves were sold during the 16th to the 19th century (Moore, [sa]; Cefrey, 2001:23 - 24).

Another theory states that the virus was transferred through the use of a polio vaccine obtained from kidney extracts used to prepare these vaccines. African Green – monkey kidneys were used for these purposes. The trail was applied during 1957 to 1960 in the Democratic Republic of the Congo, Burundi and Rwanda. It is possible that about 900 000 people could have received the possibly SIV contaminated vaccine (Cefrey 2001:23; Moore, [sa]).

2.3.3 First reports on deaths due to HIV / AIDS

The earliest death strongly related to HIV / AIDS could be traced back to 1959. The first case was in 1959 when an old sample of blood of a male who died in central Africa was re - analysed by Dr. David Ho and Dr. Tuofu Zhu. This re - analyses tested positive for the HI - virus. The second case was a re - analyses of a tissue sample taken in 1969 of an African - American teenager who died in St. Louis with symptoms similar to AIDS. The third case was a tissue sample taken in 1976 from a Norwegian family of three who also died of symptoms
similar to AIDS. The father in the last case regularly sailed by water to and from Africa and presented with a variety of diseases more than once (Cefrey, 2001:25 - 26).

### 2.3.4 Gay - related immune deficiency (GRID)

During the 1980’s the USA reported the death of 31 one people who died all with similar symptoms but with no real explanation of the cause of death. The disease was for some time closely linked with homosexual men and was referred to as GRID (gay – related immune deficiency), because it was mostly found among the gay community. Between 1982 and 1983 it became known that heterosexual people could also become infected with GRID. The Centre for Disease Control (CDC) then changed the phenomenon to AIDS as the HIV infected heterosexual people as well. So GRID was changed to HIV in 1986 and was recognised as the cause of AIDS. AIDS and related diseases such as pneumocystis carinii (PCP) and Kaposi’s sarcoma (a form of skin cancer) were diagnosed in homosexual men (Cefrey, 2001:12 - 13; Van Dyk, 2001:5). Evian (2003:3) agreed that AIDS was first depicted in 1981 in America among healthy homosexual men between the ages of 20 and 45 years. O’Brien, Kosko, Nettina, Penharlow & King (2000:797) on the other hand reported that the HI – virus was identified in 1985 after a number of deaths among young gay men in the United States.
2.3.5 Controversy about the discovery of HIV / AIDS

There is some controversy about who discovered the HI - virus whereby some agreement indicated that the HI - virus was co - discovered by Montagnier and Gallo (Connor & Kingman in Van Dyk, 2001:5). Luc Montagnier, a virologist and his team from the Pasteur Institute in France indicated in May 1983 that a virus related to AIDS was found in swollen lymph nodes of a patient. He named the virus LAV (lymphadenopathy associated virus). A year after France made their discovery of the LAV; the United States government reported in April 1984 that Robert Gallo of the National Cancer Institute found an AIDS - causing virus called HTLV – 111 (Cefrey, 2001:28 - 29). This has lead to Pasteur Institute of France taking the National Cancer Institute to court. This decision was based on the fact that Montagnier sent the sample to Gallo's laboratory after they discovered the virus. In 1992 the two agreed that the newly discovered viruses were the same and the USA acknowledged that Montagnier and his institute found the virus and not Gallo. An agreement was reached between Montagnier and Gallo as co - founders of the HI - virus (Cefrey, 2001:29).

2.3.6 Further developments

In 1983 the virus was identified as lymphadenopathy associated virus (LAV) and human T cell lymphotropic virus type 111 (HTLV - 111). Finally the name of the virus was changed to human immunodeficiency virus (HIV) in 1986.
Two types of the HIV called HIV - 1 and HIV - 2 were identified where HIV - 1 is found in Central, East, Southern Africa, and Europe, North and South America and the rest of the world while HIV - 2 is found in West Africa. HIV - 1 strain is found to be a faster moving virus than HIV - 2 (Van Dyk, 2001:5).

In September 1983, HIV was revealed as the cause of AIDS and the ELISA HIV antibody test made available in 1985. Further development took place by the introduction of the first antiretroviral drug called retrovir® that was introduced in 1987. In 1994 ART were used to prevent mother – to – child -transmission of the virus for the first time and in 1995 highly active antiretroviral therapy (HAART) commenced. HIV vaccine trails started between 1998 and 1999 (Evian, 2003:3).

2.4 Antiretroviral treatment programmes

2.4.1 International approach

HIV made a late introduction in Asia around the period of the 1980s. Countries in Asia that first reported on the epidemic were Thailand, Cambodia and Myanmar. The first report on the prevalence indicated that in 2001, a number of 1.07 million adults and children were infected with HIV. India is currently ranked with the second highest incidence of HIV / AIDS following South Africa (Asia collaborative group, [sa]). According to the UNAIDS global report (2004:10), the estimated HIV infections as of the end of 2003 were 1.5 million in East Asia, 6.5 million in South & South – East Asia and 1.9 million infections in Eastern Europe & Central
Asia. These figures lead to the need to provide a comprehensive antiretroviral treatment programme in Asia.

The Asian treatment guidelines make use of the World Health Organisation staging (see APPENDIX III) They stipulate that ART is recommended when the patient is in the WHO Stage IV disease irrespective of the CD4 cell count or if the CD4 cell count is < 200 cells / µl. Treatment may also be commenced where there is no CD4 cell count available and the patient is in WHO Stage IV irrespective of the total lymphocyte count or WHO Stage II or III with a total lymphocyte count of 1200 cells / µl. It is recommended that patients commence treatment when in the progressive stage III with recurrent oral candidiasis or invasive bacterial infections irrespective of the CD4 cell count (Asia collaborative group, [sa]).

The USA guidelines (USA collaborative group, [sa]) on the other hand indicate that a CD4 cell count and viral load (VL) is required and aught to be confirmed by a second test to ensure accuracy and reliability of the results. When the patient is in the advanced stage of HIV, treatment may be started without confirmatory results. Patients in the advanced stage of HIV disease, present with multiple new opportunistic infections varying from cytomegalovirus disease (CMV), disseminated Mycobacterium avium complex (MAC), cryptococcal meningitis and other neurological diseases for example progressive multifocal leukoencephalopathy, primary central nervous system lymphoma, HIV
encephalopathy etc. (Toronto General Hospital [sa]). According to the USA collaborative group ([sa]), patients are ready to start treatment when there is a CD4 cell count of < 350 cells / µl or a viral load level of > 55000 copies / mL. Factors that are taken into account in an asymptomatic patient is the current immune status and whether the he / she is prepared and eager to start treatment.

There are 13 recommended antiretroviral drugs available in the Asia treatment guidelines are abacavir (ABC), didanosine (Videx®), lamivudine (3TC), stavudine (Zerit®), zidovudine (Retrovir®), efavirenz (Stocrin®), nevirapine (viramune®), indinavir (Crixivan®), ritonavir (Norvir®), lopinavir & ritonavir (Kaletra®), nelfinavir (viracept®) and saquinavir (Fortovase® / Invirase®) (Asia collaborative group, [sa]). In contrast to the Asian treatment guidelines, there were 20 ARV drugs registered for use in the USA that includes an additional category of drugs referred to as fusion inhibitors (FI). Fusion inhibitors are normally spared for patients who failed their initial regimens (USA collaborative group, [sa]). In addition to the antiretroviral drugs used by the Asian guidelines, drugs available for use in the USA were emtricitabine, tenofovir, atazanavir & fosamprenavir (USA collaborative group, [sa]).

According to the Asian guidelines (Asia collaborative group, [sa]) the choice of treatment is based on the cost of treatment, how affordable and accessible it is, the client’s predicted adherence when using a specific chosen regimen and effectiveness of these drugs. Other documented factors that contribute in
deciding on a treatment regimen are side-effects, possible drug interactions and what would the next regimen be when future treatment change is required. HAART is recommended to prevent premature viral resistance (Asia collaborative group, [sa]).

ART is offered to patients to reach maximum and sustained viral suppression enabling the human body to restore and maintain the immune function, enhance quality of life and reduce HIV related deaths and ill-health (USA collaborative group, [sa]). A patient’s chance of disease progression, viral load, advantages and disadvantages of starting treatment are determinate factors when the patient is in the asymptomatic phase of the disease.

Furthermore the probability to adhere to ART after counselling and educating the patient in the asymptomatic phase of the disease is also considered. Those patients who present with symptoms like wasting, thrush and unexplained fever for more than two weeks are advised to start with ART (USA collaborative group, [sa]).

2.4.2 Resource limited settings

According to the World Health organisation (WHO), the majority of the 40 million people living with HIV / AIDS reside in developing countries (WHO, [sa]). Some of these developing countries are Thailand, Uganda, Zimbabwe, Zambia, Botswana, South Africa, Tanzania, Ivory Coast, Burkina Faso, Swaziland,
Malawi, Haiti & Brazil (Mukherjee, et al. 2003). The impact of HIV / AIDS had been experienced in all areas of the human existence especially in resource limited settings. This has lead to the reduction of life expectancy in sub – Saharan Africa from 62 to 47 years (Mukherjee, et al. 2003). The WHO expected that by the end of 2003, more or less six million people in the developing countries would require access to ART. Of these six million people, 400 000 are already on treatment and more than one third of those on treatment reside in Brazil (WHO, 2003). Mukherjee, et al. (2003) reported that Brazil implemented a successful comprehensive HIV programme which lead to a reduction in HIV infections from 24 816 in 1998 to 17 504 in 2000 and 7361 the first 9 months of 2001. Their comprehensive plan was based on experience in tuberculosis and syphilis. This included a combination of prevention, education and treatment.

According to the UNAIDS (2004: 169), Brazil, currently leads the way in cooperating with countries like Mozambique to improve the quality of AIDS and reproductive health information. Brazil also assisted countries like Bolivia, Colombia, the Dominican Republic, Elsalvador and Paraguay in providing antiretroviral drugs to these countries (UNAIDS, 2004:169).

The UNAIDS (2004:14), reported that by the end of 2003, about 57% of women in sub - Saharan Africa accounted for all HIV infections in the world. Women in sub - Saharan Africa are 30% more likely to become infected with HIV than men due to their vulnerability. Measures to reduce the impact of HIV on women need to be implemented by the provision of a save environment to reduce their
vulnerability due to poverty and poor living conditions (UNAIDS, 2004:14). Less than 12% of women in deprived countries have access to prenatal HIV testing (Mukherjee, et al. 2003). These figures emphasize the need for access to essential health care services. The crisis of HIV has lead to the demand that the global community move towards acting on the demands for HIV health care programmes and the provision of antiretroviral treatment to these countries. The UNAIDS (2004:16) reported that the impact of HIV has made the world recognize the importance to provide antiretroviral drugs in resource limited settings like Sub-Saharan Africa. They agreed that to achieve and sustain the provision of ART to resource poor limited settings, the continuous support of governments and donors is required worldwide (UNAIDS, 2004:77, 78).

In resource poor settings, treatment is started based on the WHO clinical staging (WHO, 2003):

When the CD4 cell count is available:

- WHO Stage IV regardless of the CD4 cell count;
- WHO Stage III with a CD4 cell count < 350 cells / µl
- WHO Stage I, II with a CD4 cell count of < 200 cells / µl
When the CD4 cell count is not available:

- WHO Stage IV regardless of the total lymphocyte count;
- WHO Stage III regardless of the total lymphocyte count;
- WHO Stage II with a total lymphocyte count of around ± 1200 cells / µl.

Factors considered in resource poor settings before commencing treatment are the strength and potency of ARV drugs, side-effects, existence of other conditions, monitoring of blood results, future treatment options, future adherence, pregnancy, risk for future pregnancy, and possible drug interactions (WHO, 2003).

2.4.3 The South African Government ART programme

2.4.3.1 Implementing the HIV / AIDS treatment programme

The AidsGuide (2006:104) states that the HIV incidence in South Africa has reached serious proportions and added that the Department of Health commenced the comprehensive HIV and AIDS Care, Management and Treatment Plan early 2004. At the end of August 2004, 11250 people accessed ART and this number has increased to 19500 in October 2004. One facility in 50 of the 53 districts in the country offered treatment for patients living with HIV / AIDS. A total of 103 facilities have already been accredited and is providing treatment and care for those living with HIV / AIDS. (compare Tshabalala - Msimang, 2004; AidsGuide, 2006:104.) According to the minister’s report three
centres across the country were identified to deal with the detection, assessment and prevention of adverse ARV drug reactions:

- **Medunsa**
  The centre at this university deals with the use of antiretroviral therapy and traditional medicine among adolescents and adults (Tshabalala - Msimang, 2004).

- **Free State University**
  The use of ART in pregnant women and children is dealt with at this university (Tshabalala - Msimang, 2004).

- **University of Cape Town (UCT)**
  The centre at UCT deals with adverse reactions of all drugs that are registered in SA (Tshabalala - Msimang, 2004).

### 2.4.3.2 Voluntary Counselling and Testing (VCT)
AidsGuide (2006:47) stated that in order to actively manage the HIV pandemic, people need to know their status. They added that those who fear that they might be HIV – positive, should confirm their status by undergoing a confidential HIV test. Venter (2005: 24 - 25) raised the concern that many people undergo testing when they are already in the symptomatic stages of their disease. The
problem with undergoing testing at this stage is that patients do not come to
terms with their HIV-positive status leading to poor adherence and therefore
poor effect of the antiretroviral treatment (Venter, 2005:24). The minister of
Health reported on progress made in VCT centres (Tshabalala - Msimang, 2004).
She said that sixty seven percent of all public health clinics are being utilized for
VCT and these services has been offered to about 412 696 people in 2002 / 2003
to 690 537 in 2003 / 4. She added that at the end of March 2004 more than
10 000 counsellors were available to assist with VCT and rapid HIV tests kits
were made widely available to enable people to receive their results without
delay. Venter (2005:21, 24 – 25) on the other hand raised another concern
about the huge challenge ahead of the Department of Health (DoH) to expand
VCT to more sexually active South Africans. This challenge in its complexity
might be negatively impacted by to the stigma and human rights issues that still
surround HIV (Venter, 2005:25).

2.4.3.3 Reporting on the progress made
A progress report that supported the minister of health’s speech was drafted in
September 2004, giving an update on the Department of Health’s progress on
the implementation of the government HIV / AIDS programme. Gauteng started
to implement the programme and Limpopo was the last province to implement it.
By September 2004, 3244 patients accessed treatment in Gauteng, 986 in
Eastern Cape (EC), 139 in the Free State (FS), 1556 in Kwazulu Natal (KZN), 63
in Limpopo, 202 in Mpumalanga (MM), 108 in the Northern Cape (NC), 631 in the North West (NW) and 4324 accessed treatment in the Western Cape (WC) (Department of Health, 2004:13 - 14).

Twenty laboratories were performing CD4 tests and seven performed viral loads (Department of Health, 2004:2). Venter (2005:22) said reports indicated that a number of 70 000 people are on the SA Government HIV treatment programme but the numbers could be dubious due to the alleged inclusion of patients registered on programmes in the private sector. Venter (2005:22) found that the majority of patients on the government treatment programme come from 5 provinces, the Western Cape (10 000), KZN Natal (12 000) Gauteng (about 20 000), Eastern Cape (3000) and North – West (6000).

2.4.3.5 Challenges faced by the SA Department of Health

Challenges were to mobilizing facilities to operate five days a week. Some facilities were required to improve their structures, tracking patients; referrals and community involvement. Another challenge was the insufficient number of staff and to avoid the risk of loosing staff in other health care departments. Attempts were made to draw skilled staff to remote and rural areas. Other challenges were the shortage of nutritionists, dieticians and a poor referral system that existed between the department of health and Department of Social
development. Foreign doctors reported that it takes them a long time to register with the Health Professionals Council of SA. (Department of Health, 2004:3 - 5).

The Department of Health (Republic of South Africa, 2005) highlighted major challenges in a progress report to the United Nations general assembly special session on HIV and AIDS. The issue of staff shortage, in particular skilled professionals like doctors, pharmacists and nurses still seem to remain a major challenge. Secondly there is the problem of poverty and underdevelopment due to inequalities of the past and the programme being implemented in view of this socio-economic problem. Being able to manage the information systems is highlighted as another major challenge. The last major challenges pointed out by the department of Health are the incorporation of the HIV programme services within the Primary Health care perspective and management of African Traditional medicine in view of registration, training, research and referral structure.

Venter (2005:22 – 25) critically assessed the progress made by the Department of Health and highlighted important fields of concern. These are the fact that waiting lists vary in time lines and getting patients to join the HIV programme depends entirely on how they find their way to the ARV clinics. Another concern is the continuous staff shortage especially amongst doctors and pharmacists. Other concerns recorded are the low numbers of men joining the programme, patients being expected to attend clinics up to eight visits over a three month
period, patients being denied to join the programme because of non-disclosure and poor lifestyles, and the monitoring of adherence. A few more concerns reported is that patients are required to pay fees to attend clinics, the difficulty to obtain funds to increase community involvement, drug resistance, poor access to nutritional supplements, drug provision, varying laboratory services, current response to VCT and some provinces not performing well. The provinces highlighted with poor performance are the Free State and Mpumalanga with around 1000 people on the antiretroviral treatment (Venter, 2005:22 - 25).

2.4.3.6 The SA Government’s response to challenges

The Department of Health (Republic of South Africa, 2005) acknowledged the existing challenges and indicated that there is an intensification to expand the total accredited service points to serve all the local municipalities. The DoH (Republic of South Africa, 2005) stated that continuous funding of the comprehensive response to HIV & AIDS is needed to enable the department to do progressive planning, efficient running and constant monitoring of the programme. The DoH (2005:40) further emphasized the importance of prevention being the basis of the Comprehensive HIV & AIDS Plan. Other factors indicated in this report are to increase access to services for all children impacted by the effect of HIV & AIDS, addressing the lack of capacity in the TB / HIV activities, follow up of babies on the vertical transmission prophylaxis programme and exclusive breast feeding (Republic of South Africa, 2005).
Venter (2005:25) said it is too soon to evaluate whether the SA ARV rollout is a success or failure though some successes and slow progress has been noted in some areas. Venter (2005:25) further on suggested that more training and experience at sites would assist them to remove some of the challenges and emphasized the urgency to improve data gathering, analysis of available data and critically assessing why some areas reported a slow progress in rolling out antiretroviral treatment.

### 2.4.3.7 Choice of treatment selection

Adult regimens consist of a first and second line regimen. The first line is a set of three drugs consisting of lamivudine, stavudine and Efavirenz or Lamivudine, Stavudine and Nevirapine. The second line regimen consists of Didanosine, Zidovudine and Lopinavir / Ritonavir. When using Efavirenz as part of a regimen, care need to be taken to avoid pregnancy in women in childbearing age. Health care providers are required to ensure that adequate and reliable contraception is used by HIV - positive women in the childbearing age. If this is not possible then the existing drug need to be replaced with nevirapine (Department of Health. Pocket guide, [sa]:7 - 8).

Clients who were on ART before are advised to continue with the same regimen if the existing regimen falls within the government guidelines. If this is not the case, treatment is changed when patients do well on their current regimen
Chapter two

(Department of Health. Pocket guide, [sa]:7 - 8). Expert advice is recommended before replacing any current treatment. Clients who did well on treatment and decided to stop should be investigated for reasons for treatment interruption. After these reasons were identified and dealt with, adherence counselling is enforced, treatment restarted and adherence closely monitored. A change to a completely new regimen is required where clinical treatment failure is confirmed (SA Department of Health. Pocket guide, [sa]:7; AfA, 2005:33). The state guidelines also suggests that clinical advice aught to be obtained where nevirapine (NVP) was used as a single dose in pregnancy and in children to prevent mother – to – child - transmission (Department of Health. Pocket guide, [sa]:7 - 8). According to a study done on Ugandan women receiving nevirapine for PMTCT, it was found that the K103N NVP resistance mutation was found 6 weeks after NVP was administered in three (20%) out of 15 women. This study has indicated that the K103N NVP mutation can be found in Ugandan women who received a single dose of NVP. (Eshleman, Mracna, Guay, Deseyve, Cunningham, Mirochnick, Musoke, Fleming, Fowler, Mofenson, Mmiro, & Jackson, 2001).

2.4.3.7 How to improve access to ART in the public sector

Schneider and McIntyre (2003:19, 20) listed seven ideas required to improve access to ART:

• Fully mobilize the existing healthcare system;
• Increase number of skilled personnel at both amenities and support systems;
• Reinforce the healthcare system i.e. provision of medication, laboratories, assistance and training of personnel;
• Implement measures to reach people in deprived and inaccessible areas;
• The ART programme should learn from previous and existing experiences of other programmes like the national TB control programme;
• Alternative ways need to be established to replace DOT (directly observed therapy) to improve adherence;
• Groundbreaking methods are required to implement an ART programme.

Venter (2005:22 - 25) added some suggestions to increase access to ART in the Government ART programme. He advised that patients need to be actively recruited from hospital inpatients, Tuberculosis (TB) & sexually transmitted diseases (STD) and prevention – mother – to – child – transmission (PMTCT) clinics. Furthermore, alternative ways need to be explored to dispense ART in view of the lack of skilled professionals like pharmacists and ARV rollout should therefore not be stalled due to a lack of pharmacists. Clinics need to become more accessible for the youth and VCT programmes need to be expanded to get more people to know their HIV status and join the government ARV programme.
2.4.3.8 Side-effects

All forms of side-effects affect a client's decision to adhere to their treatment. Doctors who provide the treatment should choose a suitable regimen as well as educate their clients on possible side-effects and how to manage and prevent such side-effects (Department of Health Pocket guide, 14). A concern raised by Abbott, Forbes and Taffe (2000:60) is the safety of alternative medicines in view of the fact that there is limited information available about the side–effects, dosing, drug and food interactions and the effect of toxic quantities. Aidsguide (2006:132 - 133) reported that many patients tend to combine different forms of treatment including faith healing, alternative and conventional medicine.

The South African Government approved the Traditional Health Practitioner’s Bill whereby a council for traditional healers were established. This council’s duties are to regulate traditional healers to adhere to ethical standards set by the bill. The Traditional Healers Association of South Africa (Thasa) consists of a membership of 300 000 traditional healers and many individuals who present with recurrent infections or incurable conditions tend to consult traditional healers. Van Dyk (2001:126) added that about 80% of people in Africa utilize the services of traditional healers. The SA DoH committed six million rand toward the research of traditional medicines especially those associated with HIV / AIDS (Aidsguide, 2006:132).
The most frequently used herbal medicines are ginseng, garlic, ginkgo, biloba, echinacea, St. John’s Wort and saw palmetto (See table 2.1) (Abbott, et al. 2000:60 – 63). Wilson, Naidoo, Bekker, Cotton & Maartens, (2002:430 - 434) suggested that patients need to be questioned about the use of herbal medicines before commencing ART and emphasized the need for research in the area of alternative medicines in SA. Patients need to be well-informed about herbal medicines and need to know the potential overwhelming effects on their health (Abbott, et al. 2000:55 - 56). They should be discouraged to administer herbal medicines to children and the use of it should be done with utmost care during pregnancy and lactation. Abbott, et al. (2000:56) points out that patients need to discuss their intentions to use herbal medicines with their treating doctors, avoid using unregulated and unqualified herbal practitioners and be cautious of overstated claims of the efficacy of herbal medicines.
<table>
<thead>
<tr>
<th>Herbal medicine</th>
<th>Indications for use</th>
<th>Side - effects</th>
<th>Potential drug interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Panax ginseng, P. quinquefolius</td>
<td></td>
<td></td>
<td>Furosemide, warfarin, stimulants and antipsychotic treatment</td>
</tr>
<tr>
<td>Ginkgo Biloba</td>
<td>Increase peripheral vascular blood flow, dementia, memory loss, vertigo &amp; tinnitus.</td>
<td>GIT effects, headache, palpitations, hypotension, cardiac arrhythmias, dizziness, restlessness, erythema, edema, severe itch, seizures, loss of consciousness.</td>
<td>Anticoagulants.</td>
</tr>
<tr>
<td>Echinacea</td>
<td>Colds, throat infections, urinary tract infections (UTI), burns, eczema, herpes, psoriasis.</td>
<td>Chills, shakes, dizziness, fever, hypotension, dyspnoea, dermatitis when applied directly to the skin.</td>
<td>Contraindicated in autoimmune conditions i.e. HIV infection, multiple sclerosis, TB and lupus.</td>
</tr>
<tr>
<td>St. John's Wort</td>
<td>Depression, anxiety, nervousness, sciatic and rheumatic pain.</td>
<td>Fatigue, confusion, allergic reaction, photo – sensitivity, weight gain and GIT effects.</td>
<td>Antidepressants, over – the – counter cold and flu medicines, amphetamines, narcotics, dextromethorphan &amp; yohimbine.</td>
</tr>
<tr>
<td>Hypericum perforatum</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saw palmetto</td>
<td>Benign prostate hyperplasia</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The main side-effect of efavirenz for instance is the fact that it has an impact on the central nervous system. This side-effects may vary from dizziness, sleeplessness, poor concentration, abnormal dreams, somnolence and hallucinations. Once the drug is discontinued, the side-effects may disappear by the fourth week. Care should be taken to avoid taking alcohol or psychoactive drugs with efavirenz as it may exacerbate these symptoms (Department of Health Pocket guide, 14 - 16).

Zidovudine may cause headaches, myalgia, malaise, anorexia, nausea, neutropenia and anaemia. When haemoglobin level is less than 10 gm / dL but greater than 8 gm / dL, then Zidovudine should be reduced to 200mg twice a day and haemoglobin repeated in 1 - 2 weeks. When haemoglobin is less than 8gm / dL, then clinical advice should be obtained or all ART stopped till advice is obtained if the problem drug cannot be exchanged with another drug (Department of Health Pocket guide, [sa]:14 – 16; AfA, 2005:28).

When the neutrophil count is less than 1.5 but greater than 1.00, then zidovudine need to be decreased to 200mg twice a day or full blood count repeated in a week. If the neutrophil count drops to less than 1.0 and the patient develop pyrexia, then ART should be withheld, blood cultures done and ciprofloxacin 750mg and gentamicin administered. The client should then be referred to a hospital without delay. Minor side-effects tend to appear more frequently than
major side - effects and become a cause of concern among people (Department of Health Pocket guide, [sa]:14 - 16; AfA, 2005:28).

2.4.3.9 Western Cape Department of Health (WC DoH)

A report on the implementation of the ARV treatment programme showed that Western Cape has the lowest incidence of HIV / AIDS in the whole of SA but the impact of it on healthcare in this province became a great cause of concern. In partnership with the Western Cape Department of Health, Medicins Sans Frontiers (MSF) started the first ART programme in Khayelitsha in 2001. This has given rise to hopes that ART can be given at primary care level, is viable and cost effective. By the end of March 2004 a total of 2337 patients received ART in 13 sites in the Western Cape (Department of Health WC, 2004).

Donors and international agencies at some of the treatment sites funded the cost of ART and laboratory tests. An amount of R23, 081 million was allocated by the Western Cape Department of Health for the ARV treatment programme for the 2004 - 2005 financial year. Their intention was to have 36 accredited ARV treatment sites and provide ARV treatment to 6000 patients on a daily basis by March 2005 (Department of Health WC,2004).

The ARV programme consists of VCT and general HIV care. The general HIV care includes clinical assessment, relevant blood tests, prophylaxis, lifestyle, treatment of infections and symptoms, psycho - social support, counseling and
ARV treatment. In addition to these services there is nutritional support that forms part of the Nutrition Supplementation Programme (NSP). The NSP targets HIV positive pregnant mothers, those on TB (tuberculosis) and HIV treatment as well as HIV positive adults and children attending public health facilities (Department of Health WC, 2004).

Protocols are available for ARV stock management to ensure that adequate supply of drugs is maintained. Month end reports also need to include where the ART is stored and these reports must be submitted to the Regional Pharmacist and Provincial ARV programme pharmacist, HIV / AIDS Directorate. Furthermore, training (three organizations are contracted for training purposes), monitoring, evaluation of the government programme, adherence monitoring and programme coordination all forms part of the ART programme (Department of Health WC, 2004).

By providing ART to the people of the WC, the Western Cape Department of Health intends to decrease illness and deaths directly related to HIV / AIDS. Their second intention is to increase and restore the immune system and to reduce and maintain undetectable viral loads of those who are on ART (Provincial Administration Western Cape Collaborative group, 2004, 4).

ART is recommended when patients are in the clinical WHO stage IV or WHO stage I, II, III with a CD4 cell count < 200 cells / µl, (Provincial Administration Western Cape, Collaborative group, 2004, 4, 5). In order to ensure patient
commitment to adhere to the ART programme, the following factors are seen as
determinate for future adherence (Provincial Administration Western Cape
Collaborative group, 2004:4, 5):

- Whether the patient attended at least three follow up visits to an HIV
  Clinic;
- Is not abusing alcohol or other substances;
- Has untreated depression;
- Non-disclosure;
- The patient’s insight in their disease and ART;
- Regular access to an antiretroviral treatment clinic.

When clients require ART based on the WHO staging, they are referred to the
nearest ART center. In order to give each person an equal chance to be
attended to, these visits are by appointment only. A multidisciplinary team at the
ARV center makes a final decision whether the patient need to start ART by
accessing the clinical and psychosocial readiness of the patient. Patients
defferred for ART, are referred back to the original health care center to continue
to monitor and further manage them until the criteria is fulfilled. It might become
necessary to assist patients who has existing psychosocial problems with
additional counseling or by referring them for further assistance (Provincial
Administration Western Cape Collaborative group: 2004, 5; Venter, 2005:21 -
25).
According to the Western Cape Department of Health (2004: 12, 13), the first line regimens consist of one of the following combinations:

- Stavudine + lamivudine + Efavirenz or
- Stavudine + lamivudine + nevirapine.

Efavirenz needs to be avoided in pregnant women and intramuscularly contraceptive measures are advised for women in the childbearing age who are using efavirenz as part of their regimen. The WC DoH (2004: 12, 13) furthermore recommends that any change in treatment decisions need to be made by an experienced doctor. When the client adhered to treatment and failed the first regimen then treatment can be changed to didanosine + zidovudine + lopinavir / ritonavir. Care need to be taken when patients are using didanosine. Clients needs general education about taking didanosine alone on an empty stomach an hour or two hours before food and dissolved in 30 ml of water or clear apple juice only and lopinavir / ritonavir must be stored below 25 degrees Celsius (Provincial Administration Western Cape Collaborative group, 2004: 12, 13).

2.4.4 Some Private Facilities offering ART programmes in SA

2.4.4.1 Aid for AIDS (AfA)

Members of medical schemes that are contracted with AfA may join the AfA programme when their HIV-positive status is confirmed. Early registration to the programme is encouraged and therefore AfA advices that clients should not wait
until they qualify for treatment but encourages scheme members to join the programme as soon as they are diagnosed with HIV infection. This will hold benefit for the client to access early vaccination, vitamin supplements and immunisation (AfA, 2002:65 - 67).

AfA consist of a medical team who assess the application and authorize ART based on their clinical guidelines working closely with the treating doctor at the same time. They also have a treatment support line whereby regular contact is made with clients to encourage adherence to the programme (AfA 2002:65 - 67). Services offered to HIV - positive members who wish to join the AfA programme, are access to ART, multivitamins and prophylaxis for instance co - trimoxazole. Clients are reminded to adhere to their follow up examinations and tests. Vaccinations are offered to protect clients against illnesses like flu etc. AfA can refer clients to various counsellors and support groups within South Africa. Ongoing monitoring and support is offered by the AfA team to ensure the most suitable and cost - effective regimen is selected (AfA, 2005:21).

2.4.4.2 Qualsa health risk management

Qualsa health risk management specialists have been in the managed healthcare field for a long time offering risk management to their clients. Since 2002 they formed part of Metropolitan health, a healthcare administrator and New Africa Capital Limited, a Metropolitan holding company. Qualsa offers a
complete HIV / AIDS programme to employers. They state that people infected with HIV / AIDS can lead a productive and healthy life if the disease is managed. One of the services offered by Qualsa is care and support to HIV infected persons. According to this programme, professional and other well skilled staff uses all forms of communication to their clients to manage HIV / AIDS. Support and education is offered, counselling clients pertaining to adherence to ART (Qualsa health risk management specialists, [sa]).

2.4.4.3 MX Group

MX Group managed care programme focuses on empowering and educating their clients. Hereby their clients manage their healthcare costs without settling for a lower quality of life. One of their services is to provide a 24 hour toll - free health on call line to their clients. Their disease management and support programme offers a wide and systematic HIV / AIDS disease management and support programme, assisted by specialists and experts in this field (MX Group, 2004:[sa]).

2.4.4.4 Calibre Clinical Consultants

Calibre Clinical Consultants is a privately owned company founded in 1996 representing over one million lives on their programme. They specialize in all areas of HIV / AIDS disease management and offer up to date information and
assistance to their clients. Services include a 24 hour crisis and call centre, doctor’s line, disease management, training & education, pharmacy, laboratory, HIV conference, Insurance and other products. Clients undergo pre-certification whereby a variety of tests are done to determine the appropriate treatment for their clients (Calibre Clinical Consultants, [sa]).

2.4.4.5 Lifesense
According to Lifesense, HIV / AIDS with its impact is more severe than the Bubonic plague that killed 1/3 of the population of Europe more than 700 years ago. HIV / AIDS have a much longer process than the Bubonic plague until death occurs. Their vision is to assist their clients who are HIV infected to lead a healthy, active and productive life in their society and at work. They also assist their clients with the formulation of HIV policies at work. Lifesense offer a 24 hour call centre supporting their clients. Professional staff, to provide in the needs of their clients, manages this call centre (Lifesense, [sa]).

2.5 HIV prevalence
2.5.1 Internationally
O’Brien, et al. (2000:797) reported that HIV was seen as the subsequent leading cause of mortality for persons aged 25 – 44. A number of 42 million HIV infections were reported among 9 million adults and 1.1 million children with 66%
of the world’s infections residing in Sub-Saharan Africa (O’Brien, et al. 2000:798). Cefrey (2001:37) found that further literature predicts that over 100 million people around the world would be infected with HIV by 2005. In addition to this, areas where the incidence is disturbingly high are in Africa, East Asia and India. About 24 million people are already infected with HIV in Africa, 11000 infected daily and 11 million AIDS orphans produced due to AIDS deaths. Three point seven million people in India are already infected with HIV and it is speculated that many more cases stay undiagnosed. Close to 6.5 million people in East Asia were infected with HIV in 1999 and the most common way of infection in East Asia is due to heterosexual relationships (Cefrey, 2001:37 - 39).

The first person infected with HIV was diagnosed in 1986 in Chennai, India. Statistics reported by the World Health Organisation (WHO) and UNAIDS in 2001 found that in the region of 3.97 million people in India are presently infected with HIV and it is evident that India has the second highest HIV prevalence in the world following South Africa. SA and India are particularly susceptible to this disease because of their cultural mythology, socio fiscal eminence etc. concerning sexuality and sex, and the marginality of a great amount of people (Modi & Webber, 2003:46 - 47).
2.5.2 Nationally

Allen, Simelela, Makubalo (2000:9 - 10) discussed the main grounds and influence of the HIV epidemic in SA. They added this to sexual behaviour dynamics and high incidence of sexually transmitted disease (STDs). In addition to this, they found that commercial sex, poverty, the migrant employment system, eminence of women, dishonouring and categorization of people living with HIV / AIDS contributed to their findings. The actual prevalence of AIDS in SA is in reality underestimated because of the fact that AIDS is not a notifiable disease.

If no intervention is implemented, the death rate due to HIV / AIDS will more likely double than was experienced in the year 2000. The impact will be bigger amid women and HIV / AIDS will represent 75% of early deaths in contrast with 39% in the year 2000 (Bekker, 2003:15). The report on the 2002 antenatal survey results were deceptive and stated that it gave the sense that a level of stability in the rate of HIV infection was reached in SA. As such it is still not under control. The prevalence rate of HIV / AIDS was almost 0% in the 1980s; between 1993 - 1997 the epidemic became more common; re - infection does not currently add to the occurrence rate and the epidemic rate appeared to decrease between 1998 - 2001. A saturation stage was reached because most of those who were susceptible to HIV by then became infected. In other words, if the total of deaths equals the total of infections, the HIV / AIDS prevalence will remain the same. In conclusion there is in fact an increase in the prevalence of
HIV / AIDS and the Ministry of Health should expand their surveys beyond pregnant women to men, social demographics, etc. (Evian, 2003:29 - 30).

2.6 HIV and the defence system of the body

HIV directly attacks the human immune system causing a reduction in the total number of CD4 cells, making it ineffective to fight HIV (Van Dyk, 2001:7).

2.6.1 Effect of the HIV virus on the human immune system

The impact of HIV on the immune system depends on a person’s age, character, health status and a previous diseases or illnesses. Irrespective of a person’s good health, the HIV virus will eventually cripple the immune system so that it can no longer protect the body against diseases. Rapid multiplication of HIV takes place in the infected person and eventually weakens the immune system (Cefrey 2001:8 - 9, 50; Aidsguide 2006:15).

The body’s defence (macrophages) identifies the HIV virus and attempt to capture an antigen from it. The problem starts when the macrophages make contact with CD4 cells to warn it about the invasion of the HIV virus. This is when the virus attaches its glycoprotein to the outer layer of the CD4 cell, fusing the two membranes together whereby the virus enters the body (Van Dyk, 2001:13; Aidsguide 2006:14; O, Brien, et al. 2000:799).
The viral Ribonucleic acid (RNA) needs to change to viral Deoxyribonucleic acid (DNA) to be able to manufacture more viruses. This process is called reverse transcription. HIV uses its enzyme called reverse transcriptase to change the viral RNA to a double stranded viral DNA. The viral DNA attaches itself to the DNA of the CD4 cell in the nucleus of the cell and makes thousands of replicas of viral RNA and viral proteins (Van Dyk, 2001:13; Aidsguide, 2006:14; O, Brien, et al. 2000:799).

2.6.2 CD4 cell count and Viral Load (VL)

The CD4 cell count determines the immune status or stage of the disease of the infected person. The normal value ranges between 800 to 1050 cells / µl. CD4 cell counts determine the status of the immune system and establish when someone infected with HIV requires ART. It can also be used in the diagnoses of other diseases like cryptococcal meningitis or atypical mycobacteria. The CD4 cell count is expected to increase by the fourth week of starting ART. The VL measures the total amount of viruses in the blood and how fast the virus is multiplying. The VL is also an indication of whether the ART in use is effective and how fast the client progress towards AIDS. The VL is measured in copies / ml or log values. The viral load is expected to be undetectable after 16 - 24 weeks on ART (Bartlett & Gallant, 2001:15; AfA, 2002:3, 21).
2.7 Disease management (DM)

Mc Donald (2001:30) states that HIV / AIDS affects the cost of all aspects of life and this lead to the essentiality that any medical scheme that offer a benefit for ART need to have a DM programme in place to support the stakeholders involved. A DM programme includes patient assessment, treatment guidelines, the need to know what and when investigations are required, client support, counselling, education, health status monitoring and outcome measurement.

All - inclusive clinics restructure and increased responsibility to other than physicians is necessary where skilful chronic care is required. With the latest ART regimens accessed by people living with HIV / AIDS, an increase in the rate of survival is expected. A lifelong commitment is required from both the patient and healthcare providers to make the system work effective (Barker, McCannon, Venter & Mmbara, 2004:7).

Barker, et al. (2004:7) highlighted the fact that effective programmes that will suite all settings in the public healthcare sector are required. Where well-arranged disease management programmes are in place, the outcomes has mostly been measured as favourable. In conclusion, HIV / AIDS should be managed in a disease management programme setting; effective interactive data systems utilized and rather add to than replace the current medical records (Barker, et al. 2004:11).
2.8 Antiretroviral therapy (ART)

The Medicines and Related Substances Control Act No. 101 of 1965 gave powers and functions to the Medicines Control Council to approve all medicines before it can be used in SA. In the USA, medicines have to be approved by the Food and Drug Administration (FDA) before it can be used. In 1987 the first antiretroviral drug called AZT (retrovir®) was approved and in 1989 four drugs were approved to treat opportunistic infections. The first reports on successful combination ART against AIDS was published in 1992 (Cefrey, 2001:33, 36, 50 - 53, South African Medicines Control Council, 2005).

2.8.1 Advantages of ART

ART improves the quality and quantity of life and restores the immune function. It reduces damage caused by the virus and brings a reduction in infection rates. In addition to this it increases client productivity and a reduction in healthcare costs. ART targets reverse transcription, gathering and maturation of the HIV viruses (Miller, 2002:16). The Southern African HIV Clinicians society (2002:22) reported that ART inhibit two viral enzymes required for HIV viral replication. These enzymes are reverse transcriptase (RT) and protease. RT is required to complete the beginning phase of HIV reproduction while protease is required to assemble and mature the virus.
2.8.2 Different Classes of ART

There are four classes of ART used in the treatment of HIV (See table 2.2). The fourth class (Ribonucleotide Reductase Inhibitor) consisting of Hydroxurea is not indicated on the table as it is no longer used (AfA, 2002:11 - 16). Tenofovir (TDF) is a nucleotide reverse transcriptase inhibitor (NtRTI) that enhances bioavailability that is improved by a fatty meal (AfA, 2005:19). Tenofovir can be used with all the NRTIs, PIs and NNRTIs and is mainly used in salvage therapy in SA. The main side-effect is nephrotoxicity and regular monitoring of renal function is recommended (AfA, 2005:20).
### Table 2.2  Classes of antiretroviral drugs & common side - effects

<table>
<thead>
<tr>
<th>NRTI</th>
<th>NNRTI</th>
<th>PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zidovudine (AZT / Retrovir ®)</td>
<td>Nevirapine (NVP / Viramune ®)</td>
<td>Ritonavir (RTV / Norvir ®)</td>
</tr>
<tr>
<td>Side - effects:</td>
<td>Side - effects:</td>
<td>Side - effects:</td>
</tr>
<tr>
<td>NRTI</td>
<td>NNRTI</td>
<td>PI</td>
</tr>
<tr>
<td>Zidovudine (AZT / Retrovir ®)</td>
<td>Nevirapine (NVP / Viramune ®)</td>
<td>Ritonavir (RTV / Norvir ®)</td>
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<tr>
<td>Side - effects:</td>
<td>Side - effects:</td>
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<tr>
<td>NRTI</td>
<td>NNRTI</td>
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<tr>
<td>Zidovudine (AZT / Retrovir ®)</td>
<td>Nevirapine (NVP / Viramune ®)</td>
<td>Ritonavir (RTV / Norvir ®)</td>
</tr>
<tr>
<td>Side - effects:</td>
<td>Side - effects:</td>
<td>Side - effects:</td>
</tr>
<tr>
<td>Nausea, vomiting, myalgia</td>
<td>Rash, hepatitis</td>
<td>Nausea, diarrhoea, perioral</td>
</tr>
<tr>
<td>headaches, anaemia</td>
<td></td>
<td>parasthesia, headache,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>raised liver functions.</td>
</tr>
<tr>
<td>Stavudine (d4t / Zerit®)</td>
<td>Efavirenz (EFV / Stocrin®)</td>
<td>Indinavir (IND / Crixivan®)</td>
</tr>
<tr>
<td>Side - effects:</td>
<td>Side - effects:</td>
<td>Side - effects:</td>
</tr>
<tr>
<td>Peripheral neuropathy,</td>
<td>CNS effects including</td>
<td>Kidney stones, hyper</td>
</tr>
<tr>
<td>anaemia, lactic acidosis</td>
<td>dizziness, sleeplessness,</td>
<td>bilirubinaemia, hair loss</td>
</tr>
<tr>
<td></td>
<td>delusions, acute</td>
<td></td>
</tr>
<tr>
<td></td>
<td>depression, poor</td>
<td></td>
</tr>
<tr>
<td></td>
<td>concentration, bad</td>
<td></td>
</tr>
<tr>
<td></td>
<td>dreams, inappropriate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>behaviour, somnolence</td>
<td></td>
</tr>
<tr>
<td>Lamivudine (3tc®)</td>
<td></td>
<td>Saquinavir (Invi-rase®,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fortovase®)</td>
</tr>
<tr>
<td>Side - effects:</td>
<td>Side - effects:</td>
<td>Diarrhoea, abdominal pain,</td>
</tr>
<tr>
<td>Pancreatitis</td>
<td></td>
<td>nausea</td>
</tr>
<tr>
<td>Didanosine (ddi / videx®)</td>
<td></td>
<td>Nelfinavir (Viracept®)</td>
</tr>
<tr>
<td>Side - effects:</td>
<td>Side - effects:</td>
<td>Diarrhoea, rash, abdominal</td>
</tr>
<tr>
<td>Peripheral neuropathy, initial</td>
<td></td>
<td>pain, vomiting</td>
</tr>
<tr>
<td>nausea, pancreatitis, headache</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zalcitabine (ddc / Hivid®)</td>
<td></td>
<td>Lopinavir / ritonavir (kaletra®)</td>
</tr>
<tr>
<td>Side - effects:</td>
<td>Side - effects:</td>
<td>Diarrhoea, nausea,</td>
</tr>
<tr>
<td>Peripheral neuropathy, nausea,</td>
<td></td>
<td>gastrointestinal disturbances (GIT)</td>
</tr>
<tr>
<td>gastrointestinal disturbances (GIT)</td>
<td></td>
<td>Increased lipid levels</td>
</tr>
<tr>
<td>Abacavir (Ziagen®)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Side - effects:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypersensitivity reaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>including rash, GIT</td>
<td></td>
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</tbody>
</table>

### 2.9 Drug interactions

A drug interaction is the alteration of a drug’s effect due to a previous or simultaneous administration of another drug. Mechanisms whereby drugs may
Pharmacokinetic mechanism - Gastro intestinal absorption of drugs can be affected by the use of other drugs at the same time. Drug interaction can change the spreading of a drug by either competing for plasma protein binding or displacement of a drug from its tissue binding sites.

• Competing for plasma protein binding can escalate the free concentration and effect of the displaced drug;

• Displacement has a tendency to increase the blood serum level of the displaced drug.

Metabolism of a drug can either be induced or inhibited by the simultaneous administration of other drugs. In other words the liver microsomal drug - metabolising enzyme is either induced or inhibited and consequently affects the outcome or effect of a drug. The effect of liver enzyme induction normally takes place after seven to 10 days and tends to take longer to dispel after the enzyme inducer is stopped. Some examples of drugs that may cause enzyme induction are barbiturates, carbamazepine, phenytoin, and rifampicin. Hepatic microsomal metabolism inhibition normally takes place quicker than the induction of it. Some examples of drugs causing inhibition are allopurinol, chloramphenicol, cimetidine, erythromycin, fluconazole, fluoxetine, isoniazid, sulfonamides. The simultaneous use of another drug can affect the excretion of the active drug through the
kidneys as a result change the effect of the drug (Hansten in Bertram & Katzung, 1992:931; MacDermott & Deglin, 1994:200).

- **Pharmacodynamic Mechanism** - An augmented (greater) response is seen when drugs with the same pharmacological effect is used simultaneously. On the other hand, when drugs with opposite pharmacological effects are administered simultaneously, response to one or both drugs may be decreased.

- **Combined toxicity** is when two or more drugs that have an effect on the same organ are administered simultaneously and increase the risk for damage to that specific organ.

Patients often use other medication, either chronic, over the counter or acute while receiving ART at the same time. The risk for potential drug interactions cannot be ignored. The main function of drug interactions is by meddling with hepatic metabolism. Either enzyme induction or enzyme inhibition takes place during drug interactions (AFA, 2002:27).

Non-nucleoside reverse transcriptase inhibitors (NNRTIs) and Protease Inhibitors (PIs) are metabolised by the liver and may induce or inhibit the liver enzymes. Liver enzyme induction can lead to insufficient drug levels and may eventually lead to viral resistance if the patient is using ART. Inhibition of liver enzymes may lead to an increase in drug levels causing the drugs to reach toxic levels in the blood. AFA suggests that certain drug co – administration should
rather be avoided when the drug interactions cause a significant change in drug levels (AFA 2002:27).

Cohen and Maartens (2004:8); Bartlett and Gallant (2004: 78, 86, 265) found that there is a clear pharmacokinetic drug interaction between rifampicin (part of a set TB treatment regimen) and ART. Rifampicin induces certain liver enzymes and therefore reduces the drug levels of NNRTIs and PIs. The alternative TB drug to use is rifabutin, which have a lesser impact on the liver enzymes, but is more expensive and not available within the SA Tuberculosis control programme. Cohen and Maartens (2004:8) & Bartlett and Gallant (2004:265) expanded on the discussion by indicating that efavirenz (Stocrin) a NNRTI is advised by Centres for Disease Control (CDC) as an alternative to use when the clients are using rifampicin. In this case the dose of efavirenz should be increased from the normal dose of 600 mg to 800 mg daily to compensate for the increased metabolism.

Mills, Foster, van Heeswijk, Phillips, & Wilson, (2005) found that African potato (Hypoxis hemerocallidea) and Sutherlandia notably inhibits the metabolism of antiretroviral drugs. Many antiretroviral drugs for instance protease inhibitors and non - nucleoside reverse transcriptase inhibitors use CYP3A4 route to be metabolised and herbal medicines has an impact on the CYP3A4 route, affecting the metabolism of antiretroviral drugs. All forms of the African potato (Hypoxis hemerocallidea) and Sutherlandia for example tea, capsules and tablets were
used for the purposes of this study. The study found that both African potato and Sutherlandia inhibited CYP3A4 significantly. The researchers concluded that when these two herbal medicines are used in conjunction with antiretroviral drugs, it might cause premature inhibition of ART and cause a low drug level of ART. The SA HIV clinician Society (2004:27) & AfA (2005:13) added that the African potato need to be avoided because of its toxic effect on the bone marrow and negative effect on the immune system.

No recorded human studies have shown any positive effects of garlic on the immune system. Some damaging side-effects related to garlic containing supplements were recorded. Virgin olive oil shows no evidence that it could improve the immune system and a disadvantage is the high cost of virgin olive oil (SA HIV clinician Society, 2004:27). They furthermore suggested that patients with chronic diarrhoea should use onion with care due to the gastrointestinal discomfort and abdominal distension caused by onion. They commended on the use of spirulina (blue-green algae) that can be contaminated with toxic agents like microcystis aeruginosa that is toxic to the liver (SA HIV clinician Society, 2004:27).

Sutherlandia frutescens in animal studies could not indicate any clear toxicity and there are currently no recorded human studies that show any negative or positive effect on the human immune system. Lastly phytosterols like moducare could either cause stimulation or inhibition by altering the immune system. The
stimulatory effect can be harmful and eventually lead to HIV reproduction. Studies have showed that moducare does not reduce viral load but that a reduction in viral load is due to the fact that there is a reduction in the immune system’s activity. More studies still need to be done in this field (SA HIV clinician Society, 2004:27).

Abbott, et al. in Meredith and Horan (2000: 62 – 63) reported that St. John’s Wort is commonly used for the treatment of depression, nervousness and anxiety and warned about the adverse effects of St. John’s Wort. Reported adverse effects like fatigue, confusion, severe photosensitivity, allergic reactions, GIT effects, weight gain and drug interactions were mentioned. Bartlett and Gallant (2004:86) pointed out that St. John’s Wort should not be co – administered with PIs and NNRTIs due to the risk of drug interactions.

A notice was sent by Ndlovu and Newton (2005) from Roche Pharmaceuticals warning healthcare professionals about the simultaneous use of rifampicin in combination with ritonavir and saquinavir. In a recent clinical study 11 / 28 healthy volunteers were exposed to rifampicin 600 mg daily with ritonavir 100mg and saquinavir 1000mg twice a day. These subjects developed hepatocellular toxicity of which one had to be admitted to hospital with slight liver failure. The treatment and study was discontinued immediately. This study also found that liver functions soon returned to normal in all these subjects. In light of this study
Roche advised that Rifampicin should not be used simultaneously with saquinavir and ritonavir as part of an antiretroviral regimen.

2.10 Viral resistance

The development of diverse but associated strains of HIV inside the lymph tissue and blood is endorsed by a high tempo of viral reproduction of HIV-1.

In other words this process leads to viral strains within the central nervous system, other tissues and genital system of patients and increases as the infection advances (Martin, 2002:9).

Martin found that diverse resistant viral species is produced as the ART penetration differs in these sites. These resistant viruses, found to be different from the rest of the viruses, can return back into the bloodstream. The fact highlighted was that mutations can be formed by viruses with a high multiplicative potential before the introduction of ART which may lead to the conclusion that single mutations coupled with drug resistance may exist in some clients who have not been exposed to ART as yet. Viral resistance should be suspected where there is an increase in VL while patients are adherent to therapy (AfA, 2005:33).
2.10.1 Resistance testing & treatment failure

Resistance testing can assist the doctors to choose ART regimens where virological failure is present (Miller, 2002:32; Bartlett and Gallant, 2004:23; Richman and Staszewski, 2000:32 - 33). They state that there are two types of resistance testing and these are:

- Genotype assay, a resistance test exploring reverse transcriptase (RT) and protease (PR) genes. Clients can wait up to two weeks for the outcome of the resistance test.

- Phenotype assay, a test measuring the concentration of a specific drug. Clients can wait up to eight weeks for the outcome of the resistance test results.

The costs of both resistance tests are extremely high whereby phenotype assay is more expensive than genotype assay. He added that viral resistance is a result of hereditary mutations (changes) that take place where there is an ongoing HIV replication in the presence of sub optimal drug levels. There are a few factors that contribute to sub therapeutic drug levels. These include poor diffusion of composite into certain body sites, poor patient adherence, drug interactions and poor drug absorption etc. (Miller, 2002:32 - 33).

Richman and Staszewski (1997:2, 4) & Van Dyk (2001:69) state that HIV reverse transcriptase (RT) and protease are necessary enzymes in the replication cycle of the HIV virus and by interfering in their processes you inhibit the replication of
HIV. They found that viruses survive in an altering surrounding. Poor client adherence or structured treatment interruption (drug holiday) will result in periods of suboptimal dosing which can add to faster materialization of viral resistance.

Viral resistance ought to be expected where there is an increase in viral load while clients are adhering to ART. Certain factors that may cause an increase in viral load should be ruled out and therefore it is advisable not to do a viral load if the client had a recent vaccination or acute infection. If there is a constant rise in viral load more than 5000 copies/ml, a drop in viral load of less than 1 log within a period of six to eight weeks or a rise in viral load by more than 0.5logs from the lowest viral load, treatment failure may be expected (AFA, 2002:26).

AFA (2002:26) added that if treatment failure is confirmed in the presence of good adherence to HAART, then a complete change of regimens is required. When a resistance testing is requested, it ought to be pre-authorized by AFA. It is extremely important that at the time a resistance testing is performed, the client remain adherent to the treatment. This is due to the fact that the sensitive virus quickly overruns resistant mutations. It may be useful to continue with an existing regimen a while longer if the client is clinically well and treatment failure suspected.

Volberding and De Lange (2001:S1, S2) found that irrespective of advanced progress in the manufacture of new antiretroviral drugs, treatment failure still
seems to remain a frequent problem. This fact is ascribed due to one of the following factors and that is poor adherence to treatment, drug interaction, poor absorption and the metabolism of drugs. They stated that the drugs are indirectly causing resistant mutations by changing the intracellular setting. The resistant virus grows rapidly in the presence of the antiretroviral drugs and can stay in the body long after the affected drug or drugs are discontinued.

2.11 Adherence

The UNAIDS (2002:153) raised a general concern about extensive provision of antiretroviral therapy (ART) in all societies. A further concern is whether health systems have the capacity to ensure adherence to multifaceted ART regimens. Brannon and Feist (1992:256) define adherence as the behaviour where patients follow their doctor’s prescriptions. There is a general consensus among researchers that an adherence level of 90 – 95% is required to achieve virological outcome for most clients (Compare Bartlett, 2002:27; USA collaborative group, [sa]; Provincial Administration Western Cape, 2004:4, 27; Kent & Dalgleish, 1983:323 -, 324; AfA, 2005:32). AfA points out that once there is a 20% reduction in adherence to ART, an 80% reduction in the effect of ART should be expected (AfA, 2005:32).
2.11.1 Common predictors and causes of poor adherence

Predictors and causes of poor adherence were reported by various researchers and these include:

- Poor patient – doctor relationship
- High pill burden
- Untreated depression
- Poor patient education
- Inability to follow medicine instructions
- Side – effects
- Poor health
- Forgetfulness
- Being too busy
- Travelling
- Sleeping
- Drug & alcohol abuse
- Mental illness
- Difficulty to access primary healthcare & medication
- Domestic violence
- Discrimination
- Poor support
- Regimen planning
- Food limitation
- Financial and marital problems
- Non – disclosure
- Difficulty in securing a doctor’s appointment
- Unwillingness to commence therapy
- The absence of symptoms
- Patient attitude and beliefs


2.11.2 Findings of adherence related studies

Friedland (2002:36), Kent & Dalgleish (1983:23) & Feuerstein et al. (1986:260) pointed out that treating doctors’ estimation of their patients’ adherence is found to be unreliable and Friedland added that the treating doctor’s measurement of their patients’ adherence is less accurate than their patients’ self reports. Studies have shown a difference of 45% in patient self - reporting and doctor’s reporting of their patients’ adherence to treatment. The USA collaborative group ([sa])
confirmed these findings. Clients may also report a higher than normal adherence level to please their doctors. Friedland call this type of reporting “white coat compliance” (Friedland, 2002:36, 37). Kent & Dalgleish (1983:23) furthermore explained that Davis (1966) reported in a study that many doctors who prescribed treatment assumed that their patients did in fact adhere to their treatment. It appeared as though these doctors could not differentiate whether their patients were adherent to treatment or not.

Feuerstein, *et al.* (1986: 260) found in one study that 67% of physicians accounted patient poor adherence to being uncooperative traits, 26% said doctors are responsible for poor adherence of their patients and 40% attributed poor patient adherence to the patients’ failure to understand their recommendations. There is a clear need for clients to understand their doctors’ advice. Kent and Dalgleish (1983:324 – 333) reviewed a study where sixty percent of patients misinterpreted their doctor’s vocal instructions and that doctors overrate their patients’ knowledge about their disease. They also reported that information for example labels on medicine bottles are not easy to understand and tend to be vague (Kent & Dalgleish, 1983:324 - 333).

How serious the illness is perceived by the client or caregiver and how they feel at a specific time may both determine the level of adherence. Studies showed that adherence tend to decrease when the disease is over the acute phase. There is a need for clients to understand their doctors’ advice. Sixty percent of
patients misinterpret their doctor’s vocal instructions. Other reasons for poor adherence found, are due to the fact that doctors overrate their patients’ knowledge about their disease and that information for example labels on medicine bottles are not easy to understand and tend to be vague (Kent & Dalgleish, 1983:324 – 333;). Becker & Maiman (1980) in Brannon and Feist (1992:261) reviewed several studies that have proven that there is a positive relationship between adherence to therapy and patients’ perception of the severity of their illness. Becker added that symptoms like pain tend to motivate patients to follow their doctor’s instructions as long as the symptoms persevere. In contrast to these findings, Vincent (1971) in Brannon and Feist (1992:261) reported on patients diagnosed with glaucoma with the risk of becoming blind; administering their own eye drops three times a day. They knew that they could get blind due to poor adherence but presented with an adherence level of 42% and those who became blind in one eye, reached an adherence level of only 59%. Haynes (1979a) in Brannon and Feist (1992:261) found no consistency in the fact that people with serious illnesses tend to follow their doctors’ recommendations more closely than those with mild illnesses. However, Becker (1979) in Brannon and Feist (1992:261) cited several studies that have proven that patients, who perceive their illnesses as serious, tend to adhere to their treatment regimens more than those not perceiving their illnesses as serious.

Patients who memorize their doctor’s instructions precisely tend to adhere to their treatment regimen. Studies reported that patients forget 40% of information
within 80 minutes, 50% in five minutes and more than 50% immediately after seeing their healthcare provider. The rate of not remembering is due to too many instructions at the same time and studies have shown that information must be reduced to the minimum and reinforced by both verbal and written instructions at the same time (Kent & Dalgleish, 1983:324 - 333).

A study to determine parent adherence was done on children who were put on a 10 day course of penicillin for a streptococcal infection. The parents knew why their children had to take the treatment and were responsible to supervise their treatment for this period. The treating doctors were aware of the study and beforehand informed the parents they would be followed up. By day three, 59% of the children did not receive their treatment and by day six only 29% pursued with their treatment (Kent & Dalgleish, 1983:323 -, 324; Brannon & Feist, 1992:260). Another study done by Davidson & Schrag (1969) in Brannon and Feist, (1992:260 – 261), reported that less than half of the parents who took their children to a clinical psychiatrist adhered to the recommendations given to them at the first visit. Factors that contributed to poor adherence in this study were the psychiatrist’s time of experience, whether the children came with both parents and the length of time in the waiting room. The longer the waiting period in the waiting room, the higher the poor adherence level. Brannon and Feist, (1992:261) concluded that parents tend to have the same level of adherence whether a regimen had to be followed for their own health for that of their children.
In a study done in Senegal (2002:35), 86 patients who started on ART, reached VL less than 500 copies / ml at 18 months (Friedland, 2002:35). A similar VL suppression was supported by two other studies. A study in Cape Town (SA), reported more than 95% adherence at 12 weeks and 90% at 48 weeks of ART. The adherence level was done based on pill count and adherence was similar among English, Afrikaans and Xhosa – speaking patients (Friedland, 2002:35).

Another study done at Soweto (SA) Chris Hani Baragwanath Hospital’s Adult HIV Clinic (Nachega, Stein, Lehman, Hlatshwayo, Mothopeng, Chaisson & Karstaedt, [sa]:2 – 11), measured adherence in a one month self report questionnaire and worked out as a proportion of quantity taken compared to that prescribed (n=66). The adherence level of 58 of these patients was > 95%, 90 – 95% for 6 patients, < 90% for 2 patients. The main reasons for missing dosages were being away from home, running out of pills and inconvenience of the dosing schedule. Adherence level reduced to a large extent due to fear of being stigmatized by the partners. Nachega, et al. ([sa]: 10) concluded that acceptable adherence levels and VL suppression is reachable in resource limited settings like Soweto, South Africa.

Another study included three sites in Cape Town, SA, and these sites were Cape Town AIDS Cohort (CTAC), Somerset Hospital, Médecins Sans Frontiérs (MSF) ARV programme, Khayelitsha and Hannan Crusaid Treatment Centre, Gugulethu (Orrell, et al. 2003:20 – 22). Each site had a different method to gather
adherence data. CTAC collected data though pill counting where patients had to bring their pills with every follow up visit over a study period of 48 weeks. These patients received education before entering the trail and this was reinforced by nurses and doctors with each follow up visit. The overall majority of these patients did not speak English and 42% had a poor socioeconomic background (Orrell, et al. 2003:20 – 22).

The MSF sites (n=177) in Khayelitsha used the AIDS clinical trial group (ACTG) self – report 4 – day recall questionnaire to determine how many dosages were missed the last 4 days. The questionnaire was translated into Xhosa. Patients had support from lay counsellors, a friend or family member trained to offer support away from the site. The third site, Hannan Crusaid Treatment Centre (n=43) used the 4 – day recall questionnaire, pill counting, on – site and off – site education by treatment support counsellors and surprise visits to do pill counting (Orrell, et al. 2003:20 – 22).

CTAC cohort presented with an adherence outcome of 94.1% with 63% of patients with an adherence level of more than 95% and 73% with fully suppressed VL at 12 weeks follow up (n=270). At 48 weeks the adherence level was 87.2% with 56.1% patients who had an adherence level of > 95%. At three months, the MSF cohort presented with 89% of patients who were > 95% adherent and 91% achieved VL suppression. Ninety five percent of the Hannan Crusaid Treatment Centre cohort were adherent and 93% had VL suppression.
This study has proven that poor adherence should not be assumed in resource limited settings in South Africa (Orrell, et al. 2003:20 – 22).

2.11.3 Measuring adherence

There are various ways to measure adherence to a treatment regimen. Examples are client self-report, pill counting, report by the primary caregiver, MEMS caps, clinical outcome, claims history and when clients have missed or attend late visits to the clinics. (Asia collaborative group, [sa]; Friedland, 2002:36, 37; USA collaborative group, [sa]; Bartlett & Gallant, 2004: 59 – 60; Provincial Administration Western Cape, 2004:28, 29).

Self-reporting is commonly used as one of the methods to measure adherence but was found to be an unreliable measure. The clients’ report on their use of ART is used as one way to determine whether they do in fact take their prescribed treatment. Self-reporting is defined as the client’s knack to recollect the dosages used or missed in a three, seven or thirty-day recall questionnaire. Clients tend to recollect more precisely when the selected questions are sensibly chosen; recollect period is short and done in a non-judgmental attitude. Types of questions that can assist when probing about adherence are how many doses the patient missed the last seven days, total doses missed since the last visit, was the treatment taken correctly including time delay and whether there were
any specific reasons why treatment was not taken or skipped (Asia collaborative group, [sa]; Friedland, 2002:36, 37; USA collaborative group, [sa]).

Kent and Dalgleish (1983:324) said that the level of adherence to treatment when asking the patients seem to be good but do not always correlate with factual tests like urine or stool testing. In conclusion they state that by asking patients about their adherence to treatment are found not to be sufficient to measure adherence and added that if factors that predict poor adherence are dealt with, then adherence will improve. Measuring patients’ blood tests results is a more accurate way of measuring adherence of those patients using ART. Patients are expected to reach undetectable VL (< 50 copies / ml) at 16 to 24 weeks on ART and an increase in CD4 cell counts is expected within four to 24 weeks on therapy (Bartlett & Gallant, 2004:61 - 62).

The treating doctor’s estimation of their client’s adherence is said to be unreliable. Friedland reported that the treating doctor’s measurement of their client’s adherence is less accurate than their client’s self - reports. Studies have shown a difference of 45% in client self - reporting and doctor’s reporting of their client’s adherence to treatment (Friedland, 2002:36; USA collaborative group, [sa]). According to Brannon and Feist (1992:257), although patient self – report is more accurate that that of their physicians, they may lie or be uncertain about their adherence to therapy.
MEMS caps are a form of measuring adherence whereby a special medicine bottle is used with a computer chip in the cap. Every time the bottle is opened up, it is recorded and the results can then be downloaded, printed and analysed. MEMS caps sometimes can give a more accurate measure of adherence than self-reporting but cannot be used where clients remove their daily dosages (Friedland, 2002:36 - 37).

All the aids to measure adherence need to be used hand in hand with patient self-reporting. Combining different adherence measures seems to be the most convincing predictor of adherence to treatment (Friedland, 2002:36, 37; USA collaborative group, [sa]).

2.11.4 Strategies to improve adherence

According to AfA (2002:31), regimens and dosages has to be simplified where possible, drug charts kept to monitor compliance and the value of counselling and regular follow up visits should be seen as important factors. Clients need to be assessed for readiness to commit to long-term therapy and the level of adherence need to be measured before changing regimens.

It is important to build a trust relationship between the client and treating doctor. Health care givers should be an accessible source of information with ongoing support. Clients should be allowed to ask questions anytime between their visits,
adherence to ART monitored and intensified where poor adherence is identified. It is important to utilize the whole health care team as well as peer - educators. The impact of new diseases or illness should never be underestimated. Staff training regarding ART and adherence is important and the USA guidelines state that adherence interventions should be included in the job description of healthcare workers (Friedland, 2002:37 - 38; USA collaborative group, [sa]).

Low literacy was found to predict poor adherence. Clients always require information about HIV and they need to know the advantages and risks of the treatment. Specific instructions need to be conveyed to the clients regarding the correct dosing, results of poor adherence and how their health will be affected. Clients need to be educated about HIV, advantages and adverse effects, how treatment should be taken and the importance of not missing dosages emphasized. The total and frequency of pills taken per day should more or less fit within the client's daily routine. Attempts should be made to reduce the number of pills taken daily and food restrictions avoided as far as possible. Support of family and friends must be encouraged as well as continuous support from health care providers (Friedland, 2002:37 - 38; USA collaborative group, [sa]).

The provision of free antiretroviral drugs and access to rural areas by means of mobile vans will benefit people living with HIV / AIDS in resource poor settings. Involvement of family and the community, family based care, use of blister packs
or pill boxes, directly observed therapy (DOT), sufficient stock and storage of ART should be encouraged. The Asian HIV programme recommends that clients who started ART should have a follow up visit one month after starting treatment. Adherence has to be emphasized at every contact with the client. Clients are advised to attend to their follow up visits every three to four months after the first visit. The clients are encouraged to report any side effects or other problems probably due to HIV (Asia collaborative group, [sa]). Before starting treatment, client willingness to start treatment should be clearly determined. The treatment plan should make it easy for clients to commit to. Clients need to know why it is important to take their treatment regularly and what to expect when treatment is not taken regularly or not taken at all. It is advisable to give instructions in writing to assist clients in understanding the use of their prescribed treatment (Asia collaborative group, [sa]).

Clients need to be educated about possible side-effects of the treatment and involving family and friends about adherence matters can contribute to adherence to HAART. It may be to the client’s advantage when issues like active drug / substance abuse or mental illness is dealt with beforehand. In order to improve adherence, clients require emotive and practical support and the ability to fit ART into their daily routine. They need to be educated about the importance of taking ART regularly and adhering not only to ART but also to their follow up visits to their treating doctors (Asia collaborative group, [sa]).
The question asked is whether the client will be able to adhere to long-term treatment. There need to be a client-doctor agreement on the choice of regimen. A consistent assessment and assistance of adherence is required ongoing and intensive client education and support is needed to support adherence to ART. Treating doctors need to discuss the long-term treatment plan with their clients. Ongoing assessment of the level of adherence and counselling has proven to assist adherence to long-term treatment. A clinical finding indicated that one out of three of clients missed doses before the third day of a study done on adherence to therapy (USA collaborative group, [sa]).

Treatment is started based on psychosocial and medical criteria. The medical criteria require that clients be in the WHO stage 4 disease (tuberculosis is not a criteria to start ART unless the CD4 cell count is < 200 cells / µl) or WHO stage 1, 2 and 3 with a CD4 count < 200 cells / µl (Provincial Administration Western Cape, 2004:4). Clients are required to attend three clinic visits before starting treatment and should not have any active substance / alcohol abuse or untreated active depression. Disclosure, insight about the disease, ability to attending the HIV clinic regularly are all factors considered before starting ART. Clients are required to use co-trimoxazole (an antibiotic used to prevent some opportunistic infections) for one month to measure their adherence as a way of preparing them for long-term treatment (Provincial Administration Western Cape, 2004:4).
Once ART is authorized and started, a monthly visit to the HIV clinic is required for three months then a quarterly visit thereafter (Provincial Administration Western Cape, 2004:4). There are many factors that can promote adherence to ART. When clients are motivated, have a good understanding of the ART and the importance thereof, educated in their home language, take part in support groups then adherence tend to increase. Adherence to ART can also be positively affected when there are less side-effects, a lower pill count and when clients are in the late or symptomatic stage of the disease (Provincial Administration Western Cape, 2004:5).

Patients who respond with poor adherence need to be re-educated about the importance of ART and its long-term benefits. They should be encouraged to join a support group and circumstances at home in specific the family situation need to be assessed through the use of a social worker and treatment counsellor. The use of a pillbox and/or a diary to record dosage taken should also be considered including weekly home visits for spot pill counts. Another resort to consider is direct observed therapy (Provincial Administration Western Cape, 2004:28).

Health care providers therefore need to emphasize the importance to take ART regularly and correctly as well as what to do when patients experience adverse effects of the drugs. The importance of treatment readiness is also emphasized (AfA, 2005:32). The doctor and patient need to agree on a regimen and patients
empowered by providing them with information that will help them to increase their insight in ART and the importance of adherence. When deciding on a regimen, consideration needs to be taken to avoid food restrictions as well as a high pill burden where possible. Patients need to be allowed to feel ready to start ART. Depression should be excluded before starting treatment and family and friends’ support ought to be encouraged to act as “treatment buddies” (AfA, 2005:32). The use of any form of memory aids is beneficial and patients need to be encouraged to collect the following month’s treatment a few days before the current treatment is completed. Adherence need to be checked at each visit and side-effects and the treatment thereof should be considered. Patients need have access to healthcare assistance in and outside working hours (AfA, 2005:32 - 33).

2.11.5 Tuberculosis and Direct observed therapy (DOT)

HIV has shifted a lot more attention on the treatment of tuberculosis (TB) due to the association between HIV and TB (Martinson, Hausler, Churchyard & Lawn, 2005:33). This association is due to the fact that HIV infection is the most forceful risk for active TB. They added that adult cohort studies indicated that ART have a huge preventative effect on active TB although ART does not repair the function of the immune system. Hausler in Martinson, et al (2005:33 - 34) reported that there were 8.8 million new cases of TB in the world in 2003 and of the new TB infections, 674 000 (13%) were infected with HIV. Hausler added the
concern that the incidence of TB increased despite the DOTS programme and in order to control TB more effectively, emphasis should be placed on TB prophylactic treatment, more advanced diagnostic measures, new and stronger anti – TB drugs, escalating the search for TB cases and interventions to prevent HIV and TB.

Churchyard in Martinson, et al. (2005:34) reported on the results of 11 randomised trails of pulmonary TB in HIV – infected patients (n=8130) and found that prophylactic treatment reduced the risk of active TB by 33%. Churchyard added that there is an adherence range of 3 – 68% of patients using 6 months prophylactic treatment and that an increase in adherence is achieved where a customized DOTS programme is applied.

Multi – drug - resistant TB (MDR – TB) is steadily on the increase in SA (Bodibe, 2006:8). The total number of TB cases increased from 185 000 in 2003 to 279 000 in 2004 and the current cure rate is 54% compared to the WHOs’ objective of 85%. Bodibe’s (2006:8) report stated that Dr.Lindiwe Mvusi, national TB manager in the SA Department of Health, recognized the fact that there are many problems surrounding the treatment of patients with TB with adherence remaining a problem. She says the increase in TB cases is due to the fact that more people access clinics at an earlier stage of the disease. The result of poor adherence is MDR – TB and the problem of multi – drug – resistant TB is the fact
that it does not respond to the normal TB drugs and requires more expensive
drugs for a period of about 18 months (Bodibe, 2006:8).

Nachega and Chaisson (2000:33) stated that the WHO commenced DOTS
(Directly observed therapy) in 1993. As such it was introduced as a tool to
globally improve the control over tuberculosis (TB). This tool has given rise to
evidence of cost – effectiveness, prevention of multi - drug resistant (MDR) TB
and enhancement to cure.

A summary of five fundamentals important to an effective DOTS programme was
reported by Nachega and Chaisson (2000:33):

- To maintain TB control, the government need to commit
  themselves;
- To diagnose infectious patients, sputum microscopy is
  required;
- The best and most cost effective drug regimen must be a
  standard;
- DOTS must be applied at least the first two months on
  treatment;
- A system (monitoring, reporting) must be set in place in
  order to assess treatment outcome;
- The efficacy of the TB control programme need to be
  evaluated on an ongoing basis.
Nachega and Chaisson (2000:33) stated that the aim of the new SA National Tuberculosis Programme (NTP) is to implement the DOTS programme with 85% uncovering of cases and 70% cure rate in mind. Already 50% of all health districts are applying DOTS and 20% of TB patients in SA have poor adherence to TB drugs with a risk to develop MDR - TB.

“Alternatives to the main approach to tuberculosis care, namely ‘directly observed therapy’, however are needed if the stringent adherence requirements of ARVs are to be achieved.” (Schneider & McIntyre, 2003: 20).

2.12. Counselling

Bekker (2002:30) highlighted the fact that it became necessary for healthcare workers to have counselling skills. Counselling mainly consist of a supportive relationship in an environment structured for these purposes. One person help another through introspection to know more about their situation, emotions, thoughts and how to act around the newly diagnosed disease as well as develop coping mechanisms (Bekker, 2002: 30). According to Baruth and Huber (1985:6), people who search for help are displeased with their lives and seek assistance to change their situation. They furthermore added that the main goal of counselling is to obtain a positive outcome.

Baruth and Huber (1985:6 - 8) documented three areas that influence the performance of people and these are emotional, behavioural and cognitive orientated therapies.
The emotional – slant is where the therapist undertake to accept the client with an understanding of empathy. In this area the patient experiences distrust in themselves and is out of touch with their own feelings. Here the therapist supports the client to trust him/her and to discover their true feelings.

Baruth and Huber elaborated on the behavioural – slant where the client seems to be negative about themselves and does not handle criticism and rejection very well. The therapist will attempt to find baseline information of the rate of behaviour occurrence that will determine where the clients find themselves at the present moment, what behaviour they want to accomplish and how reasonable this goal is. The cognitive – slant is where the client presents with depression and experience self – destruction when they cannot reach their set goals. The therapist will assist the client to substitute self – destructive behaviour with a more plausible outlook on life.

The HIV Clinician Society (2004:28) found that all - inclusive counselling is a huge advantage to people living with HIV / AIDS. The intention of counselling is to assist the individual to get used to a major change in their lives, adopt ways to adjust to it as well as access the medical, social, emotional and psychological support. According to Van Dyk (2001:258 – 259), people living with HIV / AIDS often experience fear, loss, grief, guilt, denial, anger, low self – esteem, depression, suicidal behaviour, hypochondria, loss of income, discrimination and relationship changes. She added that HIV not only affects the HIV – positive individual but also their partners, family & friends and pointed out the need for
them to undergo counselling as well. Counselling is therefore seen as a process whereby people are assisted with problem-solving, reasonable planning and stress management in a practical manner (Blocher, 1987:9). Van Dyk (2001:200) defines counselling as a structured way of assisting clients to review their existing problem and to find ways to adjust to it.

Counselling assist the client to gain more knowledge about their problem, manage their emotions, do introspection about their feeling and thoughts, find answers to their problems and cultivate ways to cope in future (Bekker, 2002:30). The HIV Clinician Society (2004:28) found that it is beneficial for patients to receive counselling from trained healthcare professionals or counsellors from the individual’s own community. In addition to this, extra care may be provided by support groups that are under the supervision of a trained counsellor or member of the support group. They further on emphasized the need for counsellors to undergo debriefing to be able to deal with sensitive information, emotions, fatigue and burnout.

There are four types of counselling and these are voluntary counselling and testing (VCT), pre-test counselling, post-test counselling, life-skills, crisis intervention, family planning counselling and management-related counselling (HIV Clinician Society, 2004:28-29).
2.12.1 Requirements for good counselling

The person offering counselling need to be empathic with a non-judgmental attitude, show the client that he/she has a concern about the issue involved. There need to be a trust relationship between the counsellor and the client therefore it is important to ensure that everything discussed will be treated with the utmost confidentiality. It is advisable to keep the interview private, avoid interruptions as far as possible, keep records brief and if possible attempt to provide the same counsellor with every follow up visit (HIV Clinician Society, 2004:29 – 30; Van Dyk, 2001: 211 - 214). Van Dyk added the values that underlie the counselling process as being:

- Respect: The mindset that depicts the belief that every person has value and the ability to make decisions and has the possibility for growth;
- Genuineness: Where the counsellor represent honesty and transparency in the counselling relationship,
- Empowerment: Where the counsellor give the power to clients to take responsibility for themselves, discover, acquire and utilize means to deal with their circumstances;
- Confidentiality: Where the counsellor is bound by a confidentiality agreement with the patient where no information about the patient’s HIV status or any other information discussed during the counselling process is divulged to anyone not attending the same counselling session.
The client needs to have the idea that the counsellor is listening to what is said. Counsellors are advised to be especially attentive to what is said behind the words. It is important to ensure that the client understand any medical information given. The interview should be client-centred and therefore the counsellor must try and understand their belief system and culture. It is advisable to ask about feelings and to encourage family and partner participation. Some form of realistic hope or a plan needs to be communicated to the client. The use of open-ended questions about concerns needs to be included in discussions to allow more interactions during the interview (HIV Clinician Society, 2004:29 - 30).

Spencer (2003:15 - 17) highlighted the fact that people living with HIV/AIDS have a need to speak out about their thoughts. “When I counsel I’m in the arena of stigma, betrayal, grief and loss, guilt, anger, fear and shame, and countless other emotions, beliefs, disappointments. I seldom look at joy or even tranquillity, except perhaps briefly when the viral load has become undetectable or the CD4 cell count has risen unexpectedly.” Bekker (2002:31), found that ongoing counselling is beneficial for clients because of the client’s requirement to disclose to their partners, problems in relationships and the need to obtain more information about treatment and their well-being.
2.13 Behaviour changes

Feuerstein, et al. (1986:237) found that out of ten foremost causes of death in the USA, seven were related to the non-existence of a range of health behaviours. They added that 37.8% of deaths in the USA were due to coronary heart disease, 20% were cancer and 9.6% were cerebro-vascular accidents and that a correlation exists between good health and a healthy lifestyle such as nutrition, sleep, exercises, food and alcohol self-control. While in Wilson – Barnett (1983:16 – 17) agreed that behaviour is an imperative supporter to illness and loss of life. While furthermore pointed out that positive health behaviour is beneficial for good health and that all areas that could positively impact health should be endorsed.

2.13.1 The Health Belief Model

There are three factors that can predict health and illness behaviour. These are perceived susceptibility to illness, perceived severity and expectancies for efficacy of treatment. People, who believe they could acquire an illness, might be expected to take action to prevent a specific illness than those who believe they are unable to get sick (perceived susceptibility). The patient’s perception of their disease will determine their decision to adhere to therapy. Those who believe that the occurrence of an illness will have serious effects, have the tendency to adhere to their treatment regimens (perceived severity). Brannon et al. found that the severity of an illness is not enough to ensure adherence to therapy and that patients need to believe in the effect of the treatment in order to act on it. Barriers that can impact adherence negatively are the perception of pain, difficulty to access service, side - effects, duration, costliness and complexity of treatment (Feuerstein, et al. 1986:252; Brannon & Feist, 1992:227).

2.13.2 Basic concepts in behaviour change

Kanfer & Saslow (1965) in Phares (1984: 336) suggest that we need to attempt to answer the following questions in behaviour assessment:

- Which specific behaviour patterns need change?
- What are the best practical means to change the behaviour (do we need to manipulate the environment, the behaviour or self - attitude of the patient)?
• What factors are maintaining this behaviour and under what conditions are this behaviour sustained?

Van Dyk (2001:91) gave a summary of theoretical principles of behaviour change in nine points whereby a person is likely to alter their sexual behaviour i.e.:

• The person must realize the need to alter behaviour;
• Know precisely what behaviour needs altered and how to change it;
• Has the intention to execute the new behaviour;
• Has a positive mind - set towards the new behaviour;
• Has the support of family and / or friends;
• Has a resilient belief in the ability to change to the new behaviour;
• Know how to carry out the expected behaviour successfully;
• See that the new behaviour will reap more advantages and rewards;
• Have the skills to execute and sustain the new behaviour.

An individual has a variety of likely behaviours that may be attempted to achieve a certain goal (Phares, 1984: 360). For example when two people meet for the first time, a specific behaviour may be selected to leave a specific impression. Then there is expectancy whereby behaviour potential is controlled by how seriously you want something and the extent to which you believe that a specific behaviour will achieve a specific goal. Reinforcement Value is the measure whereby a person places preference for anything that may lead to other reinforcements of value. For example money has no value in itself but it can buy
other reinforcements of value like food, clothes, cars etc. Other factors that might contribute to behaviour change are psychological situation, predictive values, problem-solving expectancies and this is the degree to which one can depend on the words of others.

2.13.3 Stages of behaviour change

The four stages of behaviour alteration are precontemplation where the person is unaware of having a problem. The next stage is contemplation whereby the person becomes aware that a personal problem exists and is earnestly thinking of behaviour change. Then there is action stage where the person actually changes the behaviour and environment that affect their behaviour. The last stage is maintenance where the person works towards sustaining this newly acquired behaviour (Van Dyk, 2001:92; Draye in Meredith & Horan, 2000:116).

2.14 Mother-to-child transmission (MTCT)

HIV can be transmitted to the unborn baby in utero, during delivery or by means of breastfeeding. Should no intervention be done to reduce the risk of transmission of HIV, the chances for transmission rate is 20 to 40%. Expecting mothers on the AfA programme are encouraged to undergo Caesarean section instead of a normal delivery; pregnant mothers are encouraged to adhere to ART. AfA’s clinical guidelines suggest HAART from the beginning of twelve
weeks pregnancy if ongoing ART is not required. Mothers are discouraged to breastfeed after delivery. With all interventions, the risk for transmission is reduced to less than five percent. Eight hours after delivery, the baby is required to commence with AZT syrup (retrovir®) up to six weeks after delivery and 2kg formula milk is authorized monthly for six months. Mothers are requested to take their babies for a full blood count follow up test after two weeks on AZT syrup. A qualitative HIV PCR is requested to be performed six weeks after birth to determine whether transmission of the virus was prevented through MTCT (AfA, 2002:38–39; Bartlett & Gallant, 2004:102–112).

2.15 Adapting a healthy lifestyle

Brannon & Feist (1992:192–193) & Feuerstein, et al. (1986:237) found that coronary heart disease and cerebro-vascular disease are closely linked with a lifestyle that can negatively impact their health. These types of behaviour are normally accomplished over years and many people do not wish to change this behaviour. People need to acknowledge that unhealthy behaviour put their health at risk before they work towards changing this behaviour.

A lot of emphasis has been placed on endorsing health and preventing illness in a health care setting (Draye, 2000:111). Draye added that many people in the USA are embracing healthy lifestyles with respect to keeping fit, nutrition and steering clear of risk to health such as smoking. The aim of endorsing a healthy
lifestyle is to increase consciousness of health hazards and means to reduce or eradicate these hazards through education and counselling. HIV / AIDS made it necessary for those infected to make essential lifestyle choices. There is a need to provide those infected with the necessary information and skills that will enable them to lead a healthy lifestyle. Nutrition, exercise, hygiene, stress management and timely treatment of infections are the five ways whereby a healthy lifestyle can be maintained according to Calibre, ([sa]:36). In addition to these are sleep, access to health care systems, personal hygiene, emotional and psychological well – being, weight watching, limit or avoid smoking, use of medication, alcohol use, drug or other substance intake and the environment (Feuerstein, et al.1986:243).

2.15.1 Nutrition

HIV infection reduces body proteins, specifically in the late stage of HIV, resulting in weight loss (AfA, 2005:12). Weight loss could be attributed to depression, poor dental care, oral thrush and other HIV related conditions. Patients might experience loss of appetite or diarrhoea caused by ART. AfA also noted that patients can loose weight rapidly due to TB and cancer. According to the Aidsguide (2006:82 – 83), good nutrition can assist to maintain and improve the nutritional status of a person living with HIV / AIDS and delay the progression from HIV to AIDS. People infected with HIV need to realize the importance of taking control of their nutrition in order to increase their quality of life. Multiple
nutrient deficiencies start once HIV infection takes place and there is a 20% higher need for resting energy than those not infected with HIV. This is explained by the fact that energy is consumed in the attempt to fight HIV (Calibre, [sa]:36). Saunders (1994) in Van Dyk (2001:371 – 374) noted that good nutrition including, vitamin supplements and protective food may improve the immune response to HIV infection and protection against opportunistic infections.

2.15.2 Weight loss and HIV wasting syndrome

Nutrition plays a very important role in all stages of HIV infection. Clients need to concentrate on eating healthy, following a balanced diet and regular exercises. Many factors can cause diminished food intake. These factors are socio-economic circumstances, fear, depression, oral and oesophageal candidiasis and diarrhoea (The HIV Clinician Society, 2004:22; AfA, 2005:12).

A person’s physical activities decrease where there is a weight loss of more than 10% of the initial body mass. Hospitalisation tends to increase in patients where there is a weight loss of more than 20%. Death may occur when weight reduces around 54% of the initial body mass (The HIV Clinician Society, 2004:26).

When patients loose > 10% of their body weight and in addition to this, present with diarrhoea with no clear cause for more than a month, or chronic weakness and unexplained fever for more than a month, they are said to have HIV wasting syndrome (AfA, 2005:12; Bartlett, 2004:4). Chlebowski, Beall, Lillington,
Richards, Abbruzzese, Mccamish & Cope (1995: 250) added that there is an increasing weight loss occurrence among a great majority of individuals infected with HIV. Strategies to counter HIV wasting syndrome is stalled by improper nutrition and energy consumption, hypermetabolism, endocrine malfunction, malabsorption, GIT infections and systemic consequence of infections.

According to Calibre ([sa]: 36 – 37), HIV affects the body’s ability to manufacture and sustain muscle, which is an important store of nutrition. The body can use these stores as a reserve when there is a reduced intake of nutrients in the body. HIV infection can seriously affect appetite and infections of gastrointestinal tract (GIT) can further reduce the absorption of nutrients eventually adding to loss of weight, malnutrition and increase risk of infections.

There are two types of HIV-related wasting syndromes, the starvation - related wasting syndrome and Cachexia - related wasting syndrome (HIV Clinician Society, 2004:22). The first mentioned wasting syndrome results from voluntary or involuntary food deprivation. This condition can be improved through nutritional support. Cachexia - related syndrome is an imbalanced decrease in lean body mass (LBM). This condition happens because of changes that take place in the body’s metabolism. The body looses proteins and nutritional support is found to be insufficient to improve this condition.
2.15.3 Maintaining body mass

According to Brannon and Feist (1992:393), body weight is maintained when the calories taken in from food, is equivalent to food consumed by the body’s metabolism and physical activity. Adequate energy and protein intake is important to maintain body mass. The following types of food are recommended (The HIV Clinician Society, 2004:26):

- Different types of food;
- A lot of vegetables and fruit;
- Carbohydrates as the basis of each meal;
- Portions of meat and dairy products daily;
- Fats, sugar and oil should be added to the meals especially after recent weight loss;
- Dried beans, peas, lentils, soy or peanuts should be taken in regularly;
- Eat frequent small meals during loss of appetite;
- Soft moistened food is advices when there are sores in the mouth or when there is a sore throat;
- Isotonic fluids are advised when the person presents with diarrhoea and / or vomiting. Patients are advised to eat bananas, porridge and oats when presenting with these symptoms;
- Drink a lot of clean water;
- Exercises are important.
Salt need to be used in moderation and patients must avoid lying down after a meal. Food should preferably be eaten at room temperature when there are symptoms of nausea. Spicy, acidity, sticky, coarse food need to be avoided when there is a sore mouth or throat. When patients have symptoms like diarrhoea or vomiting, it is better to avoid caffeine - containing products like coke and coffee (The HIV Clinician Society, 2004:26). Van Dyk (2001:371 – 372) divided the different types of food into three categories and suggested that in order to eat a balanced meal, everyone should always include food from all three categories into every meal. These are:

*Energy giving* foods, body building foods and protective foods. Energy foods are carbohydrates that include potatoes, yams, wheat, samp, brown rice, maize meal, rice, oats, mabela, rye, brown and whole wheat bread. Sugar, animal fats and vegetable oil is necessary when patients want to gain weight;

*Body building* foods are proteins, important for the development of muscle, cells, teeth and bones. Body building foods include dry peas, beans, soy, lentils, peanuts, nuts, eggs, red meat, chicken, fish, cheese and milk;

*Protective* foods are vitamins and minerals that include vegetables and fruit, important in fighting infections and supporting the immune system. These are carrots, pumpkin, sweet potatoes, pawpaw, spinach, marogo, cabbage, beetroot, oranges, tomatoes, guavas, green beans and lettuce.
2.15.4 **Exercise and rest**

Brannon and Feist (1992:444) reviewed the advantages of exercising and found it to be beneficial in muscle building, adds flexibility, reduces depression, anxiety, stress reduction and increases self-worth. The HIV Clinician Society (2004:22) & Van Dyk (2001:367) added that exercises help breathing, cleanses lymph nodes, removes toxins from the body by enhancing sweating, increases the flow of oxygen to all parts of the body and helps to build muscle by preventing wasting and nutritional shortages. Van Dyk furthermore reported that people living with HIV/AIDS should get enough rest and sleep to enable them to continue with an exercise programme.

Clients need to discuss a planned exercise programme with their treating doctor before commencing the exercise programme. An exercise programme needs to be followed about three or four times a week for 30 minutes at a time. Exercises should be done in moderation and it is important to avoid excessive exercises because it may lead to increased metabolism resulting to a speed up in wasting (Calibre, [sa]:42; The HIV Clinician Society 2004:22). Van Dyk (2001:367) agreed that a regular exercise programme includes three times a week sessions but said it should be kept moderate when patients present with diarrhoea, fever or cough.
2.15.5 Illness and stress

Stressful life events contribute to various physical disorders and these are tension headaches, cardiovascular disease, ulcers as well as psychological disorders like depression, schizophrenia and anxiety disorders (Brannon & Feist, 1992:95 -104). Brannon and Feist stressed that one should expect a reasonable association between illness and stress and found that many researchers validated this prospect. They added that people who experience more stress than others are more likely to develop an illness but pointed out that some people are able to manage high stress levels without getting sick while others might get sick.

Kent and Dalgleish (1983:247 - 249) found that a person is equally affected biologically as well as psychologically when becoming ill. Many studies have shown that the effects of illness are amalgamated by social dynamics. The reaction to kidney failure and viral infections is depression. Devlin et al. in Kent et al. reported that 25% of people who went through anorectal cancer surgical intervention mainly presented with depression. Many patients complained that their sexual relationships were affected, due to fear of spilling contents and shame. Impotence prevalence was high and less than 50% took pleasure in a normal sex life.

Doubt and unpredictability about health care is partly related to stress during illness. To be moved from a known environment at home to a hospital, moving
from one ward to the other, observing illness and death of other patients can also negatively affect patients. In a study done with twenty-nine patients in a coronary care unit, 17 observed death and emergencies in the coronary unit. Their blood pressure and anxiety levels were weighed against the rest who did not observe death and emergencies in the coronary care unit. They found that 13 had unusual physiological response while more than half of the 17 patients had increased anxiety levels (Kent & Dalgleish, 1983: 249).

2.16 Coping with new circumstances

Fractions of people’s beliefs, values and attitudes about events determine the way they react to stressful events. Researchers found that the reasons for people’s stressful responses are due to their perceptions that point towards their belief standpoint. Their viewpoint is that once these belief standpoints are changed, the events will be less stressful (Kent & Dalgleish, 1983:260).

Van Dyk (2001:274 – 275) advised that stress can be treated with medication when there are physical symptoms; stress management by means of relaxation exercises; by enhancing quality of life; avoiding stressful situations; exercising; eating balanced meals; meditation and by talking to family and friends about stress related problems.
2.17 Summary

In summary, the impact of HIV / AIDS and its treatment highlighted the importance of the need to have an effective disease management programme in place. It has also brought about the emphasis for health care workers to have counselling skills in place. People living with HIV / AIDS have a need to be empowered with knowledge about the disease and its impact in order to make informed decisions about their health and their future in the midst of myths and mixed messages. Poor adherence to a treatment regimen has remained a huge problem throughout the world and effective management is needed to improve adherence to treatment. Not only should patients be educated about their disease but also encouraged towards behaviour change that would enhance their health status. In order to reach this goal, the commitment of the patient and health care providers are required and patients need to be encouraged to involve family, friends and the community for social support.
Chapter three

Methodology

3.1 Introduction

The objectives of this study were to estimate the impact of adherence guidelines used by treatment support counsellors. This chapter offers a comprehensive description of the research methodology followed during this research project. A detailed description of the participants, the research design, study population, data collection and data instrument will be given in this chapter.

3.2 Research approach

Standardized methods were used to obtain answers to the research questions. The research approach was systematic to enable the researcher to check for accuracy and the ability to generalize the results to the AfA population. The study strongly focussed on the effect of guidelines on the behaviour of clients towards an increase in adherence to HAART. The objective was to determine whether or not there will be a significant difference in the adherence outcome between the intervention group (IG) and comparison group (CG) in other words, whether adherence guidelines prompted an increase in the adherence level of clients towards HAART. Information was obtained telephonically and directly from those clients who registered on the AfA programme. This information was obtained from the study population through the application of adherence
guidelines by means of questions, information and reminders. Biographical variables, baseline results, primary and secondary outcomes were obtained through a CRF.

3.3 Research design

A Quazi-experimental design was chosen for the purposes of this study (McBurney, 2001:333 – 336; Blocher, 1987:383; Sarafino, 1996:380). The researcher was unable to randomly allocate subjects to the two groups and wanted to observe the outcome of the experiment in a natural setting. Not being able to randomly select the two groups and by applying adherence guidelines in a natural setting, limited the researcher's control over the experiment. The IG was exposed to the independent variable (adherence guidelines) and the CG was not exposed to the independent variable. Both groups were measured under the same outcome test. The outcome test included total contacts made with clients, CD4 & VL results, claims history, doctor visits and hospital admissions. A comparison was drawn by means of biographical and baseline data to determine the similarity of the two groups. Another comparison was drawn by means of primary and secondary outcomes.

The researcher aimed at determining the effect of an independent variable (adherence guidelines) on dependant variables. The research was conducted by means of data gathering and all the data selected were seen as part of an
experiment where the formulated adherence guidelines were tested in the IG. The data analysis aimed at determining the face value and content validity of the guidelines. Reliability of the research instrument was tested by training treatment support staff about the accurate use of the instrument, getting them to apply the adherence guidelines through a pilot study and by obtaining feedback about potential errors in the research instrument. Every designed procedure need to be tested to search for and correct any errors that might prevent the smooth application of the instrument (McBurney, 2001: 228 – 229; Blocher, 1987: 164 - 165). McBurney added that the reliability of the results increase enormously when a study was lead by a pilot study.

### 3.4 Study population

Two groups were selected for the purposes of this study. One group was identified as the IG where adherence guidelines were applied and subjects contacted monthly for the study period of six months since starting therapy. The second group was a historical group called CG where no structured adherence guidelines were applied and there were no control over a total number of contacts with the subjects.

The study population included all men and women over the age of 21 years who registered on the AfA programme for the first time, had no previous experience of ART and qualified for HAART. The researcher selected adults over the age of 21
to limit the potential age variables. A number of 40 participants for the IG were systematically selected (McBurney, 2001:248) from the overall population who registered on the AfA programme from 01 October 2004 until 30 November 2004 in other words, the first 40 patients who registered on the AfA programme over this period and who met the inclusion criteria (See 3.5) were selected. A total of 40 participants for the CG were systematically selected from the overall population who registered on the AfA programme from 01 February 2004 until 31 March 2004 and who met the same inclusion criteria as the IG. Patients who registered on the AfA programme and met the inclusion criteria had a 100% chance to be selected for this study (McBurney, 2001:248).

3.5 Inclusion criteria

Men and women over the age of 21 years;

Registered on the AfA programme;

Started HAART for the first time within the period (months) as mentioned in the study population section;

CD4 cell count of $\leq$ 250 cells/µL or qualified for ART based on an Aids defining illness;

Subjects had to be members of a medical scheme administered by Medscheme Pty Ltd. Treatment support staff does not have direct access to the claims history of medical schemes that is not administered by Medscheme Pty Ltd. To ensure reliability and avoid a delay in access to claims history of patients, the
researcher chose to exclude all schemes not administered by Medscheme Pty Ltd.

### 3.6 Exclusion criteria

The exclusion criteria included the following:

- All clients under the age of 21 years;
- All medical schemes not administered by Medscheme at the time of the study period due to delay and no direct access to their claims history;
- All corporate clients of AfA;
- All medical schemes administered by external parties;
- All international clients of AfA;
- All the clients who received post exposure prophylaxis (PEP) at the time;
- All clients with a CD4 cell count over 250 cells / µL who had no Aids defining illness;
- Clients who had experience in using ART were also excluded.

### 3.7 Intervention group (IG)

A systematic sampling selection was used to choose the participants of the IG. This was done by means of a predetermined system. Prospective data were obtained for the IG. The study population was chosen from the overall AfA population who started ART for the first time from 01 October 2004 to 30
November 2004. Selection criteria were followed for the purposes of this study. A total number of 40 subjects were selected from the overall AfA population based on the inclusion criteria.

A standard operating procedure (formulated adherence guidelines); emphasizing factors that may affect adherence in a positive or negative way were applied at every contact with these subjects. Subjects were contacted on a monthly basis for the study period of six months. The contacts with subjects started from the beginning of treatment for six months.

3.8 Comparison group (CG)

A systematic sampling selection was used to choose the participants of the CG. A predetermined system was used for these purposes. Retrospective data were obtained for the CG. The study population were selected from the overall AfA population who started ART for the first time during 01 February until 31 March 2004. Selection criteria were applied to ensure that both groups were more or less the same.

The initial 40 subjects selected from the overall population were reduced to 34 subjects after the selection criteria were applied. The CG was not exposed to the formulated adherence guidelines before. There were no control over when and whether these subjects were contacted, what information was exchanged
between the treatment support counsellors and these subjects. The study period was a period of six months after starting ART.

3.9 Research instrument

3.9.1 Adherence guidelines

The adherence guidelines were administered to all subjects in the IG. The research instrument was a newly formulated adherence guideline that was applied at every contact with the participants (see APPENDIX II). This tool was formulated based on adherence literature as well as inputs from AfA. The researcher included inputs based on personal experience in the AfA treatment support department. The research instrument consisted of questions, advice to subjects and explanations to the treatment support counsellors to enable them to understand the context in which the questions were asked. Factors like self-reporting (tolerability of ART, missed dosages), AfA adherence assessment, use of other medicines, problems experienced / adherence barriers, disclosure, reminders of follow up blood tests, emphasizing adherence to HAART, healthy lifestyle and intervention based on the interaction were included in the research instrument. The guidelines were administered in English and completed by 40 subjects.
3.9.2 Increased contact

All contact details of subjects were confirmed at every contact and subjects in the IG were encouraged to contact AfA should there be any problems with the treatment. The intention was to contact these subjects once a month for the study period of six months. In some cases there was an increased attempt to get hold of some of the subjects in the IG. The attempts were not being reported on because what were important were the actual contacts made with the subjects. The research instrument also provided a reminder about the next contact date.

3.10 Data gathering instrument / CRF

A CRF or data gathering instrument (see page 171) was completed for each participant. The participants were identified on the CRF by means of a study number. Items on the CRF covered age, gender, province, race, history of previous antiretroviral therapy, date of registration, baseline CD4 and viral load results. Other information included the date when treatment was authorized, total attempts made to contact the subjects, reasons for not getting hold of subjects as well as how many successful contacts were made with them. The total number of visits to the treating doctor, hospitalisation during this period was observed. Outcomes by means of claims history follow up visits, CD4 cell counts, viral loads, side-effects and deaths were recorded. All the demographic data, baseline and outcome results were obtained from the AfA data base.
3.11 Validity and reliability

3.11.1 Content validity

The content validity of the instrument was evaluated. According to McBurney (2001:128) and Blocher (1987:164), the content of the instrument must be representative of a variety of behaviour or knowledge in order to measure the question that need to be answered. The researcher did a thorough literature review on all aspects that could affect adherence to treatment. This literature was obtained from international and national data that formed the basis of the adherence guidelines. These are disclosure, insight in HIV / AIDS, ART, drug resistance, treatment failure, tolerability of treatment, side-effects, adherence barriers, support systems, lifestyle issues etc. The researcher received inputs from specialists in the field of HIV / AIDS and the management team of AfA. The inputs from the treatment support staff was also obtained before the guidelines were implemented.

3.11.2 Face validity

Face validity of the instrument was tested. Face validity is the appearance of the research instrument. In other words whether the instrument appears to what it intended to be (McBurney, 2001:128; De Vos, et al. 2005:161). The research instrument was introduced to treatment support staff and used for training purposes. The researcher observed the guidelines to be responsive to the methods used in treatment support and proved its usefulness in the application of
Treatment support staff found the guidelines to be user friendly and easy to apply in their daily tasks. They found that these guidelines assisted them to become more focussed and structured in their approach to clients. The subjects in the IG were not resistant to questions asked and were happy about the regular contacts made with them, giving them a sense of importance. This research instrument not only measured the subjects’ adherence to ART but was also a relevant measure of those features.

3.11.3 Construct validity

The research instrument was based on the social learning and cognitive learning theories. McBurney (2001:128) stated that “…the test should actually measure whatever theoretical construct it supposedly tests, and not something else.” This instrument meant to measure adherence to HAART, to empower clients with knowledge about their disease, how to adapt to a new lifestyle, the importance of adherence not only to HAART but also attending to important follow up blood tests and doctor visits. This instrument also acknowledged every positive attempt by subjects towards good adherence in other words, behaviour change. The aim of this instrument was to move subjects from potentially poor adherence behaviour towards good adherence behaviour.
3.11.4 Reliability

In order to be a useful instrument in science, a research instrument must be valid and reliable (McBurney: 2001:127). The researcher had to test whether the research instrument, when measured, would give the same results every time. This was achieved by giving a workshop to treatment support counsellors to ensure that they know exactly how to use the guidelines and by doing a pilot study to test the research instrument.

The researcher and some of the treatment support staff also made a few calls to clients to determine whether the time spend per client were not going to bore clients and to determine whether there will be any resistance from the respondents. Thirdly the researcher measured through the pilot study whether the same kind of response was obtained from each client and whether the guidelines were clear and easy to apply. The researcher found the research instrument to be measurable and consistent. The CRF was used to extract data from the AfA client data base and all the information recorded and evaluated.

3.12 Data analysis and processing

The data gathering instrument (CRF) was checked for consistency and completeness of information before storing the information on an excel spreadsheet. The Excel software was used to capture the data from the data gathering instrument. The data on the spreadsheet was double checked by one of the AfA staff to confirm accuracy of the collected data. The data from the data
gathering instrument was re-captured from the excel spreadsheet using the SAS statistical package (SAS institute Inc., Cary, NC, USA). The findings of the study were reported in chapter four. The results discussed in chapter four were based on corrected data that was sent. The first part of the data analysis gave descriptive statistics for each group separately.

3.13 Summary

In summary, a quasi-experimental comparative study design was used for the purposes of this study. There were two groups that took part in the study, IG and CG. Adherence guidelines were tested in the IG to determine its impact on adherence levels to HAART. Reliability and validity of this instrument was tested. Data analysis and processing of the data was done to compare the two groups at baseline level for comparability as well as primary and secondary outcomes to determine the adherence level to HAART.
4.1 Introduction

The aim of the analysis was to examine if any differences between the intervention group (IG) and comparison group (CG) has occurred. Biographical and baseline data are presented to show that the groups were comparable before the intervention. These include, age, gender, geographical area and baseline CD4 and VL counts.

The primary outcomes of the study were:

CD4 count; VL; Claims history; Follow up blood tests; Change in medicine.

The secondary outcomes were:

Contacts made with clients; Doctor visits; Hospital admissions; side – effects and deaths.

Statistical comparison of nominal, ordinal and continuous variables were analysed using the SAS (SAS Institute Inc., Cary, NC, USA) statistical programme. Tests of homogeneity of variance were applied to continuous variables. If the variables were homogenous, the ANOVA test was applied. If variables were heterogeneous, the Kruskal - Wallis Test was applied. The Chi - square test was used for proportion and the Fisher’s Exact test used when
numbers were less than five. The results are expressed as means (standard deviation) or proportions i.e. 7 / 10 (percentage). A relative risk (RR) and 95% confidence interval is also given. If the CI does not include one, then the result is statistically significant at $p = 0.05$. Bar and pie charts are used to graphical portray the results. Descriptive tables and discussions of the findings are used to present the results.

4.2 Sample size

A total number of 80 subjects were selected from the overall population of AfA. Forty participants were selected for the IG and 40 for the CG. The researcher extracted a list of all clients who started ART for the first time from the AfA database. After completing the data-gathering instrument, the total of the IG remained the same but the CG reduced to 34 subjects. The six clients from the CG were excluded from the study due to previous experience with ART. Thus they did not meet the entry criteria as they were not ART naïve and merely required a change in treatment. The researcher went back to the data base but there were no other candidates who met the criteria, thus only 34 were included for analyses (Table 4.1).
Table 4.1  Sample size

<table>
<thead>
<tr>
<th>Intervention group</th>
<th>Comparison group</th>
</tr>
</thead>
<tbody>
<tr>
<td>All new clients enrolled on AFA data base who met inclusion and exclusion criteria. Between 1 October – 30 November 2004. N = 40</td>
<td>Identified from existing data base all clients from 1 February – 31 March 2004 who met inclusion and exclusion criteria. N = 34</td>
</tr>
<tr>
<td>Baseline data collected</td>
<td>Baseline data collected</td>
</tr>
<tr>
<td>Intervention: For a six month period. Regular telephonic contact using specific guidelines during conversation.</td>
<td>No intervention for a six month period. Routine follow up calls with no specific guidelines during conversation.</td>
</tr>
<tr>
<td>Results on 40 clients</td>
<td>Results on 34 clients</td>
</tr>
</tbody>
</table>

4.3 Baseline biographical data

4.3.1 Age

All the subjects met the minimum age of 21 as stated in the inclusion criteria. The IG had clients in all the age ranges but the CG that had no clients in the 50 – 56 year range. The range for the IG was 25 - 56 years and for the CG was 26 – 48 years. There was no significant difference (p = 0.164) between the mean ages IG 37.4 (8.9) and CG 38.1 (5.0). Half of all the subjects were between ages 30 - 39. Figure 4.1 graphically display the number of clients in each age category.
4.3.2 Gender distribution

The majority of the subjects were women 55 / 74 (74%). There were slightly more women in the IG 31 / 40 (77.5%) vs. 24 / 34 (70.6%) in the CG. The difference was not significant RR 0.829 (0.492-1.397) p = 0.497. There were slightly less males 9 / 40 (22.5%) in the IG compared to the CG with 10 / 34 (29.4%) males.
4.3.3 Client distribution per province

The majority of subjects came from KZN, 31 / 74 (42%), 19 / 41 (47.5%) were in the IG and 12 / 34 (35%) in the CG. The same number of subjects came from Gauteng 8 in each group. The least subjects came from Northern Cape 1 / 40 IG and Western Cape 1 / 34 CG.
Figure 4.3: Combined client distribution per province

![Combined client distribution per province](image)

Figure 4.4: Client distribution per province

![Client distribution per province](image)
4.4 Baseline data of primary outcomes

4.4.1 Baseline CD4 cell count

Baseline CD4 counts was available on all the subjects. Nearly all subjects 70 / 74 (94.5%) had a baseline CD4 of ≤ 250 cells / µl which met the ARV treatment inclusion criteria. Only four subjects had a baseline CD4 cell count of more than 250 cells / µl, two in the IG (334 & 386 cells / µl) and two in the CG (256 & 267 cells / µl). The mean cells / µl were the same between the two groups 121.05 (93.5) cells / µl IG and 121.47 (83.5) cells / µl CG, p = 0.983. Some subjects had cell counts of as little as 3 cells / µl and the ranges were IG (3.00 - 386 cells / µl) and CG (5.00 - 267 cells / µl). The difference was not significant (p = 0.983).

Figure 4.5: Baseline CD4 cell count
4.4.2 Baseline viral load

All subjects in the IG had baseline viral loads done and the mean viral load for the IG was 156500.8 (177491.2) copies / ml. One subject in the CG did not have a baseline viral load. The mean viral load in the CG was slightly higher 204 125.9 (244 467.1) but the difference was not significant, p = 0.412. Only 8 / 73 (10.9%) subjects had baseline viral loads of less than 100 000 copies / ml. It is recommended that viral load measures should rather be reported in Log_{10} because viral loads values may vary by up to three times, such as from 5000 – 15 000 and the variation appear to be large but this variation is within the margin of error of the test (AFA, 2005:9). The mean of the Log_{10} readings of the baseline viral load was similar IG 4.83 (626) with a range of 3.72 - 5.80 and CG 4.90 (747) with a range of 2.63 to 5.87 (p = 0.671).

It is important to note that no statistical differences were found in the baseline data between the intervention and the comparison groups. Thus the comparison group was found to be comparable with the intervention group.
4.5 Primary outcomes

4.5.1 CD4 cell counts

It is recommended that a follow up CD4 count should be done six months after the client commenced ART. The mean CD4 count has doubled in both groups. More than half 29 / 50 (58%) of all the subjects had CD4 counts of above 200 cells / µl. There were no differences between the number of clients who had a CD4 count above 200 cells / µl between the groups. A number of eight out of thirteen in the CG (61.5%) had CD4 counts above 200 cells / µl with a RR 0.92 (0.55 – 1.54). The mean CD4 cell count for the intervention group was 229.2 (146.3) cells / µl with a range of 45 – 568 cells / µl and for the comparison group 263.5 (263.5) cells / µl and the range 53 – 1000 cells / µl, p = 0.824. But this difference was not statistically significant, p = 0.824. This result should thus be interpreted with caution due to missing data in the CG.
It is important to recognised the big difference (IG 37 / 40 (92.5%) vs. CG 13 / 34 (38.2%) in the number of follow up bloods between the groups.

**Figure 4.7: Mean CD4 cell count**

![CD4 cell count chart]

**4.5.2 Viral load**

Viral suppression is defined as a viral load below detection after six months of therapy (Bartlett & Gallant, 2004: 59, 61; AfA, 2005:27). An undetectable viral load (< 400 copies) was achieved in 35 / 49 (71.4%) of the subject. Subjects in the intervention group were more likely to achieve a viral load of below 400 copies IG 28 / 36 (77.7%) vs. CG 7 / 13 (53.8%), but the result did not reach significance RR 1.44 (0.85 – 2.46) p = 0.152. The outcome mean VL was 10625.58 copies / ml (SD 45891.3) in 36 / 40 subjects in the IG ranging from 50 – 200 000 copies / ml compared to the outcome mean VL of 5530.38 copies / ml (SD 13581.0) in 13/37 subjects in the CG ranging from 50- 44212 copies / ml
with p value of 0.196. The Log\textsubscript{10} mean result was IG 2.7 (.967) vs. CG 2.45 (1.00) \( p = 0.381 \).

Similarly as with the CD4 follow up blood results, must these result be interpreted with care as the follow up tests were low in the comparison group (IG 36 / 40 (90%) vs. 13 / 34 (38.2%). The interpretation should be done with care due to missing data in the CG. What is of importance is the difference in the total of patients who attended to their follow up blood tests.

**Figure 4.8:** Mean viral load

![Mean viral load chart](image)

4.5.3 Adherence to follow up blood tests

The adherence outcomes of the two groups were also compared based on their adherence pattern to the CD4 and VL follow up blood tests. There were 37 / 40 (92.5%) in the intervention group who had their CD4 blood tests done after six
months on ART versus only 13 / 34 (38.2%) in the comparison group. Thus only three clients in the intervention group did not have their CD4 blood tests done compared to the 21 in the comparison group. This difference reaches a statistical significant difference with a RR 2.42 (CL 1.56 – 3.74) and a p value 0.001.

Similarly were there 36 / 40 (90%) of clients in the intervention group who had their VL blood tests done after six months on ART, compared to only 13 / 34 (38.2%) of the comparison group with a RR 2.35 (1.52 – 3.65) and p = 0.001.

Figure 4.9: CD4 follow up blood tests
Figure 4.10: Viral load (VL) follow up blood tests

![Viral load follow up blood tests](image)

### 4.5.4 ART claims history

The intervention group had a total of 32 / 40 (80%) regular claims. This number was more than double the total regular claims for the comparison group 15 / 34 (44%). Significantly more subjects in the intervention group claim their ART more regularly RR 1.81 (1.20 – 2.73), p = 0.003. One subject in each group did not submit a claim at all.
4.5.5 Change in treatment

Fewer subjects in the intervention group changed treatment over the six month follow up time period (4 / 40 (10%) vs. 6 / 34 (17.6%) with a RR 0.57 (0.17 – 1.84) p = 0.497.) Side - effects such as a rash were the most common reason for changing therapy.

4.6 Secondary outcomes

4.6.1 Contacts

The intervention guideline recommended that the subjects in the intervention group should be contacted by the counsellor at least five to six times over a period of six months. The total attempts were also recorded and no random element was available to determine how many attempts were actually required.
What were relevant were the actual contacts (successful calls) to clients. The hypothesis was that the total successful calls to the intervention group will be more than in those in the comparison group and that the call would make a difference to adherence to treatment and follow up blood tests.

The mean number of the total contacts to clients in the intervention group was 4.07 (1.22) compared to the mean number of the total contacts to clients in the comparison group of 1.0 (1.02). Significantly more clients 37 / 40 (92%) in the intervention group were contacted between three to six times compared to the 1 / 34 (2.9%) in the comparison group with RR 31.45 (4.25 – 217.32) p = 0.000.

Table 4.2: Contacts to clients

<table>
<thead>
<tr>
<th>Time</th>
<th>IG</th>
<th>CG</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>1</td>
<td>0</td>
<td>14</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>3</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>5</td>
<td>17</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>164 calls</td>
<td>35 calls</td>
</tr>
</tbody>
</table>
4.6.2 Doctor visits

The average doctors visits for the intervention group was 5.3 (3.34) range 0 - 14 compared to the average doctors visits of 5.1 (3.96) range 0 – 16 for the comparison group. This difference was not significant (p = 0.455).

4.6.3 Hospital admissions

More subjects were admitted to the hospital in the intervention group 13 / 40 (32.5%) vs. CG 6 / 34 (17.6%), RR 1.84 (0.79 – 4.32). The mean number of hospital admissions for the intervention group was 0.45 (0.749) and a range of 0 – 3 visits compared to 0.26 (0.665) with a range of 0 - 3 visits over the six month study period. The difference was not significant (p = 0.480).

4.6.4 ART side - effects

More subjects suffered from side - effects in the intervention group 10 / 39 (25.6%) vs. CG 5 / 34 (14.7%) RR of 1.74 (CL 0.66 to 4.60) and p = 0.388. Rash and peripheral neuropathy (PN) were more common within the intervention group.

It is important to note that questions related to doctor visits, hospital admissions and side - effects are not reliable in the comparison group and could be underestimated as these questions did not form a structured part of the counsellor’s conversation with the client.
4.6.5 Deaths

No deaths were recorded in the intervention group and two deaths were recorded in the comparison group.

4.7 Summary

The two groups were comparable as no significant differences were found between the groups regarding the baseline data such as age, gender, province, baseline CD4 and VL. We hypothesized that a specific guideline and regular contacts would make a difference in the primary outcomes. We accept the hypothesis in that significantly more patients adhered to the requirement of a follow up blood test at six months and significantly more clients claimed their
ART more regularly. Fewer subjects changed their treatment during the six months period. The researcher could not show that the CD4 cell count and viral load were significantly reduced, but a major obstacle in this conclusion is the fact that the subjects in the comparison group did not go for their follow up blood tests.

Secondary outcomes analysed showed that subjects in the intervention group were contacted significantly more than those in the routine comparison group. Due to the fact that they had a better claims history can one conclude that they took their ART more regularly which caused the slight increase in side-effects, doctor visits and hospital admissions in the intervention group. The reasons for visits were commonly related to side-effects of the ART and not to diseases associated with HIV/AIDS. Two deaths were recorded in the comparison group. It is thus clear that a specific guideline and frequent telephonic contact by counsellors do increase adherence.
Chapter five

Discussion of results, study limitations, conclusion & recommendations

5.1 Introduction

This chapter discusses the findings of the study that was aimed at determining the impact of newly formulated adherence guidelines applied to AfA patients. This study also looked at comparisons between itself and other studies. Study limitations, conclusion and recommendations will be included in the discussion.

5.2 Relevance of a HIV / AIDS programme

ART cannot be used without managing and monitoring the progress of patients on ART. ART need to be taken with the necessary knowledge and skills. Well-trained health care workers can make a positive impact on patient adherence to ART. Staff that is not well - trained in the field of HIV / AIDS has detrimental effects in so much that if treatment is used wrongly it can increase the risk of treatment failure and eventually spread an ART resistant virus (Martin, 2002: 32). Side - effects and toxicity of the drugs without monitoring can increase negativity and fear about ART in communities. Due to the complexity of the different ART regimens and the impact of ART on an existing lifestyle, it is safer to be managed under a well - established HIV / AIDS disease management programme (McDonald, 2001:30). Different studies have shown that 95% adherence is required to achieve the required clinical effect of ART. The role of health care workers
and DM companies can therefore not be underestimated. Doctors all over the world especially in areas with a high HIV / AIDS prevalence are bombarded with a high influx of patients and therefore do not always have the time and resources available to include HIV / AIDS DM programmes to their already busy schedules. The assumption that could be made is the fact that an increase in doctor visits does not necessarily cause an increase in adherence to ART. A structured adherence programme is required to achieve an acceptable adherence level that could make a difference to patients' clinical outcomes as well as an increase in their quality of life.

5.3 The relationship between age and adherence

There are some studies that suggest that age is a significant predictor of adherence to treatment. Boyle (2003) reported on a clinical trial where the overall sustained virological response (SVR) rate to Pegasus and Copegus (combined therapy for chronic hepatitis C virus infection) was measured. For those patients who were infected with HCV genotype 1, only the baseline VL (pre-treatment) had a greater impact over age to achieve a sustained virological response. Another study indicated that the chances for a 20 year old patient to achieve a SVR were significantly higher than a 60 year old (74% vs. 44.2%).

There were more subjects in the IG in the lowest age range (25 - 29) as well as in the highest age range (50 - 56 years) compared to the CG where less than half
the number of subjects were in the youngest group and no subjects were in the highest age range. In contrast to Boyle’s report (2003), findings of a study done by Hinkin, Charles, Hardy, David, Mason, Karen, Castellon, Steven, Durvasula, Ramani, Lam, Mona, Stefaniak and Marta (2004) indicated that older patients had a significantly higher adherence rate compared to younger patients. Hinkin et al. (2004) reviewed a study where participants on ART between the ages 25 - 69 years were monitored over a one - month period. An electronic monitoring device was used to measure adherence. All these patients underwent a comprehensive neuropsychological tests as well as a structured psychiatric interview. The results indicated that the average adherence of patients ≤ 50 years had an 87.5% adherence rate above the younger group with an adherence level of 78.3%. If the second argument is considered as correct, then we may argue that since both the lowest and highest age groups came from the IG, the fact that older patients are more adherent than younger patients, cancels out this variable.

5.4 Gender, a determining factor to ART adherence

It appears as though gender tend to play a significant role not only in accessing health care services but also adherence to ART. In the Khayelitsha HIV / AIDS pilot the findings were that access to ART were higher in women (70%) compared to men (De Pinho, 2003:5, 15). A reason for this trend was possibly because women, utilize services to primary health services more than men.
Women access the HIV / AIDS services through vertical transmission prophylaxis (VTP). There is no clarity whether men utilize these services through the private sector. In contrast to these findings, international studies found that men tend to access HIV / AIDS treatment within the private sector, workplace and pilot studies. This could be because men are able to pay for their treatment, more men are employed compared to women and they have better access to medical schemes. Pregnancy can affect the outcome of trails; therefore there is a tendency to exclude women from accessing certain trails (De Pinho, 2003: 5, 15).

Both the IG and CG had more females than males registered on the AfA programme. Interestingly, both female groups in this study presented with a 70.5 to 77.5% females, which is more or less in line with the Khayelitsha HIV / AIDS pilot where 70% women accessed ART. The Khayelitsha HIV / AIDS pilot proved that there is a clear improvement in mortality rate compared to people not on ART. They found that the survival rate is higher among women and men were 1.89 times likely to die, present with poor adherence in follow ups over a period of 18 months since starting treatment. Support systems and counselling services are not sufficiently supportive for men and there are more female caregivers who do not encourage men to participate in these programmes (De Pinho, 2003: 6). Studies have shown that gender has an impact on access to health care services and adherence to treatment. There was no significant difference between the IG and CG.
5.5 **The baseline and outcome CD4 and VL**

Both groups had a mean CD4 of 121 cells / µl. The CD4 cell count of the IG ranged between 3 to 386 cells / µl while that of the CG ranged between 5 to 267 cells / µl. Once people know their HIV positive status, they tend to experience emotional turmoil, many times a loss of self-esteem. Fear of discrimination cause people not to participate in programmes like VCT to get to know their status. Some people get tested late in the disease where they already present with AIDS defining illnesses. Venter (2005: 24 - 25) raised the concern that many people undergo testing when they are already in the symptomatic stage of their disease. Venter added that many people refrain from knowing their HIV status due to the stigma and human rights issues that affects it. This could be explained why some of the subjects in the two groups had baseline CD4 cell counts below 200 cells / µl. The infected individual becomes progressively symptomatic as the HIV disease advances. When the CD4 cell count drop below 50 cells / µl, patients are said to have advanced HIV disease with a survival rate of 12 - 18 months. The total CD4 cells circulating the human system may fall at a rate of 60 cells / µl per year reducing by 20 - 40% after infection with HIV (Regensberg, 1999:52).

AfA requests follow up viral loads six months after starting treatment and expect the VL to reduce to < 50 copies / ml when 95% adherence is maintained over this period. A 95% adherence level is supported by Bartlett (2002:27), Kent and Dalglish (1983:324); Department of Health, Western Cape (2004:4) and AfA (2005:9).
The majority of subjects in the IG were adherent to HAART and went for the requested blood tests. There was an increase in their CD4 cell counts and a reduction in VL (<50 copies / ml). Most subjects in the CG were not adherent to ART and did not undergo the requested blood tests. It is evident that adherence to ART reduces VL to undetectable levels and increases CD4 cell counts. We can therefore make the assumption that those subjects in the CG, who did not claim their treatment, were non-adherent and would therefore, not have had undetectable VL and an increase in CD4 cell counts. One subject in the IG did not undergo a VL test due to the fact that there was uncertainty about the pathology payments. Currently most schemes managed under the AfA DM programme, include the required follow up blood tests as part of the annual HIV benefits. In order to exercise this benefit, clients need to know where the benefits are coming from. The high adherence level to follow up blood tests was a very important outcome that clearly proved that the designed adherence intervention done by the researcher made a huge impact not only to follow up blood tests but also to the clinical outcome of these tests. The researcher also found it beneficial to remind patients of the follow up tests at every contact.

5.6 The impact of regular contacts with clients using HAART

The aim of the information during contacts was to empower the subjects with enough knowledge about their disease to be able to make informed decisions about their health, ART and to bring about a behaviour change that would benefit
their health. The telephone was the only means of contact to all the subjects. It was the intention of the researcher to contact the IG on a monthly basis over the six-month study period. The subjects in the IG were not always reachable by telephone and therefore there were an increase in attempts in some cases to get hold of patients. Modern technology made it possible for many people have access to cell phones and therefore simplify the tasks of the treatment support counsellors to get hold of patients. Many people carry their cell phones with them therefore treatment support counsellors are encouraged to confirm patient telephone and/or cell phone details at every contact. There were many reasons why patients could not be reached at times. Some were either working shifts, were not allowed to answer their cell phones at work, worked shifts and not available during the day. Because of these facts, the researcher found that it would sometimes become necessary to increase attempts to get hold of clients that could not be reached. The attempts will not be reported on since what was important for this study was the total number of actual contacts made with subjects.

The type of counselling provided by the treatment support counsellors was that of a supportive as well as preventative nature. The subjects in the IG group were firstly equipped with enough information about HIV/AIDS, ART and lifestyle issues. Emphasis was placed on the importance to adhere to ART as well as lifestyle issues at every contact with these subjects. Lifestyle issues included diet, stress reduction, exercises, safe sex and change in behaviour.
5.7 Increase in ART claims vs. side-effects

The intervention group had a total of 32 / 40 (80%) regular claims. This number was more than double the total of regular claims for the comparison group 15 / 34 (44%). The adherence percentage of the comparison group was found to be in line with literature that indicated that the general poor adherence rate ranges from 30 to 60% (Brannon & Feist, 1992: 259 - 261; Goudge, Ngoma, Schneider, 2004:4). Significantly more subjects in the intervention group claim their ART more regularly RR 1.81 (1.20 – 2.73), p = 0.003. One subject in each group did not submit a claim at all. Feuerstein et al. (1986:268) reported a 90% adherence level in a study done by Carney, Schechter & Davis (1983) on non-adherent youths suffering from diabetes.

The researcher had the advantage of immediate access to the claims history of all the subjects. Reasons behind the irregular claims history in the IG were the following:

Patient 58 (study number) had problems obtaining treatment from the pharmacy;
Patient 71 had a poor CD4 and VL outcome although she claimed to be adherent to therapy. She used immune boosters, antihypertensive treatment and antiretroviral therapy. The outcome of the blood results could be because of poor adherence to therapy or potential drug interactions;
Patient 80 took his treatment the wrong times;
Patient 81 was adherent to therapy but had a urinary tract infection (UTI) when the blood tests were done. This could have caused an increase in VL;
Patient 89 presented with severe diarrhoea. Her doctor decided to stop the ART until the TB treatment is completed. The side – effects disappeared once the ART was stopped;

Patient 94 preferred traditional medicines above ART although she received intensive counselling on three occasions. She was no longer contactable.

Obtaining these adherence barriers enabled the researcher to use the opportunity to educate, advice or refer the subjects for clinical intervention at AfA in conjunction with their treating doctors where necessary. This kind of intervention would not have been possible if the researcher did not intentionally contact the clients on a regular basis.

When patients take their treatment regularly, more side - effects tend to appear. The most common side - effects reported by subjects in the IG were rash and peripheral neuropathy. Unfortunately the side - effects of the two groups could not be compared due to missing data in the CG. It is possible that there might have been subjects in CG who presented with side - effects but never contacted the treatment support counsellors. Side - effects could be one of the reasons why clients decide to discontinue their treatment (Brannon et al., 1992:262; Andrews, 2002:19). It is possible that in some cases, side - effects could have caused the subjects in the CG to either discontinue their treatment or claim their treatment irregularly. If this assumption is correct, then poor adherence could probably have been avoided if these subjects were contacted regularly. The subjects in the IG were informed about possible side - effects, how to manage
side-effects and encouraged to continue treatment. Most side-effects disappear after three months of ART.

5.8 Does regular doctor visits lead to increased adherence?

The mean total of doctor consultations was not much different in the IG and CG. In both groups there was an average of five visits per month for the entire study period of six months. It is not clear why the subjects visited their doctors, as this was not a requirement for this study. It is therefore difficult to determine whether many doctors’ visits were a good or a bad thing. Patients could have gone to see their doctors for the smallest ailments that did not really require the intervention of a treating doctor. Interestingly it seems as if the regular doctor visits did not make an impact on the adherence level of the CG. The doctor visits recorded were of those health care providers who registered the patients on the AfA programme in other words, they were aware of the fact that their patients were using ART. Studies have shown that patient self-reporting is not a reliable measure of adherence (Brannon & Feist, 1992:257 – 258). It is possible that some of the subjects were not completely honest with their doctors about their adherence to ART.
5.9 **CD4 and VL predicting hospital admissions**

Nine out of 40 patients in the IG were admitted to hospital at least once over the six-month study period compared to 4/34 in the CG. Adherence levels of patients predict future hospital admissions and mortality (Friedland, 2002:36). Hospital admissions ranged from pneumonia, gastrointestinal disturbances, meningitis, nephritis, non-Hodgkin lymphoma, fever of unknown origin, suicidal attempts, pleural effusion, acute abdomen, chronic viral hepatitis, myocarditis, chronic pyelonephritis, urinary tract infection (UTI) and anaemia. Some of these diagnoses for instance nephritis, pleural effusion, acute abdomen, myocarditis, chronic pyelonephritis, UTI might not directly related to HIV/AIDS but it might be indirectly related to HIV/AIDS.

Clients, who start ART and adhere to the treatment, should have an undetectable viral load within six months of therapy (Bartlett, 2004:61; AfA, 2005:27). There should also be a slight increase in the CD4 cell count (Bartlett, 2004:62; AfA, 2005:28) as well and the total increase sometimes depends on the CD4 baseline starting point. It is highly unlikely for an increase in hospitalisation to take place when clients start HAART with a CD4 count over 200 cells/µl. If HAART is commenced with a CD4 cell count slightly below 200 cells/µl, then a gradual increase to over 200 cells/µl within a few months on HAART is expected as well as a reduction in the risk for opportunistic infections (Regensberg, AfA). A client's immune system is significantly suppressed once the CD4 cell count is below 200 cells/µl. Once patients start HAART, there is a significant reduction
in opportunistic infections since starting treatment (see figure 1: JAMA, 1999: 282:2220). According to Dr Regensberg (AfA) there should be a significant reduction in hospital admissions after six months on HAART.

Figure 5.1: Opportunistic disease after HAART

![Graph showing opportunistic diseases after HAART](JAMA 1999;282:2220)

5.10 Study limitations

- The size of the sample obtained from the AfA overall population was small and could have misrepresent the overall AfA population;

- The interviews were done in English. This could have caused that patients misunderstood the questions;

- Clients could have been dishonest in their response to the questionnaires;
The researcher has chosen a historical group as the comparison group due to ethical reasons. Factors like the weather, new developments, HIV awareness could have impacted the results;

The researcher had to do all the interviews because of a severe staff shortage. Interviews were done in English, a second language for most of the subjects. Questions could have been misinterpreted.

Patients were contacted at an average of four calls over the six-month period. The high number of telephone contacts with patients could have impacted the outcome of the study.

5.11 Conclusion of the study

Adherence guidelines are needed to maintain consistency in adherence related factors. These guidelines provide in all aspects that can impact on adherence. It also provides an opportunity for patients to give feedback to treatment support counsellors. Patient feedback is an important part of any HIV disease management programme. The outcomes of the IG have shown that it is possible to apply treatment support via telephone contact with clients.

This study has proven that adherence guidelines work and is effective. It has also placed emphasis on the importance of contacting patients regularly. These guidelines are patient-centred and can make them feel important.
5.12 Recommendations to AfA

- The researcher recommends that AfA formally implement adherence guidelines by building it electronically into the AfA disease management system by means of tick boxes;
- Treatment support staff need to be trained about the correct use of adherence guidelines;
- The treatment support supervisor need to introduce quality assurance (QA) measures that will ensure that staff adheres to the application of adherence guidelines. This should include an automated QA reporting system whereby the system will enable the supervisor to draw a report on the correct use of the adherence guidelines;
- The treatment support staff total need to be increased to meet the demand of all the AfA clients. More than 25 000 HIV positive medical scheme members were registered on the AfA programme at the time of the completion of this study. It will become increasingly impossible for treatment support counsellors to contact patients at least twice a year if the staff total remains the same.

5.13 Progress made by AfA

- The number of treatment support staff increased by three staff members at the end of the study period. More staff will be required in the near future due to an increase in AfA's number of contracted clients;
• The researcher is actively involved in the training of new treatment support staff;
• The researcher supervised the treatment support staff ensuring that adherence guidelines are applied on a regular basis;
• Quality assurance was introduced to treatment support staff to ensure increased quality of treatment support to clients;
• Adherence guidelines were implemented;
• Treatment support staff undergo regular training to utilize the guidelines correctly;
• AfA is now able to accurately report to medical schemes about treatment support to their members.

5.14 Summary

Treatment support counsellors need to be equipped with adherence guidelines in order to make an impact on patient adherence to ART. An adherence guideline goes hand in hand with regular contacts between the client and treatment support counsellor. The conclusion made by the researcher is that the positive hypothesis has proven to be correct. The researcher therefore recommends the use of adherence guidelines in the private sector where the telephone contact is most of the time the only means to get hold of patients. The researcher found that the telephone is most of the time the easiest and most convenient communication tool between the patient and treatment support counsellor and its
value, hand in hand with adherence guidelines should therefore not be underestimated.
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Accessed on 2005/05/03

# APPENDIX I: DATA GATHERING INSTRUMENT

## DATA GATHERING INSTRUMENT

<table>
<thead>
<tr>
<th>Reference #</th>
<th>Study #</th>
</tr>
</thead>
</table>

### 1. Demographic data

<table>
<thead>
<tr>
<th>Age</th>
<th>Gender</th>
<th>Province</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>m</td>
<td>f</td>
</tr>
</tbody>
</table>

| Race | W | B | C | I | other |

### 2. History of previous treatment

| History of ART | Y | N | Date started | y | y | m | m | d | d |

- If yes, tick off ART used

- Retrovir
- Zerit
- Viramune
- Kaletra

- 3TC
- Videx
- Stocrin
- Hydrea

### 2. Registration details

| Date of registration | y | y | m | m | d | d |

| Baseline blood results | CD4 | Viral load |

### 3. Current treatment

| Date ART authorized | y | y | m | m | d | d |

- Tick off current treatment

- NRTIs
  - Retrovir
  - 3tc
  - Zerit
  - Videx
  - Combivir

- NNRTIs
  - Viramune
  - Stocrin

- PIs
  - Kaletra
  - Norvir
  - Fortovase/Invirase
  - Viracept

### 4. Treatment support

| How many attempts | 1 | 2 | 3 | 4 |

- Records details why the client could not be reached
### 5. Doctor’s visits

<table>
<thead>
<tr>
<th>How many visits to treating doctor</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
</table>

### 6. Treatment outcome

| CD4 | m | m | d | d |
| Viral load | m | m | d | d |

### Side-effects

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rash</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhoea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin / nail discolour</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 7. Claims history

<table>
<thead>
<tr>
<th>Claims history: year:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Drug</th>
<th>Date: mm / dd</th>
<th>Date: mm / dd</th>
<th>Date: mm / dd</th>
<th>Date: mm / dd</th>
<th>Date: mm / dd</th>
<th>Date: mm / dd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retrovir®</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3TC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zerit®</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Videx®</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Combivir®</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Viramune®</td>
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<tr>
<td>Stocrin®</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kaletra®</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Reasons for omitting/not claiming/starting treatment

___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

8. Hospitalisation
How many times hospitalised 1 2 3 4 5

<table>
<thead>
<tr>
<th>Date</th>
<th>Diagnoses</th>
<th>Tick off</th>
</tr>
</thead>
<tbody>
<tr>
<td>y y m m d d</td>
<td>PCP</td>
<td></td>
</tr>
<tr>
<td>y y m m d d</td>
<td>Pneumonia</td>
<td></td>
</tr>
<tr>
<td>y y m m d d</td>
<td>TB</td>
<td></td>
</tr>
<tr>
<td>y y m m d d</td>
<td>Diarrhoea</td>
<td></td>
</tr>
<tr>
<td>y y m m d d</td>
<td>Meningitis</td>
<td></td>
</tr>
</tbody>
</table>

9. Pregnancy (only for females)
If female, was she pregnant Y N

If yes, was MTCT authorized Y N

10. Membership

<table>
<thead>
<tr>
<th>Membership terminated</th>
<th>Y</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, date of termination</td>
<td>y y m m d d</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deceased</th>
<th>Y</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, date of death</td>
<td>y y m m d d</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX
II: RESEARCH INSTRUMENT

SELF- REPORT:

Did you disclose your HIV-positive status to anyone?

Yes  No

If the answer is no, inform the patient about the advantages of disclosing to someone i.e.: Being able to talk freely about his/her condition including the support from family and friends.

Who did you tell about your status?

Partner / Spouse  Mother  Father

Brother  Sister  Children

Aunt  Uncle  Cousin / Nephew

Friend  Employer

Have you started treatment?

Yes  No

If the answer is no, inform the patient that antiretroviral treatment was authorized and refer the patient back to the treating doctor to obtain a prescription. Ask the patient to contact you as soon as he/she receive the treatment. Probe for treatment readiness. Allocate a follow up date within a week.

What medicines are you taking at the moment?

Patient knows  Not sure  Don't know

Ensure that the patient know exactly how the treatment has to be taken by explaining the instructions in detail.

Did you skip any of your medication the last four days?

Yes  No

If yes, find out why dosages were missed and remind the patient about the risk of the virus developing resistance against the antiretroviral treatment when medication is not taken regularly.
Are you tolerating the antiretroviral treatment?

Yes  No

If the answer is no and the patient is complaining of side-effects, probe to get more details about it:

When did the side-effects start for the first time?

Before treatment  After treatment

How bad is it?

Tolerable  Bad  Very bad

Side-effects:

Nausea  Vomiting  Diarrhoea
Dizziness  Sleeplessness  Headache
Abdominal pain  Bizarre behaviour  Depression
PN  Other

Is this problem affecting your daily activities?

Yes  No

If the side-effect is tolerable, not affecting the patient’s daily living and started shortly after treatment commenced, encourage the patient to continue taking treatment correctly. Advice the patient that side-effects should disappear once the body adjusted to the treatment. Advice the patient to see the doctor should the side-effects persist and become intolerable. It is important to do a follow up call on a weekly to two weekly basis.

CLAIMS HISTORY:

Do a claims check to determine the patient’s claims pattern and discuss this with the patient, whether good or bad. Reward the patient by acknowledging a regular claims history. Find out why there are irregular or no claims and discuss the disease progression and advantages of taking antiretroviral treatment regularly and correctly. Remind the patient of the risk of viral resistance when treatment is not taken regularly and correctly.

ART claims:

Regular  Irregular  No claims

ADHERENCE LEVEL ASSESSMENT:

This is done based on patient’s self-report and claims history.

Adherence level:

Compliant  Poor compliance  No commitment
SINMTANOUS USE OF OTHER MEDICINES:

Are you taking any other medicines except antiretroviral treatment?

Yes  No

If yes, specify:

Chronic  TB  Herbal

Immune boosters  Traditional  Acute

Does your doctor know about it?

Yes  No

If the patient is using alternative treatment, advise him / her about the risk of using different medicines which will interfere with each other and could reduce the effect of antiretroviral treatment? If the answer is no, encourage the patient to inform the doctor in future if he / she intends using other medicines.

PROBLEMS:

Do you think there is anything at the moment that could prevent you from taking your treatment? These are problems that could affect the patient's adherence to antiretroviral treatment.

Find out if any of the following adherence barriers exist:

Side - effects  Non - disclosure  No medicine

Financial problems  Too busy  Afraid to take ART

Hospitalized  Incorrect use  Poor support

Alcohol/drug abuse  Depression  Forgetfulness

Family problems  Too ill  Not happy with doctor

Advice:

No medicine

Encourage the patient to collect treatment 3 - 5 days before his previous month's medicine is finished and advice the patient to contact you should the patient have any problems to claim the treatment from the pharmacy.

Too busy to take treatment & forgetfulness:

Educate the patient about the importance of taking treatment regularly and correctly to
prevent viral resistance.
Encourage the patient to make use of reminders i.e. cell phone, calendars, family / friends.

Alcohol / drug abuse
Educate the patient about the risks of taking antiretroviral treatment with alcohol
(potential increase in liver functions) and the negative impact alcohol and drugs may have on adherence to ART.

Depression / Psychiatric problem
Find out if this problem is currently being treated. If the answer is no, refer the patient to his / her treating doctor.
Encourage the support of family & friends.

Fear of ART
Find out what is the source of the patient's fear. Re-assure him / her of your continuous support while he / she is taking treatment and that if it is taken correctly, regularly and follow up visits and blood tests are attended to, then there is nothing to fear.

Too ill to take treatment
Find out if the patient has disclosed his / her status and encourage the support of family, friends and the community.
Ask for the contact details of a family member that can assist the patient during his / her illness.

Incorrect use of treatment
Inform and educate on the correct ways of using treatment.
Discuss the risk of viral resistance when treatment is not taken correctly.

Hospitalized or too ill
Encourage the patient to disclose his / her status to the treating doctor and a family member for support.

Potential drug interaction
Remind the patient that different medicines can interfere with each other, making ART ineffective to fight the HI - virus. Encourage the patient to inform the doctor about any other medicines that he / she is taking.
Advice the patient to limit his medication to only that which is authorized by his / her treating doctor.

Financial & family problems
Find out if the patient has disclosed his / her status and encourage the support of family, friends and the community.

FOLLOW UP VISITS:

When last did you see your doctor?

<table>
<thead>
<tr>
<th>Recently</th>
<th>2-3 months ago</th>
<th>4-5 months ago</th>
</tr>
</thead>
</table>

| > 6 months ago |

If more than 6 months ago, emphasize the importance of attending regular visits to the doctor and obtain a commitment from the patient to see the doctor.
Do you know when your next blood tests are due?

Yes  
No  
Not sure

Remind the patient of the next follow up dates and explain the importance of attending to these regular follow up blood tests. Obtain a commitment date. By doing the blood tests, we’ll be able to see the effect of the antiretroviral medication on your body.

HEALTHY LIFESTYLE:

A healthy lifestyle consist of eating balanced meals, stress reduction, exercises, allowing the body to rest enough and regular condom use.

1. A balanced meal consist of:

   Energy foods provide energy.
   Examples are maize, maltabella, mealiness, peas, butternut, rice, potato / sweet potato, pumpkin, whole wheat bread, samp, oats, sorghum and small amounts of sugar.

   Protective foods that provides protection against diseases.
   Examples are fresh & dried fruit & vegetables.

   Building foods builds muscle, bones, blood.
   These are protein containing foods. Examples are beans, meat, chicken, fish, eggs, milk, maas, cheese, yoghurt, liver, lentils, dried beans, soy mince, tinned pilchards.

2. Stress reduction is obtained by:

   Disclosing your status to someone you can trust; Doing relaxation exercises, allowing your body to rest when required.

3. Exercises: Need to be done in moderation three to four times a week, half an hour per day.


5. Condom: Remember it is important to use a condom correctly and at all times. By not using a condom, you can either infect your partner or you can become re-infected every time you come in contact with the HI-virus.

CONTACT DETAILS:

Are your contact details still the same?

Yes  
No

If the answer is no, obtain the correct contact details.

Please feel free to contact us should you experience any problems with your treatment or if you need to inform us of any change in your contact
Remind the patient that you will call him/her again in one month to do a follow up call. Ensure that the patient have your contact number.
WHO Disease Staging System for HIV infection and Disease in Adults and Adolescents

Clinical Stage I:
Asymptomatic
Generalized Lymphadenopathy

Clinical Stage II:
Weight loss, < 10% of body weight
Minor mucocutaneous manifestations (seborrheic dermatitis, prurigo, fungal nail infections, recurrent oral ulcerations, angular cheilitis)
Herpes zoster within the last five years
Recurrent upper respiratory tract infections (e.g. bacterial sinusitis)

Clinical Stage III:
Weight loss, > 10% of body weight
Unexplained chronic diarrhoea > 1 month
Unexplained prolonged fever (intermittent or constant), >1 month
Oral candidiasis (thrush)
Oral hairy leucoplakia
Pulmonary tuberculosis within the last year
Severe bacterial infections (i.e. pneumonia)

Clinical Stage IV (AIDS):
HIV wasting syndrome*
Pneumocystis pneumonia
Toxoplasmosis of the brain
Cryptosporidiosis with diarrhoea >1 month
Cryptococcosis, extrapulmonary
Cytomegalovirus disease of an organ other than liver, spleen or lymph node (e.g. retinitis)
Herpes simplex virus infection, mucocutaneous (> 1month) or visceral
Progressive multifocal leucoencephalopathy
Any disseminated endemic mycosis
Candidiasis of oesophagus, trachea, bronchi
Atypical mycobacteriosis, disseminated or lungs
APPENDIX IV  LETTER TO AID FOR AIDS

The Board of Directors
Attention: Mr. R. Cowlin
Aid for AIDS
The Parks
Pinelands
7405

04 November 2004

Dear Mr. Cowlin

MASTERS DEGREE RESEARCH PROPOSAL- FULL THESIS

I hereby request approval from the Aid for AIDS Board of Directors to perform a research project for AfA through the University of the Western Cape. Please see the attached document with the research proposal layout.

I hope that this project will identify new avenues that can only improve the Aid for AIDS treatment support functions. A detailed outcome of the research project will be presented to the Aid for AIDS Board of Directors once the research project is complete.

Thanking you in anticipation.

Yours sincerely

Melanie Marais

130 Hoff Street, Peerless Park East, 7570, Telephone: 021-514 1273; cell phone number 082 447 6244
Mrs. Melanie Marais  
Treatment Support Counsellor  
Aid for AIDS  

11 November 2004  

Dear Melanie  

Masters Degree Research Proposal  

I am happy to inform you that both the Board of Directors and the Clinical Advisory Committee have approved your proceeding with the research proposal as outlined in the document you sent to me on 4 November 2004.  

AfA will be happy to support you in whatever way is reasonably possible and wish you the best of luck for a successful outcome.  

Yours Sincerely  

Ann Strydom  
Operations Manager  
