

**An audit of the standard of care received by HIV positive patients on ART at a
Community Health Centre in KZN, South Africa**

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Plagiarism:

DECLARATION

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DEDICATION

I dedicate this dissertation to my husband and children for their love, patience and support.

ACKNOWLEDGMENTS

I WOULD LIKE TO ACKNOWLEDGE THE SUPPORT AND ASSISTANCE PROVIDED BY MY SUPERVISOR, DR K NAIDOO, AS WELL AS THE DEPARTMENT OF FAMILY MEDICINE.

ACRONYMS AND ABBREVIATIONS

AIDS- Acquired immune deficiency syndrome

ALT- Alanine transaminase

ART- Antiretroviral therapy

AZT- Zidovudine

BMI- Body mass index

CD4- Cluster of differentiation

CHC-Community Health Centre

CXR- Chest X-ray

FBC- Full blood count

HIV- Human immunodeficiency virus

INH- Isoniazid

KZN- Kwa-Zulu Natal

LFT- liver function test

NVP- Nevirapine

PHC- Primary health care

PLWHA-people living with HIV/AIDS

PMTCT- Prevention of mother to child transmission

RPR- Rapid Plasma Reagin

SANAC- South African National Aids Council

TDF- Tenofovir

TB- Tuberculosis

U&E – Urea and electrolyte

UNAIDS- United Nations Aids Organisation

VL- Viral load

WHO- World Health Organisation

TABLE OF CONTENTS

| | |
|--|--------------|
| DECLARATION | 1 |
| DEDICATION..... | 2 |
| ACKNOWLEDGEMENTS | 3 |
| ACRONYMS AND ABBREVIATIONS. | 4 |
| ABSTRACT / SUMMARY..... | 6 |
| CHAPTER I..... | 7 |
| INTRODUCTION | |
| Background..... | 7 |
| Problem Statement..... | 7 |
| Purpose of the Research | 7 |
| Specific Objectives | 7 |
| CHAPTER II.. | 8 |
| LITERATURE REVIEW | 8-10 |
| CHAPTER III..... | 11-15 |
| METHODS..... | 11-15 |
| Study Design | 11 |
| Study location..... | 11 |
| Target Population and Study Sample | 11-12 |
| Sample size and strategy..... | 11-12 |
| Bias and Limitations..... | 14 |
| Ethics | 15 |
| CHAPTER IV. | 16-21 |
| RESULTS | 16-21 |
| CHAPTER V..... | 22-24 |
| DISCUSSION..... | 22-24 |
| CHAPTER VI..... | 25 |
| CONCLUSIONS AND RECOMMENDATIONS..... | 25 |
| REFERENCES | 26-27 |
| APPENDICES..... | 29-31 |
| APPENDIX 1 | 28 |
| APPENDIX 2..... | 29 |
| APPENDIX 3..... | 30 |
| APPENDIX 4..... | 31 |

ABSTRACT / SUMMARY

Introduction: South Africa has the highest number of HIV infected individuals in the world.² The South African government has established National treatment guidelines for HIV positive patients to help ensure quality of care. The success of these guidelines depends on the commitment and level of adherence to them by hospitals and clinics.

Aim: A descriptive study evaluating the standard of care received by HIV positive patients was undertaken at a community health centre in KwaDabeka, a semi-urban town in Kwa-Zulu Natal. This was benchmarked against the National ART Guidelines for 2010, which was the national policy at the time this study was undertaken. The objectives were to identify any deficiencies in the care of patients with HIV/AIDS, and to suggest possible solutions as well as to identify a demographic profile of the patients accessing care.

Methods: The researcher selected three hundred and sixty patient files using a random process and then analyzed them. This sample size was calculated using a confidence interval of 95% of a total number of six thousand patients. Adult patients using ART for the period of 01 January 2011 until 31 December 2011 were only included. Pregnant patients and children were excluded from the study. The variables analyzed were generated using the pre-initiation, initiation and monitoring recommendations of the National ART Guidelines of 2010. A data sheet was drawn-up consisting of the various variables. This was analyzed using SPSS version 21. Simple descriptive statistics, univariate analysis, and frequency distribution tables were used to analyze the data. Tables, pie charts, and graphs have been used to represent the analyzed data.

Results: Females comprised 65% and the mean patient age was 39 years. While the overall patient management was in accordance to the guidelines, there were major areas of non-compliance. These included the more than 80% of patients who did not have: pap smears; nutritional assessments; follow-up Tuberculosis (TB) symptom reviews; and mental health evaluations. In addition, there was a significant delay from obtaining a CD4 count to initiation of therapy of two months or longer in more than 50% of patients. Furthermore, the clinic did not comply with fast-tracking 84.5% of patients who needed to be initiated within two weeks of obtaining a CD4 count. Adverse events due to antiretroviral therapy were reported in approximately 41% of the patients, however, 25% did not have their regimen changed despite having a serious adverse event documented. The incidence of concurrent infection with TB was 32%, however none of the remaining non-infected patients (68%), received Isoniazid prophylaxis.

Recommendations: The management of KwaDabeka CHC have significant challenges to overcome in order to optimise their treatment of HIV positive patients. Possible solutions must include access to the National ART Guidelines for all relevant health-care workers, regular medical update programmes on the management of HIV positive patients, and improving resources and relevant procedural skills.

CHAPTER I: BACKGROUND

INTRODUCTION

South Africans have, in the past, encountered challenges that have tested the strength of the human spirit in ways that few other nations have experienced.¹ The ray of optimism that accompanied the new democracy in 1994, which followed the fall of the former apartheid* regime, has since been threatened by a very different enemy. Today, South Africa often finds itself in the global spotlight for its huge burden of disease due to HIV/AIDS. In 2009, the United Nations estimated that 5.6 million South Africans are HIV positive, which is the largest number of infected individuals in any country, worldwide.² Anti-retroviral therapy (ART) has provided a ray of hope in the face of this scourge. Studies have revealed that ART has prevented millions of deaths globally.⁴ In a country like South Africa which has such a huge burden of HIV, ART may not only play a role in improving survival rates but also helping to maintain family units by decreasing the number of AIDS orphans. These young children face the daunting task of attempting to survive in a country facing many other challenges such as high levels of violent crime and unemployment. Furthermore, ART has also helped socio-economically by providing those afflicted with HIV an opportunity to remain positive contributors to society by reducing morbidity and disability. This study has highlighted key areas of improvement in the ART programme at Kwadabeka CHC, which if addressed, can make an enormous difference to both the physical and social well-being of this community.

PROBLEM STATEMENT

Clinical guidelines for the management of HIV and AIDS in Adults compiled by the National Department of Health South Africa 2010, provides a step-by-step process for screening and initiating patients on treatment. However, whether these guidelines are being adhered to has not well established. It is possible that institutions, such as KwaDabeka Community Health Centre (appendix 1), which are often resource-limited, may find adherence to these guidelines more challenging.

PURPOSE OF THE STUDY

The study was conducted to determine if the National Guidelines (2010) for the management of HIV positive adult patients on ART was adhered to at Kwadabeka CHC for the period of 2011.

SPECIFIC OBJECTIVES

1. To review the demographic profile of patients on antiretroviral therapy.
2. To assess the level of adherence to National Treatment Guidelines for management of HIV positive patients.
3. To identify the problems in the care of HIV positive patients on ART at a Community Health Centre.
4. To make recommendations on ways to improve the quality of patient care.

***apartheid: A system of racial segregation instituted by the National government of South Africa between 1948-1994, in which the rights of non-whites were curtailed and white supremacy maintained .**

CHAPTER II

LITERATURE REVIEW

Introduction

HIV/AIDS is one of the main challenges facing South Africa (SA) today.³ It is estimated that in 2010-2011, 72% (1.8 million) of deaths due to HIV infection are from sub-Saharan Africa, with at least 194 000 deaths in SA.⁴ Antiretroviral therapy (ART) has increased the life expectancy of people living with HIV/AIDS (PLWHA).⁵ UNAIDS estimates that since 2005, the advent of ART has prevented approximately 2.5 million deaths globally.⁴ In 2011, SA is reported to have the largest ART programme in the world with 1.4 million PLWHA on ART and 30 000 new ART initiations per month.⁶ In a study in the Western Cape, the initiation of ART had the effect of reducing the 6 month mortality from 12.7% to 6.6%, i.e. approximately 50% for the study period 2001-2005.⁷

History of HIV and antiretroviral therapy (ART) in South Africa:

The first confirmed case of HIV infection in South Africa was reported in 1982.⁸ The subsequent years saw an exponential rise of cases from 100 000 in the year 2000, to the current estimate stated above.⁹ Following the initial controversy regarding the provision of ART, the actual roll out was established in the public health sector in 2004.¹⁰ The government adopted a 'strategic plan' between 2007 and 2011, to address this pandemic.⁹

This plan included the goals of increasing the number of new adults using ART from 120 000 (24%), to 420 000 (80%) , the projected estimates at the time, as well as increasing the proportion of health facilities providing comprehensive HIV care, including ART, from 10% to 80%. The provision of ART can be viewed, from these goals, as being a major intervention in the government's plan to combat HIV/AIDS.

National guidelines:

The number of HIV positive South Africans utilising ART was estimated at 1.7 million in May 2011.¹¹ This number on ART, the largest in the world, coupled with a need for a multi-disciplinary approach and the different levels of health-care facilities involved in the management of HIV positive patients, supports the need for national guidelines that standardise the care of these patients. The South African National Aids Council (SANAC) is responsible for drawing up the National Guidelines for the comprehensive management of HIV positive patients.¹²

An analysis of the extent to which these National guidelines are being adhered to, particularly in a rural community, has yielded important information regarding the challenges that face the treatment of HIV in a developing country such as South Africa.

The principal investigator has conducted a clinical audit of the standard of care received by HIV positive patients on ART and has benchmarked this against the National treatment guidelines at a Community Health centre in KZN.

Results of previous audits:

A clinical audit of the Prevention of Mother to child Transmission (PMTCT) programme at a regional hospital in South Africa in 2009 concluded that a significant proportion of HIV positive mothers did not have CD4 counts taken after testing positive and many were not initiated on ART despite having CD4 counts less than 200cells/mm³.¹³ Another audit of antenatal services in a rural clinic in KZN, found that at least one quarter of pregnant mothers did not enrol for the PMTCT programme.¹⁴ This is a significant number considering the 38.7% estimated HIV prevalence in pregnant females in KZN.¹⁵

A PUBMED search using the keywords: HIV positive patients, standards and quality care, audit, assessment, ART, KZN, South Africa and National Guidelines yielded few relevant studies that assessed the care of HIV positive patients. One study looked at the care of patients with TB/HIV/STI infections in a rural district in KZN. It found that weaknesses in training and support of staff at primary healthcare clinics (PHC), pharmaceutical and laboratory failures as well as inadequate monitoring of patients contributing to poor HIV service implementation.¹⁶ Another study, which utilised a file audit, to evaluate the retention in care and patient outcomes in a programme to decentralise ART to PHC facilities concluded that 'PHC sites still needed to ensure that patients received CD4 and viral load monitoring six monthly'.¹⁷ A further shortfall noted was the unclear recording of adverse drug events in patients' files.¹⁷ However, neither PUBMED nor Cochrane searches yielded any studies that analysed the standard of care of HIV positive patients when tested against the South African National Guidelines.

A search for additional relevant publications was made in the South African Family Practitioners Journal, HIV Clinicians Society Journal and African PHC and FM Journals. One study that analyzed adherence to French National ART Guidelines was conducted in Paris. This study followed the management of one hundred and eighteen patients for the period of one year. The study revealed that the time for ART initiation was in agreement with National Guidelines for 54% of patients, 42% had started ART with CD4 counts of less than 200 copies/ml, 97% had treatment regimens in accordance with guidelines.¹⁸ A second study was Audit of the treatment of people with HIV in Britain according to their recommended guidelines. This study found that most patients were initiated on ART with CD4 counts lower than what had been recommended, 97% were on three or more drugs as per the guidelines.¹⁹ However, both these studies were carried out in developed countries that have a very different socio-economic and disease profile to South Africa. Further results revealed studies within South Africa and India that had looked at specific aspects of the ART programme for example; the initial regimens used or the side-effect profile of some of the drugs or the patients' perceptions of the standard of care received.

CONCLUSION:

Implementation of National guidelines for HIV positive patients on ART in a socio-economically challenged country like South Africa, can be difficult, perhaps more so in a rural community. The lack of literature detailing the care of these patients further supports

the need for research in this domain. The results of an audit of this nature is anticipated to reveal not only major deficiencies in the treatment of HIV positive patients utilising ART, but also to indicate areas of improvement to managers of healthcare institutions and the KZN department of health.

SUMMARY OF THE NATIONAL ART GUIDELINES 2010

The National ART Guidelines 2010 recommend ART for HIV positive patients with CD4 counts of less than 200 cell/mm³ or up to 350 cells/mm³ if co-infected with TB, have a stage 4 HIV illness(listed in appendix 4), or are diagnosed with MDR or XDR TB. Once eligibility for ART has been established, subsequent blood tests should be performed. These should include a FBC, U&E, LFT, and tests to exclude Hepatitis B and Syphilis infection. Female patients should have pap smears performed in order to exclude cervical cancer. All patients should have a sputum sample or chest x-ray taken to exclude TB. INH prophylaxis is recommended for those patients who are not co-infected with TB. A nutritional assessment that includes calculation of the BMI and a social assessment which evaluates living conditions, access to basic services e.g. running water and the financial situation of patients are required. These assist with assessing the need for disability grant provision as well as additional nutritional supplementation. All patients commencing ART should be placed on Bactrim prophylaxis. A treatment supporter has to be identified to improve compliance with treatment and a mental health review needs to be conducted as serious mental illness can result in poor adherence with therapy. The recommended first line triple drug regimens include TDF and 3TC and NVP/EFV or D4T and 3TC and EFV/NVP or AZT and 3TC and EFV/NVP. The second line therapy is reserved for failed first line therapy. Subsequent monitoring of blood tests will depend on the side-effect profile of the chosen regimen or the symptoms that the patients present with. At each subsequent visit patients need to be evaluated for new opportunistic infections especially TB. At six and twelve months CD4 counts and viral loads need to be repeated. The Guidelines advise that the waiting time for patients with very low CD4 counts i.e. less than one hundred should be two weeks.

CHAPTER III

METHODS

Study design:

This was a retrospective descriptive study. The category of study design used was an audit.

Study location:

KwaDabeka community health centre is a primary health care clinic situated within the municipal boundary of EThekweni (Durban). It serves a population of approximately

150000, predominantly black people. The residents of this district have a socio-economic profile similar to many rural communities within South Africa: poverty, unemployment, many informal homes with inadequate water supplies and poor sanitation, as well as a high prevalence of HIV/AIDS. The ARV clinic in KwaDabeka CHC has an estimated eight thousand patients registered and six thousand of whom already utilizing ART. This clinic is open on weekdays from 08h00am until 16h00pm. The patients are consulted, at least once per month, by either a nurse, doctor or both. There were three full-time CHC doctors assigned to the HIV clinic. In addition, there was a doctor, employed by a non-governmental organisation, that did sessions at the HIV clinic. There was one nursing sister in charge with three professional nurses, two staff nurses and three enrolled nursing assistants. There were two adherence counsellors and two lay counsellors. The HIV clinic has its own clerk and the HIV positive patients' charts were filed separately from the general out-patient files. There was one data capturer who was responsible for statistics and one social worker who was assigned to specifically manage HIV positive patients on ART.

Study Population:

The total number of HIV positive patients attending Kwadabeka CHC, at the time of this study, was six thousand. This number consisted of men, women and children. Many of the patients accessing care at this institution reside in informal settlements. The area is semi-urban so basic services such as running water and electricity remains a daily challenge.

Sample size and strategy:

The study sample included adult patients only who were on ART for at least one year. A minimum of one year was required to ensure that all the variables listed could be evaluated. The period analysed was 01 January 2011 until 31 December 2011 as this study was benchmarked against the National Guidelines of 2010 and it would be inaccurate to evaluate the management of patients prior to publication of these guidelines. Pregnant females and children were excluded because the PMTCT and Paediatric Guidelines for ART differ from the National Adult Guidelines.

Patient charts are numbered and filed according to these numbers in filing cabinets. In order to obtain a sample size, the researcher first consulted with the biostatistician at UKZN. He emailed various online websites that provided tools to perform an online

sample calculation. The researcher used the Creative Research Systems website.²⁰ The researcher chose a confidence level of 95% and a confidence interval of 5. A confidence level of 95% indicated that the researcher was 95% sure that the study sample was representative of the total population of patients on ART at this clinic. A confidence interval or the margin of error is a plus-minus figure, often used in polls. The researcher chose a confidence interval of 5, so if for example the study revealed that 40% of the study population were males, for example, then it could then deduced that there was a 95% confidence that the total percentage of males on ART at this CHC was between 35% (40-5) and 45% (40+5). This particular sample size calculator requires for both the confidence interval and level to be entered in order to generate a sample size.

After entering this data the researcher was given a sample size of three hundred and sixty. In order to determine the interval between the files selected from the patient register, the total number of patients i.e six thousand was divided by three hundred and sixty which gave the researcher the number sixteen. This meant that in order to obtain a sample size of three hundred and sixty the researcher would have to select every sixteenth file after the first randomly selected file was chosen. This was done from the patient register for the period of 01 January 2011 to 31 December 2011. The numbers one to sixteen were written on individual pieces of paper and a number was selected using the lucky draw process. The number chosen had determined the first file selected. For example, if the number 4 was selected then the 4th file on the patient register was chosen. Thereafter, every sixteenth file formed part of the sample. In order to analyse all the variables listed in the data collection tool (appendix 2), the researcher only analyzed the files of patients who had been on ART for at least one year. In addition, pregnant females and children were excluded, as the PMTCT program has its own set of guidelines and the National guidelines for children differs from adults. In the event that a selected file belonged to a patient that had been on treatment for less than one year; a pregnant female, a child or if that file was missing, the subsequent file number was selected.

Variables

The 2010 National ART Guidelines was divided into pre-initiation, initiation and monitoring recommendations. In order to compare the management of HIV positive patients at KwaDabeka CHC to these guidelines, which was the second objective of this study, in a systematic manner, the data collection tool (appendix 2) was also divided along the same lines. The following variables formed part of the first and subsequent visits (or pre-initiation) work-up as per National Guidelines:

- Baseline CD4 counts: Taken at the time of being diagnosed with HIV. CD4 counts of less than 200 copies/mm³ need ART.
- Co-trimoxazole (Bactrim) prophylaxis: This should be have been commenced if a patient had a CD4 count of less than 200 copies/mm³ or in the presence of a stage 2, 3, or 4 HIV illness. It should ideally be commenced prior to ART initiation.

- Pap smear: All HIV positive females require cervical cancer screening upon diagnosis and if normal then three yearly irrespective of ART status. In this study, the researcher specifically looked at whether a pap smear was performed at all i.e. at the time of diagnoses, or subsequently, but within the range of the study period.
- Mental health review: According to the National Guidelines, depression and anxiety is more common in HIV positive patients than HIV negative. The presence of mental illness can affect adherence to treatment. Furthermore, patients with untreated depression or on psychotropic drugs should not have been placed on Efavirenz as it could aggravate their symptoms.
- TB screen: All HIV positive patients require screening for signs and symptoms of TB prior to ART. Ideally, a sputum specimen needs to be tested but if not possible then a chest x-ray should be ordered if TB symptoms are present.
- Baseline bloods including a Hepatitis screen and RPR: These would include a full blood count, urea and electrolytes and liver function tests. Patients that have Hepatitis would require Tenofovir as part of their initial regimen. Syphilis is also a sexually transmitted infection and if present needs to be treated.
- Nutritional assessment: Malnourished patients may require additional nutritional supplementation. Patients who experience unintentional weight loss of more than 1.5 kilograms in one month may require screening for TB.
- Social assessment: These assist with identifying the living conditions and establish if patient may need additional assistance for example social grants.
- Treatment supporter: Disclosure to a close friend or partner is encouraged as HIV. This helps to improve adherence.
- INH prophylaxis: TB preventive therapy is an effective intervention for HIV positive patients prior to ART initiation.

The recommended timeline for fast-tracked patients for initiation of ART, as per National Guidelines, is two weeks, and the timeline variable helped to identify if this institution had complied. The patients that require fast tracking include CD4 counts of less than 100 copies/mm³; stage four illnesses irrespective of CD4 count and patients with MDR or XDR TB. The initiation regimen variable was compared to that of the recommended regimens as per National Guidelines. The appropriateness of the regimen was then compared to the special considerations recommendations in the National Guidelines. For example, Tenofovir should be avoided in a patient with a glomerular filtration rate of < 50 millilitres/min. The appropriate management of abnormal results variable compared the National Guidelines recommendations for drug-induced side effects of ART with that of the CHC.

The last aspect was monitoring. The data sheet used the following variables, which from part of the National Guidelines monitoring tools:

- Follow-up clinical monitoring- TB symptom check (to exclude Immune reconstitution syndrome). Patients needed to be screened for TB symptoms at every visit. The risk of TB is highest around the time of initiation.
- Follow-up bloods (FBC, U&E, and LFT) in order to monitor for side effects.
- Pill counts to check adherence.
- Management of poor adherence as compared with the National guidelines recommendations.
- Immunological response- CD4 count and VL as per the National guidelines stipulated intervals.

The first objective of this study was to establish a demographic patient profile and therefore the first two variables of the data sheet recorded gender and age. The third and fourth objectives of the study were achieved following the collection and analysis of data. The problems with implementation of National ART guidelines at this CHC have been discussed and possible solutions have been suggested.

Inclusion criteria:

Adult(defined as 18 years old and over) HIV positive patients utilizing ART from the period 01 January 2011 to 31 December 2011, at KwaDabeka CHC, and who had received ART for at least one year prior to the commencement of this study.

Exclusion criteria:

Pregnant patients, children and patients who had received less than one year of ART had been excluded.

Data collection methods and tools:

The patient files selected in the sample was analyzed according to the variables that are listed on the data capture sheet (appendix 2). The patient management was compared to the recommended National ART guidelines of 2010, using these variables. The data collection tool had been piloted at KwaDabeka CHC, using a sample size of thirty patients. No modification to the tool was required. Data was captured on an Excel spreadsheet using categorical and numerical variables.

Data Analysis techniques:

The data obtained was entered into a computer using a Microsoft Excel spreadsheet and subsequently imported into SPSS version 21 for analysis. Simple descriptive statistics,

univariate analysis, and frequency distribution tables were used. Tables, pie charts, and graphs were utilised to represent the analysed data.

Limitations:

1. Information Bias:

- Poor record keeping.
- Lost results.

Both the above factors may compromise the results of the audit. However, poor-record keeping and lost results provide some reasons for poor quality care. The intention of this study was to audit the standard of care and not to determine why this may have been. Hence, these factors were not individually analysed in the data collection tool.

2. External validity: This study was only undertaken at Kwadabeka CHC; therefore, generalizing the results to other CHC's may not be possible. However, the results of this study may encourage managers of other institutions to conduct similar internal audits, which may help identify pitfalls of individual institutions and ultimately provide opportunities for changes focused on quality improvement.

3. The staffing levels and resources or structural criteria were not evaluated in this study. The National ART Guidelines do not provide recommended staff to patient ratios. This would make it impossible to assess if this CHC had complied with those recommendations or not and this has been, after all, a study directed at comparing the management recommended by these guidelines with the management at the CHC.

Ethical considerations:

This protocol was submitted to both the Biomedical Research Ethics Committee as well as the Postgraduate Committees at UKZN for approval (appendix 3). Subsequent permission to conduct the proposed study was requested from the medical manager of KwaDabeka CHC. Permission from the Kwa-Zulu Natal Department of Health was also obtained both for the patient file audit as well as for the use of laboratory results prior to commencing this study. A waiver of informed consent to use patients' medical records was not obtained. Patients were identified by numbers and not names and no potential harm could have been incurred on the part of the patient.

CHAPTER IV

RESULTS

A total number of 360 files were analysed. Forty of the initially selected sample did not meet the inclusion criteria. In order to ensure that the 360 files were met, forty additional files were selected, as per the process previously described under sampling strategy. The demographic profile of the patients is represented in figure 1.

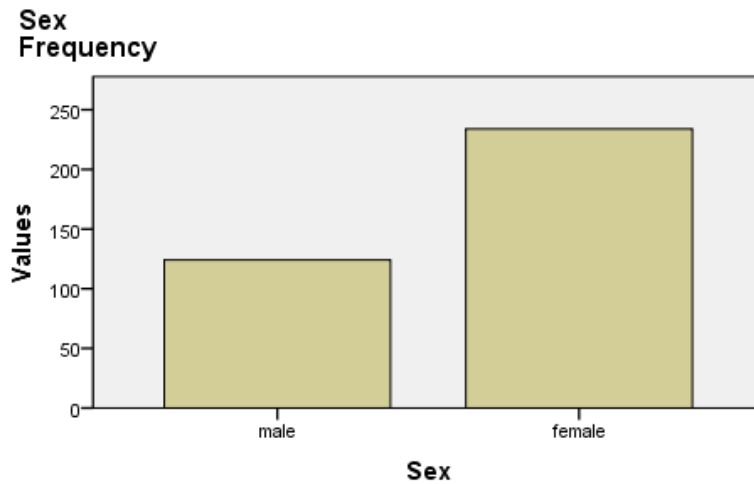


Figure 1: Gender distribution graph

The mean age of the patients was 39 years. The age distribution has been illustrated in figure 2.

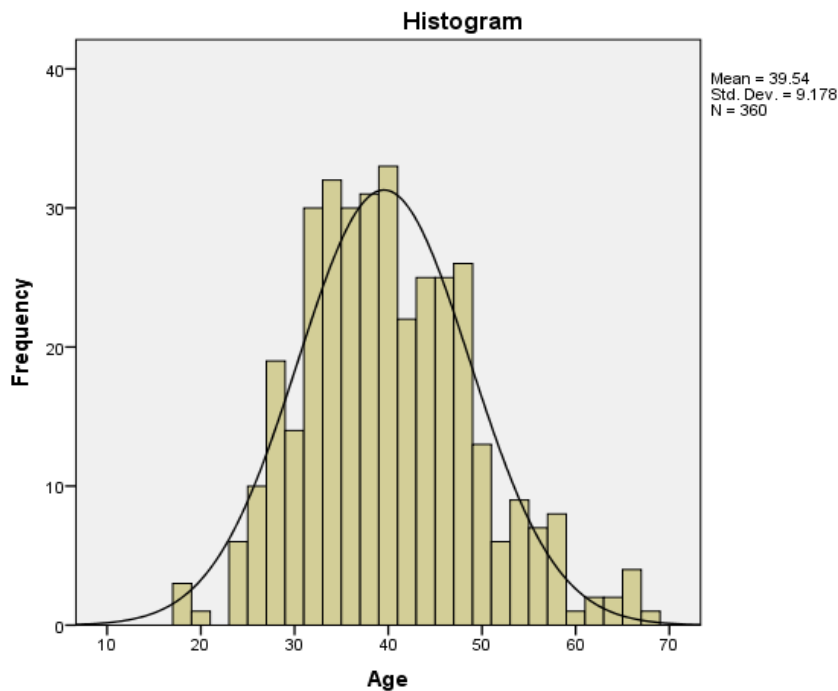


Figure 2: Age distribution histogram

The variables analyzed against the National ART guidelines have been summarized in Table 1.

TABLE 1 : Summary of the variables analyzed

| | YES | NO | NOT APPLICABLE |
|---|----------|-----------|----------------|
| Baseline CD4 count taken | 352(97%) | 8(3%) | 0 |
| Staging of illness | 355(98%) | 5(2%) | 0 |
| INH prophylaxis for patients without TB | 0 | 244(68%) | 114(32%) |
| Bactrim prophylaxis provided for stage 2, 3 or 4 illness or CD4 count less than 200 copies/ml | 337(94%) | 21(6%) | 0 |
| Pap smear for all female patients | 48(13%) | 191(53%) | 121(33%) |
| Mental health review | 0 | 360(100%) | 0 |
| TB screen for all HIV positive patients prior to ART initiation | 316(96%) | 11(3%) | 0 |
| FBC, U&E and LFT* taken prior to ART initiation. | 347(97%) | 12(3%) | 0 |
| F/U TB review on subsequent visits post ART initiation | 55(15%) | 291(82%) | 11(3%) |
| Vital signs checked at every visit | 44(12%) | 312(87%) | 0 |
| BMI calculated | 87(24%) | 273(76%) | 0 |
| Social assessment prior to ART | 339(94%) | 21(6%) | 0 |
| Investigation of abnormal blood results | 29(8%) | 45(13%) | 285(79%) |
| Adverse events | 149(41%) | 211(59%) | 0 |
| New regimen initiated | 124(34%) | 234(65%) | 0 |
| F/U Bloods taken | 356(99%) | 4(1%) | 0 |
| Treatment supporter identified | 355(99%) | 5(1%) | 0 |
| Pill counts taken on every visit | 356(99%) | 4(1%) | 0 |

* If any one of the baseline bloods i.e. FBC, U&E or LFT was not performed then “No” was entered.

Baseline CD4 counts were performed in 352 (97%) of patients. The mean CD4 count was 125 copies/mm³ (SD 67). There was a total of 123 (34%) of patients whose baseline CD4 counts were less than 100 copies/ml. The CD4 counts are illustrated in figure 3.

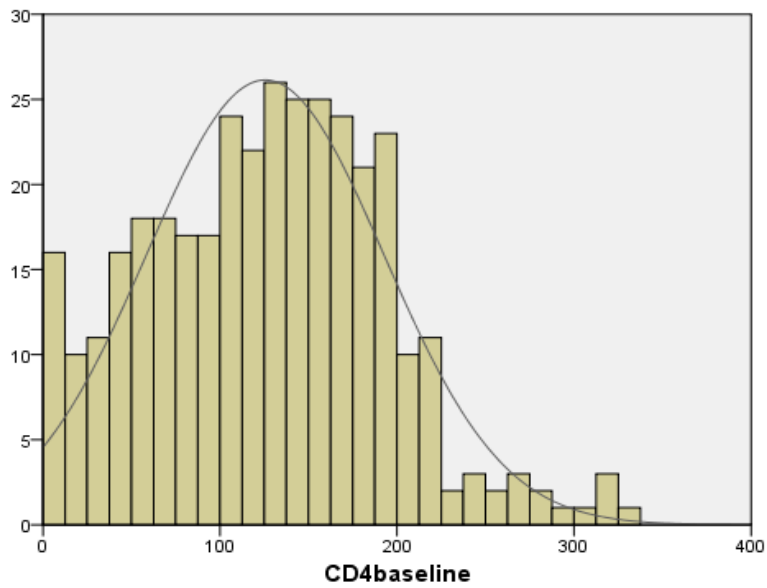


Figure 3: Baseline CD4 distribution histogram

The WHO staging of HIV (appendix 4) was used to classify patients' stages of illness. A total number of 355 patients were staged and of these 152(42%), the majority, were classified as stage 1, 64(17.8%) were stage 2, 122(33.9%) were stage 3 while 17(4.7%) were stage four (figure 4).

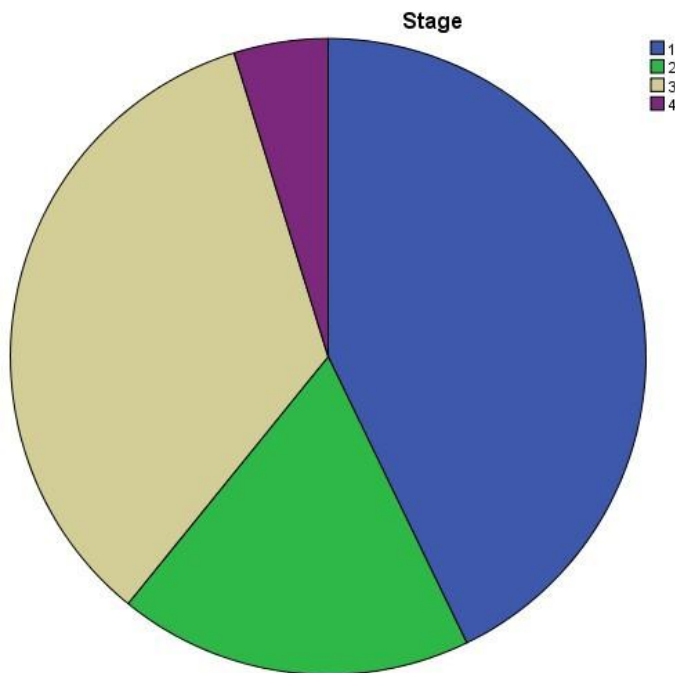


Figure 4: Patient distribution according to WHO staging

None of the patients were initiated on INH prophylaxis despite 244(68%) qualifying for it. The remainder 114(32%) were confirmed to have Tuberculosis (TB) and were taking anti-TB drugs.

Pap smears had been performed on 48(20%) of female patients while 191(80%) did not have it done.

Abnormal blood results were found in a total number of 74(20%) of the patients. Of these 74 patients, 29(39%) had further investigations performed while the remaining 45(61%) did not have any active intervention. The other 285(79%) did not have abnormal blood results. Adverse events were documented in 149(42%) and of these 25% did not have their regimen changed despite having a serious adverse event documented. Stavudine related lipodystrophy accounted for 104(70%) of adverse events while stavudine related peripheral neuropathy accounted for the remaining 30%. Regimen 1 was being used by 226(63%) and 123(37%) were changed to regimen 2 due to adverse events (Table 2).

TABLE 2: Summary of the ART regimens used by patients.

| REGIMEN | | | |
|----------|-----------|---------|--------------------|
| | Frequency | Percent | Cumulative Percent |
| 2 | 124 | 34.2 | 34.2 |
| 1 | 226 | 62.8 | 96.9 |
| Valid 1a | 2 | .6 | 97.5 |
| 1b | 9 | 2.5 | 100.0 |
| Total | 360 | 100.0 | |

The mean CD4 count at six and twelve months was 271 copies/mm³ and 360 copies/mm³ respectively (figures 5 and 6). The CD4 count was repeated at six months on 322(89%) of the patients and at twelve months on 315(88%) of the patients.

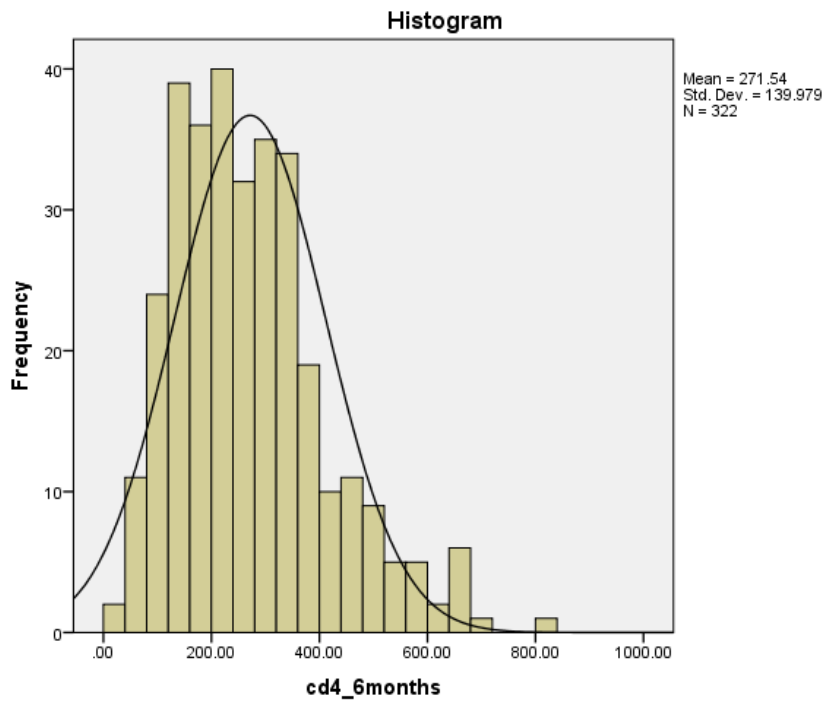


Figure 5: CD4 Distribution at 6 months after ART initiation

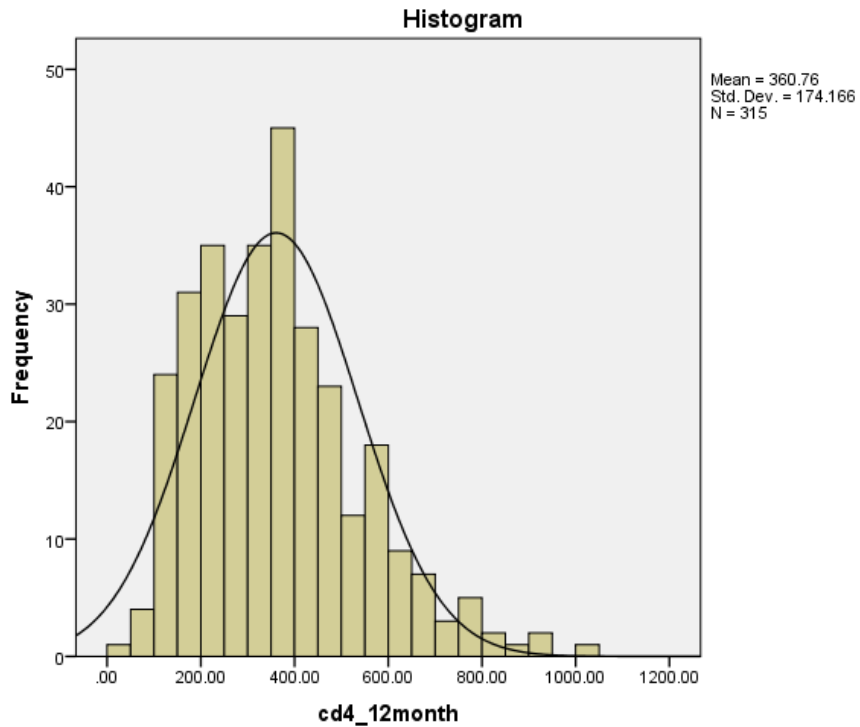


Figure 6: CD4 distribution after 12 months of ART.

The viral load at six months was undetectable in 28% of the patients and less than 40

copies/ml in 50% of patients (table 3). At twelve months, the viral load was undetectable in 38% and less than 40 copies/ml in 45% of the patients (table 3 below).

TABLE 3: Viral loads at six and twelve months

| | Undetectable | <40copies/ml |
|-----------------------|--------------|--------------|
| Viral load(6 months) | 28% | 50% |
| Viral load(12 months) | 38% | 45% |

The mean time interval from the taking of a CD4 count to the initiation of a patient on ART was 2.2 months and SD1.7. (figure 7). Twenty-one (15%) of patients were initiated on ART within two weeks.

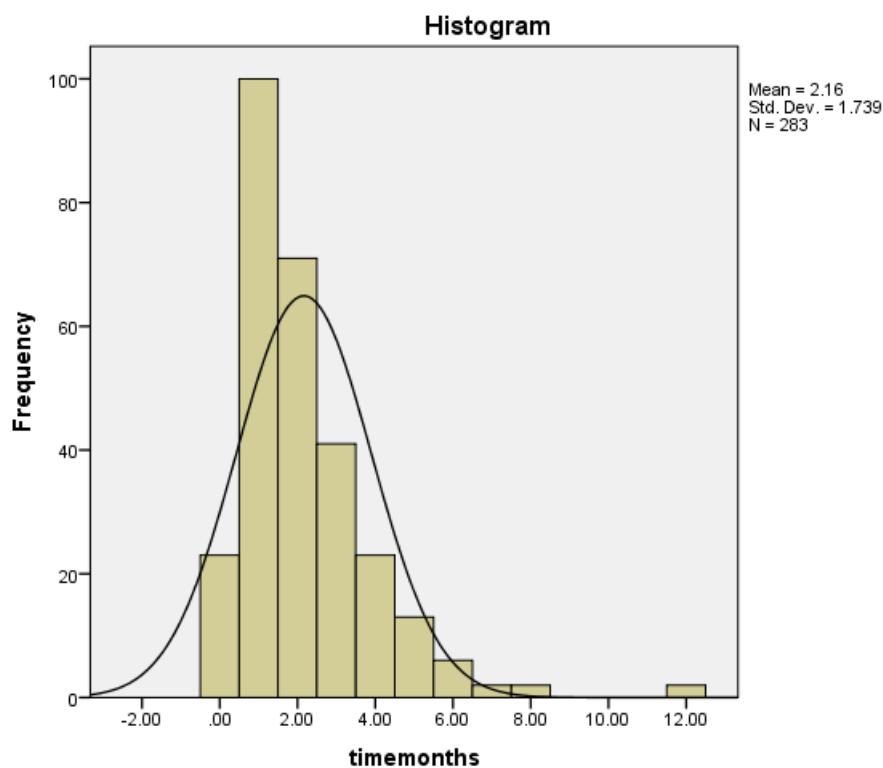


Figure 7: Timeline from baseline CD4 count to initiation of ART.

CHAPTER V

DISCUSSION

The study found that most patients on ART were female and between the ages of 30-48 years (mean 39 and SD9). These findings were comparable with the United Nations AIDS findings for Sub-Saharan Africa published in the World AIDS day report in 2011.²¹

The following steps as advised by the National Guidelines were adhered to by more than 90% of the participants: performing a baseline CD4 count; staging the illness; commencement of Bactrim prophylaxis; screening for TB; conducting baseline blood tests; making social assessments; performing follow-up blood tests; ensuring a treatment supporter; and taking pill-counts on each visit.

The steps that were not well adhered to included: lack of INH prophylaxis; poor percentage of pap-smears performed; no mental health evaluation conducted; poor follow-up of TB symptoms; lack of assessment of vital signs and BMI; poor management of adverse drug reactions; and a longer than recommended time-interval from taking a CD4 count to initiating ART.

INH prophylaxis was not issued to 68% of patients who qualified for it. This was despite the multiple studies, which have shown that INH prophylaxis reduced the incidence of TB in HIV-infected individuals by 62% in those with positive Tuberculin skin tests (TST) and by 11% in TST negative patients.²² The research findings suggest that the lack of adherence to INH prophylaxis may be attributable to a lack of knowledge of the guidelines. These findings require further investigation from the medical staff themselves.

Pap smears were not performed on 191(80%) of the total number of females in this study. The relationship between HIV and cervical cancer has been well established. Abnormal cytology results have been reported in 65% of HIV positive women.²³ Early detection of cervical cancer and prompt treatment makes a difference in mortality and morbidity. There is therefore a possibility that poor screening at this CHC may have resulted in pre-cancer and cancerous cervical cytology being missed in many females.

The prevalence of depression or other psychiatric disorders in HIV positive patients has not been well established in Sub-Saharan Africa yet. However, one study in Tanzania found that 15% of HIV infected individuals had concurrent depression and 4.5% had other anxiety disorders.²⁴ This article also mentioned that depression has been linked to faster disease progression and reduced drug adherence. It is therefore significant that none of the 360 patients had any form of mental health assessment. The psychosocial implication as well as the stigma associated with HIV is well known. Many patients suffer with social alienation and its impact on mental health warrants attention. This audit could have brought to light much needed information about the possible concurrent existence of mental illness in HIV positive patients, had mental health assessments been conducted.

However, if we had to draw similarities between South Africa and Tanzania, both of whom are emerging economies with resource limitation, this could imply that a significant

percentage of mental illness may not have been diagnosed.

The highest risk factor for TB is HIV infection. Patients who have commenced ART are at risk of experiencing clinical deterioration due to the inflammatory response against pathogens of which TB would be the most common. This is referred to as Immune Reconstitution Inflammatory Syndrome (IRIS). TB symptoms were not followed-up in 82% of patients following the commencement of ART. This represents a significant number bearing in mind that the incidence of TB-IRIS following ART initiation ranges from 8-43%.²⁵

Vital signs and BMI's were not performed on at least 80% of patients. Vital signs usually consist of blood pressure, pulse and temperature recordings. Deranged vital signs may be a marker of acute illness. BMI assesses nutritional status. Many HIV infected patients are ill and malnourished at the time of ART initiation due to their vulnerable immune status and weight loss so the recording of vital signs and BMI would be very important. A study conducted in Burkina Faso can further support this as it had established a relationship between the wasting syndrome and mortality.²⁶

A large number of adverse events were documented at the CHC (42%). These had related to the drug Stavudine, which was provided as first line therapy a few years ago. This finding is also supported by a study that had established Stavudine as the possible causative agent in 93% of adverse events.²⁷ Fortunately, this drug, which had potentially life-threatening side-effects, has now been phased out in favour of the use of Tenofovir.²⁸ Adverse effects can result in mortality, morbidity and poor compliance. Therefore, patients need to be monitored for them. This was another area requiring attention at the CHC.

The National Guidelines recommend a two-week interval from obtaining a CD4 count to ART initiation for patients with CD4 counts of less than 100 copies/mm³, patients with a stage 4 illness and those with XDR/MDR TB. There were 123(34%) who had CD4 counts of less than 100 copies/mm³ and 17(4.7%) with a stage 4 illness. This meant that 136 patients needed to be fast-tracked i.e. commenced on treatment within two weeks. Twenty-one patients were commenced on treatment within two weeks which implies that 115(84.5%) were not fast-tracked.

The management of poor adherence was difficult to assess in this study. This was most likely because of scanty notes made on the actual steps taken to improve adherence. Patients that were suspected of being non-adherent with ART were referred to the adherence counsellors according to their files. The National ART Guidelines advise the methods listed below to improve adherence:

- More visits and more frequent adherence checks.
- Enlisting the support of family and friends.
- Increasing home visits if possible.
- Using reminders and reinforcing adherence tools.

- Actively addressing food security.

The adherence counsellors had been consulted regarding this matter and they stated that they do employ the above methods with poorly adherent patients. However, it was not possible to ascertain if they had used these methods with the patients that were included in this study, due to lack of documentation in the files.

The South African government has revised the National Strategic plan for the management of HIV, TB and STI's for 2012-2016.²⁸ The five goals that they hope to achieve are:

- halving the number of new HIV infections
- ensuring that at least 80% of people who are eligible for treatment for HIV is receiving it (at least 70% should be alive and still on treatment after five years)
- halving the number of new TB infections and deaths from TB
- ensuring that the rights of people living with HIV are protected
- halving the stigma related to HIV and TB

The manner that they propose to achieve these goals are quoted below.²⁸

- Address social and structural factors that drive these epidemics, influence their impact, and affect the way we care for affected people.
- Prevent new HIV, STI's and TB infections through a combination of interventions.
- Sustain health and wellness, primarily by reducing deaths and disability from HIV infection and TB.
- Protect the human rights of people living with HIV and improve their access to justice

CHAPTER VI

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSION:

The demographic profile generated reveals a predominant number of female patients and the average age of patients on ART was 39 years.

The level of adherence to National ART Guidelines was poor. Specifically, six major areas were identified with which the clinic did not comply in at least 50% of the patients sampled and has been discussed previously.

The problems in the care of HIV positive patients at this CHC largely stem from the poor adherence with vital aspects of the guidelines, which this study was able to prove. Recommendations have been proposed. The overall impression was that the current management of HIV positive patients requires improvement by this institution.

RECOMMENDATIONS:

The results of this study have revealed several aspects of the National Guidelines with which KwaDabeka CHC does not comply with. The researcher recommends that the management of this institution conduct an investigation to establish the reasons for this non-compliance.

It may be advisable to ensure that copies of the National ART Guidelines is made available to the healthcare workers involved in the management of HIV positive patients.

Staff meetings specifically addressing problems and concerns regarding the ART programme need to be held on a regular basis.

Random auditing of patients' files and presenting the results at staff meetings may identify new areas of concern and prevent problems from accumulating.

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APPENDICIES

APPENDIX 1 : photos of KwaDabeka CHC



Source: <http://teaandblisters.blogspot.com/2011/06/monday-morning.html> (accessed 22/10/13)



Source: <http://teaandblisters.blogspot.com/2011/06/monday-morning.html> (accessed 22/10/13).

APPENDIX 2

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|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | Vital Signs | | | | | | | | | | | | | | | | | | |
| | BMI | | | | | | | | | | | | | | | | | | |
| | Treatment supporter | | | | | | | | | | | | | | | | | | |
| | CD4 6& 12 month | | | | | | | | | | | | | | | | | | |
| | V/L 6& 12 month | | | | | | | | | | | | | | | | | | |
| | New regimen | | | | | | | | | | | | | | | | | | |
| | Pill count correct | | | | | | | | | | | | | | | | | | |
| | FF-up bloods | | | | | | | | | | | | | | | | | | |
| | FF-up TB symptom r/v | | | | | | | | | | | | | | | | | | |
| | Appropriate management of abnormal blood results | | | | | | | | | | | | | | | | | | |
| | Adverse event | | | | | | | | | | | | | | | | | | |
| | Initial regimen | | | | | | | | | | | | | | | | | | |
| | Timeline | | | | | | | | | | | | | | | | | | |
| | INH prophylaxis | | | | | | | | | | | | | | | | | | |
| | Rx supporter | | | | | | | | | | | | | | | | | | |
| | Social assessment | | | | | | | | | | | | | | | | | | |
| | Nutritional assessment | | | | | | | | | | | | | | | | | | |
| | Baseline | | | | | | | | | | | | | | | | | | |
| | FBC/U&E/LFT/HEP/RPR | | | | | | | | | | | | | | | | | | |
| | TB screen (b) | | | | | | | | | | | | | | | | | | |
| | Mental health r/v | | | | | | | | | | | | | | | | | | |
| | Pap smear | | | | | | | | | | | | | | | | | | |
| | Bactrim prophylaxis | | | | | | | | | | | | | | | | | | |
| | Stage of d/s | | | | | | | | | | | | | | | | | | |
| | CD4(b) | | | | | | | | | | | | | | | | | | |
| | Age | | | | | | | | | | | | | | | | | | |
| | M/F | | | | | | | | | | | | | | | | | | |
| | FILE NO | | | | | | | | | | | | | | | | | | |

KEY:

M- Male F- Female d/s- Disease r/v- Review
 (b)- baseline FBC- Full blood count LFT- Liver function test
 U&E- Urea and electrolytes INH- Isoniazid
 Hep- Hepatitis RPR- Rapid Plasma Reagin(syphilis test) Rx- Treatment
 FF-up- Follow-up V/L- Viral load BMI-Body Mass Index
 Colour coded columns as per National ART guidelines divided into:

- Pre- initiation requirements
- Initiation regimen
- Monitoring tools

APPENDIX 3



RESEARCH OFFICE
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05 October 2012

Dr. N Inderjeeth
PO Box 40988
Redhill
4071

Dear Dr Inderjeeth

PROTOCOL: Audit of the standard of care received by HIV positive patients on Antiretroviral (ART), in rural district of KZN, South Africa. REF:BE050/12.

EXPEDITED APPLICATION-RATIFICATION

This letter serves to notify you that at a full sitting of the Biomedical Research Ethics Committee meeting held on 14 August 2012, the Committee **RATIFIED** the sub-committee's decision to approve the above study.

Yours sincerely

Mrs A Marimuthu
Senior Administrator: Biomedical Research Ethics

APPENDIX 4

| | |
|--|---|
| <p><u>Stage 1</u></p> <ul style="list-style-type: none"> • Asymptomatic • Persistent generalized lymphadenopathy <p><u>Stage 2</u></p> <ul style="list-style-type: none"> • Moderate unexplained weight loss (<10% of presumed or measured body weight) • Recurrent respiratory infections (sinusitis, tonsillitis, otitis media, and pharyngitis) • Herpes zoster • Angular cheilitis • Recurrent oral ulceration • Papular pruritic eruptions • Seborrheic dermatitis • Fungal nail infections <p><u>Stage 3</u></p> <ul style="list-style-type: none"> • Unexplained severe weight loss (>10% of presumed or measured body weight) • Unexplained chronic diarrhea for >1 month • Unexplained persistent fever for >1 month (>37.6°C, intermittent or constant) • Persistent oral candidiasis (thrush) • Oral hairy leukoplakia • Pulmonary tuberculosis (current) • Severe presumed bacterial infections (eg, pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteremia) • Acute necrotizing ulcerative stomatitis, gingivitis, or periodontitis • Unexplained anemia (hemoglobin <8 g/dL) • Neutropenia (neutrophils <500 cells/μL) • Chronic thrombocytopenia (platelets <50,000 cells/μL) | <p><u>Stage 4</u></p> <ul style="list-style-type: none"> • HIV wasting syndrome • Pneumocystis pneumonia • Recurrent severe bacterial pneumonia • Chronic herpes simplex infection (orolabial, genital, or anorectal site for >1 month or visceral herpes at any site) • Esophageal candidiasis (or candidiasis of trachea, bronchi, or lungs) • Extrapulmonary tuberculosis • Kaposi sarcoma • Cytomegalovirus infection (retinitis or infection of other organs) • Central nervous system toxoplasmosis • HIV encephalopathy • Cryptococcosis, extrapulmonary (including meningitis) • Disseminated nontuberculosis Mycobacteria infection • Progressive multifocal leukoencephalopathy • Candida of the trachea, bronchi, or lungs • Chronic cryptosporidiosis (with diarrhea) • Chronic isosporiasis • Disseminated mycosis (eg, histoplasmosis, coccidioidomycosis, penicilliosis) • Recurrent nontyphoidal Salmonella bacteremia • Lymphoma (cerebral or B-cell non-Hodgkin) • Invasive cervical carcinoma • Atypical disseminated leishmaniasis • Symptomatic HIV-associated nephropathy • Symptomatic HIV-associated cardiomyopathy • Reactivation of American trypanosomiasis (meningoencephalitis or myocarditis) |
|--|---|

Sourced from:

http://www.med.wright.edu/sites/default/files/medu/Electives/WHO_criteria_staging_HIV.pdf (accessed 21/10/13)

