

HIV Management in a Mining Company in South Africa

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Declaration

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Abstract

The mining industry having been identified as a particularly vulnerable sector to the potentially devastating effects of HIV and AIDS, it became clear that proper management thereof is essential if we are to mitigate these. Two-hundred-and-seventy-nine of the 720 patient files from the mine's wellness clinic were reviewed for clinical appropriateness. These files were scrutinised to evaluate adherence to treatment guidelines. The review was conducted using the wellness clinic's treatment guidelines, adapted from the South African HIV Clinicians Society (SAHIVCS) 2008 guidelines asking the four questions: "when to start therapy", "what therapy to start", "co-existence of other illnesses", "when to change therapy".

The guidelines were largely adhered to as far as starting the right type of therapy at the right time. "When to start therapy" was adhered to in 97.1 percent of the cases, "when to start" in 99.6 percent. However evaluation of "co-existence of other illnesses" came in at a rather low figure of 45.5 percent. Although the need for change of therapy was very low (2.5 percent), 57.5 percent of those who needed a change in therapy were prolonged on failing regimens for periods of more than three months.

Opsomming

Die mynindustrie in Suid-Afrika is as 'n uiters kwesbare sektor geïdentifiseer en behoorlike bestuur van hierdie sektor is van kritieke belang in die suksesvolle bestuur van MIV/Vigs in Suid-Afrika.

Die mediese inligting van 279 pasiënte is vir die doel van die studie ontleed en die mate waartoe pasiënte getrou hou by behandelingsriglyne is in die studie ge-evalueer. Die ontleding was gebaseer op die 2008 welwees kliniese riglyne van die South African HIV Clinicians Society (SAHIVCS).

Die studie bevind dat pasiënte in 'n groot mate by die kliniese riglyne gehou het en dat die datum waarop met behandeling begin is in bykans 97 % van die gevalle ooreenkomstig die riglyne was.

Die grootste bron van kommer was die groot relatief groot aantal gevalle waar die invloed van ander siektetoestande nie behoorlik in ag geneem is nie en die MIV/Vigs medikasie nie dienooreenkomstig aangepas is nie.

Voorstelle word in die studie gemaak vir aksies wat geneem behoort te word om 'n groter mate van voldoening aan die riglyne te bewerkstellig.

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Chapter 1: Introduction

The South African economy is expected to be affected by the Human Immunodeficiency Virus (HIV) in different sectors and to varying extents. The direct impact of HIV on the size of the population (and the size of labour available), the increase in mortality rate and the deterioration of the health of the population in general translate into a disruption of the economic activities of the country, both at the macro- and micro-economic level. Businesses require a stable macro-economy to operate at optimum levels. HIV prevalence figures show that the epidemic affects people who are mostly in the prime of their economic life (i.e. 15 to 49 year olds) (Shisana, Rehle, Simbayi, Zuma, Jooste, Pillay-van-Wyk, Mbele, Van Zyl, Parker, Zungu & Pezi 2009:63). The reduction in the productivity by labour is likely to have several consequences. Arndt and Lewis (2000:11) found that, in the absence of any interventions, the reduction in the real Gross Domestic Product (GDP) growth rate of South Africa would be as much as 2.6 percent over a twelve year period as a direct result of AIDS, coupled with a reduction in per capita GDP of around eight percent as well as an increase in opportunity costs for AIDS-related expenditure.

Arndt and Lewis (2000) suggest that semi-skilled and unskilled labourers are a high risk group and have an infection rate nearly three times that of highly skilled workers. This exposes companies with high low-skill level personnel to potential threats to the bottom line. Botswana's Debswana Diamond Company, which employs just over 6000 employees, found a 27.6 percent HIV prevalence rate among its skilled workers. Their prevalence studies revealed significant mortality and morbidity with a rise in ill-health retirements from 40 percent to 75 percent between 1996 and 1999 (Debswana, 2001).

HIV affects the labour force in different way according to the South African Business Coalition on HIV & AIDS (SABCOHA) (2003):

HIV affects the productivity of the labour force since they have to spend fewer days at work due to ill-health.

The illness and death benefits due to increased morbidity and mortality increase and therefore increase the Cost to Company. Lastly, there is also an expected increase in cost to companies since more people have to be trained to replace those affected.

Correct and cost-effective management of HIV in the workplace is vital to the continued profitability of any organisation. Clear and precise guidelines should therefore be followed in

order to achieve consistency and reduce the cost of running such programmes. A well thought-out HIV policy and HIV workplace programme should form the basis of an HIV management programme. A HIV management programme that incorporates provision of antiretroviral (ARV) drugs is more cost-effective to companies in the long-term. However, such provision of drugs should be closely monitored for treatment adherence, proper patient follow-up and monitoring as well as correct provision of appropriate drug regimen and dosages to avoid drug resistance, side-effects and complications that may arise as a consequence. These may prove more expensive than the omission of ARV provision.

HIV management guidelines assist healthcare workers to follow uniform treatment standards and maximise the benefits of HIV treatment. This study set out to ascertain the compliance of healthcare workers to prescribed HIV management guidelines in the mining industry. A review of literature with regards to the current HIV trends as well as the response by the industry is outlined in the first chapter. Research methodologies as well as ethical considerations are outlined in Chapter 3, while the results of the research are presented and discussed in Chapter 4. Chapter 5 will deal with limitations of the study and recommendations going forth. The study summary and conclusion is to be found in Chapter 6.

Chapter 2 : Literature Review

South Africa is now home to about 5.7 million people living with HIV and AIDS (UNAIDS, 2011). In terms of numbers, this is by far the world's highest number of people infected with HIV in one country. Sub-Saharan Africa accounts for about 69 percent of the people living with HIV globally; with a total prevalence of about 4.9 percent in 2011 (down from 5.9 percent in 2005 (UNAIDS Global Report, 2012). Although the epidemic seems to be stabilising and the number of new infections declining, new infections are still being recorded daily nonetheless. UNAIDS (2012) reports a steady, but progressive decline of about 25 percent of new HIV infections between the years 2001 and 2011 for the sub-Saharan Africa region.

According to UNAIDS (2012) the number of AIDS deaths and morbidity is also on the decline which can only augur well for the economy and the population at large. The World Health Organisation's (WHO) (2011) goal of getting to *zero new infections, zero discrimination and zero AIDS related deaths* appears to be within reach but this is going to need a continued commitment from both the public and the private sector. Although these figures appear to be impressive and encouraging, the intended target of halving new HIV transmission by 2015 as set out in the 2011 United Nations Political Declaration on HIV and AIDS is unlikely to be met if efforts are not increased. Continued commitment will need to be accelerated by the public and private sectors as well as civil society at large. HIV prevalence figures indicate that the worst affected population group is the 15 to 49 year age group (Shisana, Rehle, Simbayi, Zuma, Jooste, Pillay-van-Wyk, Mbele, Van Zyl, Parker, Zungu & Pezi, 2009; UNAIDS, 2009). This is also the age group in their prime working stage.

Although the rate of new HIV infections (incidence) seems to be on a steady decline, a significant number of people continue to get infected with the virus. An estimated 1.8 percent of new infections occurred in 2008 (down from 2.2 percent in 2000), mostly among people in their prime working lives (15 to 49 year old) (UNAIDS, 2009). These are people whom the South African economy depends on for growth and from whom many families depend for their survival.

The vast majority of HIV infections occur amongst the low-skill employees. The South African economy receives a major contribution from the mining sector into the Gross

Domestic Product (GDP). According to the South African Chamber of Mines (2012), the mining industry contributed about 8.8 percent of the country's GDP in 2011 (up from 7.9 in 2002). The industry also employs about 8.2 of the total private non-agricultural sector (Chamber of Mines, 2012). Mining is labour intensive and the mining industry is also a large employer of unskilled as well as semi-skilled workers. The mining industry remains the hardest-hit by HIV and AIDS in South Africa (SABCOHA, 2005; Evian, Fox, MacLeod, Slotow, & Rosen, 2004). The industry therefore stands to benefit from the protection of these workers if it is to continue its economic successes. HIV has the potential to undermine these gains if not properly managed. The implementation of HIV management programmes in workplaces is therefore crucial in this regard. The very nature of the mining environment makes the industry vulnerable to the negative consequences of HIV on a number of levels.

The high prevalence of single-sex hostels, easy accessibility of alcohol, and high concentration of sex workers around mining towns as well as the low education levels of most miners makes the spread of HIV easier.

The economic implications of HIV could prove rather disastrous for businesses if not managed properly. SABCOHA (2004) identified mining and manufacturing to be the most affected industries. To its credit, the mining industry has been at the forefront of the fight against HIV, pioneering the development of workplace HIV policies, programmes as well as providing care, treatment and support to employees affected by the epidemic (Ellis, 2007). Workplace HIV programmes need to be managed to be both cost-effective and clinically appropriate in order to be sustainable in the long term.

For HIV treatment programmes to be sustainable, they need to be cost-effective, especially in resource-limited settings.

Appropriate patient management is therefore of importance for a number of reasons. Poor treatment adherence has the potential to lead to viral mutation and viral resistance rendering HIV drugs ineffective (Sethi, Celentano, Gange, Moore & Gallant, 2003). The viral resistance testing process is expensive, especially in resource-limited settings. The second line-drugs used to treat drug-resistant HIV in resource-limited countries could cost three times as much as the amount of first-line medication (Orrell, Harling, Lawn, Kaplan, McNally, Bekker & Wood, 2007). Secondly, opportunistic infections are likely to be more manifested in the absence of poor viral suppression as a result of decreased antiviral drug blood concentration. Not only is the treatment for opportunistic infections expensive, but the

rate of hospitalisation tends to increase with an added associated cost. In Cape Town, South Africa, in a study evaluating the cost-effectiveness of HAART for 265 HIV-infected adults without AIDS (World Health Organization (WHO) stage 1, 2, or 3) and 27 with AIDS (WHO stage 4), mean inpatient days per person per year (PPY) for patients with AIDS was 2.04 for the HAART versus 15.36 for the No-ART group. The increase in the rate of hospitalisation of the patients not on HAART is likely to be a result of opportunistic infections. HAART has been instrumental in preventing mortality related to opportunistic infections (Egger, Hirschel, Francioli, Sudre, Wirz, Flepp, Rickenbach, Malinverni, Vernazza & Battegay, 1997; Egger, May, Chene, Phillips, Ledergerber, Dabis, Costagliola, D'Arminio Monforte, de Wolf, Reiss, Lundgren, Justice, Staszewski, Leport, Hogg, Sabin, Gill & Salzberger, 2002; Hogg, Heath, Yip, Craib, O'Shaughnessy, Schechter & Montaner, 1998; Palella Jr, Delaney, Moorman, Loveless, Fuhrer, Satten, Aschman & Holmberg, 1998). The added cost of sickness and death benefits in poorly managed HIV people as well as the cost of recruiting and training replacement employees makes good HIV management good business sense (SABCOHA, 2004). Lastly, although the cost of HIV drugs has come down significantly over the past decade, treatment remains expensive in relative terms in resource-limited settings and use of appropriate but lesser expensive drugs and appropriate clinical and laboratory monitoring by health professionals is crucial (WHO, 2006). Health workers need to follow prescribed treatment guidelines to guard against potential rise in the costs related to poor adherence, poor monitoring and poor clinical management of HIV.

Unless clients/employees present themselves to get tested, they are unlikely to receive the proper HIV disease management that they require. The decision by health workers to initiate treatment usually depends on either the self-presentation of patients to health facilities to get tested or provider-initiated in-house or outreach HIV-testing campaigns. Provider-initiated testing and educational campaigns have been shown to be as important, if not more effective, as client-initiated health-seeking behaviour in managing HIV. The South African Department of Health (DoH) has taken a decision to offer provider-initiated HIV counselling and testing (HCT) to every individual presenting themselves for healthcare, replacing the old patient-initiated voluntary counselling and testing (VCT). The campaign managed to exceed more than 73 percent of its intended 15 million people tested for HIV by 2011 (DOH, 2010).

Uniformity in HIV management is at the heart of success in turning the epidemic around. Health workers are more likely to follow treatment guidelines if these are clear, simple and

precise. The importance of starting treatment at the right time has been studied and shown in a number of studies. Timely initiation of HAART reduces the morbidity and mortality rates and the cost of treatment among HIV infected individuals (Braitstein, Brinkhof, Dabis, Schechter, Boule, Miotti, Wood, Laurent, Sprinz, Seyler, Bangsberg, Balestre, Sterne, May & Egger, 2006; Lawn, Myer, Orrell, Bekker & Wood, 2005; Merito and Pezzotti, 2006). Current studies on what to start and when to start treatment differ by design, size, setting and availability, however, the WHO has devised recommendations thereof. Guidelines are compiled to guide clinicians when making important decisions about patient management. HIV treatment guidelines have changed substantially since they were first published by the US Department of Health and Human Services (DHHS) in the late nineties. These guidelines have evolved substantially over the past decade and are updated whenever new evidence-based treatment information comes to light. Initial treatment of HIV positive individuals in developed countries recommended ART initiation after adherence counselling when CD4 count dropped to below 500mmol/l (DHHS, 1998). These have since been amended to initiate treatment at a CD4 count of 350mmol/l or less following studies that show no benefit for treatment at higher values. In South Africa, current recommendations which take into account the lifelong implications of HIV treatment, possible drug toxicities and drug resistance recommend ART initiation at a CD4 count of less than 350mmol/l, and the WHO clinical staging of HIV infection coupled with existing co-morbidities (The South African HIV Clinicians Society, 2008; 2012). In a review to determine health workers adherence to treatment guidelines and treatment of opportunistic infection in adults in the United States, Kaplan, Parham, Soto-Torres, van Dyck, Greaves, Rauch, Ellis & Amandus (1999) found an encouraging rate of more than 85 percent adherence to prevention of opportunistic infections. In Sydney, Australia, Bloch, Hoy, Cunningham, Roth, Bailey, Pierce, Watson & Andrew (2012) observed an 87.6 percent adherence on “when to start”, a 69.0 percent adherence on “what to start guideline preferred regimens” and a 56.8 percent adherence to co-morbid disease assessment.

In South Africa, Vijayaraghavan, Efrusy, Mazonson, Ebrahim, Sanne & Santas (2007) compared the benefits of WHO recommendations versus using the developed countries’ treatment criteria found that the patients on the developed worlds’ criteria had a higher life expectancy and increased cost of treatment coupled with an improved Quality Year Life Year (QUALY). However, South Africa, being a developing country with limited resources has adopted a treatment regimen which is more in line with that of the WHO (based on the WHO

2006 treatment guidelines). The criteria are a far much more advanced stance compared to most other developing countries. Although many studies have examined the reasons for non-adherence to treatment by patients, very little information is available with regards to the nature of adherence to recommended treatment guidelines by health workers. What is apparent though is that adherence to treatment by HIV positive people is strongly associated with patients' overall satisfaction and trust with health workers (Ong, De Haes, Hoos & Lammes, 1995; Fehr, Nicca, Sendi, Wolf, Wagels, Kiss, Bregenzer, Vernazza, Jäger, Spirig & Battegay; WHO, 2006). Adherence to recommended treatment guidelines by health workers is likely to strengthen this relationship between health workers and patients with favourable outcomes in the fight against the epidemic. Early testing and timeous commencement of HIV has been associated with favourable outcomes. Healthworkers' knowledge of the type of treatment to start as well as evaluation and treatment of other illnesses that may impact on HIV treatment failure/success decreases the probability of morbidity and mortality. This is likely to be achieved if there are consistencies in treatment guidelines followed by healthcare workers.

The research methodology for this study will be discussed in the next Chapter.

Chapter 3: Research Methodology

3.1 Research Problem

Inconsistencies in HIV management can lead to complications in HIV positive employees resulting in productivity losses as a consequence of increased employee absenteeism, high labour turnover, increased cost of treating AIDS complications and cost of training new employees. It is not known if adherence to guidelines in HIV/AIDS management has been followed in the management of HIV positive employees.

3.2 Research Question

The research question for this research was: To what extent has the Wellness Clinic adhered to prescribed guidelines in employee HIV management for the past three years?

3.3 Significance of Study

Economic growth has been touted by many economic scholars as a “panacea” to many of South Africa’s problems. Most of South Africa’s social ills have been blamed solely on the high poverty levels that are prevalent in the country. Economic success, on the other hand, is virtually impossible without the preservation of the available labour base. The preservation of the labour force is, therefore, the backbone of South Africa’s economy. The proposed review with focus on the appropriateness of clinical management of HIV in this sector will benefit the concerned stakeholders on different levels.

The mining industry is the single largest private employer in South Africa. The industry is also one of the largest employers of unskilled and semi-skilled workers. This is also the hardest-hit group in terms of HIV infections. The sector, therefore, stands to be one of the biggest beneficiaries of improved health outcomes as a result of good management of the HIV epidemic. The South African Business Coalition on HIV& AIDS (SABCOHA) (2003: iii) survey found that most businesses surveyed expected HIV to have an impact on their businesses in five years’ time. The increases in labour costs are likely to have a negative impact on profitability. The less profitable companies become, the less employment opportunities for the community become available, with negative implications for both the macro-economy and social development.

Employees experience both psychological and physical problems as a result of HIV infection. Not only does this affect their performance and ability to fulfil their roles as workers, family and community members but also impedes socioeconomic development of the country with a resultant adverse effect on the macro-economy. In the high-unemployment context such as

South Africa, often these employees are the breadwinners. In the event of the breadwinner falling ill, the other household members may have to change roles in order to survive. This often means that there is an increased burden of looking after the sick family member added to the reduction in the family income. The number of female and child-headed households tends to increase in this environment with dire consequences for social development, business profitability and the economy in general. Proper HIV management is, therefore vital to improve socio-economic, macro-economic as well as micro-economic operations in the country.

The health professionals responsible for managing these employees are likely to experience less workload and enable them to improve healthcare delivery employee general wellness as a result of improved health outcomes and less complications arising from inconsistent HIV management.

3.4 Aim of the Study

The aim of the study was to review the HIV treatment programme followed by the Zondereinde Wellness Clinic in order to make recommendations to implement prescribed best practice HIV management if necessary.

3.5 The Objectives of this Study

The more specific objectives for this study were the following:

- To identify best practice for HIV management
- To identify current practice at the wellness clinic
- To identify the gap between current practice and best practice
- To make recommendations for the wellness clinic to close the gap between current practice and best practice

3.6 Research Design and Methods

This is a quantitative content analysis study. The study sought to review the files of those who are on the HIV Disease Management programme employed at a mine in Limpopo Province, South Africa.

The study included a review sample of a total of 279 patient records out of a total of about 720 patient files retrieved from the Zondereinde Wellness Clinic that have been on the

Antiretroviral (ARV) programme in the last three years. The study was conducted from November 2013 for a period of three months.

The review included data obtained from the wellness clinic records (whether manual or electronic records) as well as pharmacy records.

The records reviewed included patient history, patient examination, laboratory results, TB investigation and treatment as well as assessment of other chronic diseases and pregnancy status. Only data reflected explicitly in these records was recorded. If not, these were considered not to have been performed.

A de-identified, web-based data collection form was used to aggregate data including age (expressed as a range), sex, laboratory (to be described as ranges rather than absolute values) and clinical data (described using the World Health Organisation (WHO) HIV clinical staging as opposed to specific illnesses). This will not contain any names. This collection form was used to compute data and during analysis. The available HIV ARV management data was evaluated for best practice. The mine's wellness clinic ART guidelines were used to evaluate the data. These were adapted from the South African HIV Clinicians' (SAHIVC) guidelines released in January 2008. These guidelines were used to look at:

- When to start therapy (patient and clinical readiness)
- What therapy to start (the type of regimen to start)
- When to change therapy and (monitoring of treatment response and toxicities)
- The evaluation of co-morbidities (other existing illnesses that may impact on treatment success/failure and drug interactions)

Assessment to therapy guidelines

The assessment to therapy guidelines was clustered into categories as explained above. The when to start therapy assessment was determined by:

When to start therapy

The following steps had to be fulfilled to satisfy the “when to start therapy” as outlined by the guidelines:

- Pre-counselling about HIV should be given by registered nurse
- Rapid HIV test to be done after pre-counselling and written consent done

- Post counselling should be done by the nurse irrespective of outcome of the test
- In cases where the rapid test is reactive, blood for Elisa confirmatory test should be taken,
- If the confirmatory test is positive, blood for CD4 only should! be taken & the following steps followed:
 - ❖ CD4 of less than 350 microliters- counselling for ART by the doctor and wellness sister.
 - ❖ CD4 of more than 350 microliters and WHO stage 3 or 4 - counselling for ART by the doctor and sister
 - ❖ WHO Stage 4, irrespective of CD4- counselling for ART by the doctor and sister
 - ❖ CD4 of more than 350 microliters- counselling by the wellness sister and lifestyle modification,
- FBC,U&E, Viral load, AST, ALT, and CXR are done routinely before initiating ART following CD4 review and patient agrees to treatment
- The following investigations may be done when indicated:
 - ❖ Sputum AFB & TB culture when chest x-ray and clinical picture is suggestive of TB
 - ❖ Lipogram in diabetic and hypertensive patients
 - ❖ LFT & hepatitis studies when transaminase is three times higher than the upper normal limits
 - ❖ Pregnancy tests in all female patients
- Start two weeks trial of compliance with Vitamin B Complex and Ferrous Sulphate (FeS04) immediately after doing the routine investigations - (30 days treatment to be issued)
- Assessment of compliance to be done by nurse after the 2 weeks trial by counting the remaining pills
- Refer to TB & ART policy for starting ART in patients who passed two weeks trial of compliance
- Refer patients who failed two weeks trial of compliance to the social worker for re-counselling on ART and subsequently to IR if still non-compliant

- Patients may only be started on ART after passing the two week trial of compliance and have normal routine investigations

What Treatment to Start

This was also based on the recommended guidelines of the SAHIVC of 2008. It is based on the following:

Patients who are HIV seropositive and fulfil criteria for ART may be started on first line regimen.

First line regimen consists of:

- Two nucleoside reverse transcriptase inhibitors (NRTI's) and
- One non-nucleoside reverse transcriptase inhibitor (NNRTI)
- ❖ Efavirenz or Nevirapine if pregnant for all females of child-bearing potential not only pregnant females.

Evaluation of Co-morbidities

These refers to the evaluation of any other co-existing illnesses or pre-conditions that may impact on the type of treatment selected, the interaction between the treatment of those conditions and HAART and the impact of those co-morbidities on the possible progression of HIV.

When to Change Therapy

Patients on first line regimen developing treatment failure (clinical or virological), drug toxicity and drug intolerance may be changed to 2nd line regimen after further evaluation, counselling and 6 weeks DOTS on further first line regimen.

Second line regimen:

- Didanosine: one tablet, two times a day
- Abacavir: one tablet, two times a day
- Lopinavir / Ritonavir (Aluvia): two tablets, two times a day.

Failure to first and second line regimens requiring salvage therapy should be referred to a specialist

3.7 Ethics

The main ethical consideration in this study was that of confidentiality. The study did not conduct any interviews with patients or health workers. The researcher did not intend using identifying patient data in accordance with section 16 (2) of the National Health Act (2003), therefore individual consent was waived. No other person/people were be allowed access to information pertained in the documents under review whilst in the possession of the researcher. Each patient record and included in the study was given a pre-coded study number. These study numbers, ranging from NPL 001 to NPL 279 were linked to the patients file and did not contain identifying data (name, and hospital number). The coded study numbers with identifying data will be kept in a password protected digital file to ensure no one else has access to them. Ethical clearance was obtained from Stellenbosch University before commencing with the study.

Chapter 4: Results and Discussion

The data was analysed using the Statistical Package for the Social Sciences (SPSS 16.0).

4.1 General Information about the Mine

The mine is a platinum group metals (PGM) producer operating in the western end of the bushveld complex in the Limpopo province in South Africa. It's a 1989-listed Johannesburg Stock Exchange (JSE) company employing over 7000 people. Just over 3500 of these employees live on the mine premises in single-sex hostels.

A comprehensive HIV policy has been drawn up and is visible in the mine premises. As part of HIV prevention and general awareness there is an active HIV peer education and health awareness drive with intensified wellness campaign days every three months. These encompass HIV testing as part of healthy living.

In terms of management of HIV infection, the company has a dedicated HIV wellness clinic focusing exclusively on HIV and AIDS. The company funds the treatment of their employees through a health insurance company that they have contracted to manage the processes, logistics and clinical outcomes of their members. The said insurance company also staffs the clinic with a nurse and a doctor and supports them through their HIV Disease Management Programme (HIVDMP). The mine further provides primary healthcare, emergency care as well as a dedicated TB clinic in accordance with Department of Mineral Resources (DMR) requirements.

4.2 Patient Demographics

Of the 720 patients on HAART at the Wellness clinic 279 were included in the study. These consisted of all the patients initiated on HAART for the three year review period undertaken between the periods 1 January 2010 and 31 December 2012. Those patients who started HAART at other treatment facilities and then transferred to later we not included. Only patients started on therapy at the wellness clinic were included in the study.

4.3 Results

The majority of the patients initiated on HAART were male (96.8 percent) (Table 1) and those between the ages of 18 and 49 (male and female) accounted for 86 percent of the review, while the remainder (14 percent) comprised of the more than 49 years old group (Table 4.2).

Table 4.1: Gender

Gender					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	F	9	3.2	3.2	3.2
	M	270	96.8	96.8	100.0
	Total	279	100.0	100.0	

Table 4.2: Age

Age					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	<49	240	86.0	86.0	86.0
	>49	39	14.0	14.0	100.0
	Total	279	100.0	100.0	

When to Start Therapy

In terms of deciding when to start therapy, the decision to commence therapy was taken correctly in 97.1 percent of the cases.

Table 4.3: When to start therapy

When to Start Therapy					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	8	2.9	2.9	2.9
	Yes	271	97.1	97.1	100.0
	Total	279	100.0	100.0	

What Therapy to Start

In 99.6 (Table 4.4) percent of the cases the mine’s wellness clinic staff started the patients on the recommended regimens

Table 4.4: What therapy to start

What Therapy to Start					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	1	.4	.4	.4
	Yes	278	99.6	99.6	100.0
	Total	279	100.0	100.0	

Evaluation of Co-morbidities

The evaluation of co-morbidities came at 45.5, lower than the preceding variables.

Table 4.5: Evaluation of Co-morbidities

Evaluation of Co-morbidities					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	152	54.5	54.5	54.5
	Yes	127	45.5	45.5	100.0
	Total	279	100.0	100.0	

When to Change Therapy

It is encouraging that cases that needed to be changed to second line treatment were only seven (2.4 percent), but of those 57 percent were kept on the failing regimen.

Table 4.6: When to change therapy

When to Change Therapy					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		272	97.5	97.5	97.5
	No	4	1.4	1.4	98.9
	Yes	3	1.1	1.1	100.0
	Total	279	100.0	100.0	

4.4 Discussion

Treatment guidelines are formulated to integrate the best possible clinical evidence with the best possible cost-effective strategies so as to render patient treatment effective yet sustainable. There is a dearth of literature regarding adherence to HIV treatment adherence. In the most comprehensive study assessing adherence to treatment guidelines to date, by the Australasian Society of HIV Medicine in 2012, adherence to “when to start” was 87.6 percent, “what to start” was 69.0 percent and “assessment of co-morbidities” was 56.8 percent

Demographics

Traditionally females tend to take up HIV counselling and testing more readily than their male partners (Venkatesh, Madiba, Bruyn, Lurie, Coates & Gray, 2011). The mining industry is largely male-dominated and one would expect to see far less males taking up HIV testing than the employees of this mine; but at ten percent of employees on the programme the mine compares favourably with the national statistics of eleven percent HIV prevalence nationally (Shisana et. al, 2009). However, the mining industry is known to exhibit higher HIV infection rates than the general public because of an interplay of related factors. The expressed prevalence in the mine is therefore likely to be an under-representation of the true nature of the HIV infection rates in the company.

Of those started on treatment, 86.0 percent were those between the ages of 18 (the legal working age in South Africa) and 49. An estimated 17.9 percent of people aged 15 to 49 years are living with HIV in South Africa (UNAIDS, 2012). This the highest HIV prevalence rate amongst different age groups in South Africa (UNAIDS, 2012). This is also the economically active section of the population; the fact that they make the largest number of employees on treatment serves as comfort as they are likely to restore productivity.

When to Start Therapy

The mining industry, and more appropriately, this mine under review, is fortunate enough to have a comprehensive HIV management programme at the coal face, and the resources to make it work. This is reflected in the fact that more than 97.1 percent of patients who needed treatment were started on HAART timeously. Early initiation of HAART prevents occurrence of opportunistic infections and rapid deterioration of the immune system. Patients started on treatment with very low CD4 counts have been shown to have a slow immune recovery process while some never fully recover (Goulet, Fultz, McGinnis & Justice, 2005; Justice, 2006). The 97.1 percent adherence to the “when to start therapy” guideline compares favourably to the 87.6 percent seen in Australasia in 2012.

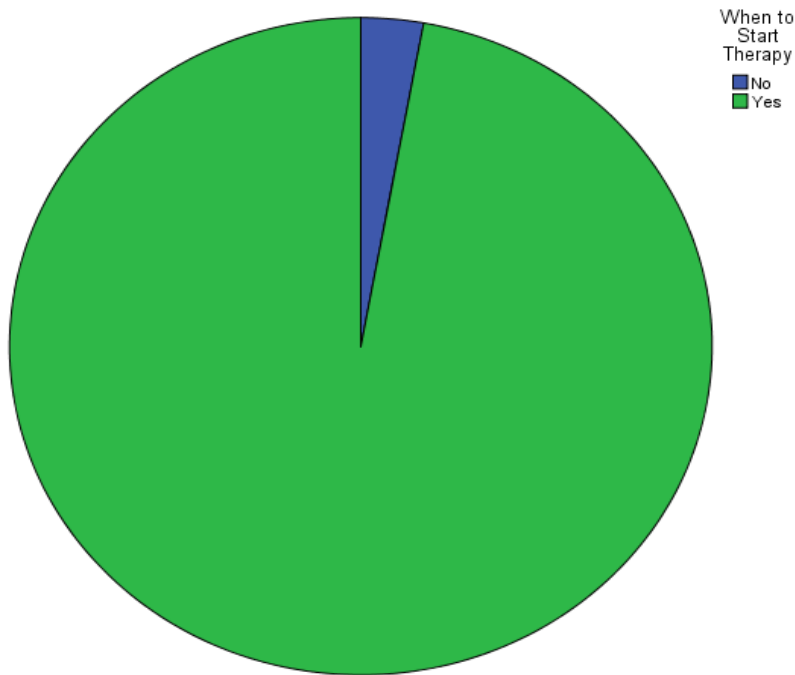


Figure 4.1: When to Start Therapy

Those patients who did not fulfil the “when to start”, eight percent were delayed to be initiated even though they met criteria for initiating HAART. They were, however, initiated on treatment subsequently. Only one patient was initiated on treatment without any clear criteria for doing so.

Table 4.7: When to start therapy

When to Start Therapy				
	Frequency	Percent	Valid Percent	Cumulative Percent
Valid	270	96.8	96.8	96.8
Delayed Initiation	8	2.9	2.9	99.6
No Clear Criteria to Initiate	1	.4	.4	100.0
Total	279	100.0	100.0	

What Therapy to Start

Guideline-preferred treatment regimen was chosen in 99.6 percent of new patients being started on HAART. It is imperative that the correct first-line treatment be adhered to and preserved for as long as possible in order to be able to also preserve second-line regimen in case of patients failing their current treatment, clinically and virologically.

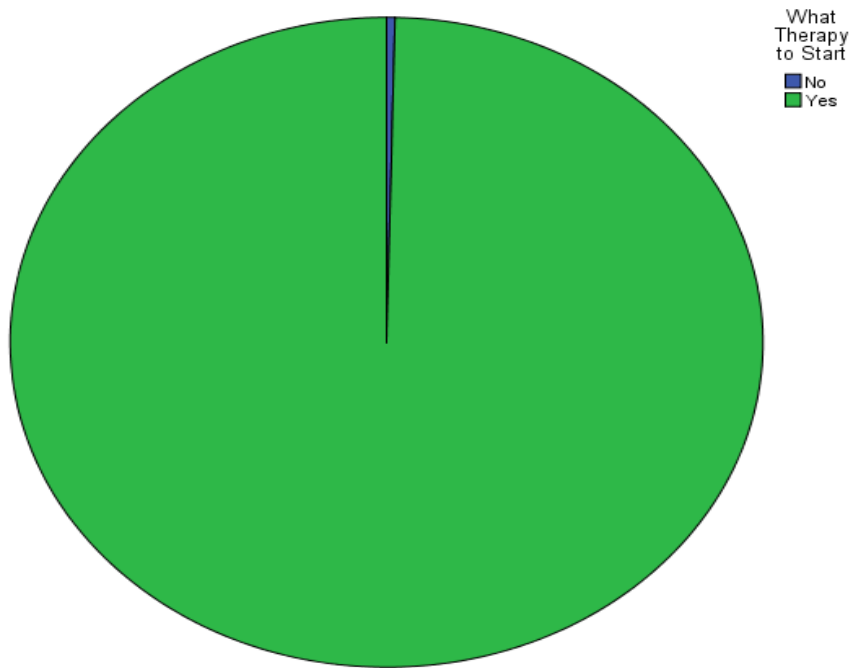


Figure 4.2: What Therapy to Start

Evaluation of Co-Morbidities

The presence of any other illnesses may be detrimental to the prognosis of the individual if not managed properly. In Nigeria, in a retrospective study to evaluate the prevalence of co-morbidities in HIV infected individuals, 36.9 percent of people on HAART had at least one co-morbidity (Denu, Gashau, Ekong & Ngoshe, 2012). Not only is HIV infection often associated with presence of other illnesses as a direct result of the oppressed immune system, but the onset of the ageing process and age-related co-morbidities starts earlier than non-HIV infected individuals (Appay, Almeida & Sauce, 2007; Bestilny, Gill, Mody & Riabowol, 2000; Oursler, Sorkin, Smith & Katzel, 2006). Some of these co-morbidities may be a result of prolonged lifespan and the normal ageing process since HAART has been shown to prolong life by about 20 to 30 years (Hogg, Lima & Sterne, 2008). HAART itself may be responsible for the development of these co-morbidities (Bisson, Gross, Miller, 2003; Wilson, Chambers, Bacon, Rueda, Ragan & Rourke, 2010).

It is concerning that there is no record of evaluation of co-morbidities in more than half (54.5 percent) of those on HAART at the Zondereinde clinic. Untreated and inadequately treated illnesses may be detrimental to both company and workers. An increase sick leave taken as well as hospitalisation is likely to result as a consequence. This has a potential to result in a strain to resources and insurance. Loss of production as well as compromise to the health and safety of those employees reporting for work as a result of staff shortages is of concern.

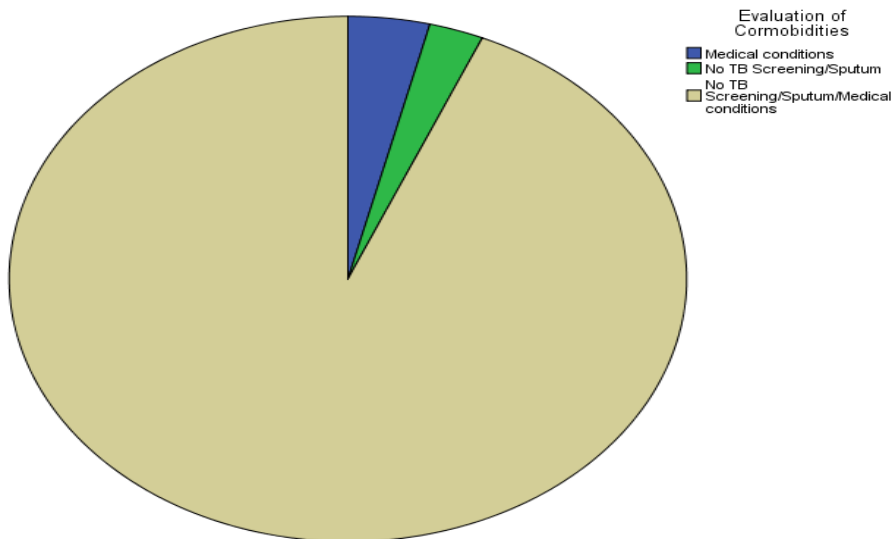


Figure 4.3: Evaluation of Comorbidities

Of those patients that were evaluated for co-morbidities, some patients were evaluated for other medical conditions while others were evaluated for TB, but the majority had no record of co-morbid evaluation (93.5 percent).

Table 4.8

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid Medical conditions	6	3.9	3.9	3.9
No TB Screening/Sputum	4	2.6	2.6	6.5
No TB Screening/Sputum/Medical conditions	144	93.5	93.5	100.0
Total	154	100.0	100.0	

When to Change Therapy

It is encouraging that only seven (2.5 percent) of the 279 patient files under review required a change in treatment. This is probably indicative of the early commencement and correct choice of treatment for patients. However it should be pointed out, that four out of seven (57.1 percent) of patients who needed treatment change were prolonged on ineffective and failing treatment regimen.

Table 4.9

		Need to Change Therapy			Cumulative
		Frequency	Percent	Valid Percent	Percent
Valid	No	4	57.1	57.1	57.1
	Yes	3	42.9	42.9	100.0
Total		7	100.0	100.0	

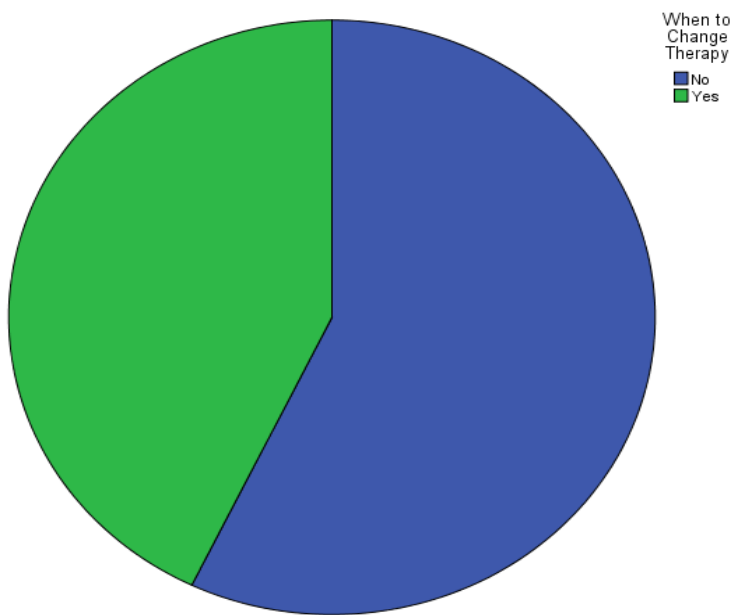


Figure 4.4: When to Change Therapy

The adherence to guidelines has largely been adhered to with regards to “when to start therapy” (97.1 percent”), what therapy to start” (99.6 percent). The low level of co-morbidity evaluation (45.5 percent) is concerning considering that per definition AIDS is a syndrome consisting of many illnesses. Although only a small number of patients needed to be changed to second-line therapy, it is concerning that most of them were unnecessarily prolonged on failing treatment for an extended amount of time.

Chapter 5: Limitations and Recommendations

5.1 Limitations

In an industry that employs well over 500 000 people (Chamber of Mines, 2012), this study is but a small one in the bigger employment picture of the mining industry. This study is also limited to those who choose to present themselves to the wellness clinic for treatment. There may well be a large proportion of the workforce that chooses to receive treatment elsewhere in public or private facilities.

This researcher's interpretation of the documents is also limited to that of the attending health worker/clinician at the time. This exposes the data collected and the analysed results to bias. Another limitation of the study is the fact that only documents in the three year period between 2010 and 2013 were analysed. This was a period in which major scale-up of antiretroviral treatment was being implemented in South Africa. The workload required of the healthworkers at this time may cause some important factors to be overlooked.

5.2 Recommendations

It is recommended that bigger studies with larger reviews and more inclusive documents be conducted to determine the actual extent of adherence to guidelines. It is further recommended that clear precise guidelines be formulated with regards to assessing patient co-morbidities in HIV management. It is also apparent that there may not be seamless co-operation between the wellness clinic, chronic disease department and the TB clinic. It is therefore also recommended that guidelines for co-operation and integration amongst the three departments.

Chapter 6: Conclusion

The South African mining industry is one of the biggest contributors to the GDP. It is also the single largest private employer of the South African labour force. In a high unemployment rate country as well as high unskilled labour force such as South Africa, the mining industry's survival is crucial. Because the industry in South Africa is heavily dependent on labour, any factors that have the potential to affect the labour force negatively are likely to have a knock-on effect on production. Preservation of the labour force is therefore vital.

The history of mining in South Africa makes those who work in it both vulnerable and susceptible to HIV infection. This study sought to establish whether those who are HIV positive as a consequence were managed in a consistent and systematic fashion. Part of this evaluation was to establish whether in so doing, those responsible for managing these patients adhered to prescribed guidelines. The conclusion is that HIV management guidelines were largely adhered to. There is one area, albeit an important one, of concern; the management of other illnesses tend to be overlooked when healthworkers are focusing on treating HIV and AIDS.

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Approval Notice Response to Modifications- (New Application)

06-Nov-2013
MOFOMME, Steven

Proposal#: HS991/2013

Title: HIV Management in a Mining Company in South Africa

Dear Dr Steven MOFOMME,

Your **Response to Modifications - (New Application)** received on **04-Nov-2013**, was reviewed by members of the **Research Ethics Committee: Human Research (Humanities)** via Expedited review procedures on **06-Nov-2013** and was approved.

Please note the following information about your approved research proposal:

Proposal Approval Period: **06-Nov-2013 -05-Nov-2014**

Please take note of the general Investigator Responsibilities attached to this letter. You may commence with your research after complying fully with these guidelines.

Please remember to use your **proposal number (HS991/2013)** on any documents or correspondence with the REC concerning your research proposal.

Please note that the REC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

Also note that a progress report should be submitted to the Committee before the approval period has expired if a continuation is required. The Committee will then consider the continuation of the project for a further year (if necessary).

This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki and the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health). Annually a number of projects may be selected randomly for an external audit.

National Health Research Ethics Committee (NHREC) registration number REC-050411-032. We

wish you the best as you conduct your research.

If you have any questions or need further help, please contact the REC office at 0218839027.

Included Documents:

Revised Research proposal
Research proposal
Permission letter
letter of response
REC Application
DESC form

Sincerely,

Susara Oberholzer REC
Coordinator
Research Ethics Committee: Human Research (Humanities)

Investigator Responsibilities

Protection of Human Research Participants

Some of the general responsibilities investigators have when conducting research involving human participants are listed below:

- 1. Conducting the Research.** You are responsible for making sure that the research is conducted according to the REC approved research protocol. You are also responsible for the actions of all your co-investigators and research staff involved with this research. You must also ensure that the research is conducted within the standards of your field of research.
- 2. Participant Enrollment.** You may not recruit or enroll participants prior to the REC approval date or after the expiration date of REC approval. All recruitment materials for any form of media must be approved by the REC prior to their use. If you need to recruit more participants than was noted in your REC approval letter, you must submit an amendment requesting an increase in the number of participants.
- 3. Informed Consent.** You are responsible for obtaining and documenting effective informed consent using **only** the REC-approved consent documents, and for ensuring that no human participants are involved in research prior to obtaining their informed consent. Please give all participants copies of the signed informed consent documents. Keep the originals in your secured research files for at least five (5) years.
- 4. Continuing Review.** The REC must review and approve all REC-approved research proposals at intervals appropriate to the degree of risk but not less than once per year. There is **no grace period**. Prior to the date on which the REC approval of the research expires, **it is your responsibility to submit the continuing review report in a timely fashion to ensure a lapse in REC approval does not occur**. If REC approval of your research lapses, you must stop new participant enrollment, and contact the REC office immediately.
- 5. Amendments and Changes.** If you wish to amend or change any aspect of your research (such as research design, interventions or procedures, number of participants, participant population, informed consent document, instruments, surveys or recruiting material), you must submit the amendment to the REC for review using the current Amendment Form. You **may not initiate** any amendments or changes to your research without first obtaining written REC review and approval. The **only exception** is when it is necessary to eliminate apparent immediate hazards to participants and the REC should be immediately informed of this necessity.
- 6. Adverse or Unanticipated Events.** Any serious adverse events, participant complaints, and all unanticipated problems that involve risks to participants or others, as well as any research related injuries, occurring at this institution or at other performance sites must be reported to Malene Fouch within **five (5) days** of discovery of the incident. You must also report any instances of serious or continuing problems, or non-compliance with the REC's requirements for protecting human research participants. The only exception to this policy is that the death of a research participant must be reported in accordance with the Stellenbosch University Research Ethics Committee Standard Operating Procedures. All reportable events should be submitted to the REC using the Serious Adverse Event Report Form.
- 7. Research Record Keeping.** You must keep the following research related records, at a minimum, in a secure location for a minimum of five years: the REC approved research proposal and all amendments; all informed consent documents; recruiting materials; continuing review reports; adverse or unanticipated events; and all correspondence from the REC
- 8. Provision of Counselling or emergency support.** When a dedicated counsellor or psychologist provides support to a participant without prior REC review and approval, to the extent permitted by law, such activities will not be recognised as research nor the data used in support of research. Such cases should be indicated in the progress report or final report.
- 9. Final reports.** When you have completed (no further participant enrollment, interactions, interventions or data analysis) or stopped work on your research, you must submit a Final Report to the REC.
- 10. On-Site Evaluations, Inspections, or Audits.** If you are notified that your research will be reviewed or audited by the sponsor or any other external agency or any internal group, you must inform the REC immediately of the impending audit/evaluation.