

**A clinical audit of the implementation of the
Tuberculosis screening tool amongst clients who
are on anti-retroviral therapy in the eThekweni local
municipality clinics**

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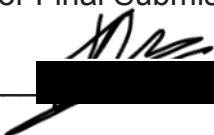
Declaration

This is to certify that the work is entirely my own and not of any other person, unless explicitly acknowledged (including citation of published and unpublished sources). The work has not previously been submitted in any form to the Durban University of Technology or to any other institution for assessment or for any other purpose.

Signature of student

Date

Approved for Final Submission



Dr I Botha
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Date

ABSTRACT

BACKGROUND

Tuberculosis (TB) is a global public health concern and is identified as the leading cause of morbidity and mortality in the population infected with Human Immune Deficiency Virus (HIV). South Africa (SA), particularly the KwaZulu-Natal Province, is burdened with persistently high rates of both TB and HIV infections. In an attempt to improve TB and HIV co-infection outcomes the South African health care system has adopted the World Health Organisation (WHO) guidelines for intensified TB case findings in all HIV positive individuals for regular screening of TB symptoms in order to promptly diagnose and treat active TB disease or to exclude TB for initiation Isoniazid Prophylactic Therapy (IPT). IPT has proven effective in preventing TB disease in People Living with HIV or AIDS (PLWHA). This critical first step of TB symptom screening is regarded as the intervention that could significantly reduce the challenge currently faced with TB-HIV co-infection.

The study was conducted in selected eThekweni Municipality Primary Health Care (PHC) facilities with the focus on an investigation to determine the extent of the implementation of the TB symptom screening tool in HIV infected individuals, in addition to identifying treatment initiation or further investigations based on the tool implementation. It has been found during the literature review, that there is a lack of research in SA to show that this critical first step in TB identification has been investigated, yet one in six South African's is HIV positive and the incidence of TB-HIV co-infection is not declining.

METHODOLOGY

A quantitative, descriptive approach was utilised to conduct a retrospective patient chart review. A multistage cluster sampling technique comprising three stages was implemented to identify the sample. There was a random selection of clinics, and the required number of client records was obtained through convenience sampling from the selected clinics.

RESULTS

The findings of this study revealed there is inadequate implementation of the current national and provincial TB protocols. The study provides varied levels of information about TB symptom screening in HIV infected individuals in the PHC clinics of eThekweni Municipality. It was observed that Health Care Worker's (HCW) in some facilities carried out TB symptom screening to an extent. However, the inconsistent and partial application of this screening tool warrants improvement to facilitate the broad success of TB-HIV care strategies.

DEDICATION

I dedicate this study to the Lord for my constant strength and inspiration. Secondly, I dedicate this study to my family for their continued support and encouragement of my studies, as well as to all the orphans of parents whose demise was a consequence of TB-HIV co-infection.

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ACRONYMS

| | |
|--------|---|
| AIDS | Acquired Immune Deficiency |
| ART | Antiretroviral Therapy |
| ARV | Antiretroviral |
| CDC | Centre for Disease Control Prevention |
| DHS | District Health System |
| DNA | Did Not Attend |
| DOH | Department of Health |
| DOTS | Directly Observed Therapy Short-Course |
| HCP | Health Care Provider |
| HCW | Health Care Worker |
| HIV | Human Immune Deficiency Virus |
| ICAP | International Centre for AIDS Care and Treatment Programmes |
| ICF | Intensified Case Findings |
| IDP | Integrated Development Plan |
| IPHC | Integrated Primary Health Care |
| IPT | Isoniazid Prophylactic Therapy |
| KZN | KwaZulu-Natal |
| KZNPSP | HIV and AIDS Strategy for the Province of KZN |
| MDG | Millennium Development Goals |
| MDR-TB | Multiple Drug Resistant TB |
| NHI | National Health Insurance |
| NIMART | Nurse Initiated Management of ART |
| NSP | National Strategic Plan |
| PHC | Primary Health Care |
| PLHIV | People Living with HIV |
| PLWHA | People Living with HIV/AIDS |
| RLS | Resource Limited Setting |
| SA | South Africa |
| SANC | South African Nursing Council |
| STI | Sexually Transmitted Infection |
| TB | Tuberculosis |

| | |
|--------|--|
| UNAIDS | Joint United Nations Programme on HIV/AIDS |
| UNGASS | United Nations General Assembly |
| WHO | World Health Organization |
| XDR-TB | Extremely Drug Resistant TB |

DEFINITION OF TERMS

Clinical Audit: is a quality improvement process that aims to enhance patient care and improve patient outcomes through structured review and where indicated, necessary changes are initiated to improve healthcare (Travaglia and Debono, 2009).

Tuberculosis: is an infectious disease caused by *Mycobacterium tuberculosis* and is transmitted by inhalation of infective droplets possibly from patients with pulmonary TB through coughing, sneezing or talking (DOH, 2009).

Human Immune Deficiency Virus: is a retrovirus that enters the body and destroys vital cells responsible for maintaining and protecting the immune system, rendering the immune system ineffectual (Evian, 2006).

Acquired Immune Deficiency Syndrome: is the condition that develops when an individual's immunity is so destroyed from the HIV infection that the immune system is no longer able to defend the body from infections when compared to an individual with an intact immune system (Evian, 2006).

TB-HIV co-infection: refers to people having both HIV and TB infections simultaneously (WHO, 2011).

Tuberculosis symptom screening: refers to the WHO strategy for regular screening of all HIV positive individuals for signs and symptoms of TB, followed by prompt diagnosis and treatment of TB or initiation of IPT when TB is excluded (Kranzer, 2011).

Isoniazid Prophylactic Therapy: is the administration of the anti-Tuberculosis drug Isoniazid to prevent TB in HIV infected people. It is essential to exclude active TB disease prior to the initiation of IPT (DOH: 2010a).

Primary Health Care: is essential health care based on a practical, scientifically reliable and socially acceptable approach that is accessible to everyone in the community with self-reliance and continuity of care been the key characteristics (WHO, 1978).

Primary Health Care Facility: is a clinic or health care facility that offers comprehensive quality health care; inclusive of promotive, preventive, curative, rehabilitative, and palliative interventions at a level below that of the hospitals (DOH, 2001).

Municipality: refers to a particular area of land, the residents and communities within it, the governing council and the employees of this council that administer this region (Nicholson, 2001).

CHAPTER ONE – OVERVIEW OF THE STUDY

1.1 INTRODUCTION AND BACKGROUND TO THE STUDY

An estimated 34 million people globally were infected with the Human Immune Deficiency Virus (HIV) in 2011, with sub-Saharan Africa being the most involved by way of holding two thirds of the global HIV infected population, yet comprising only 12% of the world wide population. South Africa (SA) is labelled as the country with the leading number of HIV positive people at 5.9 million. The region currently most affected is Southern Africa with adult HIV prevalence rates in excess of 20% (The Joint United Nations Programme on HIV/AIDS, 2011 and Getahun, Kittikraisak, Heilig, Corbett, Ayles, Cain, Grant, Churchyard, Kimerling, Shah, Lawn, Wood, Maartens, Granich, Date and Varma, 2011).

In 2011 South Africa (SA) had a population of approximately 50.6 million people (0.7% of the world's population), with an HIV prevalence for the adult population (15-29 years) in SA estimated at 17%. The antenatal HIV prevalence in 2011 was almost 30%, with some districts in KwaZulu-Natal (including eThekweni) exceeding 40%. South Africa is also faced with one of the largest dual epidemics of HIV-TB co-infection in the world, due to our Tuberculosis (TB) incidence being the second highest in the world (60% TB-HIV co-infection in SA), (DOH: National Strategic Plan (NSP) 2012-2016, 2011).

The DOH: HIV and AIDS Strategy for the Province of KwaZulu-Natal (KZNPSP) 2012-2016 (2011) and the DOH: National TB Guidelines (2009) discuss how HIV infection leads to progressive immunodeficiency and increased susceptibility to infections, especially TB. As HIV infection progresses the immune system is less able to prevent the growth and spread of TB resulting in the progression of recent or latent TB infection to active TB disease. Laserson and Wells (2007), and Maher, Borgdorff and Boerma (2005), state that TB is found to be the most common opportunistic infection in HIV infected people, and results in increased mortality and an accelerated progression of HIV infection. Likewise, Corbett, Marston, Churchyard

and De Cock (2006), and Laserson *et al.* (2007), assert that HIV is the leading propellant of the TB pandemic.

In individuals with an intact immunity, 90% will not progress to active TB disease, whilst individuals with a compromised immunity have a tendency to develop active TB disease by up to 60% more than individuals with a normal immune system. The annual risk of TB in an HIV infected individual is 10% compared to a lifetime risk of 10% in an HIV uninfected individual (DOH: KZNPS, 2011 and DOH: National TB Guidelines, 2009).

Similarly, the DOH: National Strategic Plan (NSP) (2011) states that TB is the leading cause of fatality and the most frequent opportunistic illness observed in HIV infected people. Furthermore, TB advances the development of HIV illness. The DOH: National TB Guidelines (2009) and the DOH: HIV and AIDS Strategy for the Province of KZN (KZNPS) (2011) state that TB can occur at any point in the course of progression of HIV infection but the clinical pattern of disease changes and becomes more difficult to diagnose as immune suppression progresses. Co-infected clients have an increased mortality due to late diagnosis of TB and they also pose an increased risk of TB transmission to the general community.

Laserson *et al.* (2007) discuss how the United Nations General Assembly (UNGASS) reassessed international obligations to ease the HIV burden in June 2011. The UNGASS declaration acknowledged the necessity to eradicate TB by enhancing TB screening, prevention, diagnosis, treatment and inclusion into antiretroviral (ARV) therapy. In addition, the declaration called on all member nations to employ collaborative TB and HIV strategies in accordance with the Global Plan to Stop TB 2011-2015 which attempts to develop and strengthen national TB and HIV programmes (DOH: NSP 2011 and DOH: KZNPS, 2011).

Furthermore, the World Health Organization (WHO) Strategy on HIV and AIDS 2011-2015 endorses implementation of amalgamated TB and HIV interventions. Vital to this strategy is the application of clinical guidelines and effective tools for TB prevention and treatment within HIV care settings, inclusive of the three I's (intensive case finding, Isoniazid prevention therapy and infection control). Support for

Isoniazid Prophylactic Therapy (IPT) and prevention of TB in the HIV positive cohort is deemed critical (DOH: NSP, 2011).

Abdool Karim, Churchyard, Karim and Lawn (2009) note that South Africa is placed fifth amongst the 22 nations most weighed down with TB infections and bears 17% of the world wide load of HIV. Some provinces in South Africa, for instance KwaZulu-Natal (KZN), have a TB-HIV co-infection rate of 75-80%.

Early screening for TB is vital in HIV positive clients due to a higher predisposition for acquiring the disease, as well as the TB presenting in atypical clinical manifestations. Prompt diagnosis and treatment of TB in clients who are HIV positive or initiation of prophylactic TB treatment (Isoniazid) in HIV positive clients who screen negative for TB symptom results in a decreased negative impact on morbidity, mortality and risk of TB transmission to the public in addition to reducing the burden on an already laden public health system. TB and HIV co-infection leads to a larger treatment burden on clients resulting in defaulting of both TB and HIV treatment. Prevention of TB by using prophylactic treatment (after the utilisation of the TB screening tool) can improve adherence to ARV treatment and overall wellbeing (DOH: National TB Guidelines, 2009).

Likewise, Howard and El-Sadr (2010) write that the most effective method of preventing TB transmission in the individual or community is to find and cure all cases of TB by effective treatment of diagnosed TB in HIV positive individuals and initiating prophylactic TB treatment to prevent active TB disease in all HIV positive individuals. The effective utilisation of the TB screening tool has the effect of prolonging the lives of people living with HIV, helping to minimise the negative effects of TB on the course of HIV and preventing the transmission of TB to the community

Ngowi, Mfinanga, Bruun and Morkve (2008), and Getahun *et al.* (2011), describe how TB is considered the principal opportunistic infection and cause of mortality in HIV infected people in countries that are beginning to advance. In view of this, Worodria, Massinga-Loembe, Mayanja-Kizza, Namaganda, Kambugu, Manabe, Kestens and Colebunders (2011) articulate that the HIV epidemic is answerable for

31% of all new TB cases in sub-Saharan Africa and contributes to TB persisting as the chief cause of morbidity and mortality in the HIV population. Regular symptom screening is endorsed by the WHO to precede ARV initiation in the light of this strategy having demonstrated an increase in the amount of TB cases detected.

The DOH: Guidelines for Tuberculosis Preventive Therapy among HIV Infected Individuals in South Africa (2010a) state that the supply of one or more anti-tuberculosis drugs to clients to avert active TB disease is defined as TB preventive therapy, commonly referred to as IPT. Reddy, Brady, Gilman, Coronel, Navincopa, Ticona, Chavez, Sanchez, Rojas, Solari, Valencia, Pinedo, Benites, Friedland and Moore (2010) stipulate that TB should first be excluded prior to commencing IPT in the HIV infected population.

The exponential increase in the HIV outbreak all through sub-Saharan Africa in the last few decades has resulted in a four-fold expansion of TB cases (DOH: Guidelines for Tuberculosis Preventive Therapy among HIV Infected Individuals in South Africa, 2010a). Since 70% of TB cases in South Africa are associated with HIV infection and is the widespread reason for illness and death amongst this cohort, TB prevention practices should be offered to all HIV positive individuals who have no signs or symptoms of active disease. The guidelines recommend an integrated HIV and TB stratagem where HIV agendas are held liable for carrying out IPT. Clients should be screened for TB before commencement of IPT and followed up monthly for monitoring and continual exclusion of TB.

Reid, Saito, Nash, Scardigli, Casilini and Howard, (2012) performed an investigation into the carrying out of TB infection control measures in 663 health care facilities across nine TB affected countries in sub-Saharan Africa, including South Africa. The results of the study indicated less than half of the facilities possessed written TB infection control plans and the implementation of infection control measures were inadequate in numerous facilities. The authors state that there is a critical requisite for the improvement of infection control practices, especially at HIV care and treatment settings, to safeguard TB transmission to HIV infected patients and other clients and health care workers present in the facilities, in addition to averting the advance of the public health crisis of TB.

KwaZulu-Natal (KZN) is one of the nine provinces in South Africa and is located on the east coast of the country (See Figure 1.1). The province shares international boundaries with Lesotho, Mozambique and Swaziland and is surrounded internally by the Free State, Mpumalanga, and the Eastern Cape provinces. Approximately 72% of the inhabitants of KZN are less than 35 years old, yet burdened with the highest incidence of TB and HIV nationwide.

The DOH: KwaZulu-Natal Strategic Plan (KZNSP) 2010-2014 (2010), DOH: KZNPS (2011) and Statistics South Africa (2008) identify KZN as the second most populated province in South Africa with the total population comprising 21.4% of the South African population, nonetheless according to the DOH: KZNPS (2011), in excess of half (54%) of the South African adult HIV infected population resides in KZN. In addition, the social and economic effects are significant with over one million children losing one or both parents to HIV related infections in the province. Furthermore, KZN also has the largest TB case load and mortality rate due to TB in the country. The KZN TB case load is greater than four times the epidemic threshold as defined by the WHO. One of the goals of the KZN plan is to increase prevention strategies to facilitate early identification, diagnosis and treatment of TB to 80% of HIV infected people by the year 2016.



Figure 1.1 Map displaying the nine provinces of South Africa

Source: SA Places, 2013

Statistics South Africa (2013) confirms eThekweni is one of 11 districts in the KZN province (See Figure 1.2). As indicated by the DOH: KZNSP (2010) and the DOH: KZNPSP (2011), the eThekweni district has the greatest population density with around 1394 people per square kilometre; yet the average population density for the KZN province is approximately 108 people per square kilometre. This factor has a substantial impact on the burden of disease and disease profiles, access to and consumption of health services and the proper distribution of available resources. The immigration of people into the eThekweni metropolitan area augments the population by 35% when compared to estimated increases of 10% for other districts (DOH: KZNSP, 2010).

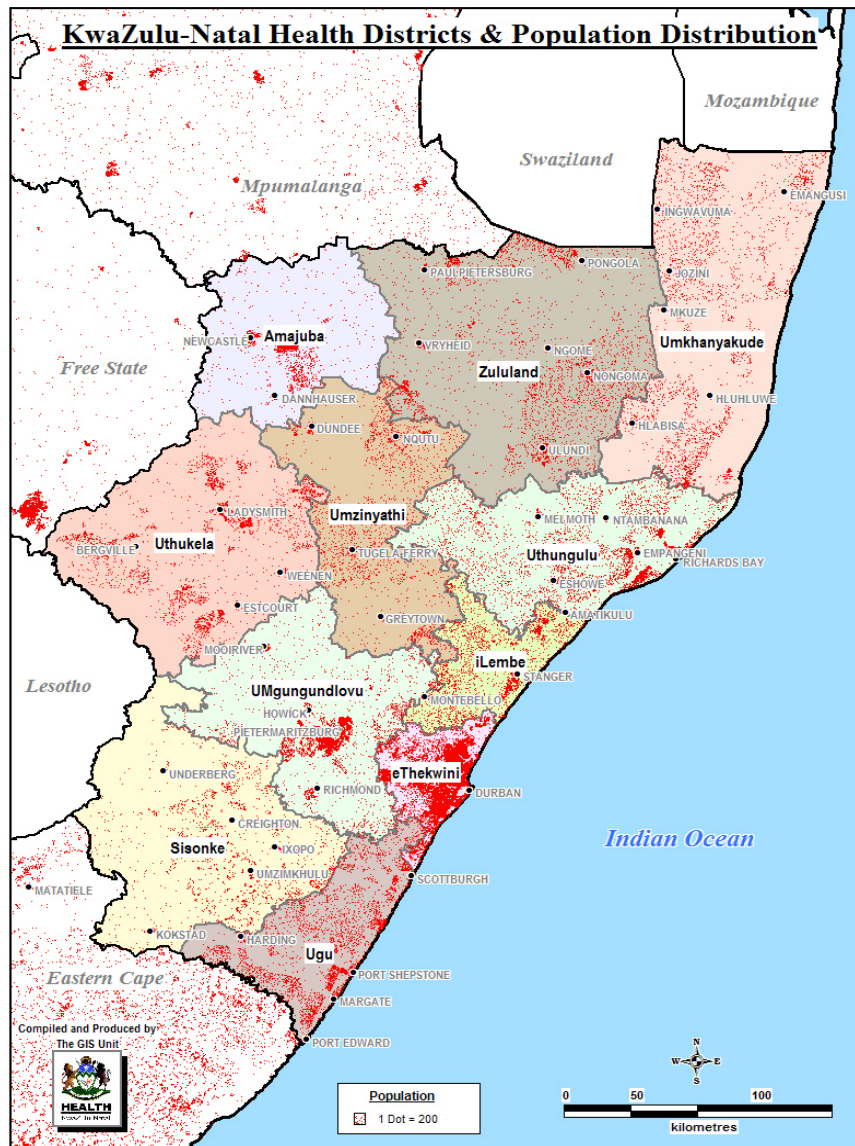


Figure 1.2 Map of KwaZulu-Natal health districts and population distribution
 Source: University of KwaZulu-Natal, 2013

According to the eThekweni Municipality Integrated Development Plan (IDP) (2010), Primary Health Care (PHC) services in the eThekweni district are distributed amongst the eThekweni municipality and the KZN Provincial administration subsequent to the signing of a service level agreement between these two government departments. Ngxongo, (2011) states that almost 60% (59) of the 100 health care facilities in the eThekweni district are managed by eThekweni municipality, whilst the remaining 40% are administered by the KZN Provincial government.

The goal of the eThekweni municipality clinical services is to provide comprehensive PHC by capacitating personnel, endorsing collaboration between priority health programmes (like TB and HIV) and enabling all PHC facilities to offer the full package of uninterrupted services (eThekweni Municipality: Clinical Services, 2011).

The eThekweni Municipality Integrated Development Plan (IDP) (2010) discusses how the eThekweni municipality is aligned to the national and provisional frameworks which gives approval to the WHO's stance on the concept of health as being full physical, psychological and social wellness and not merely the nonexistence of illness. Both preventive and curative services are offered to the community and there is a focus on advancing clinical management activities to impart quality care. A critical goal of the Municipality's strategic objectives is to intensify TB reporting and management by expanding TB diagnosis and treatment, increasing ARV therapy allotment to all PHC facilities and to combine TB and HIV care. This goal is also observed earlier in the KZN: eThekweni TB Crisis Plan (2008). The poor outcomes associated with TB and HIV has led the eThekweni municipality to respond to the president's mandate of increasing the threshold for commencement of ARV's in all TB/HIV co-infected individuals (irrespective of the CD4 count) by expanding their health care programmes to align with this clinical directive. Moreover, the KZNSP (2010) encourages the assimilation of programmes to make certain there is quality management of TB-HIV co-infection.

Cullinan (2006) recounts how in 1994 the South African government adopted the PHC approach derived from the WHO 1978 Alma Ata Declaration as a basis for primary level health care. The DOH: KZNSP (2010) and Gilbert, Selikow and Walker (2010) outline the National Health Act which encompasses 11 key principles to facilitate the revitalisation of the PHC agenda, including, granting access to services, overcoming fragmentation, making comprehensive services available and promotion of an inter-sectoral approach.

The new South African constitution in 1996 stipulated the right for everyone to have access to health care services and the 1997 White Paper on Health Services Transformation planned a decentralised district health system that would be steered by nurses. This goal has been achieved by means of the country dividing into 53

health districts to ensure that everyone has access to a comprehensive package of PHC services (Cullinan, 2006).

Walley, Lawn, Tinker, de Francisco, Chopra, Rudan, Bhutta, Black, and Lancet Alma-Ata Working Group (2008), affirm PHC as the best approach to provide access to every citizen and as being integral to the attainment of the MDG's by the year 2015. The authors recommend integrated and comprehensive health care activities to facilitate the rejuvenation of PHC in poorer income nations. Cullinan (2006) describes how admission to health care for all South Africans is now at a primary level by way of nurse driven local clinics which are intended to provide preventative, promotional, curative and rehabilitative care. In the year 2000, the DOH promulgated a list of directives for clinics which included the requirement for clinics to deliver comprehensive and integrated PHC services for a minimum of eight hours daily, over five days a week. Sibiyi (2009), in her investigation on the examination of the meaning of comprehensive and integrated PHC (IPHC) in PHC settings in KZN, explains IPhC as an approach utilised to expand access and availability at PHC facilities for enhanced health service consumption.

The DOH: National Health Insurance in South Africa (NHI) (2011) proposal explains that South Africa is presently introducing a method of health care financing referred to as the National Health Insurance (NHI) to make certain all members of the population have access to suitable, competent and quality health services. The NHI will be phased in over a 14 year period and the improvement to the South African health system will be based on strengthening PHC. There will be a re-engineering of the PHC strategy with the intention to provide a comprehensive primary package of services focussing on health promotion, preventative, curative and rehabilitative services. The District Health System (DHS) is identified as the medium through which PHC will be dispensed.

A clinical audit is a tool utilised to investigate whether the healthcare provided is aligned to standards and highlights possible areas for improvement. Consequently, it is seen as a possible instrument to assess the implementation of the TB screening tool in the eThekweni local municipal clinics.

1.2 PROBLEM STATEMENT

Getahun, Gunneberg, Granich and Nunn (2010) are of the view that the increased adverse outcomes arising from TB and HIV co-infection during the last decade has threatened the attainment of the United Nations Millennium Development Goals for TB and HIV infection, as well as the aims of the Global Plan to stop TB. Due to the lack of response to the TB /HIV co-infection challenge the WHO has advocated the TB Directly Observed Therapy-Short Course (DOTS) approach to all nations with an escalated HIV infection rate coupled with an increased TB incidence. An assessment of these initiatives at a sub district to national level verified HIV and TB collaboration is a practical necessity.

According to Laserson *et al.* (2007) poor involvement from the government, inadequate economic and human resources, unsuccessful TB control strategies, increase in MDR TB and the substantial rise in HIV associated TB (due to the escalated HIV infection rates) are some obstacles identified in preventing effective TB management. Consequently, African health ministers confirmed TB to be a regional emergency in 2005. The Joint United Nations Programme on HIV/AIDS (UNAIDS) (2011) and (2012) and Friedman, Churchyard and Nardell, (2007) note that sub-Saharan Africa was responsible for almost 70% of all HIV infections and mortality in 2011, despite the African continent comprising approximately 15% of the global population. The fatal combination of TB and HIV co-infections in many resource limited nations has resulted in the TB rate growing five to ten-fold since the onset of the HIV outbreak. Subsequently, there is evidence that 90% of HIV infected people die within months of contracting TB disease.

Uwimana, Jackson, Hausler and Zarowsky (2012) believe that the application of integrated HIV and TB strategies in South Africa has been protracted. The NSP (2011) claims that since South Africa contains one fifth of the global population infected with HIV-TB co-morbidity, there is a crucial need for coordination of the national response with international HIV and TB policies.

Getahun *et al.* (2011) and Were, Moore, Ekwaru, Mwima, Bunnell, Kaharuzza, Rutherford and Mermin (2009) describe how individuals infected with HIV have a greater than 20-fold increased likelihood of contracting TB with the possibility of TB developing at any stage of the HIV disease. Up to 50% of these individuals without ARV treatment die within the first six to eight months of TB treatment and this risk is escalated to 72-98% in the cases of MDR TB. Regular TB screening provides a juncture for rapid diagnosis and treatment of TB and to recognise those clients without TB who may qualify for IPT. Since IPT is beneficial and can decrease the rate of TB incidence, the WHO recommends routine TB screening with all HIV infected persons for the prompt initiation of treatment to those clients identified with TB, or to exclude active TB infection for assisting in the uptake of IPT. Nevertheless, only 1.7 million (5%) of the approximate 33 million people living with HIV were screened for TB in 2009, and a mere 0.2% of these individuals were provided with IPT.

Cullinan (2006) identifies that since the responsibility of health services has moved to the primary rostrum one of the foremost challenges is acquiring and retaining professional nurses, who are already in short supply. In addition, the South African HIV/TB pandemic and its associated health activities are viewed as a further strain on the existing health sector. Furthermore, Were *et al.* (2009) suggest TB diagnosis is delayed by insufficient laboratory facilities and an inadequately trained workforce. The use of less trained staff in resource constrained settings may be necessary to diagnose or exclude TB as ARV programmes spread out. Cost effective, straight forward and proficient clinical algorithms are required to recognise or eliminate TB infection, thereby facilitating an enhancement in TB screening and active case finding.

Naidoo, Seevnarain and Nordstrom, (2012) conducted a study in eThekweni municipality local government primary health care clinics to evaluate infection control procedures. Their findings revealed poor infection control practices in clinics that already maintain high TB prevalence rates. The authors recommend implementation of infection control practices to reduce the transmission of TB to non-infected clients and health care providers in primary health care clinics. One approach to limit the spread of infectious diseases like TB is through early identification of infected

individuals or those at risk of infection and the timely initiation of treatment. This can be achieved through the application of the TB screening tool (Howard and El-Sadr, 2010).

The DOH: KZNSP (2010) and DOH: KZNPS (2011) documents further describe how the KZN burden of disease (inclusive of the high HIV and TB rates) has a drastic effect on life expectancy; prospects for the year 2011 were 42.7 years for males and 47.8 years for females as compared to the national life expectancy for males of 53.5 years and females 57.2 years. Contending with HIV/AIDS and reducing TB diseases is deemed a core strategy of the KZN government to increase the life expectancy of its citizens.

It is thus paramount to assess implementation of the policies to limit the morbidity of TB in order to increase the wellbeing of KZN's citizens.

1.3 PURPOSE OF THE STUDY

The purpose of this study was to investigate the utilisation of the TB screening tool amongst clients on ARV therapy in the eThekweni local municipality clinics.

1.4 OBJECTIVES

The objectives of the study were to:

1. To determine the implementation of the TB screening tool by health care workers in all clients that are enrolled in ARV care by conducting a clinical audit.
2. To investigate the extent of the implementation of the TB screening tool when utilised.
3. To determine further investigations or TB treatment initiation based on the TB screening tool implementation.
4. To identify initiation of Isoniazid prophylactic therapy.
5. To determine the frequency or consistent utilisation of the TB screening tool across the eThekweni municipality sub-districts.

1.5 SIGNIFICANCE OF THE STUDY

Naidoo, Naidoo, Padayatchi and Karim, (2011) and the DOH: KZNPSP (2011) regard the reduction and improved management of TB in HIV infected persons as a worthwhile effort to assist nations in achieving their MDG health goals. The DOH: KZNSP (2010) and Abdool Karrim *et al.* (2009) state that the need for integrated and comprehensive strategies is great because the co-infection of TB and HIV infection of 70% in South Africa is so high. Presently the KZN province has the largest number of co-morbidity in TB cases, in addition to the uppermost HIV prevalence rate in South Africa. There was a national increase in TB mortality from 78 per 100 000 population in 1990 to 218 per 100 000 population in 2006. This union of rising TB incidence and HIV-TB co-infection, MDR and XDR TB with the ever-increasing mortality, represents a calamity requiring urgent and unrelenting intervention.

South Africa has an extremely high TB-HIV co-infection rate, yet there is a lack of research focussing on the implementation of TB screening in the HIV population. When successfully implemented, this vital first step in the WHO mandated strategy for TB identification can prevent active TB disease or facilitate the commencement of early TB treatment resulting in decreased morbidity and mortality usually associated with TB-HIV co-infection. The only other evaluation of TB symptom screening in the HIV population is mentioned in a presentation at a conference and was sharing of programmatic experiences and not a research project (Wessels, Verkuil, Reed, Futshane, Nogoduka, Jagwer and Maharaj, 2009). Information presented was based on routinely collected data for monitoring and evaluation of TB screening and was augmented by an evaluation requested by the Eastern Cape Department of Health. The DOH: NSP (2011) considers the facilitation and promotion of research into TB identification, treatment and prevention as a core component of the Global Plan to Stop TB. Additionally, the WHO advocates the expansion of a vigorous research agenda and enhanced monitoring and evaluation on HIV-TB co-infection.

According to national, provincial and district health plans, South Africa has intentions to decrease the burden of TB-HIV co-infections through varied health care strategies, namely, the IPHC approach. The WHO and MDG guidelines further

highlight goals and interventions that the country subscribes to. Nevertheless, HIV and TB prevalence continues to escalate despite available policies, and the KZN province is observed bearing the highest rates of TB and HIV nationally.

Consequently, the citizens of KZN have a considerably lower life expectancy when compared to the population nationally. The significance of this challenge is further highlighted since the majority of the inhabitants of KZN are less than 35 years old. Given that the eThekweni district is the most densely populated region in KZN, the study can assist the provincial and local authorities to enhance TB and HIV planning and management to impede the growing predicament. The findings of this study can aid stakeholders and policy makers to improve IPHC strategies for the facilitation of enhanced TB care in the HIV infected population. Additionally, results from this research can benefit the eThekweni Municipality health department to strengthen their current practices. An improvement to the eThekweni districts' TB-HIV co-infection rates will result in substantial progress towards national and global TB-HIV outcomes.

1.6 CONCLUSION

This chapter introduced the study and provided the background to the research. The purpose and objectives were highlighted and the significance of the study was clarified. The problem statement was elaborated and operational concepts were defined. Chapter Two will focus on the relevant reviewed literature relating to this study.

CHAPTER TWO – LITERATURE REVIEW

2.1 INTRODUCTION

For the purposes of this study, the literature under review will discuss issues pertaining to Human Immunodeficiency Virus (HIV), Tuberculosis (TB), the relationship between HIV and TB, Isoniazid prophylaxis (IPT) and the TB symptom screening tool used for assessment of TB in HIV positive individuals. Relevant research articles and sources have been reviewed.

2.2 TUBERCULOSIS (TB)

TB is an infectious disease that is usually caused by five related bacteria, with the commonest being *Mycobacterium tuberculosis*. It can be transmitted among humans through the airborne route; by droplet nuclei when an infected person with possibly pulmonary or laryngeal TB coughs or sneezes (DOH: National TB Guidelines, 2009). King and Tomasic (1999) explain that TB can also be transmitted when people talk, laugh, or sing thereby facilitating entry of the TB bacillus into the lungs where it is able to multiply. A droplet carrying the TB bacteria is usually inhaled into the alveoli where it can remain inactive or progress to active TB disease, if macrophages are unable to contain the bacilli at the site of infection, depending on the immunity of the affected individual (King and Tomasic., 1999; DOH: National TB Guidelines, 2009).

TB can infect many different organs in the body, for example the gastrointestinal tract, the skin, or the lungs. In those with an intact immunity, 90% will not progress to active TB disease (DOH: National TB Guidelines, 2009). Should the bacilli spread from the lungs into other sites of the body (extra pulmonary TB) such as the joints, lymph glands, reproductive and digestive systems, signs and symptoms specific to these sites may develop. Some of the signs and symptoms of active TB are fever, sweating at night, weakness, difficulty breathing and fatigue. TB can develop years later when a person's immunity is suppressed due to aging, or disease, causing the bacilli to once again activate (King and Tomasic, 1999). Individuals with a

compromised immunity have a tendency to develop active TB disease by up to 60% more frequently than individuals with a normal immune system. The annual risk of TB in an HIV infected individual is 10% compared to a lifetime risk of 10% in an HIV uninfected individual (DOH: National TB Guidelines, 2009).

People who are considered to be at an increased risk for TB infection are those individuals who have had close or prolonged exposure to a TB infected person. At risk individuals include family, health care workers, populations inhabiting long term care facilities, prisons and patients with suppressed immune systems such as patients on immunosuppressive treatment or patients with HIV or AIDS. People with low incomes, alcohol and intravenous drug users are also considered to be at risk due to their tendency to be malnourished resulting in diminished immunity (King and Tomasic, 1999).

Diagnosis is usually made using laboratory diagnostic methods, for example sputa specimens are sent for smear microscopy examination for bacteriological confirmation of TB. Management for TB involves drug therapy for a period of not less than six months (DOH: National TB Guidelines, 2009).

Naidoo *et al.* (2011) add that due to TB being one of the foremost reasons for worldwide morbidity and mortality, further challenges to TB care become evident in the escalating occurrence of multidrug-resistant (MDR) and extremely drug-resistant (XDR) TB.

2.2.1 Global Incidence of TB

From a global perspective, TB continues to be the main cause of death from an infectious agent. In the year 2008 there appeared to be an estimated 40% increase in TB cases compared to the year 1990. This significant increase was largely due to the increase in sub-Saharan Africa and European areas, chiefly driven by the HIV epidemic. A total of 5.7 million new global TB cases were reported by national TB-control programs. In excess of half (55%) of the estimated number of TB cases were in Asia, with Africa following (30%), and the last 15% spread over the rest of the

regions (Getahun, Gunneberg, Granich and Nunn, 2010). Bassett, Wang, Chetty, Giddy, Losina, Mazibuko, Bearnot, Allen, Walensky and Freedberg (2010) agree with this: Africa, which has only 15% of the global population, is responsible for almost a third of the world's load of TB and TB related deaths. Approximately 2.8 million new TB cases and 639 000 TB related deaths occur in Africa each year. The TB prevalence in African countries that have an elevated HIV prevalence has tripled since the year 1990, and is still increasing at an annual rate of 3-4%. In the years 1998-1999 a rise of 20% in TB cases was reported from some African countries that were adversely affected by HIV or AIDS (Ngowi, Mfinanga, Bruun and Morkve, 2008).

TB is the most frequent opportunistic infection and the leading cause of death in people with HIV in developing countries, accounting for an estimated 40% of the opportunistic infections observed in the HIV population. The authors suggest that proper diagnosis and management of TB by early detection and treatment is necessary to reduce the TB load (Ngowi *et al.*, 2008).

2.2.2 Sub-Saharan Africa and South Africa

Meintjes and Wilkinson (2010) assert that the substantial rates of both diagnosed and undiagnosed TB among patients in ART care is the leading constraint to the implementation of ART in sub-Saharan Africa. Bassett *et al.* (2010) mention that South Africa has the third largest global TB incidence, with 948 cases per 100 000 people per annum. When HIV infected patients in sub-Saharan ART or health clinics are screened for TB using the intensified case finding strategy, 4% to 25% of these patients are diagnosed with TB disease. Should TB not be screened for and diagnosed, these patients will progress to active TB with an amplified risk of death, as well as posing a greater risk of TB transmission to other patients in full clinics (Meintjes *et al.*, 2010).

2.3 HUMAN IMMUNODEFICIENCY VIRUS (HIV)

Evian (2006) describes HIV as a retrovirus that was found to be the cause of the Acquired Immunodeficiency Syndrome (AIDS) in 1983. The movement of people, socio-economic constraints, intravenous drug use and unprotected or unsafe multiple partner sexual interactions have caused the virus to swiftly spread globally. The virus enters the body and destroys vital cells responsible for maintaining and protecting the immune system by infecting these immune cells with the HI virus. Wilson, Naidoo, Bekker, Cotton and Maartens (2008) and Evian (2006) explain how after a period of usually 3-7 years, a large portion of the immune system has been destroyed, while the HIV virus has been produced in a large quantity. The individual is now considered immune-compromised as the body is no longer able to defend and protect itself against opportunistic infections. An individual is considered to have developed AIDS when the immune system is so destroyed that it is left exposed to multiple life-threatening infections, diseases or cancers that an individual with an intact immune system would have been able to defend themselves from (Evian, 2006).

The WHO and the Joint United Nations Programme on HIV/AIDS (UNAIDS) make a distinction between three phases of the HIV epidemic: a

- low level HIV epidemic, in countries where the HIV infection rate is mainly confined to people in groups with high risk behaviours (for example sex workers) and the HIV prevalence in these groups is less than 5% with no proliferation as yet to the general population;
- concentrated HIV epidemic where the infection is still confined to the groups with high risk behaviours with an expeditious spread of HIV within these groups with a HIV prevalence exceeding 5%;
- generalised HIV epidemic where the HIV is entrenched in the general population with some countries exceeding a 15% prevalence rate (Matjila, Hoosen, Stoltz and Cameron, 2008).

Management of HIV involves methods to improve the immune system, provision of prophylactic treatment to prevent common opportunistic infections and or

antiretroviral therapy (ARV). These interventions usually involve a lifetime commitment (Evian, 2006).

2.3.1 Global Incidence of HIV

According to Getahun *et al.* (2010), there was an estimated 33.2 million people infected with HIV by the end of year 2008, of whom 2.1 million were children. Venkatesh *et al.* (2011) affirm that by the end of the year 2009, HIV had been transmitted to approximately 33.3 million people, with 2.6 million persons accounting for new HIV infections and 1.8 million dying of AIDS in that year alone. Most of the HIV infected population is undiagnosed and there is not as yet research available to reveal the global proportion of people who know their HIV status. Nonetheless statistics provided by the WHO shows there has been significant growth in HIV testing in numerous countries. Between 2006 and 2007, 17 countries that provided data to the WHO revealed that the quantity of HIV testing sites had increased by 2.5 fold. In spite of this, only one in five people know their HIV status in environments of increased HIV prevalence. By the end of 2008, more than four million people were in receipt of ART (Getahun *et al.*, 2010).

2.3.2 Sub-Saharan Africa and South Africa

Getahun *et al.* (2010:2) state: "Approximately two-thirds of all persons infected with HIV live in sub-Saharan Africa". This is supported by Matjila *et al.* (2008). The authors affirm that the sub-Saharan region has the greatest load of HIV infections globally. In the year 2007, this region alone was responsible for 35% of new HIV cases and 38% of worldwide AIDS-related deaths. The HIV prevalence of eight countries in this region (Botswana, Lesotho, Mozambique, Namibia, South Africa, Swaziland, Zambia and Zimbabwe) in the year 2005 surpassed 15% (an amount that no other country in the globe had yet attained).

Bassett *et al.* (2010) concur with the above statement by maintaining that South Africa has the one of the largest HIV prevalence in the world in adults with the rate being close to 20%. Statistics SA (2013) confirm that close to 16% of the population

of South Africa in the age band 15-49 years is living with HIV. In the year 2013, there was an estimated 5.26 million HIV positive people in the country. According to Matjila *et al.* (2008) South Africa is considered to be the nation that has the leading total of HIV infected citizens globally (4.9-5.7 million), with about 25% of those persons infected being children. The approximate number of deaths of adults and children from AIDS in South Africa was 350 000 in the year 2007.

Matjila *et al.* (2008) discuss a review that established that the risk of women aged 20-29 years was six times that of men in the matching age band, and females comprised a staggering 90% of new HIV infections in the 15-24 year age group. The existing significant prevalence of the HIV population, unsafe sexual activities, elevated levels of Sexually Transmitted Illnesses (STI's), progressive HIV disease and extreme amounts of vulnerability are some of the key factors in the advancement of HIV infections in South Africa.

2.4 RELATIONSHIP BETWEEN HIV AND TB

The global escalation in HIV disease is having an astounding effect on the spread and control of TB, especially in areas where both these infections are already prevalent. HIV or AIDS is the foremost threat to the acquisition and spread of TB. This is because HIV destroys the two vital immune cells, namely, macrophages and CD4 receptor lymphocytes, which usually suppress the TB bacilli (Long, Houston and Hershfield, 2003). Naidoo, Naidoo, Padayatchi and Karim (2011) explain that HIV positive individuals are 20 times more susceptible than HIV negative people to contract TB in countries with an HIV epidemic. TB is found to be the most widespread illness among HIV infected individuals, all of whom will continue to be at an elevated risk for TB infection throughout their lives. The HIV infected population on ART have a TB incidence 10-fold greater than the HIV negative population. Long *et al.* (2003) consider the risk for TB in the HIV population before the accessibility of ARV's to have been approximately 170 times greater for AIDS and 113 times greater for HIV without AIDS. Re-activated TB cases as a result of HIV infection further multiply the probability of TB disease within the population.

Venkatesh *et al.* (2011) maintain that TB is considered to be the commonest opportunistic infection among HIV positive individuals and co-infection of HIV-TB continues to be a large global public health challenge, mainly in areas with an already high HIV rate. An estimated 9.4 million new cases of TB were identified in the year 2009 with over 10% of the cases having HIV as well. Data derived from the WHO points to TB being responsible for almost 25% of AIDS associated deaths worldwide. Naidoo *et al.* (2011) are of the same opinion that TB is one of the main causes of disease and death throughout the world. Of the estimated 9.3 million new cases of TB that were diagnosed in 2007, 1.37 million (15%) were also infected with HIV. Getahun *et al.* (2010) concur that one third of HIV infected individuals globally are co-infected with TB, leading to 26% of deaths in this population. Approximately 1.4 million new cases of TB in HIV infected people and 520 000 deaths were reported in the year 2008. The HIV epidemic has accelerated the TB rate especially in those countries with an already high HIV prevalence, starting from the 1980's with a 3-fold increase in TB disease over that decade, especially in Sub-Saharan Africa. El-Sadr and Tsiouris (2008) acknowledge that TB and HIV are two of the greatest global public health challenges, and they pose more of a threat when an individual is co-infected with both these diseases. HIV greatly enhances the risk of TB disease, and is a major cause of mortality. HIV considerably escalates one's risk of reactivation of dormant TB and advancement to actual TB disease. HIV-TB co-infection causes significant challenges due to the various drug interactions and toxicities.

Venkatesh *et al.* (2011) concur with Naidoo *et al.* (2011). These authors cite a study from South Africa which reveals that HIV infected individuals maintain a higher risk for acquisition of TB when compared with non-HIV infected individuals even when the HIV infected individuals have been on ART for numerous years. Death rates among HIV-TB co-infected persons who have not accessed ART can be as elevated as 91%. The authors state that concomitant management of both TB and HIV (ART) significantly improves outcomes as contrasted to delaying ART. According to Getahun *et al.* (2010) the risk of HIV infected individuals contracting TB is 20-30 fold compared to the risk of HIV uninfected individuals. In the year 2008, 81 countries had tested more than 50% of their patients infected with TB for HIV, yet only 4% of all individuals infected with HIV were screened for TB. Venkatesh *et al.* (2011)

explain that although TB can reveal itself at any phase of HIV illness, the severity of the TB is exacerbated by the level of immune suppression due to the HIV.

Venkatesh *et al.* (2011) and Getahun *et al.* (2010) state that the combination of TB-HIV co-infection is responsible for the annual demise of approximately 4 million individuals, most of whom reside in developing nations with Sub-Saharan Africa been the area most largely affected. This region is responsible for 80% of the global HIV-TB reported in 2009. Naidoo *et al.* (2011) explain that Sub-Saharan Africa was responsible for 79% of the HIV-TB co-infections. There were 456 000 TB related deaths within the HIV population, leading to 23% of the global HIV mortality. South Africa has less than 1% of the world's population, but is responsible for 17% of the global burden of HIV and around 25% of all HIV-TB co-infected patients. Getahun *et al.* (2010) substantiate that South Africa is responsible for an estimated one third of the global challenge. Matjila *et al.* (2008) are in agreement with identifying TB as the foremost cause of death in HIV infected people in South Africa. The yearly risk of TB in the HIV infected population is ten times that of the non-HIV infected population and Southern Africa leads with the greatest TB prevalence globally.

A study undertaken in Botswana during the period 2004-2006 showed that 40% of HIV deaths were due to co-infection with TB and that over 80% of HIV infected individuals were also co-infected with TB. This study also demonstrated that IPT was significant in reducing infection from TB (Mosimaneotsile, Mathoma, Chengeta, Nyirenda, Agizew, Tedla, Motsamai, Kilmarx, Wells and Samandari, 2010).

In 1997 the WHO commenced pilot projects in three sub-Saharan countries (South Africa, Malawi and Zambia) to support voluntary HIV assessment and facilitate TB screening with implementation of IPT when indicated. The goal was to cultivate a district-based approach to combine TB and HIV management. The evaluation of these projects showed that TB and HIV interventions are capable of joint successful performance and are both essential and viable. This resulted in the WHO policy on Collaborative TB/HIV Activities which proposed vital strategies to improve outcomes in the TB/HIV infected population (Getahun *et al.*, 2010). The WHO and the Stop-TB partnership outline the HIV-TB guidelines and policies to deal with TB in high HIV burdened areas. The Millennium Developmental Goal (MDG) for TB was designed to

reduce by half the prevalence and death rate of TB by the year 2015. The ultimate objective of this initiative is to decrease the risk of TB among HIV infected individuals through intensified case findings, isoniazid preventive therapy (IPT) and infection control (known as the 3 "I's"). The idea is for prevention of HIV associated TB as well as the early introduction of Antiretroviral Therapy (ART) to decrease the HIV associated TB rate (Venkatesh *et al.*, 2011).

The WHO's response to the foremost public health challenge of TB-HIV co-morbidity focuses on intensified case findings (ICF) for TB among HIV infected individuals. The two key objectives of this response are to decrease TB related infections and death by early diagnosis, as well as decrease TB transmission. Directly Observed Treatment Strategy (DOTS) is the global principle for TB management, but it relies heavily on case findings for TB when individuals present to healthcare settings (passive TB case findings). ICF broadens DOTS by actively screening people with no or little symptoms of TB, but who are nevertheless at risk for TB disease, such as those individuals who are HIV infected. Therefore ICF is seen as having the capability of improving TB case identification and management (Shah, Demisse, Lambert, Ahmed, Leulseged, Kebede, Melaku, Mengistu, Lemma, Charles, Wuhib, and Nelson, 2009).

Venkatesh *et al.* (2011) clarify how admission into ART care in resource limited settings (RLSs) appears to be increasing, however a large number of people gain entry into this programme later, already having developed active TB. They repeat that the risk of TB infection is increased twofold with HIV, and continues to amplify with immune suppression. It is imperative for TB to be diagnosed and treated or prevented in individuals with TB-HIV co-infection especially since ART is now advocated for all individuals in this cohort. El-Sadr *et al.* (2008) mention that another factor which broadens these challenges is co-infection in resource limited settings (RLS). They suggest that strategies should be implemented to screen or identify for TB in HIV infected individuals that are inexpensive and practical. De Cock (1995) describes his experiences in resource poor countries. The amplified rate of TB among the HIV population illustrates the enhanced risk for progression to active TB disease. Recognition and management of TB is an integral component of TB control in developing nations. Passive case finding (detection of TB cases among patients

visiting healthcare venues) as a method for TB case identification is considered to be more effective when compared with active case finding. In order for patients with TB who are enrolled in HIV management to receive optimal care, it is necessary to augment the relationship between TB and HIV programmes. HIV positive and HIV negative TB follow a significantly dissimilar course; with TB and HIV co-infected patients demonstrating an escalated risk for drug side effects as well as other complications of HIV disease.

Howard and El-Sadr (2010) agree that encouraging the relationship between TB and HIV care in resource limited settings is critical in the overall management of both these diseases. The authors cite their involvement in TB/HIV interventions which incorporated ICF's, IPT, infection control and commencement of ART. Their experiences showed successful amalgamation of TB and HIV care in RLS's is practical. An approach which takes the reality of challenges with infrastructural and human resource elements, as well as the increased patient load into consideration is encouraged.

Kali, Gray, Violari, Chaisson, McIntyre and Martinson (2006:2) explain how the rate of TB in pregnant HIV positive women is 10 times the rate of TB in HIV-uninfected women: "In that population, the attributable fraction of TB related to HIV was 71.7%". TB in pregnant women carries a large risk for the mother, the foetus and the new born child because congenital TB has an increased mortality. Naidoo *et al.* (2011) go on to state that HIV-TB co-infection is also a leading cause of death in pregnancy in Sub-Saharan Africa. Research conducted in KwaZulu-Natal shows that it carries a 32-fold increased risk of mortality when compared to those HIV positive women who are TB free. TB has shown to also be a leading cause of illness and death in HIV infected children with HIV positive children attracting a 20-25 fold increased risk when compared to HIV negative children. Kali *et al.* (2006) provide details of a study undertaken in Durban, South Africa, which showed a 16% risk of maternal transmission of TB, thus making it an urgent matter for interventions to reduce TB in HIV prevalent areas by incorporating early screening, diagnosis and treatment of pregnant women who are susceptible.

2.5 ISONIAZID PROPHYLACTIC THERAPY (IPT)

The DOH: National TB Guidelines (2009) explain that IPT involves the use of the anti-tuberculosis drug Isoniazid to prevent TB infection and should be taken for a period of a minimum of six months to offer the optimal resistance against TB. Episodes of recurrent TB are greater in the HIV infected population inclusive of new and re-activated TB infections. Mosimaneotsile *et al.* (2010) highlight that in 1993 the WHO advocated IPT for all HIV infected people in high TB prevalent countries. See Figure 2.1 for the South African adaptation of the WHO TB symptom screening algorithm that is used prior to IPT commencement. There are IPT policies in 84 countries, yet in the year 2006 the WHO stated that globally less than 0.1% of the HIV population had received IPT. The authors' research in Botswana showed the addition of IPT to ART reduced the risk for TB by 58-76%.

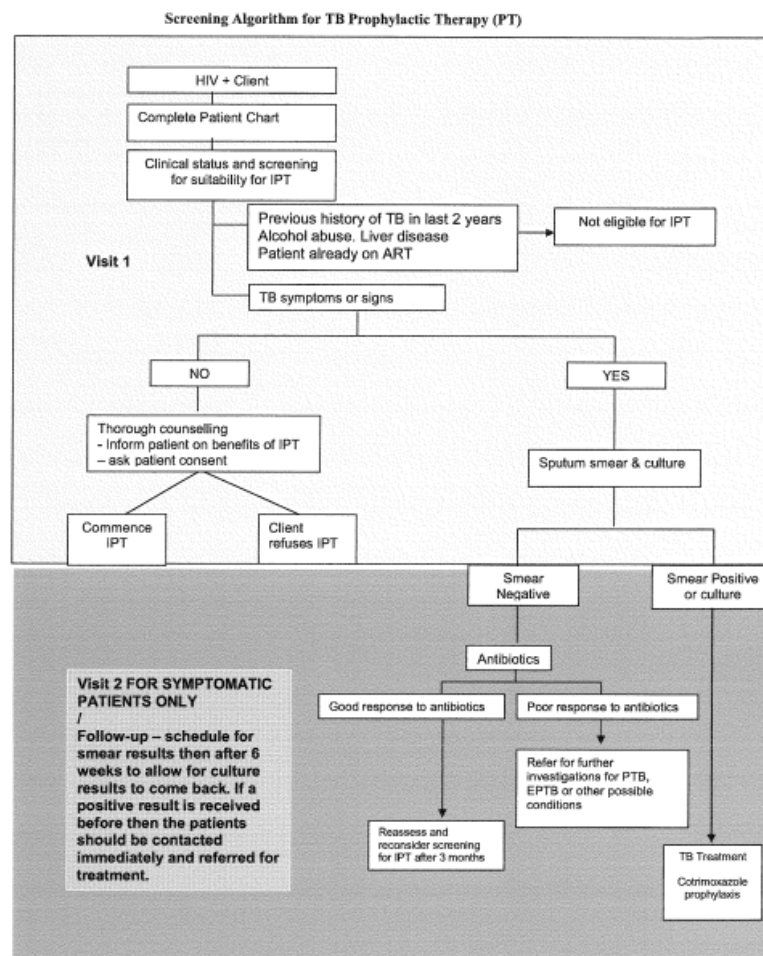


Figure 2.1 South African adaptation of the WHO TB symptom screening tool

Source: SA DOH, 2010a

Howard and El-Sadr (2010) articulate the value of IPT in deterring initial occurrences of TB in the HIV infected population; it can lower the TB rate by 33% in ART naive clients. While IPT has been shown to diminish the threat of TB morbidity and mortality during the initial phases of ART, the synthesis of IPT and ART brings about a further decline in the possibility of TB infection than either intervention by itself. Mosimaneotsile *et al.* (2010) feel that excluding active TB disease at screening is a vital component prior to IPT treatment.

Padmapriyadarsini and Swaminathan (2005) concur that before the initiation of IPT, it is imperative to first exclude active TB, since they feel people who do not display symptoms of TB are doubtful to have TB. Research from Mosimaneotsile *et al.* (2010) found that utilisation of IPT in patients is acceptably safe and they recommended that IPT be included in all public health facilities as sub-Saharan countries scale up access to ART. Utilisation of the TB symptom screening tool will assist in hastening or facilitating the uptake of IPT thereby reducing the morbidity and mortality associated with HIV-TB co-infection.

Venkatesh *et al.* (2011) describe how IPT reduces the risk of TB in HIV infected individuals by more than a third. Data from studies in Brazil and South Africa demonstrate the risk is further reduced by up to 76–89% in HIV infected patients who are on ART. An increased incidence of recurrent TB is associated with HIV infection, especially in resource limited settings. Padmapriyadarsini and Swaminathan (2005) discuss a study conducted among miners receiving IPT in South Africa which illustrated a 55% reduction in recurrent TB when compared with those miners not receiving IPT. Literature and studies that the authors reviewed showed the usage of IPT to prevent TB can reduce TB disease by 60-69%. It is further implied that IPT can also prolong the interval from asymptomatic HIV infection to advanced HIV disease. Venkatesh *et al.* (2011) maintain that the introduction of IPT into HIV care in TB endemic areas reduces the probability of TB re-infection, yet a wide scale uptake of this confirmed approach is still to be put into practice due to restricted resources. The increased risk of TB among HIV infected individuals necessitates the urgency for all Health Care Provider's (HCP) to be able to screen, identify, treat and prevent this disease among the entire population, especially the HIV infected population.

Padmapriyadarsini and Swaminathan (2005) observe that constraints to IPT implementation are usually related to limited resources; therefore the utilisation of a TB symptom screening tool is advantageous. The authors recommend that until most, if not all the HIV infected population globally have full opportunities to receive ART, IPT should be utilised to prevent the risk of contracting TB. IPT should be incorporated as part of any HIV care programme and should be advocated to all people living with HIV as it has displayed a significant role in lowering TB morbidity and mortality in the HIV infected cohort. Venkatesh *et al.* (2011) refer to the current WHO directive proposing IPT as a daily treatment in HIV infected individuals who are not likely to have TB, irrespective of the extent of immune-suppression, ART utilisation, pregnancy, or preceding TB therapy. “Despite the promising clinical data, IPT among HIV infected individuals has been relatively underused as a safe and well tolerated means of TB control, although it could be a cost-effective strategy in resource limited settings with rampant latent TB among HIV-infected individuals” (Venkatesh *et al.*, 2011:1137).

Getahun *et al.* (2010) cite statistics from over 55 countries revealing HIV positive people with TB disease have a four-fold higher probability of death than HIV negative people suffering from TB. Laserson and Wells (2007) are of the same opinion. They feel that the WHO proposed TB and HIV joint practices require urgent implementation in order to prevent the profound effects of HIV related TB disease. The authors mention that although IPT has proven to diminish susceptibility for acquiring TB disease among HIV infected individuals, only Botswana has provided IPT on a countrywide level. According to Howard and El-Sadr (2010) integration of IPT into HIV management in resource restricted settings has been inadequate. Regardless of results from evaluations signifying the diminutive influence of IPT on isoniazid resistance, one of the causes for non-implementation of IPT is the unease over possible isoniazid resistance due to non-exclusion of TB prior to IPT commencement. Laserson and Wells (2007) cite reasons for public programmes being disinclined to provide IPT which include financial implications, concern for not ruling out active disease, and other operational difficulties. An estimated three million HIV infected people should be provided with IPT in order for the WHO TB global plan to be deemed a success. Nonetheless Howard and El-Sadr (2010) established that

regular TB case finding interventions permitted the application of IPT at HIV care sites. This was realised by merging the TB symptom screening tool with a checklist for IPT inclusion once patients had a negative outcome for TB.

Getahun *et al.* (2010) affirms that there generally has been an unhurried implementation of combined TB and HIV activities devised to minimise TB among the HIV infected population. The focus of these activities being *the three I's* for HIV and TB infection; *intensified* TB case finding, *IPT* and *infection* control for TB. Nonetheless there has been a global 14-fold expansion in the HIV infected populace that had TB screening from the year 2005 to 2008 and initiation of IPT improved by 21 000 between the year 2007 and 2008. This is in accordance with Howard and El-Sadr's (2010) assertion that accomplishing IPT in resource limited conditions is achievable and the authors are optimistic that the evidence from various programmatic reviews will aid the expansion of IPT in HIV-TB co-infected prevalent environments.

2.6 TB SYMPTOM SCREENING TOOL

Howard and El-Sadr (2010) advocate that early screening and assessment of individuals with a high suspicion of TB should also involve immediate management to improve the individuals overall health and to minimise transmission in the community and health facilities. TB screening is considered vital in assessing clients with HIV infection for identification and management of TB or for possible IPT therapy after having excluded active TB infection. The authors state that ICF for TB in RLS's has predominantly utilised screening tools for detection of symptoms linked to TB. Hoffmann, Variava, Rakgokong, Masonoke, van der Watt, Chaisson and Martinson (2013) reinforce that symptom screening is stipulated as the initial stage in the WHO recommended TB ICF algorithm for the HIV infected population. Individuals who display any symptoms are investigated to include or exclude TB, thereby decreasing the number and expenses of further laboratory tests. Asymptomatic persons or those with negative laboratory tests qualify for ART and or IPT. Getahun *et al.* (2011) are of the opinion that although the WHO proposes TB screening for all HIV positive individuals, resulting in TB treatment or IPT, TB

screening and IPT commencement has been inadequate in resource inhibited environments. The authors performed an examination of primary studies with the objective of formulating a basic, standardized TB screening directive for resource limited situations. The separation of HIV infected people into two classifications: persons with no TB and persons requiring additional investigations to confirm TB in suspected TB patients is regarded as the purpose of TB screening.

In a prior publication, Laserson and Wells (2007) promote the WHO supported TB/HIV collaborative approach to advance HIV and TB control interventions. Effective TB control necessitates activities including HIV counselling, screening and testing for TB in HIV care venues, enhanced implementation of IPT and ART in HIV infected people and amalgamation of TB and HIV services in all settings. Such settings including VCT and PMTCT centres and primary health care clinics which provide optimal settings for active TB screening. Improved TB identification and TB treatment cure or completion is facilitated by prompt TB diagnosis and management in the HIV care facilities, or possible TB exclusion with provision of IPT. Venkatesh *et al.* (2011) discuss the present WHO policy which proposes initiating ART soon after commencing TB treatment in the co-infected population, irrespective of the CD4 count. The use of concomitant TB and ART drugs is usually a consequence of co-infected patients in RLS's presenting for care with advanced immune suppression. The authors discuss the fact that the increased pill administration leading to a higher risk of drug interactions and or toxicities with management of HIV-TB co-infection could adversely impact treatment adherence. Anti-retrovirals and anti-TB drugs joined with co-morbid circumstances can result in complications to the liver of HIV infected persons. Adherence to both ART and TB medication is crucial for the immunological improvement and survival of the HIV infected individual.

Naidoo *et al.*, (2011) note: "To overcome diagnostic infrastructure and human resource constraints, a TB symptom screening questionnaire is increasingly being utilised to more effectively and efficiently screen for TB". The authors agree with the views of the prior researchers. There is a tendency for HIV and TB to be treated in divided health care programmes and venues. The unhurried approach of TB clinics to provide HIV care and ART has led to the formation of separate HIV clinics that do not concentrate on TB co-infection. Integration of HIV and TB care in the HIV

infected population is considered an effective method leading to a decline in mortality of 56% when contrasted to those patients who had ART initiation postponed until completion of TB treatment. The decreased risk for transmitting TB by prompt recognition and diagnosis produces successful results for program objectives. Venkatesh *et al.* (2011) believe that because initiation of IPT and/or ART before a further compromise in HIV suppression shows a reduced risk of developing HIV related TB, early screening, detection and management of TB is necessary and should become an urgent goal. They advocate an accelerated and improved integration between HIV and TB screening and treatment thus facilitating infection control by reducing the transmission risk. Given that TB is a leading fatality in the HIV infected population with death taking place in up to 50% of this cohort in the first two months after TB identification in some countries, Cain, McCarthy, Heilig, Monkongdee and Tasaneeyapan (2010) highlight that a notable contributor to the mortality rate is the delay in detection of TB. ART is known to decrease the probability of death but can also result in immune-reconstitution syndrome in an individual with untreated TB.

A number of enquiries have highlighted that TB management should be integrated into routine HIV care. Laserson and Wells (2007) state the key function of HIV care provision should be dealing with TB and is also fundamental for the necessary IPT programme. The Global Plan to stop TB appeals for the TB screening of 210 million HIV infected individuals by the year 2015. The authors also highlight the enormous burden on human resources in health care facilities. With a steady or decreasing labour force, the increased magnitude of the TB epidemic has destabilized TB programme infrastructure resulting in reduced TB outcomes, increases in defaulting of treatment and mortality as well as the appearance of XDR TB. Godfrey-Faussett, Maher, YaDiul and Nunn (2002) assert that the stigma associated with HIV and TB has harmful consequences for TB programmes. Subsequently, individuals with an unrelenting cough may have reservations about visiting a TB clinic or being placed in a TB queue where they can be recognised by the community. This can be prevented by the provision of active case finding strategies in all health care settings. The further goal for TB control is to diagnose and cure all HIV associated TB which can be accomplished by decreasing diagnostic and treatment intervals. It is found that people accessing HIV care can benefit from intensified TB case finding and TB

screening. Cases with active TB disease will qualify for prompt TB management, while cases in which TB is excluded can gain entry into the IPT programme. Van't Hoog, Meme, Laserson, Agaya, Muchiri, Githui, Odeny, Marston and Borgdorff's (2012: 6) investigation in Kenya found that symptom screening on its own has merit for TB case finding and say that "Symptom screening alone is attractive because it is simple, does not require expensive equipment, and has been applied in several surveys".

In the absence of a precise, expeditious and cost effective TB diagnostic examination, a standardized TB symptom screening procedure is necessary for augmenting TB screening, diagnosis and treatment in the HIV infected population. Commencement of ART and expansion of IPT following dependable exclusion of TB will result in a decline in TB incidence. Similarly, early diagnosis and treatment of TB leads to a decrease in TB transmission and improved morbidity and mortality usually associated with TB-HIV co-infection according to Getahun *et al.* (2011:10) who say: "Our findings show that the utility of the proposed symptom-based screening rule have excellent performance in most settings with TB and HIV burden". Naidoo *et al.* (2011) draw attention to information from nine health facilities in the Eastern Cape, South Africa which have shown the advantages of using the questionnaire in RLS. They concur that since South Africa has a HIV-TB co-infection rate that is greater than 69%, HIV/ART care settings should utilise this screening tool to provide optimal occasions for TB detection in HIV infected people.

Cain *et al.* (2010) completed a prospective study with the purpose of designing an algorithm to exclude or diagnose TB in HIV infected persons in resource constrained environments. The study was conducted in clinics in Cambodia, Thailand and Vietnam. Questioning clients only about chronic cough is an incomplete or ineffective method of TB symptom screening. Instead, clients questioned about multiple symptoms, of at least three symptoms, proved to be more ideal in excluding active TB disease in the HIV infected population. This in turn facilitated entry into the ART or IPT programme. This study recommends that until laboratory diagnostic interventions are more readily available or feasible in health settings, TB symptom screening may be implemented to detect or exclude TB in HIV infected individuals. Koole, van Griensven and Colebunders (2010) are of the same opinion. They

responded to the Cain *et al.* (2010)'s publication and are in agreement with the usage of the three screening criteria (cough of any duration, fever of any duration and night sweats lasting 3 or more weeks) as promoted by the researchers. Koole *et al.* (2010: 2139) believe that this "simplifies the screening and diagnosis of pulmonary and extra pulmonary TB and will facilitate the implementation of screening and diagnosis at country level." Meintjies and Wilkinson (2010) affirm the WHO and United States Centres for Control and Prevention's position (after a study) on endorsing symptom screening for excluding TB in the HIV positive population prior to commencing IPT.

As indicated by Howard and El-Sadr (2010), though there may not always be agreement on what items or questions to include in the screening tool, studies reveal that a combination of symptoms screened is more valuable than just screening for a single symptom. Corbett *et al.* (2010) conducted a study in Zimbabwe to consider approaches to TB screening in HIV infected people. A TB symptom screening questionnaire or tool was utilised to either confirm or exclude TB. A person with any TB symptom was classified as a TB suspect and these symptoms included present cough, haemoptysis, fever, night sweats and loss of weight. They discovered that when only a chronic cough was questioned the response to this TB symptom was 47.9%. Howard and El-Sadr (2010) developed a 5-item questionnaire to be simply administered by a range of HCP's. The need was to improve TB detection in large volume clinics providing HIV management. If a client answered yes to any question, then the client was considered a TB suspect or at high risk for contracting TB, and were referred for further TB investigations. This TB screening tool was initially piloted in Rwanda, but is now utilised for screening clients with HIV infection at more than 450 HIV facilities and is supported in nine Sub-Saharan African countries. The study undertaken by Corbett *et al.* (2010) demonstrated that when five TB symptoms were questioned the response improved to 81.3%. Furthermore, the response was greater when cough with duration of less than two weeks was questioned, compared to cough with duration of greater than two weeks.

Numerous studies have focussed on the value of TB symptom screening. In their review, Corbett *et al.* (2010) show that TB symptom screening can lead to identification of HIV clients who are at a low risk of TB and ART and/or IPT may be

initiated without further TB investigations. Unnecessary TB testing is not cost effective for both the client and HCP, resulting in prolonged intervals before essential treatment can be implemented. The experiences of Howard *et al.* (2010) showed that implementation of this symptom screening tool into routine HIV management in RLS's was not only possible but resulted in large numbers of HIV infected people being identified as having active TB disease, therefore also receiving appropriate life saving treatment. With the usage of this tool their study revealed an increase from 44% to 76% of individuals with HIV infection who were now screened for TB over an 18 month period. There was also an increase from 4% to 6% of individuals who now received TB treatment. Van't Hoog *et al.* (2012) used a symptom questionnaire as part of the TB prevalence study that was conducted in Kenya in the years 2006-2007. The aim of the study was to create a simpler screening for TB prevalence and to investigate suitable algorithms for active case findings. If the symptom screening identified any TB suspects further examinations were conducted using sputa testing. The study revealed that symptom screening by itself has merit for TB identification. It is relevant to first start screening for any symptom and prior to pursuing other investigations like chest x-rays and sputum testing in populations with increased HIV rates.

Investigations in sub-Saharan Africa and South Africa have uncovered significant results. Hoffmann *et al.* (2013) conducted a study in South African community care clinics among HIV positive pregnant women receiving antenatal care. TB symptom questions included the presence and period of existing cough, sputum production, fever, night sweats and loss of weight. The study identified a high prevalence of TB (3.3%) among these women, almost three-fold higher than the overall prevalence for South Africa (1.3%).) Meintjies and Wilkinson (2010) discuss literature that promotes sputum culture testing in areas of widespread TB without considering symptoms. This would have profound significance in disease and death, particularly in demanding ART facilities where a cohort with unidentified TB is in contact with patients with diminutive CD4 counts. However, culture testing is unavailable in the majority of sub-Saharan African countries. South Africa does have access to sputa culture facilities, though laboratories are inundated and additional human and physical resources are essential. Economic, functional and sustainable aspects relating to culture testing may hinder ART commencement in challenging South

African public health areas where there are waiting lists in overburdened clinics. Furthermore, culture screening for all patients may impede starting of ART, especially in an era where policies are being reviewed and made simpler to permit nurse initiated and managed ARV therapy (NIMAART), which will enable a larger eligible HIV infected population access to life saving ARV's. The focus of the analysis performed by the researchers (Getahun *et al.* 2011) was on clinical symptoms that could be measured across all points of health care; current cough, haemoptysis, fever, night sweats and weight loss. The majority of patients were from sub-Saharan Africa (77%) with the rest from Southeast Asian nations. An uncomplicated TB screening algorithm for public health implementation in the HIV infected population was made available by the researchers in order to facilitate the supply of IPT where TB was excluded or to additionally assess individuals for active TB disease.

Howard and El-Sadr (2010) found that people who are HIV infected have a sustained risk of contracting TB throughout their lives, even after management with ART. Therefore they advocated that TB screening should be performed throughout their follow up and routine HIV care. However they indicated that conducting TB screening at every health visit can be difficult in areas that are resource challenged, especially in settings that have a high volume of HIV infected clients and where routine HIV care is a new concept being implemented. Meintjies and Wilkinson (2010) assert that as patients attend health care facilities more often at the time of ART preparation and commencement, there is an increased probability that asymptomatic patients may develop to symptomatic as TB symptom screening is performed successively at each visit. Venkatesh *et al.* (2011) acknowledge that previously HIV and TB programmes were conducted separately with little integration between the two platforms. However, it can be seen that more recently there is an improved relationship between HIV and TB care. Frequently TB is not identified before commencing ART. However, TB symptom questionnaires are now being utilised in HIV care provided in RLS's and are effective in excluding TB in individuals being assessed for ART or IPT. ICF for TB in RLS's is based on a combination of TB related questions in the screening tool. It has displayed relevance in a range of healthcare settings.

It was discovered that HCP's utilised the screening tool more frequently with improved recording when utilising the HIV clinical record. Statistics from routine monitoring indicated the percentage of HIV infected persons screened for TB in nine health facilities in the Nelson Mandela Bay district, Eastern Cape, South Africa, revealed an increase from 73% to 95% in the year 2007 to 2008. This involved the inclusion of the TB screening tool into the HIV clinical record. Overall, this led to a significant amount of HIV infected clients receiving a diagnosis of TB resulting in appropriate treatment being implemented. Although the benefits of the tool are noted, the ideal frequency of usage of the tool still needed to be clarified (Howard and El-Sadr, 2010). Venkatesh *et al.* (2011) suggest that because HIV infected persons remain at risk for TB infection, repeated screening should be conducted during all follow up care. They have found that ICF, inclusive of TB screening, resulted in higher detection rate of TB facilitating prompt treatment. They highlight a study showing a 2-fold reduction in the incidence of TB in the first four months of ART when a vigorous TB screening approach is applied.

The WHO has approved a four-part symptom screen (cough, fever, night sweats and loss of weight) to detect TB suspects or to recognise those persons who appear unlikely to have TB (Hoffman *et al.* 2013). This approach is supported by Meintjies and Wilkinson (2010). Their study showed that when symptom screening focussed on identifying one of the four symptoms; current cough, fever, night sweats and loss of weight irrespective of duration of these symptoms, it had a negative predictive value of 98%. Dependability of symptom screening frequently relates to the grouping of specific symptoms and the time period that are applied in the screening, the degree of the HIV infected person's immunity and the particular health care provider. Hoffman *et al.* (2013) performed a meta-analysis of previous studies of the four-part symptom screen and concluded it is a successful strategy for detecting most patients with an elevated risk of TB and for facilitating rapid diagnosis and treatment. In addition it is also advantageous in detecting patients with a small probability of TB infection, permitting intensified uptake of ART and or IPT. The WHO also advocates symptom screening for this cohort of the population.

Hoffman *et al.* (2013) articulate that since TB is a major contribution towards maternal mortality in a high HIV prevalent environment, TB diagnosis and treatment

is vital in pregnant women. TB has been found to have adverse consequences on the foetus and infants, including premature delivery, low birth weight, and congenital or neonatal TB infection. Although there appears to be limited statistics on symptom screening for HIV infected pregnant women, the WHO offers the four-part symptom screen as a directive for this group of individuals. The principal aim of the study undertaken by Kali *et al.* (2006) was to assess the practicability of implementing active TB case finding in HIV infected women accessing a prevention of mother-to-child transmission of HIV (PMTCT) program. PMTCT programs provide a platform for putting into operation a TB screening policy. A 10-item TB symptom screen was conducted. Symptoms included cough, sputum production, haemoptysis, night sweats, shortness of breath, fever, chest pain, weight loss, loss of appetite and tiredness. Symptomatic pregnant women were examined by the nurse and a sputum sample was collected for further investigations. From their findings the authors noted that TB is a profound public health issue in HIV pregnant women in Soweto, South Africa, and that symptomatic TB screening amongst these HIV infected women is possible and should be investigated further for inclusion into the usual HIV care, instead of waiting for the women to seek care for TB only once symptoms present themselves (passive case finding). This could significantly reduce the incidence of TB related morbidity and mortality for the women and their newborns.

Getahun *et al.* (2010) also write about research from South Africa. HIV positive pregnant women were inflicted with TB at 10 times the rate when compared with HIV negative women and TB was responsible for about 15% of maternal mortality. Likewise, data from Zambia illustrated an escalation in maternal mortality related to TB and HIV co-infection. The authors campaign for maternal health facilities in environments with increased HIV infection incidence to incorporate primary TB screening, diagnosis and prevention into their programmes of care. The aforementioned views are supported by Venkatesh *et al.* (2011). TB screening and preclusion should be a vital element in maternal health facilities with an elevated HIV prevalence. There is already an existing increased TB case load among HIV infected pregnant women. This intervention addresses the Millennium Development Goals (MDGs) 4, 5 and 6; to decrease child mortality, to expand maternal health and to oppose HIV and other major diseases by 2015.

Research by Shah *et al.* (2009) asserts that all HIV infected people enrolled in their study were screened for TB symptoms. The objective of the research was to examine accessible TB diagnostic methods, for example, symptom screening. The screening of collective symptoms of cough, fever and night sweats identified 78% of cases. The investigation revealed TB symptom screening is a valuable tool for excluding active TB, even though it was unsuccessful in recognizing all TB cases. The benefits of the study were that everyone who had active TB disease were enrolled in TB treatment, and those who did not have symptoms of TB qualified for inclusion in the IPT programme, ART care or appropriate medical management where necessary. Some other limitations of TB symptom screening are highlighted in the study conducted by Hoffman *et al.* (2013) in pregnant women. These include possible partial reporting of symptoms and a low sensitivity of symptom screening in antenatal care and this could be explained by the physiological changes related to pregnancy that may disguise some symptoms of TB, for example weight loss. A concern was that an asymptomatic yet culture positive person is still capable of transmitting TB and advancing to active TB disease. The study recommended ongoing screening and monitoring for TB in HIV infected women, and it may be reasonable to provide additional training for HCP's in identifying and managing TB until improved yet cost effective alternate screening measures are accessible. Getahun *et al.* (2010) conclude their report by discussing that the shortage of a uniform symptom screening intervention presents a difficulty for HCP's in RLS to detect or exclude TB, and to facilitate IPT management. They recommend utilisation of existing information and resources to create and implement a simplified, uniform TB screening method.

Naidoo *et al.* (2011) explain that in countries with a high TB incidence and a significant HIV prevalence, recurrent TB makes up a large number of TB cases. The definition of recurrent TB according to the WHO includes individuals who have been successfully treated for TB (cured or completed treatment). Statistics from South Africa reveal the TB rate for HIV infected individuals on ART is an estimated 10-fold higher than the TB rate in HIV negative individuals in the same cohort. Howard and El-Sadr (2010) support the belief that individuals with TB can be present in any health care settings; HIV care facilities, maternal and child health venues, general outpatient units and inpatient areas. As a result, any interval in TB identification and

treatment provision aids the spread of TB amid other patients and health care providers. This is escalated in circumstances of overcrowding and inadequate ventilation, in addition to the HIV infected populations' increased risk to TB. Naidoo *et al.* (2011) describe how TB recurrence was shown to be five times more likely for HIV infected persons in a study conducted among South African gold miners. Although ART diminishes the risk for TB in HIV positive populations by 70-90%, they still remain at risk for TB infection. In view of the heightened threat of recurrent TB, TB symptom screening should be implemented to prevent active TB disease or treat established TB without delay.

A few of the infection control strategies that the WHO and Centres for Disease Control and Prevention (CDC) have proposed to diminish the spread of TB in HIV care facilities in resource limited environments include rapid recognition of people displaying TB symptoms, segregating transmittable individuals, improving cough decorum and hygiene, and reducing the overall period of time in health care settings for those persons suspected or diagnosed with TB. Howard and El-Sadr's (2010) call to minimise TB exposure in health care environments has been strengthened by the current spate of multidrug-resistant (MDR) and extremely drug-resistant (XDR) TB. Naidoo *et al.* (2011) are in agreement with the proposals of the previous authors. There is a considerable amount of undiagnosed TB in HIV infected individuals and an increased fatality rate with TB-HIV co-infection. The increased risk of TB transmission and exposure of MDR TB to health care providers and the general public in HIV prevalent settings has created international awareness after the Tugela Ferry XDR-TB outbreak in rural South Africa. Laserson and Wells (2007) emphasise that reinforcing simple TB policy is a core strategy in dealing with TB in HIV settings. This will also assist in halting the consequence of inadequate TB management; which is MDR-TB and XDR TB.

Howard and El-Sadr (2010) reflect on strategies to promptly detect people with TB and to swiftly provide TB treatment, to be considered as a reasonable method to apply infection control in resource limited settings. The authors relate their experience with HIV care facilities in the Eastern Cape, South Africa. All personnel obtain training in infection control and a triage chart is utilised by lay employees to screen HIV infected individuals for cough on entry into the facility. This facilitates the

rapid movement of TB suspects to an improved ventilated area, where they are positioned to be promptly assessed by the health care provider. Naidoo *et al.* (2011) are in agreement with improving the integration of HIV and TB screening, and regard treatment strategies necessary in order to reduce the spread of TB and promote infection control processes in HIV prevalent settings particularly in therapeutic areas where HIV infected people are in close proximity with each other. Feasible infection control approaches in clinical areas comprise combined TB and HIV programmes, suitable ventilation, appropriate cough management; and triaging of individuals who are coughing to different areas of the health facility. The TB symptom screening tool allows for the first critical step in TB-HIV management; earliest recognition of TB suspects.

Although programmes exist to merge HIV-TB management, recent information shows that screening for TB in HIV facilities is limited. The increased risk of mortality with HIV-TB co-infection escalates the need for screening amongst HIV infected individuals especially for those individuals in RLS.

The National Department of Health (DOH: National Strategic Plan, 2011) highlights the existence of a developing crisis in our country with XDR-TB: South Africa has the fourth leading MDR-TB prevalence globally. In spite of this, only 46% of MDR-TB cases begin treatment; a large number of patients die or move prior to being informed of their diagnosis. There is now a move to integrate MDR-TB services into clinic and community levels by combining HIV and TB programmes. Vital to this plan is merging TB prevention and treatment into the HIV care package; embracing the WHO strategy of the three I's of intensive TB case finding, Isoniazid therapy and infection control. Corbett, Zezai, Cheung, Bandason, Dauya, Munyati, Butterworth, Rusikaniko, Churchyard, Mungofa, Hayes and Mason (2010) accentuate that symptom questionnaires or tools create a fast and cost effective route for detecting TB in individuals with HIV infection. Symptom screening for TB has a prominent sensitivity when employed to identify TB in people who present themselves to health care facilities (passive case-finding) for HIV care and it is a key aspect of the WHO's DOT's policy in reducing TB.

Corbett *et al.* (2010) relate in recent times that TB screening conducted by HCP's (active case-finding) has become an integral component of HIV care in resource limited environments, since it is essential for TB management and control. They write that symptom screening is frequently the sole manner for a practical approach and failure to screen may result in negative results. Undiagnosed TB in clients initiating ART can result in increased risk of morbidity and mortality, and particularly in South Africa, outbreaks of TB in healthcare settings is also related to increased morbidity and mortality in clients who are HIV infected. The DOH: National Strategic Plan (2011) gives details of how South Africa subscribes to the DOH: National Strategic Plan for HIV and AIDS, STI's and TB (NSP) 2102-2016; with the foremost intention of widespread HIV testing and TB screening of every South African above 12 years of age. The premise is that an individual can only gain entry into suitable health care programmes once they have established an awareness of their condition. Symptomatic TB screening is regarded as an important initial tool in accomplishing the first "I" of intensified case finding and is stipulated as standard procedure in all health care environments. The two more "I"s that have been attached to South African practice are integration of HIV and TB services and initiation of early treatment.

The KwaZulu-Natal (KZN) province of South Africa has the greatest prevalence of HIV (15.8%) and TB in the country. In excess of half (54%) of the adult HIV infected population reside in this province; with a total of 115 716 related AIDS associated fatalities in the year 2009. For the HIV positive population of KZN TB continues to be the most widespread opportunistic infection and the foremost cause of mortality. The province implements the NSP 2012-2016 with TB management converging on the NSP goals of decreasing the TB incidence and TB connected deaths. In addition, KZN endorses the United Nations General Assembly Special Session on HIV/AIDS (UNGASS) Political Declaration of June 2011 and the WHO Global TB strategy of 2006 to increase TB screening, prevention, diagnosis and treatment of drug sensitive and drug resistant TB, to diminish TB related mortality in HIV infected persons by 50% and to attend to TB/HIV and MDR-TB complexities. The DOH: KZN HIV and AIDS, STI's and TB Provincial Strategic Plan (KZNPSP) 2012-2016 is aligned to the NSP 2012-2016. The plan strives to decrease TB cases to fewer than 200 new smear positive TB per 100 000 population by the year 2016. (DOH: KZNPSP, 2011).

The eThekweni district and municipality have aligned their TB and HIV programme goals with those of the NSP and KZNPS. The eThekweni TB Crisis plan (eThekweni Municipality, 2009) includes as one of their goals to increase early detection of TB by improving active case finding and to strengthen management of TB-HIV co-infected patients. The fundamental objective of this goal is to advance TB, HIV and AIDS collaboration by facilitating clinics to provide integrated management of TB and HIV. One of the key activities emphasized within this objective is to expand and monitor TB screening for all people living with HIV (PLHIV).

The objectives of the KZNPS plan comprise ensuring 80% of men and women aged 15-49 are knowledgeable about their HIV status and receive STI and TB screening by the year 2016. This will be accomplished by offering recurring HIV testing and TB screening as a component of the full Primary Health Care (PHC) package. Another key objective is to intensify early identification, diagnosis and prompt treatment of TB to 80% of HIV exposed persons by 2016. This will be achieved by implementing TB prevention services according to global, national and provincial policies and guidelines. This objective will be actualised by applying infection control measures to all health care facilities involved in HIV and TB care, supplying IPT to all HIV infected persons once active TB has been excluded, initiating active TB case finding measures and rapid identification and management of MDR and XDR TB (DOH: KZNPS, 2011). This is attainable and supported by (Shah *et al.*, 2009:45), who state that TB symptom screening is a very advantageous method to exclude TB disease: "... symptom screening may be a useful tool for HIV care and treatment programmes to use for excluding active TB in patients being considered for ARV therapy or IPT".

2.7 CONCLUSION

The preceding discussion emphasises the critical relationship shared by HIV and TB and highlights the importance of promoting a rapid and efficient response to its manifestation. The studies and research reviewed above show that it is essential and advantageous for a TB combination symptom screening tool be implemented for use in all routine HIV care settings.

CHAPTER THREE – RESEARCH METHODOLOGY

3.1 INTRODUCTION

The preceding chapter focussed on a review of literature with the purpose of discussing available literature in order to substantiate the relevance for the study undertaken. This chapter describes the research methodology utilised in the study.

3.2 RESEARCH OR STUDY DESIGN

A quantitative descriptive research design was employed in the study. A retrospective review of clients' case records was conducted.

According to Burns and Grove (2011) quantitative research is an accurate and unbiased form of research used in an organised manner to produce numerical data. Quantitative research is objective and is undertaken with the purpose of clarifying new occurrences or concepts and exploring the associations between variables. The practise of quantitative investigations usually includes a hypothesis, a research design, a data collection process and statistical analysis with the outcomes presented numerically and or statistically (Parahoo, 2006).

Descriptive research attempts to study and provide evidence or verify phenomena and its possible frequency as it occurs in its natural environment (Polit and Beck, 2008). The research design of this study allowed for the exploration of observable facts without manipulation of any variables.

3.3 STUDY SETTING

The study was undertaken in the Primary Health Care facilities of the eThekweni Municipality, KwaZulu-Natal. Mobile clinics and health posts were excluded from the study as the majority of these sites were not providing antiretroviral medication. There are approximately 60 fixed local municipal Primary Health Care clinics in the

eThekwini district. Antiretroviral therapy was offered in 44 of these facilities at the time of the study (eThekwini Municipality, 2012).

The eThekwini district is divided into three sub districts comprising North, South and West sub districts (DOH: KZN, 2008). There are 32 fixed municipal PHC facilities in the South sub district, 17 in the North sub district and 11 in the West sub district (eThekwini Municipality, 2012). (See Figure 3.1 for the map illustrating the North, South and West sub districts).

3.4. POPULATION AND SAMPLING

3.4.1 Study Population

The study population refers to the whole group of people, objects or cases that the researcher intends to focus the investigation on, whilst the target population is that group which meet certain criteria permitting them to be included in the sample and allow for the researcher to generalise. The accessible population is that segment of cases or individuals that the researcher has actual access to during the study (Burns and Grove, 2011).

The target population in this study comprised clients who were receiving antiretroviral treatment at the municipal PHC health facilities.

3.4.2 Sampling

Burns and Grove (2011) explain sampling as being a method of identifying a set of individuals, behaviours or constituents that are generally representative of the population being researched. Since each subject or element has a very similar probability or likelihood of being added to the investigation, random sampling offers a sample that is representative of a population. Due to people, behaviours or elements being chosen based on convenience sampling rather than random sampling, descriptive studies are on a regular basis accomplished with non-probability samples.

In this study, a multistage cluster sampling technique comprising three stages was implemented to identify the sample. There was a random selection of clinics, and the required number of client records was obtained through convenience sampling from the selected clinics.

Polit and Beck (2008) describe cluster sampling as being beneficial for application in large widespread populations. The consecutive random sampling of units occurs through multiple stages from larger to smaller sampling groups or units, allowing for a representative sample. It is also useful when the researcher wants to attain a geographically dispersed sample. Convenience sampling is explained as a technique utilising the most conveniently or readily available individuals, cases, records or elements until the required sample size is achieved.

There was an estimated 20 000 patients on antiretroviral treatment in these 44 public health municipal facilities that were offering antiretroviral treatment. One quarter (12) of the facilities was randomly selected as a sample and patients meeting inclusion criteria from within the selected institutions were investigated. This equated to a sample size of approximately 20-25% of the total population of patients receiving antiretroviral treatment. Four hundred case records required review.

Stat graphics Centurion version 15.0 was used to determine the following possible sample size for the study based on a population of 5000.

Parameter to be estimated: normal mean

Desired tolerance: ± 0.1

Confidence level: 95.0%

Sigma: 1.0 (to be estimated)

The required sample size was $n=387$ observations.

This procedure determined the sample size required when estimating the mean of a normal distribution. Assuming that the standard deviation of the normal distribution equals 1.0, 387 observations were required to estimate the mean to within ± 0.1 with 95.0% confidence (Singh, 2012).

It was anticipated that a high response rate (>80%) would be attained using the data collection process outlined below.

Map of Sub Districts

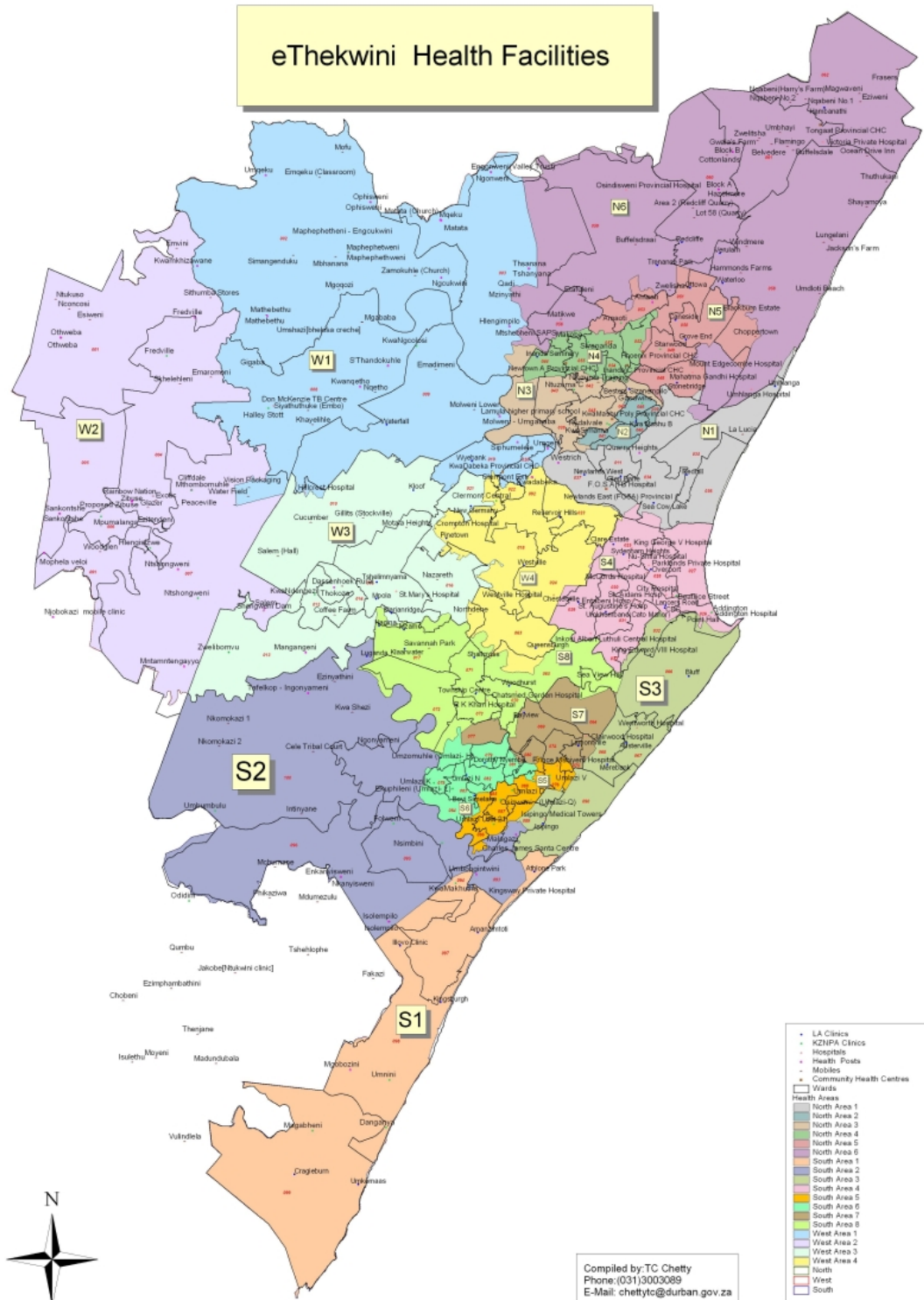


Figure 3.1 Map displaying North, South and West sub Districts
 Source: eThekweni Municipality (2011)

3.4.2.1 Stage One

From the 60 clinics in the district, 44 facilities were identified as sites that offered ARV treatment.

3.4.2.2 Stage Two

In Stage Two, 12 facilities were selected as sites to conduct the study. As discussed in Section 3.3, the eThekweni Health Department is divided into three geographical regions or sub districts: North, South and West. The 12 clinics were selected proportionally and were representative of the geographical distribution. The 12 clinics were selected according to the proportion of ARV clinics in each of the three regions. Fifty seven percent of the ARV clinics were based in the South region, therefore 57% of the 12 clinics i.e. six clinics, was randomly selected from the South region. Twenty percent of ARV clinics were based in the North region, therefore 20% of the 12 clinics i.e. three clinics, was randomly selected from the North region. Twenty three percent of the ARV clinics were based in the West region, therefore 23% of the 12 clinics i.e. three clinics, was randomly selected from the West region. (Refer to Appendix 4a for distribution of clinics per sub district) (See Figure 3.2 for a sample of case records for each sub district)

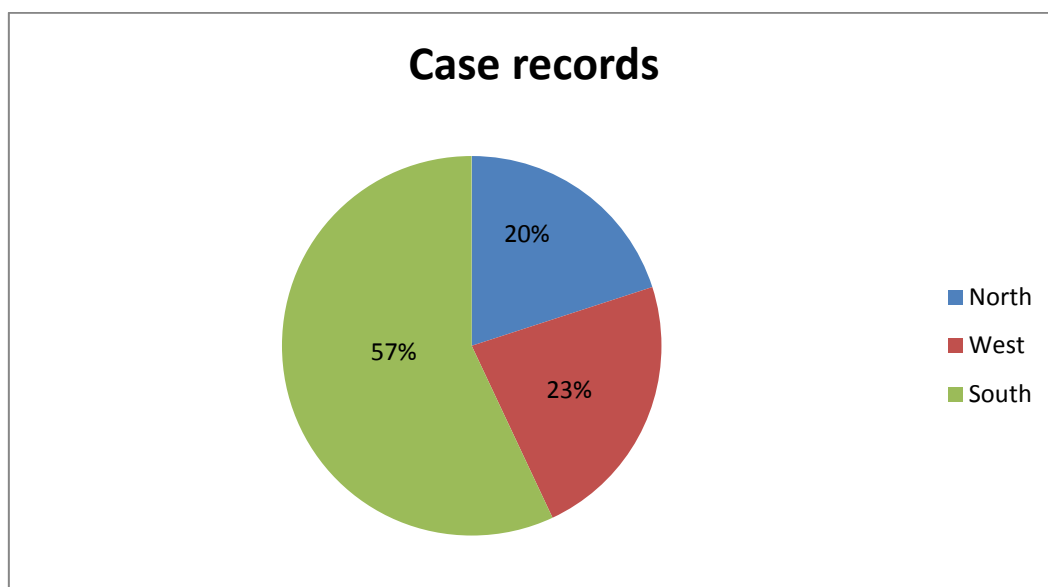


Figure 3.2: Sample of case records from each sub district

3.4.2.3 Stage Three

During the final stage, the required sample size of 400 (more than required) were proportionally selected from the 12 facilities across the three geographical areas, inclusive of a large clinic from each sub district. Fifty seven percent of the case records were reviewed from the six clinics in the South sub district, equating a total of 228 case records. Twenty percent of the case records were reviewed from the three clinics in the North sub district, numbering a total of 77 case records. Twenty three percent of the case records were reviewed from the three clinics in the West sub district, totalling 95 case records. The number of case records reviewed from each of these 12 facilities was based on the percentage of total ARV case records from each facility and this was proportionate to all the clinics selected in the sampling process for that specific sub district. (See Table 3.1 and Figure 3.3 for sampling of case records). (Refer to Appendix 4b for table on calculation on records that were sampled)

Table 3.1 Sample of case records from each clinic

| | Count | Percent |
|------------------|--------------|----------------|
| Clinic AU | 16 | 4.00 |
| Clinic CE | 30 | 7.50 |
| Clinic I | 70 | 17.50 |
| Clinic A | 40 | 10.00 |
| Clinic C | 50 | 12.50 |
| Clinic WH | 22 | 5.50 |
| Clinic R | 34 | 8.50 |
| Clinic N | 34 | 8.50 |
| Clinic CS | 9 | 2.25 |
| Clinic M | 37 | 9.25 |
| Clinic W | 43 | 10.75 |
| Clinic MR | 15 | 3.75 |

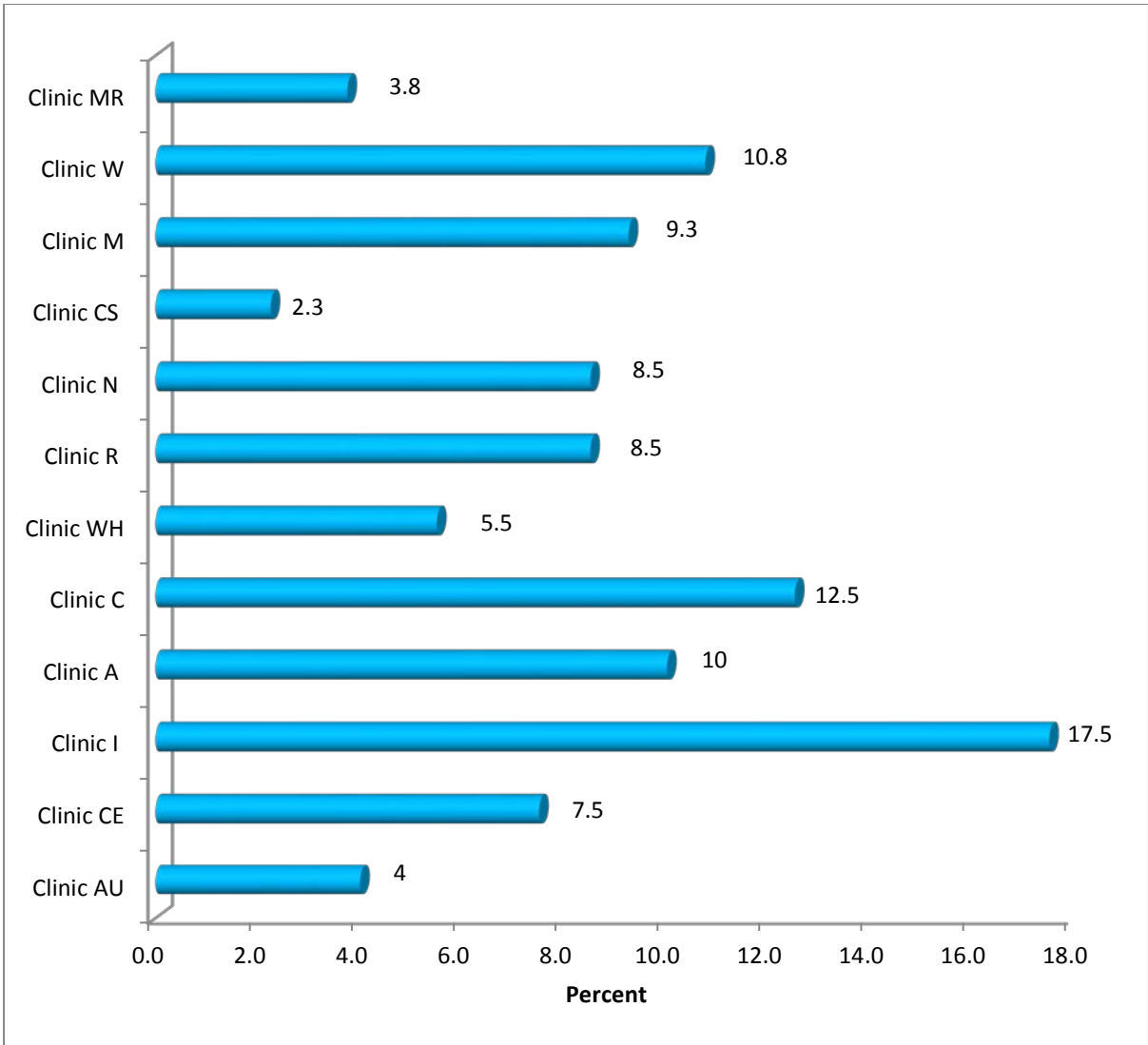


Figure 3.3 Percentage of case records sampled per clinic

3.4.3 Inclusion Criteria for Records

Clients were not recruited; data was gathered from case records available in the clinics.

1. Case records of adult clients older than 18 years of age.
2. Case records of HIV positive clients who were on ARV treatment at the time of the study.
3. Case records of HIV positive clients who were on ARV treatment prior to the study. (Namely clients who were no longer on treatment due to non-compliance, death or treatment complications).

3.4.4 Exclusion Criteria of Records

1. Case records of clients less than 18 years of age.
2. Case records of HIV positive clients not receiving ARV treatment.
3. Case records of HIV negative clients.

3.5. DATA COLLECTION

3.5.1 Procedure

A retrospective review of client case records was conducted and continued until the full sample was acquired. Blanket consent was obtained from the eThekweni Health Department (See Appendix 3) for access to the client records. Anonymity and confidentiality was in place as no client names were recorded.

3.5.2 Delimitation

This study did not seek to explain reasons for implementation or non-implementation, but to audit the utilisation of the TB screening tool. Since the focus of the study is on utilisation of the tool, the findings will guide recommendations. The findings can indicate one of the following: complete and or consistent implementation, partial implementation or non-implementation of TB screening. Recommendations will therefore be based on the research results.

3.5.3 Data Collection Tools

Data was collected using a data collection tool (See Appendix 6). The data collection tool is a checklist based on the TB symptom screening tool (See Appendix 5) and was developed in consultation with the statistician who deemed it adequate and negated the need for a pilot study. The TB screening questionnaire and the case record document were used and correlated with the WHO requirements to generate the checklist. It is closely linked to the research objectives as it provided the means to check the implementation of TB screening at the onset of ARV initiation at

eThekwini municipality clinics and at each follow up visit, in addition to capturing whether or not TB treatment or IPT medication was initiated.

The case records were reviewed by the researcher and the relevant observations or information was electronically entered into the data collection tool. Missing data or information from the case records was interpreted as non-implementation or not performed by the health care provider. The scope of the nursing profession and practice in South Africa is governed and regulated by the South African Nursing Council (SANC). According to SANC, section 35 of the Nursing Act, 1978, the SANC can take disciplinary steps against a nurse who has "...wilful or negligent omission to keep clear and accurate records of all actions which he performs in connection with a patient" (SANC, 1990: 2). In nursing, if an action or procedure is undertaken and is not recorded or documented then it is regarded as not having been done.

Four hundred client case records were reviewed utilising this collection tool. The records were drawn by the registered nurse in each health facility where the study was conducted. Convenience sampling was used until the desired number of samples (case records) had been obtained. The data that was examined and collected ranged from the period of time the client had received ARV treatment in the Municipal health clinics until the date of data collection.

3.6 DATA ANALYSIS

The data was reduced and analysed with the assistance of a statistician, using the statistical software SPSS version 21.0. The statistical aspect of the research encompassed descriptive statistics and inferential techniques.

Chi square tests were used to determine significance of relationships between variables. In instances where chi square was violated due to expected frequency counts, the more robust Fisher's test was used. Non-parametric tests were used as

the data was not nominally distributed. As all of the data was not interval, Spearman correlation was used to rank Yes, No, Not done etc.

The results are presented using descriptive statistics in the form of graphs, cross tabulations and other figures for the quantitative data that was collected. Inferential techniques include the use of correlations and chi square test values which are interpreted using p-values.

3.7 RELIABILITY AND VALIDITY

There was no observer bias as the data collected from the case records was either absent or present. The data collection tool assisted in eliminating any form of bias as the researcher merely recorded the information that was observed in the case records. The researcher collected and recorded all the required information from the case records onto the data collection tool. The tool ensures that the observations are objective and leave no room for subjective inference.

3.8 ETHICAL CONSIDERATION

This research proposal was reviewed by the Faculty of Health Sciences Research and Higher Degrees Committee and received ethical clearance from the Durban Institutional Research Ethics Committee (Ethical Clearance number – IREC 008/13), DUT (See Appendix 1). Consent was obtained from the eThekweni Municipality Department of Health prior to the study being conducted (See Appendix 3). The research proposal and a letter requesting permission was forwarded to the eThekweni Municipality Health Research Ethics Committee (See Appendix 2). Access to the records was requested in terms of the National Health Act (Department of Health: South Africa, 2004: 24):

“Access to health records by health care provider

- 16.** (1) A health care provider may examine a user’s health records for the purposes of-
- (b) study, teaching or research with the authorisation of the user, head of the health establishment concerned and the relevant health research ethics committee.
- (2) If the study, teaching or research contemplated in subsection (1)(b) reflects or obtains no information as to the identity of the user concerned, it is not necessary to obtain the authorisations contemplated in that subsection”

Accordingly, health records were examined but no identifiers were captured in the data collection tool. All data collected was retained under protected safekeeping and managed with confidentiality. This information was only accessible to the research team.

3.9 CONCEPTUAL FRAMEWORK

The theoretical framework within which the study was undertaken is that of a clinical audit. According to Travaglia and Debono (2009), a clinical audit is seen as a quality improvement process that aims to enhance patient care and improve patient outcomes through structured review and where indicated, necessary changes are initiated to improve healthcare. This definition is sanctioned by Cooper and Benjamin (2004) and the National Institute for Clinical Excellence (NICE) (2002), who in addition state the components of care are assessed against clear measures or standards. Clinical governance is defined as a framework through which health system authorities develop an atmosphere for quality clinical care by continually enhancing performance and sustaining elevated standards of care.

Flottorp, Jamtvedt, Gibis and McKee (2010) and Travaglia and Debono (2009) explain there is often a disparity between the actual care that is obtained by patients compared to the recommended norms or policies. There are dissimilarities in patient care and the consequent outcomes in both primary and secondary health management practices. The occurrence of avoidable exposure to risks in addition to unsafe conduct or therapies for patients are numerous and frequent. For these reasons Seddon and Buchanan (2006) and Cooper and Benjamin (2004) believe the clinical audit facilitates optimal patient care by measuring current practice against established standards (local, national and international).

Since audit and research occasionally utilise shared methods and analysis, they are at times confused. However, the difference is in their purpose (NICE, 2002). Cooper and Benjamin (2004) explain that an audit is usually undertaken routinely, devoid of informed consent and not submitting to ethical approval. Research, on the other hand, is regarded as a systematic scientific enquiry commenced with an unambiguous hypothesis or objectives requiring a substantial number of cases and

utilises careful sampling approaches. Comprehensive new data is produced to offer a reliable foundation for clinical practice. Research aims to broaden scientific knowledge by employing complex statistical analysis, with quantitative data being analysed to demonstrate statistical significance.

The theoretical framework of the clinical audit process for this study is adapted from the NICE (2002) clinical audit cycle process. Brink (2008) and Burns and Grove (2011) describe the theoretical framework as the foundation of a study which permits the researcher to coordinate the research by facilitating the circumstances or environment in which a problem or question is explored. The framework further directs the data collection and analysis, allowing the researcher to finally relate the outcomes to the scientific body of knowledge.

The clinical audit is usually described as a spiral or a cyclical process (Flottorp *et al.*, 2010 and Travaglia and Debono, 2009). According to NICE (2002) there are five stages within the cycle that pursue a methodical progression through each phase (Refer to Figure 3.4). These stages are:

3.9.1 Identify the Topic or Problem

The first stage entails selecting the topic or issue that requires auditing. This phase focuses on problem areas or areas in clinical practice that necessitate change for an improvement to service delivery.

3.9.2 Set Criteria and Standards

The second stage is criteria and standards. The audit criteria comprise the general purpose or objectives of the study. These criteria describe clearly what are being assessed and correspond to health interventions that can be impartially evaluated. The standards usually identify adherence to healthcare guidelines or policies that have demonstrated optimum results for patients and are derived from the best obtainable data.

3.9.3 Select Sample and Collect Data

The third stage involves selection of the sample that is representative of the entire group under investigation and maintains statistical validity. Data may be gathered from a computerised information system or manually and can be captured electronically. Only necessary information is to be collected; associated with the objectives of the study. Ethical issues must be taken into account with the focus on patient anonymity and confidentiality.

3.9.4 Analyse Data and Compare Performance with Standards

In the fourth stage, the data is summarised and analysed using statistical data analysis methodology. The information is then compared with the existing standards and policies. Situations or occurrences that reveal non-compliance create opportunities for improving health care.

3.9.5 Discuss Results and Formulate Recommendations

The fifth stage is where the findings are discussed and presented. Reasonable and achievable recommendations are formed. Results from the audit should be circulated both locally and nationally. Professional journals tend to publish the results of valuable audits that feature generalisable methodology.

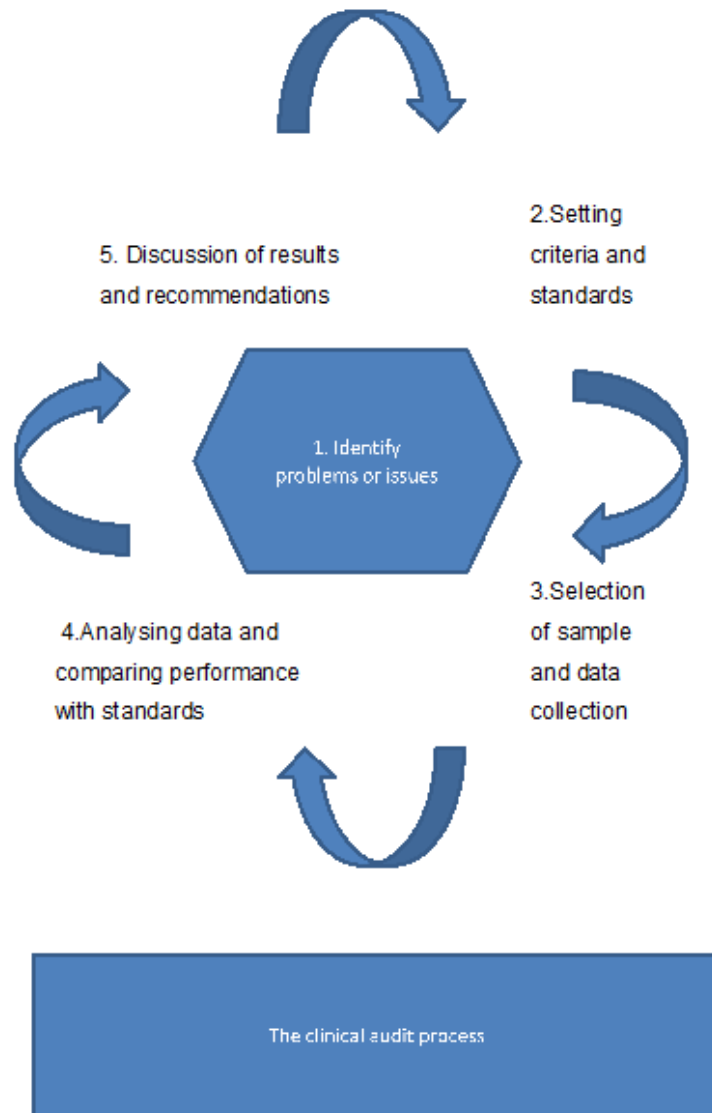


Figure 3.4 The five stages of the clinical audit process
 (Adapted from NICE, 2002)

3.10 CONCLUSION

This chapter detailed the methodology utilised in the study. The study design, study setting, stages of sampling, data collection and data analysis was described. Chapter Four presents the results of the study.

CHAPTER FOUR – PRESENTATION OF RESULTS

4.1 INTRODUCTION

Chapter Three reviewed the research methodology utilised in the study. A record review of 400 case records was conducted in 12 health care facilities across three sub districts of the eThekweni Municipality. The data collection instrument (See Appendix 6) was based on the KZN DOH TB symptom screening tool (See Appendix 5) and was designed to address the objectives of the research. This chapter will present the findings that were gathered from the data analysis. The data was analysed and organised in alignment with the research objectives.

4.2 THE RESEARCH INSTRUMENT

The research instrument consisted of 343 items, with a level of measurement at a nominal level. The data was divided into 18 sections which measured various themes as illustrated below:

Section 1 – Biographical data in terms of Gender

Section 2 – Initial screens

Section 3 – Follow up screens

4.3 BIOGRAPHICAL DATA

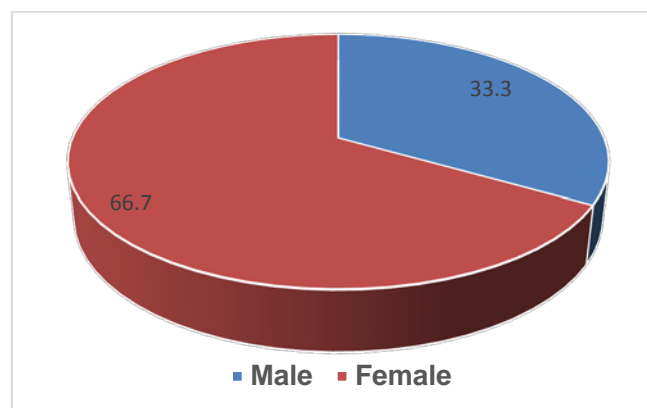


Figure 4.1: Gender composition of the sample

Figure 4.1 indicates the gender composition of the sample. The ratio of females to males is approximately 2:1 (66.7%:33.3%). The reasons for the observed ratio are as follows:

- The case records were selected as a result of convenience sampling
- Gender was not a factor in the selection process

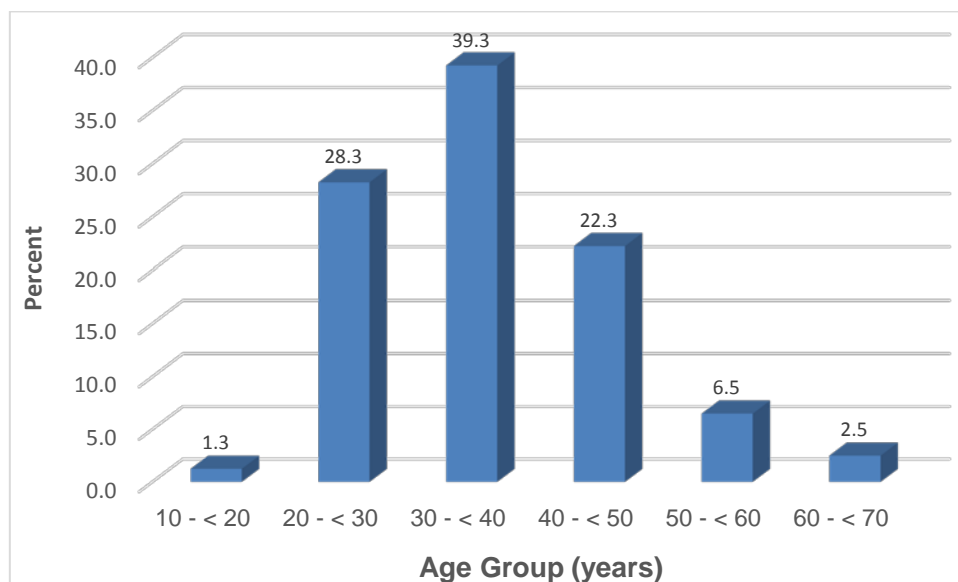


Figure 4.2: The ages of the patients.

Figure 4.2 specifies the age bands of the patients. The majority of the patients were between the ages of 20 to 50 years (90%) with the age group 30 to 40 years displaying the highest percentage of 39.3%.

The chi-square hypothesis test was used to determine whether the frequencies for each variable were significantly different in terms of the options. For example, the null hypothesis claims that the patient distribution for gender is similar.

Table 4.1: Chi-square test for gender

Test Statistics

| | Gender | Age |
|-------------|--------|---------|
| Chi-Square | 44.890 | 293.450 |
| df | 1 | 5 |
| Asymp. Sig. | 0.000 | 0.000 |

Since the chi-square value is less than the level of significance of 0.05 ($p = 0.000$), it implies that the distribution of the number of males and females is significantly different.

This is also true for the age variable.

Table 4.2: The gender of the patients by age
Age * Gender Cross tabulation

| | | Gender | | Total | |
|--------------|-----------------|-----------------|--------|--------|--------|
| | | Male | Female | | |
| Age | Count | 0 | 5 | 5 | |
| | 10 - < 20 | % within Age | 0.0% | 100.0% | 100.0% |
| | | % within Gender | 0.0% | 1.9% | 1.3% |
| | | % of Total | 0.0% | 1.3% | 1.3% |
| | Count | 34 | 78 | 112 | |
| | 20 - < 30 | % within Age | 30.4% | 69.6% | 100.0% |
| | | % within Gender | 25.6% | 29.3% | 28.1% |
| | | % of Total | 8.5% | 19.5% | 28.1% |
| | Count | 50 | 107 | 157 | |
| | 30 - < 40 | % within Age | 31.8% | 68.2% | 100.0% |
| | | % within Gender | 37.6% | 40.2% | 39.3% |
| | | % of Total | 12.5% | 26.8% | 39.3% |
| | Count | 37 | 52 | 89 | |
| | 40 - < 50 | % within Age | 41.6% | 58.4% | 100.0% |
| | | % within Gender | 27.8% | 19.5% | 22.3% |
| | | % of Total | 9.3% | 13.0% | 22.3% |
| | Count | 8 | 18 | 26 | |
| | 50 - < 60 | % within Age | 30.8% | 69.2% | 100.0% |
| | % within Gender | 6.0% | 6.8% | 6.5% | |
| | % of Total | 2.0% | 4.5% | 6.5% | |
| Count | 4 | 6 | 10 | | |
| 60 - < 70 | % within Age | 40.0% | 60.0% | 100.0% | |
| | % within Gender | 3.0% | 2.3% | 2.5% | |
| | % of Total | 1.0% | 1.5% | 2.5% | |
| Total | Count | 133 | 266 | 399 | |
| | | % within Age | 33.3% | 66.7% | 100.0% |
| | | % within Gender | 100.0% | 100.0% | 100.0% |
| | | % of Total | 33.3% | 66.7% | 100.0% |

Table 4.2 illustrates the gender of the case files viewed by age. A little more than 68% of the patients were female between the ages of 30 to 40 years, while almost 32% of the patients were male. This grouping of patients formed 40.2% of all the female and 37.6% of all the male patients (only). Of the total sample, this grouping of patients formed 12.5% of the total male patients and 26.8% of the total female patients, comprising the highest number of patients in the study emerging from this age group (39.3%). The next age group demonstrating the second most elevated percentage of patients is from the 20 to 30 years age band with 28.1%. The results for the age group 10 to 20 years were appropriate as it was aligned to the inclusion criteria of the study; only the case records of adult clients older than 18 years of age were reviewed.

The chi square test investigated whether there was a significant relationship between gender and age (Table 4.3).

Table 4.3: Chi-square test for gender and age
Chi-Square Tests

| | Value | df | Asymp. Sig. (2-sided) | Exact Sig. (2-sided) | Exact Sig. (1-sided) | Point Probability |
|------------------------------|-------|----|-----------------------|----------------------|----------------------|-------------------|
| Pearson Chi-Square | 6.151 | 5 | 0.292 | 0.294 | | |
| Likelihood Ratio | 7.609 | 5 | 0.179 | 0.211 | | |
| Fisher's Exact Test | 5.810 | | | 0.317 | | |
| Linear-by-Linear Association | 2.377 | 1 | 0.123 | 0.129 | 0.069 | 0.013 |
| N of Valid Cases | 400 | | | | | |

The Fisher's exact test p-value (0.317) is greater than the level of significance implying that the relationship between gender and age was not significant.

4.4 ANALYSIS OF THE OBJECTIVES

The sections that follow report the results as per the objectives of the study.

4.4.1 Objective 1: Implementation of TB screening

4.4.1.1 The results for the Initial TB screens

Figure 4.3 shows that, of the 400 case records reviewed, 33% of initial screens were not conducted while 66.7% of initial TB screens were conducted.

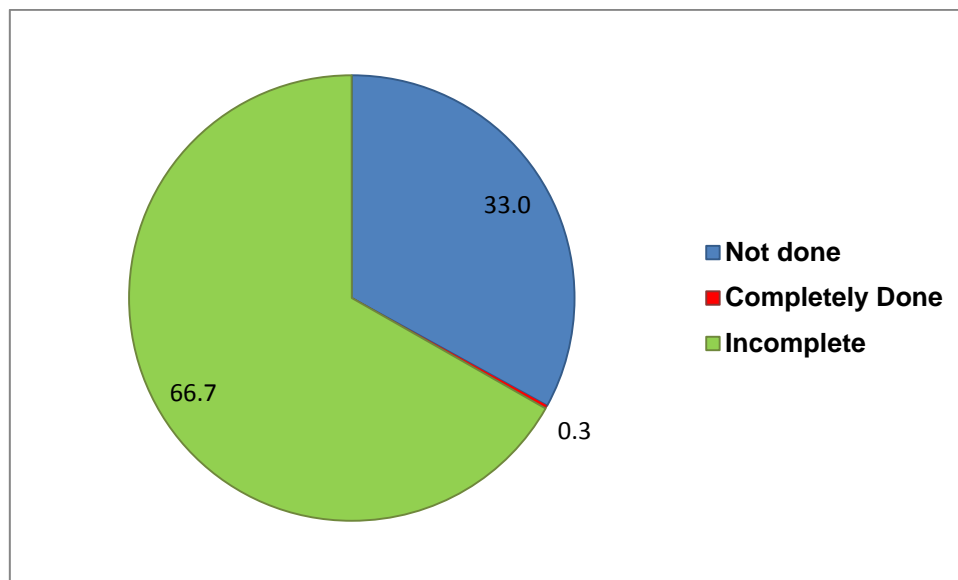


Figure 4.3: Initial TB screens conducted

Table 4.4 and Figure 4.4 describe the initial TB screens that were carried out or not carried out for males and females. Of the initial TB screens for males, 33.8% were not carried out while 32.6% of the initial TB screens for females were not carried out. Of the initial TB screens for males, 66.2% were carried out, while 67.4% of the initial TB screens for females were carried out.

There were similar numbers of Initial TB screens that were carried out and not carried out for both males and females.

Table 4.4: Initial TB screens completed according to gender

| | | Gender | | | | Total | |
|---------------------------|------------------------|--------|---------|--------|---------|-------|---------|
| | | Male | | Female | | | |
| | | Count | Percent | Count | Percent | Count | Percent |
| Initial TB Screens | Not carried out | 45 | 33.8 | 87 | 32.6 | 132 | 33 |
| | Carried out | 88 | 66.2 | 180 | 67.4 | 268 | 67.1 |
| | Total | 133 | 100 | 267 | 100 | 400 | 100 |

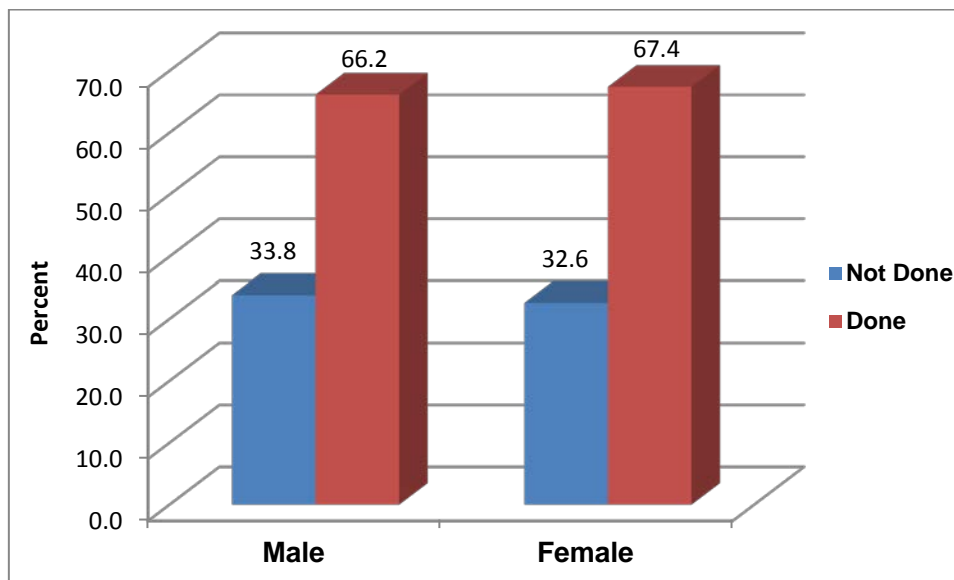


Figure 4.4: Initial TB screens completed according to gender

The chi square test investigated whether there was a significant relationship between gender and Initial TB screens (Table 4.5).

Table 4.5: Chi-square test between gender and Initial TB screens

Chi-Square Tests

| | Value | df | Asymp. Sig. (2-sided) | Exact Sig. (2-sided) | Exact Sig. (1-sided) | Point Probability |
|------------------------------|-------|----|-----------------------|----------------------|----------------------|-------------------|
| Pearson Chi-Square | 2.103 | 2 | 0.349 | 0.416 | | |
| Likelihood Ratio | 2.298 | 2 | 0.317 | 0.416 | | |
| Fisher's Exact Test | 1.972 | | | 0.416 | | |
| Linear-by-Linear Association | 0.106 | 1 | 0.745 | 0.764 | 0.385 | 0.028 |
| N of Valid Cases | 400 | | | | | |

The Fisher's exact test value of 0.416 implies that there was no relationship between gender and initial TB screens.

4.4.1.2 The results for Follow-up TB screens

Table 4.6 and Figure 4.5 indicate the status of the follow-up TB screens. Nearly 86% of the follow-up screens were not carried out, whilst only 8.9% were carried out. The remaining 5.6% of patients did not attend (DNA).

Table 4.6: Follow-up TB screens conducted

| | | Total | |
|-----------------------------|------------------------|--------------|-------|
| | | Count | Total |
| Follow-up TB screens | Not carried out | 3027 | 85.5 |
| | Carried out | 314 | 8.9 |
| | DNA | 200 | 5.6 |
| | TOTAL | 3541 | 100 |

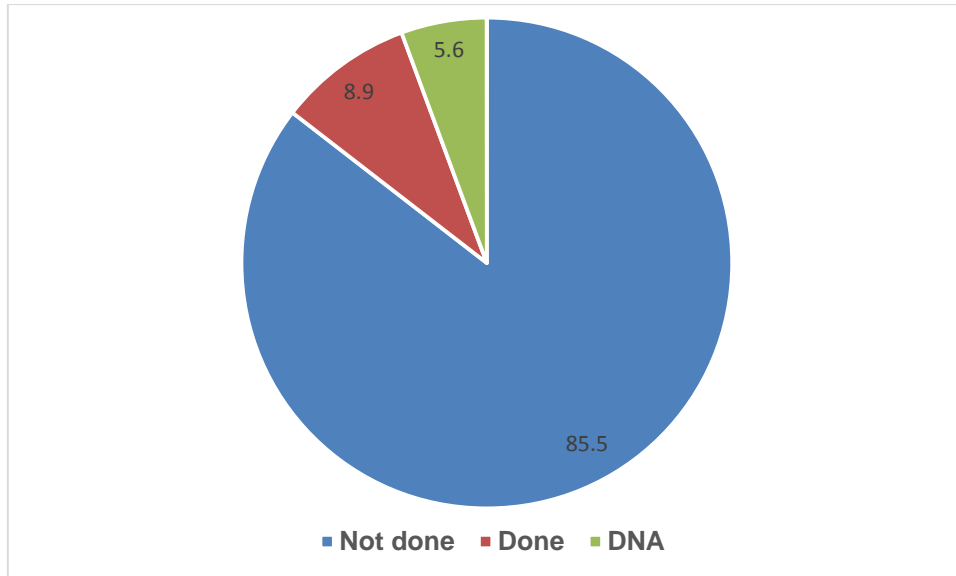


Figure 4.5: Status of the follow-up TB screens

Table 4.7 describes the follow-up TB screens carried out and not carried out according to gender. There were similar percentages of follow-up screenings carried out for males (8.3%) and females (9.1%), as well as follow-up screenings not carried out for males (83.8%) and females (86.3%).

All of the p-values for the follow-up TB screens were greater than 0.05, except for follow up 11.

Table 4.7: Follow-up TB screens carried out according to gender

| | | Male | | Female | | Total | |
|-----------------------------|------------------------|-------|---------|--------|---------|-------|-------|
| | | Count | Percent | Count | Percent | Count | Total |
| Follow-up TB screens | Not carried out | 928 | 83.8 | 2099 | 86.3 | 3027 | 85.5 |
| | Carried out | 92 | 8.3 | 222 | 9.1 | 314 | 8.9 |
| | Did Not Arrive | 88 | 7.9 | 112 | 4.6 | 200 | 5.6 |
| | TOTAL | 1108 | 100.0 | 2433 | 100.0 | 3541 | 100.0 |

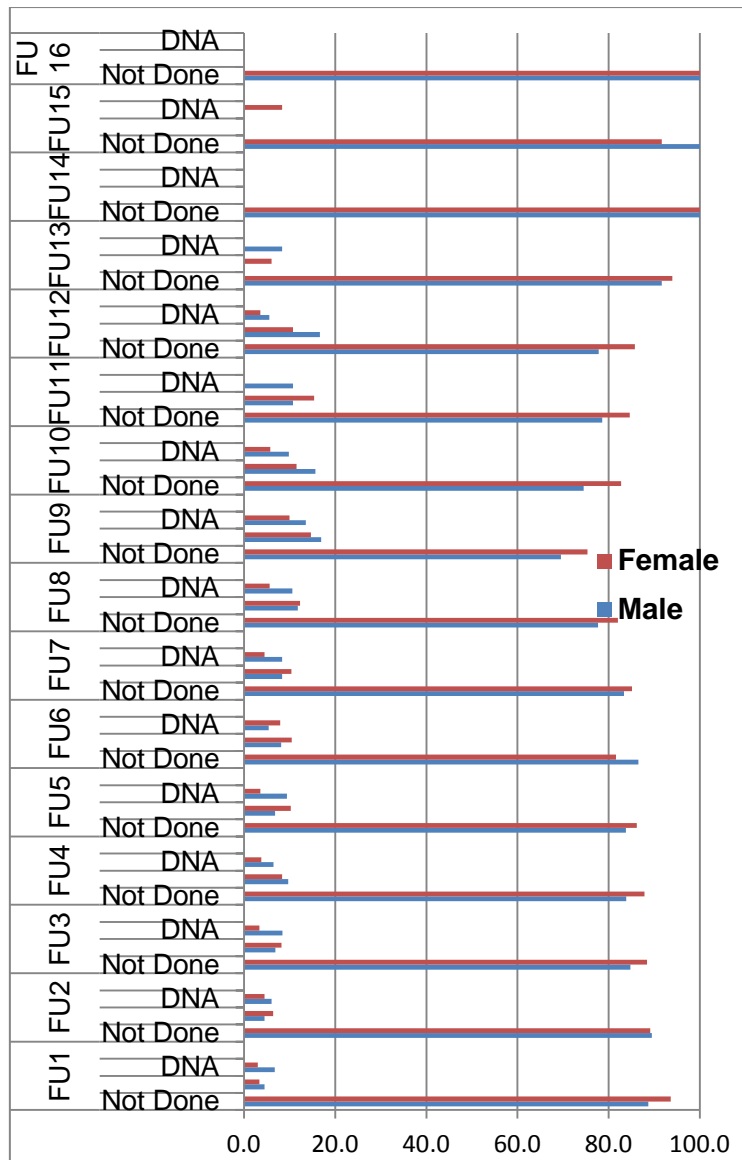


Figure 4.6: Follow-up TB screens performed over the range of follow-up visits

Figure 4.6 illustrates the decline in the follow-up TB screens performed as the patients attended the clinic for successive visits. It is evident that eventually no TB screens were performed.

4.4.2 Objective 2: Extent of implementation of TB screening

4.4.2.1 Initial TB screens

Table 4.8 and Figure 4.7 illustrate the extent of the implementation of the initial TB screens. The extent of the implementation of the TB screening tool indicates whether symptoms on the data collection tool were enquired (cough, haemoptysis, loss of weight, night sweats, fever, lymphadenopathy, and dyspnoea or chest pain). Of the initial TB screens 33% were not carried out whilst almost 70% of the initial TB screens were performed. They were, however, carried out incompletely.

Table 4.8: The extent of implementation of the initial TB screens

| | | Not carried out | Completely Carried out | Carried out Incompletely | DNA | Total |
|--------------------|---------|-----------------|------------------------|--------------------------|-----|-------|
| Initial TB Screens | Count | 132 | 1 | 267 | 0 | 400 |
| | Percent | 33.0 | 0.3 | 66.8 | 0.0 | 100.0 |

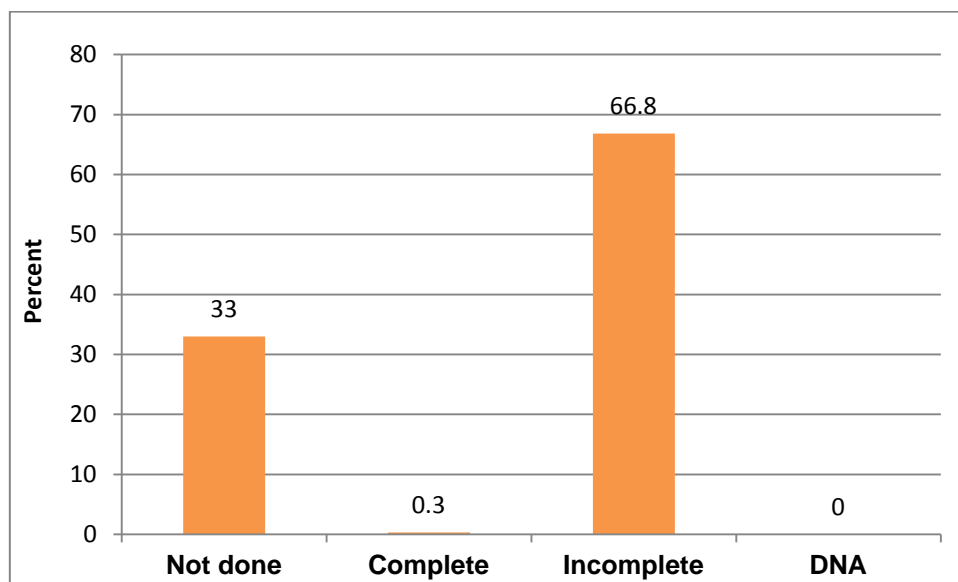


Figure 4.7: The extent of implementation of the initial TB screens

Completely performed and incompletely performed initial TB screens are displayed in Table 4.9 and Figure 4.8. Only one complete initial screen was carried out from the total of 268 initial TB screens carried out.

Table 4.9: The extent of the total initial TB screens carried out

| | | Complete | Incomplete | Total |
|---------------------------|---------|----------|------------|-------|
| Initial TB Screens | Count | 1 | 267 | 268 |
| | Percent | 0.4 | 99.6 | 100.0 |

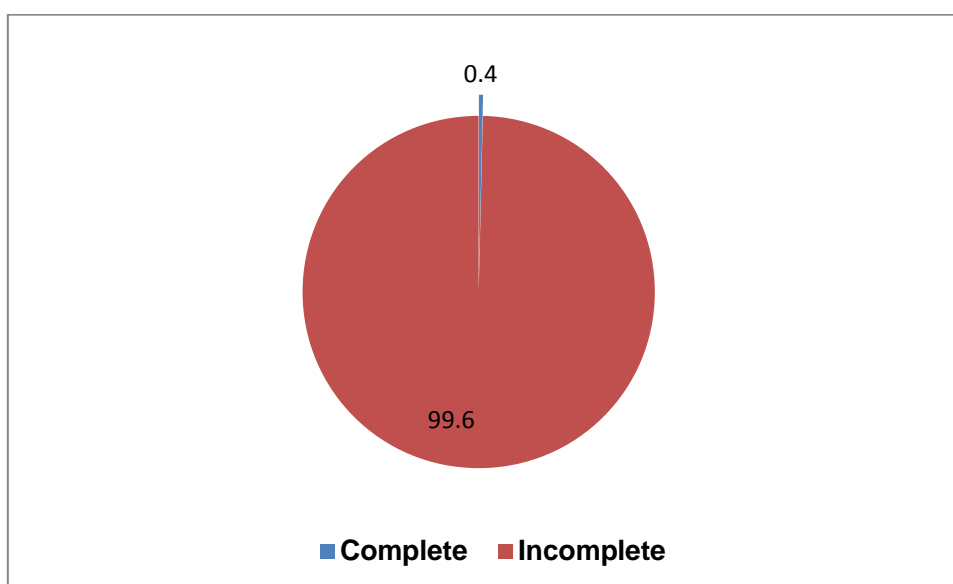


Figure 4.8: The extent of the total initial TB screens carried out

Table 4.10 summarises the extent of the implementation of initial TB screens that were undertaken according to gender. There were similar percentages of completely carried out initial screens for males (0.8%) and females (0%), as well as initial screens carried out incompletely for males (65.4%) and females (67.4%).

Table 4.10: Extent of implementation of initial TB screens according to gender

| | | Gender | | | | Total | |
|---------------------------|-------------------------------|--------|---------|--------|---------|-------|---------|
| | | Male | | Female | | | |
| | | Count | Percent | Count | Percent | Count | Percent |
| Initial TB Screens | Not carried out | 45 | 33.8 | 87 | 32.6 | 132 | 33.0 |
| | Completely Carried out | 1 | 0.8 | 0 | 0.0 | 1 | 0.3 |
| | Incomplete | 87 | 65.4 | 180 | 67.4 | 267 | 66.8 |
| | Total | 133 | 100.0 | 267 | 100.0 | 400 | 100.0 |

4.4.2.2 Follow-up TB screens

Table 4.11 and Figure 4.9 reveal approximately 86% of the follow-up TB screens were not carried out. This is a significant proportion and is highlighted by a chi square test p-value of 0.000, which indicates that the differences in the observed frequencies were highly significant.

Table 4.11: The extent of implementation of Follow-up TB screens

| | Not carried out | Completely Carried out | Carried out Incompletely | DNA | Total |
|---------|------------------------|-------------------------------|---------------------------------|------------|--------------|
| Count | 3027 | 299 | 15 | 200 | 3541 |
| Percent | 85.5 | 8.4 | 0.4 | 5.6 | 100.0 |

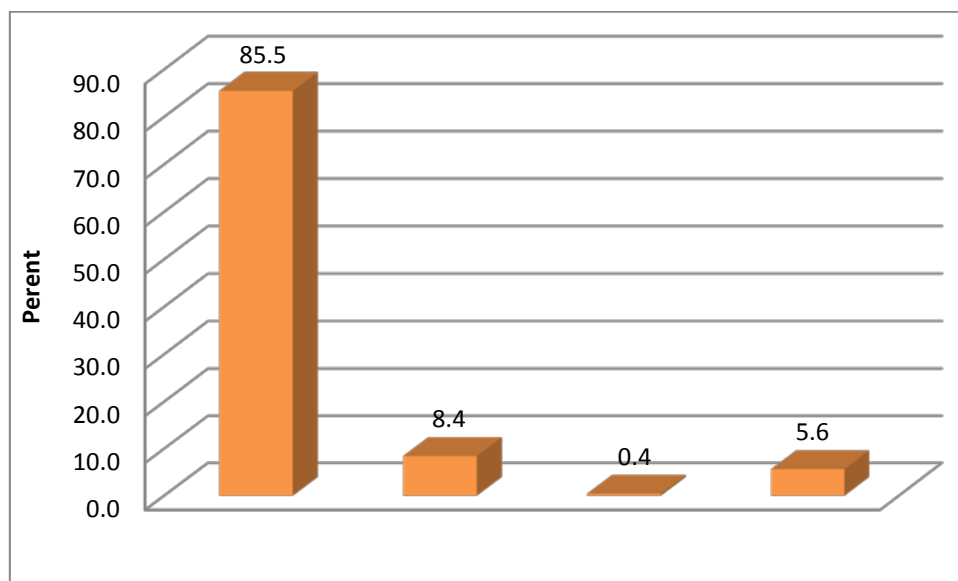


Figure 4.9: The extent of implementation of Follow-up TB screens

Completely performed and incompletely performed follow-up TB screens are displayed in Table 4.12 and Figure 4.10. An analysis of the complete and incomplete follow-up TB screens revealed the following: only 15 (4.8%) completed follow-up TB screens were carried out from the total of 314 follow-up TB screens carried out. Follow-up TB screens that were completely carried out added up to 299 (95.2%).

Table 4.12: The extent of the total follow-up TB screens carried out

| | Complete | Incomplete | Total |
|---------|-----------------|-------------------|--------------|
| Count | 299 | 15 | 314 |
| Percent | 95.2 | 4.8 | 100.0 |

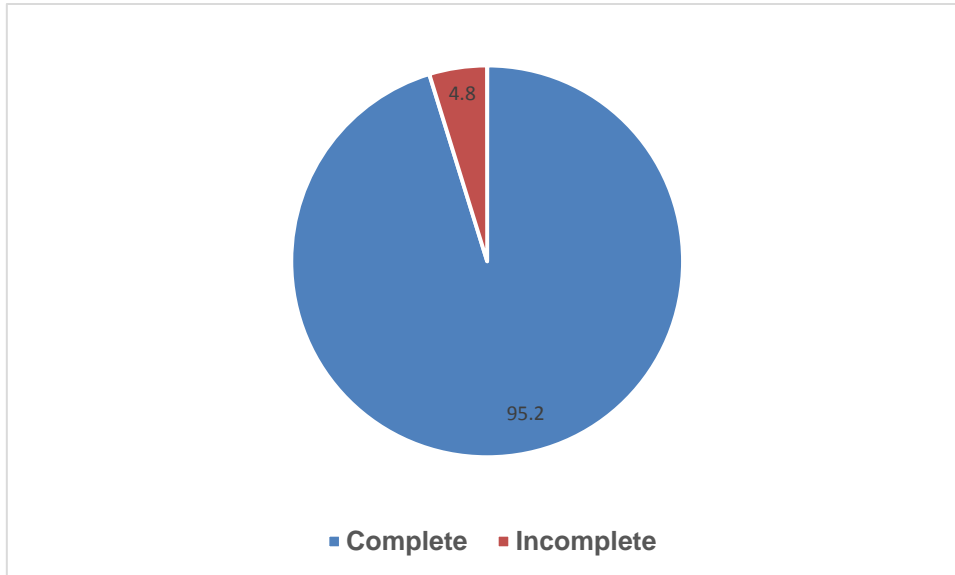


Figure 4.10: The extent of the total Follow-up TB screens carried out

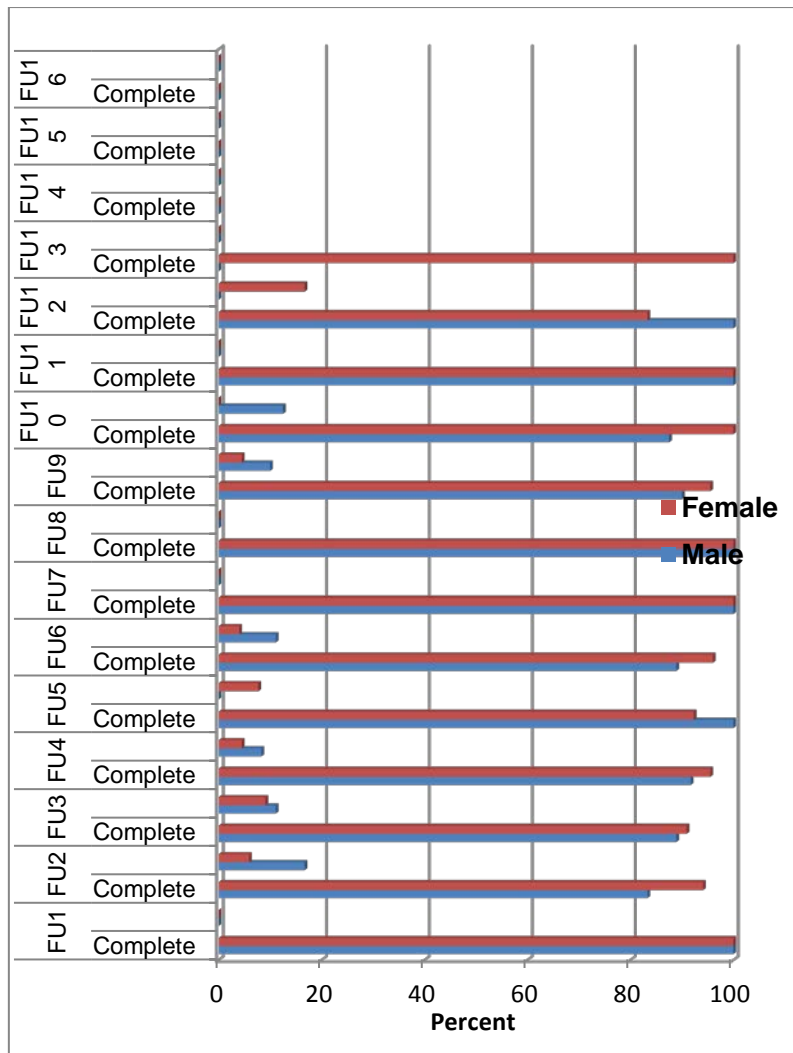


Figure 4.11: Complete and incomplete follow-up TB screens performed over the range of follow-up visits

Figure 4.11 illustrates the decline in the follow-up TB screens performed as the patients attended the clinic for successive visits, as evident in Figure 4.6 as well. However, when the follow-up TB screens were performed, they were thoroughly completed.

4.4.2.3 WHO four-part TB symptom screens

The data presented in Table 4.13 and Figure 4.12 reveal that of the 400 case records reviewed; 33% of initial screens were not conducted while 67% of initial TB screens were conducted by applying the WHO four-part TB symptom criteria.

Table 4.13: Initial TB screens completed according to WHO four-part TB symptom screen

| Initial TB Screens | Not Carried out | Carried out | DNA | Total |
|--------------------|-----------------|-------------|-----|-------|
| Count | 132 | 268 | 0 | 400 |
| Percent | 33.0 | 67.0 | 0.0 | 100.0 |

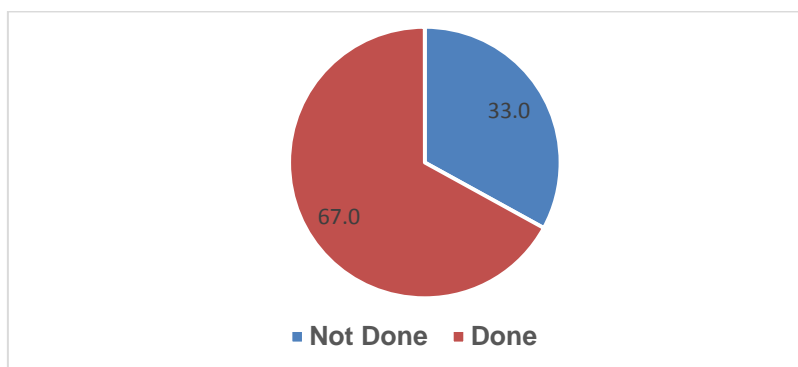


Figure 4.12: Initial TB screens completed according to WHO four-part TB symptom screen

Table 4.14 and Figure 4.13 indicate the status of the follow-up TB screens by utilising the WHO four-part TB symptom screen. Nearly 90% of the follow-up screens were carried out, whilst only 4.4% were not carried out using these criteria. The remaining 5.6% of patients did not attend (DNA).

Table 4.14: Follow-up TB screens completed according to WHO four-part TB symptom screen

| Follow-up TB Screens | Not Carried out | Carried out | DNA | Total |
|----------------------|-----------------|-------------|-----|-------|
| Count | 156 | 3185 | 200 | 3541 |
| Percent | 4.4 | 89.9 | 5.6 | 100.0 |

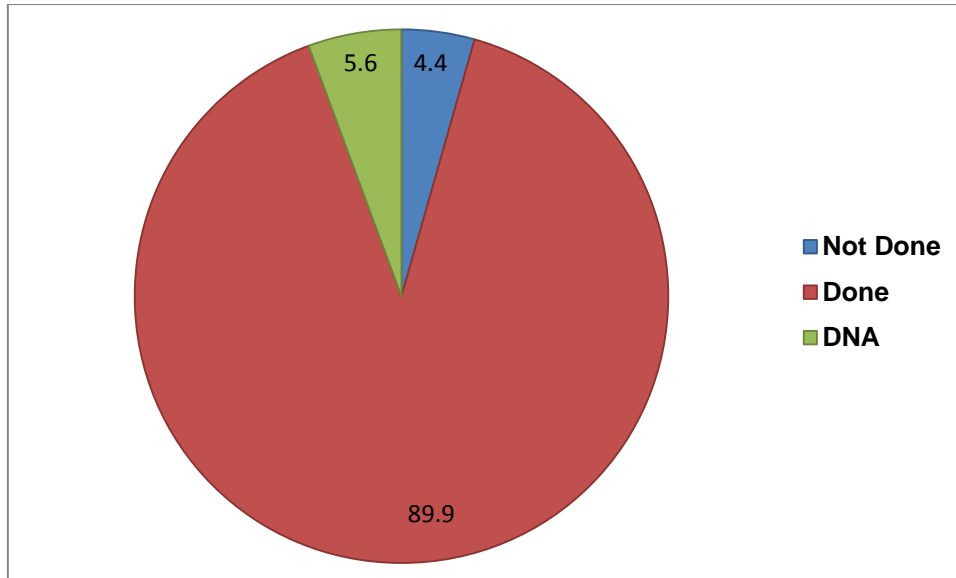


Figure 4.13: Follow-up TB screens completed according to WHO four-part TB symptom screen

The data presented in Table 4.15 and Figure 4.14 demonstrates the extent of the implementation of initial TB screens according to the WHO four-part symptom screen. Whilst 94.8% of the initial TB screens were completely implemented making use of these criteria, 5.2% of the initial TB screens were not performed completely.

Table 4.15: Extent of implementation of initial TB screens according to WHO four-part TB symptom screen

| Initial TB Screens | Count | Percent |
|--------------------|------------|--------------|
| Complete | 254 | 94.8 |
| Incomplete | 14 | 5.2 |
| Total | 268 | 100.0 |

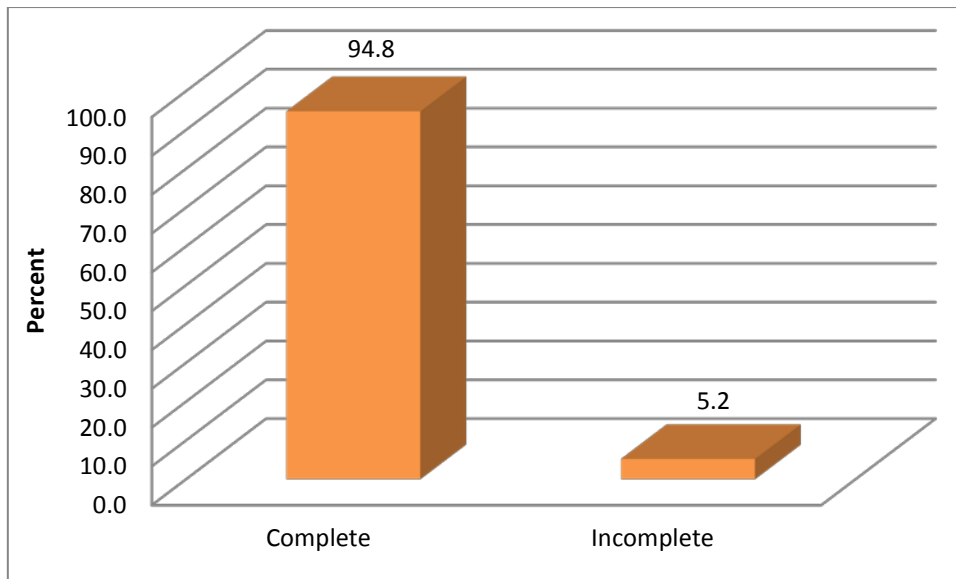


Figure 4.14: Extent of implementation of initial TB screens according to WHO four-part TB symptom screen

Completely performed and incompletely performed follow-up TB screens (according to the WHO four-part TB symptom screen) are displayed in Table 16 and Figure 4.15. Of the 3185 follow-up screens conducted, only 300 (9.4%) complete follow-up screens were carried out. Follow-up TB screens that were incompletely carried out totalled 2885 (90.6%).

Table 4.16: Extent of implementation of follow-up TB screens according to WHO four-part TB symptom screen

| Follow-up TB Screens | Count | Percent |
|----------------------|-------|---------|
| Complete | 300 | 9.4 |
| Incomplete | 2885 | 90.6 |
| Total | 3185 | 100.0 |

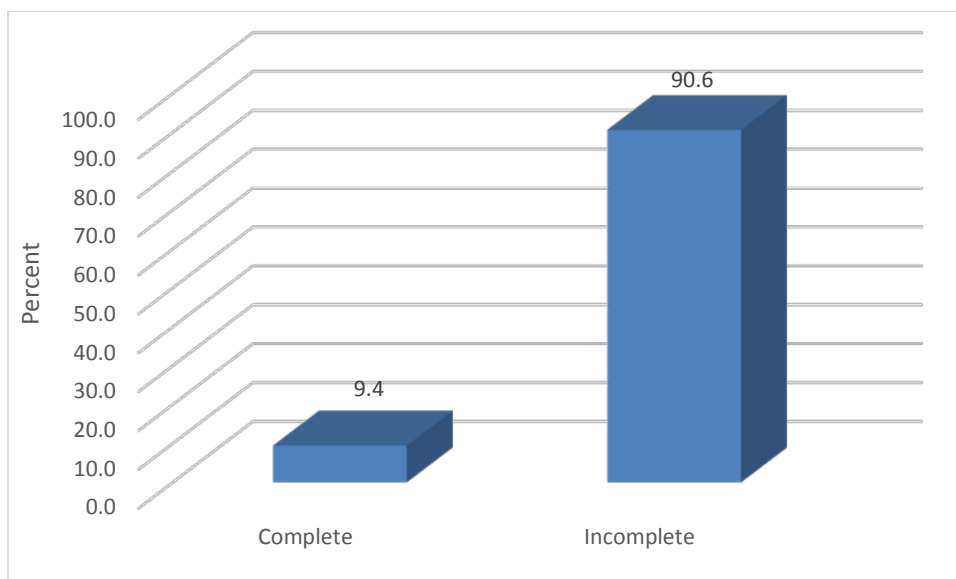


Figure 4.15: Extent of implementation of follow-up TB screens according to WHO four-part TB symptom screen

4.4.3 Objective 3: Further investigations or TB treatment initiation based on TB screening

Table 4.17 shows the total number of suspected cases of TB were 23 for the initial TB screen and the subsequent investigations carried out. Sputa testing and radiological examinations were the two types of assessments conducted. These two tests added up to 65.2%, whilst 34.8% of the TB suspected cases received no further investigations.

Table 4.17: TB suspected at initial TB screenings and investigations conducted

| | Yes | Percent |
|---------------------------------------|-----------|--------------|
| SPUTUM | 14 | 60.9 |
| RADIOLOGY | 1 | 4.3 |
| OTHER INVESTIGATIONS | 0 | 0.0 |
| INVESTIGATIONS NOT CARRIED OUT | 8 | 34.8 |
| TOTAL | 23 | 100.0 |

As illustrated in figure 4.16, the majority of the investigations were sputa tests (60.9%). Radiological tests amounted to 4.3%. The number of patients who did not have further investigations even though being identified as TB suspects added up to eight (34.8%).

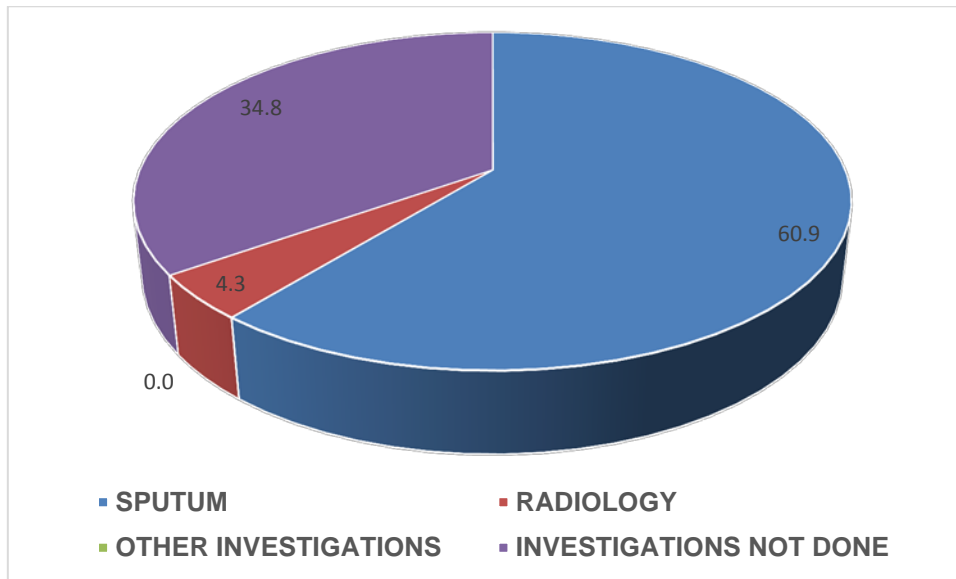


Figure 4.16: Investigations conducted

Table 4.18 indicates the number of suspected TB cases who were diagnosed with TB disease during the follow-up screens. Of the 15 patients suspected of having TB, six (40%) patients were confirmed with TB.

Table 4.18: Suspected TB cases who were diagnosed with TB during follow-up screens

| TB Suspected | | TB Diagnosed | |
|--------------|---------|--------------|---------|
| Count | Percent | Count | Percent |
| 15 | 100.0 | 6 | 40.0 |

Data from Table 4.19 reveals that of the 45 patients who had a TB diagnosis on initial TB screening, 40 (88.9%) of these patients had records showing they had received TB treatment. The other five (11.1 %) of patients with a TB diagnosis had no record of receiving TB treatment.

Table 4.19: Cross tabulation of patients with a TB diagnosis on initial TB screening who received TB treatment

TREATMENT START * TB DIAGNOSIS Y N Cross tabulation

| | | TB DIAGNOSIS Y N | | | Total | |
|---------------------------|---------------------------|---------------------------|--------|--------|--------|--------|
| | | Did not do | Yes | No | | |
| TREATMENT START | Did not do | Count | 5 | 5 | 0 | 10 |
| | | % within TREATMENT START | 50.0% | 50.0% | 0.0% | 100.0% |
| | | % within TB DIAGNOSIS Y N | 100.0% | 11.1% | 0.0% | 2.5% |
| | | % of Total | 1.3% | 1.3% | 0.0% | 2.5% |
| | Yes | Count | 0 | 40 | 0 | 40 |
| | | % within TREATMENT START | 0.0% | 100.0% | 0.0% | 100.0% |
| | | % within TB DIAGNOSIS Y N | 0.0% | 88.9% | 0.0% | 10.0% |
| | | % of Total | 0.0% | 10.0% | 0.0% | 10.0% |
| | N/A | Count | 0 | 0 | 350 | 350 |
| % within TREATMENT START | | 0.0% | 0.0% | 100.0% | 100.0% | |
| % within TB DIAGNOSIS Y N | | 0.0% | 0.0% | 100.0% | 87.5% | |
| | % of Total | 0.0% | 0.0% | 87.5% | 87.5% | |
| Total | Count | 5 | 45 | 350 | 400 | |
| | % within TREATMENT START | 1.3% | 11.3% | 87.5% | 100.0% | |
| | % within TB DIAGNOSIS Y N | 100.0% | 100.0% | 100.0% | 100.0% | |
| | % of Total | 1.3% | 11.3% | 87.5% | 100.0% | |

The chi square test investigated whether there was a significant relationship between a TB diagnosis on initial TB screening and TB treatment (Table 4.20).

Table 4.20: Chi-square test comparing patients with a TB diagnosis on initial TB screening who received TB treatment
Chi-Square Tests

| | Value | df | Asymp. Sig. (2-sided) | Exact Sig. (2-sided) | Exact Sig. (1-sided) | Point Probability |
|------------------------------|----------------------|----|-----------------------|----------------------|----------------------|-------------------|
| Pearson Chi-Square | 577.778 ^a | 4 | 0.000 | 0.000 | | |
| Likelihood Ratio | 320.061 | 4 | 0.000 | 0.000 | | |
| Fisher's Exact Test | 308.204 | | | 0.000 | | |
| Linear-by-Linear Association | 381.633 ^b | 1 | 0.000 | 0.000 | 0.000 | 0.000 |
| N of Valid Cases | 400 | | | | | |

Since the Fisher p-values presented in Table 4.20 are less than 0.05 (level of significance), it implies that there is a significant relationship between the variables. As can be seen from Table 4.21, the total number of follow up visits where the patients presented themselves for HIV care or treatment was 3341. During these follow-up visits six patients received a TB diagnosis. However only two (33.3%) of these patients are recorded as having received TB treatment. The remaining four (66.1%) patients have no information in the ARV case records on treatment received.

Table 4.21: TB treatment initiated for patients diagnosed with TB during the follow-up visits

| | Count | Percent |
|--|-------|---------|
| TB diagnosed during follow up visits | 6 | 100 |
| Treatment started during follow up visits | 2 | 33.3 |

4.4.4 Isoniazid prophylactic therapy (IPT)

Table 4.22 and Figure 4.17 indicate the percent of IPT provided at initial TB screens. Less than 10% of the patients received IPT at the initial screen. The records show the remaining 71.3% of patients who were eligible for IPT did not receive this therapy. The other patients (19.3%) who were marked not applicable (N/A) did not meet the qualifying criteria for treatment initiation.

Table 4.22: IPT at initial TB screens

| | Frequency | Percent | Valid Percent | Cumulative Percent |
|------------|-----------|---------|---------------|--------------------|
| Yes | 38 | 9.5 | 9.5 | 9.5 |
| No | 285 | 71.3 | 71.3 | 80.8 |
| N/A | 77 | 19.3 | 19.3 | 100.0 |
| Total | 400 | 100.0 | 100.0 | |

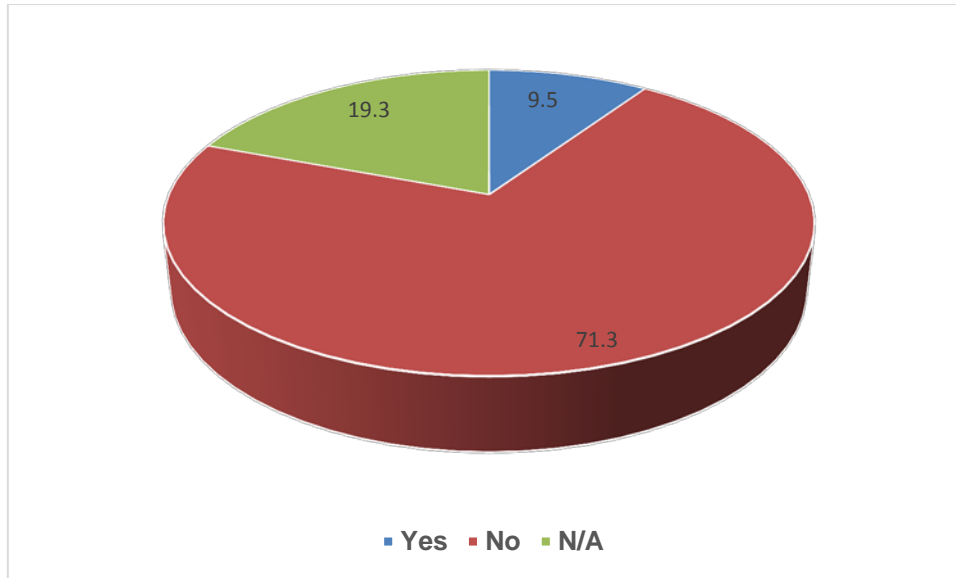


Figure 4.17: Patients receiving IPT at initial TB screens

Table 4.23 indicates that IPT was issued to 38 (9.5%) of the 400 initial screened patients, 15 (3.75%) patients were investigated for TB due to being a TB suspect and the remainder of 67.5% patients did not receive IPT. This is graphically represented in Figure 4.18.

Table 4.23: Further TB investigations and IPT at Initial TB screens

| | IPT Issued | N/A | Investigations For TB | IPT Not Issued |
|---------|-------------------|------------|----------------------------------|-----------------------|
| Count | 38 | 77 | 15 | 270 |
| Percent | 9.5 | 19.25 | 3.75 | 67.5 |

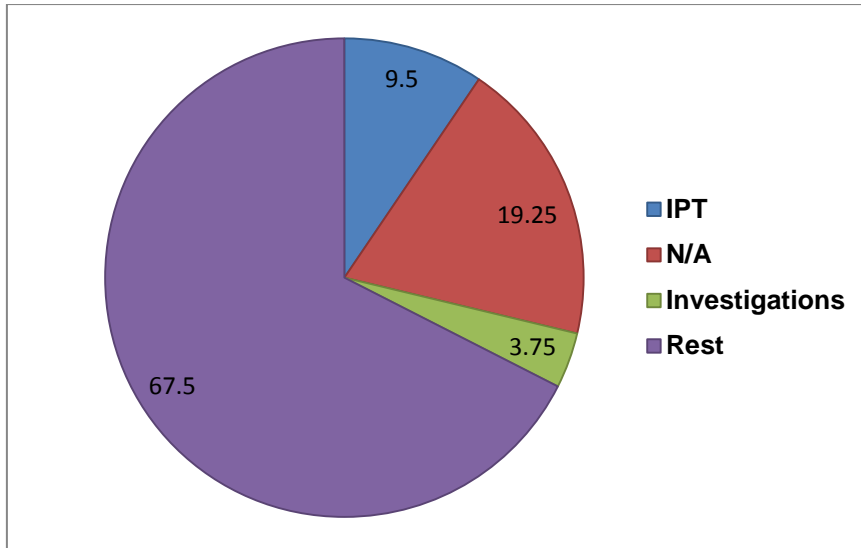


Figure 4.18: Further TB investigations and IPT at Initial TB screens

Table 4.24 and Figure 4.19 denote the quantity of IPT issued during follow-up TB screens. A significant amount of less than 4% of the patients received IPT at the initial screen. The case records reveal the outstanding 96.1% (2442) of patients who were eligible for acquiring IPT did not receive it. This number includes the N/A patients (200) who did not meet the qualifying criteria for treatment initiation.

Table 4.24: IPT issued at follow-up TB screens

| Issued | Not Issued | Total |
|--------|------------|--------|
| 100 | 2442 | 2542 |
| 3.9% | 96.1% | 100.0% |

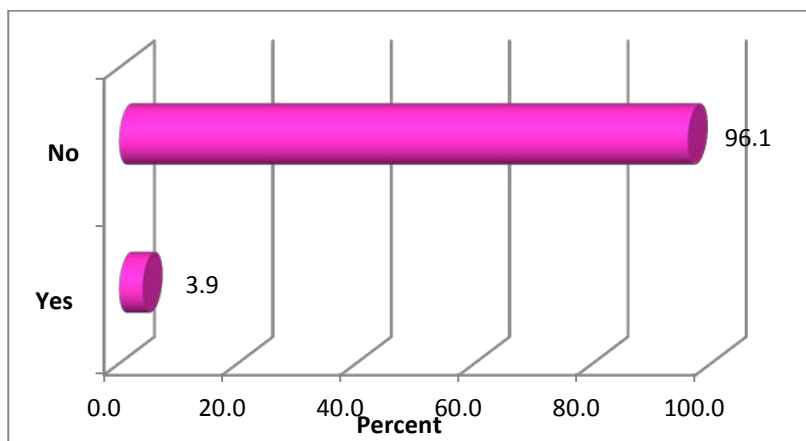


Figure 4.19: Percent of patients receiving IPT at follow-up visits

Table 4.25 indicates the number of patients identified during the initial TB screen who had been diagnosed previously with TB and who had now received IPT. Eighty six patients were recognised as having had previous TB during the initial screens. Six (7%) out of 86 patients who had previous TB were given IPT. The number of patients who were eligible for IPT but were not given this therapy totalled 47 (54.7%). Thirty three patients (38.4%) did not meet the requirements to receive IPT.

Table 4.25: Cross tabulation of previous TB cases receiving IPT
ISONIZIAD * PREVIOUS TB Cross tabulation

| | | PREVIOUS TB | | | Total | |
|----------------------|----------------------|----------------------|--------|--------|--------|--------|
| | | Did not do | Yes | No | | |
| ISONIZIAD | Yes | Count | 1 | 6 | 31 | 38 |
| | | % within ISONIZIAD | 2.6% | 15.8% | 81.6% | 100.0% |
| | | % within PREVIOUS TB | 1.5% | 7.0% | 12.4% | 9.5% |
| | | % of Total | 0.3% | 1.5% | 7.8% | 9.5% |
| | No | Count | 54 | 47 | 184 | 285 |
| | | % within ISONIZIAD | 18.9% | 16.5% | 64.6% | 100.0% |
| | | % within PREVIOUS TB | 83.1% | 54.7% | 73.9% | 71.3% |
| | | % of Total | 13.5% | 11.8% | 46.0% | 71.3% |
| | N/A | Count | 10 | 33 | 34 | 77 |
| % within ISONIZIAD | | 13.0% | 42.9% | 44.2% | 100.0% | |
| % within PREVIOUS TB | | 15.4% | 38.4% | 13.7% | 19.3% | |
| | % of Total | 2.5% | 8.3% | 8.5% | 19.3% | |
| Total | Count | 65 | 86 | 249 | 400 | |
| | % within ISONIZIAD | 16.3% | 21.5% | 62.3% | 100.0% | |
| | % within PREVIOUS TB | 100.0% | 100.0% | 100.0% | 100.0% | |
| | % of Total | 16.3% | 21.5% | 62.3% | 100.0% | |

The chi square test investigated whether there was a significant relationship between previous TB cases and cases currently receiving IPT (Table 4.26).

Table 4.26: Chi-square test of the relationship between previous TB cases and cases currently receiving IPT
Chi-Square Tests

| | Value | df | Asymp. Sig. (2-sided) | Exact Sig. (2-sided) | Exact Sig. (1-sided) | Point Probability |
|------------------------------|---------------------|----|-----------------------|----------------------|----------------------|-------------------|
| Pearson Chi-Square | 32.930 ^a | 4 | 0.000 | 0.000 | | |
| Likelihood Ratio | 32.183 | 4 | 0.000 | 0.000 | | |
| Fisher's Exact Test | 30.589 | | | 0.000 | | |
| Linear-by-Linear Association | 8.966 ^b | 1 | 0.003 | 0.003 | 0.002 | 0.001 |
| N of Valid Cases | 400 | | | | | |

Relationship is significant between the two variables as illustrated in Table 26, thus indicating a significant difference between the cases that previously had been diagnosed and treated for TB, and those currently receiving IPT.

4.4.5 The utilisation of the TB screening tool at the various facilities across the North, South and West sub-districts

Table 4.27 displays a summary of the 3 sub-districts (North, South and West) for the initial TB screens. Sub-districts in the North and West had similar ratios for initial TB screens performed. The Southern sub-district had many more screens that were not carried out.

Table 4.27: Initial TB screens performed for each sub-district

| | Not carried out | Screen carried out |
|--------------|-----------------|--------------------|
| South | 62.9 | 54.1 |
| North | 11.4 | 23.1 |
| West | 25.8 | 22.8 |

The total records viewed were in line with the sampling methodology outlined in chapter 3. Table 4.28 and Figure 4.20 further illustrate the implementation of initial screening at each clinic. Overall the implementation of the initial screening is fair, but variable.

Table 4.28: Initial TB screens carried out for each clinic

| | | | Initial screen | | TOTAL RECORDS REVIEWED |
|------------------|------------------|---------|-----------------|--------------------|------------------------|
| | | | Not carried out | Screen carried out | |
| Clinic | Clinic AU | Count | 5 | 11 | 16 |
| | | Percent | 31.3 | 68.8 | 100 |
| | Clinic CE | Count | 2 | 28 | 30 |
| | | Percent | 6.7 | 93.3 | 100 |
| | Clinic I | Count | 48 | 22 | 70 |
| | | Percent | 68.6 | 31.4 | 100 |
| | Clinic A | Count | 24 | 16 | 40 |
| | | Percent | 60.0 | 40.0 | 100 |
| | Clinic C | Count | 3 | 47 | 50 |
| | | Percent | 6.0 | 94.0 | 100 |
| | Clinic WH | Count | 1 | 21 | 22 |
| | | Percent | 4.5 | 95.5 | 100 |
| | Clinic R | Count | 15 | 19 | 34 |
| | | Percent | 44.1 | 55.9 | 100 |
| | Clinic N | Count | 0 | 34 | 34 |
| | | Percent | 0.0 | 100.0 | 100 |
| | Clinic CS | Count | 0 | 9 | 9 |
| | | Percent | 0.0 | 100.0 | 100 |
| | Clinic M | Count | 28 | 9 | 37 |
| | | Percent | 75.7 | 24.3 | 100 |
| Clinic W | Count | 4 | 39 | 43 | |
| | Percent | 9.3 | 90.7 | 100 | |
| Clinic MR | Count | 2 | 13 | 15 | |
| | Percent | 13.3 | 86.7 | 100 | |

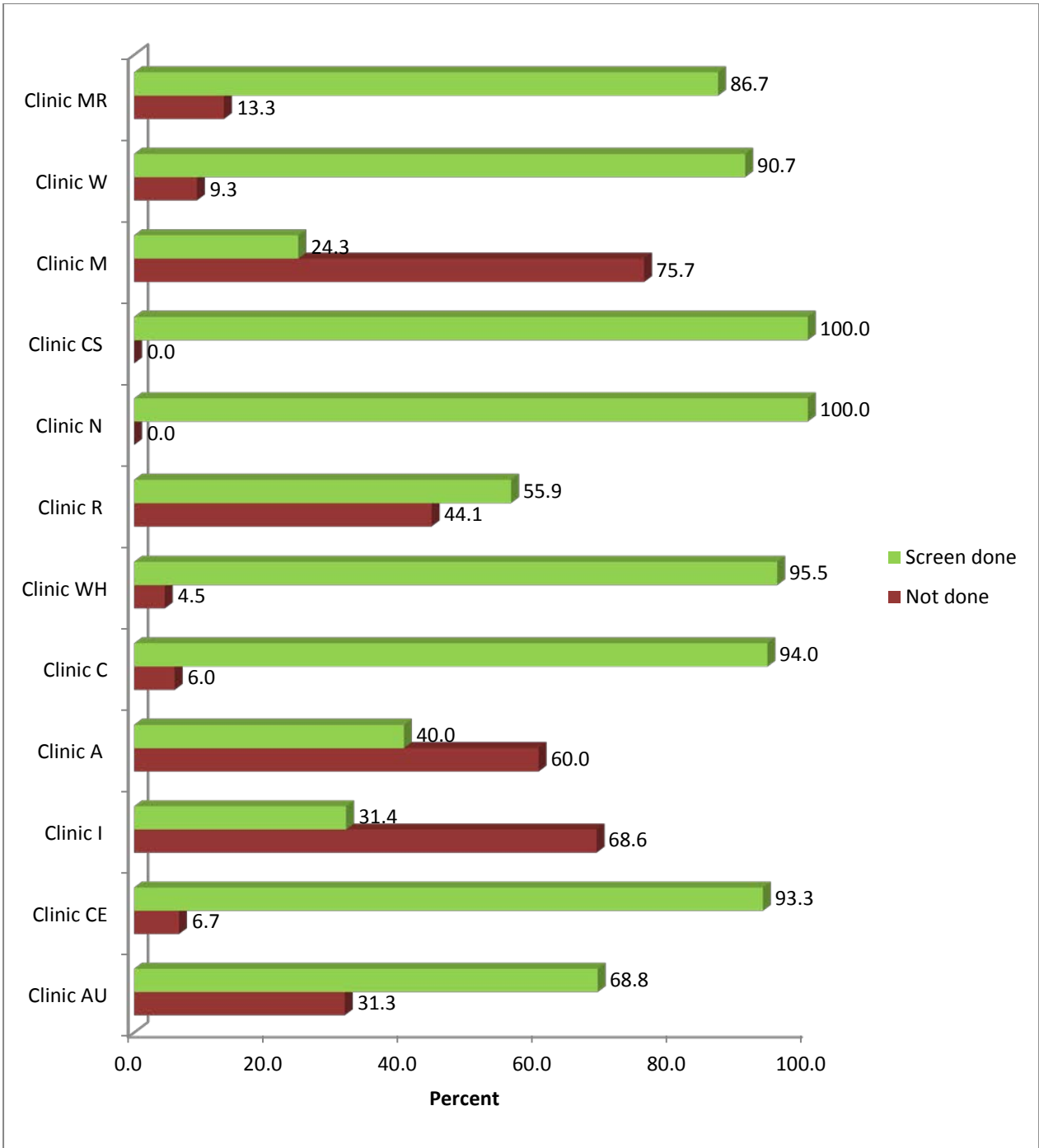


Figure 4.20: Initial TB screens per clinic

Figure 4.20 shows that clinic CS and clinic N conducted 100% of the initial TB screens. A total of six clinics illustrate a greater than 90% performance in carrying out initial TB screens.

Table 4.29 shows the follow-up TB screens per clinic in terms of carried out or not carried out. This is graphically represented in Figure 4.21.

Clinic M did not conduct 99% of follow-up TB screens. A total of 5 clinics demonstrate a greater than 90% performance in failing to carry out follow-up TB screens. Clinic MR performed the most follow-up TB screens (55.9%).

Table 4.29: Follow-up TB screens for each clinic

| | Count | | | | Percent | | |
|-----------|-----------------|-------------|-----|-------|-----------------|-------------|------|
| | Not Carried out | Carried out | DNA | Total | Not Carried out | Carried out | DNA |
| Clinic AU | 146 | 12 | 3 | 161 | 90.7 | 7.5 | 1.9 |
| Clinic CE | 183 | 67 | 7 | 257 | 71.2 | 26.1 | 2.7 |
| Clinic I | 466 | 16 | 65 | 547 | 85.2 | 2.9 | 11.9 |
| Clinic A | 233 | 30 | 32 | 295 | 79.0 | 10.2 | 10.8 |
| Clinic C | 371 | 0 | 18 | 389 | 95.4 | 0.0 | 4.6 |
| Clinic WH | 302 | 1 | 16 | 319 | 94.7 | 0.3 | 5.0 |
| Clinic R | 229 | 30 | 7 | 266 | 86.1 | 11.3 | 2.6 |
| Clinic N | 244 | 37 | 28 | 309 | 79.0 | 12.0 | 9.1 |
| Clinic CS | 93 | 1 | 7 | 101 | 92.1 | 1.0 | 6.9 |
| Clinic M | 398 | 2 | 2 | 402 | 99.0 | 0.5 | 0.5 |
| Clinic W | 305 | 37 | 8 | 350 | 87.1 | 10.6 | 2.3 |
| Clinic MR | 57 | 81 | 7 | 145 | 39.3 | 55.9 | 4.8 |

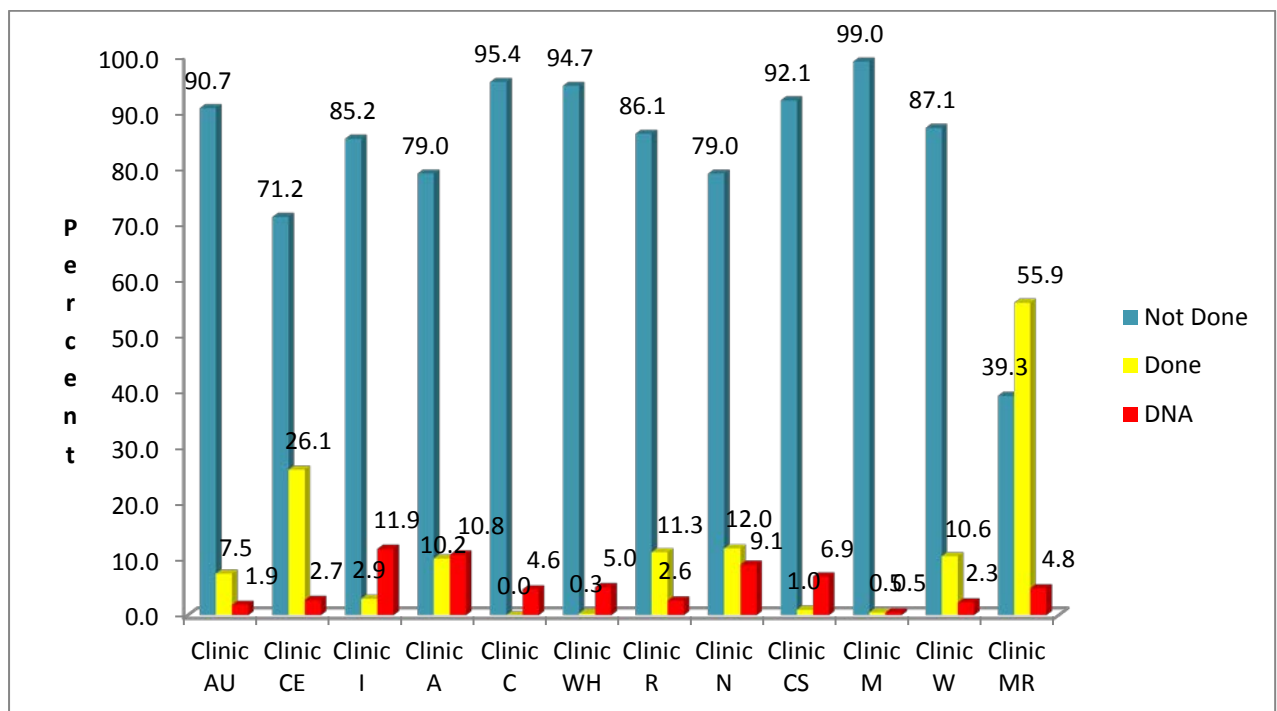


Figure 4.21: Follow-up TB screens performed in each clinic

Table 4.30 details the numbers of initial TB screens that were implemented either completely or incompletely. Eleven clinics did not perform a single complete follow-up TB screen. Clinic CS was the only facility that performed one complete screen.

Table 4.30: Extent of implementation of initial TB screens for each clinic

| | Complete | Incomplete |
|-----------|-----------------|-------------------|
| Clinic AU | 0 | 11 |
| Clinic CE | 0 | 28 |
| Clinic I | 0 | 22 |
| Clinic A | 0 | 16 |
| Clinic C | 0 | 47 |
| Clinic WH | 0 | 21 |
| Clinic R | 0 | 19 |
| Clinic N | 0 | 34 |
| Clinic CS | 1 | 8 |
| Clinic M | 0 | 9 |
| Clinic W | 0 | 39 |
| Clinic MR | 0 | 13 |

Statistics from Table 4.31 depict the total follow-up TB screens that were carried out completely or incompletely. This is graphically represented in Figure 4.22. Clinic MR leads with the highest percentage (55.9%) of follow-up TB screens completely performed. This was also the only clinic that had performed above 30% of the follow-up screens completely. Clinic CS had 0% of follow-up screens carried out completely.

Table 4.31: Extent of implementation of follow-up TB screens per clinic

| | Count | | | | | Percentage | | | | |
|-----------|-----------------|----------|------------|-----|-------|-----------------|----------|------------|------|-------|
| | Not carried out | Complete | Incomplete | DNA | Total | Not carried out | Complete | Incomplete | DNA | Total |
| Clinic AU | 146 | 11 | 1 | 3 | 161 | 90.7 | 6.8 | 0.6 | 1.9 | 100.0 |
| Clinic CE | 183 | 64 | 3 | 7 | 257 | 71.2 | 24.9 | 1.2 | 2.7 | 100.0 |
| Clinic I | 466 | 14 | 2 | 65 | 547 | 85.2 | 2.6 | 0.4 | 11.9 | 100.0 |
| Clinic A | 233 | 30 | 0 | 32 | 295 | 79.0 | 10.2 | 0.0 | 10.8 | 100.0 |
| Clinic C | 371 | 0 | 0 | 18 | 389 | 95.4 | 0.0 | 0.0 | 4.6 | 100.0 |
| Clinic WH | 302 | 1 | 0 | 16 | 319 | 94.7 | 0.3 | 0.0 | 5.0 | 100.0 |
| Clinic R | 229 | 30 | 0 | 7 | 266 | 86.1 | 11.3 | 0.0 | 2.6 | 100.0 |
| Clinic N | 244 | 33 | 4 | 28 | 309 | 79.0 | 10.7 | 1.3 | 9.1 | 100.0 |
| Clinic CS | 93 | 0 | 1 | 7 | 101 | 92.1 | 0.0 | 1.0 | 6.9 | 100.0 |
| Clinic M | 398 | 1 | 1 | 2 | 402 | 99.0 | 0.2 | 0.2 | 0.5 | 100.0 |
| Clinic W | 305 | 34 | 3 | 8 | 350 | 87.1 | 9.7 | 0.9 | 2.3 | 100.0 |
| Clinic MR | 57 | 81 | 0 | 7 | 145 | 39.3 | 55.9 | 0.0 | 4.8 | 100.0 |

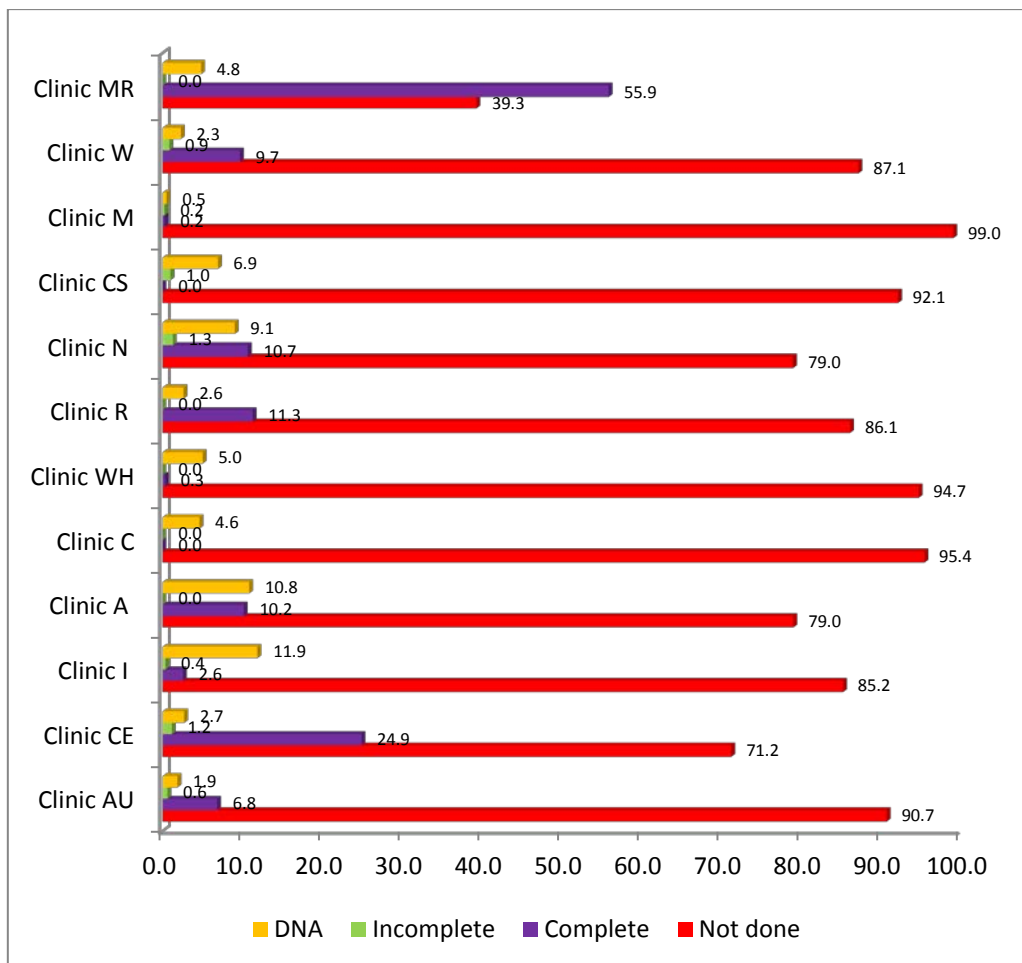


Figure 4.22: Complete or Incomplete screens for each clinic

Table 4.32 summarises the data for each sub-district (South, North and West). This is graphically represented in Figure 4.23. There were similar levels of follow-up TB screens not carried out in the various sub-districts. The levels of incomplete follow-up screens were also alike. The chi-square values indicate that there is a significant relationship between the clinics (sub-districts) and the Initial Screen for Follow-up screens 1 to 1 p-value is ($p < 0.001$).

Table 4.32: Follow-up TB screens for each sub-district

| | South | | North | | West | |
|------------------------|-------|---------|-------|---------|-------|---------|
| | Count | Percent | Count | Percent | Count | Percent |
| Not carried out | 1701 | 86.4 | 566 | 83.7 | 760 | 84.7 |
| Complete | 120 | 6.1 | 63 | 9.3 | 116 | 12.9 |
| Incomplete | 6 | 0.3 | 5 | 0.7 | 4 | 0.4 |
| DNA | 141 | 7.2 | 42 | 6.2 | 17 | 1.9 |
| Total | 1968 | 100.0 | 676 | 100.0 | 897 | 100.0 |

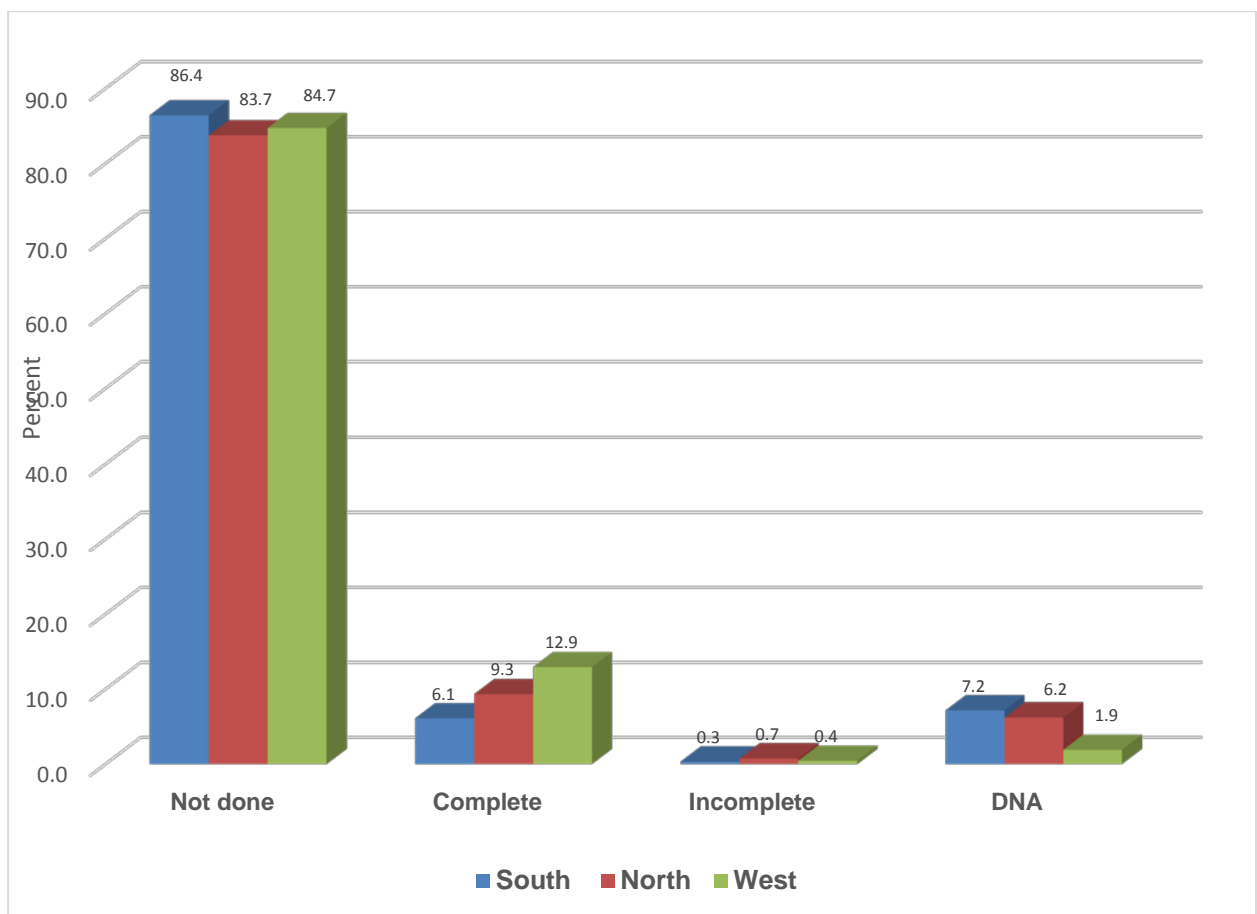


Figure 4.23: Complete and incomplete follow-up TB screens

4.5 PREVIOUS TB CASES AND CURRENT TB CASES

According to data from Table 4.33, 86 (21.5%) patients were recognised as having a previous diagnosis of TB during the initial TB screenings.

Table 4.33: Number of Initial TB Screens related to Previous TB
PREVIOUS TB

| | Frequency | Percent | Valid Percent | Cumulative Percent |
|------------|-----------|---------|---------------|--------------------|
| Did not do | 65 | 16.3 | 16.3 | 16.3 |
| Valid | Yes | 86 | 21.5 | 37.8 |
| | No | 249 | 62.3 | 100.0 |
| Total | 400 | 100.0 | 100.0 | |

Figure 4.24 illustrates 16.3% of case records having missing data related to the absence or presence of previous TB.

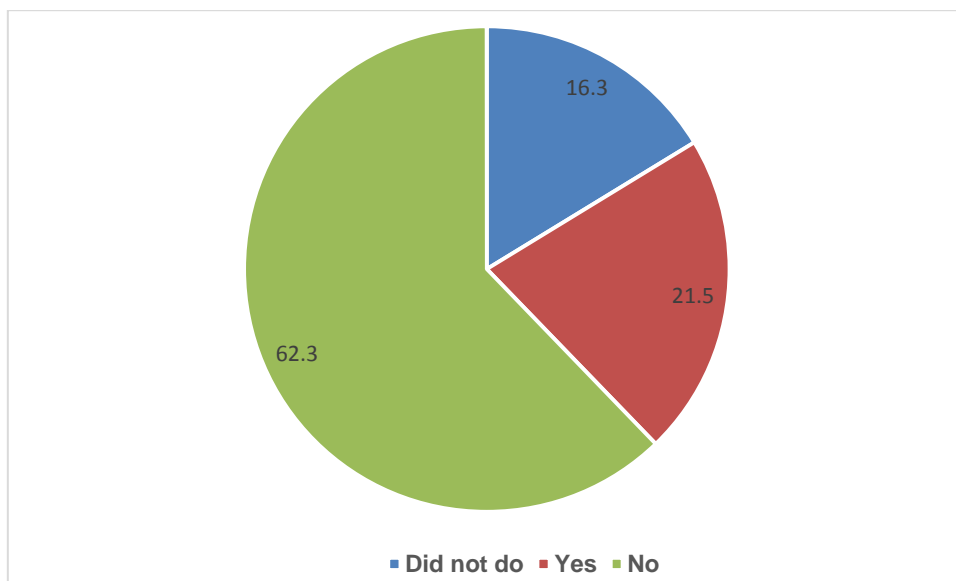


Figure 4.24: Percent of previous TB cases on initial TB screening

Table 4.34 indicates the relationship between the number of previous TB cases and current TB cases identified during the initial TB screen. There were 86 previous TB cases. Five of these patients with previous TB also have current TB. (Record was incomplete for one patient, therefore the total is 85.)

Table 4.34: Cross tabulation of previous TB cases and current TB cases

CURRENT TB * PREVIOUS TB Cross tabulation

| | | PREVIOUS TB | | | Total | |
|----------------------|------------|----------------------|--------|--------|--------|--------|
| | | Did not do | Yes | No | | |
| CURRENT TB | Yes | Count | 11 | 5 | 32 | 48 |
| | | % within CURRENT TB | 22.9% | 10.4% | 66.7% | 100.0% |
| | | % within PREVIOUS TB | 16.9% | 5.9% | 12.9% | 12.0% |
| | | % of Total | 2.8% | 1.3% | 8.0% | 12.0% |
| | No | Count | 54 | 80 | 217 | 351 |
| | | % within CURRENTTB | 15.4% | 22.8% | 61.8% | 100.0% |
| | | % within PREVIOUS TB | 83.1% | 94.1% | 87.1% | 88.0% |
| | | % of Total | 13.5% | 20.1% | 54.4% | 88.0% |
| | Total | Count | 65 | 85 | 249 | 399 |
| % within CURRENTTB | | 16.3% | 21.3% | 62.4% | 100.0% | |
| % within PREVIOUS TB | | 100.0% | 100.0% | 100.0% | 100.0% | |
| | % of Total | 16.3% | 21.3% | 62.4% | 100.0% | |

The chi square test investigated whether there was a significant relationship between previous TB and current TB (Table 4.35).

Table 4.35: Chi-square test illustrating the relationship between Previous TB and Current TB Chi-Square Tests

| | Value | df | Asymp. Sig. (2-sided) | Exact Sig. (2-sided) | Exact Sig. (1-sided) | Point Probability |
|------------------------------|--------------------|----|-----------------------|----------------------|----------------------|-------------------|
| Pearson Chi-Square | 4.665 ^a | 2 | 0.097 | 0.102 | | |
| Likelihood Ratio | 5.137 | 2 | 0.077 | 0.080 | | |
| Fisher's Exact Test | 4.880 | | | 0.082 | | |
| Linear-by-Linear Association | 0.053 ^b | 1 | 0.818 | 0.840 | 0.441 | 0.077 |
| N of Valid Cases | 399 | | | | | |

As evident in Table 4.35, the Fisher's test p-value (0.082) is greater than the level of significance implying that there is no significant relationship between Previous TB diagnosis and Current TB diagnosis.

Individual frequencies re: Table 4.35.

PREVIOUS TB

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|-------|------------|-----------|---------|---------------|--------------------|
| Valid | Did not do | 65 | 16.3 | 16.3 | 16.3 |
| | Yes | 86 | 21.5 | 21.5 | 37.8 |
| | No | 249 | 62.3 | 62.3 | 100.0 |
| | Total | 400 | 100.0 | 100.0 | |

CURRENT TB

| | | Frequency | Percent | Valid Percent | Cumulative Percent |
|---------|--------|-----------|---------|---------------|--------------------|
| Valid | Yes | 48 | 12.0 | 12.0 | 12.0 |
| | No | 351 | 87.8 | 88.0 | 100.0 |
| | Total | 399 | 99.8 | 100.0 | |
| Missing | System | 1 | .3 | | |
| Total | | 400 | 100.0 | | |

4.6 CONCLUSION

This chapter presented the findings and analysis from the data generated from the record reviews. Non implementation or incomplete implementation of TB screening during the initial and follow up screens were highlighted. There was also variability between clinics. Chapter Five will explore and discuss the findings of the study.

CHAPTER FIVE – DISCUSSION

5.1 INTRODUCTION

The previous chapter presented the findings of the study and this chapter focuses on the discussion of the results. The discussion of the results is based on the research objectives of the study as outlined in Chapter One and Chapter Four. Literature is reviewed where necessary as it relates to the findings. This chapter also presents recommendations for further research.

5.2 OVERVIEW OF BIOGRAPHICAL DATA

5.2.1 Gender Composition

The gender composition of the sample revealed a majority of females. The ratio of females to males was approximately 2:1. According to the Joint United Nations Programme on HIV/AIDS (UNAIDS) (2011), the prevalence of HIV infection is greater for women than men with 13 women infected for every 10 men infected in sub-Saharan Africa. Females form nearly 60% of HIV cases and this disparity is widening as women in this region are acquiring HIV infection at younger ages. Similarly, Statistics South Africa (2013) affirms that the ratio of HIV incidence for new HIV infections of adult females to males in the year 2013 was 1.5 to 1 for the 15-49 year age band (17.4% HIV prevalence rate for females). The DOH: KwaZulu-Natal Health Strategic Plan (2010) discusses the discrepancy of female to male statistics in HIV with the female prevalence being elevated. On a national scale one in three women were identified in the age bracket 25-29 years with HIV infection in the year 2008.

The DOH: National Strategic Plan (2012) supports the above information. The antenatal HIV prevalence escalated from less than 1% to 30% during the years 1989 to 2009. The most significant increase was noticed between 1995 and 2004 where the antenatal prevalence climbed from 10% to 30%. This spiralling HIV prevalence triggered a proliferation of TB cases amongst women; TB incidence for females

advanced from 35% to 44%. The KwaZulu-Natal government is alarmed by the increased HIV and TB prevalence in women of child-bearing age and emphasize this matter requires an all-inclusive and assimilated preventive and promotive health interventions (The KwaZulu-Natal Health Strategic Plan, 2010). Countries with HIV prevalence in excess of 1% tend to demonstrate a larger TB case load in females when compared to males (The WHO Guidelines for Intensified Tuberculosis case-finding and Isoniazid preventive therapy for people living with HIV in resource-constrained settings, 2011).

5.2.2 Age Distribution

The majority of the patients in the study were between the ages of 20 to 50 years (90%) with the age group 30 to 40 years displaying the highest percentage of 39.3%. The next age group demonstrating the second most elevated percentage of patients is the 20 to 30 years age band with 28.1%. Statistics South Africa (2013) report that HIV prevalence is the highest nationally in age category 15-49 years with 15.9% of this cohort infected. The DOH: KwaZulu-Natal Health Strategic Plan (2010) articulate that since an estimated 70% of the population in KwaZulu-Natal are younger than 35 years, there are considerable consequences for planning and implementation of service delivery particularly with reference to the existing health burden which is predominantly HIV/AIDS and TB. This has further implications towards the nation's obligation regarding the Millennium Development Goals.

5.3 IMPLEMENTATION OF THE TB SYMPTOM SCREENING TOOL

The first objective of the study was to determine the implementation of the TB symptom screening tool by health care workers in all clients that were enrolled in ARV care in the selected clinics. The findings of the study showed that of the 400 case records reviewed only 67% initial TB screens were conducted while 33% initial screens were not conducted. There were similar numbers of initial TB screens that were not carried out for both males and females.

The DOH: Guidelines for Tuberculosis Preventive Therapy among HIV Infected Individuals in South Africa (2010) stipulate that screening of the HIV positive person for signs and symptoms of TB is critical for the exclusion of TB or for the diagnosis of active TB infection. TB screening is described as a means of strengthening TB case findings amid the HIV population and it entails enquiring about TB symptoms to recognise any TB suspects. Were, Moore, Ekwaru, Mwima, Bunnell, Kaharuza, Rutherford and Mermin (2009) rationalize that since HIV-TB co-infection is usually connected to an escalated degree of developed HIV illness and mortality, appropriate TB screening and or TB treatment is pertinent for the decrease of transmittable TB in society and for the enhanced quality of life and survival. The study conducted by these authors in Uganda found that uncomplicated TB symptom screening algorithms are capable of detecting people who are unlikely to have active TB, thereby lessening the TB diagnostic load in sub-Saharan Africa ARV interventions.

Reid and Shah (2009) are of the same opinion as Cain *et al.* (2010). The two vital functions of TB screening are to recognise patients with TB or rule out TB disease so patients can access other therapies like IPT. Gupta, Chandresehar, Gupte, Patil, Bhosale, Sambarey, Ghorpade, Nayak, Garda, Sastry, Bharadwaj and Bollinger (2011) found TB symptom screening valuable for excluding TB in their HIV infected study cohort. Reid *et al.* (2009) discuss the WHO guidelines advocating consistent TB screening for people infected with HIV. In spite of these recommendations, intensified TB case findings have been poorly applied. In 2006 less than 1% of the people were screened for TB; unsupportive infrastructure and the need for an internationally standardised screening approach are cited as the reason for this low percentage. In addition, Getahun *et al.* (2011) are concerned about the continued increase in mortality due to poor or interrupted diagnosis of TB and these authors feel straightforward clinical algorithms should be utilised to screen HIV positive individuals for TB; separating them into those who require further investigations and those who have TB ruled out.

Long *et al.* (2003) highlight the value of prompt recognition and treatment of TB in HIV infected patients. Their view is that the exploration for TB should be commenced at the time of HIV diagnosis and should continue at subsequent visits. The

questioning for TB should include symptoms that are indicative of TB disease like cough, haemoptysis, fever, night sweats, weight loss as well as history of any previous TB disease. Choun, Pe, Thai, Lorent, Lynen and van Griensven (2013) utilised TB screening and diagnostic algorithms recommended by WHO as a part of their study aimed at lessening the delay from diagnosis of TB to ARV initiation. The motivation for the study was the overwhelming TB related mortality in HIV infected populations in resource limited settings. Their investigation demonstrated a general reduction in HIV associated TB disease, in addition to an earlier identification of TB; thereby facilitating a rapid uptake of ARV therapy. This notion is supported by Naidoo *et al.* (2011) and Worodria, Massinga-Loembe, Mayanja-Kizza, Namaganda and Kambugu (2011) who advise implementation of a TB symptom screening tool at ARV therapy venues will provide significant prospects for TB screening.

The signs and symptoms to be screened for TB disease according to DOH: The Guidelines for Tuberculosis Preventive Therapy among HIV Infected Individuals in South Africa (2010a) include cough, fever, unintentional weight loss, night sweats, chest pain, dyspnoea, haemoptysis, and lymphadenopathy. Despite this policy advocated by the DOH, the application of TB symptom screening in South Africa is protracted. Even though the DOH clinics retain patients with elevated levels of TB-HIV co-infection and there is known evidence of the fatal synergy between TB and HIV; the South African DOH estimates a mere 25% of the HIV infected population in receipt of health care in the year 2006 obtained TB screening (Basset *et al.*, 2010).

TB is the foremost cause of morbidity and mortality in public health hospitals in South Africa, and is the second most frequent condition observed in PHC clinics in KZN and nationally (DOH: KwaZulu-Natal Health Strategic Plan, 2010). In response to these alarming statistics The HIV and AIDS Strategy for the Province of KwaZulu-Natal (DOH: KZNPSP) (2011) aims to make certain 80% of men and women between the ages of 15 to 49 (by the year 2016) are familiar with their HIV status and receive TB screening. The endeavour also includes improving access to timely identification, diagnosis and treatment for TB in at least 80% of the HIV infected population.

According to the findings of this study, almost 86% of the follow-up TB screens were not carried out, whilst only 8.9% were carried out. The remaining 5.6% of patients did not attend (DNA) their follow up visits. There were similar percentages of follow-up TB screenings carried out for males and females, as well as follow-up TB screenings not carried out for males and females.

The DOH: Guidelines for Tuberculosis Preventive Therapy among HIV Infected Individuals in South Africa, (2010a) stipulate that health care workers are obliged to symptomatically screen patients for TB on every follow up visit during their regular monthly visits for routine HIV care. Active TB infection must be eliminated, furthermore symptomatic patients should be assessed and receive possible treatment according to TB guidelines. The International Centre for AIDS Care and Treatment Programs-South Africa (ICAP) (2010) sustain this concept in their policy document. The ICAP model of care comprises the necessary components for provision of valuable and inclusive HIV care; with TB and HIV integrated management promoted as one of the key pillars. Symptomatic TB screening for all patients receiving HIV care should be conducted at the first and every visit thereafter. Symptomatic patients should obtain urgent continued assessments.

The study revealed the decline in follow-up TB screens performed as the patients attended the clinic for successive visits. It is evident that eventually no TB screens were performed. Shah *et al.* (2009) found in their study the increased threat of TB misdiagnosis in the HIV population, lengthy intervals in diagnosis, TB drug resistance and enhanced transmission of TB in the community. Consequently Long *et al.* (2003) and Corbett *et al.* (2010) sanction the WHO TB symptom screening policy of recurring screening during regular monthly HIV care management. Getahun *et al.* (2011) and Worodria *et al.* (2011) are of the same opinion as the authors above. HIV infected individuals who are provided with IPT or ARV therapy should receive routine TB symptomatic screening during every visit to the health care facility.

The conclusions of the study undertaken by Were *et al.* (2009) made known the tiny percentage (4%) of HIV positive people who are infected with TB yet are asymptomatic during initial screenings. Identification of these individuals is still

probable as patients on ART therapy present themselves to health settings for periodic care, where the symptoms become evident with time. Meintjies and Wilkinson (2010) cite Basset *et al.*'s (2010) study of ARV initiation in HIV infected patients in South Africa. During initial evaluations a fraction of patients were asymptomatic, yet were infected with TB. Since there is a raised prevalence of undiagnosed TB among the ART initiation cohort, there is a need for health care providers to continually screen for TB symptoms during successive attendance.

5.4. EXTENT OF THE IMPLEMENTATION OF THE TB SCREENING TOOL

The second objective of the study was to investigate the extent of the implementation of the TB screening tool when utilised. The results of the study revealed 33% of the initial TB screens were not carried out and even though almost 70% of the initial TB screens were performed, they were, however, incompletely carried out. This indicates that not all symptoms on the data collection tool were questioned (cough, haemoptysis, loss of weight, night sweats, fever, lymphadenopathy, and dyspnoea or chest pain). Significantly, only one complete initial screen was performed from the total of 268 initial TB screens carried out. There were similar percentages of initial screens that were carried out incompletely for males (65.4%) and females (67.4%).

According to the DOH: South African Antiretroviral Treatment Guidelines (2013) the following symptoms contribute to identifying possible TB suspects; cough, sputum production, fever, night sweats, unexplained weight loss, loss of appetite, dyspnoea, chest pains and lymphadenopathy. Getahun *et al.* (2011) reflect on how National TB policies previously classified a TB suspect as somebody with a cough lasting more than two weeks. A key transformation to the present approach will be the substitution of chronic cough with current cough, as well as the addition of other symptoms. In their meta-analysis of other research, they discovered the utilisation of only chronic cough for symptom screening would result in unidentified TB cases and diagnostic deferrals.

Approximately 86% of the follow-up TB screens were not carried out. This is a significant proportion and is highlighted by a chi square test p-value of 0.000, which indicates that the differences in the observed frequencies were highly significant. An analysis of the complete and incomplete follow-up TB screens revealed the following: only 15 (4.8%) follow-up TB screens were carried out incompletely from the total of 314 follow-up TB screens carried out. Follow-up TB screens that were completely carried out added up to 299 (95.2%). As mentioned earlier, the results communicated a decline in the follow-up TB screens performed as the patients attended the clinic for successive visits. However, when the follow-up TB screens were performed, most of the screens were thoroughly completed.

The investigation completed by Reid and Shah (2009) showed an assortment of symptoms which were more convenient and effective for TB screening in the HIV population than the sole use of cough. Given that lung diseases other than TB are also capable of causing cough, utilising cough as the only means of TB screening is challenging. Cain *et al.* (2010) support Reid and Shah (2009) in their study that enquiring about a grouping of symptoms rather than only chronic cough in individuals with HIV infection is optimal. Getahun *et al.* (2011) conclude their investigation by affirming the value of attaching cough, fever, night sweats and weight loss into a simple TB symptom screening tool in a backdrop of resource limitations. Implementation of this screening algorithm will result in prompt TB diagnosis and management, in addition to facilitating the expansion of IPT and ARV therapy.

5.4.1 Implementation of the TB screening tool relative to the WHO four-part TB symptom screen

The data from the study reveal that of the 400 case records reviewed; 33% of initial TB screens were not carried out while 67% of initial TB screens were conducted by applying the WHO four-part TB symptom criteria. The study results demonstrate the extent of the implementation of initial TB screens according to the WHO four-part symptom screen; whilst 94.8% of the initial TB screens were completely implemented making use of these criterion, and only 5.2% of the initial TB screens were not performed completely.

When the four-part WHO symptom screen criteria was applied the extent of the implementation of the initial TB screens improved from only one complete screen carried out to almost 95% TB screens performed completely.

According to the WHO Guidelines for Intensified Tuberculosis case-finding and Isoniazid preventive therapy for people living with HIV in resource-constrained settings (2011), the distinction between the 1998 WHO/UNAIDS policy and the new WHO 2010 guidelines is the significance of ICF and IPT as part of the comprehensive package of care in the HIV affected population. The amended guidelines utilise a simple TB screening algorithm that is evidence based and applies four clinical symptoms (current cough, fever, weight loss and night sweats) to recognise those patients who qualify for IPT or should be referred for further investigations. Kranzer (2011) conducted a meta-analysis investigation into TB case finding in the HIV infected population. Her study revealed that regardless of the straightforward TB symptom screening tool recommended by the WHO; only 1.7 million (5%) of the approximate 33 million HIV infected people received TB screening in the year 2009.

Nearly 90% of the follow-up TB screens were performed, whilst only 4.4% were not carried out utilising the criteria of the WHO four-part TB symptom screen. According to the study results, without the application of the WHO four-part TB symptom screen almost 86% of the follow-up TB screens were not performed. Utilisation of the WHO four-part TB screen criterion observed an increase to almost 90% of follow up screens.

The WHO Guidelines for Intensified Tuberculosis case-finding and Isoniazid preventive therapy for people living with HIV in resource-constrained settings (2011), emphasise that all HIV positive individuals should be screened for the symptoms of TB on a regular basis and the absence of symptoms will facilitate IPT uptake whilst the presence of any one symptom requires the client to undergo further examinations for TB. In view of the fact that the WHO suggests ongoing TB symptom screening for HIV positive clients during each interaction with a HCW, Kranzer

(2011) asserts that there has to be an intensification of TB case finding amongst health care providers.

An examination of the findings into the extent of implementation for complete and incomplete follow-up TB screens revealed of the 3185 (almost 90%) follow-up screens conducted, only 300 (9.4%) complete follow-up screens were carried out. According to the WHO four-part TB symptom screen, follow-up TB screens that were incompletely carried out totalled 2885 (90.6%). The study results reveal that although there was a profound increase (almost 90%) in the carrying out of follow up TB screens using the WHO four-part TB symptom screen, less than 10% of these follow up screens were completely performed applying the WHO criteria.

The study carried out by Gupta *et al.* (2011) utilised a TB screening method that involved the criteria from the WHO 2010 TB four-part symptom screen to investigate TB screening amongst HIV positive patients. The study findings endorse the revised WHO TB symptom screen to exclude TB in HIV positive adults and affirm the tool's worth in populations with widespread TB infection. Additionally, since the exclusion of TB preceding IPT is a requirement, the TB symptom screening tool is invaluable in the HIV infected population.

5.5 DETERMINING FURTHER INVESTIGATIONS OR TB TREATMENT INITIATION BASED ON TB SYMPTOM SCREENING

The third objective of the study was to determine further investigations or TB treatment initiation based on the TB symptom screening tool. The results of the study revealed the total number of suspected TB cases was 23 for the initial TB screens. Sputa testing and radiological examinations were the two types of investigations carried out. These two tests added up to 65.2%, whilst 34.8% of the TB suspected cases received no other investigations. The majority of the investigations were sputa tests (60.9%). Radiological tests amounted to 4.3%. The number of patients who did not have further investigations despite being identified as TB suspects added up to eight (34.8%).

The SA National Tuberculosis Management Guidelines (DOH, 2009) assert that since sputum microscopy is considered the foundation of TB diagnosis even in increased HIV prevalent settings, all clients suspected of TB ought to have two sputum specimens collected for microscopy testing. A third sputum specimen should be collected for culture if the first two specimens are smear negative or incongruous in the HIV infected population. Sputum culture is considered the principal standard for TB diagnosis and it significantly expands TB diagnosis in this cohort. This policy is collaborated by the Palsa Plus Clinical Guidelines for the Primary Care Management of Adults (DOH, 2010b) which is the document guiding care for HIV infected individuals in a primary health care setting in South Africa.

Similarly, The International Centre for AIDS Care and Treatment Programs-South Africa (ICAP) (2010) and Basset *et al.* (2010) recommend all HIV positive persons must be assessed in a suitable manner, abiding by national policies or algorithms once screened for and suspected of TB.

Statistics from this study showed 15 suspected TB cases were diagnosed with TB disease during the follow-up screens. Of the 15 patients suspected of having TB, six (40%) patients were confirmed with TB, and no information indicating additional investigations was available for the outstanding 60% of patients.

All patients should be further evaluated for TB infection following national TB principles once symptomatic for one or more TB symptoms. Symptomatic patients can only be started on IPT after TB has been excluded by sputum smear microscopy and or culture according to The Guidelines for Tuberculosis Preventive Therapy among HIV Infected Individuals in South Africa (DOH, 2010a). Most authors like Reid and Shah (2009) and Long *et al.* (2003) agree that individuals suspected of TB ought to commence specific investigations like sputum smears and sputum cultures.

The study reveals that of the 45 patients who had a TB diagnosis on initial TB screening, 40 (88.9%) of these patients had records showing they had received TB treatment. The other five (11.1 %) of these patients with a TB diagnosis had no record of receiving TB treatment. Six patients received a TB diagnosis during the follow-up visits. However, only two (33.3%) of these patients are recorded as having

received TB treatment. The remaining four (66.1%) of the patients have no information in the ARV case records on treatment received.

De Cock (1995) depicts TB as having considerably dissimilar consequences for HIV infected and non HIV infected populations. Understandably, Godfrey-Fausset *et al.* (2002) describes the urgency for all TB infected individuals to receive a suitable TB diagnosis and treatment, especially in an advanced HIV prevalent setting. Unsuccessful implementation of TB diagnosis and treatment in countries with major HIV burdens will lead to an escalated number of TB cases and an amplified risk for drug resistance. The morbidity and mortality rates are further increased by MDR-TB creating additional difficulties for TB management.

The HIV infected population maintains an enhanced susceptibility to MDR-TB infection and the development from infection to disease is hastened in this cohort. MDR-TB is considered a problem created as a result of human error due to probable compromised patient care, for example incomplete treatment management. PHC facilities perform a vital position in diminishing the possibility of resistance by practising optimal TB control to prevent MDR-TB (DOH: SA National Tuberculosis Management Guidelines, 2009). Research by Naidoo *et al.* (2011) and Getahun *et al.* (2010) demonstrated the inferior outcomes for HIV infected individuals with MDR-TB. The risk of mortality is increased due to numerous complications arising including adherence, drug toxicities, drug susceptibility testing; in addition to the elevated danger of transmission to the community and HCW's. "Delays in the diagnosis of TB have been associated with worse outcomes, so initiation of treatment as soon as possible is recommended" (The S A National Tuberculosis Management Guidelines, 2009: 75).

5.6 ISONIAZID PROPHYLACTIC THERAPY (IPT)

The fourth objective of the study was to identify initiation of IPT during the initial TB screening and the supply of IPT during the follow up visits. The research findings reveal that less than 10% of patients received IPT at the initial TB screen. The records show almost 70% of patients who were eligible for IPT did not receive this

therapy. The other patients (19.3%) who were marked not applicable (N/A) did not meet the qualifying criteria for IPT initiation. Patients investigated for TB due to being a TB suspect comprised (3.75%).

As discussed in sub-section 5.4, the latest guidelines from the WHO advocates utilisation of the four-part TB symptom screening tool to exclude possible TB symptoms prior to initiating IPT. IPT is regarded as a component of a comprehensive bundle of HIV management and should be issued to HIV positive individuals without active TB for a minimum period of six months. Pregnant women, clients on ARV therapy and patients with a previous history of TB ought to receive IPT irrespective of the extent of immune suppression (The WHO Guidelines for Intensified Tuberculosis case-finding and Isoniazid preventive therapy for people living with HIV in resource-constrained settings, 2011).

The WHO policy for IPT is endorsed and employed by South Africa. According to The Guidelines for Tuberculosis Preventive Therapy among HIV Infected Individuals in South Africa (DOH, 2010a), IPT is a part of routine HIV care that has to be proposed once patients are screened to eliminate the likelihood of TB. IPT has demonstrated a substantial yield in the HIV infected population and is a valuable means of averting the excessive rates of morbidity and mortality usually associated with TB-HIV co-infection. Likewise, The DOH: South African Antiretroviral Treatment Guidelines (2013) endorses TB screening for all HIV positive people previous to and during ARV treatment. IPT should be offered to every patient when the signs and symptoms of TB are not present.

The DOH: National Strategic Plan (2012) mentions the exceptionally low rate of IPT in South Africa (almost 4%). In response to the poor rollout of IPT; the KZN provincial government has identified performance of active TB case finding and distribution of IPT to all HIV positive patients as a crucial strategy to overcome this predicament (DOH: HIV and AIDS Strategy for the Province of KwaZulu-Natal (KZNPS) (2011).

Authors like Shah *et al.* (2009) and Cain *et al.* (2010) support the WHO mandate for TB symptom screening prior to commencement of IPT in HIV positive people. IPT is

usually the first assistance offered to the HIV infected individual; seeing as CD4 count is no longer an eligibility prerequisite for IPT (Mosimaneotsile *et al.*, 2010).

In their study, Choun *et al.* (2013) found that altering the TB symptom screening standards in HIV infected persons to that of the revised WHO guidelines, in addition to applying the IPT policy, lead to a reduction in the number of TB cases. Reddy *et al.* (2010) explain the uncoordinated screening interventions for exclusion of TB in HIV positive individuals has resulted in a huge disparity between international guidelines and the actual execution (achieving <0.08%). The authors consider IPT as having the capability of assisting in TB control in the HIV community, thereby saving millions of people from infection. Intensifying the screening of eligible clients from the existing <0.1% to merely 10% may possibly prevent more than a million new cases of TB.

Howard and El-Sadr (2010) describe how the percentage of HIV infected individuals in Namibia improved from 2% to 42% over a duration of one year. Adherence counsellors were trained to recognise eligible IPT clients by implementing an integrated TB symptom screening and IPT questionnaire.

Reid and Shah (2009) and Getahun *et al.* (2011) discuss key obstacles to wide scale application as being unease over the capacity to effectively first exclude TB ahead of IPT and the threat of Isoniazid monotherapy resistance. Similarly, Corbett *et al.* (2010) affirm that the chief motives for the limited application of IPT in Africa are inadequate TB screening and the danger of drug resistance.

However, the WHO guidelines state that since IPT does not multiply the threat of INH drug resistant TB apprehension over INH resistance must no longer be an obstruction to making IPT available (The WHO Guidelines for Intensified Tuberculosis case-finding and Isoniazid preventive therapy for people living with HIV in resource-constrained settings, 2011).

Data from this study shows a significant amount of less than 4% of the patients received IPT at the follow up screens. The case records reveal that approximately 90% of patients were eligible for acquiring IPT yet did not receive it.

The DOH: SA National Tuberculosis Management Guidelines (2009) substantiate that IPT decreases the HIV positive individual's likelihood of becoming infected with TB and is a function of routine HIV care. The client should be offered IPT at the initial visit or during any subsequent visit to the health facility, with IPT being issued for a minimum period of six months. Screening clients for signs and symptoms of TB during the initial and follow up visits is regarded as a necessity prior to provision of IPT. This sustained TB symptom screening approach is also stipulated in the Palsa Plus Clinical Guidelines for the Primary Care Management of Adults (DOH, 2010b).

The International Centre for AIDS Care and Treatment Programs-South Africa (ICAP) (2010) and The Guidelines for Tuberculosis Preventive Therapy among HIV Infected Individuals in South Africa (DOH, 2010a), share the same view. An offer of IPT at the initial or follow up visit (if IPT was not already used for six months) to the HIV infected person is deemed to be an essential requirement of HIV management.

During the initial TB screens 86 patients were identified in this study as having had previous TB. Six (7%) of patients were given IPT. The number of patients who were eligible for IPT but were not given this therapy totalled 47 (54.7%). The relationship was significant between the two variables as illustrated in Table 26, thus indicating a significant difference between the cases that previously had been diagnosed and treated for TB, and those currently receiving IPT.

The SA National Tuberculosis Management Guidelines (2009) states patients with HIV infection tend to have increased mortality rates throughout and subsequent to TB treatment when compared with HIV negative individuals. Naidoo *et al.* (2011) describe the WHO definition of recurrent TB as TB identified in clients that had prior TB treatment and were pronounced cured or had concluded their therapy. HIV infection poses an escalated threat for TB recurrence and recurrent TB comprises the bulk of TB cases in nations with an increased TB incidence.

De Cock (1995) reiterates HIV positive clients exposed to TB infected patients have increased risks of contracting active TB disease in addition to the possibility of TB re-infection after finishing TB treatment. Nonetheless, Reddy *et al.* (2010) discuss how

IPT in numerous populations has led to a decrease in the lifetime risk of recurrent TB to less than 4%.

According to the findings of this study, 86 (21.5%) patients were recognised as having a previous diagnosis of TB during the initial TB screenings. Missing data related to the absence or presence of previous TB was observed in 16.3% of the case records. Additionally, the study explored the relationship between the number of previous TB cases and current TB cases identified during the initial TB screen. There were 86 previous TB cases. Five of these patients with previous TB also had current TB.

Naidoo *et al.* (2011) cite studies in their research that demonstrated a 10-fold increase in TB incidence in the HIV population on ARV therapy. A study in South Africa displayed recurrent TB was five times more probable in HIV positive patients. Clients on ARV treatment remain at an advanced risk for recurrent TB due to partial immune restoration. Since the lifespan of these clients' are now lengthened the threat of TB re-infection persists. Furthermore, the risk of recurrent TB attributed to drug resistant TB is very prominent with ARV clients spending a large amount of time in poorly ventilated rooms at clinics lacking appropriate infection control measures. "...data from several observational studies demonstrate that IPT is both cost effective and beneficial through combating low bacillary load latent TB which serves as a reservoir for possible recurrent disease" Naidoo *et al.* (2011: 3).

5.7 CONSISTENCY OF UTILISATION OF TB SYMPTOM SCREENING

The fifth objective was to determine the consistency of the utilisation of TB symptom screenings in the selected clinics. Clinical audits allows for optimal health care delivery by assessing existing practices and comparing them to acceptable standards. Analysis of data from the study revealed sub-districts in the North and West had similar ratios for initial TB screens performed. The Southern sub-district had many more screens that were not carried out. There were similar levels of follow-up TB screens not carried out in the various sub-districts. The levels of incomplete follow-up screens were also alike. The chi-square values indicate that

there is a significant relationship between the clinics (sub-districts) and the Initial Screen for Follow-up screens 1 to 1 p-value is ($p < 0.001$).

According to the DOH: KwaZulu-Natal Health Strategic Plan (2010) there appears to be an increase in physical, psycho-social and emotional pressures on HCW's as a result of the present burden of disease. Consequently this has a substantial effect on delivery of service. The amplified work expectations and clinical exigencies have arisen from the elevated need for and consumption of public health programmes. In order to provide suitable staff and resource allocation the major inconsistencies linking service delivery points needs to be addressed. The resulting re-engineering of health services to fulfil national norms will assist in accelerating the realization of MDG targets. The KwaZulu-Natal provincial government has responded to this challenge by aiming to reinforce TB case detection, supply proper therapies and improve treatment adherence in the existing health systems (DOH: KZNPS, 2011).

Uwimana, Jackson, Hausler and Zarowsky (2012) conducted a study in KwaZulu-Natal to gain knowledge of managers' and community care workers' insight into the possible obstacles to combined TB and HIV interventions. They found that increased workloads and the demands to accomplish targets serve as an impediment to joint planning at provincial and district levels. Long *et al.* (2003) assert that HCP's, managers and everyone engaged in TB control must endeavour to encourage collaborative TB-HIV care and promote communication and planning between HIV and TB programmes.

The current disease profile necessitates an appraisal of the national PHC staffing average of 1:40 patients for Professional Nurses (12 minutes per patient per day). According to the WHO, South Africa has to triple its present health worker human resource complement by the year 2017 to grant universal access for ARV's (The KwaZulu-Natal Health Strategic Plan, 2010). Schneider, Barron and Fonn (2007) support the need for improved staffing norms. The authors consider a reduction in health resources as one of the key limitations to expanding access in South African healthcare. There was a 27.1% vacancy rate of health personnel in 2005. The population reliant on public health increased by seven million between the years 1995 and 2005. However, there was a decline in the production of professional

nurses in this same period. The South African public's health is dependent on professional nurses; more than 90% of clients in primary health care attribute professional nurses as their principal caregiver. The increase in population and HIV prevalence rates has led to an amplified pressure on the public health structure.

Uwimana *et al.* (2012) identify separate vertical programmes of existing high burdened HIV and TB care, management and planning, imbalanced finances, human resource capability, scarcity of staff, scope of practice in HCW's and monitoring and evaluation of TB and HIV strategies as being some of the challenges. Numerous health facilities function with inadequate staffing and the complexity of HIV-TB co-management requires added training. The national nurse-initiated management of ART (NIMART) creates the potential to harmonize the limited scope of practice of nurses regarding comprehensive TB and HIV care.

Similarly, Howard and El-Sadr (2010) feel the benefits gained from ARV therapy will be forfeited if there is no integration between HIV and TB services. In addition, the human resource and laboratory components need reinforcement. For this reason Reid and Shah (2009) emphasise the importance of a TB symptom screening tool for detection of TB in HIV positive individuals in resource constrained environments.

The study findings reveal the overall implementation of the initial screening is fair, but variable for each clinic. Data shows two clinics conducting 100% of the initial TB screens. A total of six clinics illustrate a greater than 90% performance in conducting initial TB screens.

One of the aims of WHO's policy on collaborative activities for TB and HIV control programmes' main focus is decreasing the load of TB in the HIV population. The WHO recommends the expansion of a joint national plan for combined HIV and TB care (DOH: National Strategic Plan, 2012). The DOH: South African Antiretroviral Treatment Guidelines (2013) stipulate the importance of incorporating HIV/TB services and decentralising this programme to all PHC facilities. Furthermore, The Guidelines for Tuberculosis Preventive Therapy Among HIV Infected Individuals in South Africa (DOH, 2010a), states that there should be an enhanced partnership between TB and HIV services; and the HIV/AIDS programme must be accountable

for the application of IPT. An integrated HIV/TB model of care is also the core feature of ICAP (ICAP) (2010). In addition, The Palsa Plus Clinical Guidelines for the Primary Care Management of Adults (DOH, 2010b) and The S A National Tuberculosis Management Guidelines (2009) endorse TB/HIV collaborative activities for the HIV infected population.

The findings of this study reveal that eleven clinics did not perform a single complete initial TB screen. There was only a single facility that performed one complete screen.

Reid and Shah (2009) refer to the latest global statistics which show screenings for TB in HIV care is severely limited. There is growing research to suggest TB and HIV services should co-exist to facilitate an improvement in the levels of TB screening. However, there are clinical and programmatic difficulties with this intervention. Since there is a hastened decentralisation of HIV services; HIV programmes ought to counter this challenge by implementing simple, standardised TB screening tools in resource limited situations.

The KZN province has recognised the poor integration of TB and HIV services and this recognition is repeated in the DOH: KZN strategic plan (KZNPSP) (2011). Additionally, The KwaZulu-Natal Health Strategic Plan (2010) discusses how the inadequate combining of these two programmes raises doubts concerning the success of TB and HIV management. In a strategy to intensify the reaction towards the difficulty faced with TB and HIV; the South African president (Mr J G Zuma) has specified that the treatment for TB and HIV should be offered under a single roof. This will assist in the realisation of the MDG goal Six of combating HIV/AIDS, Malaria and other diseases.

Significantly, in this study, one clinic did not conduct 99% of follow-up TB screens. A total of five clinics demonstrate a greater than 90% performance in failing to carry out follow-up TB screens. The most follow-up TB screens that any clinic performed amounted to 55.9%.

Matjila *et al.* (2008) discuss the PHC strategy as conveyed in the Alma Ata Declaration over 30 years ago, which continues to be the gold standard for health care in South Africa. According to Uwimana *et al.* (2012: 2) “The South African health system is rooted in the concept of primary health care”. The benefits for an integrated PHC approach are discussed by Sibiya (2009). This intervention offers support to HCW’s in the application of improved assessments and treatment for optimal health care. Furthermore, a combined PHC strategy assists with the attainment of national and provincial objectives to provide a comprehensive package of services.

Matjila *et al.* (2008) mention a study which investigated the combination of TB and HIV services at three sites; one in Malawi and two local sites in South Africa. The study proved that integrating TB and HIV services is feasible when carried out through a robust PHC approach. Uwimana *et al.* (2012) discuss the difficulty in accomplishing collaborative TB/HIV services in South Africa and most of sub-Saharan Africa due to the vertical nature of TB and HIV activities. The findings of their study highlighted the need for a clearer understanding of the term ‘integration’ amongst the managers and HCW’s. This was observed as an obstacle to improved joint HIV and TB service delivery.

The results of this study depict the contrasting numbers of follow-up TB screens that were carried out completely or incompletely per facility. The clinic that had performed the most follow up TB screens (55.9%) was also identified as the clinic with the highest percent (55.9%) of follow-up TB screens completely performed. Furthermore, this was also the only clinic that had performed above 30% of the follow-up screens completely. One clinic had 0% of follow-up screens carried out completely.

Several authors like Howard and El-Sadr (2010) and Getahun *et al.* (2010) describe the poor co-ordination between TB and HIV programmes which necessitates a strengthened public health response to integrate and scale up TB and HIV activities at a provincial and national level. An immediate recognition of TB symptoms in HIV infected individuals and prompt implementation of IPT or TB treatment is a strategy that is urgently required.

As stated by Laserson and Wells (2007), the Global Plan to Stop TB 2006-2015 is concerned with the bleak prospect of global objectives not been achieved due to the poor performance of Africa. They believe these universal targets are possible once TB and HIV integration strategies in Africa are strengthened.

5.8 LIMITATIONS OF THE STUDY

The study did not explore the reasons for the poor implementation of the TB symptom screening tool. More information could be acquired if the HCW's and PHC facility managers are studied as well. This research would benefit the health care profession and health system if their awareness, understanding and experiences are researched. Despite these limitations, the study does achieve the objectives elaborated upon in Chapter One.

5.9 CONCLUSION

This chapter discussed the findings of the study. Utilisation of a clinical audit framework facilitated the research by providing varied levels of information about TB symptom screening in HIV infected individuals in selected Primary Health Care clinics of eThekweni Municipality. HCW's in several facilities were attempting to implement TB symptom screening to an extent; however, the inconsistent and incomplete utilisation of this screening tool warrants an improvement to facilitate widespread success.

5.10 RECOMMENDATIONS

Based on the findings of the research, the following recommendations are presented to focus on the disparities identified by the study.

5.10.1 Policy Implementation

Despite the existence of national and provincial policies, there is poor implementation of the protocols. It is imperative that all relevant policies and

guidelines related to TB symptom screening be widely available in all health care facilities. HCP's and facility managers ought to be made aware of and trained in the application of these practices so that reliable and standardised health care can be offered.

5.10.2 Organisational Management and Practice

The literature reviewed identified an ineffectual collaboration between HIV and TB activities as a major cause of inadequate TB symptom screening in HIV positive individuals. Recommendations here include supportive management interventions, an evaluation of human and material resource distribution and improved interaction and feedback strategies between HIV and TB care. Combined TB and HIV care should be strengthened and aligned to existing policies and guidelines for facilitation of accessibility to all services and activities stipulated in the South African comprehensive package of services. This is essential for the application of monitoring, evaluation and reporting procedures to be ongoing and sustainable.

5.10.3 Further Research

The researcher recommends further research is undertaken on particular areas that were recognised during the study that will assist in the facilitation and strengthening of TB symptom screening. Complimentary research (qualitative) is required to evaluate the poor implementation of TB symptom screening, and the inadequate administration of IPT. In addition, an investigation into patients' perceptions of TB screening and IPT treatment would be beneficial.

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INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC)

7 February 2013

IREC Reference Number: REC 85/12

Mrs M Munsamy
32 Victory Drive
Ashley
Pinetown
3610

Dear Mrs Munsamy

A clinical audit of the implementation of the Tuberculosis screening tool amongst clients who are on anti-retroviral therapy in the eThekweni local municipality clinics

I am pleased to inform you that Full Approval has been granted to your proposal REC 85/12, subject to the following:

- Summary (3rd paragraph) and context of research (last paragraph): HIV people/ HIV population should read 'HIV infected/ positive people/ population.'
- The 'ethics clearance required' section on the first page must be ticked appropriately.
- Ethics checklist: number 13 should be ticked 'no.'

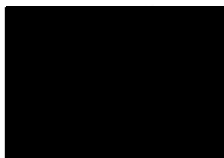
The Proposal has been allocated the following Ethical Clearance number IREC 008/13. Please use this number in all communication with this office.

Approval has been granted for a period of one year, before the expiry of which you are required to apply for safety monitoring and annual recertification. Please use the Safety Monitoring and Annual Recertification Report form which can be found in the Standard Operating Procedures [SOP's] of the IREC. This form must be submitted to the IREC at least 3 months before the ethics approval for the study expires.

Any adverse events [serious or minor] which occur in connection with this study and/or which may alter its ethical consideration must be reported to the IREC according to the IREC SOP's. In addition, you will be responsible to ensure gatekeeper permission.

Please note that any deviations from the approved proposal require the approval of the IREC as outlined in the IREC SOP's.

Yours Sincerely

Dr D F Naude
Chairperson: IREC

Appendix 2



Mrs. M Munsamy

32 Victory Drive

Ashley

Pinetown

3610

The Head of Health / Research Committee

eThekwini Municipality

9 Archie Gumede Place

Durban

4001

22 February 2013

Dear Madam

Requesting Permission to conduct a Study on TB Symptom screening

My name is Michelle Munsamy and I am a Masters student from the Durban University of Technology, Health Sciences: Nursing Department. I am requesting permission to conduct a study; the focus being on Adult Clinical Case Records of clients on Anti-retroviral therapy.

Title of the Research Study: A clinical audit of the implementation of the Tuberculosis screening tool amongst clients who are on anti-retroviral therapy in the eThekwini local municipality clinics.

Principal Investigator/s/researcher: Michelle Munsamy (B.Cur, B.Tech)

Co-Investigator/s/supervisor/s: Dr Izel Botha (Senior Lecturer – Dept of Homeopathy, DUT)

Outline of the Procedures: I am conducting a clinical audit focusing on Adult Clinical Case records of clients on Ant-retroviral therapy. The purpose of the study is to investigate the utilisation of the TB screening tool amongst clients on ARV therapy in the eThekweni local municipality clinics. Some of the research objectives are to identify whether the TB screening tool is consistently and correctly implemented and to investigate the relationship between the TB screening tool and the initiation of TB treatment or Isoniazid prophylactic therapy to prevent active TB.

A retrospective review of clients' case records will be conducted. There are approximately 60 local municipal Primary Health Care clinics in the eThekweni district, KwaZulu Natal. One quarter of the institutions that offer ARV services will be randomly selected as a sample and all patients meeting inclusion criteria from within the selected institutions will be investigated. The inclusion criteria for the study are adult clients older than 18 years of age, HIV positive clients who are on ARV treatment or who were on ARV treatment. I will therefore need to access the above case records to gain data on TB Symptom screening of clients on Anti-retroviral therapy.

Confidentiality: No staff or clients will be interviewed or required to participate. No names of clients will be used or recorded during the research. All information will be collected on an anonymous basis.

Persons to Contact in the Event of Any Problems or Queries:

Please contact the researcher Michelle Munsamy(0748994882), my supervisor Dr Izel Botha (0313732917.) or the Institutional Research Ethics administrator on 031 373 2900. Complaints can be reported to the DVC: TIP, Prof F. Otieno on 031 373 2382 or dvctip@dut.ac.za.

Your Co-Operation will be greatly appreciated. Please advise accordingly of your approval.

Kind Regards

Mrs. M Munsamy

Appendix 3

eTHEKWINI MUNICIPALITY
Community and Emergency Services Cluster
Health Unit

9 Old Fort Place
Durban, 4001

PO Box 2443
Durban 4000

Tel: 031-3111111
Fax: 031-311 3710

Website: <http://www.durban.org.za>



5 April 2013.

Dear Ms Michelle Munsamy,

Re: Permission to undertake research study: A clinical audit of the implementation of the Tuberculosis screening tool amongst clients who are on anti-retroviral therapy in eThekweni local municipality clinics.

Approval has been granted for you to undertake the above study at the following PHC facilities: Austerville, Adams, Chesterville, Clare Estate, Lovu, Woodhurst, Redhill, Caneside, Newlands West, Mpola, Tshelimnyama and Westville clinics.

The following to be noted:

- Submission of the indemnity form obtainable from the eThekweni Municipality Health Unit before commencement of the study.
- Prior arrangements to be made with the facility and an assurance that all services will not be disrupted.
- No staff member has to be used for data collection.
- Progress reports to be provided and the final report of the study to the eThekweni Municipality Health Unit.
- Obtain permission from the eThekweni municipality health department for press releases and release of results to communities/stakeholders.
- The department has to receive recognition for the assistance given.
- Any amended to the study to be communicated with the eThekweni Municipality Health Unit, and the relevant amendment form obtainable from the unit to be submitted.
- Withdrawal of permission to conduct research will be left to the discretion of the eThekweni Municipality Health Unit.

Yours faithfully,

Dr. [REDACTED]

Deputy Head of Health: eThekweni Municipality.

Date: 05TH APRIL, 2013



APPENDIX 4a

SAMPLING METHODOLOGY

SAMPLING PROPORTIONATELY OF 400 CASE RECORDS SELECTED FROM 12 OF THE 44 CLINICS ACROSS THE THREE SUB-DISTRICTS

| SUB-DISTRICT | NUMBER OF ARV CLINICS IN EACH SUB-DISTRICT | % OF ARV CLINICS IN EACH SUB-DISTRICT | NUMBER OF SAMPLE (CASE RECORDS) |
|---------------------|---|--|--|
| | | | |
| SOUTH | 25 | 57% | 228 |
| | | | |
| NORTH | 9 | 20% | 77 |
| | | | |
| WEST | 10 | 23% | 95 |
| | | | |
| TOTAL | 44 | 100% | 400 |

APPENDIX 4b

PROPORTIONATE SAMPLING PER CLINIC ACCORDING TO EACH SUB DISTRICT

| CLINICS | NUMBER OF ARV CASES | % OF CASE RECORDS | SAMPLE OF ARV CASE RECORDS |
|--------------------|----------------------------|--------------------------|-----------------------------------|
| | | | |
| SOUTH | | | |
| | | | |
| A | 116 | 7% | 16 |
| I | 536 | 31% | 70 |
| C | 380 | 21% | 50 |
| CE | 249 | 14% | 30 |
| A | 293 | 18% | 40 |
| WH | 82 | 9% | 22 |
| | | | |
| TOTAL | 1656 | 100% | 228 |
| | | | |
| NORTH | | | |
| | | | |
| R | 713 | 44% | 34 |
| CS | 193 | 12% | 9 |
| N | 705 | 44% | 34 |
| | | | |
| TOTAL | 1611 | 100% | 77 |
| | | | |
| WEST | | | |
| | | | |
| M | 385 | 40% | 37 |
| W | 422 | 45% | 43 |
| MR | 137 | 15% | 15 |
| | | | |
| TOTAL | 944 | 100% | 95 |
| | | | |
| GRAND TOTAL | 4211 | | 400 |



**TUBERCULOSIS (TB) SCREENING TOOL / RISK QUESTIONNAIRE
FOR HIV POSITIVE INDIVIDUALS**

Surname: _____ First Name: _____

Patient record or Folder Number: _____

Address: _____

Contact Number: _____

Date: __/__/____

| QUESTION | YES | NO |
|---|-----|----|
| 1. Has the client been coughing for 24 hours or longer? | | |
| 2. Has the client recently coughed blood in the sputum? | | |
| 3. Has the client experienced loss of appetite? | | |
| 4. Has the client experienced loss of weight? | | |
| 5. Has the client been sweating unusually at night? | | |
| 6. Has the client had recurrent fever / chills lasting more than three days? | | |
| 7. Has the client experienced chest pains, fast breathing and/or difficulty in breathing? | | |
| 8. Does the client have swellings in the neck, armpits or elsewhere? | | |

If "Yes" to one or more of the questions, suspect TB. Clinically evaluate the patient using National Guidelines for diagnosing TB. Enter the clients details in the **Suspect register** and continue with further investigations including Sputum for Microscopy.

If "No" to all questions, inform the patient on benefits of IPT (TB Preventive Therapy) and assess patient eligibility. Repeat the screening at every contact with the patient. Record the information on the Wellness / Pre-ART Register.

Complementary Questions:

| | | |
|---|--|--|
| 9. Has the client been treated for Tuberculosis? | | |
| If yes, when was the client treated for Tuberculosis? | | |
| 10. Was TB treatment completed? | | |
| 11. Has the client been in contact with someone diagnosed with Tuberculosis in the past year, e.g. same household | | |

