TREATMENT OUTCOME AMONG PATIENTS WITH TUBERCULOSIS AND TUBERCULOSIS CO-INFECTED WITH HIV/AIDS ON DOTS IN UNIVERSITY OF NIGERIA TEACHING HOSPITAL, ENUGU

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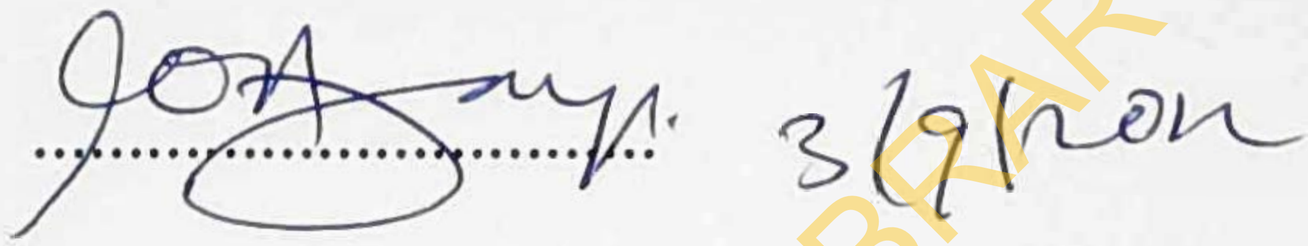
CERTIFICATION

We certify that this project was carried out under our supervision by ANIWADA Elias Chikee in the Department of Epidemiology and Medical statistics, Faculty of Public Health, College of Medicine, University of Ibadan.



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DEDICATION

In memory of my late dad, **Chief Elias Chikee Aniwada**

Ocho-udo 1 of Owa

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Thanks to the Almighty God who made it possible for me to be alive today, who has been guiding, protecting and caring for me in course of this work

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ABSTRACT

Nigeria is ranked 10th among the world TB most burdened country with an incidence of 133/100,000 , prevalence of 199/100,000 and death rate from TB dropped from11% in 2006 to 5% in 2010. The prevalence of HIV/AIDS is 4.1% in 2010 with HIV prevalence among adult TB cases being 27% in Nigeria. HIV pandemic has markedly increased TB incidence. There has been studies on TB treatment but very few compared those with TB alone and those coinfected with HIV. This study also aims to explore factors influencing the treatment outcomes.

The study utilized data from patient with smear sputum positive, enrolled in DOTS program and have completed treatment at Chest clinic University of Nigeria Teaching Hospital, Enugu. Data was collected from their case records and hospital registers and was analysed to determine factors that influenced treatment outcome and compare outcomes among patients with TB alone and those with TB coinfected with HIV. The association of the socio-demographic factors (age, sex, occupation) as well as other factors like CD4 count, disease status, distance covered to clinic with treatment outcome was ascertained using binary logistic regression model., Level of significance was at p=0.05.

A total of 437 patients who had sputum smear positive were studied out of which 66 of them were coinfected with HIV. Of the patients that tested positive for HIV, we could access CD4 count of 56 patients. Age group mostly affected by TB was 21-40years (60.7%).Mean age of patients was 35.32±14.33. Male to female ratio was 1.6:1. Apprentices/applicants, students, artisans were mostly affected. Males had higher prevalence of TB alone (62%) and females higher TB/HIV coinfection (53%). Median CD4 count was 203 cells/mm^3. Treatment outcomes incuded cured (73.7%), failure(1.8%), RAD(1.4%), Relapse(1.1%). Those that had TB alone had 76% cure against those with TB/HIV coinfection 62%. There was no association between treatment outcome and age categories, sex, occupation, CD4 count, but there were associations with disease status and distance from residence to clinic. Those that had TB coinfected with HIV were 1.7(95%CI: 0.980, 3.046) less likely to be cured than those with TB alone. Those that covered distances >20km were less likely to be cured when compared with those that covered < 20km.

Coinfection of TB/HIV constitutes a major threat to control of TB. HIV prevalence among TB patients and paucity of DOTS centres including poor citing of health facilities leading to distance in accessing TB care are some of the factors hampering treatment outcome. For treatment outcome to be improved HIV pandemic must be tackled and access to services addressed.

Keywords: Tuberculosis, Tuberculosis/Human Immunodeficiency Virus coinfection, Treatment outcome

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LIST OF ACRONYMS

TB	Tuberculosis
MDR-TB	Multiple Drug Resistance Tuberculosis
XDR-TB	Extensively Drug Resistant Tuberculosis
HIV	Human Immunodeficiency Virus
AIDS	Acquired Immune Deficiency Syndrome
UNFPA	United Nation Population Fund
FMOH	Federal Ministry of Health
UNAIDS	United Nation Action On Aids
WHO	World Halth Organisation
STD	Sexually Transitted Disease
NACA	National Agency Fof Control Of Hiv/Aids
RAD	Return After Default
ARV	Anti Retroviral Drugs
VCT	Voluntary Counseling And Testing
NTBLCP	National Tuberculosis And Leprosy Control Programme

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CHAPTER ONE

INTRODUCTION

1.0 Background

Tuberculosis and Human Immunodeficiency Virus are overlapping epidemics representing an enormous burden in terms of suffering, pain and grief globally.(WHO 2004) Tuberculosis and HIV/AIDS has been described by WHO as two monsters. They are among the three most recognized and targeted diseases afflicting developing countries. They have high mortality rates, killing millions of people each year, and most international efforts to control infectious disease focus on these diseases (Hotez et al 2008).

HIV is driving the TB epidemic in many countries, especially in sub-Saharan Africa and, increasingly, in Asia and South America. TB in populations with high HIV prevalence is a leading cause of morbidity and mortality. TB programmes and HIV/AIDS programmes therefore share mutual concerns. Human Immunodeficiency Virus (HIV) and Mycobacterium tuberculosis (TB) coinfection is a fast-growing problem in the AIDS pandemic in Africa and Asia.(Aaron et al 2004) The HIV pandemic has fueled a rise in both TB incidence and mortality, with an approximately 40% increase in incident TB cases compared to 20 years ago (UNAIDS "2008). In the USA, one quarter of all TB cases occur in HIV-infected persons (WHO 2009).

Many people who have the tubercle bacillus are not aware of it; the infection becomes reactivated when the body immune system is weakened by other infections such as the HIV. People living with HIV seem more vulnerable to tuberculosis (TB) than HIV uninfected persons. HIV promotes the progression of latent TB infection to active disease (Vazquez et al 1994) and it is responsible for the increase in the number of TB cases (Yassin et al 2004).

The emergence of multi-drug resistant TB (MDR TB) and the spread of HIV/AIDS are contributing to the worsening impact of TB as a disease. WHO estimated that 1.7% of all new TB cases may be resistant to first line anti-Tuberculosis drugs. This is the principal reasons for the WHO declaring TB a global emergency in 1993 (WHO TB report sheet 2000).

Nigeria is among the 22 high TB burden countries in the world and declared an emergency in 2003. Nigeria being the most populous country in Africa has the second(2^{nd}) highest burden of TB in Africa and fifth(5^{th}) in the world (World TB Report 2008). The prevalence is 600 and 610 per 100,000 by year 2000 and 2008 respectively with annual incidence rate of 270 and 300 per 100,000 in 2000 and 2008 respectively. There are 12.1% and 22.6% case detection rates in 2000

and 2007 under DOTS with mortality of 86 and 93 per 100 000 in 2000 and 2007 respectively (United Nations Statistical Division, MDG Database, June 2010).

There are promising interventions in Nigeria like adoption of new Stop TB Strategy, DOTS and increased access of PLWHA to ARV from 21% to 26% between 2007 and 2009. The new Stop TB Strategy being practiced in Nigeria is directed towards the overall target in MDG 6, target 8 and 9: to halt and begin to reverse the incidence of TB and HIV/AIDs by 2015. With full implementation of this Global Plan there is hope of major gains worldwide and the MDG 6 may be achieved globally, in most regions and countries including Nigeria. By 2015, global TB incidence could be reversed and its prevalence and mortality reduced by half compared to 1990 (Raviglione et al 2006, Stop TB Partnership and strategy 2006)

1.1 Statement of problem

The HIV pandemic has fueled a rise in both TB incidence and mortality, with an approximately 40% increase in incident TB cases compared to 20 years ago (Getahun et al 2010). Worldwide an estimated 1.37 million (14.8%) TB cases occur in HIV-positive persons, resulting in 456,000 TB-related deaths in this population. (WHO 2009). In the USA, one quarter of all TB cases occur in HIV-infected persons(Corbett et al 2003) and in Nigeria HIV prevalence among adult TB cases is 27%.(World TB Report 2008).

HIV/TB coinfection is particularly prevalent in populations with limited resources. Thus, the prevalence of HIV infection among patients with TB ranges from 50% to 80% in sub-Saharan Africa, as compared to 2–15% in other parts of the world (WHO 2009).

The increased number of reported TB cases is attributed to the deterioration in socioeconomic conditions, and the HIV epidemic. TB is the third most common AIDS-defining event; hence, increase in TB cases could be attributed to co-infection with HIV (Dalcolmo 1996).

Some international and very few local studies in recent time demonstrated that HIV infection has impacted negatively on TB treatment outcome. A 2006 cohort of TB/HIV dually infected patients in Cross River State showed 28% cure rate, 32% treatment completion rate and 21% death rate (NTBLCP. Annual report 2006).

Achieving STOP TB targets by the NTBLCP may remain a mirage considering these impacts of HIV epidemic on the TB control programme. The TB case detection rate and treatment success rate are only 31% and 79% respectively at the end of 2007 showing a minimal or no significant increase from 16.3% and 79% respectively in 2002 (NTBLCP. Annual report 2007).

The rise in TB suspects is putting a strain on diagnostic services. Extra-pulmonary and smear negative TB cases, which are more difficult to diagnose account for an increased proportion of total cases. There are more adverse drug reaction, high morbidity and mortality partly due to other curable HIV-related infections, high defaulter rate and cure rate, high rate of adverse drug reactions during TB treatment, increased risk of TB transmission, increased burden on TB services, delay of access to health services for TB suspects due to the stigma of HIV/AIDS. Increased smear negative tuberculosis cases has led to low case detection rate with risk of TB recurrence higher due to co-morbidity. (WHO 2004).

HIV infected patients who received a 6-month Rifampicin based course of Tuberculosis treatment or who received intermittent therapy had a higher relapse rate than HIV- infected subjects who received longer therapy or daily therapy, respectively. Standard 6-month therapy may be insufficient to prevent relapse in patients with HIV (Payam Nahid 2007).

Tuberculosis infection on its own exerts some impact on the HIV programme. These range from increased case load of active TB among PLWHA, acceleration of the progression of HIV related immuno-supression, increased morbidity and mortality from TB among PLWHA to increased burden on HIV services.

1.2 Justification for the study

Although a lot of studies has been done on HIV, TB, TB/HIV coinfection occurrence rates, little information is available on the treatment outcome among TB/HIV coinfected patients in Nigeria.

Intense transmission of M tuberculosis increases the pool of all people infected with HIV developing TB, and many TB patients are co-infected with HIV. Unfortunately at present only very small proportion of these patients have access to anti-retroviral treatment and even when available, there is ill management of TB/HIV co-infection thus impacting on treatment outcome.

Non-adherence to treatment poses a challenge to tuberculosis (TB) treatment since it increases the risk of drug resistance, death, relapse and prolonged infectiousness. TB patients co-infected with human immunodeficiency virus (HIV) constitute a large proportion of TB patients in Nigeria

This study aims to compare treatment outcome among patients with TB alone and those with TB coinfected with HIV placed on DOTS presenting at chest clinic in UNTH Enugu. The information provided in this study will show impact of HIV on treatment of TB. It may also be a

useful guide in planning or modifying TB control programs among HIV infected persons especially in this era of HIV pandemic.

1.3 Research Questions

This study addressed specific questions;

◊ What are the treatment outcomes of patients having TB alone on DOTs

◊ What are the treatment outcomes of patients having TB co-infected with HIV/AIDs on DOTs

◊ What are the differences in treatment outcomes in patients with TB alone and TB co-infected HIV/AIDS

◊ What factors influence treatment outcomes among patients with TB alone and those with TB co-infected with HIV/AIDS

1.4.1 General objective:

- To compare treatment outcome among TB and TB co-infected HIV/AIDS patients on DOTS

1.4.2 Specific objectives

1. To assess treatment outcomes of patients having TB alone on DOTs
2. To assess treatment outcomes of patients having TB co-infected with HIV/AIDs on DOTs
3. To compare outcomes in patients with TB alone and TB co-infected HIV/AIDS
4. To determine factors that influence treatment outcome among patients with TB alone and those coinfected with HIV/AIDS

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3. To compare outcomes in patients with TB alone and TB co-infected HIV/AIDS
4. To determine factors that influence treatment outcome among patients with TB alone and those coinfected with HIV/AIDS

CHAPTER TWO

LITERATURE REVIEW

2.1 The burden of TB, HIV and TB/HIV coinfection.

Worldwide, Tuberculosis (TB) incidence increased from 125 cases per 100,000 population in 1990 to 142 cases per 100,000 population in 2004, primarily because of the Human Immunodeficiency Virus (HIV) epidemic (WHO; 2010). According to the WHO Global TB Control report of 2008, worldwide, about 9.2 million new cases and 1.7 million deaths from TB occurred in 2006 and of these around 709,000 (7.7%) new cases and 200,000 deaths were estimated to have occurred in HIV positive individuals.[13] Persons with HIV are at increased risk for TB disease, and those with TB have a high risk for death. This is documented most clearly in resource-limited settings, where limited access to antiretroviral therapy (ART) and other health-care services contribute to the elevated mortality (WHO; 2010).

Despite the availability of highly efficacious treatment for decades, TB remains a major global health problem. TB is the second leading cause of death from infectious diseases worldwide after HIV, which caused an estimated 1.8 million deaths in 2008 (WHO; 2010). World Health Organization (WHO) declared TB a global public health emergency in 1993, at a time when an estimated 7–8 million cases and 1.3–1.6 million deaths occurred each year. In 2010, there were an estimated 8.5–9.2 million cases and 1.2–1.5 million deaths (including deaths from TB among HIV-positive people (World Health Statistics 2010). There were equally an estimated 8.8 million incident cases of TB (range, 8.5 million–9.2 million) globally, equivalent to 128 cases per 100 000 population. Most of the estimated number of cases in 2010 occurred in Asia (59%) and Africa (26%); small proportions of cases occurred in the Eastern Mediterranean Region (7%), the European Region (5%) and the Region of the Americas (3%). The five countries with the largest number of incident cases in 2010 were India (2.0 million–2.5 million), China (0.9 million–1.2 million), South Africa (0.40 million–0.59 million), Indonesia (0.37 million–0.54 million) and Pakistan (0.33 million–0.48 million) (WHO, 2011 TB prevalence surveys). India alone accounted for an estimated one quarter (26%) of all TB cases worldwide, and China and India combined accounted for 38%. In Nigeria Tuberculosis has remained a disease of major public health importance. Nigeria is one of the 22 countries that contributed 80% of the global

TB burden, with an estimated incidence and prevalence of is 133/100,000 and 199/100,000 populations respectively (WHO; 2010).

Of the 8.8 million incident cases in 2010 in Nigeria, 1.0 million– 1.2 million (12–14%) were among people living with HIV, with a best estimate of 1.1 million (13%). The proportion of TB cases co-infected with HIV is highest in countries in the African Region with African Region accounting for 82% of TB cases among people living with HIV. Women account for an estimated 3.2 million incident cases (range, 3.0 million–3.5 million), equivalent to 36% of all cases (WHO; 2010, WHO Report 2011; Global Tuberculosis Control).

There were an estimated 12.0 million prevalent cases (range, 11.0 million–14.0 million) of TB in 2010. This is equivalent to 178 cases per 100 000 population Globally, both incidence and prevalence rates fell slowly from 1990 to 1997, and then increased from 2001 as the number of TB cases in Africa was driven upwards by the HIV epidemic. Incidence rates peaked around 2004 in the African Region. However, current forecasts suggest that the Stop TB Partnership's target of halving TB prevalence by 2015 compared with a baseline of 1990 will not be met. Regionally Americas has halved the 1990 level of TB prevalence already, well in advance of the target year of 2015, the Western Pacific Region is close to doing so. Eastern Mediterranean, European and South-East Asia regions have been considerable since 1990, and appear to have accelerated since 2000. Nonetheless, current forecasts suggest that the 2015 target will not be reached. In African Region, estimates of TB prevalence rates are far from the target level, and halving the 1990 rate by 2015 appears unlikely (WHO Report 2011; WHO 2010).

Mortality rate due to TB is 20 deaths per 100 000 population globally (excluding deaths among HIV-positive people. (WHO, 2011 TB prevalence surveys, WHO Report 2011; Global Tuberculosis Control). Mortality rates are declining in all of WHO's six regions. The Region of the Americas and the Western Pacific Region have halved the 1990 level of mortality by 2000 and 2003 respectively, well in advance of the target year of 2015. The Eastern Mediterranean and European regions appear to have halved the 1990 level of mortality by 2010, and the South-East Asia Region is on track to reach the target by 2015. It is only in the African Region that the target of halving mortality rates by 2015 looks out of reach. In 2010, there were an estimated 650 000 cases of MDR-TB among the world's 12.0 million prevalent cases of TB (WHO Report 2011; Global Tuberculosis Control, WHO, 2009).

There are approximately 33 million HIV-infected persons worldwide, of whom approximately 2 million are children(UNAIDS "2008). An estimated 2 million deaths have been attributed annually to HIV/AIDS, with approximately 250,000 pediatric deaths. One third of the world's population is infected with Mycobacterium tuberculosis. In 2007, there were approximately 9.3 million incident cases of TB (WHO "Global Tuberculosis Control 2009), with an estimated 1 million of these occurring in children (Swaminathan et al 2010).

The first case of AIDS in Nigeria was identified in 1985 and reported at an International AIDS Conference in 1986. A sentinel surveillance system conducted among pregnant women age 15-49 years attending antenatal care (ANC) has been used to track HIV prevalence in the country since 1991. Information obtained from the ANC surveys shows that, nationally, HIV prevalence increased from 1.8 percent in 1991 to 4.6 percent in 2008. In 2008, state HIV prevalence rates ranged from 1.0 percent in Ekiti State to 10.6 percent in Benue State (FMoH 2008). In 1991, the average life expectancy was 53.8 years for women and 52.6 years for men (UNFPA 2005). The 2007 estimate had fallen to 50 for women and 48 for men (WHO. 2009). Life expectancy in Nigeria has declined partially as a result of the effects of HIV and AIDS.

2.2 Determinants and interaction of TB and HIV infection

The unholy alliance of TB and HIV and its impact on TB treatment outcome have been documented in a local study in Nigeria by a study at northern Nigera (Njepuome and Odume 2009). HIV/TB coinfection is particularly prevalent in populations with limited resources. Thus, the prevalence of HIV infection among patients with TB ranges from 50% to 80% in sub-Saharan Africa, as compared to 2–15% in other parts of the world. Approximately one-third of the world's 40 million people with HIV/Aids are co-infected with TB, and the mortality rate for HIV-TB co-infection is five-fold higher than that for tuberculosis alone. HIV/TB coinfected persons have been shown to have a higher mortality rate than those without either infection alone, regardless of CD4 count (López-Gatell et al 2007). TB accounts for 26% of AIDS-related deaths worldwide and 29% of TB-related mortality has been attributed to HIV infection(WHO 2009). This situation is made yet more urgent by the surging rates of multi drug-resistant TB (MDR-TB) in some areas with high HIV prevalence. Only one-in-ten people infected with TB develop active disease in their lifetime. HIV changes this equation. Of those whose immune systems have been weakened by HIV, 10 percent will develop active TB each year.

Poverty, low literacy levels, high rates of casual and transactional unprotected sex in the general population, particularly among youth between the ages of 15 and 24, low levels of male and

female condom use, cultural and religious factors, as well as stigma and discrimination are major factors in the transmission of HIV in Nigeria (NACA) [Nigeria]. 2007).

The rise in TB suspects is putting a strain on diagnostic services. Extrapulmonary and smear-negative pulmonary TB cases, which are more difficult to diagnose, account for an increased proportion of total cases. There are more adverse drug reactions. There is a higher morbidity and mortality, partly due to other, curable, HIV-related infections. The risk of TB reoccurence is higher. HIV is driving the TB epidemic in many countries, especially in sub-Saharan Africa and, increasingly, in Asia and South America. TB in populations with high HIV prevalence is a leading cause of morbidity and mortality. TB programmes and HIV/AIDS programmes therefore share mutual concerns (WHO report 2003, UNAIDS 2002).

Prevention of HIV should be a priority for TB control. TB care and prevention should equally be a priority concern of HIV/AIDS programmes. Previously TB programmes and HIV/AIDS programmes have largely pursued separate courses. However, a new approach to TB control in populations with high HIV prevalence requires collaboration between these programmes. HIV infection increases the demands on TB programmes, which are struggling to cope with the increased TB case load. (UNAIDS July 2002, UNAIDS. AIDS epidemic update: December 2002).

The concomitant treatment of HIV and active TB poses significant challenges, particularly relating to the duration and frequency of dosing of anti-TB drugs and the optimal timing of HAART initiation relative to TB treatment, which has important consequences vis-à-vis overlapping drug toxicities and drug-drug interactions between anti-TB drugs and antiretroviral drugs as well as the immune reconstitution inflammatory syndrome (IRIS).

Although current guidelines recommend a 6-month rifamycin-based regimen for treatment of drug-susceptible pulmonary TB regardless of HIV status (Hopewell et al 2007), the results of two randomized trials suggest that relapse rates after such therapy may be higher among HIV-infected persons than among HIV-uninfected persons (Fitzgerald et al 2000, Perriens et al 1995). A recent meta-analysis of randomized, controlled trials and cohort studies found that at least 8 months duration of rifamycin-based therapy, daily drug dosing during the initial phase of treatment, and concurrent antiretroviral therapy are associated with improved outcomes in HIV-associated TB (Khan et al 2010). Although intermittent dosing under direct observation is a mainstay of TB treatment regimens in the USA and elsewhere, highly intermittent (once or twice weekly) therapy has been associated with increased relapse rates in HIV-infected persons, often with acquired rifamycin resistance (Lutfey et al 1996),(Nolan et al 1995).

2.3 Effects of TB on HIV

Although the availability of antiretroviral therapy (ART) has transformed human immunodeficiency virus (HIV) infection into a chronic and manageable disease in those who are able to access treatment; the successes recorded can easily be destroyed by the high burden of tuberculosis (TB) co-infection in the HIV-infected population. Even after the initiation of ART, the incidence of HIV related TB remains unacceptably high (Badri, et al 2002, Lawn et al 2005, Giradi et al 2000). Therefore, prevention of TB is one of the most important measures that may help in reducing the morbidity and mortality associated with HIV infection particularly in countries with high burden of both infections.

Tuberculosis (TB) is the commonest opportunistic infection and the number one cause of death in HIV patients in developing countries, and accounts for about 40% of all manifestations seen in HIV patients (Pape 2004). About 25% to 65% of patients with HIV/AIDS have tuberculosis of any organ and tuberculosis accounts for about 13% of all HIV related deaths worldwide (Corbett et al 2003, Sharma et al 2004, Sharma et al 2005, Arora et al 1999, Gothi et al 2004). While tuberculosis prevalence has declined by more than 20% worldwide, the rates in Africa have tripled since 1990 in countries with high HIV prevalence and are still rising across the continent at 3–4% per year (WHO; 2005). TB cases occur in HIV-positive persons, resulting in 456,000 TB-related deaths in this population(WHO, "Global Tuberculosis Control 2009). TB accounts for 26% of AIDS-related deaths worldwide.

People with HIV are increasingly infected with tuberculosis because HIV weakens their immune system (Ministry of Health and Social Welfare Tanzania 2006). HIV/AIDS fuels the tuberculosis epidemics in many ways, such as promoting progression to active tuberculosis, increasing the risk of reactivation of latent tuberculosis infection, as well as increasing chance of tuberculosis infection once exposed to tubercle bacilli (Sharma et al 2005, Badri et al 2001). Autopsy studies have shown disseminated tuberculosis in 14–54% of HIV infected people in HIV prevalent countries, many of whom were undiagnosed prior to death (Haileyeus Getahun et al 2007). Although correct diagnosis and treatment of tuberculosis help to reduce the burden of tuberculosis, provided that infectious cases are detected and treated successfully, however there are difficulties in achieving the goal of reducing the tuberculosis burden due to a number of challenges, such as difficulties in diagnosing tuberculosis in HIV infected patients due to unusual clinical picture with increase in smear negative acid fast bacilli (AFB negative) pulmonary tuberculosis disease, and atypical findings on chest radiography (Lucas et al 1994, Jones et al 1993).

2.4 Effect of HIV on TB

The HIV pandemic has fueled a rise in both TB incidence and mortality, with an approximately 40% increase in incident TB cases compared to 20 years ago (Getahun et al 2010). In the USA, one quarter of all TB cases occur in HIV-infected persons (Corbett et al 2003) and worldwide an estimated 1.37 million (14.8%) TB cases occur in HIV-positive persons, resulting in 456,000 TB-related deaths in this population (WHO 2009). 29% of TB-related mortality has been attributed to HIV infection (Hotez et al 2008).

Human Immunodeficiency Virus (HIV) has contributed to a global resurgence of tuberculosis (Corbett et al 2003). In sub-Saharan Africa, the prevalence of HIV is about 5%-35% of the adult population, and one-third to one-half of HIV-infected individuals is co-infected with Mycobacterium tuberculosis(WHO, 2006). Most people infected with tuberculosis (TB) never get TB symptoms. This is called latent TB. People infected with HIV/AIDS are at increased risk of getting TB and about 30% of people with HIV who have latent TB will eventually get active TB. This results in an increase in the risk of earlier death (Akolo et al 2010).

HIV infection by impairing cell-mediated immunity is the most potent known risk factor for the reactivation of latent TB. The tuberculin skin test (TST) is the primary screening test for the diagnosis of latent TB. Although this test is over 100 years old, it represents the second longest standing test in use for TB after sputum microscopy (Mendelson 2011).

Whereas in the general population the lifetime risk of progression from latent TB infection to active disease is about 10%, HIV positive persons who are infected with M. tuberculosis have a 5-8% annual risk and a 30% lifetime risk of developing active tuberculosis and this risk increases as immune deficiency worsens (Williams et al 2003). A systematic review that included 10 trials published in 2004 showed that treatment of Latent TB infection reduces the risk of active TB in HIV positive individuals especially those with a positive Tuberculin skin test. (Woldehanna et al 2004)

HIV infection also has implications for the diagnosis and clinical presentation of TB. The proportion of PPD negative individuals with tuberculosis infection seems to be higher in HIV positive populations than in those who are not infected with HIV (Daniel et al 2000). Similarly, the percentage of sputum smear negative patients with active tuberculosis is higher in HIV

2.4 Effect of HIV on TB

The HIV pandemic has fueled a rise in both TB incidence and mortality, with an approximately 40% increase in incident TB cases compared to 20 years ago (Getahun et al 2010). In the USA, one quarter of all TB cases occur in HIV-infected persons (Corbett et al 2003) and worldwide an estimated 1.37 million (14.8%) TB cases occur in HIV-positive persons, resulting in 456,000 TB-related deaths in this population (WHO 2009). 29% of TB-related mortality has been attributed to HIV infection (Hotez et al 2008).

Human Immunodeficiency Virus (HIV) has contributed to a global resurgence of tuberculosis (Corbett et al 2003). In sub-Saharan Africa, the prevalence of HIV is about 5%-35% of the adult population, and one-third to one-half of HIV-infected individuals is co-infected with Mycobacterium tuberculosis(WHO, 2006). Most people infected with tuberculosis (TB) never get TB symptoms. This is called latent TB. People infected with HIV/AIDS are at increased risk of getting TB and about 30% of people with HIV who have latent TB will eventually get active TB. This results in an increase in the risk of earlier death (Akolo et al 2010).

HIV infection by impairing cell-mediated immunity is the most potent known risk factor for the reactivation of latent TB. The tuberculin skin test (TST) is the primary screening test for the diagnosis of latent TB. Although this test is over 100 years old, it represents the second longest standing test in use for TB after sputum microscopy (Mendelson 2011).

Whereas in the general population the lifetime risk of progression from latent TB infection to active disease is about 10%, HIV positive persons who are infected with M. tuberculosis have a 5-8% annual risk and a 30% lifetime risk of developing active tuberculosis and this risk increases as immune deficiency worsens (Williams et al 2003). A systematic review that included 10 trials published in 2004 showed that treatment of Latent TB infection reduces the risk of active TB in HIV positive individuals especially those with a positive Tuberculin skin test. (Woldehanna et al 2004)

HIV infection also has implications for the diagnosis and clinical presentation of TB. The proportion of PPD negative individuals with tuberculosis infection seems to be higher in HIV positive populations than in those who are not infected with HIV (Daniel et al 2000). Similarly, the percentage of sputum smear negative patients with active tuberculosis is higher in HIV

infected populations compared with HIV negative populations raising concerns for TB detection. Furthermore, extra-pulmonary tuberculosis is more common in patients with HIV infection than those who are not HIV-infected (Harries 1994).

The interaction between TB and HIV infection is complex. In the individual patient, HIV infection weakens the immune system and increases the susceptibility to TB. HIV increases the likelihood of reactivation, reinfection and progression of latent TB infection to active disease. It also alters the clinical presentation of TB, complicates the follow up and compromises the response to anti-TB treatment (MacDougall 1999).

According to the report by Diane Havlir of the WHO TB/HIV Working Group, the HIV epidemic has completely destabilised TB control in regions with high rates of HIV. For example, in one community of 13,000 people outside of Cape Town, South Africa, the TB patient caseload increased six-fold between 1996 and 2004, from 30 to 180 per year. Rates of TB in this community are over 150-fold higher than the national rates in many high-income countries.(Chakaya et al 2008)

Yet, according to the report, rates of multi drug-resistant tuberculosis (MDR-TB) and extensively drug-resistant TB (XDR-TB) are increasing dramatically and are often associated with HIV co-infection. The report cites an outbreak of HIV/XDR-TB in Tugela Ferry, South Africa, where the number of cases has increased five-fold in the last two years. All of the 53 people originally diagnosed with XDR-TB in this outbreak were co-infected with HIV. They suffered an extremely high mortality rate of 98 percent, and survived only an average of 16 days from the time of diagnosis. Since then, over 450 cases of MDR-TB have been reported in Tugela Ferry, of which 55 percent are XDR-TB cases, most co-infected with HIV. The mortality rate for XDR-TB has dropped slightly but is still high at approximately 85 percent, and even mortality rates among MDR-TB cases in this setting remain alarmingly high, approaching 70 percent.(Singh et al 2007)

HIV-mediated immunosuppression impairs granuloma formation, resulting in both ineffective containment of Mycobacterium tuberculosis bacilli and diminished formation of pulmonary cavities (MacDougall 1999). These effects manifest clinically as frequent extrapulmonary disease (Harries et al 2006), atypical chest radiographic findings (Reid et al 2006, Harries et al 2004), greater involvement of the lower lobes of the lung, and lower concentrations of bacteria in sputum (Ministry of Health of Ethiopia, 2004). The failure to rapidly detect TB in immunocompromised populations has important implications both for patient care and disease

control. Although the conventional wisdom is that smear-negative cases do not contribute significantly to transmission, it is not known whether this holds true in populations in which HIV-associated immunosuppression is common. What is clear is that the failure to detect TB early in HIV-coinfected individuals is lethal. Up to 20% of all patients with TB who have treatment initiated in sub-Saharan Africa die within a year (Peter Godfrey-Faussett et al 2004), and two-thirds of these deaths may occur in the first 2 months, which reflects the advanced state of illness at the time of final diagnosis. Whereas smear-negative TB has conventionally been regarded as a slowly progressive disease with limited mortality, in HIV-infected cohorts, patients with smear-negative disease often have poorer treatment outcomes and greater mortality than do their counterparts with smear-positive disease (Peter Godfrey-Faussett et al 2004, Narain JaiP et al 2004).

2.5 Control of TB and HIV

HAART also has been found to play an important role in preventing the development of active TB in HIV-positive patients, reducing the incidence of TB by up to 90% in patients receiving such therapy relative to those not receiving antiretroviral drugs (Lutfey et al 1996, Girardi,et al 2005, Santoro-Lopes et al 2002). However, despite viral suppression with HAART, the risk of TB remains higher in HIV-infected persons than in HIV-uninfected persons, suggesting incomplete immune restoration in the former group (Lawn et al 2006). Treatment of latent TB infection with isoniazid is highly effective in preventing the progression to active disease among HIV-infected persons (AIDS, vol. 13 1999, Wilkinson et al 1998). A recent meta-analysis of randomized controlled trials revealed a reduction in the incidence of active TB of over 30% in persons receiving chemoprophylactic treatment compared to those receiving placebo(Woldehanna et al 2004).

Previous studies showed that antiretroviral therapy (ART) can reduce the risk of death in patients co-infected with TB and HIV-1 (Manosuthi et al, 2006,Varma et al 2009). The World Health Organization recommends all TB/HIV-1 co-infected patients with clinical evidence of AIDS or a CD4 count < 350 cells/μl should initiate ART during TB treatment (Harries et al 2004).

The future course of the national response to the HIV and AIDS epidemic depends on a number of factors including levels of HIV and AIDS-related knowledge among the general population;

social stigmatisation; risk behaviour modification; access to quality services for sexually transmitted infections (STI); provision and uptake of HIV counselling and testing; and access to care and anti-retroviral therapy (ART), including prevention and treatment of opportunistic infections (UNAIDS/World Bank 2009).

2.6 Adverse events of drugs due to co infection

Concurrent treatment of TB and HIV is associated with a higher risk of adverse reactions compared to treatment of either infection alone. Hepatotoxicity is a side effect of both non-nucleoside reverse transcriptase inhibitor (NNRTI) and protease inhibitors based ART as well as first-line antituberculous drugs isoniazid, rifampin, and pyrazinamide (Burman et al 2001, Dean et al 2002). Study from Thailand report the rate of anti-TB drug induced hepatitis is 9.2% (Krittiyanant et al 2002) and the rate of NNRTI associated severe hepatotoxicity is 14% (Law *et al*, 2003). One study from another country reported the rate of NNRTI induced severe hepatotoxicity was 20% (Ena et al 2003). Co-administration of NNRTI with first line anti-TB drugs may have overlapping hepatotoxicity.

HIV-infected persons are at increased risk for isoniazid-induced peripheral neuropathy, these patients should take vitamin B6 and avoid antiretroviral drugs with potential peripheral neurotoxicity (e.g., stavudine and didanosine). Additionally, gastrointestinal distress and high pill burden can contribute to reduced tolerability and adherence to a combined TB/HIV therapeutic regimen (Ena et al 2003).

CHAPTER THREE

MATERIALS AND METHOD

3.1 Study area

The study area is University of Nigeria Teaching Hospital, Ituku-Ozalla, Enugu State. It is the oldest and biggest tertiary hospital in South Eastern Nigeria and the Center of Excellence in cardiothoracic surgery. It is located in one of the villages about 30 kilometers from Enugu town. Enugu state is located in the southeast geopolitical zone of Nigeria. It shares boundaries with Anambra on the West, Abia State on the South, Kogi on the North while Benue and Ebonyi on the East. Enugu was the headquarters of the former East Central State and Eastern Nigeria.

There are four tertiary health institutions which are the University of Nigeria Teaching Hospital (UNTH), Neuropsychiatric Hospital, the National Orthopaedic Hospital and the Enugu State University Teaching Hospital (ESUTH) all situated within Enugu urban.The total number of health facilities available is one thousand and ninety (1090), of which four hundred and sixty four (464) are public hospital and seventy six (76) are private health facilities (Enugu State ministry of Health).

3.2 Study Site

The study took place at Chest/Tuberculosis clinic of University of Nigeria Teaching Hospital Old site in Enugu. Data from HIV coinfected patients was sought from database of Presidential Emergency Plan For AIDS Relief (PEPFAR) program at UNTH located in Ituku-Ozalla.

The Chest clinic is one of the clinics still retained at the Old site with the rest at permanent site in Ituku-Ozalla. It is almost detached from the other units of the hospital and bound by a suburb Bunker (used during the war) and Coal camp (where miners lived in 70s). There are seven buildings housing TB consulting clinic, laboratory, medical records, male ward, female ward, drug resistant ward, nurses office, stores, security office and post.

The clinic is for management of TB cases. Doctors in the clinic consult also at HIV clinic. There is a laboratory scientist from HIV clinic attached to the clinic for counseling and testing of patients. This arrangement allows for comprehensive management of the patients especially those with TB/HIV co-infection. The centre serves as a major referral centre for all states in south east Nigeria.

There are twelve consultants, eighteen resident doctors, ten nurses, six health attendants/ ward orderliesin the clinic. The clinic runs thrice a week; Monday, Wednesday and Fridays with an average of two new patients per clinic, twenty four a month and about three hundred in a year.

3.3 Study population

This comprise patients attending Chest clinic who had TB alone and those who had TB coinfected with HIV commenced and completed on DOTS treatment.

3.4 Inclusion criteria:

All sputum smear positive AFB patients that enrolled during the study period (2008 to 2011) infected with TB alone or co infected with HIV/AIDs commenced on DOTS, completed treatment and discharged from treatment within specified study period

3.5 Exclusion criteria:

Patients that are smear negative AFB even if on treatment, with other illnesses, with TB or TB co-infected with HIV/AIDS but still on treatment

3.6 Study design:

This is a retrospective cohort study. It involved a retrospective review of the treatment outcomes among a cohort of patients with TB alone and those with TB co-infected with HIV who were initiated on TB treatment and completed treatment in the period 2008 to 2011.

3.7 Sampling method:

All patients that were enrolled for DOTS from 2008 to 2011 were studied.

3.8 Research tools:

Data collection form; used to gather information from medical records, treatment or case files and discharge summary records of patients selected for the study using the inclusion and exclusion criteria.

3.9 Procedure:

Medical records of patients who were initiated on TB treatment, completed treatment and discharged from treatment in the period 2008 to 2011 attending Chest clinic for DOTS were selected. Their treatment or case files and discharge summary records were reviewed for

extraction of relevant data. Their treatment outcome in terms of cured, failure, relapse and return after default were determined.

3.10 Definition of treatment outcomes (WHO)

Cured Patient that started treatment as sputum smear positive and at seventh month follow up tested negative, goes on to complete treatment and discharged

Failure Patient that started treatment as sputum smear positive and at fifth month follow up still tested positive.

Relapse Patient that started treatment as sputum smear positive and at seventh month follow up tested negative, goes on to complete treatment and discharged but returns later to clinic sputum positive.

Return After Default (RAD) Patient that started treatment as sputum smear positive, has been on treatment for four weeks (one month) and defaulted on follow up for eight weeks then comes back for treatment.

Treatment completed: Patient that started treatment as sputum smear positive, completed treatment but the smear examination results were not available at discharge or end of treatment.

3.11 Data management

3.11.1 Data collection

This was done using treatment or case files and discharge summary records of patients. A Proforma was used to extract required information. All cases were reviewed and only those with and four hundred and thirty seven that had all the needed information or data were included in this study.

3.11.2 Variable Definition

3.11.2a Outcome variable

The outcome variable used in this study was TB treatment outcome including cured, failure, relapse, RAD and treatment completed

3.11.2b Explanatory variables

The independent variables used in this study were age, sex, occupation, distance from residence to clinic, disease status (TB alone and TB coinfected HIV), CD4 count,

3.12 Data Analysis

Data analyses were carried out with Statistical Package for Social Sciences (SPSS) version 15. This was based on comparing treatment outcome among patients with TB alone and with TB coinfected HIV/AIDS

Frequency tables were used to describe and summarize variables of interest. Cross tabulations were carried out, using Chi-square test to investigate association between the categorical dependent and independent variables at 5% level of significance. Variables that were significant at 5% level of significance were employed in the logistic regression model using the outcome variable; not cured = 0 and cured = 1.

The logistic regression model

The existence of an unobserved continuous variable, Z is considered in the logistic regression, and is usually referred to as the 'propensity towards' the event of interest. For the purpose of this research, as in the case of treatment outcome, Z represents the propensity of not being cured with high values of Z corresponding to greater probabilities of not being cured.

The link function below describes the relationship between Z and the probability of the event of interest in SPSS as far as logistic regression model is concerned (Norusis, 2004).

$$\prod_i = \frac{e^{Z_i}}{1+e^{Z_i}} = \frac{1}{1+e^{-Z_i}}$$

Or

$$Z_i = \log\left(\frac{\prod_i}{1-\prod_i}\right)$$

Where

$\prod_i$ is the probability the i^{th} case experiences the event of interest.

Z_i is the value of the unobserved continuous variable for the i^{th} case

The model also assumes that Z is linearly related to the predictors.

$$z_i = b_0 + b_1 x_{i1} + b_2 x_{i2} + \ldots\ldots + b_p x_{ip}$$

Where

x_{ij} is the j^{th} predictor for the i^{th} case

b_j is the j^{th} coefficient

p is the number of predictors

If Z were observable, linear regression to Z would have been simply fit. However, since Z is unobserved, the predictors must be related to probability of interest, by substituting for Z.

$$\prod_i = \frac{1}{1+e^{-(b_0+b_1x_{i1}+\ldots+b_px_{ip})}}$$

The regression coefficients are estimated through an iterative maximum likelihood method.

In simple words, in the logistic regression model, we postulate that the probability, P_x of not being cured, depends on a set of X of 'n' factors $X_1, X_2, \ldots\ldots\ldots\ldots\ldots X_3$ in the following way:

$$= \frac{1}{1+\exp[-(\beta_0+\beta_1X_1+\ldots\ldots+\beta_nX_n)]}$$

Where F is a dichotomous variable denoting treatment outcome,

$F = 1$ if cured

$F = 0$ if not cured

The β's are the parameters that represent the effects of the X_i on the probability of not being cured. The β's represent regression coefficients which are estimated through an iterative maximum likelihood method and the exponentials of these regression coefficients give the odds ratios in the models.

The odds ratio for not being cured is: $P_x/q_x = \exp(\beta_0+\beta_1X_1+\ldots\ldots+\beta_nX_n)$

Where $q_x = 1 - P_x$

$\log_e(P_x/q_x) = \beta_0+\beta_1X_1+\ldots\ldots+\beta_nX_n$

Each category of the independent variables was compared to the reference category and the corresponding statistics – B, standard error, Wald, degree of freedom, significance and $ExpB$ was computed.

In each of the models that were generated, $ExpB$ represents the ratio in the odds of not being cured for one unit change in the predictor. The constant term indicated in each model represents the intercept of the logistic regression model equation.

CHAPTER FOUR

RESULTS

4.1 Frequency distribution of patients by selected Socio-demographic characteristics

The age distribution of patients in the survey shown in Table 4.1, over half of the patients (60.7%) were between ages 21 and 40, while 30.2% of the patients were 41 years and above, with the remaining 9.2% of the patients 20 years and below. The mean age of the patients was 35.32.± 14.33

Most of the patients (60.2%) were males while 39.4% were females.

The distribution of patients by occupation as shown in Table shows that there was no obvious occupational predominance though students had highest proportion of 22.4% and farmers lowest at 8.9%. In all over half (53.3%) of patients were students, artisans and applicants.

Table 4.1 Distribution of patients by sociodemographic variables

Sociodemographic variables	Number	Percent(%)
Age in categories		
<20	40	9.2
21-30	172	39.4
31-40	93	21.3
41-50	61	14.0
51-60	42	9.6
>60	29	6.6
Sex	263	60.2
Male	174	39.8
Female		
Occupation		
Civil servant/public servant	80	18.3
Student	98	22.4
Artisan	66	15.1
Applicant/apprentice	69	15.8
Farmer	39	8.9
Others mainly traders	85	19.5
Total	437	100.0

4.2 Frequency distribution of patients by distance from residence to clinic

The distribution of the patients according to the distance the patients had to cover to get to clinic as shown in Fig. 4 below, over two third(76.4%) of the patients covered 20 and less kilometers(km) while 13.3% covered between 21 and 40km with the remaining 10.2% covering 41km and above.

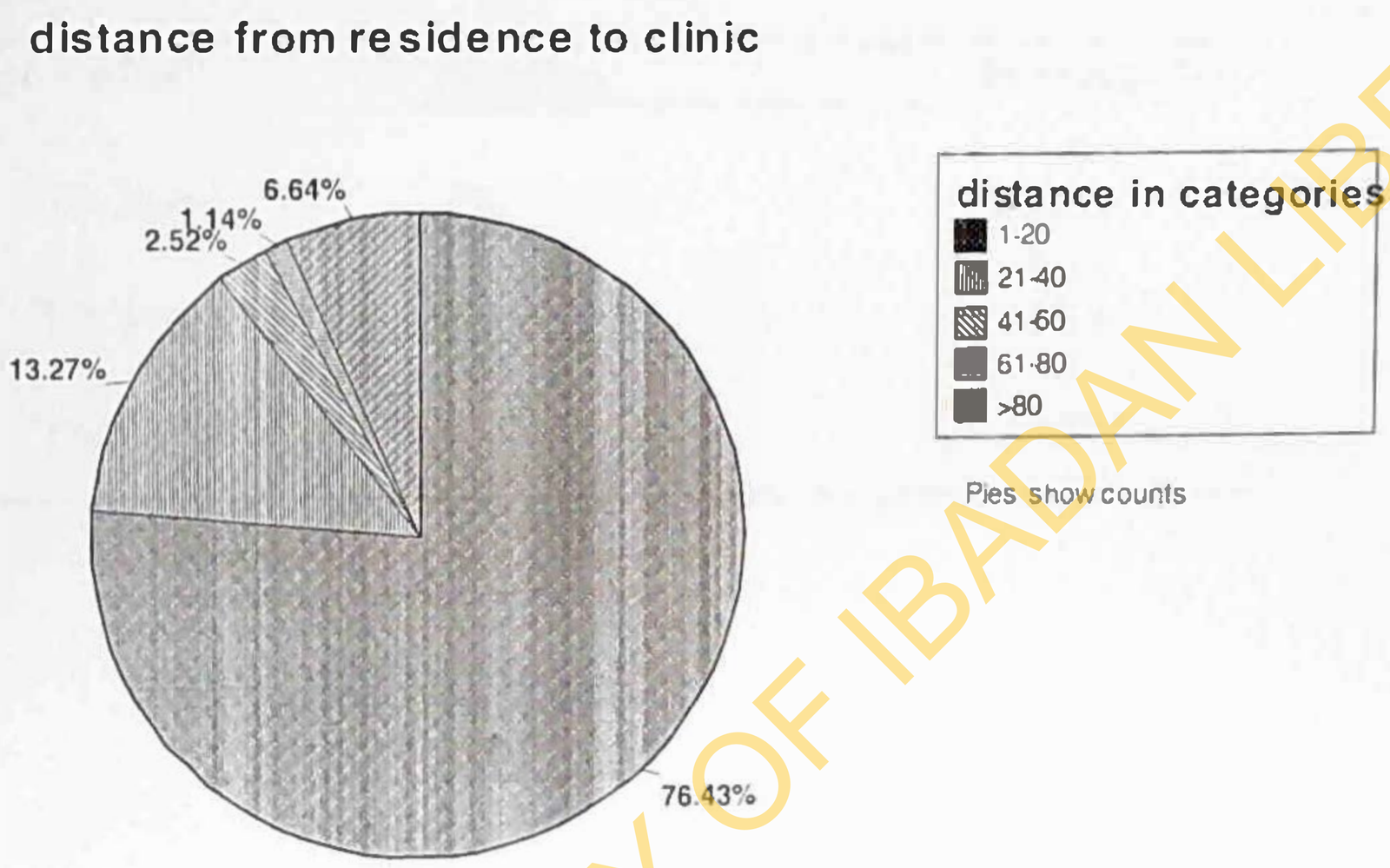

Fig. 1 Distribution of patients by distance from residence to clinic

From the distribution of the patients by disease status in Table 4.2 below, it could be seen that 84.9% of the patients had TB alone while 15.1% had TB coinfected with HIV. There was higher proportion of males having TB alone(62.5%) but higher proportion of females with TB/HIV coinfection(53.0%).

Table 4.2 Distribution of patients by Disease status

Disease status	Number	Percent(%)
TB alone	371	84.9
TB with HIV	66	15.1
Total	437	100.0

From table 4.3 below, Of the 56 patients that had TB/HIV whose CD4 count were recorded, over two third (75.9%) of those who were coinfected with TB and HIV has CD4 count below 350 and about one third remaining (24.1%) above 350.The mean (□) CD4 count is 253.57 ±195.71 cell/mm^3 and was in range of 21 to 764 cell/mm^3

Table 4.3 Distribution CD4 count of TB/HIV patients

CD4 count	Frequency	Percent(100%)
Above 350	13	24.1
Below 350	41	75.9
Total	54	100.0

Table 4.4 shows that majority of the patients (73.7%) were declared cured at end of treatment. While those with Tb alone had 75.7% cure, those with TB/HIV coinfection had 65.1%. Failure cases were 1.8%, Return After Default were 1.4% and Relapse 1.1%. The remaining 22.0% either defaulted without returning or outcome unknown.

In same table when recoded into cured and not cured, 73.7% were cured with 26.3% not cured (Failure, Return After Default, Relapsed, unknown, Defaulted without returning to clinic).

Table 4.4. 1: Distribution of patients by Treatment Outcome

Treatment outcome	Disease status		Total(%)
	TB alone Number(%)	TB/HIV Number(%)	
In 6 categories			
Cured	281(75.7)	41(62.1)	322(73.7)
Failure	8(2.2)	0.(0.0)	8(1.8)
Return after default	6(1.6)	5(7.6)	11(2.5)
Relapse	5(1.3)	0.(0.0)	5(1.1)
Rx completed	42(11.3)	11(16.7)	86(19.7)
Others(*)	29(7.8)	9(6.0)	38(8.6)
In 2 categories			
Cured	282(76.0)	41(62.1)	323(73.9)
Not cured	89(24.0)	25(37.9)	114(26.1)
Total	**371(100.0)**	**66(100.0)**	**437(100.0)**

Rx completed = treatment completed; Others(*) = dead, unknown, transferred out

4.5 Associations on disease status

From table 4.5.1 below, there was significant higher proportion of all age category having TB alone compared to those coinfected with TB/HIV with age categories >60 years, 21-30 years and <20 years more. Equally there was a higher proportion of males having TB alone (88.2% against 79.9%) while in TB/HIV coinfection females were higher than males (20.1% against 11.8). this is significant with p value of 0.02. there was no significant association among the occupations even though had higher proportion of TB alone with other occupation similar proportion.(p=0.095) .

4.5.1 Association between disease status and sociodemographic variables

	Disease status		Total (%)	Test statistic (χ^2)	P-value
	TB alone(%)	TB/HIV(%)			
Age in categories					
< 20	36(90.0)	4(10.0)	40(100)		
21-30	156(90.7)	16(9.3)	172(100)		
31-40	66(71.0)	27(29.0)	93(100)		
41-50	51(83.6)	10(16.4)	61(100)	23.06	0.000
51-60	34(81.0)	8(19)	42(100)		
> 60	28(96.6)	1(3.4)	29(100)		
Sex of patient					
Male	232(88.2)	31(11.8)	263(100)	5.664	0.020
Female	139(79.9)	35(20.1)	174(100)		
Occupation					
Civil/public servant	64(80.0)	16(20.0)	80(100)		
Student	91(92.9)	7(7.1)	98(100)		
Artisan	57(86.4)	9(13.6)	66(100)		
Applicant/apprentice	60(87.0)	9(13.0)	69(100)	9.37	0.095
Farmer	32(82.1)	7(17.9)	39(100)		
others	67(78.8)	18(21.2)	85(100)		
Total	371(84.9)	66(15.1)	437(100)		

Distance from residence to clinic had been shown below to be significantly associated with disease status, (p= 0.014)

4.5.2 Association between disease status and distance from residence to clinic

Distance to clinic	Disease status		Total (%)	Test statistic (χ^2)	P-value
	TB alone(%)	TB/HIV(%)			
0-20	294(88.0)	40(12.0)	334(100)		
21-40	45(77.6)	13(22.4)	58(100)		
41-60	7(63.6)	4(36.4)	11(100)		
61-80	4(80.0)	1(20.0)	5(100)	12.46	0.014
>80	21(72.4)	8(27.6)	29(100)		
Total	371(84.9)	66(15.1)	437(100)		

Patients aged 21-30 years were significantly 1.16 times less likely to be coinfected with TB/HIV and those over 60 years were not significantly 3.00 times less likely while those aged 31-40, 41-50, 51-60 years were not significantly 3.39, 1.63, 1.20 times as likely respectively.

Females were significantly more likely (OR=1.908)

Those covering distance of 21-40, 41-60, 61-80 and over 80km were 2.03, 3.94, 2.06 and 2.696 times as likely as those for 20 km and below with only those covering 80km and above statistically significant.

Table 4.5.3 Logistic regression on factors influencing disease status

	B	S.E	Sig	Exp(B)	95% C.I. for EXP(B)	
					Lower	Upper
Age in categories						
<20 (R)						
21-30	-0.155	0.597	0.796	0.857	0.266	2.762
31-40	1.220	0.585	0.037	3.388	1.077	10.655
41-50	0.486	0.644	0.451	1.626	0.460	5.744
51-60	0.671	0.670	0.317	1.956	0.526	7.265
>60	-1.099	1.165	0.364	0.333	0.034	3.267
Sex of patient			0.023			
Male (R)						
Female	0.646	0.285		1.908	1.092	3.334
Distance to clinic						
0-20 (R)						
21-40	0.707	0.373	0.058	2.028	0.977	4.212
41-60	1.372	0.715	0.055	3.944	0.971	16.013
61-80	0.721	1.263	0.568		0.173	24.456
				2.056		
>80	0.992	0.468	0.034		1.076	6.750
				2.696		

-2 Log L = 496.387 χ^2 = 1.323 (R)= Reference category

4.6 Associations between treatment outcomes and explanatory variables

The cross tabulation result of treatment outcome with sociodemographic variables shown in Table 4.6.1 below, for age in categories, the proportion of patients cured through all age categories was over two third with highest proportion (80%) belonging to the age group 0-20 years, as compared to 76.2% of the patient in the age group 21-30 years. The lowest proportions(68.9% and 69.0%) of the patient with cured treatment outcome were in 41-50 years and above 60 years respectively. This was not statistically significant at (p= 0.766)

From same table on cross tabulation result of treatment outcome with sex of patient, a very similar treatment outcome was observed between males and females with 73.4% and 74.7% cured respectively. (p= 0.82)

Similarly 78.3% of the patients that were applicants/apprentice were cured compared to 77.3% and 76.5% for artisans and students respectively.71.8% of others majorly traders and 70.0% of civil/public servants were equally cured. Farmers had the lowest proportion at 66.7%. This was not statistically significant.(p= 0.652).

Table 4.6.1 Association between Treatment outcome and sociodemographic variables

	Treatment outcome		Total (%)	Test statistic (χ^2)	P-value
	Cured(%)	Not Cured(%)			
Age in categories					
< 20	32(80.0)	8(20.0)	40(100)		
21-30	131(76.2)	41(23.8)	172(100)		
31-40	67(72.0)	26(28.0)	93(100)		
41-50	42(68.9)	19(31.1)	61(100)	3.004	0.766
51-60	31(73.8)	11(26.2)	42(100)		
>60	20(69.0)	9(31.0)	29(100)		
Sex of patient					
Male	193(73.4)	70(26.6)	263(100)	0.096	0.824
Female	130(74.7)	44(25.3)	174(100)		
Occupation of patient					
Civil/public servant	56(70.0)	24(30.0)	80(100)		
Student	75(76.5)	23(23.5)	98(100)		
Artisan	51(77.3)	15(22.7)	66(100)	3.312	0.652
Applicant/apprentice	54(78.3)	15(21.7)	69(100)		
Farmer	26(66.7)	13(33.3)	39(100)		
Others esp Traders	61(71.8)	24(28.0)	85(100)		
Total	323(79.3)	114(26.1)	437(100)		

From table 4.6.2 below showing cross tabulation result treatment outcome with distance the patient has to cover from residence before getting to clinic to access care, the highest proportion of cured (77.5%) was for those who cover 20 kilometres or below followed by those that live very far away (>80km). Patients covering 61 to 80 kilometres and 41 to 60 kilometers had the least cure proportions at 40.0% and 54.5% respectively. This observed difference was statistically significant (p= 0.017).

Table 4.6.2 Association between Treatment outcome and distance to clinic

Distance to clinic	Treatment outcome		Total (%)	Test statistic (χ^2)	P-value
	Cured(%)	Not Cured(%)			
0-20	259(77.5)	75(22.5)	334(100)		
21-40	36(62.1)	22(37.9)	58(100)		
41-60	6(54.5)	5(45.5)	11(100)	11.995	0.017
61-80	2(40.0)	3(60.0)	5(100)		
>80	20(69)	9(31.0)	29(100)		
Total	323(73.9)	114(26.1)	437(100)		

The result of the cross tabulation between treatment outcome and disease status as shown in table 4.6.3, the proportion of cured among patients with TB alone compared with those with TB coinfected with HIV was 76.0% against 62.1% respectively. This observation was statistically significant (p = 0.022)

Table 4.6.3 Association between Treatment outcome and Disease status

Disease status	Treatment outcome		Total (%)	Test statistic (χ^2)	P-value
	Cured(%)	Not Cured(%)			
TB alone	282(76.0)	89(24.0)	371(100)		
TB/HIV coinfection	41(62.1)	25(37.7)	66(100)	5.606	0.022
Total	323(73.9)	114(26.1)	437(100)		

Table 4.6.4 below shows the cross tabulation result of treatment outcome with CD4 count of TB/HIV patients. A higher proportion 69.2% of the patients who had CD4 count above 350 as compared to 58.5% of those who had CD4 count below were declared cured. This result was not statistically significant (p= 0.54)

Table 4.6.4 Association between Treatment outcome with CD4 count

CD4count of patients	Treatment outcome		Total (%)	Test statistic (χ^2)	P-value
	Cured(%)	Not Cured(%)			
Above 350	9(69.2)	4(30.8)	13(100)		
Below 350	24(58.5)	17(41.5)	41(100)	0.475	0.536
Total	33(61.1)	21(39.9)	54(100)		

From table 4.6.5 below, patients that covered 21-40 km were 50% as likely to be cured when compared to patients that covered 0-20 km. This observation was statistically significant . Those that covered 41-60 km, 61-80 km, over 80 km are 40%, 20%, 70% as likely not to be cured when compared with patients that covered between 0-20 km. They were not statistically significant.

Patients that have TB coinfected with HIV were 60% as likely to be cured compared to the patients infected with TB alone. However, this observed difference was not statistically significant at (p= 0.059).

Table 4.6.5 Logistic regression on factors influencing treatment outcome

	B	S.E	Sig	Exp(B)	95% C.I. for EXP(B)	
					Lower	Upper
Distance to clinic						
0-20 (R)						
21-40	-0.693	0.304	0.022	0.500	0.276	0.907
41-60	-0.930	0.628	0.139	0.395	0.115	1.351
61-80	-1.615	0.927	0.081	0.199	0.032	1.224
>80	-0.393	0.424	0.409	0.702	0.304	1.624
Disease status						
TB alone (R)						
TB/HIV coinfection	-0.547	0.289	0.059	0.579	0.328	1.021

-2 Log L = 487.135 **(R)= Reference category**

Those coinfected with TB/HIV were 1.9 times less likely to be cured compared with those with TB alone and this was statistically significant as shown in Table 4.6.6 below

On adjusting for other variables as shown on Table 4.6.6 below, those coinfected with TB/HIV were 52% as likely to be cured as those wth TB alone. Females were 1.12 times as likely to be cured as males. Students were 97% as likely to be cured as civil or public servants while artisans, applicant/apprentice, farmers and others had 1.26 times, 1.28times, 1.35times, 1.20 times respectively as likely to be cured.

Patients in age categories 21-30, 31-40, 41-50, 51-60 and >60 years were 73%, 69%, 53%, 68% and 55% as likely to be cured as those <20 years. Those who covered distances of 21-40, 41-60, 61-80 and >80km were 48%, 39%, 21% and 35% as likely to be cured when compared with those covering <20 km

Table 4.6.6 Logistic regression on influence of disease status on treatment outcome

Variables	B	S.E.	Sig	Exp(B	95% C.I.for exp(B)	
					Lower	Upper
Disease status (unadjust)						
TB alone (R)						
TB/HIV coinfection	0.659	0.281	0.019	0.518	0.298	0.898
Disease status(adjusted)						
TB alone (R)						
TB/HIV coinfection	-0.560	0.303	0.065	0.571	0.316	1.034
Age group						
< 20 (R)						
21-30	-0.314	0.479	0.512	0.731	0.286	1.867
31-40	-0.372	0.574	0.517	0.690	0.224	2.124
41-50	-0.632	0.634	0.319	0.532	0.153	1.842
51-60	-0.391	0.675	0.563	0.677	0.180	2.542
> 60	-0.597	0.722	0.408	0.550	0.134	2.267
Sex						
Male (R)	0.110	0.235	0.641	1.116	0.704	1.769
Female						
Occupation						
Civil/public servant(R)						
Student	-0.033	0.466	0.943	0.967	0.388	2.412
Artisan	0.234	0.413	0.571	1.264	0.562	2.840
Applicant/apprentice	0.246	0.451	0.586	1.279	0.528	3.096
Farmer	0.299	0.485	0.538	1.349	0.521	3.489
Other esp trader	0.173	0.362	0.632	1.189	0.585	2.415
Distance to clinic						
0-20(R)						
21-40	-0.732	0.331	0.027	0.481	0.251	0.920
41-60	-0.935	0.646	0.148	0.392	0.111	1.393
61-80	-1.550	0.958	0.106	0.212	0.032	1.387
>80	-0.411	0.443	0.353	0.663	0.278	1.579
				4.613		

-2log L=484.466 (unadjusted) -2logL=496.387 (adjusted) R=Reference

CHAPTER FIVE

DISCUSSION, CONCLUSION AND RECOMMENDATION

5.1 DISCUSSION

5.1.1 Socio-demographic characteristics of and other factors in study population

TB poses significant challenges to developing economies as it primarily affects people during their most productive years. Over half of the patients (60.7%) were between ages 21 and 40years, with mean age of 35.32 ± 14.3years. The finding was consistent with previous reports in developing countries(Ige and Oladokun 2011, Njepuome and Odume 2009, Fatiregun et al 2009, Erhabor et al 2003).' However, TB has been reported to be two-to-four times more prevalent among the elderly age group in developed countries(Davies 1991).

Most patents (60.6%) were males and male to female ratio was 1.6.The observation was consistent with findings in similar studies in Nigeria. (Nwakchokor and Thomas 2000, Salami and Oluboyo 2003) The male: female ratio in a study on risk of TB among dialysis patients was 1.8(Christopoulos et al 2009),

TB is closely associated with poor living conditions, poverty, and low socioeconomic status. From the study there was no obvious occupational predominance though students had highest proportion of 22.4% and farmers lowest at 8.9%. In all over half (53.3%) of respondents were students, artisans and applicants who comprised young dependants with poor means of livelihood, habitate congested apartments like hostels and camps. Similar study at Ife, low socioeconomic status, overcrowding, and poor living conditions were identified as major risk factors in the development of pulmonary TB.(Erhabor et al 2003)

Over two third(76.4%) of the patients covered 20 and less kilometers(km) to clinc with very few coming from far places (> 80km) who were usually admitted. The mean distance was 23.36±18.43km. This is far from DOTS strategy recommendation of 5 km so that patients can be monitored adequately.(WHO 2005).

From the distribution of the patients by disease status, 84.9% of the patients had TB alone while 15.1% had TB coinfected with HIV. Significantly there is higher proportion of males having TB alone(62.5%), but higher proportion of females with TB/HIV coinfection(53%). This is similar to the national values for 2007 TB which has up to 65% of males having sputum smear-positive results (Federal Ministry of Health 2007). This value is expected as males in sub-Saharan Africa are more exposed to predisposing factors for infection than females, being more active and socializing. Social inequalities, including gender and power relations, have an important impact

on HIV transmission (Sweet and Denison 2008). Recent reviews also suggest that women in many parts of the developing world has little or no say on how, when, and where sex takes place thereby increasing the likelihood of HIV infection in them (Aggleton and Rivers 2007). Female anatomy and socio-cultural factors also contributes to the situation.

The study showed that majority of the patients(73.7%) were declared cured at end of treatment. The findings were similar to other studies in Nigeria by Ige and Oladokun 2011, ,Fatiregun et al 2009, Egbewale et al 2007 which had cure rate of 70-80% and study in Europe by Faustini et al 2005 with cure about 75%. Other outcomes from the study of Failure 1.8%, Return After Default 1.4%, Relapse 1.1%. were different findings in another study among pregnant women in south west Nigeria of 8.5% relapsed, 12.8% treatment failures. (Adebimpe Wasiu et al 2011). Even with this encouraging result, findings from the study is below the recommended target of 85% by the WHO so there is need to improve on the outcomes (WHO 2005).

Two third (62.5%) of those who were coinfected with TB and HIV had CD4 count below 350 cells/mm^3 with mean (□) CD4 count 253.57±195.71 cell/mm^3. This was not far from expected as TB being the commonest opportunistic infection occurs as immunity drops. The finding though was in contrast with observation in Port Harcourt where the mean CD4 lymphocyte count of the HIV-infected subjects was 195 ± 40.5cells/μL. (Erhabor et al 2010)

5.1.2 Factors associated with Treatment Outcomes

There was no significant association between treatment outcome and age. Proportion of patients cured through all age categories was over two third with highest proportion (80%) belonging to the age group 0-20 years, even though there were higher prevalence among some ages, these do not in any way influence or affect treatment outcome. This was supported by study on treatment outcomes done at General hospitals in Ogbomosho which showed no better treatment outcome among any age category (Egbewale et al 2007)

A very similar treatment outcome was observed between males and females. This result was not statistically significant indicating no association in treatment outcomes between males and females (Diel and Niemann 2003, Fatiregun et al 2009) though in line with findings by Egbewale et al in south west Nigeria where both sexes had similar outcome.(Egbewale et al 2007)

There was no significant association between treatment outcome and occupation even when study showed people of low socioeconomic group being more affected (students,

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There was no significant association between treatment outcome and occupation even when study showed people of low socioeconomic group being more affected (students,

applicant/apprentice, artisan). Itah et al in his study showed traders, health workers and food vendors as having higher prevalence but no association with treatment outcome.(Itah et al 2000)

Distance from residence to clinic showed a significant association with treatment outcome. Patients that covered 20km and below as well as ab0ve 80km had a better outcome. This most likely is due to better compliance to treatment. Those close to clinic (<20km) will attend clinic better while those very far (>80km) are usually on admission and drug administered by nurses thus ensuring better compliance with direct observation by health worker as they take their drugs especially while on the intensive phase of therapy. Previous studies have equally found distance patient covere before getting to clinic to be important (Castelnuovo, 2010). This may be because the DOTS strategy adopted by the Nation specifies that patient is selected for treatment based on location of residence from the DOTS health facility. This should be about 5km

The proportion of cure among patients with TB alone compared with those with TB coinfected with HIV showed a statistically significant association. This is supported by some studies (Mukadi et al, 2001; Dheda et al., 2004; Dean et al., 2002;). which have shown that compared with HIV-uninfected TB patients, HIVinfected TB patients have substantially higher case fatality rates and default rate. The emergence of more interaction of TB with human immunodeficiency virus (HIV) infection might be one of the ways HIV has contributed to a global resurgence of tuberculosis (Corbett et al., 2003).

There is no association between treatment outcome and CD4 count. The finding may be due to relatively high CD4 count values observed among the patients(253.57±195.71 cell/mm^3).

5.1.3 Regression Analysis on significant factors associated with Treatment Outcomes

All patients that covered > 20km were likely not to be cured when compared with those that covered < 20km. Patients that had TB coinfected with HIV were almost twice more likely not to be cured as compared to the patients who were infected with TB alone. This may be as a result of effect of each disease on the other ranging from manifestation of the disease in co- morbid condition to drug- drug interaction. The effect of this was equally obvious in the unadjusted and adjusted analysis for disease status

5.2 CONCLUSION

The findings have added to the existing knowledge and insight into challenges to treatment outcomes among TB patients. Even though there was a moderate high cure rate among smear-positive pulmonary TB patients, it still fell short of expectation if Nigeria is to achieve target set for TB cure rate by 2015 hence the need for stakeholders in TB control to intensify efforts in identifying and developing solutions. Some of the factors associated with poor treatment outcome included TB patients coinfection with HIV as well as distance from residence to health facility where DOTS services are available to access drugs.

There is every need to intensify health education and communication so that people become more aware of operation sites for DOTS with social behavioral change especially among youths especially in this era of HIV pandemic.

5.3 RECOMMENDATIONS

1. The dual infection of a person by TB and HIV seen as double monster with its consequences has been seen to contribute to poor treatment outcome. There is need to increase awareness about the disease, behavioral change communication especially for youths, increase number of health facilities with resources for voluntary counseling and testing, and access to anti retroviral drugs.

2. There is need to increase the number of health facilities or centres with DOTS services. It is not just this but spreading it across the nation such that is within walking distance to everyone that requires the services. With this, there will be better compliance among the patients, better monitoring by health workers then culminating to better treatment outcome

3. TB is shown to be commoner among the low socioeconomic class and poor living condition and youths thus there is need for government at all levels to strive and improve the living condition of the masses by empowering the youths through creating job opportunities, improving the well being and care for the dependent ages as these will help improve their status and disease burden.

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Appendix

Data collection form

S/N	TB number	Sex	Age	Date of start of treatment	Date of completion of treatment	Residence/distance to clinic	AFB at start of treatment	AFB at follow up	HIV status	Viral load/CD4 count	Weight at onset	Weight at discharge	Treatment outcome	Duration on treatment

Appendix

Data collection form

S/N	TB number	Sex	Age	Date of start of treatment	Date of completion of treatment	Residence/distance to clinic	AFB at start of treatment	AFB at follow up	HIV status	Viral load/CD4 count	Weight at onset	Weight at discharge	Treatment outcome	Duration on treatment

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Date.....

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ETHICAL CLEARANCE CERTIFICATE

TOPIC: A COMPARATIVE STUDY OF TREATMENT OUTCOME AMONG PATIENTS WITH TUBERCULOSIS AND TUBERCULOSIS CO-INFECTED WITH H IV/AIDS ON DOTS IN UNTH ENUGU

BY: DR. ANTWADA ELIAS CHUKE

FOR: A DISSERTATION FOR THE AWARD OF MASTER OF SCIENCE (MSC) IN EPIDEMIOLOGY AND MEDICAL STATISTICS OF THE DEPARTMENT OF EPIDEMIOLOGY. MEDICAL STATISTICS AND ENVIRONMENTAL HEALTH, FACULTY OF PUBLIC HEALTH, UNIVERSITY OF IBADAN

This research project on the above topic was reviewed and approved by the University of Nigeria Health Research Ethics Committee.

This certificate is valid for **one year** from date of issue.

Prof. R.E Umeh
Chairman Health Research Ethics Committee

Date: 14th JUNE 2012