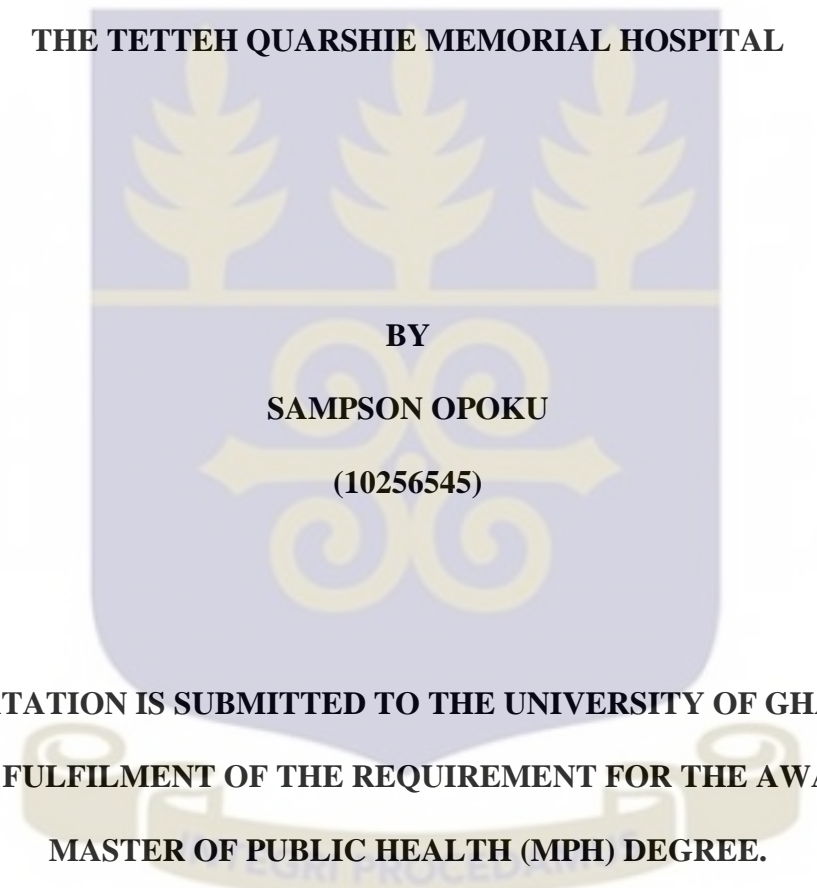


**SCHOOL OF PUBLIC HEALTH  
COLLEGE OF HEALTH SCIENCES  
UNIVERSITY OF GHANA, LEGON**

**TUBERCULOSIS TREATMENT OUTCOME AND ASSOCIATED FACTORS AT  
THE TETTEH QUARSHIE MEMORIAL HOSPITAL**

The background of the page features a large, semi-transparent watermark of the University of Ghana crest. The crest is a shield-shaped emblem with a blue background and yellow/gold elements. It contains three stylized trees at the top, a central cross with a scroll below it, and a banner at the bottom. The text of the dissertation is overlaid on this watermark.

**BY  
SAMPSON OPOKU  
(10256545)**

**THIS DISSERTATION IS SUBMITTED TO THE UNIVERSITY OF GHANA, LEGON  
IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE AWARD OF THE  
MASTER OF PUBLIC HEALTH (MPH) DEGREE.**

**JULY, 2015**

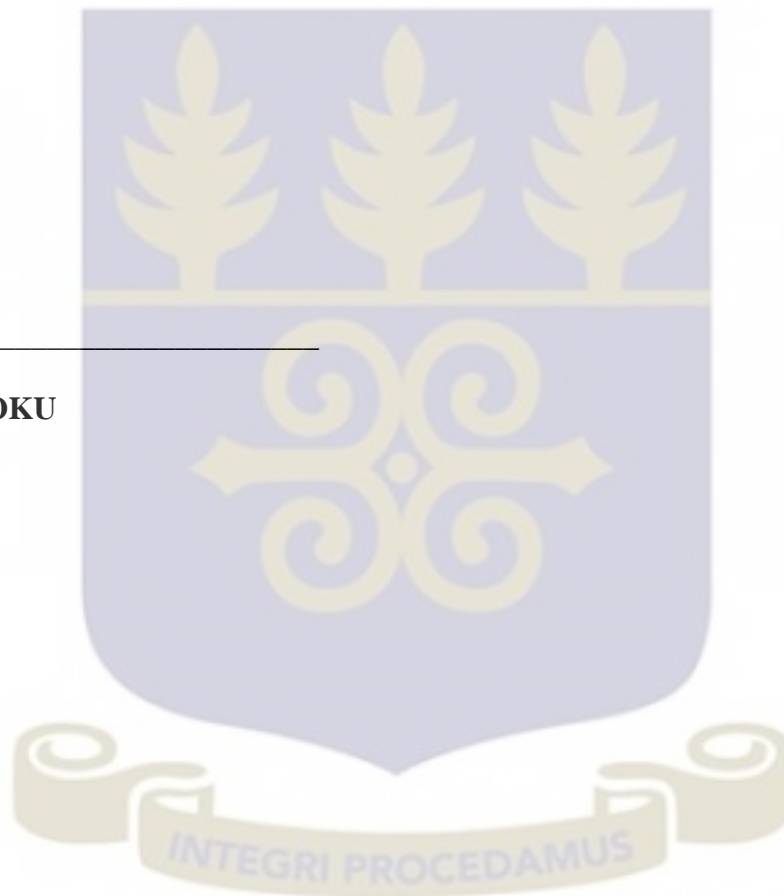
## **DECLARATION**

I hereby declare that apart from specific references which have been duly acknowledged, this study is my own work put together. I also declare that this dissertation has not been presented elsewhere, either in part or in whole for another degree.

---

**SAMPSON OPOKU**

**(Student)**



---

**DR. FRANCIS ANTO**

**(Supervisor)**

## **DEDICATION**

This work is dedicated to my family especially to my dear wife, Bless, for her immeasurable support and to Papa and Nana for coping with the stress associated with my absence from home.



## ACKNOWLEDGEMENT

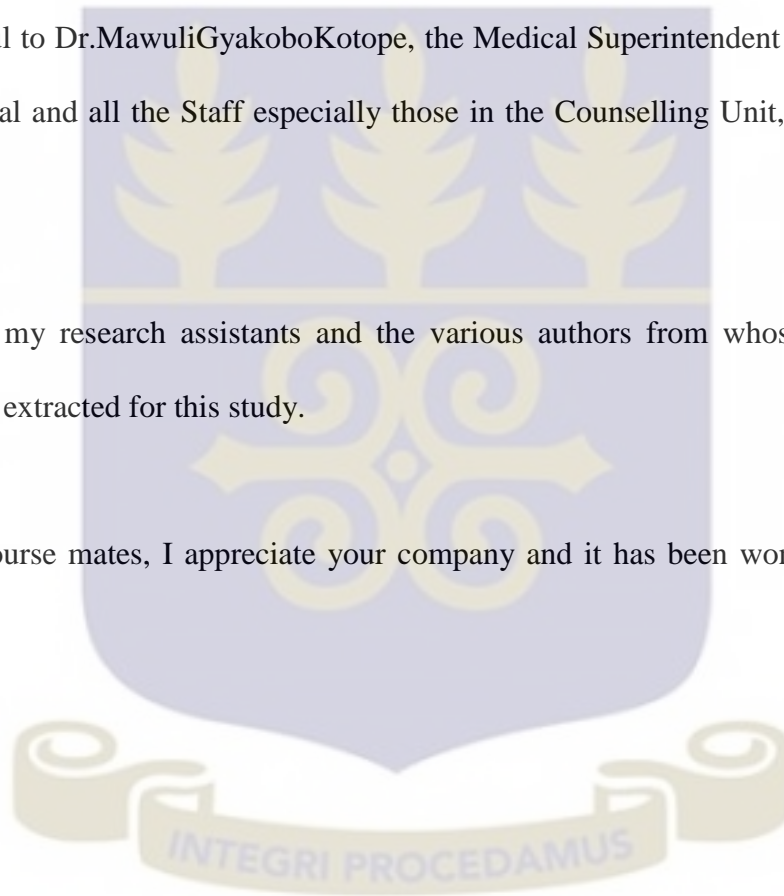
I give thanks to the Almighty God for seeing me through this course successfully.

I appreciate the meticulous supervision and enormous support of my Supervisor, Dr Francis Anto at the Department of Epidemiology and Disease Control (EPDC), School of Public Health, University of Ghana

I am also thankful to Dr.MawuliGyakoboKotopé, the Medical Superintendent of TettehQuarshie Memorial Hospital and all the Staff especially those in the Counselling Unit, you have been of great help.

I am grateful to my research assistants and the various authors from whose work important information were extracted for this study.

Finally, to my course mates, I appreciate your company and it has been wonderful being with you.



## TABLE OF CONTENTS

TITLE PAGE	
DECLARATION.....	i
DEDICATION .....	ii
ACKNOWLEDGEMENT.....	iii
TABLE OF CONTENTS.....	iv
LIST OF TABLES.....	vii
LIST OF FIGURES.....	viii
LIST OF ABBREVIATIONS.....	ix
DEFINITION OF TERMS.....	x
ABSTRACT.....	xiii
<b>CHAPTER ONE</b>	
1.0. INTRODUCTION.....	1
1.1. Background.....	1
1.2. Problem statement.....	4
1.3. Conceptual framework .....	5
1.4. Justification of the study.....	8
1.5. OBJECTIVES.....	9
1.5.1. General objective.....	9
1.5.2. Specific objective.....	9

## CHAPTER TWO

2.0. LITERATURE REVIEW.....	10
2.1. Introduction.....	10
2.2. The global burden of tuberculosis.....	11
2.3. Global TB control.....	13
2.4. Tuberculosis treatment outcome.....	16
2.5. HIV/TB co-infection.....	19
2.6. Factors associated with treatment outcome.....	21

## CHAPTER THREE

3.0. METHODOLOGY.....	25
3.1. Study design.....	25
3.2. Study area.....	25
3.3. Variables.....	26
3.4. Study population.....	30
3.5. Sampling.....	30
3.5.1. Sampling size estimation.....	30
3.5.2. Sampling method.....	31
3.6. Data collection methods & tools.....	31
3.7. Quality control.....	32
3.8. Data processing & analysis.....	32
3.8.1. Statistical methods.....	32
3.9. Pretesting of data collection tools.....	33
3.10. Ethical consideration.....	34

## **CHAPTER FOUR**

4.0. Results.....	35
4.1. Records of TB Patients and their background characteristics.....	35
4.2. Tuberculosis Treatment Outcome.....	37
4.3. HIV/TB co-infection.....	38
4.4. Patients Characteristics and Treatment Outcome (All Types).....	39
4.5. Patient characteristics and Treatment Outcome (Grouped).....	41
4.6. Crude Odds Ratio and factors associated with Treatment Success.....	43
4.7. Adjusted Odds Ratio and Factors associated with Treatment Success.....	43

## **CHAPTER FIVE**

5.0. DISCUSSIONS.....	46
5.1. Limitations.....	54
5.2. Strengths.....	54

## **CHAPTER SIX**

6.0. CONCLUSIONS AND RECOMMENDATIONS.....	55
6.1. Conclusions.....	55
6.2 Recommendations.....	55
6.2.1. Tetteh Quarshie Memorial Hospital.....	55
6.2.2. GHS/NTP.....	56

<b>REFERENCES.....</b>	<b>57</b>
------------------------	-----------

<b>APPENDICES.....</b>	<b>65</b>
------------------------	-----------

**LIST OF TABLES**

Table 1:Definition of variables and their scale of measurements.....27

Table 2:Records of Patients at TettehQuarshie Memorial Hospital (2009-2013).....35

Table 3:Background Characteristics of patients.....36

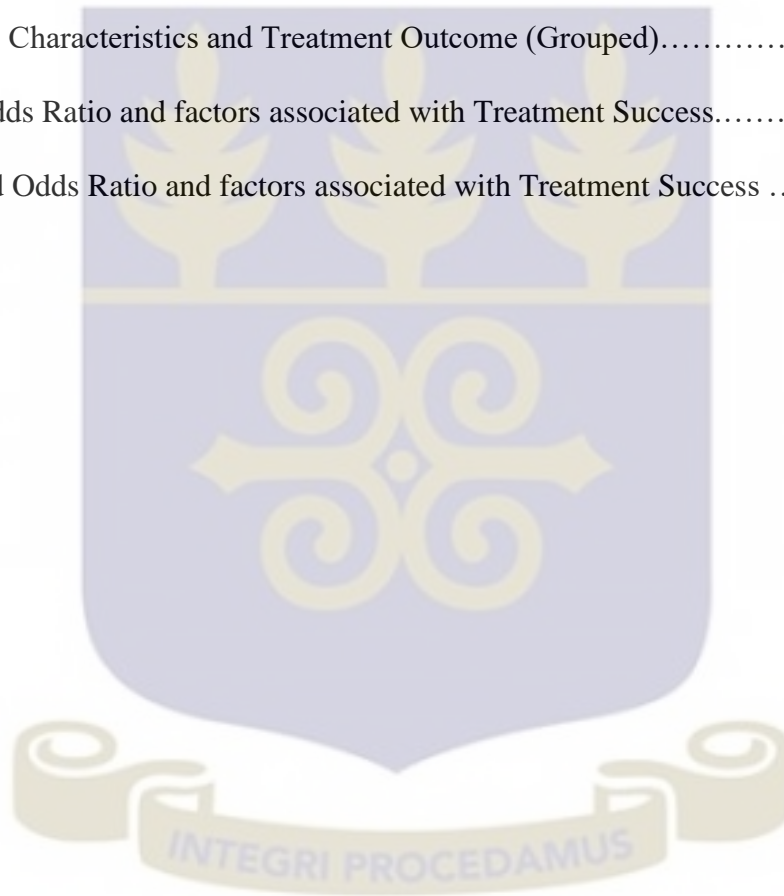
Table 4:Tuberculosis Treatment Outcome (2009-2013).....37

Table 5: Patients’ Characteristics and Treatment Outcome (All Type).....40

Table 6: Patients’ Characteristics and Treatment Outcome (Grouped).....42

Table 7:Crude Odds Ratio and factors associated with Treatment Success.....44

Table 8: Adjusted Odds Ratio and factors associated with Treatment Success .....45



**LIST OF FIGURES**

Figure 1: Conceptual framework of factors associated with treatment outcome.....7

Figure 2: HIV/TB Co-infection among patients.....38



### LIST OF ABBREVIATIONS

<b>AIDS</b>	–	Acquired Immuno- deficiency Syndrome
<b>CDC</b>	–	Centers for Disease Control and Prevention
<b>DOTS</b>	–	Directly Observed Therapy –short course
<b>EPTB</b>	–	Extra-pulmonary Tuberculosis
<b>GAC</b>	–	Ghana Aids Commission
<b>GHS</b>	–	Ghana Health Service
<b>KM</b>	-	Kilometer
<b>MDR/TB</b>	–	Multidrug Resistant Tuberculosis
<b>MOH</b>	–	Ministry of Health
<b>MSF</b>	–	Medicins sans Frontieres
<b>NACP</b>	–	National Aids Control Programme
<b>NTP</b>	–	National Tuberculosis Control Programme
<b>PTB</b>	–	Pulmonary Tuberculosis
<b>TQMh</b>	–	TettehQuarshie Memorial Hospital
<b>VCT</b>	-	Voluntary Counselling and Testing
<b>WHA</b>	–	World Health Assembly
<b>XDR-TB</b>	–	Extensively Drug Resistant Tuberculosis

## DEFINITION OF TERMS

**Adverse Outcome(Unsuccessful Treatment):** A patient who defaulted or failed treatment or died.

**Attendant:** Persons who sought TB treatment at the hospital.

**Complete data:** Where all information needed to be retrieved on TB cards are available.

**Cured:** A Client initially smear or culture positive who have completed the treatment and is sputum or culture negative in the last month of treatment and on at least one previous occasion.

**Completed treatment:** A Client registered as pulmonary sputum or culture positive, completed treatment, but had no sputum or culture at the end of treatment or one negative sputum smear at or after 5 months of treatment,

OR

A client registered as pulmonary smear negative or extra pulmonary and received a full course of treatment.

OR

A client registered as “smear not done” (e.g. Children) and received a full course of treatment.

**Died:** A client who dies for any reason during the course of treatment.

**Treatment Failure:** Initially smear-positive or culture positive client who remained, or become smear-positive again 5 months or later after commencing treatment.

OR

A sputum negative client found sputum positive at the end of 2<sup>nd</sup> month and at any point in the course of treatment if patient is found to have MDR-TB.

**Defaulted:** A client who at any time after registration had not collected drugs for 8 or more consecutive weeks (2 months). This clients are now considered as lost to follow up.

**Incomplete data:** If any one of the information which will be retrieved on TBcards (eg.age, sex type of TB) is missing.

**Transferred out:** A client who transferred to another district while still on treatment and whose outcome is unknown.

**Treatment success:** A sum of cured and completed treatment in smear- or culture-positive patients only (NTP Training Manual, 2012).

**Mycobacterium Tuberculosis:** Causative agent for the disease tuberculosis.

**Pulmonary Tuberculosis:** Tuberculosis affecting the lungs.

**Relapsed:** A patient previously treated for TB, declared cured or treatment completed, and who is diagnosed with bacteriological positive TB (smear or culture).

**Transfer in** A patient who has been transferred from another TB Register to continue treatment.

**Transfer Out:** A patient who transferred to another reporting unit and for whom the treatment outcome is not known.

**Treatment Success (Successful Treatment):** A patient who was cured or who completed treatment.

**Sputum Smear Microscopy:** A method of diagnosing TB in which bacteria are observed in sputum samples examined under a microscope.

**Treatment Supporter:** Someone who supervises a TB client to take his or her drug.

**Treatment Outcome:** The end result of tuberculosis treatment.



Source of Definitions

1. *WHO Global Report 2012*

2. *National Tuberculosis Control Programme, Ghana, Training Manual 2012*

## ABSTRACT

Tuberculosis threatens public health all over the world and affects persons mostly in their productive lives. The proportion of cases with successful treatment outcome is a key indicator to assess the effectiveness and performance of any Tuberculosis Control Programme. Effective treatment is a major element in reducing the transmission of infection and ultimately achieving elimination of the disease.

The study was conducted to determine factors associated with treatment outcome and the proportion of TB patients cured, completed treatment and defaulted treatment during the period January 2009 to December 2013. A descriptive, cross sectional study was carried out. It involved a retrospective review of TB treatment cards of patients who received tuberculosis treatment in the counselling unit of the hospital from 2009-2013. Data on age, sex, distance from place of residence to DOTS center, HIV voluntary counselling and testing, HIV status, type of patient, treatment supporter, other co- morbidities, diagnostic category, duration of treatment and adverse drug reactions were extracted. Factors associated with treatment success as well as adverse outcome during treatment were assessed by chi square test, bivariate and multivariate logistic regression models.

Of the 415 patients studied, 146 (35.2%) were cured, 167 (40.2%) completed treatment and 86 (20.7%) defaulted treatment. Treatment success was 75.4% (313/415). Patients with HIV/TB co-infection were 114 (27.5%). The treatment success of 75.4% was lower than the Ghana average for 2011 of 86.5% and WHO target of 85%. In the multivariate analysis, factors associated with treatment success were the presence of a treatment supporter (AOR 9.69, CI 4.89-19.21). Adverse treatment outcome was associated with patients aged more than 60 years (AOR 0.27, CI 0.08-0.89),

smear negative TB (AOR 0.26, CI 0.15-0.47), transferred-in patients (AOR 0.23, CI 0.02-0.75) as well as patients who experienced adverse drug reactions (AOR 0.12, CI 0.03-0.44).

Enhanced supervision to improve treatment success, improved health education with special emphasis on the need for adherence to treatment, effect of drugs and the importance of treatment supporters are encouraged. Contact tracing should be strengthened to assist patients during treatment.



## CHAPTER ONE

### INTRODUCTION

#### 1.1 BACKGROUND

Tuberculosis (TB) continues to be a global public health problem (Dooley, Lahlou, Ghali, Kuudsen, Elmessaoudis, Cherkadui, & Aould, 2011). The World Health Organization (WHO) in 1993 declared TB a global emergency in recognition of the disease as a public health problem (Yahaya, Aquah, & Sagoe, 2013). TB causes ill-health among millions of people every year and ranks as the second leading cause of death from an infectious disease worldwide, after the human immunodeficiency virus (WHO Global Tuberculosis Report, 2012).

WHO global tuberculosis report (2013) asserts that, TB is an infectious disease caused by the bacillus *Mycobacterium tuberculosis*. The disease typically affects the lungs (pulmonary TB) but can affect other parts of the human body like the bones and joints as well (extra-pulmonary TB). When people suffering from active pulmonary TB cough, sneeze, speak, or spit, they expel infectious aerosol droplets. Inhaling some of these infectious aerosols by another person may cause an infection.

In general, a relatively small proportion of people infected with *M. tuberculosis* will develop TB disease. However, the probability of developing TB is much higher among people infected with Human immunodeficiency virus (WHO, 2013). According to the WHO global tuberculosis report (2013), there were 8.6 million new TB cases in 2012. TB kills more youths and adults than other infectious diseases in the world (WHO, 2008). The disease mostly affects the poor in the society. It also affects more males than females (WHO, 2012). WHO global TB report (2014)

estimates that globally the TB mortality rate (deaths per 100 000 population per year) has fallen by 45% since 1990, although this report is encouraging, the number of TB deaths is unacceptably high given that most are preventable if people can access health care for the right diagnosis and treatment. Without treatment, mortality rates are high (WHO, 2012). Between the year 2000 and 2013, an estimated 37 million lives have been saved through effective diagnosis and treatment (WHO,2014). The reemergence of TB in the 1990s increased the need for innovative strategies for its control. This resurgence of TB could be attributed to weak health systems, drug resistance, and increasing human immunodeficiency virus (HIV) and Acquired immunodeficiency syndrome (AIDS) prevalence and other co-morbidities. One of the challenges facing the health systems is how to bring health services to the doorsteps of those who need them (WHO, 2012).

Early diagnosis of Tuberculosis and effective treatment are key elements in reducing the transmission of infection and ultimately achieving elimination of the disease. Therefore, delay in reporting and late diagnosis may worsen the disease and enhance its transmission resulting in increased TB related morbidity and mortality (Sreeramareddy, Panduru, Menten, & Van den Ende, 2009).

Identifying patients' characteristics that can lead to high risk of adverse treatment outcomes such as default may help inform country prevention strategies aiming at reducing the need for retreatment, which will result in cost savings and diminished morbidity and mortality (WHO, 2012; WHO statistics, 2012). The conventional laboratory tests for the diagnosis of TB, which have been used for decades, are sputum smear microscopy and bacterial culture (WHO, 2013).

Laboratory confirmation of TB is critical to ensure that people with TB signs and symptoms are correctly diagnosed and have access to the correct treatment as soon as possible (WHO, 2013). TB was declared an African emergency in August 2005 by WHO (Yahaya et al., 2013). Among the 22 TB “high burden” countries in the world which account for 81% of all the estimated TB cases worldwide, eight of these countries are from Africa (WHO, 2012). In Sub-Saharan Africa (SSA), the incidence of tuberculosis has increased about ten times even though the global incidence has been falling in many parts of the world (Barker, 2008). Again, the WHO (2012) report indicated that the African Region, has the highest rates of TB cases and contributes 24% of the world’s TB cases.

Monitoring treatment outcome is a vital part of the surveillance needed to successfully eliminate TB. It also serves as a tool to control the quality of TB treatment provided by the health care system (WHO, 2009). The proportion of cases with successful outcome is therefore a key indicator to assess the effectiveness and performance of any Tuberculosis Control Programme. In treatment outcome monitoring, the denominator for calculating group outcomes includes all patients who have been diagnosed with TB and who were registered for treatment during the specified time period. The WHO defines TB treatment outcome as follows; Cured, Treatment completion, Failed, Defaulted Died and Transfer out (WHO, 2013).

The counselling unit of TettehQuarshie memorial hospital was established in 2005 to give special attention to patients with HIV/AIDS and Tuberculosis diseases (TettehQuarshie Memorial Hospital Annual Report, 2006). Since the creation of the unit, there has not been any

documented scientific study on the departments work on tuberculosis treatment outcomes and the reasons for these outcomes.

## **1.2 PROBLEM STATEMENT**

Tuberculosis treatment outcomes are important indicators in the evaluation of the effectiveness and performance of any Tuberculosis control programme (WHO, 2012). The WHO has set a global target in line with the Millennium Development Goals (MDG's) to achieve a successful treatment outcome of 85% and reduce mortality rates by 50% by the year 2015 (WHO, 2012). Over the years, the Akuapem North Municipality has not been able to meet the WHO target of 85% treatment success rate. In 2009, for example, the Municipality recorded a treatment success rate of 77.7% (Eastern Regional Health Directorate Annual Report, 2011). This improved slightly during subsequent years (78.1% in 2010, 82.6% in 2011 and 83.6% in 2012). For the year 2013, the treatment success rate was 80.0% (Ghana Health Service District Health Information Management System (DHIMS II), 2013).

Low treatment success rates mean high rates of adverse treatment outcomes (default, treatment failure and death) among clients on treatment. This situation threatens the effectiveness of TB control programmes with consequences such as multiple drug resistance development which leads to prolonged treatment periods and increased cost, increased rate of transmission of the bacteria and high incidence of morbidity and mortality (WHO, 2009). This study identified possible factors influencing TB treatment outcomes in patients who sought care at the TettehQuarshie Memorial Hospital in Mampong which serves as the main diagnosis and treatment center for tuberculosis (TB) in the Akuapem North Municipality. Such a study can

contribute to improving case management and help develop strategies for TB management beyond 2015.

### **1.3. CONCEPTUAL FRAMEWORK**

A conceptual framework is an interconnected set of ideas about how a particular phenomenon operates or relates to its parts. It serves as the foundation for understanding the causal or correlational patterns of interconnections across events, ideas, observations, concepts, knowledge, interpretations and other components of experience and also assist the researcher in deciding the types of data to collect and the variables to examine (Svinicki, 2010).

According to WHO (2012), tuberculosis treatment outcome is the end results of TB treatment. There are six possible TB treatment outcomes, the patient may be cured, complete treatment, or die. The patient may also have treatment failure and default. The last treatment outcome is that, the patient may be transferred out to another reporting unit for which the specific outcome may be unknown. Certain factors can affect these outcomes differently.

One of them is HIV related factors, HIV is separated from the other co-morbidities in this conceptual framework because of the tremendous effect this infection has on patient with TB, whether the client consents to HIV testing or not and his/her HIV status. Most people infected with TB do not develop the disease due to strong immune systems, however, the likelihood of developing the disease in HIV infected client is high since HIV infection and tuberculosis are common and often co-occurring conditions, forming a lethal combination, each speeding the other's progress (WHO, 2010).

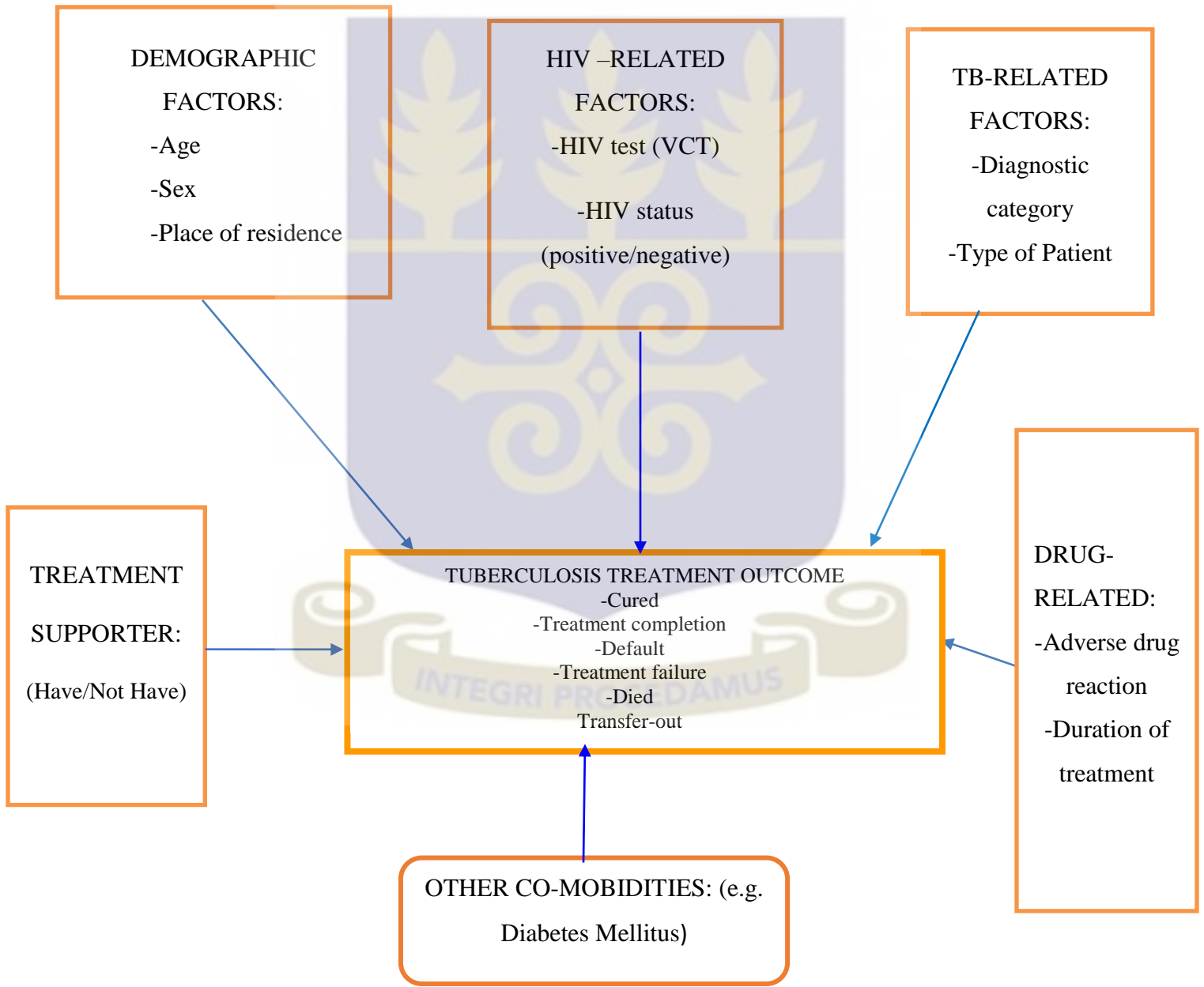
The diagnostic category (pulmonary or extra-pulmonary) and type of patient (new, return of default, relapse, retreatment, and treatment failure and other) could affect TB treatment outcomes. Adverse drugs reaction and treatment duration are other factors. The age, sex, distance of patient's place of residence during treatment to DOTS centre could also affect the treatment outcome.



A patient having a treatment supporter or not affects outcome of treatment. Other comorbidities such as diabetes mellitus could also affect TB treatment result (Pablo-villamor, Benedicto, Teresa, Benedicto, & Perez, 2014).

Fig. 1 Conceptual framework of factors associated with Tuberculosis treatment

**Outcome.**



#### **1.4. JUSTIFICATION OF THE STUDY**

TB is slowly declining each year and it was estimated that 37 million lives were saved between 2000 and 2013 through effective diagnosis and treatment. However, given that most deaths from TB are preventable, the death toll from the disease is still unacceptably high and efforts to combat it must be accelerated if 2015 global targets, set within the context of the Millennium Development Goals (MDGs), are to be met (WHO, 2014). Incidence, prevalence and mortality rates are all falling in Africa, but not fast enough to meet global targets (WHO, 2014).

In the Tetteh Quarshie memorial hospital, no study has been done on factors that contributed to the facility's inability to meet the WHO treatment success target of 85% after the adoption of fixed-dose combination drug treatment by the Ghana National Tuberculosis Control Programme in 2007 to ease the dosage burden on patients. This study tried to determine the treatment outcome of patients who sought care during 2009-2013 and the associated factors. The study came out with results that can serve as a baseline for future studies and add to existing knowledge on factors associated with treatment outcome in TB management..

It also established the relationship between treatment outcomes and the effect of demographic factors, diagnostic category, HIV/TB co-infection and other co-morbidities on treatment outcomes. It is hoped that these findings would make significant contributions to improve TB care in the hospital and the Akuapem north municipality in general.

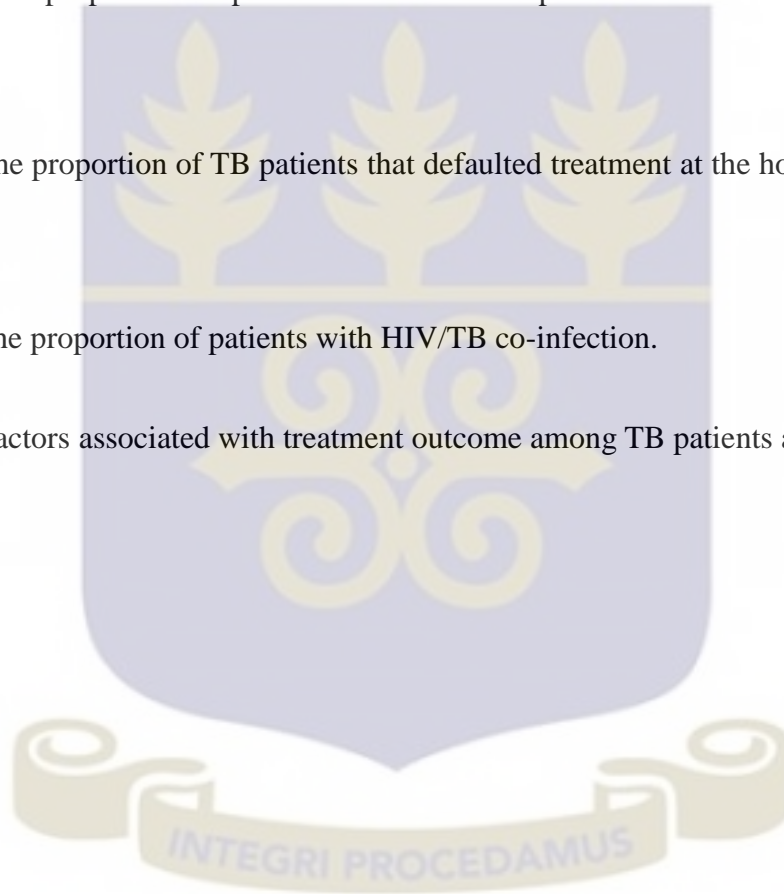
## **1.5 OBJECTIVES**

### **1.5.1 General objective:**

To determine Tuberculosis treatment outcome and associated factors among patients who sought care at the Tetteh Quashie Memorial Hospital from 2009 -2013.

### **1.5.2 Specific objectives:**

1. To determine the proportion of patients cured and completed treatment at the hospital from 2009-2013.
2. To determine the proportion of TB patients that defaulted treatment at the hospital from 2009 - 2013.
3. To determine the proportion of patients with HIV/TB co-infection.
4. To determine factors associated with treatment outcome among TB patients at the hospital.



## CHAPTER TWO

### LITERATURE REVIEW

#### 2.1. INTRODUCTION

About 130 years ago, Robert Koch discovered *Mycobacterium tuberculosis* as the cause of tuberculosis (Udwadia, 2012). TB is an airborne disease caused by *Mycobacterium tuberculosis* (*M. tuberculosis*). This organism which is highly infectious has seven very closely related mycobacterial species (*M. bovis*, *M. africanum*, *M. microti*, *M. caprae*, *M. pinnipedii*, *M. canetti* and *M. mungi*) together comprise what is known as the *M. tuberculosis complex*. Most, but not all, of these species have been found to cause diseases in humans. (Centers for Disease Control and Prevention(CDC), 2013). CDC again asserts that pulmonary tuberculosis (PTB) infection occurs when a person inhales droplet nuclei containing tubercle bacilli that reach the alveoli of the lungs.

The host immune response to the infection could be affected by age, sex, underlying immune status, coexisting disease, malnutrition, intake of corticosteroids, use of immune suppressive medications, virulence and site of infection (Lawn, & Zumla, 2011; Donald, Marais, & Barry, 2010).

*Mycobacterium tuberculosis* is one of the most pernicious human pathogens (Russell, Vandervan, Lee, Abramovich, Kim, Homolka,.... & Rohde, 2010). Whenever the immune system breaks down or fails to contain the organism, active disease then results (Christopher, & Bosede, 2010). If left untreated, a person with PTB will infect about 10-15 persons every year (WHO, 2014b).

Symptoms associated with active disease include loss of appetite, cough, and increased night sweats, malaise and anemia, chest pains and productive purulent sputum (Chris, & Peter, 2005). Studies regarding strain variation with regard to transmission and pathogenesis found the Beijing family strains with origins in Asia, strain W and strain W-like families responsible for many cases of drug resistance. This family of strains is distributed worldwide however, no study implicates this family as having genetic advantage for its pathogenesis and drug resistance (Domenech, Kolly, Leon-Solis, Fallow, & Reed, 2010). Other studies done in Burkina Faso and Cameroun implicate *M. tuberculosis* species as the main causative agent of pulmonary tuberculosis (Godreuil, Torrea, Terru, Chivenet, Diagbouga, Supply,.....&Banuls, 2007). Some studies conducted in Ghana have shown that *M. tuberculosis* accounted for about 73% of pulmonary tuberculosis whilst *M. africanum* and *M. bovis* respectively accounted for about 23% and 3% (Addo, Owusu –Darko, Yeboah –Manu, Caulley, Minamikawa, Bonsu, Lienhardt, Akpedunu, &Ofori- Adjei, 2007). Although WHO (2013) asserts that TB is preventable and curable. According to Garrido, Penna, Perez-Porcuna, de Souza, Marreiro, Albuquerque,& Bühner-Sékula (2012), TB is still a major public health problem, its reemergence in the 1990s increased the need for innovative strategies for its control.

## **2.2 THE GLOBAL BURDEN OF TUBERCULOSIS**

Tuberculosis (TB) is still one of the world's most deadly communicable diseases, according to WHO, TB ranks as the second leading cause of death from an infectious disease worldwide, after the human immunodeficiency virus (HIV). It again reports that there were 9.0 million new TB cases in 2013 and 1.5 million TB deaths (1.1 million among HIV-negative people and 0.4 million among HIV-positive people (WHO, 2014). The number of mortalities resulting from TB are

unacceptably high given that a huge number could be prevented (WHO, 2013). TB is present in all regions of the world (WHO, 2014). Among the estimated TB cases in 2013, more than half (56%) were in the South-East Asia and Western Pacific Regions. Again, 80% of the worldwide burden of TB is accounted for by 22 countries and first to fifth highest ranking countries being India, China, South Africa, Nigeria, and Indonesia (WHO, 2010). Out of the 22, eight countries are from Africa (WHO, 2014). India and China alone accounted for 24% and 11% of total cases respectively. About 60% of TB cases and deaths occur among men, but the burden of disease among women is also high. In 2013, an estimated 510 000 women died as a result of TB, more than one third of whom were HIV-positive. An estimated 1.1 million (13%) of the 9 million people who developed TB in 2013 were HIV-positive (WHO, 2014). The African Region accounts for about four out of every five HIV-positive TB cases and TB deaths. Twelve out of the 15 countries estimated to have the highest TB incidence are in Africa, among them are Nigeria and Ethiopia (WHO, 2010). However, Ghana is not among the most endemic countries (WHO, 2010).

According to the WHO (2010), there was an estimated 86 smear positive pulmonary TB cases per 100,000 population and 106 per 100, 000 of all types of TB cases per year in Ghana. This means a population of 24 million should expect about 26,000 TB cases annually, but only 15,800 cases were reported in the country in 2011 with 50% smear positive cases (Ghana National Tuberculosis Control programme (NTP) Training Manual, 2012).

Again, the training manual reveals that the reasons for low detection could be due to non-reportage of TB cases to health facilities, missed diagnosis and failure to conduct contact tracing and investigation routinely and non-capturing by the disease surveillance system.

### **2.3 GLOBAL TB CONTROL**

It has been proven that effective treatment of TB patients has significant effect on the control of TB in a region or a country (WHO, 2009). Almost 20 years after the WHO declaration of TB as a global public health emergency, major progress has been made towards 2015 global targets set within the context of the Millennium Development Goals (MDGs) (WHO, 2013). And as part of global efforts to control TB, the WHO came out with MDG 6, Target 8 is to “Halt and begin to reverse the incidence of TB by 2015.” (Babatunde, 2013; Maher, 2006).

According to the target at least 70% of new smear-positive cases should be detected and treated in the Directly Observed Therapy-short course (DOTS) program by 2015, at least 70% of people with sputum smear positive TB will be diagnosed (i.e. under the DOTS strategy), and at least 85% of this number should be cured (Maher, 2006). According to WHO, the incidence rate of TB has been falling since 2004, the case detection rate reached 63% in 2007 and the treatment success rate was 85% in 2006 (Maher, 2006).

The Stop TB Strategy is WHO’s approach to reduce the burden of TB according to the global targets. The strategy hopes to achieve its aims by providing universal access and high quality care for all people with TB, and to reduce the human suffering and socio economic burden associated with TB as well as to protect the vulnerable populations from TB /HIV and multi drug resistant tuberculosis (Ayisi, van’t Hoog, Agaya, Mchembere, Nyamthimba, Muhenje, & Marston,2011).

The goal of the strategy is to dramatically reduce the global burden of TB by 2015 in line with the Millennium Development Goals. The objectives of the strategy are to:

- Achieve universal access to high-quality care for all people with TB.
- Reduce the human suffering and socioeconomic burden associated with TB.
- Protect vulnerable populations from TB, TB/HIV and multidrug-resistant TB.
- Support development of new tools and enable their timely and effective use.
- Protect and promote human rights in TB prevention, care and control (The Lancet, 2014).

Again, components of the Stop TB strategy include:

Pursue high-quality DOTS expansion and enhancement, address TB-HIV, MDR-TB, and the needs of poor and vulnerable populations, contribute to health system strengthening based on primary health care, engage all care providers, empower people with TB, and communities through partnership and enable and promote research (The Lancet, 2014).

Globally, thirty seven million lives have been saved since 2000 by TB control programs, there has been forty five percent decrease in global TB mortality rate since 1990, however, the increasing rate of multiple drug resistant TB crises coupled with inability to reach about three million people worldwide who fall ill of TB annually for care are serious challenges facing the world TB control program (Board, 2015).

Recently, the WHO has come out with the end TB strategy- as a global strategy and targets for tuberculosis prevention, care and control after 2015. This program has been endorsed by member states at the 2014 World Health Assembly. The vision of this strategy is to have a world free of tuberculosis with zero deaths, disease and suffering due to tuberculosis. The program's goal is to end the global tuberculosis epidemic. Ending the global TB epidemic is feasible with decline in TB deaths and cases worldwide (Board, 2015), In addition to achieve this aim, it requires expanding the reach and scope of TB care and prevention, eliciting the benefits of health and development policies and systems and pursue new scientific knowledge and innovations (Board 2015). The principles of the strategy to ensure full impact of these actions are:

- Government stewardship and accountability, with monitoring and evaluation.
- Strong coalition with civil society organizations and communities.
- Protection and promotion of human rights, ethics and equity.
- Adaptation of the strategy and targets at country level, with global collaboration.

The strategy also has three pillars and components. They are: integrated patient-centered care and prevention, bold policies and supportive system and intensified research and innovation

According to the end TB strategy, in order to sustain progress beyond 2025 and achieve the sustainable development goals 2030 and End TB 2035 targets, additional tools must be made available by 2025. Particularly, new vaccine that is effective pre- and post-exposure and a safer and more effective treatment for latent TB infection are needed to reduce the number of new TB cases arising from the approximately 2 billion people worldwide who are infected with *M. tuberculosis*, as well as better diagnostics and safer and easier treatment including shorter drug regimens for TB disease (Board, 2015).

Despite the fact that Ghana is not one of the high burden TB countries in Africa, it nevertheless considers TB as an important health challenge. Together with HIV, they account for about 7% of all deaths, the second after malaria (Ghana Health Service/Ministry of Health (GHS/MOH), 2010).

The National TB Control Program (NTP) was established in 1994. Ghana has implemented the WHO/DOTS Strategy since 1994 and achieved 100% coverage countrywide within the public health sector by the year 2000 (Ghana Tuberculosis Control Programme (NTP), 2011). Currently, the NTP is implementing the new Stop TB Strategy of WHO to achieve the 2015 TB related Millennium target (NTP, 2011). Remarkable progress has been made in the TB treatment success rate that has increased from 54% in 1995 to 86% in 2008 (NTP, 2011), TB mortality remains high at 8% (WHO, 2010). Ghana has a low TB case detection, currently it is estimated at 31% which is far below the 50% African Average and 70% Global target. (NTP, 2011).

Though the Ghanaian population comprises of more females (51%) than males, there are more male TB cases notified to the NTP than female at the ratio of 2:1. About 4% of notified TB cases are children aged below 15 years (GHS/MOH, 2010).

## **2.4 TUBERCULOSIS TREATMENT OUTCOME**

Treatment outcome is an important indicator of the performance of tuberculosis control programs and regardless of the number of reported TB cases in a setting, key treatment outcomes are expected to improve in line with WHO treatment outcomes benchmarks (Amo-Adjei, & Awusabo-Asare, 2013). Tuberculosis treatment aims at curing the patient, interrupting transmission of tuberculosis to other persons and preventing bacilli from becoming drug

resistant. Unfortunately these aims are not achieved in many regions of the world even when anti tuberculosis drugs are readily available (Tessema et al., 2009). According to WHO (2013), there are six possible TB treatment outcomes, they are: cure, treatment completion, default, treatment failure, died and transfer out.

Evaluation of treatment outcome is central to the assessment of effectiveness of tuberculosis control programs (Berhe, Enquesselassie, & Aseffa, 2012; Lisha et al., 2012). Treatment outcome of a patient can also be classified as treatment success or successful treatment (cure or treatment completion) or adverse outcome or unsuccessful treatment (default or treatment failure or death). Transfer out is where a patient is transferred to another treatment centre while still on treatment and whose treatment outcome is unknown. The TB treatment outcome may vary from one region to another and possibly from one institution to the other (WHO, 2010).

For instance a study in a University teaching hospital in Northwest Ethiopia shows that patients who were successfully treated were about 30%, with about 18 % defaulting treatment (Tessema et al., 2009). Also, the fact that treatment outcome vary from region to region is supported by another study done in the Tigray Region of Northern Ethiopia. Unlike in the University teaching hospital in the Northwest Ethiopia, here 89.2% had treatment success with only 10.8% having adverse outcome (Berhe,et al., 2012).According to the WHO (2009) report on global tuberculosis control, the cure and treatment completion rate under the DOTS programs among the 22 high-burden countries (HBCs) varied from 60% in Uganda to 93% in China, with an average of 83% (WHO, 2009). Moreover, a study conducted by Shargie&Lindtjørn (2005) in Southern Ethiopia showed that the proportion of cure and treatment completion for smear positive tuberculosis cases rose from 38% to 73% in 2000.

Treatment failure varied from 0.1% in Zimbabwe to 9.1% in the Russian Federation. Treatment outcome can also vary among sexes, ages and the type of TB (WHO, 2009).

Mohammad, Basit, Tahir, Rahman, Wajid and Javaid (2004), conducted a study to determine the treatment outcome of patients registered with pulmonary tuberculosis in a district hospital in Pakistan, 54% females had treatment success compared with 46% of males. In addition, the study revealed that 74% of the patients with pulmonary tuberculosis were in the age range of 15-45years and were cured.

Completing tuberculosis treatment is a challenge for patients because treatment takes a minimum of six months, may require frequent clinic visits for drugs refilling and monitoring, and treatment may cause unpleasant side effects (WHO, 2012). In a study by Lawrence (2009), in a rural clinic in South Africa, treatment completion among participants at the age of 31 to 40 years was 42%, followed by the ages of 41 to 75 years (32%). More females (57%) than males (43%) completed the treatment. TB treatment default is an important public health problem, because patients who default may continue to transmit infection to healthy people or acquire drug- resistance TB strains and consequently treatment failure (WHO, 2012). Factors affecting default are multidimensional, determined by interplay of five sets of factors namely: social and economic factors, health care team and system related factors, condition related factors, therapy, and patient- related factors (WHO, 2010).

In a longitudinal study to assess tuberculosis treatment outcome among clients with TB at treatment centers in Ibadan, Nigeria, out of 1,254 patients who were followed up, 76.6% were cured, 6.6% defaulted treatment (Fatiregun, Ojo, & Bamgboye, 2009).

Improving treatment outcome and designing effective interventions require understanding of the factors that prevent people from adhering to treatment and those that help in treatment completion (Muture et al., 2011).

## **2.5 TB/HIV CO-INFECTION**

TB is the leading killer of HIV-infected people (WHO, 2014). TB is one of the most common treatable HIV-related disease (Agarwal, Dipanjan, & Chauhan, 2004). The Human Immunodeficiency virus (HIV) pandemic has triggered an increase in the number of TB cases globally (WHO, 2012). HIV infection and tuberculosis are common co-occurring conditions, forming a lethal combination, each speeding the other's progress, and resultant increase in mortality (WHO, 2012). In addition, HIV infection speeds up the progression from latent to active TB, TB bacteria also accelerate the progress of HIV infection (Mayer, 2010).

The co-epidemics of tuberculosis and HIV require serious efforts to handle. This is very essential due to the nexus between these two diseases. A joint effort from both TB as well as HIV/AIDS control programmes is of urgent need with complementary strategies to control these diseases. The best approach to handle the HIV epidemic has been mainly based on preventive interventions since a cure is not yet available, but, tuberculosis is curable including the HIV infected patients ( Agarwal et al., 2004).

Forty to eighty percent of HIV infected people with TB have extra pulmonary disease, compared with ten to twenty percent of people without HIV (Sterling, Pham, & Chaisson, 2010). TB is one of the gravest health threats of the world presently (Medicins Sans Frontieres Crisis Alert, 2014).

An issue of global concern now is the emergence of drug-resistant tuberculosis among TB/HIV infected patients which is on the increase in many countries worldwide (WHO, 2012; Woldeyohannes, Kebede, Erku, & Tadesse, 2011).

At global TB control level, a better understanding needs to be developed on how HIV infection impacts the epidemiology of drug resistance TB in order that there will not be "a perfect storm" of a massive MDR TB/HIV co-epidemic (Suchindran, 2009).

In 2013, an estimated 1.1 million (13%) of the 9 million people who developed TB worldwide were HIV positive. The African region accounted for 78% of the estimated number. Among the highest HIV/TB burden countries in Africa are Lesotho and Swaziland both with 74% (WHO, 2014). The prevalence of TB and HIV co-infection in DebreMarkos Referral Hospital in Northwest Ethiopia was 44% (Esmael, Tsegaye, Wubie, & Endris, 2013).

Patients with HIV comorbidity are significantly more likely to default (Muture et al., 2011). In contrast, a study from Nigeria found no difference between HIV infected and non-infected TB patients with regard to treatment default (Amaran, Osiyale, & Lawal, 2011).

Although Ghana has a stable HIV epidemic, 23% of all TB cases are amongst persons living with HIV/AIDS (Ghana Aids Commission, 2009). Integration of HIV and TB services is good though difficult, the idea of collaboration and providing both services together has already resulted in significant benefits. In 2012, WHO claimed that 900,000 lives had already been saved over six years by protecting people living with HIV from TB (WHO, 2012).

## 2.6 FACTORS ASSOCIATED WITH TREATMENT OUTCOME

TB remains a major source of morbidity and mortality throughout the world. TB is among the top ten causes of death worldwide, especially in Asia and Africa (WHO, 2008). Information about the factors associated with the disease could help identify individuals who are at high risk so that targeted interventions can be implemented to improve TB treatment (WHO, 2008). Co-morbidity has been reported as an important predictor of on-treatment mortality among TB patients (Hansel, Merriman, Haponik, & Diette, 2004). The most common diseases that were listed with TB as the cause of death included renal diseases, liver disease, cardiovascular disease, cancer, chronic obstructive pulmonary disease (COPD), and diabetes mellitus (Sterling, et al., 2006; Mathew, Ovsyanikova, Shin, Gelmanova, Balbuena, Atwood,....& Murray, 2006). However, the effect of underlying diseases other than HIV/AIDS on the risk of death due to TB has not been well explained, sometimes the actual disease that caused death is unknown (Xin, Kathryn, Zheng 'an, Mei, Zhen, Xiao Hong,....& Jian, 2009).

TB screening among patients with other conditions that increase the risk of death might be helpful to detect TB early and to improve TB treatment outcomes (Xin et al., 2009). Factors such as older age and a history of prior TB treatment, multi-drug resistance tuberculosis (MDR-TB) can affect TB mortality (Mathew et al., 2006). In another study, again old age was found in addition to the male gender as among the reported patient-related factors that influence default in different parts of the world, particularly in the sub-Saharan Africa region (Mutire et al., 2011; Belay, Abebe, & Assegedech, 2009; Dodor & Afenyadu, 2005). In contrast, a study from Madagascar found that there was no relationship between the patient's age and defaulting from TB treatment (Rakotonirina, Ravaoarisoa, Randriatsarafara, Rakkotomanga, & Robert, 2004).

Risk factors for poor treatment outcome include male sex, being elderly, and having pulmonary tuberculosis. These risk factors appear to be global in nature as they have been found to be consistent with studies in populations of different races (Ditah et al., 2008).

In a case control study done by Ai et al (2010) to investigate the factors associated with low cure rate of tuberculosis in remote areas in China, several factors were identified to have accounted for poor TB treatment outcomes. These were male sex and old age, which were consistent with findings from a study done by Ditah et al., (2008). Other factors were distance from home to the treatment center, limited social support, multidrug resistance and diabetes mellitus. All these factors were found to be related to poor TB treatment outcomes (Ai et al., 2010).

Some factors also have been proven to be associated with defaulting TB. In Nairobi, Kenya patients attributed default to ignorance, traveling long distance to treatment site, feeling better and side-effects of drugs (Muture et al.,2011). Other factors associated with default in the same study were inadequate knowledge on tuberculosis, herbal medication use, low income, alcohol abuse, previous default, co-infection with HIV and male gender (Muture et al., 2011).

In Ghana, some factors associated with TB treatment compliance have been found. Dodor and Afenyadu (2005), assessed factors associated with tuberculosis treatment default and completion at the Effia-Nkwanta Regional Hospital, and was found that treatment default was significantly associated with income per month, ability to afford supplementary drugs, availability of social support and problems relating with others while on treatment.

A retrospective cohort study was done in a specialized tuberculosis unit in Madrid, Spain to describe the risk factors for MDR-TB. Variables assessed included age, gender, country of origin, contact with a tuberculosis patient, sputum smear, and site of disease, previous tuberculosis treatment, HIV infection, diabetes mellitus and chronic obstructive pulmonary disease. A total of 696 patients were included in the study of which 30 patients were diagnosed MDR-TB and 666 of the respondents had drug susceptible tuberculosis.

In another study, patients who had history of previous treatment for tuberculosis, who were 45–64 years of age or who had no history of alcohol abuse were more likely to have treatment difficulties (Suárez-García, Rodríguez-Blanco, Vidal-Pérez, García-Viejo, Jaras-Hernández, Lopez, & Noguero-Asensio, 2009).

A national retrospective case control study was conducted in South Africa to identify risk factors associated with tuberculosis (TB) treatment default. The sample included 3165 TB patients from 8 provinces; 1164 were traced and interviewed (232 cases and 932 controls). Significant risk factors associated with default among both groups included changing residence during TB treatment and being a new patient or return after default patient. New patients in the case group were more likely than those in the control group to report having no formal education, feeling ashamed to have TB, inadequate counseling about their treatment, drinking any alcohol during TB treatment and seeing a traditional healer during TB treatment. Among re-treatment patients in the case group, risk factors identified included stopping TB treatment because they felt better, having a previous history of TB treatment default, and feeling that food provisions might have helped them to finish treatment. It was concluded that risk factors for default differ between new

and return of default TB patients in South Africa. Addressing default in both populations with targeted interventions is critical to the overall program success (Finlay, Lancaster, Holtz, Weyer, Miranda, & Van der Walt, 2012).

Monitoring tuberculosis treatment outcome and research into the factors that influence the outcome of treatment is an important part of tuberculosis control programmes. It guides policy makers to tailor effective measures in a direction that can reduce the disease burden.



## **CHAPTER THREE**

### **METHODOLOGY**

#### **3.1 STUDY DESIGN**

A descriptive, cross sectional study was carried out at the Tetteh Quarshie Memorial Hospital. It involved a retrospective review of TB treatment cards of patients who received tuberculosis treatment in the counselling unit of the hospital. Treatment cards of all patients who received treatment during the period January 2009 to December 2013 were retrieved and data on age, sex, place of residence, HIV and AIDS status, duration of treatment, and type of patient (new patient, treatment failure, relapse, transferred in and return after default) were obtained. In addition data on adverse drug reaction, disease classification (sputum smear positive TB, sputum smear negative pulmonary TB and extra-pulmonary TB) and treatment outcomes were extracted from the treatment cards.

#### **3.2 STUDY AREA**

The study was conducted at the Tetteh Quarshie Memorial hospital. It is located in the Akuapem North Municipality in the Eastern Region of Ghana. The hospital was built and commissioned on February 1961 in honour and memory of the late Tetteh Quarshie, who brought Cocoa to Ghana. The hospital was initially run as a private institution. In 1966, it was placed under the Ministry of Health and has since then remained a government hospital. The 123-bed capacity hospital serves a population of over 120,000 people spanning the entire Akuapem Ridge, its rural valley and beyond. It is the only government hospital within a radius of 30 kilometres. The hospital provides preventive as well as curative services in Obstetrics and Gynaecology, Paediatrics, Surgery, Internal Medicine. Ophthalmology, Ear Nose Throat, Psychiatry and Dentistry.

The hospital has a counselling unit which was established to take care of infectious diseases including TB. It receives cases within the municipality and from the neighbouring districts. The unit has a responsibility to conduct health education on TB and treat cases, do contact tracing and default prevention. The hospital supports the unit with a well-equipped laboratory and X-ray departments. The unit has a staff strength of five: one medical officer, two nurses and two ward assistants. The unit registers and treats an average of 100 new cases of tuberculosis yearly.

### **3.3 VARIABLES**

The dependent variable of the study was tuberculosis treatment outcome. Treatment outcome is classified using the WHO standard and the Ghana National Tuberculosis Control programme guidelines for measuring treatment outcome. Patients were grouped as cured, completed treatment, defaulted treatment, failed treatment and died. The demographic variables were age, sex and distance from place of residence to DOTS centre. Other predictor variables included HIV voluntary counselling and testing, HIV status, type of patient (new patient, treatment failure, relapse, transferred in and return after default), had treatment supporter, other co-morbidities including diabetes mellitus, diagnostic category (sputum smear positive pulmonary TB, sputum smear negative pulmonary TB and extra-pulmonary TB), duration of treatment and adverse drug reactions.

**Table 1. Definition of variables and their scale of measurements**

<b>Variables</b>	<b>Operational Definition</b>	<b>Type Of Variable</b>	<b>Scale Of Measurement</b>
<b>Cured</b>	A patient who was initially smear-positive and became smear-negative in the last month of treatment and on at least one previous occasion.	Dependent	Binary - Yes - No
<b>Treatment Completion</b>	A patient who tested smear negative at the onset of treatment, completed treatment by taking all the prescribed doses and remained smear negative at the end of treatment.	Dependent	Binary - Yes - No
<b>Default</b>	A patient who interrupted treatment for two consecutive months or more after initiation of treatment.	Dependent	Binary - Yes - No
<b>Transfer out</b>	A patient who has been transferred to another reporting and recording unit and for whom treatment outcome is not known	Dependent	Binary - Yes - No
<b>Treatment failure</b>	A patient who remains smear positive at month five of treatment regardless of the fact that the correct doses of medication were taken.	Dependent	Binary - Yes - No
<b>Death</b>	Death occurring in a patient from any cause during treatment of tuberculosis	Dependent	Binary - Yes - No

**Table 1 Cont'd. Definition of variables and their scale of measurements**

<b>Age</b>	Age in years of a patient treated for tuberculosis.	Independent	Ordered Categorical - $\leq 20$ years - 21-40 - 41-60 - $\geq 60$ years.
<b>Sex</b>	Sex of respondents	Independent	Binary - Male - Female
<b>Duration of TB Treatment</b>	The duration of tuberculosis treatment in months	Independent	Binary - $< 6$ months - $\geq 6$ months
<b>HIV/AIDS Status</b>	Results of HIV/AIDS test done	Independent	Binary - Positive - Negative
<b>Disease Classification</b>	This is defined as whether a patient is diagnosed with smear positive TB, smear negative TB or extra-pulmonary TB	Independent	Categorical - Smear positive pulmonary TB - Smear negative pulmonary TB - Extra pulmonary TB
<b>Treatment Supporter</b>	This is a person who supports and guides a patient throughout the period of treatment. The person could be a relative or a health professional	Independent	Binary - Yes - No
<b>Adverse Drug Reaction</b>	This is where a patient experiences an unpleasant effects of anti-TB drugs.	Independent	

**Table 1 Cont'd. Definition of variables and their scale of measurements**

<b>Distance from place of residence.</b>	This is the distance from where the patient stays or lives at the time of treatment to the DOTS treatment Centre.	Independent	Binary <ul style="list-style-type: none"> <li>- Other Communities (&gt;5km)</li> <li>- Mampong(&lt;5 km)</li> </ul>
<b>Voluntary Counselling and testing (VCT) for HIV</b>	This is where HIV testing is suggested to a patient.	Independent	Binary <ul style="list-style-type: none"> <li>- Yes</li> <li>- No</li> </ul>
<b>Type of patient</b>	Describes patient's TB status before therapy initiation	Independent	Categorical <ul style="list-style-type: none"> <li>- New patient</li> <li>-Relapse</li> <li>- Transferred in</li> <li>- Treatment failure</li> <li>- Return of default</li> <li>- Other</li> </ul>
<b>Other Co-morbidities (e.g. diabetes mellitus)</b>	Diagnosis of other conditions including diabetes mellitus that can affect patient's recovery	Independent	Binary <ul style="list-style-type: none"> <li>- Yes</li> <li>- No</li> </ul>
<b>Treatment Success</b>	It includes patients with Cured and those with Treatment completion outcomes	Dependent	Binary <ul style="list-style-type: none"> <li>-Yes</li> <li>-No</li> </ul>
<b>Adverse Outcome (unsuccessful treatment)</b>	It includes patients with default, treatment failure and died outcomes	Dependent	Binary <ul style="list-style-type: none"> <li>-Yes</li> <li>-No</li> </ul>

### 3.4 STUDY POPULATION

The study population was made up of all records on patients diagnosed of tuberculosis who registered and received treatment at the counselling unit of Tetteh Quarshie Memorial hospital during the period January 2009 to December 2013.

#### **Inclusion criteria**

All available TB records from January 2009 to December 2013

#### **Exclusion criteria**

Records with incomplete data were excluded

### 3.5 SAMPLING

#### 3.5.1 SAMPLE SIZE ESTIMATION

All records of patients who received treatment for tuberculosis in the period under study (January 2009 to December 2013) were used. Although all medical records of patients who were treated in the period were used, the minimum sample size needed to carry out the required sub-analysis was calculated using Cochran formula as cited in (Puszczak& Fronczyk, 2013). Because the proportion of TB prevalence in the Municipality is unknown, 50% was assumed and substituted in the formula and the sample size was calculated as follows:

$$n = \frac{z^2 pq}{d^2}$$

Cochran (1963:75)

Where n=the desired sample size

z=the standard normal deviation

p=the proportion in the target population estimated to be 50 % (0.50)

q=1.0-p

d=degree of precision desired at 0.05

$$n = \frac{(1.96)^2 * (0.5)(0.5)}{(0.05)^2}$$

n=384.16

In order to take care of missing data or inconsistencies in recording of information on TB cards, a rate of 5% was factored in to give the required sample size of 403.

### **3.5.2 SAMPLING METHOD**

All available data on patients who received treatment for tuberculosis during the period under study (January 2009 to December 2013) were used.

### **3.6 DATA COLLECTION METHODS & TOOLS**

The data that were used for the study were obtained from medical records on patients treated for TB from January 2009 to December 2013. All the patients were expected to complete the treatment regimen by the 3<sup>rd</sup> quarter of the year 2014. The treatment cards of the patients who registered and received treatment at the counselling unit were kept in the records section of the unit. TB treatment cards of patients who went through treatment from 2009-2013 were selected. The data captured on the tuberculosis treatment card include age, sex, address of patient, name and address of treatment supporter and TB district number.

In addition, data on HIV voluntary counselling and testing, HIV status, disease classification, duration of treatment and treatment outcome were captured on this card. Data comprising all the study variables were retrieved from the TB cards and entered into a data abstraction sheet purposely designed for this study. The abstraction form contains all the relevant variables needed

to meet the study objectives. The extracted data were cross-checked using the TB register which is also kept in the same unit. At the end of each day of data collection, the data collected were double checked by the principal investigator and the treatment cards from which data were retrieved were kept safely in a cabinet. This was done until all the needed information had been retrieved.

### **3.7 QUALITY CONTROL**

The following measures were put in place to ensure that the data collected were of good quality:

- a. Two research assistants were recruited and trained to assist in data collection for the study.
- b. The Principal investigator supervised the data collection.
- c. The data collected were critically examined at the end of each day. Data handled by the research assistants were cross-checked by the principal investigator for consistency and completeness by verifying from the source records (TB cards). Research assistants also double checked data gathered by the principal investigator with the aim to achieve accuracy.

### **3.8 DATA PROCESSING & ANALYSIS**

#### **3.8.1. STATISTICAL METHODS**

The completed abstraction forms were cross-checked by the principal investigator. To ensure that data entry into the computer was accurate, the research assistants and the principal investigator independently cross-checked each entry.

Data were coded, entered and cleaned using excel and imported into Stata 13 for analysis. All the abstracted records for the period of January 2009 to December 2013 were therefore defined as the denominator. The different outcomes were grouped and expressed as a proportion of the total

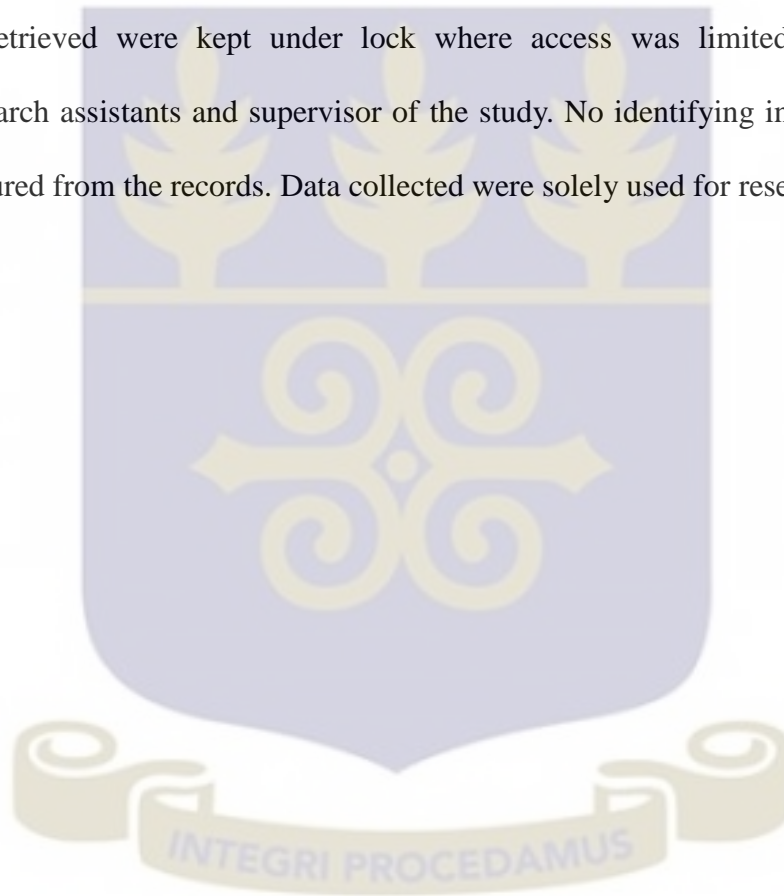
number of patients registered. Descriptive statistics was used to describe the frequencies and percentages of sex, age, distance of place of residence to DOTS centre, HIV status, and HIV voluntary counselling and testing, type of patient (new patient, treatment failure, relapse, transferred in, other and return after default), treatment supporter, and diagnostic category (sputum smear positive pulmonary TB, sputum smear negative pulmonary TB and extra-pulmonary TB). In comparing the various proportions, a chi square test of association was used to find significant differences among the different variables. Firstly, between treatment outcomes and demographic variables (sex, age and distance of place of residence to DOTS center) and secondly, treatment outcomes and other variables: HIV status, type of TB, treatment supporter, other co-morbidities (eg. diabetes mellitus), diagnostic category, duration of treatment and adverse drug reaction). A p-value of 0.05 was considered as statistically significant. To determine the strength of association between the treatment outcomes and the independent variables, logistic regression was used. Simple logistic analysis for crude odds ratio was estimated for the different independent variables. Multivariable analysis for adjusted odds ratio was done with 95% confidence interval.

### **3.9 PRETEST OF DATA COLLECTION TOOLS**

Pretesting was done at Adukrom Health centre which serves communities with similar characteristics as those treated at the TettehQuarshie Memorial hospital. It was done with research assistants to evaluate the time needed to complete each abstraction form, and also evaluate the training received by the research assistants

### **3.10 ETHICAL CONSIDERATION**

The study was submitted to the Ethical review committee of the Ghana Health Service Research and Development Division, Accra. It was reviewed and approved before the study commenced. The approval number is GHS-ERC 114/02/15. Permission was sought from the management of TettehQuarshie Memorial hospital before data collection. A room was solicited from the hospital authority to conduct the study to ensure privacy and confidentiality. The TB cards from which the data were retrieved were kept under lock where access was limited to the principal investigator, research assistants and supervisor of the study. No identifying information such as names were captured from the records. Data collected were solely used for research purpose.



## CHAPTER 4

### RESULTS

#### 4.1 Records of TB Patients and background characteristics of study participants

A total of 535 TB patients were registered during the period 2009-2013 at the hospital. Out of this, 415 (77.6%) had complete data and therefore used in the analysis. A total of 114 (21.3%) records were treated as incomplete data and not included in the analysis as some variables including disease classification and treatment outcome were not available. Six (1.1%) of the patients were transferred out to other treatment centres and therefore their treatment outcomes were undocumented so those patients were treated as lost to follow-up and also not included in the analysis (Table 2).

**Table 2. Records of Patients at Tetteh Quarshie Memorial Hospital (2009-2013)**

Year	All Attendants	Attendants with Complete Records (%)	Attendants with Incomplete Records (%)	Transferred-out (%)
2009	146	115(78.8)	28(19.2)	3(2.0)
2010	107	89(83.2)	17(15.9)	1(0.9)
2011	101	84(83.2)	17(16.8)	0(0.0)
2012	94	67(71.3)	25(26.6)	2(2.1)
2013	87	60(69.0)	27(31.0)	0(0.0)
<b>Total</b>	535	415(77.6)	114(21.3)	6(1.1)

The patients were aged 1 to 88 years (mean 42.7 years; standard deviation  $\pm$  19.4). Most patients 34.5% (143/415) were aged between 41- 60 years with a few 12.5% (52/415) aged 20 years and below. Majority of the patients were males (63.1%, 262/415). With respect to place of residence during treatment 73.7% (306/415) of the patients stayed in communities other than Mampong where the district hospital is located. Voluntary counselling and testing was done for all patients.

**Table 3. Background Characteristics of patients**

Variable	Frequency N= 415	%
<b>Age in Years</b>		
≤ 20	52	12.5
21-40	141	34.0
41-60	143	34.5
> 60	79	19.0
<b>Sex</b>		
Male	262	63.1
Female	153	36.9
<b>Residence</b>		
Mampong(<5km)	109	26.3
Other towns(>5km)	306	73.7
<b>HIV test</b>		
Tested	415	100
Not Tested	0	0.0
<b>HIV Status</b>		
Positive	114	27.5
Negative	301	72.5
<b>Other Comorbidities</b>		
Present	20	4.8
Absent	395	95.2
<b>Disease Classification</b>		
Sm+ PTB <sup>1</sup>	258	62.2
Sm- PTB <sup>2</sup>	136	32.8
Extra-pulmonary TB	21	5.1
<b>Duration of Treatment</b>		
< 6 Months	99	23.9
≥ 6 Months	316	76.1
<b>Type of Patient</b>		
New Patient	383	92.3
Relapse	8	1.9
Transferred in	7	1.7
Treatment Failure	8	1.9
Return of Default	9	2.2
<b>Treatment Supporter</b>		
Have	350	84.3
Do Not Have	65	15.7
<b>Adverse Drug Reaction</b>		
Reaction Recorded	23	5.5
No Reaction Recorded	392	94.5

<sup>1</sup>Sm+ PTB= smear positive pulmonary tuberculosis, <sup>2</sup>Sm- PTB= smear negative pulmonary tuberculosis

Few patients 20 (4.8%) had other comorbidities such as diabetes mellitus and hypertension. Twenty-one (5.1%) of the patients had extra-pulmonary TB. A greater number of patients 76.1% (316/415) spent six or more months during treatment. Most of the 415 patients 92.3% (383/415) were newly diagnosed cases of TB. A total of 350 (84.3%) patients had treatment supporters. Twenty-three (5.5%) of the patients reported adverse events of drugs. The most reported adverse events were headaches and skin rashes (Table 3).

#### 4.2. Tuberculosis Treatment Outcome

Of the 415 patients who participated in the study, 146 (35.2%) were cured, 167 (40.2%) completed treatment and 86 (20.7%) defaulted treatment. With respect to categorization of treatment outcome as Treatment Success and Adverse Outcome (Unsuccessful Outcome), a total of 313 (75.4%) recorded Treatment Success (Table 4).

**Table 4. Tuberculosis Treatment Outcome (2009-2013)**

Treatment outcome (All Type)	Frequency=415	%
Cured	146	35.2
Treatment Completion	167	40.2
Default	86	20.7
Treatment Failure	5	1.2
Died	11	2.7
<b>Treatment Success Rate</b>		
Treatment Success <sup>1</sup>	313	75.2
Adverse Outcome <sup>2</sup>	102	24.6

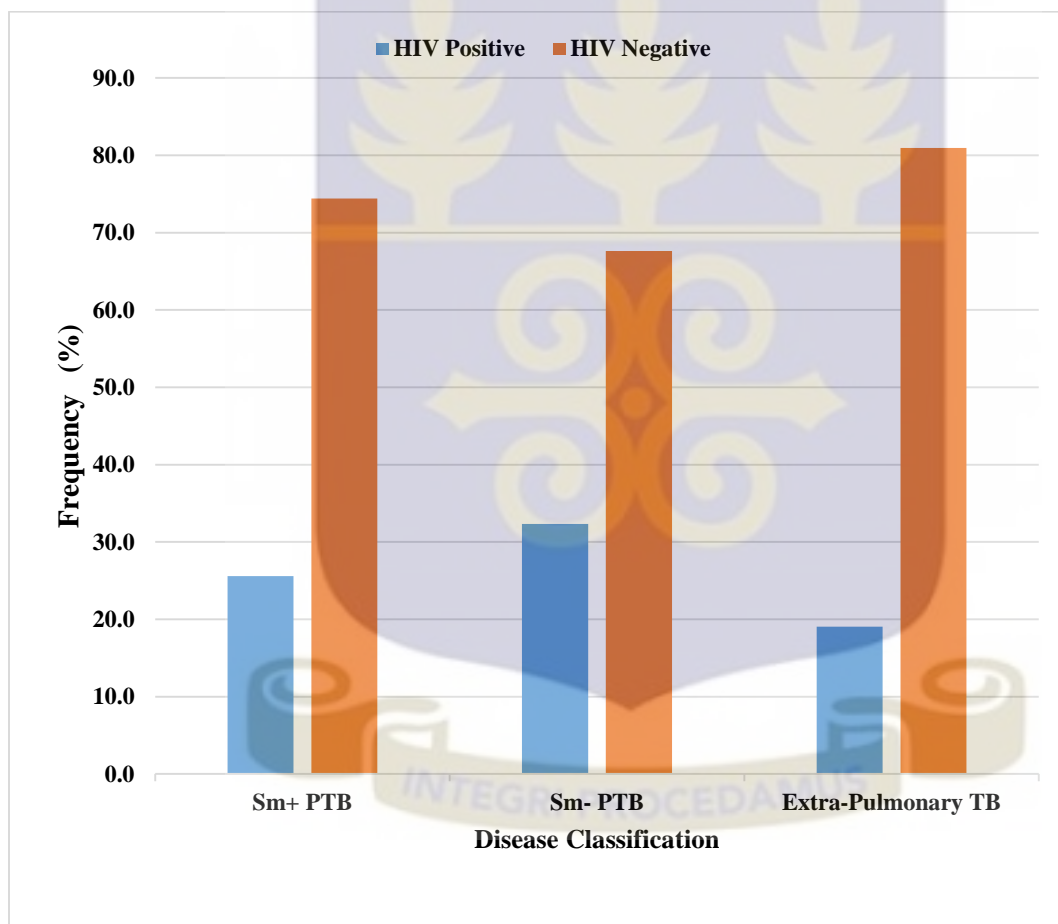
**Treatment Success<sup>1</sup> = Cured + Treatment completion,**

**Adverse Outcome<sup>2</sup> = Treatment failure + default + died**

### 4.3 HIV/TB co-infection

The proportion of patients with HIV/TB co-infection was 27.5% (114/415) (Table 3). All the disease classifications recorded HIV/TB co-infection. The sputum smear positive patients recorded 25.6% (66/258) slightly lower than those who were sputum smear negative 32.4% (44/136) (Figure 2).

**Figure 2. HIV/TB Co-infection among patients**



<sup>1</sup>PTB=pulmonary tuberculosis, <sup>2</sup>Sm+=sputum smear positive, <sup>3</sup>Sm-=sputum smear negative

#### 4.4. Patients Characteristics and Treatment Outcome (All Types)

The age groups 21-40 and the above 60 years had the highest proportion of patients who became cured 41.8% (59/141) and 41.8 % (33/79) respectively ( $p < 0.001$ ). The age group 20 years and below had the least patients defaulting 9.6% (5/52). The highest proportion of treatment completion 67.3% (35/52) was among patients 20 years and below, followed by the 41-60 years age group 44.1% (63/143).

Eleven patients died. This was made up of nine males. There was no significant difference between the proportion of females who defaulted treatment and the males (22.9% versus 19.5%;  $p = 0.66$ ). Again, there was no significant difference between patients who lived less than 5km during treatment and those who stayed more than 5km from treatment center (40.4% versus 41.3%;  $p = 0.33$ ).

From the analysis of patients HIV status and treatment outcome, more HIV negative patients were cured, 40.2% (121/301) compared to 21.7% (25/114) of HIV positive patients ( $p = 0.001$ ). In contrast, HIV positive patients had a better treatment completion rate of 43.0% (49/114) than HIV negative patients 39.2% (118/301). A significant proportion of patients with HIV/TB co-infection, 31.6% defaulted treatment. With respect to the presence of other comorbidities as a factor affecting TB treatment outcome, most patients without other comorbidities recorded treatment completion 40.3% (159/395), and it is significantly associated with treatment outcome ( $p < 0.001$ ). Patients who were treated for smear positive pulmonary TB formed the majority of the disease classification category and most of them were cured 56.6% (146/258;  $p < 0.001$ ). The extra-pulmonary TB patients had the highest proportion of treatment completion 85.7% (18/21). Similarly, smear negative patients defaulted most (53/136, 39.0%;  $p < 0.001$ ). The duration of treatment of more than six months was significantly associated with treatment outcome ( $p < 0.001$ ) (Table 5).

**Table 5. Patients' Characteristics and Treatment Outcome (All Type)**

Variable	Treatment		Outcome	N (%)		Pearson chi2(p-value)
	Cured	Treatment Completion	Default	Treatment Failure	Died	
<b>Age in years</b>						37.74(<0.001)
≤ 20	12(23.1)	35(67.3)	5(9.6)	0(0.0)	0(0.0)	
21-40	59(41.8)	42(30.0)	34(24.1)	4(2.8)	2(1.4)	
41-60	42(29.4)	63(44.1)	34(23.8)	0(0.0)	4(2.8)	
> 60	33(41.8)	27(34.2)	13(16.5)	1(1.3)	5(6.3)	
<b>Sex</b>						2.42(0.66)
Male	91(34.7)	108(41.2)	51(19.5)	3(1.2)	9(3.4)	
Female	55(36.0)	59(38.6)	35(22.9)	2(1.3)	2(1.3)	
<b>Residence</b>						4.63(0.33)
<5km	44(40.4)	45(41.3)	16(14.7)	2(1.8)	2(1.8)	
>5km	102(33.3)	122(39.9)	70(22.9)	3(1.0)	9(2.9)	
<b>HIV Status</b>						19.41(0.001)
Positive	25(21.9)	49(43.0)	36(31.6)	0(0.0)	4(3.5)	
Negative	121(40.2)	118(39.2)	50(16.6)	5(1.7)	7(2.3)	
<b>Other Comorbidities</b>						26.62(<0.001)
Present	7(35.0)	8(40.0)	1(5.0)	0(0.0)	4(20.0)	
Absent	139(35.2)	159(40.3)	85(21.5)	5(1.3)	7(1.8)	
<b>Disease Classification</b>						164.81(<0.001)
<sup>1</sup> Sm+ PTB	146(56.6)	67(26.0)	31(12.0)	5(1.9)	9(3.5)	
<sup>2</sup> Sm- PTB	0(0.0)	82(60.3)	53(39.0)	0(0.0)	1(0.7)	
Extra-pulmonary TB	0(0.0)	18(85.7)	2(9.5)	0(0.0)	1(4.8)	
<b>Duration of Treatment</b>						399.84(<0.001)
< 6 Months	0(0.0)	0(0.0)	84(84.9)	4(4.0)	11(11.1)	
≥ 6 Months	146(46.2)	167(52.9)	2(0.6)	1(0.3)	0(0.0)	
<b>Type of Patient</b>						83.72(<0.001)
New Patient	142(37.1)	156(40.7)	75(19.6)	4(1.0)	6(1.6)	
Relapse	1(12.5)	1(12.5)	6(75.0)	0(0.0)	0(0.0)	
Transferred in	2(28.6)	1(14.3)	1(14.3)	1(14.3)	2(28.6)	
Treatment Failure	1(12.5)	5(62.5)	2(25.0)	0(0.0)	0(0.0)	
Return of Default	0(0.0)	4(44.4)	2(22.2)	0(0.0)	3(33.3)	
<b>Treatment Supporter</b>						107.13(<0.001)
Have	142(40.6)	152(43.4)	42(12.0)	5(1.4)	9(2.6)	
Do Not Have	4(6.2)	15(23.1)	44(67.7)	0(0.0)	2(3.1)	
<b>Adverse Drug Reaction</b>						49.30(<0.001)
Reaction Recorded	1(4.6)	3(13.0)	16(69.6)	0(0.0)	3(13.0)	
No Reaction Recorded	145(37.0)	164(41.8)	70(17.9)	5(1.3)	8(2.0)	

<sup>1</sup>Sm+= smear positive pulmonary TB, <sup>2</sup>Sm- =smear negative pulmonary TB

With respect to the type of patients, majority 383 (92.3%) were new patients. They had the highest proportion of cured patients 142 (37.1%) than those who relapsed, transferred in, treated after default and treatment failure ( $p < 0.001$ ). Patients who had treatment supporters during the treatment period had a greater chance of achieving treatment completion than those who did not (43.4% versus 23.1%;  $p < 0.001$ ). The other predictor variable associated with treatment outcome was absence of drug reaction (Table 5).

#### **4.5 Patient characteristics and Treatment Outcome (Grouped)**

Treatment success was highest, 92.3% (48/52) among patients 20 years and below, patients aged 21-40 years recorded the lowest success rate 71.6% (101/141). The latter age category again had the highest proportion of adverse outcome 28.4% (40/141;  $p = 0.03$ ). Staying less than 5km and the absence of other comorbidities were not associated with treatment success. A negative HIV status had significant association with successful treatment 80.1% (241/301;  $p < 0.001$ ). Patients who were classified as suffering from extra-pulmonary TB had the highest proportion of treatment success 85.7% compared with the smear positive and smear negative disease classifications ( $p < 0.001$ ).

The length of treatment of six months or more was also associated with treatment outcome 98.7% (312/316;  $p < 0.001$ ). New patients had a higher proportion of treatment success 78.3% (300/383) compared with those who relapsed, transferred in and return of default ( $p < 0.001$ ). As expected, the study revealed that patients with treatment supporters had a better treatment success rate 84.3% (295/350) compared with those without treatment supporters ( $p < 0.001$ ), as well as the absence of adverse TB drug reaction 79.1% (310/392;  $p < 0.001$ ) [Table 6].

**Table 6. Patients' Characteristics and Treatment Outcome (Grouped)**

Variable	Treatment		Outcome N (%)	Pearson chi2 (p-value)
	Success <sup>1</sup>	Adverse Outcome <sup>2</sup>		
<b>Age in Years</b>				9.30(0.03)
	≤ 20	48(92.3)	4(7.7)	
	21-40	101(71.6)	40(28.4)	
	41-60	106(74.1)	37(25.9)	
	> 60	60(76.0)	19(24.0)	
<b>Sex</b>				0.26(0.61)
	Male	201(76.7)	61(23.3)	
	Female	114(74.5)	39(25.5)	
<b>Residence</b>				3.59(0.06)
	<5km	90(82.6)	19(17.4)	
	>5km	225(73.5)	81(26.5)	
<b>HIV Status</b>				10.38(0.001)
	Positive	74(64.9)	40(35.1)	
	Negative	241(80.1)	60(19.9)	
<b>Other Comorbidities</b>				0.01(0.92)
	Present	15(75.0)	5(25.0)	
	Absent	300(76.0)	95(24.0)	
<b>Disease Classification</b>				22.22(<0.001)
	<sup>3</sup> Sm+ PTB	213(82.6)	45(17.4)	
	<sup>4</sup> Sm-PTB	84(61.8)	52(38.2)	
	Extra-pulmonary TB	18(85.7)	3(14.3)	
<b>Duration of Treatment</b>				377.50(<0.001)
	< 6 Months	3(3.0)	96(97.0)	
	≥ 6 Months	312(98.7)	4(1.3)	
<b>Type of Patient</b>				21.62(<0.001)
	New Patient	300(78.3)	83(21.7)	
	Relapse	2(25.0)	6(75.0)	
	Transferred in	3(42.9)	4(57.1)	
	Treatment Failure	6(75.0)	2(25.0)	
	Return of Default	4(44.4)	5(55.6)	
<b>Treatment Supporter</b>				85.84(<0.001)
	Have	295(84.3)	55(15.7)	
	Do Not Have	20(30.8)	45(69.2)	
<b>Adverse Drug Reaction</b>				39.06(<0.001)
	Reaction Recorded	5(21.7)	18(78.3)	
	No Reaction Recorded	310(79.1)	82(20.9)	

**Treatment Success = Cured + Treatment completion, Adverse Outcome = Treatment failure + default + died**

<sup>3</sup>Sm+ = smear positive pulmonary TB, <sup>4</sup>Sm- = smear negative pulmonary TB

#### **4.6 Crude Odds Ratio and factors associated with Treatment Success**

A univariate logistic regression model to test the strength of association revealed that all age groups above 20 years were less likely to achieve treatment success compared to those aged 20 years and below. There was a strong evidence of association between treatment success, HIV status, and treatment supporter ( $p < 0.05$ ). A relapsed patient was less likely to achieve treatment success. A transferred-in patient or a patient who returned to treatment after default was more likely to have adverse outcome than completing treatment or being cured.

Patients with smear negative pulmonary TB were about 70% less likely to achieve treatment success compared with smear positive patients (OR 0.32 CI 0.20-0.51). Patients with extra-pulmonary TB were 1.27 times more likely to have treatment success though this finding was not statistically significant. Those who experienced adverse drug reaction were less likely to have treatment success compared to those who did not have adverse reaction (OR 0.06 CI 0.02-0.17) (Table 7).

#### **4.7 Adjusted Odds Ratio and Factors associated with Treatment Success**

In the multivariate logistic regression, having a treatment supporter was strongly associated with treatment outcome (aOR 9.69 CI 4.89-19.21). Patients aged 20 years and below were more likely to achieve treatment success compared with those more than 60 years. Patients with adverse drug reactions were independently associated with adverse treatment outcome (Table 8).

**Table 7. Crude Odds Ratio and factors associated with Treatment Success**

Variable	Treatment Success <sup>3</sup>		cOR <sup>4</sup>	95%CI	P-value
	Yes n (%)	No n (%)			
<b>Age in Years</b>					
≤ 20	48(92.3)	4(7.7)	1(-)		
21-40	101(71.6)	40(28.4)	0.27	0.10-0.72	0.01
41-60	106(74.1)	37(25.9)	0.29	0.11-0.79	0.02
> 60	60(76.0)	19(24.0)	0.33	0.12-0.96	0.04
<b>Sex</b>					
Male	201(76.7)	61(23.3)	1(-)		
Female	114(74.5)	39(25.5)	0.93	0.58-1.47	0.74
<b>Residence</b>					
<5km	90(82.6)	19(17.4)	1(-)		
>5km	225(73.5)	81(26.5)	0.61	0.35-1.06	0.08
<b>HIV Status</b>					
Positive	74(64.9)	40(35.1)	1(-)		
Negative	241(80.1)	60(19.9)	2.08	1.29-3.35	0.002
<b>Other Comorbidities</b>					
Present	15(75.0)	5(25.0)	0.97	0.35-2.76	0.96
Absent	300(76.0)	95(24.0)	1(-)		
<b>Disease Classification</b>					
Sm+ <sup>1</sup> PTB	213(82.6)	45(17.4)	1(-)		
Sm- <sup>2</sup> PTB	84(61.8)	52(38.2)	0.32	0.20-0.51	<0.001
Extra-pulmonary TB	18(85.7)	3(14.3)	1.27	0.36-4.49	0.71
<b>Duration of Treatment</b>					
< 6 Months	2(2.0)	96(98.0)	1		
≥ 6 Months	313(98.7)	4(1.3)	1(-)		
<b>Type of Patient</b>					
New Patient	300(78.3)	83(21.7)	1(-)		
Relapse	2(25.0)	6(75.0)	0.95	0.02-0.48	0.004
Transferred in	3(42.9)	4(57.1)	0.21	0.05-0.97	0.05
Treatment Failure	6(75.0)	2(25.0)	0.86	0.17-4.32	0.85
Return of Default	4(44.4)	5(55.6)	0.23	0.06-0.87	0.03
<b>Treatment Supporter</b>					
Have	295(84.3)	55(15.7)	12.71	6.93-23.30	<0.001
Do Not Have	20(30.8)	45(69.2)	1(-)		
<b>Adverse Drug Reaction</b>					
Reaction Recorded	5(21.7)	18(78.3)	0.06	0.02-0.17	<0.001
No Reaction Recorded	310(79.1)	82(20.9)	1(-)		

<sup>1</sup>Sm+ PTB= smear positive pulmonary tuberculosis, <sup>2</sup>Sm- PTB= smear negative pulmonary tuberculosis. Treatment Success<sup>3</sup>=Cured + Treatment completion, cOR<sup>4</sup>= crude odds ratio.

**Table 8. Adjusted Odds Ratio and Factors associated with Treatment Success**

Variable	Treatment Success <sup>3</sup>		aOR <sup>4</sup>	95%CI	P-value
	Yes (%)	No n (%)			
<b>Age in Years</b>					
≤ 20	48(92.3)	4(7.7)	1(-)		
21-40	101(71.6)	40(28.4)	0.28	0.09-0.85	0.03
41-60	106(74.1)	37(25.9)	0.35	0.11-1.06	0.06
> 60	60(76.0)	19(24.0)	0.27	0.08-0.89	0.03
<b>Sex</b>					
Male	201(76.7)	61(23.3)	1(-)		
Female	114(74.5)	39(25.5)	0.96	0.53-1.75	0.9
<b>Residence</b>					
<5km	90(82.6)	19(17.4)	1(-)		
>5km	225(73.5)	81(26.5)	0.54	0.27-1.08	0.08
<b>HIV Status</b>					
Positive	74(64.9)	40(35.1)	1(-)		
Negative	241(80.1)	60(19.9)	1.36	0.72-2.59	0.34
<b>Other Comorbidities</b>					
Present	15(75.0)	5(25.0)	0.74	0.21-2.62	0.64
Absent	300(76.0)	95(24.0)	1(-)		
<b>Disease Classification</b>					
<sup>1</sup> Sm+ PTB	213(82.6)	45(17.4)	1(-)		
<sup>2</sup> Sm- PTB	84(61.8)	52(38.2)	0.26	0.15-0.47	<0.001
Extra-pulmonary TB	18(85.7)	3(14.3)	0.87	0.20-3.72	0.85
<b>Type of Patient</b>					
New Patient	300(78.3)	83(21.7)	1(-)		
Relapse	2(25.0)	6(75.0)	0.14	0.02-1.01	0.05
Transferred in	3(42.9)	4(57.1)	0.23	0.02-0.75	0.02
Treatment Failure	6(75.0)	2(25.0)	0.5	0.09-2.79	0.43
Return of Default	4(44.4)	5(55.6)	0.57	0.12-2.82	0.5
<b>Treatment Supporter</b>					
Have	295(84.3)	55(15.7)	9.69	4.89-19.21	<0.001
Do Not Have	20(30.8)	45(69.2)			
<b>Adverse Drug Reaction</b>					
Reaction Recorded	5(21.7)	18(78.3)	0.12	0.03-0.44	0.001
No Reaction Recorded	310(79.1)	82(20.9)			

<sup>1</sup>Sm+ PTB= smear positive pulmonary tuberculosis, <sup>2</sup>Sm- PTB = smear negative pulmonary tuberculosis.

Treatment Success<sup>3</sup>=Cured + Treatment completion, aOR<sup>4</sup>= Adjusted odds ratio.

## CHAPTER FIVE

### DISCUSSIONS

This was a cross-sectional study involving the review of records on TB patients who sought care at TettehQuarshie Memorial Hospital from 2009 to 2013. The purpose of the study was to determine the treatment outcome of patients and associated factors over the period. Of the 415 records reviewed, 146 (35.2%) were cured, 167 (40.2%) completed treatment and 86 (20.7%) defaulted treatment. Patients with HIV/TB co-infection were 114 (27.5%). Having a treatment supporter was significantly associated with treatment outcome (aOR 9.69 CI 4.89-19.21).

A high number of patients' data 114 (21.3%) were incomplete especially on disease classification and treatment outcome. This is noteworthy and could be mainly as a result of lapses in staff documentations and patients' follow-up services. This observation points to an urgent need to improve TB programme documentations and follow up procedures by health personnel responsible for TB care in the hospital in order to minimise default outcome and the spread of drug resistant TB.

An earlier study by Gafar (2013), to determine factors affecting treatment outcomes in tuberculosis patients in Limpopo province, South Africa revealed that 15% of the data were incomplete. This was as a result of inadequate follow ups of TB patients in the province. The number of patients who sought care at the hospital over the period decreased consistently year by year from 2009 to 2013 (Table 2). Possibly due to effective health promotion programmes on TB prevention and management in the municipality. Some reports have shown similar observations.

The Eastern Regional Health Administration 2011 Annual Report showed a decreasing trend in TB case detection from 81.8% in 2009 to 74.7% in 2011 (Report, 2011).

Ghana Health Service report on the prevalence rate of TB in Ghana demonstrated a downward trend from 311/100,000 cases in 1990 to 106/100,000 cases in 2010 and this was attributed to the implementation of multiple interventions by the Ghana Health Service and relevant stakeholders in health (Report, 2011b). This suggests that the municipality should intensify health promotion activities to ensure further decline in TB prevalence.

According to WHO 2012, the global target for TB treatment success in line with the MDG's is 85%. This target also serves as a benchmark for assessing the performance of tuberculosis control programs worldwide. In this study, the overall treatment success which is the total proportion of patients that were cured and those that completed treatment was 75.2%. This was lower than Ghana's success rate for 2011 of 86.5% (NTP, 2011) and 84% success rate for new and relapse TB cases in Ghana in 2012 (WHO, 2014). This 75.2% success rate could be as a result of the high default rate (20.7%) recorded in the study. Another study by Azagba (2013) to determine treatment outcomes using treatment supporters in Ketu South Municipality revealed a similar success rate (79.6%) and attributed it to problems with using treatment supporters. This study's success rate though lower is better than what was reported in a study conducted in a University Teaching hospital in Northwest Ethiopia that showed only 30% success rate (Tessema et al., 2009). The low success rate according to that study was due to high transferred out rate (42%), default rate (18.3%) and death rate (10.1%). So the study suggested that the high treatment default rate deserved special attention. The low success rate in this study could also be due to the high default rate (20.7%) recorded. A successful treatment outcome could depend on patients'

motivation by the staff to ensure full adherence to the treatment regimen. Active supervision and monitoring measures should be used to achieve better treatment success in future.

As indicated earlier, a total of 86 patients representing 20.7% defaulted treatment. This is far more than the WHO target of less than 5% default rate. This is comparable to a study conducted to determine predictors of TB treatment default among informal dwellers in Ethekewini municipality in South Africa where a defaulter rate of 18.9% and 29% were recorded in 2007 and 2009 respectively. In 2011, the same municipality reported a defaulter rate of 24.3%, all these were far higher than the WHO default rate target. These high default rates were attributed to excessive smoking, alcohol use and having a family member with TB (Rajagopaul et al., 2014). Another study by Dodor and Afenyadu (2005) in Ghana reported a high default rate of 13.9% and attributed it to old age and TB disease stigma. Recent studies on factors that influence default in different parts of the world, particularly in the sub-Saharan Africa region have demonstrated that being a male, ignorance on the need for treatment compliance and disease stigma have an association with default (Muture et al., 2011; Belay et al., 2009). A contrary finding was seen in a study to assess tuberculosis treatment outcome among TB patients at treatment centers in Ibadan Nigeria, out of 1,254 patients, only 6.6% defaulted treatment, and this was as a result of improvement in service delivery at the treatment centers (Fatiregun, et al., 2009). The high default rate in this study suggests that measures used by the municipal TB control programme to improve adherence to anti- TB drugs may not be enough or recommendations on treatment monitoring by WHO which aim to improve TB patients' compliance were not optimally implemented. Therefore, monitoring strategies such as contact tracing of patients should be improved to help reduce the high default rate.

Ghana recorded 11,387 (73%) patients with HIV/TB co-infection in 2013 (WHO, 2014). According to this study, 114 (27.5%) patients had HIV/TB co-infection. A similar situation was realized in a retrospective study in FelegeHiwot Referral Hospital, Northwest Ethiopia where HIV/TB co-infection was 25% (Biadlegne, Anagaw, Debebe, & Anagaw, 2013). A study to determine TB-HIV co-infection and possible associated factors among patients in DebreMarkos Referral Hospital in Northwest Ethiopia reported a higher HIV/TB co-infection rate (44%) (Esmael et al., 2013). The high HIV/TB co-infection rate seen in this study could be as a result of the hospital's role as the referral and treatment centre for HIV/AIDS cases in the municipality, so all TB patients and other patients with signs and symptoms suspicious of HIV infections are routinely tested for HIV. This process might have led to increased detection of HIV infection in the facility. This high rate may also indicate that HIV/AIDS is still a major problem in the municipality.

The multivariate logistic regression analysis showed that patients in the age group of more than sixty years were less likely to achieve treatment success compared to the 20 years and below age group.

According to WHO, treatment outcome in children are generally good, even in immune-compromised ones who are at a higher risk of disease progression, provided that treatment is initiated early (WHO, 2006). This result was expected because patients in this age group were children and adolescents who mostly receive their treatment through their parents and this may play an important role in improvement of compliance. This study also revealed that the more than 60 years age group was significantly associated with death. A situation similar to studies from other parts of the world. A study on factors affecting treatment outcome for pulmonary TB

in Istanbul, Turkey showed a significant association between adverse treatment outcome and age more than 65 years, especially those with other chronic condition like hypertension (Babalık, Kılıçaslan, Kızıldaş, Gencer, & Öngen, 2013). An earlier study to determine factors influencing the successful treatment of infectious pulmonary TB in Taiwan also revealed that patients of advanced age were less likely to achieve treatment success. This was as a result of non-adherence to anti-tuberculosis treatment and advanced disease (Chung, Chang, & Yang, 2007). Advanced age has been reported to be a risk factor for death, partly due to the general physiological deterioration with age (Collins, 2012). Because of these observations, it is vital for health workers in the hospital to exercise close monitoring of TB treatment in older patients.

From the multivariate logistic regression analysis, the proportion of females with treatment success was slightly lower than males and females were less likely to have treatment success compared with males though this was not statistically significant. This may be due to the higher number of females with adverse outcomes, it could also mean more males followed the treatment regimen better than females. A similar results was reported in a study of tuberculosis among Medical Doctors in South Africa, where there was no statistically significant difference in the sexes and treatment outcome (Naidoo, Naidoo, Gathiram, & Lalloo, 2013). On the contrary, a study in Nigeria showed that default was associated with males more than females (Effiong & Nwakaego, 2015). In other studies where differences have been reported in outcomes between the sexes, the females were more likely to have successful treatment outcome (Babalik et al., 2013; Belay et al., 2009; Doodley et al., 2011; Muture et al., 2011). Reasons for the high female unfavourable outcomes in this study should be explored further and solutions implemented to change the situation.

Information on the distance from place of residence to treatment centre was retrieved to determine its association with treatment success. Though not statistically significant, patients who lived more than 5km during treatment were less likely to have treatment success compared with those who lived less than 5km. This may be as a result of the proximity to the treatment centre and reduced transportation cost. The place of stay during treatment of most of the TB patients were far away from the treatment centre. Some patients came from neighbouring districts. In addition, many roads are inaccessible in the municipality, especially during the rainy season, and this may negatively affect compliance with TB treatment. This finding agrees with studies where long distance travelled by TB patients from home to treatment center was associated with adverse treatment outcome (Ai et al., 2010; Boateng, Kodama, Tachibana, & Hyoui, 2010).

A study by Salgar (2014), to determine treatment outcomes of TB patients in Azezo Health Centre, Ethiopia revealed a significant successful treatment outcome among HIV negative patients compared with HIV positive patients. This was as a result of high death rate among HIV positive patients. Another study revealed that HIV negative patients on TB treatment were associated with better treatment success when compared with HIV positive patients (Ayeno, Regasa, Lenjisa, & Tesfaye, 2014). The above findings mirror well with this study results where patients who were tested HIV negative were about two times more likely to achieve treatment success compared with HIV positive patients. This was not statistically significant. This could mean that the immunocompromised state of HIV positive patients affects their recovery. However, according to Collins (2012), being HIV seropositive was significantly associated with better treatment success rate and he attributed this to the variability in treatment protocols of

seropositive TB patients and seronegative TB patients. A report by Daniel et al. (2006) explained TB/HIV co-infection relationships by pointing out that, HIV/TB co-infected patients often had to attend separate clinics or health facilities for TB and HIV care services, thus increasing transport and other costs. Besides, the drugs adverse effects profile is magnified in patients on concurrent anti-retroviral therapy (ART) and anti-TB drugs (Fry, Khoshnood, Vdovichenko, Granskaya, Sazhin & Shpakovskaya, 2005). Integration of HIV and TB services is good though may be difficult, should be used to help improve health care delivery to patients.

The prevalence of other comorbidities (diabetes mellitus and hypertension) among patients in the study was 4.8%. Twenty percent of these patients died. These patients were less likely to achieve treatment success compared to those without these comorbidities. It can be explained that these other diseases might have negatively influenced the affected patients' treatment outcome. Recent studies to identify risk factors of treatment default in South Africa revealed that drinking of any alcohol beverage during treatment was associated with default (Finlay et al., 2012; Rajagopaul, Kistnasamy, & Reddy, 2014). Another study found treatment outcomes among TB patients with or without diabetes mellitus to be similar (Pablo-villamor et al., 2014).

Majority of the patients in this study had smear positive tuberculosis (62.2%). These patients were more likely to achieve treatment success compared to participants with smear negative TB. The high default rate (39.0%) among the smear negative patients could probably be the reason for the low success rate. A similar finding was realised in a study in Benin where smear negative patients had a higher proportion of unsuccessful treatment outcome compared with smear positive patients owing to death and loss to follow ups of the patients (Ade, et al., 2013). But a study in Andhra Pradesh, India found smear negative patients with better treatment outcomes

than smear positive patient (Srinath, Sharata, Santosha, Chadha, Roopa, Chandha, ...Harries, 2011). Therefore, diagnostic procedures should be strengthened to improve TB diagnosis.

Other patients (relapsed, transferred in and return of default) were less likely to achieve treatment success compared with new patients. This could probably be due to inadequate supervision and education on treatment expectations to these patients. In a study by Suárez-Garcia et al. (2009), patients who had history of TB treatment were more likely to have adverse treatment outcomes compared with new patients. Having a history of default was a significant risk factor to default treatment again (Finlay et al., 2012). Continuous health education programs can enormously improve patients' adherence to treatment regimen.

Treatment supporters are very essential in TB treatment. They are selected to support patients on anti-tuberculosis drugs in order to help them complete the full course of the medications. According to Ali (2008), treatment supporters were collecting TB drug for their patients monthly and were giving it to them daily. He also indicated that out of 71 patients under direct supervision of treatment supporters, 61 completed treatment. The presence of a treatment supporter as seen in this study was independently associated with treatment success (AOR 9.69, CI4.89-19.21).

A similar reflection was revealed by Boateng et al. (2010), where patients with treatment supporters mostly relatives, were less likely to default treatment. Therefore, the presence of a treatment supporter is pivotal in ensuring that patients adhere to their treatment regimen. All efforts should be made to use them in the DOTS strategy.

Headaches, skin rashes and bodily weaknesses were the adverse drug reactions reported in this study. In all, twenty three patients (5.5%) experienced these adverse drug reactions. Patients who did not experience any adverse drug reaction were more likely to achieve treatment success compared with those who had adverse drug reactions. A study in the New Juabeng municipality in Ghana found that treatment default was significantly associated with adverse effect of drugs (Boateng et al.,2010). In view of the above, it is necessary for the staff to spend more time on educating and allaying the fears of the patients on possible side effects of the drugs.

### **5.1 LIMITATIONS**

This study like other studies was not devoid of limitations. It was a retrospective study and based only on data that were available on the patients' treatment cards. It was not possible to collect additional data to confirm or refute the findings of the study. At the time the data were being extracted, some of the records were incomplete, hence there could be underestimation of the actual treatment outcomes.

### **5.2 STRENGTHS**

Notwithstanding the above limitations, the length of the study period conferred rigour to the analysis and make the inferences arising from it valid and relevant.

## CHAPTER SIX

### CONCLUSIONS AND RECOMMENDATIONS

#### 6.1 Conclusion

This study identified factors associated with TB treatment outcome at the TettehQuarshie memorial hospital which is the main TB treatment centre in the Akuapem North municipality. The study identified that the treatment success rate of 75.4% was lower than the national average of 86.5% for 2011 and WHO targets of 85%. The presence of a treatment supporter was associated with treatment success. Adverse treatment outcome was associated with patients aged more than 60 years, a smear negative and transferred-in patients as well as patients who experienced adverse drug reactions.

#### 6.2 Recommendations

In order to improve the treatment success of TB patients in the hospital and in the municipality as a whole, the following recommendations were made:

##### 6.2.1 Tetteh Quarshie Memorial hospital

1. The use of treatment supporters to help patients on treatment should be encouraged.
2. Enhanced supervision, adequate monitoring and follow ups of treatment outcomes of all transferred-out patients in all TB treatment centres countrywide and recording them in the treatment cards should be ensured.
3. Intensify patients' education on the importance of completing the full course of treatment.
4. Defaulter tracing by health care workers to reduce treatment interruption should be encouraged.

5. Documentation of patients details by Staff should be taken very seriously as these records are used to monitor the effectiveness of the TB control programme.

6. Further studies with a larger sample size is recommended.

### **6.2.2 Ghana Health Service/National TB control Programme**

1. Ghana Health service should come out with a policy to test all TB patients in Ghana for diabetes mellitus.



## References

- Abebe, G., Deribew, A., Apers, L., Woldemichael, K., Shiffa, J., Tesfaye, M., ... Colebunders, R. (2010). Knowledge, health seeking behavior and perceived stigma towards tuberculosis among tuberculosis suspects in a rural community in Southwest Ethiopia. *PLoS ONE*, 5. <http://doi.org/10.1371/journal.pone.0013339>
- Addo, K.K., Owusu –Darko, K., Yeboah –Manu, D., Minamikawa. M., Bonsu, F., Lienhardt C.....Ofori- Adjei, D. (2007). Mycobacterial species causing pulmonary tuberculosis at the Korle-Bu Teaching Hospital, Accra, Ghana. *Ghana Medical Journal*, 41 (2):52-57
- Ade, S., Harries, A. D., Trébucq, A., Hinderaker, S. G., Adè, G., Agodokpessi, G., ... Anagonou, S. (2013). National profile and treatment outcomes of adult smear-negative pulmonary TB patients in Benin. *Transactions of the Royal Society of Tropical Medicine and Hygiene*, 107 (12), 783–788. <http://doi.org/10.1093/trstmh/trt09>
- Afutu, F. K., Zachariah, R., Hinderaker, S. G., Obeng, E. A., Bonsu, F. A., & Harries, A. D. (2012). High initial default in patients with smear-positive pulmonary tuberculosis at a regional hospital in Accra, Ghana. *Transactions of the Royal Society of Tropical Medicine and Hygiene*, 10–12. <http://doi.org/10.1016/j.trstmh.2012.05.002>
- Agarwal, S. P., Dipanjan, R., & Chauhan, L. S. (2004). *Tb –hiv a lethal combination*.pp 145-154. Retrieved from <http://tbcindia.nic.in/pdfs/Tuberculosis%20Control%20in%20India16.pdf>
- Ai, X., Men, K., Guo, L., Zhang, T., Zhao, Y., Sun, X., ... Van Den Hof, S. (2010). Factors associated with low cure rate of tuberculosis in remote poor areas of Shaanxi Province, China: a case control study. *BMC Public Health*, 10 (1), 112.
- Ali, D.A. (2008).TB-dots program. Retrieved from: <http://www.theprofesional.com/article/2008/Vol-15-No-04/Prof-1388.pdf>
- Amo-Adjei, J., & Awusabo-Asare, K. (2013).Reflections on tuberculosis diagnosis and treatment outcomes in Ghana. *Archives of Public Health =Archives Belges d Santé Publique*, 71(1), 22. [doi.org/10.1186/2049-3258-71-22](http://doi.org/10.1186/2049-3258-71-22)
- Amoran, O., Osiyale, O., &Lawal, K. (2011). Pattern of default among tuberculosis patient on directly observed therapy in rural primary health care centres in Ogun State Nigeria. *Academic Journals*, 3: 90–95. Retrieved from [http://academicjournals.org/JIDI/PDF/pdf2011/May/Osiyale et al.pdf](http://academicjournals.org/JIDI/PDF/pdf2011/May/Osiyale%20et%20al.pdf)
- Ayeno, H. D., Regasa, B. M., Lenjisa, J. L., & Tesfaye, G. (2014). A three years tuberculosis treatment out come at Adama hospital of Medical College , southeast Ethiopia , a retrospective cross-sectional analysis: *International Journal of Pharmaceutical and Biological Sciences Research and Development JPBSR* 2:1–162, 1–16.

- Ayisi, J. G., van't Hoog, A. H., Agaya, J. A., Mchembere, W., Nyamthimba, P. O., Muhenje, O., & Marston, B. J. (2011). Care seeking and attitudes towards treatment compliance by newly enrolled tuberculosis patients in the district treatment programme in rural western Kenya: a qualitative study. *BMC Public Health*, *11* (1), 515.
- Azagba, C.K.(2013).Tuberculosis treatment outcomes using treatment supporters in Ketu South Municipality of Volta Region in Ghana. Retrieved from <http://ugspace.ug.edu.gh>, (2013), (July).Retrieved on 24<sup>th</sup> November,2014.
- Babatunde, O. A. (2013). Factors affecting treatment outcomes of tuberculosis in a tertiary health center in southwestern Nigeria..*International Review of Social Sciences and Humanities*, *4* (2) pp. 209–218.
- Babalık, A., Kılıçaslan, Z., Kızıltaş, Ş., Gencer, S., & Öngen, G. (2013). A Retrospective Case-Control Study , Factors Affecting Treatment Outcomes for Pulmonary Tuberculosis in İstanbul , Turkey, *Balkan Medical Journal* 204–210. doi.org/10.5152/balkanmedj.2013.005
- Barker, R. D. (2008). Clinical tuberculosis. *Medicine*, *36* (6), 300–305.
- Belay, T., Abebe, M., &Assegedech, B. (2009).Treatment outcome of tuberculosis patients at Gondar University Teaching Hospital. *BMC Public Health*; 9:371:5.
- Berhe, G., Enquesselassie, F., & Aseffa, A. (2012). Treatment outcome of smear-positive pulmonary tuberculosis patients in Tigray Region, Northern Ethiopia. *BMC Public Health*, *12*, 9. doi.org/10.1186/1471-2458-12-537
- Biadlegne, F., Anagaw, B., Debebe, T., & Anagaw, B. (2013). A retrospective study on the outcomes of tuberculosis treatment in Felege Hiwot Referral Hospital , Northwest, *International Journal of Medicine and Medical Science* *5*, 85–91. doi.org/10.5897/IJMMS12.142
- Board, E. (2015). Global strategy and targets for tuberculosis prevention , care and control after 2015,(November 2013), 1–23. 23.Accessed 4 May 2015 [http://www.who.int/tb/post2015\\_tbstrategy.pdf](http://www.who.int/tb/post2015_tbstrategy.pdf)
- Boateng, S. A., Kodama, T., Tachibana, T., & Hyoui, N. (2010). Factors Contributing to Tuberculosis (TB) Defaulter Rate in New Juaben Municipality in the Eastern Region of Ghana. *J. Natl. Inst. Public Health*, *59*, 3.
- Centers for Disease Control. (2013). *Core Curriculum on Tuberculosis : What the Clinician Should Know*. (6th ed.), 1–320. <http://doi.org/10.1128/IAI.00057-06>
- Christopher O., Bosede, I. (2010). Health seeking behaviour of tuberculosis patients in Ekit State, Nigeria. *Studies on Ethno-Medicine*, *4* (3):191–197.

- Chris, G & Peter, D. (2005). New tests for identifying tuberculosis Infection. *The Biomedical Scientist* 784- 788. Retrieved from <http://www.mrc.ac.uk/newevents/publications/leading-research-for-better-health> on 24 November, 2014
- Chung, W. S., Chang, Y. C., & Yang, M. C. (2007). Factors influencing the successful treatment of infectious pulmonary tuberculosis. *International Journal of Tuberculosis and Lung Disease*, 11(1), 59–64. Retrived from <http://www.ncbi.nlm.nih.gov/pubmed/17217131> on 13th May, 2015.
- Collins, B. N. (2012). Assessing the outcome of tuberculosis treatment in the Cameroon Baptist convention health board tuberculosis treatment centers. Retrieved from [www.phmed.umu.se/digitalAssets/.../91837\\_bong-ngeasham-collinsnew](http://www.phmed.umu.se/digitalAssets/.../91837_bong-ngeasham-collinsnew) on 14th April, 2015
- Daniel, T. M. (2005). Robert Koch and the pathogenesis of tuberculosis. *The International Journal of Tuberculosis and Lung Disease: The Official Journal of the International Union against Tuberculosis and Lung Disease.*, 9, 1181–1182.
- Ditah, I. C., Reacher, M., Palmer, C., Watson, J. M., Innes, J., Kruijshaar, M. E. ...AbubakarI. (2008). Monitoring tuberculosis treatment outcome: analysis of national surveillance data from a clinical perspective. *Thorax*, 63(5), 440–446.
- Dodor, E., & Afenyadu, G. (2005). Factors associated with tuberculosis treatment default EffiaNkwanta Regional Hospital in Ghana. *Transacts of the Royal Society of Medicine and Hygiene*. 99 (11): 32-827
- Domenech, P., Kolly, G.S., Leon-Solis, L., Fallow, A, & Reed M.B. (2010). Massive gene duplication even among clinical isolates of the mycobacterium tuberculosis/Beijing family. *J Bacterial* 192, 4562–70.
- Donald, P. R., Marais, B. J., & Barry, C. E. (2010). Age and the epidemiology and pathogenesis of tuberculosis. *The Lancet*, 375, 1852–1854. doi:10.1016/S0140-6736(10)60580-6
- Dooley, K. E., Lahlou, O., Ghali, I., Knudsen, J., Elmessaoudi, M. D., Cherkaoui, I., & El Aouad, R. (2011). Risk factors for tuberculosis treatment failure, default, or relapse and outcomes of retreatment in Morocco. *BMC Public Health*, 11, 140. doi:10.1186/1471-2458-11-140
- Effiong, J. O., & Nwakaego, I. F. (2015). Gender differences among clients attending tuberculosis unit of a teaching hospital in southern Nigeria. *Scholars Journal of Applied Medical Sciences* 3, 228–233. Retrieved from <http://www.saspublisher.com/wp-content/uploads/2015/01/SJAMS-31D228-233.pdf> on 21st May, 2015

- Esmael, A. (2013). Tuberculosis and human immune deficiency virus co-infection in Debre Markos referral hospital in northwest Ethiopia: A five years retrospective study. *Journal of AIDS & Clinical Research*, 04 (12), 10–13. doi:10.4172/2155-6113.1000263
- Fatiregun, A. A., Ojo, A. S., & Bangboye, A. E. (2009). Treatment outcomes among pulmonary tuberculosis patients at treatment centers in Ibadan, Nigeria. *Annals of African Medicine*, 8, 100–104. doi:10.4103/1596-3519.56237
- Finlay, A., Lancaster, J., Holtz, T. H., Weyer, K., Miranda, A., & Van der Walt, M. (2012). Patient-and provider-level risk factors associated with default from tuberculosis treatment, South Africa, 2002: a case-control study. *BMC Public Health*, 12(1), 56. Retrieved from <http://www. www.biomedcentral.com/1471-2458/12/56> on 23 January, 2015.
- Fry R, Khoshnood K, Vdovichenko E, Granskaya J, Sazhin V & Shpakovskaya L. (2005). Barrier to completion of tuberculosis treatment among prisoners in St. Petersburg, Russia *International Journal on Tuberculosis and Lung Diseases*.9:1027- 33. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/16158896> on 12<sup>th</sup> March, 2015.
- Gafar, M. M. (2013). Factors affecting treatment outcomes in tuberculosis patients in the Limpopo Province, South Africa. *Supervisor*, 10. Retrieved on 5<sup>th</sup> December, 2014 from [http://www.ul.netd.ac.za/bitstream/handle/10386/1017/Gafar\\_mm\\_2013.pdf](http://www.ul.netd.ac.za/bitstream/handle/10386/1017/Gafar_mm_2013.pdf);
- Garrido, M. da S., Penna, M. L., Perez-Porcuna, T. M., de Souza, A. B., Marreiro, L. da S., Albuquerque, B. C., ... Bühner-Sékula, S. (2012). Factors associated with tuberculosis treatment default in an endemic area of the Brazilian Amazon: A case control-study. *PLoS ONE*, 7. doi:10.1371/journal.pone.0039134
- Ghana AIDS Commission (GAC) (2009). *Annual Status Report 2009* pp. 14-51. Retrieved 20<sup>th</sup> May, 2015 from <http:// www.ghanaid.gov.gh/>
- Ghana Health Service/Ministry of Health (2010) *National Tuberculosis Annual Report*. Accra Ministry of Health; Retrieved on 20<sup>th</sup> May, 2015 from [http://www.ghanahealthservice.org/tb\\_news](http://www.ghanahealthservice.org/tb_news)
- Ghana Health Service, Ghana (2013). District Health Information Management System (DHIMS II) Akuapem north district, unpublished document
- Ghana NTP. (2011). National Tuberculosis Control Programme 2011 *Annual Report* Ghana.
- Global tuberculosis control: surveillance, planning and financing. WHO Report WHO/HTM/TB/2008.393? Geneva 2008. Retrieved on 20<sup>th</sup> May, 2015 from [http://www.who.int/tb/publications/global\\_report/2008/pdf/fullreport.pdf](http://www.who.int/tb/publications/global_report/2008/pdf/fullreport.pdf)

- Godreuil, S., Torrea, G., Terru, D., Chivenet, F., Diagbouga, S., Supply, P..... Banuls, A.L (2007). First molecular epidemiology study of Mycobacterium tuberculosis Burkina Fasso *J Clin Microbiol.*, 45(3):921-927. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/17251410>
- Hansel, N. N., Merriman, B., Haponik, E. F., & Diette, G. B. (2004). Hospitalizations for tuberculosis in the United States in 2000: predictors of in-hospital mortality. *Chest*, 126 (4), 1079–1086. <http://doi.org/10.1378/chest.126.4.1079>
- Lawn, S. D., & Zumla, A. I. (2011). Tuberculosis. *The Lancet*, 378(9785), 57–72. [http://doi.org/10.1016/S0140-6736\(10\)62173-3](http://doi.org/10.1016/S0140-6736(10)62173-3)
- Lawrence, M. (2009). Tuberculosis treatment outcomes in adult tuberculosis patients attending a rural hiv clinic in South Africa ( Bushbuckridge ). Retrieved on 20<sup>th</sup> May,2015 from [http://www.wiredspace.wits.ac.za/.../Research%20Report\\_L%20Mashimbye.pdf](http://www.wiredspace.wits.ac.za/.../Research%20Report_L%20Mashimbye.pdf)
- Lisha, P., James P., & Ravindran, C., (2012). Morbidity and mortality at five years after initiating category 1 treatment among patients with new sputum smear positive pulmonary tuberculosis. *Indian J. Tuberc.*, 59 (2): 83-91. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/22838205>
- Maher, D. (2006). The Global Plan to Stop TB, 2006-2015. Actions for life: Towards a world free of tuberculosis. *International Journal of Tuberculosis and Lung Disease*, 10(3), 240–241. Retrieved on 7<sup>th</sup> March,2015 from <http://www.stoptb.org/assets/documents/global/plan/GlobalPlanFinal.pdf>
- Mathew, T., Ovsyanikova, T., Shin. S., Gelmanova, I., Balbuena, D., Atwood S..... Murray, M., (2006). Causes of death during tuberculosis treatment in Tomsk Oblast, Russia. *International Journal Tuberculosis and Lung Disease*, 10(8):857-863.
- Mayer, K. H., & Hamilton, C. D. (2010). Synergistic pandemics: confronting the global HIV Sterling, and tuberculosis epidemics. *Clinical Infectious Diseases*, 50, 67-S70. doi: 10.1086/651475
- Mohammad, W., Basit, A., Tahir, M., Rahman, I., Wajid, A., & Javaid, A. (2004). Treatment outcome of patients with pulmonary tuberculosis from a district general hospital involved in tuberculosis control programme in NWFP. *Pak J Chest Med*, 10 (3), 25–30
- MSF Crisis Alert : The new face of an old disease : urgent action needed to tackle global drug-resistant TB threat. (2014). Retrieved on 23<sup>rd</sup> March,2015 from [http://www.msf.org/sites/msf.org/files/msf\\_crisis\\_alert\\_dr-tb\\_final.pdf](http://www.msf.org/sites/msf.org/files/msf_crisis_alert_dr-tb_final.pdf)
- Muñoz-Sellart M, Cuevas LE, Tumato M, Merid Y, Yassin M.A.,(2010) Factors associated with pulmonary tuberculosis treatment outcome in the southern region of Ethiopia. *Int J Tuberc Lung Dis* ; 14:973–979. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/20626941>

- Mutere, B. N., Keraka, M. N., Kimuu, P. K., Kabiru, E. W., Ombeka, V. O., & Oguya, F. (2011). Factors associated with default from treatment among tuberculosis patients in Nairobi province, Kenya: A case control study. *BMC Public Health*, *11*( 1), 696. Retrieved from <http://www.biomedcentral.com/1471-2458/11/696>
- Naidoo, a., Naidoo, S., Gathiram, P., & Lalloo, U. (2013). Tuberculosis in medical doctors - A study of personal experiences and attitudes. *South African Medical Journal*, *103*(3), 176–180. <http://doi.org/10.7196/SAMJ.6266>
- National Tuberculosis Control Programme, Ghana (2011). Annual Report
- National Tuberculosis Control Programme, Ghana (2012). Training Manual, unpublished document
- Pablo-villamor, M. P., Benedicto, J. P., Teresa, M., Benedicto, J. U., & Perez, V. M. (2014). Screening for diabetes mellitus in patients diagnosed with pulmonary tuberculosis, *Phillipine Journal of Internal Medicine* *52*(4), 1–9.
- Puszczak, K., & Fronczyk, A. (2013). Task force on quality of BCS data analysis of sample size in consumer surveys, theoretical considerations and factors determining minimum necessary sample sizes , link between country size and sample size ( impact of larger structural heterogeneity ), *gros*, .Retrieved on 4<sup>th</sup> March, 2015 from <http://www.oecd.org/>.
- Rajagopaul, A., Kistnasamy, E. J., & Reddy, P. (2014). Predictors of tuberculosis treatment defaulting in informal dwellers within the eThekweni Municipality , *KwaZulu-Natal*, *29*(1), 27–32
- Report, A. (2011a). Eastern Regional Health Directorate. Retrieved on 5<sup>th</sup> December, 2014 from <http://www.erhd.org/cgi/erhd/report.php>
- Report, A. (2011b). Ghana Health Service 2011 Annual Report, unpublished document
- Rakotonirina, C., Ravaoarisoa, L., Randriatsarafara, F., Rakkotomanga, D. & Robert (2004). Factors associated with tuberculosis treatment non-compliance I Antananarivo City, Madagascar. *Sante Publique*. *21*(2): 46- 136.
- Russell, D. G., VanderVen, B. C., Lee, W., Abramovitch, R. B., Kim, M. J., Homolka, S., ... Rohde, K. H. (2010). Mycobacterium tuberculosis wears what it eats. *Cell Host and Microbe*. *5*(2) doi:10.1016/j.chom.2010.06.002
- Salgar, S. T. (2014). Stress in first year medical students. *International Journal of Biomedical and Advance Research*, *05*(01), 79–80. <http://doi.org/10.7439/ijbar>

- Sreeramareddy, C. T., Panduru, K. V, Menten, J., & Van den Ende, J. (2009). Time delays in diagnosis of pulmonary tuberculosis: a systematic review of literature. *BMC Infectious Diseases*, 9, 91. <http://doi.org/10.1186/1471-2334-9-91>
- Srinath, S., Sharath, B., Santosha, K., Chadha, S. S., Roopa, S., Chander, K., ... Harries, a. D. (2011). Tuberculosis “retreatment others”: Profile and treatment outcomes in the state of Andhra Pradesh, India. *International Journal of Tuberculosis and Lung Disease*, 15(1), 105–109.
- Sterling, T. R., Pham, P. a, & Chaisson, R. E. (2010). HIV infection-related tuberculosis: clinical manifestations and treatment. *Clinical Infectious Diseases : An Official Publication of the Infectious Diseases Society of America*, 50 (3), S223–S230. <http://doi.org/10.1086/651495>
- Suárez-García, I., Rodríguez-Blanco, A., Vidal-Pérez, J. L., García-Viejo, M. A., Hernández M. J., López, O., & Noguero-Asensio, A. (2009). Risk factors for multidrug-resistant tuberculosis in a tuberculosis unit in Madrid, Spain. *European Journal of Clinical Microbiology & Infectious Diseases*, 28(4), 325–330.
- Suchindran, S. "Is HIV infection a risk factor for multi-drug resistant tuberculosis? systematic review" *PLoS one*, 4(5): e5561 Retrieved from <http://www.plosone.org/article/>
- Svinicki, M. D. (2010). A Guidebook on conceptual frameworks for research in engineering education. *Rigorous Research in Engineering Education* NSF DUE-0341127, DUE-0817461.
- Tessema, B., Muche, A., Bekele, A., Reissig, D., Emmrich, F., & Sack, U. (2009). Treatment outcome of tuberculosis patients at Gondar University Teaching Hospital, Northwest Ethiopia. A five-year retrospective study. *BMC Public Health*, 9(1), 371.
- Tetteh Quarshie memorial Hospital, Ghana (2006). Annual Report page 8, unpublished document
- The Lancet. (2014). Stop Tb, 384(9940), 282. [http://doi.org/10.1016/S0140-6736\(14\)61244-7](http://doi.org/10.1016/S0140-6736(14)61244-7)
- Udwadia, Z. F. (2012). Totally drug-resistant tuberculosis in India: Who let the djinn out? *Respirology*, 17, 741–742. <http://doi.org/10.1111/j.1440-1843.2012.02192.x>
- Worlanyo, P.B. (2012). Pulmonary tuberculosis prevalence among female commercial head potters in Accra. Retrieved on 24<sup>th</sup> May, 2015 from [http:// University of Ghana http://ugspace.ug.edu.gh](http://University of Ghana http://ugspace.ug.edu.gh),” (2012)
- WHO. (2008). Global Tuberculosis Report 2008. Retrieved on 11<sup>th</sup> May, 2015 from [http://www.unaids.org/sites/default/files/media\\_asset/who2008globaltbreport\\_en\\_0.pdf](http://www.unaids.org/sites/default/files/media_asset/who2008globaltbreport_en_0.pdf)

- WHO. (2009). Global tuberculosis control: a short update to the 2009 report. Geneva: World Health Organization. Retrieved on 6th April, 2015 from [http://www.who.int/tb/publications/global\\_report/2009/en/index.html](http://www.who.int/tb/publications/global_report/2009/en/index.html)
- WHO. (2010). Global Tuberculosis Control: *WHO/HTM/TB*, 218. <http://doi.org/WHO/HTM/TB/2010.7>.
- WHO. (2012). Global tuberculosis report 2012. *WHO*, 258. [http://doi.org/978\\_92\\_4\\_156450\\_2](http://doi.org/978_92_4_156450_2)
- WHO. (2012). *World Health Statistics. WHO World Health Organization* (Vol. 27). <http://doi.org/10.2307/3348165>
- WHO. (2013). Global Tuberculosis Report 2013. Retrieved on 2nd May, 2015 from [www.who.int/iris/bitstream/10665/91355/1/9789241564656\\_eng.pdf](http://www.who.int/iris/bitstream/10665/91355/1/9789241564656_eng.pdf)
- WHO. (2014). Global tuberculosis report 2014. Retrieved on 4th May, 2015 from [WHO/HTM/TB/2014.08](http://www.who.int/iris/bitstream/10665/112658/1/9789241564656_eng.pdf)).
- Woldeyohannes, D., Kebede, N., Erku W., & Tadesse, Z. (2011). Ten years' experience of directly observed treatment short-course (dots) therapy for tuberculosis in Addis Ababa, Ethiopia. *Ethiop Med J.* 2011, 49(3): 221-229.
- Xin, S., Kathryn, D., Zheng'an, Y., Mei, S., Zhen. X., Xiaohong, G..... Jian, M. (2009) Deaths among tuberculosis cases in Shanghai, China: who is at risk? *BMC Infectious Diseases*.9:95.
- Yahaya, A., Aquah, S. E. K., & Sagoe, K. (2014). Incidence of pulmonary tuberculosis ( Per 100 , 000 People ) in northern Ghana (a retrospective study at the Tamale Teaching Hospital, 2004-2012), 3(6),15–21. *International Journal of Research in Medical and Health Sciences*, Retrieved on 11 October, 2014 from [http://www.ijsk.org/uploads/3/1/1/7/3117743/3\\_tuberculosis.pdf](http://www.ijsk.org/uploads/3/1/1/7/3117743/3_tuberculosis.pdf)



**2. PREDICTOR VARIABLES ASSOCIATED WITH TREATMENT OUTCOME**

4. Voluntary Counselling and Testing (VCT) for HIV Yes

No

5. HIV Status Positive

Negative

6. Other Co-morbidities (e.g. Diabetes mellitus) Yes

No

7. Disease Classification

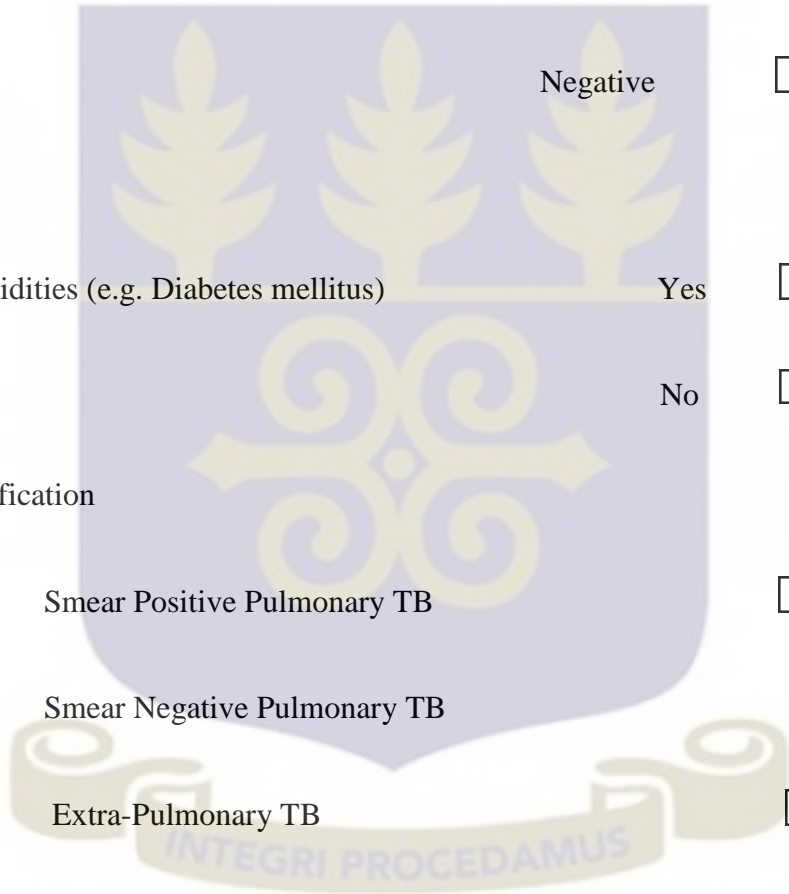
Smear Positive Pulmonary TB

Smear Negative Pulmonary TB

Extra-Pulmonary TB

8. Duration of Tuberculosis Treatment (Months) <6 Months

≥6 Months



9. Type of Patient

New  Relapse  Transfer in   
Failure  Return of Default  Other

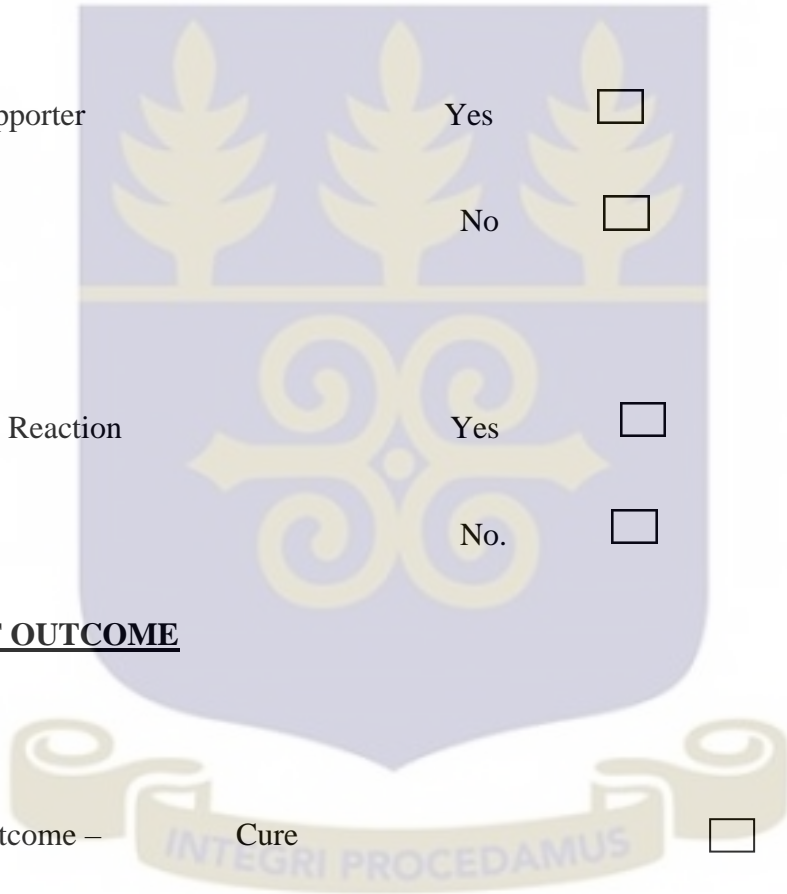
Other (Reason).....

10. Treatment Supporter Yes   
No

11. Adverse Drug Reaction Yes   
No.

**3. TREATMENT OUTCOME**

12. Treatment Outcome – Cure   
Treatment Completed   
Default   
Treatment Failure   
Died



**APPENDIX II**

**GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE**

*In case of reply the  
number and date of this  
Letter should be quoted.*



Research & Development Division  
Ghana Health Service  
P. O. Box MB 190  
Accra.

*My Ref. : ERC-  
Your Ref. No.*

*Tel: +233-0302681109  
233-0302679323*

*Fax + 233-0302685424  
hannah.frimpong@ghsmail.org*

**23rd March, 2015**

Sampson Opoku  
School of Public Health  
University of Ghana  
Legon, Accra

**GHS-ERC  
Review Summary**

**Protocol ID NO:** GHS-ERC 114/02/15

**Country of Review:** Ghana

**Protocol Title:** "Tuberculosis Treatment Outcome and Associated Factors in the Tetteh Quarshie Memorial Hospital"

Dear Sampson Opoku,

Please find the review summary of the Protocol titled: "**Tuberculosis Treatment Outcome and Associated Factors in the Tetteh Quarshie Memorial Hospital**" that was submitted to the ERC Secretariat for review.

We wish to inform you that the above-mentioned Protocol underwent full general meeting review and that approval has been granted for its implementation

However, please address the following issues and submit 1 copy of the corrected version to the secretariat:

- i. Schedule of activity Page 34: Include period of ethical clearance.
- ii. Insert the name of your study site, page 2 of the GHS-ERC administrative form.

Please note that the revised protocol should have all the requirements for submission. (PI's response letter, other supporting letters, GHS-ERC completed administrative

information form, checklist, participant information sheet and informed consent form, questionnaire, CVs, etc)

Your approval letter is being processed.

We wish you a successful project implementation.

Accept our congratulations.

Administrative Secretary, Ghana Health Service Ethics Review Committee

For: Chairman

Name: Hannah Frimpong

