

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY

COLLEGE OF HEALTH SCIENCES

FACULTY OF PHARMACY AND PHARMACEUTICAL SCIENCES

DEPARTMENT OF CLINICAL AND SOCIAL PHARMACY



**TUBERCULOSIS TREATMENT OUTCOMES IN THE TARKWA NSUAEM
MUNICIPALITY.**

MSc CLINICAL PHARMACY

BY

THEOPHILUS KOJO ACKOM

JULY, 2016

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MUNICIPALITY.**

**A THESIS SUBMITTED TO THE DEPARTMENT OF CLINICAL AND SOCIAL
PHARMACY OF THE COLLEGE OF HEALTH SCIENCES, KWAME
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FULFILMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTERS OF
CLINICAL PHARMACY.**

BY

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JULY, 2016

KNUST



DECLARATION

I hereby declare that, except for specific references which have been duly acknowledged, this work is the result of my own field research and it has not been submitted either in part or whole for any other degree elsewhere.

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Prof (Mrs) Frances T Owusu-Daaku Signature Date
(Head of Department)

DEDICATION

My heart goes out to all persons affected in one way or the other by the devastating influence of the tuberculosis disease, especially those in the Tarkwa Nsuaem Municipality. Also dear to my heart are all those who lost their livelihood and those who suffered terrible stigmatization during their morbidity with tuberculosis. To all these, I do dedicate this piece of research work.



ACKNOWLEDGEMENT

My utmost thanks and deepest appreciation go to the Life Giver through whose generous mercies I have been alive to go through this programme.

I should like to acknowledge my project supervisor in the person of Mrs. Mercy Opare-Addo for her tireless guidance and deep thoughts shared with me on this project.

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To the immediate past Municipal Health Director; Dr. Jack Galley, I say thank you for granting me access to the data collection points and source data in the municipality.

All those who worked so hard on the various institutional TB teams and the district TB team for the Tarkwa Nsuaem Municipality to generate the source data for my research, I here do extend my warm appreciation to you all.

To my family and all dear friends who supported me in various ways during my programme, my heartfelt appreciation goes out to you, especially to Pharmacist Robert Incoom for his generous tutorship on data collection and management.

ABSTRACT

BACKGROUND

Research has shown that mineral mining is a high risk for tuberculosis morbidity and mortality. It is against this background that this study was conducted at Tarkwa Nsuaem Municipality, which is a busy mining community. This study was conducted to examine the pattern of tuberculosis prevalence and treatment outcome in the municipality. Special attention was given to the TB treatment outcome among persons involved with illegal mining activities in the municipality.

METHOD

A retrospective study was conducted in Tarkwa, a mining community in the Western Region of Ghana. There are six TB treatment centers in the Tarkwa Nsuaem Municipality. The various institutional TB registers in the six TB treatment centers and the district TB register were used as the source data. A data collection tool was developed, guided by the study objectives and used to extract relevant information on each TB patient from the source data. All 510 registrants from 2011 to 2013 were enrolled.

The data collected was entered into SPSS® statistics 21 version and analysed.

RESULTS

510 clients' treatment cards and registration in the treatment register were reviewed. There were 416 (81.57%) males and 94 (18.43%) females. 197 (38.63%) of total TB patients were involved with illegal mineral mining (galamsey) whiles 313(61.37%) were involved with occupations other than 'galamsey'. Irrespective of occupation, the most affected age groups were those in the

productive years (20 – 59). 96.3% (491) of all registrants had pulmonary TB and only 3.7% (19) had extrapulmonary TB.

There was very high treatment success rate among ‘galamsey’ population as well as the ‘nongalamsey’ population throughout the study period. 90.9% (179) and 86.6% (271) respectively for the ‘non-galamsey’ and ‘galamsey’ populations. There was no case of relapse throughout the study period. However there were more cases of TB re-treatment and TB treatment failure among the ‘galamsey’ than the ‘non-galamsey’ population. There were however more cases of treatment interruption due to ‘lost to follow-up’ and mortality in the ‘non-galamsey’ population than the ‘galamsey’ population.

CONCLUSION

Overall, the ‘non-galamsey’ population did not have better TB treatment outcome compared to the ‘galamsey’ population. The ‘non-galamsey’ population also did not have any better results for presumed resistant TB in comparison to those in the ‘galamsey’ population, neither did they have a better chance for TB treatment success than their ‘galamsey’ counterpart. Illegal mineral miners do not require additional TB care intervention beside that offered to the general population to improve their TB treatment outcome.

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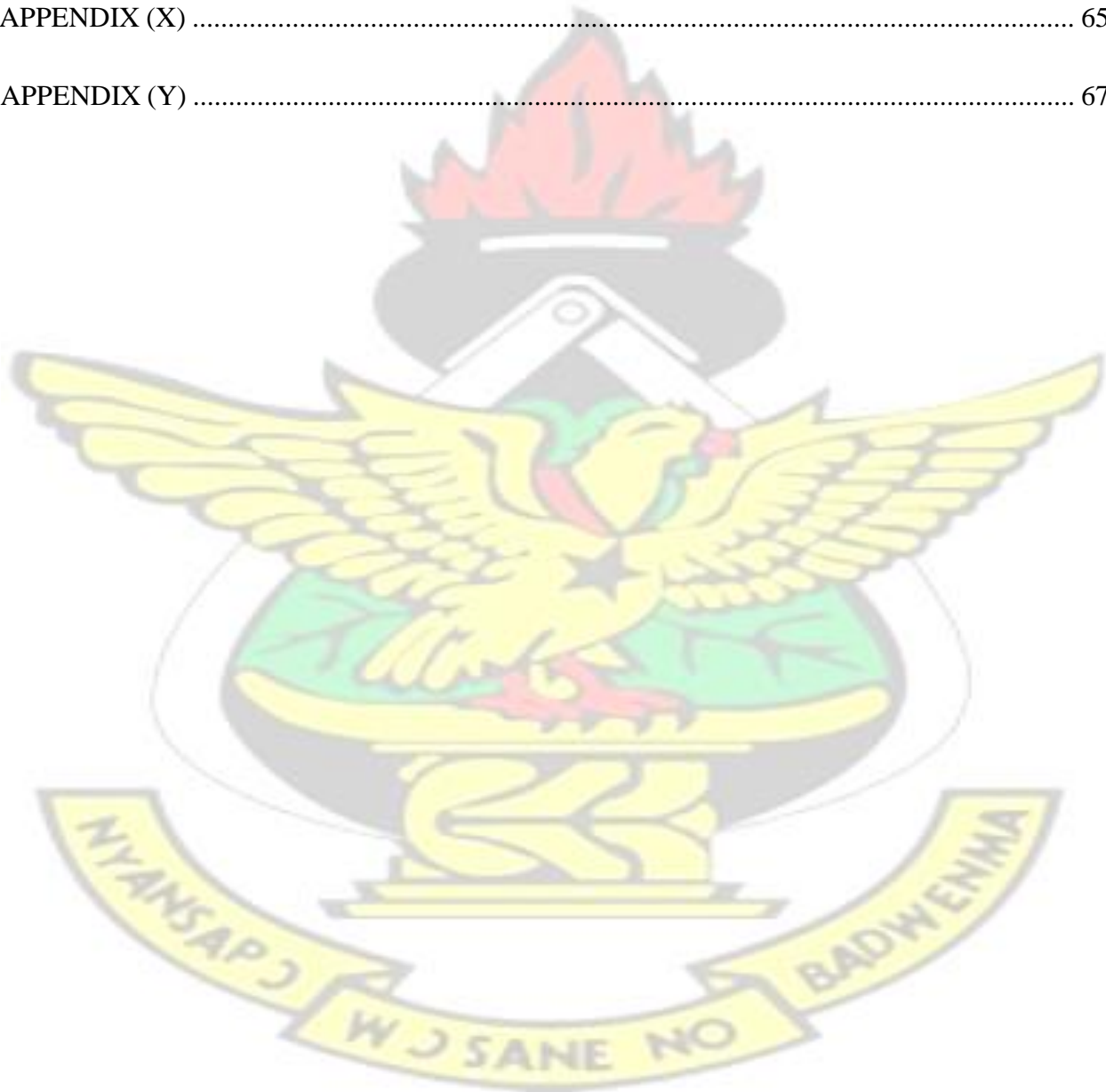
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CHAPTER ONE

INTRODUCTION

1.0 TUBERCULOSIS DISEASE

The World Health Organization's (WHO) 2014 report on Tuberculosis (TB) indicates that the TB disease remains one of the world's deadliest communicable disease. It reported that TB is present in all regions of the world and in 2013, an estimated 9.0 million people developed TB and 1.5 million died from the disease (WHO, 2014). In its 2012 report it claimed that almost 9 million new cases and 1.4 million TB deaths occurred worldwide by the year 2011 (WHO, 2012). The 2014 report made a further claim that TB is slowly declining each year and it estimated that 37 million lives were saved between 2000 and 2013 (WHO, 2014).

There have been many studies conducted in sub-Saharan Africa to investigate the association between tuberculosis (TB) incidence, prevalence and mortality among mineral miners as against the general population (Stuckler, Basu, McKee, & Lurie, 2011). Mortality is however just one outcome of TB treatment (Jasmer et al., 2004). Other outcomes which have not attracted the attention of researchers are as equally important as mortality because they can cause the development of resistant TB strains and ultimately to preventable deaths.

Many of the 'galamsey' miners in the Tarkwa municipality are presumed to be migrants. They are thought to always be on the move to where the harvest for the mineral is greater. This lifestyle may expose them not only to high incidence of TB but it is also likely to dispose them to poor TB treatment outcomes due to possible treatment interruptions.

Tuberculosis has been described as an infectious bacteria disease caused by *Mycobacterium tuberculosis* (WHO, 2013a). Other species of mycobacterium have been found to also cause the disease. These include *Mycobacterium africanum*, *Mycobacterium avium*, and *Mycobacterium*

bovis. All such organisms have been described collectively as tubercle bacilli. They most commonly affect the lung parenchyma leading to the development of pulmonary tuberculosis. Victims of pulmonary tuberculosis who are naïve to anti-tuberculosis drug therapy are highly infectious. It is the commonest type of tuberculosis in the world, accounting for about 80% of the disease. The spread is by inhalation of aerosols produced from the airway of an infected person. These droplets of bacilli are usually formed when the infected person coughs, sneezes or spits into the open environment. Sometimes laughing and singing can spread the infection (WHO, 2013b).

The Tubercle bacilli can also invade and cause disease to any other part of the human body in which case it is described as extrapulmonary tuberculosis. This type is usually not infectious and account for about 20% of tuberculosis the world over. These extrapulmonary sites include the pleura, meninges, intestinal, genitourinary tract, bones and joints, lymph nodes, ocular and oral structures. Most people who suffer extrapulmonary TB are co-morbid with pulmonary TB. Tuberculosis as a disease is curable but infection with *Mycobacterium tuberculosis* remains for life. A third of the world's population is suspected to be infected with TB (WHO, 2012).

1.1 PROBLEM STATEMENT

In 1993, the WHO declared TB as a global public emergency and in 2005 as an African public health emergency (WHO, 2013). The Millennium Development Goal (MDG), target 6.c aims to halt and begin to reverse the incidence of TB by 2015 (WHO, 2010).

The Stop TB Partnership also set additional TB targets for the MDGs. These include, the target to reduce the prevalence and death rate by 50%, compared with their levels in 1990 by 2015 and to reduce the global incidence of TB cases to less than 1 case per 1 million population per year (WHO, 2010) In Ghana the 1990 prevalence rate of TB per 100,000 populations was 481 (191 – 923) (WHO, 2013a). Speaking at the 2014 world TB Day (March 24 to remember Dr. Robert

Koch's discovery of T. bacilli in 1882) in Accra, the program manager of the National Tuberculosis Program (NTP) mentioned that the Ghanaian TB prevalence for adult as at 2013 was 300 per 100,000 populations. Mortality rate as at 2010 was 8% which is high (WHO, 2010) and the total cases of MDR-TB notified to the NTP were 14, according to the TB CARE 1GHANA report to WHO (WHO, 2010).

It is estimated that over the course of one year, people ill with TB pose the risk of infecting up to 10-15 other people through close contact and without adequate treatment it is expected that up to two thirds of people with TB morbidity will die (WHO, 2013b).

In 2012, sub-Saharan Africa had the highest ratio of new TB cases per population with over 255 cases per 100 000 population (WHO, 2013b).

TB has been considered as the biggest single cause of mortality among mine workers apart from trauma (Kleinschmidt & Churchyard, 1997). Adhoc surveys and data from the district TB register of the Tarkwa-Nsuaem Municipal Health Directorate suggest that TB among patients involved in 'galamsey' practices have poor TB treatment outcomes compared with the general population who do not practice such. If this observation is factual and global it will have a high potential to affect the MDGs target for TB.

This study therefore seeks to investigate if the observation that 'galamsey' miners have poor TB treatment outcome is factual.

1.2 PROJECT OBJECTIVES

1.2.1 Main objective

The main thrust of this study is to examine if there are significant differences in the tuberculosis treatment outcomes between 'galamsey' miners and the 'non-galamsey' population.

1.2.2 Specific objectives

- To estimate the 2011 to 2013 tuberculosis prevalence in the Tarkwa Nsuaem municipality.
- To assess the proportion of TB cases among the ‘galamsey’ population as oppose to the ‘non-galamsey’ population that had treatment failure, lost to treatment follow up and treatment relapse.
- To assess the likelihood of a TB case involved with ‘galamsey’ to develop drug resistant TB in comparison with the ‘non-galamsey’ population.
- To assess TB survival prevalence among ‘galamsey’ miners in comparison with the ‘nongalamsey’ population.
- To assess TB mortality among ‘galamsey’ miners in comparison to the ‘non-galamsey’ population.

1.3 RATIONAL OF CONDUCTING THE STUDY

Illegal mineral miners are notorious for unsafe practices that pose danger to health and life. They are also wild migrants exposing communities to contagious diseases. They could sometimes spend weeks and even months in the pit. This attitude coupled with their migration patterns may disrupt medical treatments. Poor TB treatment outcomes can engender resistant bacterial strains. It also has serious economic implications.

This study is therefore seeking to investigate if TB treatment outcomes among this group is worse in comparison with the ‘non-galamsey’ population in order to inform stake holders in TB care of the need to fashion out a strategy to improve treatment among ‘galamsey’ miners.

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CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 TUBERCULOSIS AND MINING

Report from South Africa and other research publications have identified mineral miners as a special risk group for TB (Packard R. White Plague et al, 1987; Rees D, Murray J. 2007; Sonnenberg P, Glynn JR.et al, 2005; South Africa, Ministry of Health, 2007).

According to Basu et al, the incidence of TB among South African miners is higher than those of the general population by ten folds and asserts that tuberculosis epidemics in the general population is attributable to migration pattern of miners (Basu, Stuckler, Gonsalves, & Lurie, 2009). A South

African report placed TB only second to trauma as the leading cause of mortality amongst mine workers (Leon R, Davies J, Salomon M, Davies A, 1995).

Reports from Lesotho and South Africa suggest that miners pose risk of infecting their close contacts of the general population with TB particularly drug-resistant forms as they visit home with sub-clinical condition or inadequately treated (Agence France Presse, 2006).

Leon R et al has attributed poor Health and Safety conditions within the mines as a powerful drive for the transmission of TB bacilli within close quarters (Leon R, Davies J, Salomon M, Davies A, 1995).

TB mortality among miners in comparison with other workers have been reported to be 3.6-fold greater. Reports dating as far back as 1903 identified miners as a risk group for TB incidence and mortality. Environmental and occupational challenges have been largely blamed as the possible explanation for the elevated tuberculosis morbidity and mortality among miners (Reid PJ, Sluis-Cremer GK, 1996).

High TB treatment default rates have been reported among mineral miners (Sonnenberg P, Ross M H et al, 1998; Sonnenberg P, Murray J et al, 2001; Mqoqi N, Churchyard GA et al, 1997).

2.2 TB BURDEN AND TARGETS

The Millennium Development Goals (MDGs) aims to have the global TB incidence falling by 2015. The actual target is to achieve rates of TB prevalence and mortality in 2015 being half the 1990 levels. In 2009, the WHO had the following notification for estimated global TB burden: 14 million prevalent cases, 9.4 million incident cases, 0.38 million deaths among HIV positive clients and 1.3 million deaths among HIV negative client. In that report, 30% of the global TB prevalence was associated with the African Region. An estimated 250,000 of TB notification to the WHO in 2009, had multidrug resistant TB (WHO, 2010).

In its latest report, the WHO estimates that there are 9.0 million new TB cases and 1.5 million TB deaths. This makes TB second only to human immunodeficiency virus (HIV) as the leading cause of death from an infectious disease worldwide (WHO, Global Tuberculosis Report, 2014).

Among people infected with *M. tuberculosis*, only a relatively small proportion develop the TB disease. However, people infected with HIV have been identified as a special risk group for TB morbidity. The male gender has relatively higher risk for TB than their female counterpart. TB affects mainly adults in the most economically productive years (WHO, 2014).

2.3 TB AND CO-INFECTIONS

Both Silicosis and HIV infection have been labelled as strong risks for TB and have been linked with higher risk of deaths. Strategies to reduce TB incidence and mortality among mineral miners have examined ways of minimizing Silicosis and HIV infection (Churchyard et al., 2000).

Cowie R L also demonstrated that there is a relationship between tuberculosis and silicosis (Cowie R L, 1994).

In a cross sectional study of mine workers, Ross et al observed incremental in the proportion of gold miners with residual air flow impairment with each episode of TB. 18.4% after one episode of TB, 27.1% after two episodes of TB and 35.2% after three or more episodes of TB (Ross, Ehrlich, Hnizdo, White, & Churchyard, 2010). Latent TB progresses to active disease easily with the presence of HIV infection (Havlir DV, Barnes PF., 1999).

The cornerstone for the reduction of *M. tuberculosis* transmission and elimination is early diagnosis and adequate treatment of infectious patients with pulmonary TB. Prompt initiation of infectious patients on adequate combination of TB medicines for 6 to 9 months, quickly render

them noninfectious and eventually cured. Key challenges to TB control are HIV co-infection and drug resistance (E. L. Corbett, C. J. Watt et al., 2003; C. Dye, M. A, C. J. Watt et al, 2002).

HIV co-infection is the most powerful known risk factor for progression of latent TB infection to TB disease (T. R. Frieden, C. J. Watt, T. R. Sterling, S. S. Munsiff, and C. Dye, 2003). Published reports shows that HIV co-infection does not influence TB treatment failure the way it does mortality among sub-Saharan African patients (Y. D. Mukadi and A. Harries, 2001).

2.4 GLOBAL TB REPORTS

The WHO has six TB reporting regions globally. These are the Eastern Mediterranean Region, the African Region, Region of the Americas, the South-East Asia Region, the European Region and the Western Pacific Region. Each of the six regions is expected to undertake Regional TB analyses annually.

According to WHO report, of the 6.1 million cases of TB notified by NTPs in 2013, 5.7 million were newly diagnosed and 0.4 million were previously diagnosed TB patients whose treatment regimen had to be changed.

The report continued that most notified TB cases were adults and that children under 15 years of age accounted for only 6% of notified cases. The male to female ratio of TB cases notified across all age groups was 1.6 globally (WHO, 2013).

Table 2.4.1 Estimates of 2013 TB burden of WHO African Region (47 member states)

POPULATION		26 MILLION	
Estimates of TB burden 2013	Number(thousands)	Rate (per 100,000 population)	
Mortality (excludes HIV+TB)	390 (300 - 500)	42	(32 - 54)
Mortality (HIV+TB only)	300 (250 - 350)	32	(27 - 38)
Prevalence (includes HIV+TB)	2800 (2400 - 3200)	300	(263 - 341)
Incidence (includes HIV+TB)	2600 (2300 - 2900)	280	(251 - 311)

Incidence (HIV+TB only)	870 (790 - 960)	94 (86 - 104)
Case detection, all forms (%)	52 (46 - 57)	
TB case notifications 2013	New	Relapse
Pulmonary, bacteriologically confirmed	591,519	45,232
Pulmonary, clinically diagnosed	457,249	18,093
Extrapulmonary	224,742	1,368
Total new and relapse	1,338,203	
Previously treated, excluding relapse	75,882	
Total case notified	1,414,085	

A total of 1,050,607 new and relapse cases were reported. Of these 95,764 (9.1%) cases were less than 15 years of age. The male to female ratio for the 1,036,642 reported new and relapse cases disaggregated by sex is 1.4:1

Table 2.4.2 Estimate of 2013 TB treatment success rate for African region of WHO

Treatment success rate	%
New and relapse cases registered in 2012	81
Previously treated cases, excluding relapse, registered in 2012	48
HIV-positive TB cases, all types, registered in 2012	68
RR-/MDR-TB cases started on second-line treatment in 2011	47
XDR-TB cases started on second-line treatment in 2011	16

Table 2.4.3 Estimates of 2013 MDR-TB burden for African Region of WHO

Estimates of MDR-TB burden * 2013	New	Retreatment	
% of TB cases with MDR-TB	2.4 (0.2 - 5)	13 (0.02 - 27)	
MDR-TB cases among notified pulmonary TB cases	25,000 (2,100 – 52,000)	18,000 (28 -37,000)	

Reported cases of RR-/MDR-TB 2013	New	Retreatment	Totals
Cases tested for RR-/MDR-TB	5083 (1%)	9,925 (7.1%)	292,797
Laboratory-confirmed RR-/MDR-TB cases			32,480
Patients started on MDR-TB treatment			14,418

2.4.1 2013 Ghana TB report to the WHO

Table 2.4.4 Estimates of 2013 TB burden and notification of Ghana as reported to the WHO

POPULATION		26 MILLION	
Estimates of TB burden 2013	Number(thousands) Rate (per 100,000 population)	
Mortality (excludes HIV+TB)	1.1 (0.69 – 2.1)	4.4	(2.7 – 8)
Mortality (HIV+TB only)	0.52 (0.35 – 0.72)	2	(1.4 – 2.8)
Prevalence (includes HIV+TB)	18 (7.9 – 33)	71	(30 – 129)
Incidence (includes HIV+TB)	17 (16 – 19)	66	(63–74)
Incidence (HIV+TB only)	3.6 (3.4 – 4)	14	(13– 16)
Case detection, all forms (%)	88 (78 – 93)		
TB case notifications 2013	New	Relapse	
Pulmonary, bacteriologically confirmed	7 301	416	
Pulmonary, clinically diagnosed	5977		
Extrapulmonary	1347		
Total new and relapse	15043		
	10		

Previously treated, excluding relapse	563
Total case notified	15606

Of the 15,043 new and relapse cases, 783 (5%) cases aged under 15years; male to female ratio is 1.8:1

Table 2.4.5 Estimates of 2013 TB success rate of Ghana reported to WHO

Treatment success rate	%
New and relapse cases registered in 2012	84
Previously treated cases, excluding relapse, registered in 2012	72
HIV-positive TB cases, all types, registered in 2012	73
RR-/MDR-TB cases started on second-line treatment in 2011	50
XDR-TB cases started on second-line treatment in 2011	

Table 2.4.6 Estimation of 2013 MDR-TB burden of Ghana reported to WHO

Estimates of MDR-TB burden * 2013	New	Retreatment	
% of TB cases with MDR-TB	1.9 (0.1–5.3)	20 (0.1 - 40)	
MDR-TB cases among notified pulmonary TB cases	250 (13–700)	200 (1 - 390)	
Reported cases of RR-/MDR-TB 2013	New	Retreatment	Totals
Cases tested for RR-/MDR-TB	0 (0%)	690 (70%)	690
Laboratory-confirmed RR-/MDR-TB cases			65
Patients started on MDR-TB treatment			26

2.5 STRUCTURE OF THE GHANA MINING INDUSTRY

2.5.1 General structure

Ghana is a West African country with a total land area of 238,538 square kilometers. The local government system operates through ten administrative regions namely; Eastern, Western, Volta, Ashanti, Greater Accra, Northern, Brong Ahafo, Central, Upper East and Upper West.

Ghana is a mineral rich country and has been producing a variety of these minerals. Large-scale production companies together with small-scale operators all engage in the mining and processing of these minerals scattered in the country. The large-scale companies concentrate mainly on the production of manganese, gold, bauxite and diamond. The small-scale miners who use to focus on industrial minerals such as silica sand, limestone and kaolin are now busy with gold mining. The large-scale mining companies are mainly owned by foreigners. Small-scale mining activity has been made a statutory preserve of Ghanaians.

Akabzaa and Darimani observed that as at October 2000, the number of local and foreign companies holding mineral rights for gold exploration and exploitation in the country amounted to 224. There were about 600 registered small-scale miners and an estimated 200,000 unlicensed miners, popularly called ‘galamsey’ operators. These were scattered over several prospecting grounds in the country (Akabzaa & Darimani, 2001).

2.5.2 Small-Scale Mining Sector

Small-scale mining has contributed in no small way to the strength of Ghana’s economy.

Mining by indigenous Ghanaians dates as far back as the 4th century. 1905 marked the turning point in indigenous mining. Colonial authorities made indigenous mining activities illegal but until

that time indigenous mining was the only means of gold and diamond production. In 1989 the Ghana government reversed the illegality of indigenous mining and regularized their activities.

Small-scale mining still remains important to the Ghanaian economy as it is estimated to provide employment to people in excess of one million. It is the highest producer of diamond and competes favourable in gold production.

Finally, the small scale mining sector was formalized by the enactment of PNDC Law 218 - the Small Scale Gold Mining Law. The Small Scale Mining Project department of the Minerals Commission exercises oversight responsibility of registering and supervising small-scale mining activities in Ghana. There are still a large proportion of small scale miners who operate without due registration with the minerals commission. These are considered as illegal mineral miners.

Initially only the Precious Minerals Marketing Corporation could purchase productions from small-scale miners but over time, other licensed buyers were given permit to buy such productions (Akabzaa & Darimani, 2001).

2.6 STANDARD DEFINITIONS IN TB CASE DESCRIPTION

The Ghana Ministry of Health, Ghana Health Service, National Tuberculosis Programme Training Manual guideline (Ghana MOH-GHS-NTP Training Manual, 2012) adopted the following TB case and treatment outcome definitions from the WHO.

Smear-positive pulmonary TB

This is the case of a patient who had at least one initial sputum smear examinations showing positive for acid-fast-bacilli (AFB) or one sputum examination AFB-positive plus radiographic abnormalities consistent with active pulmonary TB as determined by a clinician.

Smear-negative pulmonary TB

This describes a situation where a patient's radiographic abnormalities is consistent with active pulmonary TB but sputum microscopy does not meet the definition for smear-positive disease. A case of culture positive but AFB-negative sputum examinations also falls in this group.

Extrapulmonary TB

This describes TB affecting any other organ other than the lung parenchyma (e.g. abdomen, lymph nodes, meninges, genitourinary tract, pleura, skin, joints and bones). Diagnosis is established by the presence of one culture-positive specimen or histological or strong clinical evidence consistent with active extrapulmonary disease. In a situation where a patient has both pulmonary and extrapulmonary TB, it is classified as a pulmonary case.

2.6.1 Tuberculosis treatment Outcomes definitions

Ghana adopted the joint recommendations by a Working Group of WHO and the International Union Against Tuberculosis and Lung Disease (IUATLD) on the use of a minimum set of six mutually exclusive categories of treatment outcome namely; cure, treatment completed, failure, death, treatment interrupted, and transfers out (WHO, 1997).

Cure

This describes the treatment out where a patient upon completion a full course of anti-TB therapy has at least one result indicating culture conversion from growth to no growth during the continuation phase or produces two negative sputum smears results during the continuation phase, one being the results at end of treatment.

Treatment completed

This describes the treatment outcome of a patient who has been discharged off anti-TB medication upon completion of treatment but lack evidence of culture conversion or sputum conversion at end of treatment.

Treatment failure

This describes the outcome of a patient who is on treatment but fails to culture or sputum convert at month five of treatment or becomes sputum smear or culture positive again after previous conversions.

Died

Once a patient is initiated on anti-TB therapy, if he or she dies of any cause while still on treatment it is described as TB death except for HIV co-morbidity.

Treatment interrupted

These patients used to be described as defaulters. This is the situation when a patient who has been placed on therapy did not take medicines for more than two consecutive months, or failed to complete a six month regimen within 9 months or nine month regimen within 12 months.

Chronic case

When a patient on a full course retreatment therapy fails treatment, he or she is described as having a chronic case. This happens when patients continue to interrupt treatment or carry resistant TB strains.

One way of dealing with such difficulty is to prolong treatment to 12 months (J. Veen, M. Raviglione, H. L. Rieder et al., 1998).

2.7 TB REPORTING PARAMETERS

The Technical Appendix of the 2013 WHO global TB report titled Methods used to estimate the global burden of disease caused by TB provides definition for the following parameters for TB reporting; prevalence, incidence, case fatality rate, mortality, case notification rate (WHO, 2013).

Incidence is defined as the total number of new and recurrent (relapse) cases of TB of all forms occurring in a given year. A recurrent case is defined as a new episode of TB in a person who has had TB in the past and for whom there was bacteriological confirmation of cure and/or evidence that treatment was completed. A recurrent case may be true relapse or a new episode of TB caused by reinfection. Relapse cases and cases of patients requiring a change in treatment have been categorized as 'retreatment cases'. A person requiring change of treatment within the same episode of TB is counted as a prevalent case and not an incident case.

Prevalence is defined as the total number of all forms of TB cases at a given point in time.

Mortality from TB is defined as the number of deaths caused by TB in HIV-negative people. TB deaths among HIV-positive people are classified as HIV deaths according to the latest revision of the International classification of diseases (ICD-10).

Case fatality rate refers to the risk of death from TB among people with active TB disease.

A **case notification rate** refers to new and recurrent episodes of TB notified to WHO for a given year, expressed per 100,000 population (WHO/HTM/TB/2013.2).

2.8 TUBERCULOSIS TREATMENT STRATEGY

TB mortality rates are high when TB treatment are absent. Research reveals that about 70% of sputum smear-positive pulmonary TB in HIV-negative clients die within 10 years of the disease. Among people with sputum culture-positive but smear-negative cases, 20% died within 10 years (Tiemersma EW et al, 2011). WHO developed and promoted the Stop TB Strategy with the goal of drastically reducing the global TB burden by 2015 (Raviglione M, Uplekar M, 2006).

The Stop TB Strategy has been adopted by the Ghana National Tuberculosis Programme to facilitate the elimination of tuberculosis. The standardized empirical treatment as recommended by WHO consists of two months intensive phase, during which period patients take drugs under direct observation by a health staff, following that is a continuation phase of four months for new TB cases. The re-treatment cases provides three months of intensive phase and five months of continuation phase for susceptible TB. The drugs used for the initial empiric treatment of new TB cases consists of isoniazid, rifampin, pyrazinamide, and ethambutol which are administered as a four drug regimen daily for two months. There is drastic reduction in bacteria load as they kill the tubercle bacilli rapidly. Infectious patients are rendered non-infectious in about two weeks of therapy. The continuation phase follows immediately after the intensive phase with daily administration of isoniazid and rifampin for four more months. The standard treatment regimen for re-treatment cases consist of five drugs in the initial phase and three drugs in the continuation phase; streptomycin is added to the intensive phase of the new case regimen and ethambutol to the continuation phase (Clark, Roger, 2010).

The directly observed treatment approach to administering TB medication has been found to be highly effective in managing the disease. The treatment success rate of all tuberculosis cases in Ghana is 81% (WHO, 2014) which is comparable with results from other regions of the world where DOTS strategy is currently being operated. In Cotonou, Benin Republic, 82% and 78% success rates were reported among new and retreatment cases with 1% and 3% failure rates, respectively (M. Gninafon, L. Tawo, F. Kassa, et al., 2004).

2.9 TUBERCULOSIS STIGMATIZATION

Stigma against TB patients is common knowledge the world over. Many researchers have endeavored to investigate the causes for such stigmatization. A meta- analysis by Courtwright et

al, (Courtwright, Andrew, and Abigail Norris Turner, 2010), revealed that the reasons for such a trend cut across geographical and cultural dimensions. Topmost on the list of research findings concerning the cause of TB stigmatization is the perceived contagiousness of the TB disease (AhChing LP, Sapolu M, Samifua M, Yamada S, 2001). Some stigmatize TB due to inadequate understanding of its mode of transmission (West EL, Gadkowski LB, Ostbye T, Piedrahita C, Stout JE., 2008). Others with good understanding of TB transmission, still fear the perceived risk of transmission with the consequence of stigmatization (Mak WW, Mo PK, Cheung RY, Woo J, Cheung FM, Lee D., 2006).

The association of HIV with TB in areas of high co-infection has contributed to TB stigmatization (O'Donoghue M., 2006). In some areas, TB is perceived as a marker for HIV positivity and therefore, HIV-associated stigma is transferred to TB-infected individuals

(Ngamvithayapong J, Winkvist A, Diwan V., 2000).

Other causes of TB stigma include the perceived associations of TB with Poverty (Mata JI, 1985), with malnutrition, (Westaway MS, Wolmarans L., 1994) and with low social class (Baral SC, Karki DK, Newell JN., 2007).

In some communities it is believed that TB infection is deserved punishment for wrong doing and therefore the stigmatization (Macq J, Solis A, Martinez G, Martiny P, Dujardin B., 2005).

That TB infection is believed to be a divine punishment for a moral or personal failing with consequence stigmatization has also been demonstrated (Baral SC, Karki DK, Newell JN., 2007).

KNUST

CHAPTER THREE

METHODS

3.1 STUDY DESIGN

A comparative cross-sectional study with analytical components based on documentary review to investigate six TB treatment outcomes among all TB patients in the Tarkwa Nsuaem Municipality from 2011 to 2013.

The treatment outcomes that were investigated are:

- Cure
- Treatment completed
- Treatment failure
- Lost to follow up
- Relapse

- Death

3.2 STUDY AREA

The study was conducted in the Tarkwa-Nsuaem Municipality. It is one of the seventeen districts in the Western Region of Ghana. The administrative capital of the municipality is Tarkwa. It is situated in the south central part of the region and shares common boundaries with Prestea-Huni Valley District to the north, Ahanta West District to the south, Nzema East and Ellembele to the west and Mpohor Wassa East District to the east. The municipality covers a land area of 2,354 square kilometers (sqkm) and lies on latitudes $4^{\circ} 50'$ and $0^{\circ} 5' 00''$ N, 0° longitude 1° and $2^{\circ} 10'W$

(District profile, TMHD, 2014).

One of the major economic activities in the area is surface mining and small scale mining popularly called 'galamsey'. There are also multi-national companies engaged in the mining of gold and manganese. Other minor occupations include lumbering and teak plantation. Rubber, palmnut and cocoa are also cultivated.

Tarkwa has nearly a century of gold mining history and has the largest concentration of mines in a single district on the continent of Africa, with virtually all the six new gold mines operating surface mines. It is characterized by an undulating terrain.

3.2.1 Municipal Health Directorate

The Municipal Health Directorate serves as the administrative head of all the health facilities in the municipality. There are 24 facilities in the area and these include: 2 government hospitals, 3 corporate hospitals, 3 private hospitals, 11 health centers, 3 Community based Health Planning and Services (CHPS) centers and 2 maternity homes. Six of these facilities provide TB care services in the municipality.

The directorate is headed by the Municipal Health Director and managed by the directorate health management team. The team is made up of the director, a pharmacist, nutrition officer, disease control officer, health information officer, accountant and public health officer who is usually a nurse.

There are six facilities that provide tuberculosis treatment services within the municipality and they are: Tarkwa Municipal Hospital, Nsuaem Health Center, ABA Hospital, Ghana Manganese Company Hospital-Nsuta, Simpa Health Center and Atuabo Health Center. These facilities together with the Municipal Health Directorate were the data collection points for this study.

3.2.2 Demographics of the Municipality.

The 2010 population and housing census of Ghana, indicates that the population of the TarkwaNsuaem Municipality is 90,477 making it the eleventh most populated district in the region. It is estimated to have a population growth rate of 3.0% (2010 population census). Many who migrate to the municipality are in search of job in the mining sector leading to the population of the municipality being concentrated in Tarkwa where the mines are located.

The indigenes of the municipality are the Wassa, but it has assumed a cosmopolitan dimension due to the mining activities. The total population distribution by sex is dominated by females by nine folds with the productive age group constituting about two third. 24.8% of the population were children not exceeding ten years of age. This is opposed to the national average of 45%. Those aged 65 year upwards make up 4.6% of the population. The high rate of labour migration for mining jobs and related trades around the mines has been suggested for the unusual population distribution (Akabzaa & Darimani, 2001).

3.3 STUDY SITE:

Tarkwa Nsuaem Municipal Health Directorate together with the six TB treatment health facilities in the municipality served as the data collection points. The source data included: institutional TB register at the six TB treatment sites for 2011, 2012 and 2013 together with the district TB register at the Municipal Health Directorate also for the periods of 2011, 2012 and 2013. The individual TB treatment cards of registrants for index TB case for 2011, 2012 and 2013 were also reviewed.

3.4 STUDY POPULATION DEFINITION

A ‘galamsey’ miner here included all who were involved in illegal mineral mining activities at time of diagnosis or have been involved with such a trade previously but stopped not more than a year at time of diagnosis. Also included are small scale miners.

In the context of this study, the ‘non-galamsey’ population included all persons diagnosed with TB who have never been involved with ‘galamsey’ mining or have done so previously but stopped over a year prior to the diagnosis.

The study included corporate miners to the ‘non-galamsey’ population but legal small scale miners to the ‘galamsey’ population.

3.5 DATA COLLECTION

A data collection tool was designed and used to extract all relevant parameters that will reflect the main objective of the study from the source data. Soft copy of data were kept under password while hard copy was kept under lock and key.

3.6 ELIGIBILITY CRITERIA

Inclusion criteria: All TB cases registered in any of the six treatment centers within the Tarkwa

Nsuaem Municipality from 2011 to 2013 which were notified to the district and the National TB Programme and completely captured on the data collection tool were included in the study.

Exclusion criteria: All incomplete records that could not be updated with the source data were rejected.

3.7 SAMPLING

3.7.1 Sample size: statistical determination of sample size

Formula:

$$n = \frac{t^2 \times p(1-p)}{m^2}$$

Description:

n = required sample size **t** = confidence level at 95%
(standard value of 1.96) **p** = estimated prevalence of subject
matter in the project area **m** = margin of error at 5%
(standard value of 0.05)

Ghana's TB prevalence at 2012 was 92 per 100,000 population.(WHO, 2013a)

$$92 \text{ per } 100,000 = 100/100\,000 \times 92$$

$$= 0.092\%$$

Choosing confidence interval of 95% and margin of error of 0.05:

$$n = \frac{1.96^2 \times 0.092(1-0.092)}{0.05^2}$$

$$0.05^2$$

$$= \frac{3.8416 \times 0.092(0.908)}{0.0025}$$

$$= \frac{0.3209}{0.0025}$$

$$= 128$$

The sample used in this study was 510 which is more than the statistically determined sample size by 382 case registrations. This highlights the significance of this research results within population dimensions.

3.7.2 Sampling technique

A data collection tool was developed and used to extract relevant information from the institutional tuberculosis registers and TB treatment cards at the various treatment centers within the Tarkwa Nsuaem Municipality and crosschecked with the district TB register at the municipal health directorate. Sample size included all registered cases of TB from January 2011 to December 2013 who were diagnosed and put on TB therapy in the Tarkwa Nsuaem Municipality.

3.8 DATA ANALYSIS

The data was coded and entered into IBM SPSS® statistics 21 and Microsoft Office Excel 2007 software and analysed.

The main focus was to measure the ratios of the six TB treatment outcomes in the two target populations. The associations between TB outcomes of the two populations were investigated using cross-tabulation followed by chi-square analysis. Differences between targets were

expressed as odds ratios (OR) with 95% confidence intervals (95%CI). A p-value < 0.05 was considered significant.

3.9 ETHICAL CONSIDERATION

Application was submitted to the Committee on Human Research, Publication and Ethics (CHRPE) of KNUST-School of Medical Science and Komfo Anokye Teaching Hospital for ethical clearance in respect of this study. Approval was granted as indicated in a letter dated 17th November, 2014 (appendix Y).

Approval was also sought from the Municipal Health Director of the Tarkwa Nsuaem Municipal Health Directorate for access to data collection points and source data. This was also granted. A high level of confidentiality was maintained throughout the data collection process. The data was collected from their storage site and the raw and processed data was locked under a password. The hard copy of raw data was also kept under lock and key.

CHAPTER FOUR

RESULTS

This chapter deals with the presentation and in depth analysis of the results obtained to help make relevant conclusions.

4.1 PATIENT DEMOGRAPHICS AND DISTRIBUTION OVER PERIOD OF STUDY

The period of study spans from 2011 to 2013 with 2013 recording the highest number of TB cases (n=211) representing 41.4% as presented on table 4.1.1.

The overall age distribution as well as the age distribution over the two target populations as text clearly presented and table 4.1.2 illustrating it well shows that the worse affected age group are adults in the working class (middle age bracket).

Table 4.1.1 Demographic characteristics of registrants: age, sex, occupation and treatment category.

VARIABLES	DESCRIPTION	2011		2012		2013		TOTAL n=510	%
		n=141	%	n=158	%	n=211	%		
AGE	<10	2	1.42	2	1.27	1	0.47	5	0.98
	10-19	6	4.26	13	8.23	7	3.32	26	5.10
	20-29	24	17.02	26	16.46	31	14.69	81	15.88
	30-39	44	31.21	44	27.85	56	26.54	144	28.24
	40-49	40	28.37	40	25.32	64	30.33	144	28.24
	50-59	8	5.67	20	12.66	32	15.17	60	11.76
	60-69	11	7.80	7	4.43	10	4.74	28	5.49
	70-79	4	2.84	5	3.16	9	4.27	18	3.53
	80-89	2	1.42	1	0.63	0	0.00	3	0.59
	90-99	0	0.00	0	0.00	1	0.47	1	0.20
SEX	MALE	113	80.14	121	76.58	182	86.26	416	81.57
	FEMALE	28	19.86	37	23.42	29	13.74	94	18.43
OCCUPATION	'GALAMSEY'	72	51.06	40	25.32	85	40.28	197	38.63
	GENERAL POPULATION	69	48.94	118	74.68	126	59.72	313	61.37
TREATMENT CATEGORY	NEW CASE	137	97.16	147	93.04	191	90.52	475	93.14
	RE-TREATMENT	4	2.84	11	6.96	20	9.48	35	6.86

Table 4.1.2 Central tendencies of age distribution of patients

YEAR	OF	OCCUPATION

REGISTRATION	'GALAMSEY'			NON-'GALAMSEY'		
	MEAN AGE	MEDIAN	MODE	MEAN AGE	MEDIAN	MODE
2011	40.3	40	35; 40; 43	38.2	36.5	32;36
2012	36.8	35.5	35	39.27	38.5	37;42
2013	41	40.5	40	41.3	43	50

4.2 ESTIMATED POPULATION OF THE MUNICIPALITY FOR PERIOD UNDER STUDY

Information on the total populations of the municipality for each year under study is required to estimate the annual TB incidence and prevalence of the area for the various periods.

According to the 2010 Ghana population and housing census, the total population strength of the Tarkwa Nsuaem Municipality for that year was 90,477 with an estimated population growth rate of 3%.

Table 4.2.1 Estimated total population of the municipality for the years under study

YEAR	ESTIMATED TOTAL POPULATION
2011	93,192
2012	95,987
2013	98,867

4.3 PREVALENCE OF TB IN THE MUNICIPALITY

Prevalence of TB = $\frac{\text{Total cases of TB in a period}}{10,000 \text{ population}}$

Total population of the period

$$\text{2011 TB Prevalence} = \frac{141}{93,192} \times 10,000$$

93,192

$$= 15 \text{ TB cases per } 10,000 \text{ populations.}$$

The 2012 and 2013 prevalence were computed as above and yielded the results shown table 4.3.1 below.

Table 4.3.1 Estimated TB prevalence of the municipality for the years under study

YEAR UNDER STUDY	TB PREVALENCE PER 10,000 POPULATIONS.
2011	15
2012	17
2013	21

4.4 INCIDENCE OF TB IN THE MUNICIPALITY OVER THE STUDY PERIOD

$$\text{Incidence of TB} = \frac{\text{New TB cases in a period}}{\text{Total population of the period}} \times 10,000 \text{ populations}$$

Total population of the period

$$\text{2011 incidence of TB} = \frac{137}{141} \times 10,000 \text{ population.}$$

93,192

= 15 new TB cases per 10,000 populations.

The incidences for 2012 and 2013 were computed as above and yielded the results as shown in table 4.4.1 below.

Table 4.4.1 Estimated incidences of TB in the municipality for the periods under study

YEAR UNDER STUDY	INCIDENCE OF TB PER 10,000 POPULATIONS
2011	15
2012	15
2013	19

4.5 TB CHARACTERISTICS AT PRESENTATION AND TREATMENT OUTCOMES

There were significant differences in the various measuring parameters for TB characteristics at presentation, the treatment outcomes and patronage at the various TB treatment centers within the municipality as shown on figure 4.5.1

4.5.1 REGISTRANTS PER TREATMENT CENTER

The TB treatment centers in the Tarkwa Nsuaem Municipality include the Tarkwa Municipal Hospital, Nsuaem Health Center, Atuabo Health Center, Nsuta Health Center, A.B.A Hospital, Simpa Health Center.

Out of a total number of 510 TB patient registered in the Tarkwa Nsuaem Municipality, Tarkwa

Municipal Hospital recorded the highest number which is 413 representing 81.0%, Nsuaem Health center followed with a total number of 65 patients representing 12.7%, followed by A.B.A. Hospital with a total number of 17 representing 3.3%. Atuabo Health Centre recorded a total number of 12 patients with TB representing 2.4% of the total number of 510 TB patients. Simpa Health Center recorded 2 patients representing 0.4% and Nsuta Health Center recorded 1 patient representing 0.2% as shown in figure 4.5.1 below.

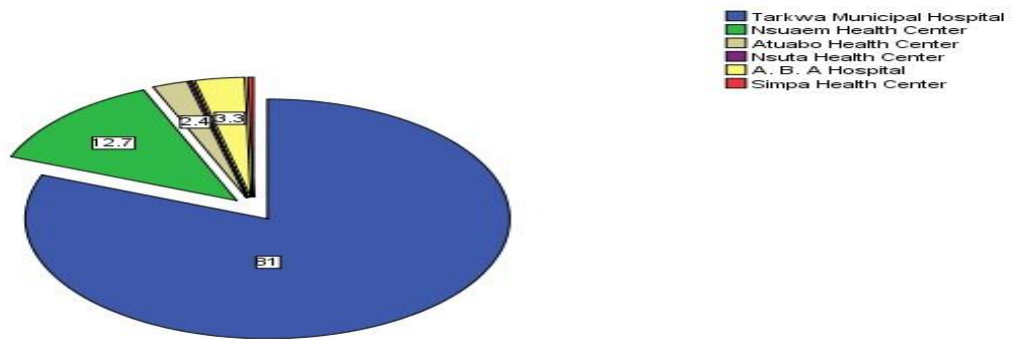


Figure 4.5.1 Patients distribution over treatment centers

4.5.2 OCCUPATION OF REGISTRANTS

In this report the occupation of clients have been divided into two; 'galamsey' and the 'nongalamsey' populations. 197 registrants were of the 'galamsey' population representing 38.6% as shown in figure 4.5.2 below

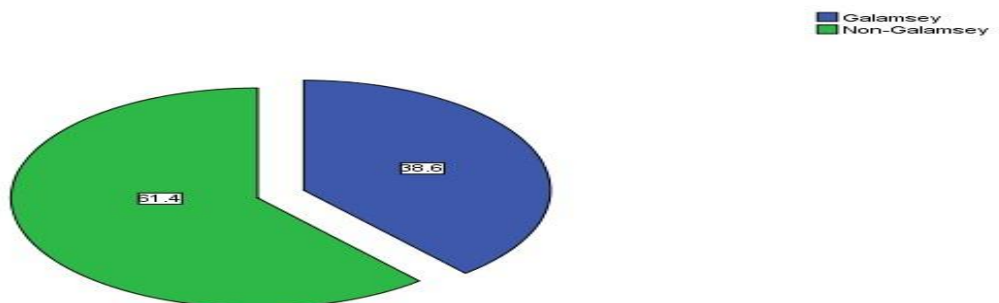


Figure 4.5.2 Distribution of patients by occupation

4.5.3 RESULTS OF SPUTUM MICROSCOPY

76.9% of the total registered TB patients tested positive to the sputum microscopy while 23.1% tested negative as shown in figure 4.5.3

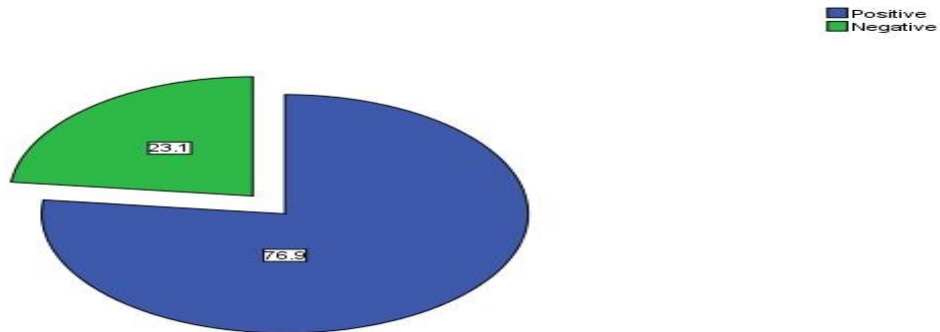


Figure 4.5.3 Distribution of patients by results for sputum microscopy

4.5.4 RESULTS OF TYPE OF TB FOR REGISTRANTS

Two main types of TB were considered namely, pulmonary and extra-pulmonary. 96.3% had pulmonary TB while 3.7% had Extra-Pulmonary TB as illustrated pictorially by figure 4.5.4 below.

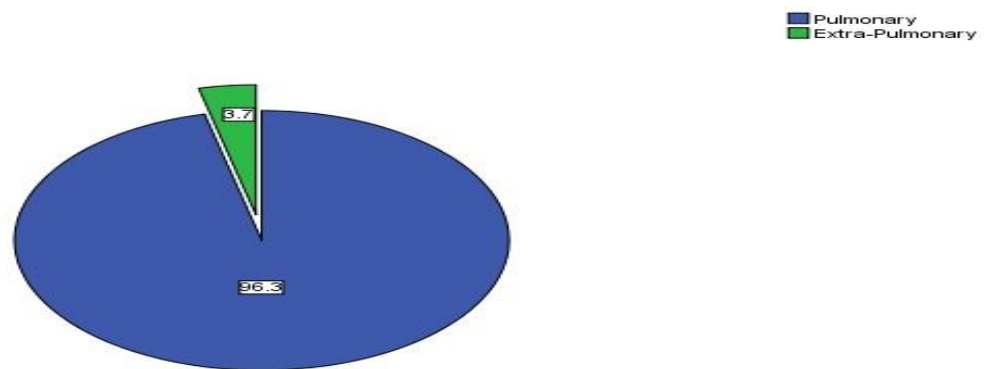


Figure 4.5.4 Distribution of patients by results for type of TB

4.5.5 REGISTRANTS' TREATMENT CATEGORY

There are two treatment categories- New Case and Retreatment. 93.1% of the total registered TB cases were new cases while 6.9% were retreatment.

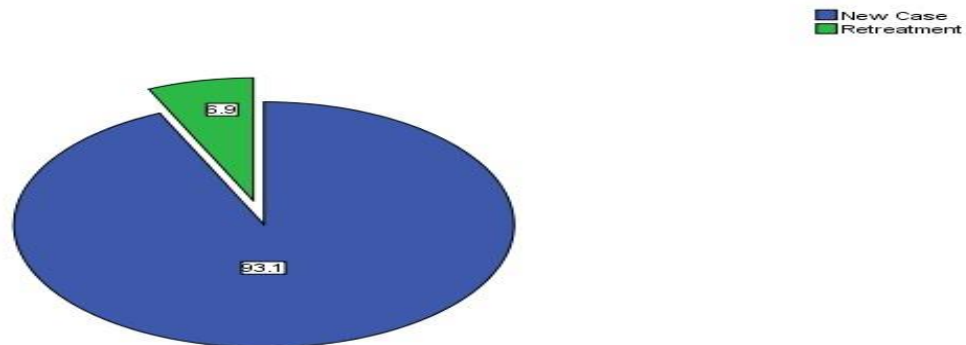


Figure 4.5.5 Distribution of patients by results for type of TB treatment

4.5.6 TREATMENT OUTCOME

Treatment outcome was divided into the following categories; cured, treatment completed, treatment failure, loss to follow up and death. 50.6% were cured, 36.7% completed treatment, 0.4% failed treatment, 8.6% were lost to follow up and 3.7% died.

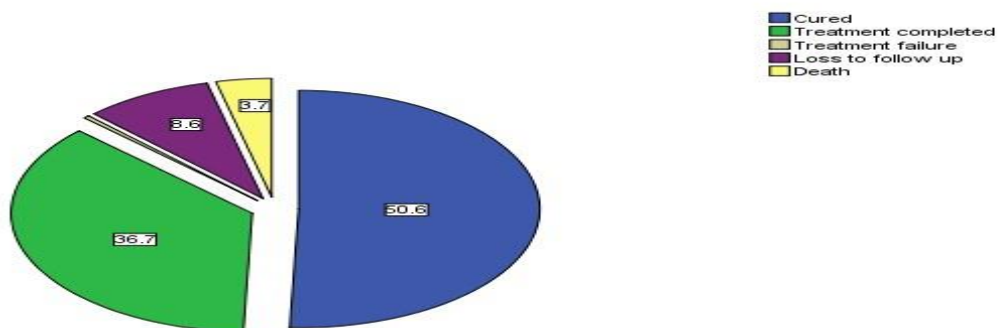


Figure 4.5.6 Distribution of patients by results for TB treatment outcomes

4.5.7 CANDIDATES WITH PRESUMED RESISTANT TB

An index case of TB is presumed to be or presumed to have resulted is a resistant TB following treatment relapse, failure or loss to follow up. All TB index cases with sputum positive microscopic results at initiation of therapy who do not ‘sputum convert’ at month three of therapy are considered to have failed treatment and are presumed to carry resistant strains of the TB bacilli. Out of the total registrants for the study, 9% had to be re-registered in the presumed resistant TB register whiles 91% were not.

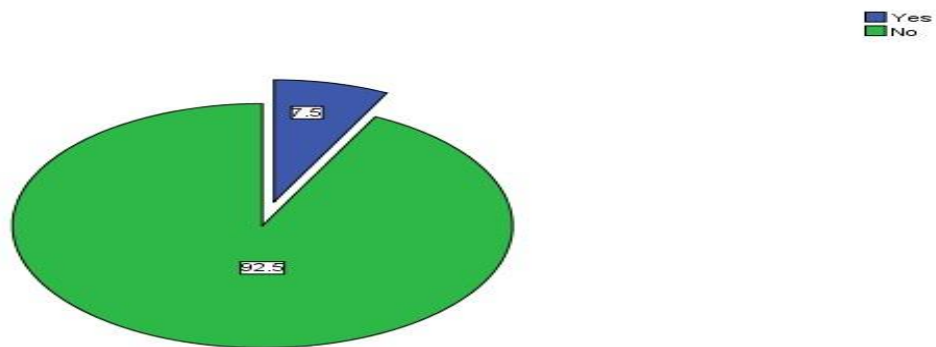


Figure 4.5.7 Distribution of patients by results of presumed resistant TB

4.6 CROSS-TABULATION FOR CATEGORICAL VALUES

A cross-tabulation is performed for occupation of patients against several TB characteristics and outcomes to enable a comparison leading to the appreciation of the influence or otherwise of occupation of registrant on TB presentations and management.

Table 4.6.1 Distribution of patients' occupation over TB characteristics and outcome

VARIABLES	DESCRIPTION	G-P n=197	%	NG-P n=313	%	CHI-SQUARE	P-VALUE
-----------	-------------	--------------	---	---------------	---	------------	---------

TREATMENT OUTCOME	CURE	112	56.85	146	46.65	10.947	0.027
	TREATMENT COMPLETED	67	34.01	120	38.34		
	TREATMENT FAILURE	2	1.02	0	0.00		
	RELAPSE	0	0.00	0	0.00		
	LOST TO FOLLOW UP	11	5.58	33	10.54		
	DEATH	5	2.54	14	4.47		
PRESUMED RESISTANT TB	YES	13	6.60	33	10.54	2.292	0.13
	NO	184	93.40	280	89.46		
TYPE OF TB	PULMONARY	196	99.49	295	94.25	9.267	0.002
	EXTRAPULMONARY	1	0.51	18	5.75		
SPUTUM MICROSCOPY RESULT	POSITIVE	165	83.76	227	72.52	8.577	0.003
	NEGATIVE	32	16.24	86	27.48		
TREATMENT CATEGORY	NEW CASE	175	88.83	300	95.85	9.306	0.002
	RE-TREATMENT	22	11.17	13	4.15		

KEY: G-P means 'galamsey population' and GN-P means 'non-galamsey population.'

Table 4.6.2 Distribution of patients' occupation over TB characteristics for the various study periods

Description		Population within Occupation		
		'galamsey'	General	Total
2011 Treatment category Total	New Case	68	69	137
	Re-treatment	4	0	4
		72	69	141
2012 Treatment category Total	New Case	33	114	147
	Re-treatment	7	4	11

		40	118	158
2013 Treatment category Total	New Case	74	117	191
	Re-treatment	11	9	20
		85	126	211

Table 4.6.3 Gender distribution over patients' occupation

Description		Population within Occupation		Total
		'galamsey'	'non-galamsey'	
Gender of client	Male	190	226	416
	Female	7	87	94
Total		197	313	510

4.6.1 OCCUPATION OF CLIENTS AND RESULTS OF SPUTUM MICROSCOPY

4.6.1.1 Hypothesis

Null Hypothesis(H_0): 'galamsey' and 'non-galamsey' populations have equal chances for sputum positive microscopic results.

Alternative Hypothesis(H_1): ‘galamsey’ and ‘non-galamsey’ populations do not have equal chances for sputum positive microscopic results.

Table 4.6.4 below shows that the ‘galamsey’ population had more positive and less negative results for sputum microscopy than it was expected. The ‘non-galamsey’ population had less positive but more negative results for sputum microscopy than it was expected.

Table 4.6.4 Distribution of patient's result for sputum microscopy over their occupation

OCCUPATION OF PATIENTS	DESCRIPTION	RESULT OF SPUTUM MICROSCOPY		TOTAL
		POSITIVE	NEGATIVE	
‘GALAMSEY’ POULATION	Actual Count	165	32	197
	Expected Count	151.4	45.6	197
	% within Occupation	83.80%	16.20%	100%
	% within Results	42.10%	27.10%	38.60%
	% of Total Registrants	32.40%	6.30%	38.60%
	Residual	13.60	-13.60	
‘NON-GALAMSEY’ POPULATION	Actual Count	227	86	313
	Expected Count	240.6	72.4	313
	% within Occupation	72.50%	27.50%	100%
	% within Results	57.90%	72.90%	61.40%
	% of Total Registrants	44.50%	16.90%	61.40%
	Residual	-13.60	13.60	
TOTAL POPULATION	Actual Count	392	118	510
	Expected Count	392	118	510
	% within Occupation	76.90%	23.10%	100%
	% within Results	100.00%	100.00%	100%
	% of Total Registrants	76.90%	23.10%	100%

4.6.1.2 Chi-Square Test for the Result of Sputum Microscopy

The probability of the chi-square test statistic (chi-square=8.577) was $p=0.003$ which is less than the alpha level of significance of 5%. Thus the alternate hypothesis is supported by this analysis. This means that the 'galamsey' population and the 'non-galamsey' population do not have equal chances for sputum positive microscopic results.

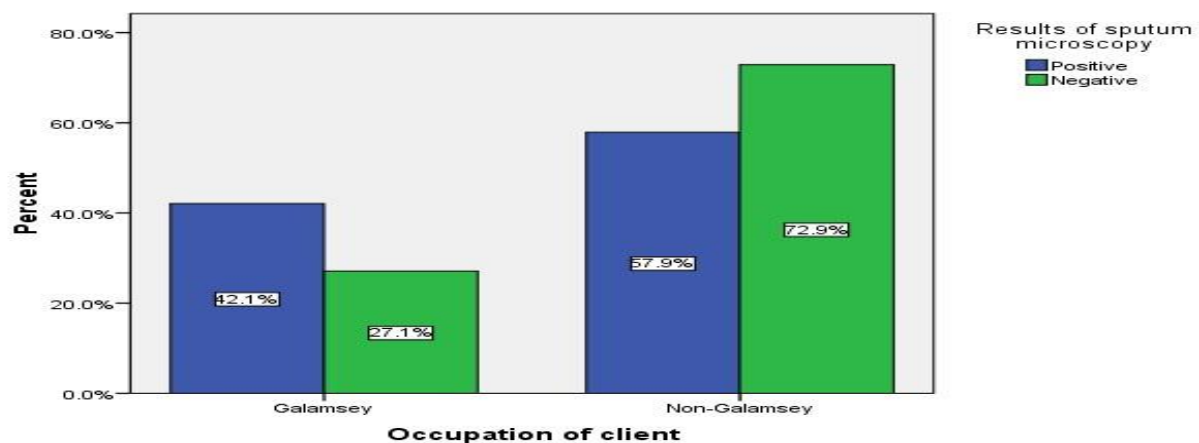


Figure 4.6.1 Distribution of patients' results for sputum microscopy over their occupation groups.

4.6.2 OCCUPATION OF CLIENTS AND THE TYPE OF TB

4.6.2.1 Hypothesis

Null Hypothesis(H_0): 'galamsey' and 'non-galamsey' populations have equal risk for Pulmonary TB and Extrapulmonary TB.

Alternative Hypothesis(H_1): 'galamsey' and 'non-galamsey' populations do not have equal risk for Pulmonary TB and Extrapulmonary TB.

The SPSS® analysis as shown on table 4.6.5 indicates that the 'galamsey' population had more Pulmonary TB and less Extra-Pulmonary TB than was expected. The 'non-galamsey' population

had more extrapulmonary TB and less pulmonary TB than was expected. This is actually the reverse of what was observed in the 'galamsey' population

Table 4.6.5 Distribution of the results of type of TB over patients' occupation

OCCUPATION OF PATIENTS	DESCRIPTION	TYPE OF TB		TOTAL
		PULMONARY	EXTRA-PULMONARY	
'GALAMSEY' POPULATION	Actual Count	196	1	197
	Expected Count	189.7	7.3	197
	% within Occupation	99.50%	0.50%	100%
	% within Results	39.90%	5.30%	38.60%
	% of Total Registrants	38.40%	0.20%	38.60%
	Residual	6.30	-6.30	
'NON-GALAMSEY' POPULATION	Actual Count	295	18	313
	Expected Count	301.3	11.7	313
	% within Occupation	94.20%	5.80%	100%
	% within Results	60.10%	94.70%	61.40%
	% of Total Registrants	57.80%	3.50%	61.40%
	Residual	-6.30	6.30	
TOTAL POPULATION	Actual Count	491	19	510
	Expected Count	491	19	510
	% within Occupation	96.30%	3.70%	100%
	% within Results	100.00%	100.00%	100%
	% of Total Registrants	96.30%	3.70%	100%

4.6.2.2 Chi-Square Test for the Type of TB

The probability of the chi-square test statistic (chi-square=9.267) was $p=0.002$ which is less than the alpha level of significance of 5%. Thus the alternate hypothesis is supported by this analysis. This means that TB patients in the municipality who are involved with 'galamsey' and those of the 'non-galamsey' population do not have equal risk for pulmonary and extrapulmonary TB

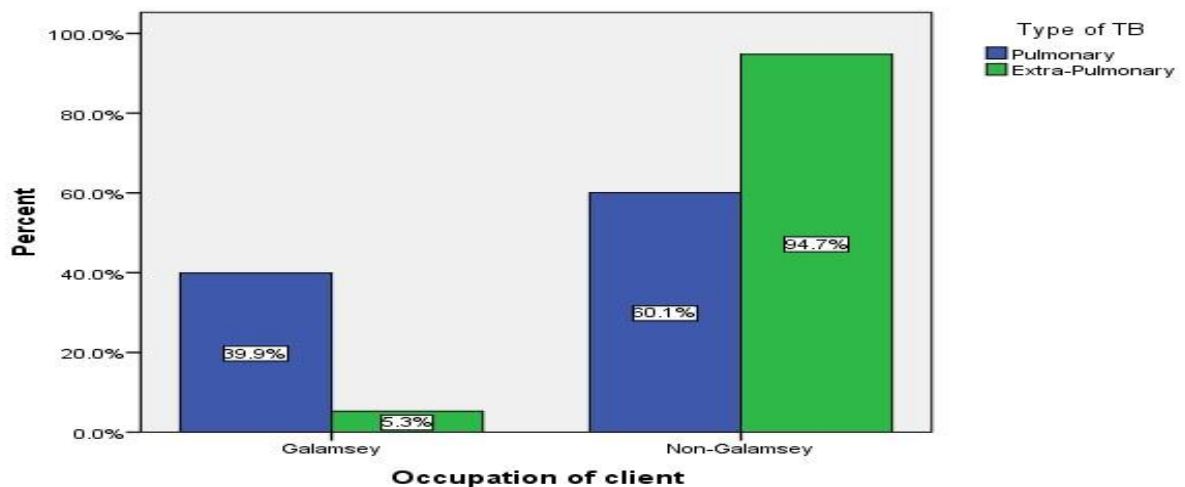


Figure 4.6.2 Distribution of patients' results for type of TB over their occupation groups.

4.6.3 OCCUPATION OF CLIENTS AND THE TREATMENT CATEGORY

4.6.3.1 Hypothesis

Null Hypothesis(H_0): 'galamsey' and 'non-galamsey' populations have equal risk for TB retreatment and new TB infection

Alternative Hypothesis(H_1): 'galamsey' and 'non-galamsey' populations do not have equal risk for TB re-treatment and new TB infection.

The SPSS® analysis as presented on table 4.6.6, shows that there were more patients of the ‘galamsey’ population reporting for re-treatment than expected but less number of patient reported with new cases of TB than expected.

There were fewer than expected of the ‘non-galamsey’ population that reported for re-treatment but more than expected reporting with new TB cases

Table 4.6.6 Distribution of the results of treatment category of TB over patients' occupation

OCCUPATION OF PATIENTS	DESCRIPTION	TREATMENT CATEGORY		TOTAL
		NEW CASE	RE-TREATMENT	
‘GALAMSEY’ POULATION	Actual Count	175	22	197
	Expected Count	183.5	13.5	197
	% within Occupation	88.80%	11.20%	100%
	% within Results	36.80%	62.90%	38.60%
	% of Total Registrants	34.30%	4.30%	38.60%
	Residual	-8.50	8.50	
‘NON-GALAMSEY’ POPULATION	Actual Count	300	13	313
	Expected Count	291.5	21.5	313
	% within Occupation	95.80%	4.20%	100%
	% within Results	63.20%	37.10%	61.40%
	% of Total Registrants	58.80%	2.50%	61.40%
	Residual	8.50	-8.50	
TOTAL POPULATION	Actual Count	475	35	510
	Expected Count	475	35	510
	% within Occupation	93.10%	6.90%	100%

	% within Results	100.00%	100.00%	100%
	% of Total Registrants	93.10%	6.90%	100%

4.6.3.2 Chi-Square Test for the Treatment Category

The probability of the chi-square test statistic (chi-square=9.306) was $p=0.002$ which is less than the alpha level of significance of 5%. Thus the alternate hypothesis that the 'galamsey' population and the 'non-galamsey' population do not have equal risk for new TB infection and TB re-treatment is supported by this analysis.

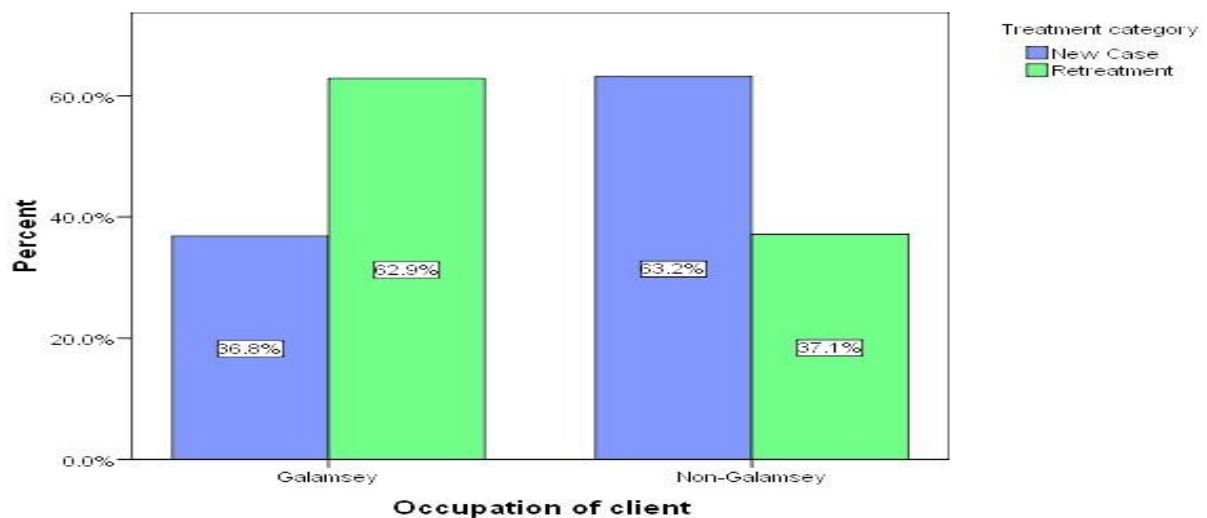


Figure 4.6.3 Distribution of patients' results for treatment category over their occupation groups.

4.6.4 OCCUPATION OF CLIENTS AND TREATMENT OUTCOME

4.6.4.1 Hypothesis

Null Hypothesis(H_0): 'galamsey' and 'non-galamsey' populations have the same performance for TB treatment outcomes

Alternative Hypothesis(H_1): ‘galamsey’ and ‘non-galamsey’ populations do not have the same performance for TB treatment outcomes.

The SPSS® analysis presented on table 4.6.7 indicates that more of the ‘galamsey’ population had ‘cured’ and treatment failure than was expected but less number had ‘treatment completed’, ‘loss to follow up’ and death than was expected.

The ‘non-galamsey’ population had more TB patients with treatment completed, lost to follow up and death than was expected but less number of patients with ‘cured’ and treatment failure than it was expected.



Table 4.6.7 Distribution of the results of treatment outcomes of TB over patients' occupation

OCCUPATION OF PATIENTS	DESCRIPTION	TREATMENT OUTCOMES					TOTAL
		CURE	TREATMENT COMPLETED	TREATMENT FAILURE	LOSS TO FOLLOW UP	DEATH	
'GALAMSEY' POULATION	Actual Count	112	67	2	11	5	197
	Expected Count	99.7	72.2	0.8	17	7.3	197
	% within Occupation	56.90%	34.00%	1.00%	5.60%	2.50%	100%
	% within Results	43.40%	35.80%	100.00%	25.00%	26.30%	38.60%
	% of Total Registrants	22.00%	13.10%	0.40%	2.20%	1.00%	38.60%
	Residual	12.30	-5.20	1.20	-6.00	-2.30	
'NON-GALAMSEY' POPULATION	Actual Count	146	120	0	33	14	313
	Expected Count	158.3	114.8	1.2	27	11.7	313
	% within Occupation	46.60%	38.30%	0.00%	10.50%	4.50%	100%
	% within Results	56.60%	64.20%	0.00%	75.00%	73.70%	61.40%
	% of Total Registrants	28.60%	23.50%	0.00%	6.50%	2.70%	61.40%
	Residual	-12.30	5.20	-1.20	6.00	2.30	
TOTAL POPULATION	Actual Count	258	187	2	44	19	510
	Expected Count	258	187	2	44	19	510
	% within Occupation	50.60%	36.70%	0.40%	8.60%	3.70%	100%
	% within Results	100.00%	100.00%	100.00%	100.00%	100.00%	100%
	% of Total Registrants	50.60%	36.70%	0.40%	8.60%	3.70%	100%
	Residual						

4.6.4.2 Chi-Square Test for the Treatment Outcome

The probability of the chi-square test statistic (chi-square = 10.947) was $p=0.027$ which is less than the alpha level of significance of 0.05. Thus the alternate hypothesis is supported by this analysis. This means that patients of the two population group do not have equal performances of TB treatment outcomes.

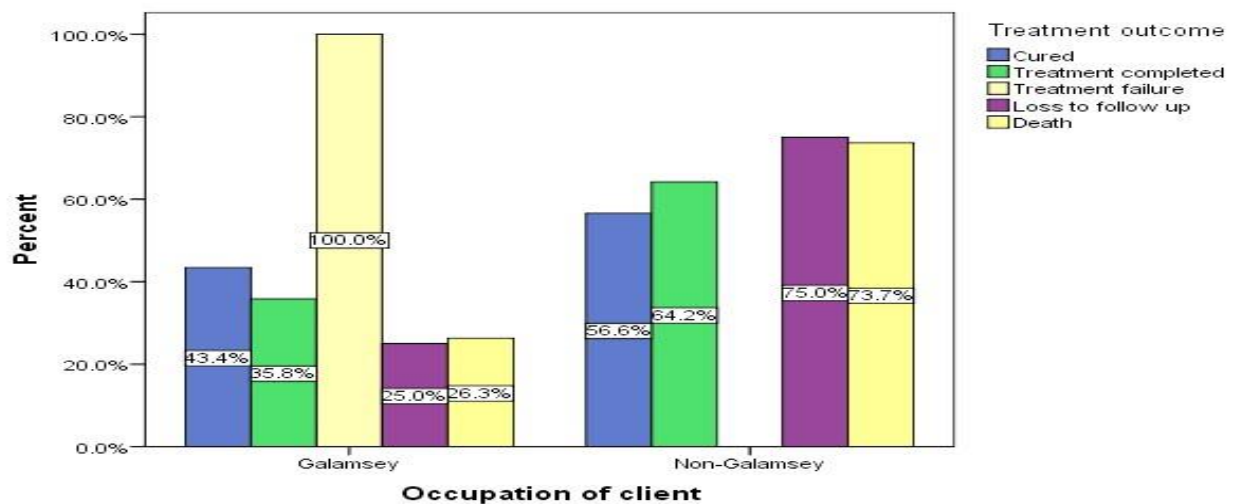


Figure 4.6.4 Distribution of patients' results for TB treatment outcomes over their occupation groups.

4.6.5 OCCUPATION OF CLIENTS AND RISK OF PRESUMED RESISTANT TB

4.6.5.1 Hypothesis

Null Hypothesis(H_0): 'galamsey' and 'non-galamsey' populations have equal risk for presumed resistant TB.

Alternative Hypothesis(H_1): 'galamsey' and 'non-galamsey' populations do not have equal risk for presumed resistant TB.

The SPSS® analysis presented on table 4.6.8 shows that there were more 'galamsey' miners without presumed resistant TB than was expected as against those of the 'non-galamsey' population who had more presumed resistant TB than was expected.

Table 4.6.8 Distribution of the results of presumed resistant TB over patients' occupation

OCCUPATION OF PATIENTS	DESCRIPTION	PRESUMED RESISTANT TB		TOTAL
		YES	NO	
'GALAMSEY' POULATION	Actual Count	13	184	197
	Expected Count	17.8	179.2	197
	% within Occupation	6.60%	93.40%	100%
	% within Results	28.30%	39.70%	38.60%
	% of Total Registrants	2.50%	36.10%	38.60%
	Residual	-4.80	4.80	
'NON-GALAMSEY' POPULATION	Actual Count	33	280	313
	Expected Count	28.2	284.8	313
	% within Occupation	10.50%	89.50%	100%
	% within Results	71.70%	60.30%	61.40%
	% of Total Registrants	6.50%	54.90%	61.40%
	Residual	4.80	-4.80	
TOTAL POPULATION	Actual Count	46	464	510
	Expected Count	46	464	510
	% within Occupation	9.00%	91.00%	100%
	% within Results	100.00%	100.00%	100%
	% of Total Registrants	9.00%	91.00%	100%

4.6.5.2 Chi-Square Test for risk of presumed resistant TB

The probability of the chi-square test statistic (chi-square = 2.292) was $p=0.130$ which is greater than the alpha level of significance of 5%. Thus the null hypothesis is supported by this analysis.

This means that TB patients of the 'galamsey' population and those of the 'non-galamsey' population have equal risk for presumed resistant TB.

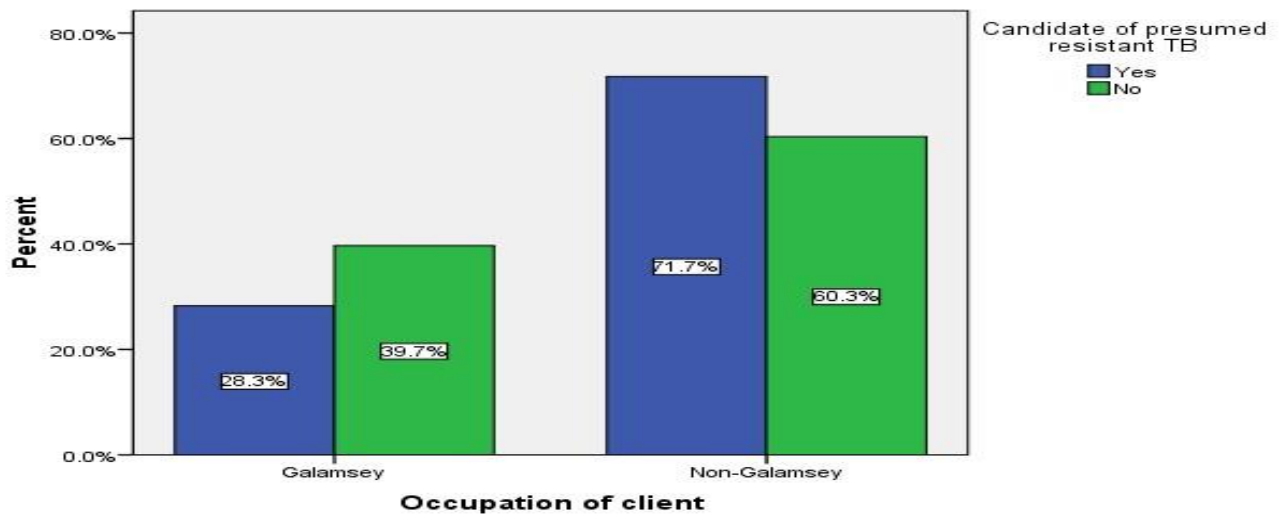


Figure 4.6.5 Distribution of patients' results for presumed resistant TB over their occupation groups.

4.6.6 OCCUPATION OF CLIENTS AND INDEX CASE WITH TREATMENT SUCCESS

4.6.6.1 Hypothesis

Null Hypothesis(H_0): 'galamsey' and 'non-galamsey' populations have equal chances for TB treatment success.

Alternative Hypothesis(H_1): 'galamsey' and 'non-galamsey' populations do not have equal chances for TB treatment success.

The SPSS® analysis presented on table 4.6.9 shows that the 'galamsey' population had more treatment success than was expected as against the 'non-galamsey' population who had less number of treatment success than was expected.

Table 4.6.9 Distribution of the results of TB treatment success over patients' occupation

OCCUPATION OF PATIENTS	DESCRIPTION	TREATMENT SUCCESS		TOTAL
		YES	NO	

'GALAMSEY' POULATION	Actual Count	179	18	197
	Expected Count	173.8	23.2	197
	% within Occupation	90.90%	9.10%	100%
	% within Results	39.80%	30.00%	38.60%
	% of Total Registrants	35.10%	3.50%	38.60%
	Residual	5.20	-5.20	
'NON-GALAMSEY' POPULATION	Actual Count	271	42	313
	Expected Count	276.2	36.8	313
	% within Occupation	86.80%	13.40%	100%
	% within Results	60.20%	70.00%	61.40%
	% of Total Registrants	53.10%	8.20%	61.40%
	Residual	-5.20	5.20	
TOTAL POPULATION	Actual Count	450	60	510
	Expected Count	450	60	510
	% within Occupation	88.20%	11.80%	100%
	% within Results	100.00%	100.00%	100%
	% of Total Registrants	88.20%	11.80%	100%
	Residual			

4.6.6.2 Chi-Square Test for the index case with treatment success

The probability of the chi-square test statistic (chi-square = 2.135) was $p=0.144$ which is greater than the alpha level of significance of 0.05. Thus the null hypothesis is supported by this analysis.

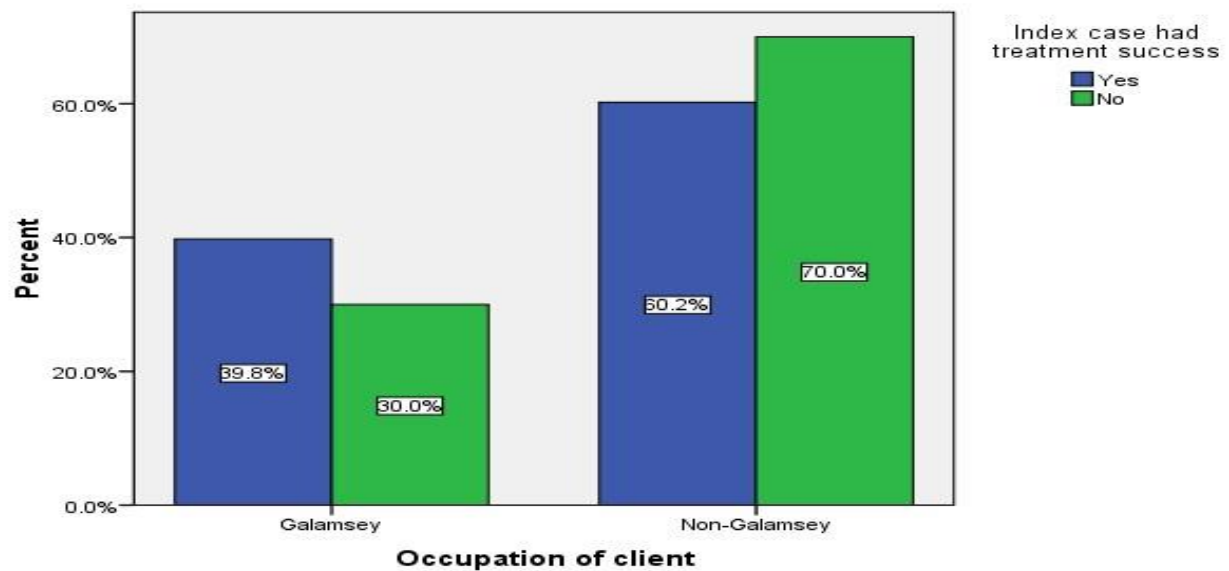


Figure 4.6.6 Distribution of patients' results for TB treatment success over their occupation groups.

CHAPTER FIVE

5.0 DISCUSSION OF RESULTS

5.1. DEMOGRAPHICS OF TB PATIENTS

Sex

A total of 510 individual registered cases of TB in the source documents were reviewed within the study period of 2011 to 2013. The gender distribution of registrants was heavily dominated by males. The male and female counts were 416 and 94 representing 81.6% and 18.4% respectively. The overall male to female ratio was over 4.4:1. Generally more males reported with TB than females at all times irrespective of occupation. The 2014 global TB report observed the same trends at the global, African regional and Ghana national levels (WHO, 2014) It may be fairly safe to make the inference that the male gender has higher risk for TB disease than the female gender

There were 197 and 313 patients of the 'galamsey' and 'non-galamsey' populations respectively, representing 38.6% and 61.4% respectively. The total population of 'galamsey' miners per year for the Tarkwa Nsuaem Municipality could not be estimated for lack of record, however they are relatively few compared to the 'non-galamsey' population. 38.6% of total TB notification in three years for only 'galamsey' miners is high and supports Stuckler et al, that there is high incidence and prevalence among mineral miners than the general population (Stuckler, Basu, et al, 2011).

It was observed that both populations recorded progressive increases in male to female ratio over the periods. The 'galamsey' population recorded totals of 190 males and 7 females representing 96.4% and 3.6% respectively. The 'non-galamsey' population recorded 226 males and 87 females representing 72.2% and 27.8% respectively. The proportions of female for the two populations were 7.4% and 92.6% respectively for 'galamsey' and 'non-galamsey' populations. The male gender presents a different relativity for the comparing populations. 45.6% and 54.3% of the total male count were in the 'galamsey' and 'non-galamsey' populations respectively. Again the male relative high risk for TB is observed in both populations as was reported in the global TB report (WHO, 2014).

Age

The central tendencies of the age distributions over both occupation groups are almost the same. The mode ages for the 'galamsey' population are; 35, 40 and 43. Those for the 'non-galamsey' population are 32 and 36. The mean ages are 40 and 38 respectively for 'galamsey' and 'nongalamsey' populations. It can be inferred from the foregoing that the TB disease affects dominantly persons in their productive years. The WHO also reported that most notified TB cases in 2013 to the organization at the global level were adults. The report added that children less than 15 years accounted for only 6% of notified cases (WHO, 2014). Considering the fact that the very

young and the very elderly are among the most immunocompromised but were not the most affected by the TB disease, points to an inference that the work place may be more fertile for the spread of the TB disease than the home.

5.2 DISTRIBUTION OF TB CHARACTERISTICS AT PRESENTATION.

The ‘non-galamsey’ population reported more new cases of TB disease than those of the ‘galamsey’ population; 63.2% and 36.8% respectively for the ‘non-galamsey’ and ‘galamsey’ populations. However, the reverse is the observation for cases of re-treatment; recording 37.1% and 62.9% respectively for the ‘non-galamsey’ and ‘galamsey’ populations.

In all the other parameters for TB characteristic at presentation, the ‘galamsey’ population recorded lower percentages for all markers within each parameter. The sputum microscopy results recorded a sputum positive microscopy of 42.1% and 57.9% respectively for the ‘galamsey’ and ‘non-galamsey’ populations while the record for sputum negative microscopy showed 27.1% and 72.9% respectively for the ‘galamsey’ and ‘non-galamsey’ populations. Both markers within the sputum microscopy parameter yielded lower percentages for the ‘galamsey’ population as against the ‘non-galamsey’ population. The same trend is observed with the type of TB parameter.

5.3 TB INCIDENCE AND PREVALENCE IN THE MUNICIPALITY

A progressive increase in TB case incidence and prevalence was observed. There were 12% and 33% increases of TB incidence respectively over previous years from 2011 and 2013. At the global level a contrary observation is reported. TB is said to be slowly declining each year (WHO, 2014).

The Millennium Development Goal, target 6.c (WHO, 2013a), aims to halt and begin to reverse the incidence of TB by 2015. The trend in the municipality points to a progression and not a

reversal of the prevalence and calls for more work to be done. According to Churchyard et al such trends are reversible. Relevant education to promote occupational health, prevention of spread to contacts through cough etiquette and proper sputum disposal habits would have to be encouraged and evidence of adherence probably rewarded. Active case search and prompt management should be pursued by all health facilities in the municipality (Churchyard et al., 2000).

5.4 PERFORMANCES OF THE TWO POPULATIONS FOR TREATMENT FAILURE, LOSS TO FOLLOW UP AND RELAPSE

There were only two cases of TB treatment failure and both were from the 'galamsey' population which is consistent with the report by Agence France Press that mineral miners are more likely to carry drug-resistant forms of TB which is a source of TB treatment failure (Agence France Press, 2006). According to Basu et al migration to and from the mines may be amplifying TB epidemics in the general population (Basu, Stuckler, Gonsalves, & Lurie, 2009). There were more treatment interruptions due to 'lost to follow up' among the 'non-galamsey' population than among 'galamsey' population. This observation is contrary to that of many research publications which reported higher defaulter rate among mineral miners (Sonnenberg P, Ross M H et al, 1998; Sonnenberg P, Murray J et al, 2001; Mqoqi N, Churchyard GA et al, 1997). Of the 197 'galamsey' registrants, only 11 representing 5.6% were lost to follow up as opposed to the 10.5% of the 313 in the 'non-galamsey' population that were 'lost to follow up'. Illegal miners are frequent migrants and are thought to be more likely to suffer 'lost to follow up' but the trend in the Tarkwa Nsuaem Municipality is different. It seems illegal mineral miners in the Tarkwa Nsuaem Municipality do not really migrate to other areas. They might be rotating at different 'galamsey' sites in the municipality. They may also have been desisting from going into the pit, especially for long days when they are down with TB but engage in other tasks associated with the

‘galamsey’ operations. This attitude may be due to education on TB care in the municipality. It is absolutely important that we are able to assign reasons for the 33 registrants in the ‘nongalamsey’ population who were ‘lost to follow up’. This is especially so because ‘lost to follow up’ breeds resistant strains of TB. What is evident from this study is that TB treatment disruption due to ‘lost to follow up’ in the Tarkwa Nsuaem municipality has no bearing on the occupation but may be more due to emerging circumstances in the individual’s life necessitating a move and the individual’s appreciation or perception of the consequences of treatment disruptions. Probably education on the harmful effect of treatment disruption due to ‘lost to follow up’ has been biased towards ‘galamsey’ operators with minimal attention on those of the ‘non-galamsey’ population. I believe the foregoing of this study calls for equal attention and content of education during pre-treatment and intra-treatment adherence counseling sections with clients of all backgrounds.

5.5 TRENDS OF PRESUMED RESISTANT TB AND TB TREATMENT SUCCESS

The ‘galamsey’ population had 6.6% TB treatment outcome that could lead to the development of TB resistant strains. Of the ‘non-galamsey’ population 10.5% suffered the same outcome. The chi-square analysis for presumed resistant TB for the two populations shows equal chances of susceptible TB resulting in presumed resistant TB. Interestingly the only diagnosed case of multi drug resistant TB in the municipality within the study period did not have a background with ‘galamsey’ activities.

The ‘galamsey’ and ‘non-galamsey’ populations had 90.9% and 86.6% treatment success respectively. The chi-square test disproved the alternative hypothesis that registrants of the general and the ‘galamsey’ populations had the same performance for treatment success (chisquare = 2.135).

It is obvious from this study results that if the municipality could not achieve the millennium development goal: target 6c, 'galamsey' operations in the municipality would not be the special reason.

This study reveals that 'galamsey' activities in the municipality pose no special treat to tuberculosis treatment outcome in the area. It also indicates that the TB treatment regimen used in the country is effective leading to the zero record of relapse and high treatment success rate within the study period of three years, which is consistent with national rate of 81% for 2013 (WHO, 2014).

5.5 TRENDS OF TB MORTALITY

In contrast to the observation by Reid et al (Reid PJ, Sluis-Cremer GK, 1996) that miners have 3.6 greater odds of dying from TB than other workers, this study showed no significant difference in mortality between the two occupational groups. 2.5% of registrants in the 'galamsey' group died while 4.5% of those of the 'non-galamsey' group died. Referring to the high cure rate among TB clients on therapy, points to the evidence that TB death may be due to co-morbidities at presentation or very late reporting for clinical care; much like dying with TB than dying from TB.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

6.1.1 Incidence and Prevalence of TB in the Tarkwa Nsuaem Municipality

Incidence and prevalence of TB in the municipality kept rising progressively from 2011 to 2013. The TB medication was highly efficacious as revealed by the high treatment success rate coupled with zero relapse rate, but the growing trends of TB incidence and prevalence also revealed that the current TB intervention strategy in the municipality is neither adequate for the eradication of the TB disease nor the reversal of its incidence and prevalence.

6.1.2 Performances of patients' end of treatment outcomes

The overall performances at the end of TB treatment did not differ significantly between the two populations. It was observed that both populations did not record any treatment relapse and both had equal chances for presumed resistant TB and TB treatment success.

The 'galamsey' population however, had better outcomes for cure, 'lost to follow up' and death but poorer outcomes for treatment failure and treatment completed in comparison with their counterparts of the 'non-galamsey' population.

6.1.3 Implications of overall study findings on TB care interventions

It is evident from the findings of this study that patients with tuberculosis disease who were involved with illegal mineral mining did not present as a special group in the Tarkwa Nsuaem Municipality. They do not require additional TB care interventions besides the package in general practice.

All existing TB care interventions such as directly observed treatment, TB education, contact tracing and screening, prophylaxis, enablers package, treatment supporter services, pre-treatment counseling and defaulter tracing should be administered equally to all TB patients of both populations.

Evidently, ‘galamsey’ miners in the municipality do not demonstrate the same carelessness and notoriety for health with regards to TB treatment as is generally perceived of them nationwide.

6.2 RECOMMENDATIONS

6.2.1 Interventional studies to halt or reverse TB incidence and prevalence

There is the need to carry out interventional studies designed for our local setting with the goal of discovering the missing factor for the TB care intervention strategy needed to halt and reverse incidence and prevalence of TB in the municipality.

6.2.2 Duplication of study in other mining communities

There are several other mining communities in Ghana that are very similar to the Tarkwa Nsuaem Municipality with regard to their socio-cultural practices and health administration. It will be worth duplicating this study in some of these communities to ascertain if the findings are national trends or peculiar to the Tarkwa Nsuaem Municipality.

6.2.3 Health promotion

There should be active promotion of public education on TB information at all levels of society including media, schools, religious organizations, prisons, market and where ever people gather aimed at prevention of TB.

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APPENDIX (X)

DATA COLLECTION TOOL

A. PATIENT DEMOGRAPHICS

1. CASE REGISTRATION NUMBER.....

2. YEAR OF REGISTRATION: a. 2011 ☐ b. 2012 ☐ c. 2013 ☐

3. MONTH OF REGISTRATION:

Jan ☐ Feb ☐ Mar ☐ April ☐ May ☐ Jun ☐ Jul ☐ Aug ☐ Sept ☐ Oct ☐ Nov
☐ Dec ☐

4. TREATMENT CENTER: TMH ☐ Nsuaem HC ☐ Atuabo HC ☐ Nsuta HC ☐
ABA ☐ Simpa HC ☐

5. AGE OF CLIENT.....

6. GENDER OF CLIENT a. MALE ☐ b. FEMALE ☐

7. OCCUPATION: a. 'GALAMSEY' ☐ b. GENERAL POPULATION ☐

B. DISEASE AND TREATMENT CHARACTERISTICS

8. RESULTS OF SPUTUM MICROSCOPY (AFB)

a. POSITIVE ☐

b. NEGATIVE ☐

9. TYPE OF TB

a. PULMONARY ☐

b. EXTRAPULMONARY ☐

C. TREATMENT OUTCOMES:

10. TREATMENT OUTCOME

a. CURE ☐

b. TREATMENT COMPLETED ☐

c. TREATMENT FAILURE ☐

d. RELAPSE ☐

e. LOSS TO FOLLOW UP ☐

f. DIED ☐

11. TREATMENT CATEGORY

a. NEW CASE ☐

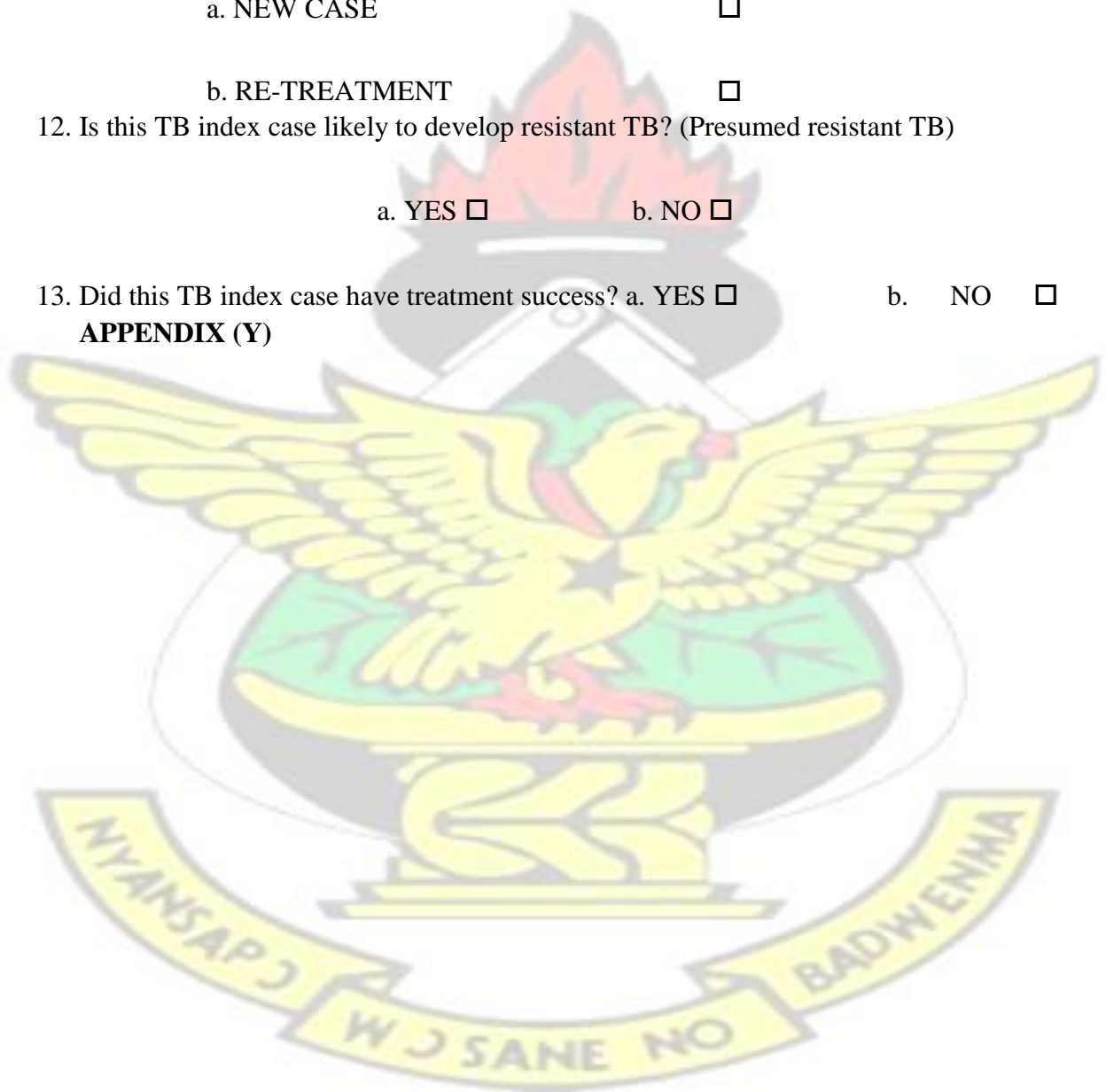
b. RE-TREATMENT ☐

12. Is this TB index case likely to develop resistant TB? (Presumed resistant TB)

a. YES ☐ b. NO ☐

13. Did this TB index case have treatment success? a. YES ☐ b. NO ☐

APPENDIX (Y)





**KWAME NKURUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY
COLLEGE OF HEALTH SCIENCES**



**SCHOOL OF MEDICAL SCIENCES / KOMFO ANOKYE TEACHING HOSPITAL
COMMITTEE ON HUMAN RESEARCH, PUBLICATION AND ETHICS**

Our Ref: CHRPE/AP/368/14

17th November, 2014.

Mr. Ackom Theophilus Kojo
Tarkwa Municipal Hospital
Post Office Box 10
TARKWA.

Dear Sir,

LETTER OF APPROVAL

Protocol Title: "Tuberculosis Treatment Outcomes in the Tarkwa Nsuaem Municipality."

Proposed Site: Tarkwa Nsuaem Municipality – Tuberculosis Treatment Centers.

Sponsor: Principal Investigator.

Your submission to the Committee on Human Research, Publications and Ethics on the above named protocol refers.

The Committee reviewed the following documents:

- A notification letter of 5th September, 2014 from the Principal Investigator seeking permission from the Tarkwa Municipal Hospital (study site) which was approved.
- A Completed CHRPE Application Form.
- Participant Information Leaflet and Consent Form.
- Research Proposal.
- Questionnaire.

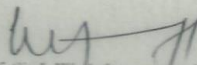
The Committee has considered the ethical merit of your submission and approved the protocol. The approval is for a fixed period of one year, renewable annually thereafter. The Committee may however, suspend or withdraw ethical approval at anytime if your study is found to contravene the approved protocol.

Data gathered for the study should be used for the approved purposes only. Permission should be sought from the Committee if any amendment to the protocol or use, other than submitted, is made of your research data.

The Committee should be notified of the actual start date of the project and would expect a report on your study, annually or at the close of the project, whichever one comes first. It should also be informed of any publication arising from the study.

Thank you Sir, for your application.

Yours faithfully,


Osonifua Prof. Sir J. W. Acheampong MD, FWACP
Chairman