TREATMENT ADHERENCE AND COST EFFECTIVENESS OF UTILISING COMMUNITY HEALTH WORKERS IN THE MANAGEMENT OF TUBERCULOSIS IN KENYA

JANE RAHEDI ONG'ANG'O

DOCTOR OF PHILOSOPHY

(Epidemiology)

JOMO KENYATTA UNIVERSITY OF

AGRICULTURE AND TECHNOLOGY

2016

Treatment adherence and cost effectiveness of utilising Community Health Workers in the management of Tuberculosis in Kenya

Jane Rahedi Ong'ang'o

A thesis submitted in partial fulfillment for the degree of Doctor of Philosophy in Epidemiology in the Jomo Kenyatta University of Agriculture and Technology

2016

DECLARATION

This thesis is my original work and has not been presented for a degree in any other University.

Signature: _____   Date: _____

Jane Rahedi Ong'ang'o

This thesis has been submitted for examination with our approval as University Supervisors:

Signature: _____   Date: _____

Prof Simon Karanja,

JKUAT, Kenya

Signature: _____   Date: _____

Dr Christina Mwachari,

KEMRI, Kenya

DEDICATION

I wish to dedicate this work to my children, Laban, Josephat and Davies for their support and prayers during my studies.

ACKNOWLEDGEMENT

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

LIST OF ABBREVIATIONS AND ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
ART	Anti-retroviral therapy
BOD	Burden of disease
CDC	Centres for Disease Control and Prevention
CHW	Community Health Worker
CHEW	Community Health Extension Worker
CHS	Community Health Strategy
CIA	Central Intelligency Agency
CP	Continuous phase
CPT	Cotrimoxazole prophylaxis therapy
DALY	Disability adjusted life year
DOTS	Directly Observed Therapy, Short Course
EPTB	Extra pulmonary tuberculosis
FGD	Focus group discussion
GDF	Global Drug Facility
GDP	Gross Domestic Product
HIV	Human immunodeficiency virus
HF	Health facility
IDI	In-depth interview
IP	Intensive phase
KEMRI	Kenya Medical Research Institute
LTBI	Latent tuberculosis infection
MDR	Multiple drug resistance
NTP	National Tuberculosis Programme
PSN	Pulmonary smear negative
PSP	Pulmonary smear positive
RH	Rifampicin, Isoniazid
RHE	Rifampicin, Isoniazid, Ethambutol

RHZE	Rifampicin, Isoniazid, Pyrazinamide, Ethambutol
STATA	Statistics and data
SRHZE	Streptomycin, Rifampicin, Isoniazid, Pyrazinamide, Ethambutol
TB	Tuberculosis
VAS	Visual analogue scale
UNITAID	International Drug Purchasing Facility
USA	United States of America
USD	United States of America Dollar
WHO	World Health Organisation
WHO-CHOICE	WHO's Choosing Interventions that are Cost-Effective project
YLD	Years lived with disability

DEFINITION OF OPERATIONAL TERMS

Tuberculosis Patient: a patient with *Mycobacterium tuberculosis* identified from a clinical specimen either by smear microscopy, culture or by molecular diagnostic methods. A case of tuberculosis diagnosed clinically and put on a full course of TB treatment was also considered a tuberculosis patient.

Cured: a TB patient who completed treatment and had a negative bacteriological result at the end of the treatment.

Treatment complete: a TB patient who completed the treatment course but had no bacteriological results.

Defaulter: a TB patient who stopped treatment for more than a week during the intensive phase or more than a month during the continuous phase through defaulting.

Treatment failure: a patient who remained smear positive by the 4th month of the 6 months' regime or by 5th month of the 8-month regime.

Dead: a TB patient who died from any reason during the course of TB treatment.

Transferred out: a TB patient registered for treatment in one district but transferred to another district for treatment.

TB Treatment adherence: patients who were adherent in both treatment phases intensive phase (IP) and continuous phase (CP). Within the IP; a period equivalent to a minimum 42 days to a maximum of 63 days was considered adherent, while in the CP all patients with the following treatment outcomes; cured, treatment complete, died, and failure were adherent.

Non- adherent to TB treatment: patients with treatment duration in the intensive phase of less than the minimum 42 days or more than the maximum days of 63 and/or had treatment outcomes of default or transfer out.

ABSTRACT

Tuberculosis (TB) is a public health concern in Kenya contributing highly to the disease burden of the country. Effective control of TB requires good treatment adherence. In Kenya Community Health Workers (CHWs) have been utilised for TB management since 1998 to provide directly observed treatment at household level. The use of CHWs has had challenges of implementation including the lack of clear supervisory structures, inadequate provision of incentive for the CHWs, uneven coverage and equity of community health services in the country. As a result, this has compromised the sustainability of their utilisation due to high rates of attrition among volunteer CHWs and in addition there seems to be no evidence to show the effectiveness of using CHWs to promote TB treatment adherence. The overall objective of this study was to determine the TB treatment adherence and cost effectiveness of utilising CHWs in the management tuberculosis. The study was carried out in both urban and rural settings within health facilities utilising CHWs and those not utilising for the purpose of comparison. This was an amphi-directional cohort study that retrieved clinical records for each TB patient from health facility TB treatment registers for the years 2005 to 2010 retrospectively and prospectively collected similar data from patients for the year 2011. The study enrolled 2778 TB patients and among them 1499 (54%) utilized CHWs for their TB treatment. Tuberculosis treatment adherence among patients who had utilized CHWs was 83% compared to 68% in those that did not utilize CHWs ($\chi2=76.28$, df=2, p<0.05). Use of CHWs in the urban set up had a significantly higher adherence rate of 90% compared to the rural set up with 73% ($\chi2=76.57$, df=1, p<0.05). Utilisation of CHWs remained a dominant factor on its own in enhancing treatment adherence in the cohort as revealed by the bivariable and multivariable regression odds ratios; OR 2.25, (95% 1.86 – 2.73) p<0.05 and OR 1.98 (95% 1.51 – 2.5) p<0.05 respectively. Utilisation of CHWs was most effective in the urban set-up, OR 2.65 (95% 2.02-3.48, p<0.05) compared to the rural set up, OR 0.74 (95% 0.56 -0.97) p<0.05. The cost effect analysis revealed that the average cost per Disability Adjusted Life Years (DALYs) averted for treatment success was higher (184 USD) in the cohort that utilised CHWs compared to the cohort that did

not utilise CHWs (87 USD). Treatment success rate was significantly higher in the cohort that utilised CHWs; 82.15% compared to 72.25% (p-value <0.05). Utilising CHWs resulted in less DALYs (5688) from death compared to not utilising CHWs (5725). Of the patients who died, a majority died within the first month of their treatment and they were in the cohort that did not utilise CHWs. Utilisation of CHWs in the treatment of TB resulted in better TB treatment adherence compared to no utilisation of CHWs. The urban setting had the best effects on treatment adherence compared to the rural setting. CHWs should be used in the management of TB to enhance treatment adherence and to avert death more so in the early months of TB treatment. Use of CHWs in rural setting requires strategies to improve their mobility and accessibility to patients' homes. Disability Adjusted Life Years (DALY) is an appropriate tool for evaluation of interventions used in the management of TB. It should be adopted for routine use.

CHAPTER ONE

INTRODUCTION

1.1 Utilisation of Community Health Workers

Community Health Workers (CHWs) have been utilised for various primary health care activities in different parts of the world, including Asia (Lariosa, 1991, Newell *et al.*, 2006), United States of America (USA) (Love & Gardner, 1992; Brownstein *et al.*, 2005) and Africa (Menon, 1991; Delacollette *et al.,* 1996; Friedman, 2002; Nyonator *et al.,* 2005). The term "Community Health Worker" encompasses a variety of health assistants who are recruited by respective ministries in-charge of health. Usually they are trained and work with communities in which they live. It is generally felt that engagement of CHWs impacts positively on human health by encouraging increased utilization of health care services and supporting preventive health programmes (Lehmann *et al.*, 2004, Dick *et al.,* 2005).

To ensure the sustainability and effectiveness of CHWs, it has been realised that they require some form of incentive (Okanurak & Ruebush, 1996; Friedman, 2002; Dick *et al.,* 2005). To emphasise this need, the rising incidence of poverty in many sub-Saharan African countries has resulted in the dying spirit of volunteerism because people have to use their time to get an earning. Thus, any engagement that would not contribute some resources to their survival may not be sustainable. When the success by CHWs is minimal, the principal reason is usually failure of the health system to provide them with the necessary support. This is exemplified by what was experienced in the Philippines where there was inadequate training, insufficient logistics support, poorly motivated schemes and lack of community support resulting to below optimal contribution from the CHWs (Lariosa, 1991). With the dramatic increase in the burden of tuberculosis (TB) related to HIV, many countries are utilising community participation in TB control (Maher *et al.,* 1999). Consequently, there has been a growing demand for CHWs to take on the management of other diseases, including malaria (Winch *et al.,* 2005; Kalyango

1

et al., 2012). Utilisation of CHWs has the potential to positively affect the health and treatment behaviour in communities where they live and work. The challenge in utilizing them is, how to determine the best effective way to implement and manage this type of public health intervention (Dick *et al.,* 2005).

1.2 TB Treatment and Directly Observed Therapy, Short Course (DOTS)

Poor adherence to treatment remains a major obstacle in the global fight against TB (Sabaté, 2003). Reasons for non-adherence are complex and multifaceted involving more than the patients' personal characteristics and attitudes (Sumartojo, 1993). Factors, such as the chronic nature of the disease, the socio-cultural context and poverty, and interacting with physicians, nurses, and other health care workers, all affect access to and adherence to treatment (Snider, 1982; Menzies *et al.,* 1993; Daniel *et al.,* 2004; Byakika *et al.,* 2005; Hill *et al.,* 2005; Shargie & Lindtjorn, 2007; Bagchi *et al.,* 2010). In Kenya, the National TB Programme (NTP) provides free TB treatment that consists of a standard 6-month regimen (2 months intensive phase of combined rifampicin, isoniazid, pyrazinamide, and ethambutol (RHZE), followed by 4 months continuation phase of combined isoniazid and rifampicin (RH)) for the new TB cases diagnosed that are sensitive to first line treatment. Retreatment TB cases are treated with a standard 8-month regimen (2 months intensive phase of combined streptomycin, rifampicin, isoniazid, pyrazinamide, and ethambutol (SRHZE), a continuation phase of 1 month (RHZE) followed by 5 months of combined rifampicin, isoniazid and ethambutol (RHE).

Directly observed therapy (DOT) is central to the global strategy for effective TB control launched by the WHO in 1994 and named directly observed therapy, short course [DOTS] (WHO, 1994). In 2002, WHO recommended flexibility in implementing DOTS and promoted "a comprehensive and multifactorial approach." (WHO, 2002a). Qualitative studies have shown that patients who receive the support and care of their families were more likely to adhere to therapy and achieve cure (Macq *et al.,* 2003).

Some newly patient-centred approaches have been tested in observational studies performed in Kenya, Malawi, Uganda and Tanzania which showed that the choice of a DOT supporter by the patient, associated with the decentralization of treatment, improved treatment success rates (Adatu *et al.,* 2003; Kangangi *et al.,* 2003; Nyirenda *et al.,* 2003; Egwaga, *et al.,* 2009). More studies (Menon., 1991; Clarke *et al.,* 2005; Nyonator *et al.,* 2005; Newell *et al.,* 2006; Zvavamwe and Ehlers, 2009) have reported good treatment outcomes when CHWs are involved in TB control.

In Kenya, most TB treatment facilities practice DOT only during clinic days, when drugs are issued weekly during the intensive phase and monthly during the continuous phase. Apart from this, each TB patient is encouraged to have a family supporter in their households to supervise DOTS. Ideally, whenever there is a defaulter of treatment, one ought to be traced by the Public Health Officers in the treatment centres but this has not been effectively done.

1.3 Community Health Workers and TB Treatment, Kenya

In Kenya, the National Tuberculosis Programme (NTP) has within its strategic plan a policy that encourages utilisation of CHWs for DOTS supervision (Division of Leprosy, Tuberculosis & Lung Disease, 2011 -2015). There have been attempts to implement this support in some of the TB treatment setups, but many a times this support ends up being unsustainable. Thus, very few treatment centres still utilise CHWs and those that do, may most probably have support from development partners. The various treatment centres that have continuously utilised CHWs for well over 5 years are more likely to be organised because of the following factors; they have well defined terms of reference describing the duties of the CHWs in the health facilities, the community and within households, there are clear guidelines with regards to the incentives provided to motivate the CHWs. In addition, there is provision of supervisory support, continuing education and logistic support to enable the CHWs work.

Within this whole set up there is a coordinated system that harmonises the operations of the CHWs and the professional health care providers. It is important to understand how effective the use of CHWs in the management of TB is compared to not utilizing them so that the NTP has credible information it could use to decide on engaging CHWs in TB control. This study assessed the treatment adherence of TB patients who utilised CHWs in their management in comparison to those that did not.

1.4 The Cost Effect Analysis of Utilising the CHWs

To measure the effectiveness of utilising the CHWs in TB management, Disability Adjusted Life Years (DALYs) and cost measurements of treatment inputs were used. Disability Adjusted Life Years (DALY) is a common measurement unit for morbidity and mortality. It facilitates comparisons of all types of health outcomes. Disability Adjusted Life Years (DALYs) may be used for quantitative analysis of the burden of disease, to analyse the cost-effectiveness of alternative interventions and to help select a package or list of interventions deliverable within an available budget (Janovsky, 1996).

The Global Burden of Disease study (WHO, 2010) provides a quantitative overview of the burden of disease world-wide, expressed in DALYs. A DALY is a health outcome measure with two main components; Quality of life reduced due to a disability and lifetime lost due to premature mortality (Burden is measured along two dimensions: time lived with disability and time lost due to premature mortality). The effectiveness of utilising the CHWs was measured in terms of cost per DALY averted using the number of tuberculosis cases that were successfully treated being considered as averted. A comparison of mortality using DALY between the cohort that utilised CHWs and that which did not utilise was also used to assess effectiveness.

1.5 Statement of the Problem

TB now ranks alongside HIV as a leading cause of death worldwide. HIV's global death toll in 2014 was estimated at 1.2 million, which included the 0.4 million TB deaths

among HIV positive people (WHO, 2015a). Worldwide, 9.6 million people are estimated to have fallen ill with TB in 2014: 5.4 million men, 3.2 million women and 1.0 million children (WHO, 2015a). Globally, 12% of the 9.6 million new TB cases in 2014 were HIV-positive. The WHO Global TB report, 2015 estimated that there were 1.5 million TB deaths of which approximately 890 000 were men, 480 000 were women and 140 000 were children. The report states that 480 000 cases of multidrug-resistant TB (MDR-TB) occurred in 2014.

The African Region contributed to 28% of the world's TB cases in 2014 and had the highest burden relative to population: 281 cases for every 100,000 people, more than double the global average of 133 (WHO, 2015a). In Sub Saharan Africa TB cases have markedly increased as a consequence of the HIV epidemic (WHO, 2005; WHO, 2007).

TB is a public health concern in Kenya, with a TB/HIV co-infection rate of 38% (National Tuberculosis, Leprosy & Lung Diseases Unit, 2013) and it is ranked as the 4th cause of death (Kenya Health Policy, 2012 - 2030). Kenya notified a total number of 89,760 TB cases in 2013, giving a case notification rate of 217/100,000 population (National Tuberculosis, Leprosy & Lung Disease Unit, 2013). Tuberculosis treatment usually consists of 2 phases: an intensive phase with a combination of four drugs for 2 months and a continuation phase with 2 drugs for 4 to 6 months. Poor compliance and patients defaulting anti TB treatment contribute to the increase of multi-drug-resistant (MDR) TB (Borgdroff *et al.,* 2002) which requires very expensive drugs for treatment. Treatment of MDR may cost more than USD 2,400 (UNITAID, 2015). The MDR patients receive treatment for 20 months and most experience the side effects of the treatment drugs. The disease burden of MDR is worsened by the long duration of treatment and the discomfort of side effects and in addition treatment success rates are much lower compared to drug sensitive TB. Various studies indicate that risk factors for defaulting treatment include: distance from the hospital (Shargie & Lindtjorn, 2007; Katabira *et al.,* 2009), not being on the first course of TB medications (MDR treatment) (Nuwaha, 1999), experiencing drug side effects, having no family support, poor

knowledge about TB treatment, use of public transport (Tekle *et al*., 2002; Shargie & Lindtjorn, 2007).

Disease burden of a condition may also be measured using DALY apart from quantifying the morbidity and mortality caused by the condition. Disability adjusted life-years (DALY) measures the negative health effects by using a numerical value representing both the sum of years-of-life-lost due to premature death and years lived with disability. The Global burden disease study 2010 (WHO, 2010) provides disability weighting of various conditions between values of 0-1, whereby 0 represents best of quality of life with minimal disability and 1 equates to death. Disability weighting of TB disease is provided as 0.3 (WHO, 2010).

In Kenya, the Community Health Strategy (CHS) was rolled out in 2006 by the Ministry of Health with the main agenda of providing a plan to expand community access to health care (Ministry of Health, 2007). The strategy recommends building the capacity of the community health extension workers (CHEWs) and community health workers (CHWs) to provide services at household level. The National TB programme has utilised the CHWs since 1998 to provide directly observed treatment, short course (DOTS), meaning that they follow up TB patients to ensure that they are taking the drugs correctly (community-based DOTs). The CHWs also support case finding by referring those with presumed TB in the community for TB screening. This strategy has had challenges of implementation including the lack of clear supervisory structures, inadequate provision of incentive for the CHWs, uneven coverage and equity of community health services in the country. As a result, this has compromised the sustainability of the strategy due to high rates of attrition among volunteer CHWs and there seems to be no evidence to show the effectiveness of using CHWs to promote community health. To fill the gap in knowledge on the effectiveness of utilising CHWs, this study evaluated the effectiveness and value of utilising CHWs for the management of TB, so as to determine its worthiness.

1.6 Justification

The NTP has a policy on engagement of CHWs in TB control, but there is no clear focus to support its implementation. There have been attempts to utilise CHWs in various health facilities in the country but this has not been sustainable. Reasons for this include, but are not limited to lack of supervision of CHWs, inadequate or inappropriate incentives and poor organisational framework. There is also lack of data to support the effectiveness of CHWs and this may lead to loss of credibility of their roles. It is imperative for the NTP to engage CHWs in TB control in a way that results to favourable treatment outcome for TB patients. Community health workers (CHWs) usually provide social support to TB patients enhancing treatment adherence. The impact of poor TB treatment adherence results in increased burden of TB in the form of treatment failure, drug resistant TB and death. This study assessed the treatment adherence of TB patients who utilised CHWs in their management in comparison to those that did not. A cost effect analysis was undertaken to determine the value of this intervention. Results from this study are expected to inform policy makers on the merits and demerits of utilising CHWs in the treatment of TB.

1.7 Research Questions

1. What is the level of adherence to TB treatment by patients from health facilities that utilise CHWs and facilities not utilising CHWs in an urban and rural setting of Kenya?
2. What are the factors related to TB treatment adherence among patients utilising CHWs and those not utilising CHWs in an urban and rural setting of Kenya?
3. What is the cost- effectiveness of engaging CHWs in the management of TB in an urban and rural setting of Kenya?

1.8. Hypothesis

There is no difference in treatment adherence among TB patients on treatment in health facilities that utilise CHWs for TB management as compared to those that do not.

7

1.9 Study Objectives

1.9.1 General Objectives

To determine Tuberculosis treatment adherence and cost-effectiveness of utilising Community Health Workers in the management of tuberculosis in an urban and rural setting of Kenya.

1.9.2 Specific Objectives

1. To determine the level of adherence to TB treatment by patients from health facilities that utilise CHWs and facilities not utilising CHWs in an urban and rural setting of Kenya.
2. To determine factors associated with TB treatment adherence among patients utilising CHWs and those not utilising CHWs in an urban and rural setting of Kenya.
3. To assess the cost-effectiveness of engaging CHWs in TB management in an urban and rural set up of Kenya.

CHAPTER TWO

LITERATURE REVIEW

2.1 Tuberculosis

2.1.1 Aetiology of Tuberculosis

Tuberculosis is an infectious disease caused by the bacillus *Mycobacterium tuberculosis (M. tuberculosis)*. It typically affects the lungs (pulmonary TB) but can affect other sites as well (extra-pulmonary TB). The disease is spread in the air when people who are sick with pulmonary TB expel the aetiological bacteria, for example by coughing. Overall, 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 HIV. Tuberculosis is more common among men than women, and affects mainly adults in the most economically productive age groups (Division of Leprosy,TB & Lung Disease, MOH, Kenya, 2013; Centers for Disease Control and Prevention, 2016).

2.1.2 Pathogenesis of Tuberculosis

Infection occurs when a person inhales droplet nuclei containing tubercle bacilli that reach the alveoli of the lungs. These tubercle bacilli are ingested by alveolar macrophages; the majority of these bacilli are destroyed or inhibited. A small number may multiply intracellularly and are released when the macrophages die. If alive, these bacilli may spread by way of lymphatic channels or through the bloodstream to more distant tissues and organs, including areas of the body in which TB disease is most likely to develop: regional lymph nodes, apex of the lung, kidneys, brain, and bone (Dheda *et al.,* 2010).

Within 2 to 8 weeks, special immune cells called macrophages ingest and surround the tubercle bacilli. The cells form a barrier shell, called a granuloma, that keeps the bacilli contained and under control, this is known as latent TB infection (LTBI). If the immune

system cannot keep the tubercle bacilli under control, the bacilli begin to multiply rapidly leading to TB disease. This process can occur in different areas in the body, such as the lungs, kidneys, brain, or bone. Persons with LTBI have *M. tuberculosis* in their bodies, but do not have TB disease and cannot spread the infection to other people. People who have TB disease are usually infectious and may spread the bacteria to other people. Anyone who has LTBI can develop TB disease, but some people are at higher risk than others. HIV infection is the highest risk factor for development of TB disease in persons with LTBI owing to weakening of the immune system (Kawabata, 1998; Division of Leprosy, TB & Lung Disease, MOH, Kenya, 2013).

2.1.3 Symptoms and signs of Tuberculosis Disease

Common symptoms of active TB disease may include: a persistent cough that lasts 2 or more weeks, chest pain, constant fatigue, weight loss, loss of appetite, fever, coughing up blood and night sweats. Extrapulmonary TB signs and symptoms vary according to the organs involved. For example, tuberculosis of the spine may present with back pain, and tuberculosis in the kidneys might cause blood in the urine (WHO, 2016).

2.1.4 Diagnosis of Tuberculosis

The most common method for diagnosing TB worldwide is sputum smear microscopy (developed more than 100 years ago), in which bacteria are observed in sputum samples examined under a microscope. Following recent breakthroughs in TB diagnostics, the use of rapid molecular tests to diagnose TB and drug-resistant TB is increasing. In countries with more developed laboratory capacity, cases of TB are also diagnosed using culture methods, the current reference standard (American Thoracic Society, 2000).

2.1.5 The Burden of Tuberculosis

Tuberculosis remains one of the world's deadliest communicable diseases. Worldwide, 9.6 million people are estimated to have fallen ill with TB in 2014: 5.4 million men, 3.2 million women and 1.0 million children (WHO, 2015a). Globally, 12% of the 9.6

million new TB cases in 2014 were HIV-positive. The WHO Global TB report, 2015 estimated that there were 1.5 million TB deaths of which approximately 890 000 were men, 480 000 were women and 140 000 were children. The report states that an estimate of 480 000 cases of multidrug-resistant TB (MDR-TB) occurred in 2014 globally. Tuberculosis is slowly declining each year and it is estimated that 37 million lives were saved between 2000 and 2013 through effective diagnosis and treatment (WHO, 2014). Tuberculosis is present in all regions of the world. In 2013, the African Region had approximately one quarter of the world's cases, and the highest rates of cases and deaths relative to population (280 incident cases per 100 000 on average, more than double the global average of 126), (WHO, 2014). Kenya notified a total number of 89,760 TB cases in 2013, giving a case notification rate of 217/100,000 population (National Tuberculosis, Leprosy & Lung Disease Unit, 2013).

2.2 Treatment of Tuberculosis

Without treatment, TB mortality rates are high. In studies of the natural history of the disease among sputum smear-positive/HIV-negative cases of pulmonary TB, around 70% died within 10 years; among culture-positive (but smear-negative) cases, 20% died within 10 years (Tiemersma *et al*., 2011). Effective drug treatments were first developed in the 1940s. The most effective first-line anti-TB drug, rifampicin, became available in the 1960s. The currently recommended treatment for new cases of drug-susceptible TB is a six-month regimen of four first-line drugs: isoniazid, rifampicin, ethambutol and pyrazinamide. Treatment success rates of 85% or more for new cases are regularly reported to WHO by its Member States. Treatment for multidrug-resistant TB (MDR-TB), defined as resistance to isoniazid and rifampicin (the two most powerful anti-TB drugs) is longer, and requires more expensive and more toxic drugs. For most patients with MDR-TB, the current regimens recommended by WHO last 20 months, and treatment success rates are much lower. Globally, only 50% of the MDR-TB patients in the 2012 cohort of detected cases were successfully treated (WHO, 2015b).

The treatment success rate for new smear positive TB cases in Kenya was 87% in 2013, HIV testing rate of TB patients was 93%, while antiretroviral therapy (ART) and cotrimoxazole prophylaxis treatment (CPT) uptake was 83% and 99% respectively (National Tuberculosis, Leprosy & Lung Disease Unit, 2013). Cotrimoxazole is a fixed-dose combination of two antimicrobial drugs (sulfamethoxazole and trimethoprim) that covers a variety of bacterial, fungal and protozoan infections. Cotrimoxazole prophylaxis treatment (CPT) is a well tolerated and inexpensive intervention for people living with HIV that prevents occurrence of HIV-related morbidity and mortality (WHO, 2014). Standard antiretroviral therapy (ART) consists of the combination of antiretroviral (ARV) drugs that maximally suppress the HIV virus and stop the progression of HIV disease. WHO recommends ART for all people with HIV as soon as possible after diagnosis without any restrictions of CD4 counts or clinical status (WHO, 2013).

2.3 Adherence to Treatment

2.3.1 Definition

Adherence to treatment encompasses numerous health-related behaviours that extend beyond taking prescribed pharmaceuticals. Seeking medical attention, filling prescriptions, taking medication appropriately, obtaining immunizations, attending follow-up appointments, and executing behavioural modifications that address personal hygiene, asthma, diabetes, smoking, contraception, risky sexual behaviours, unhealthy diet and insufficient levels of physical activity are all examples of therapeutic behaviours. The definition of adherence to long-term therapy, as defined by Haynes (1979) and Rand (1993) is the extent to which a person's behaviour of taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider (Haynes, 1979; Rand, 1993).

2.3.2 Factors related to Adherence

Adherence is a multidimensional phenomenon determined by the interplay of five sets of factors, which include patient-related factors, health system related factors, social/economic factors, condition related factors and therapy related factors.

2.3.2.1 Socio-economic Factors

The low socioeconomic status patients may be put in the position of having to choose between competing priorities to being adherent to treatment. Such priorities frequently include demands to direct the limited resources available to meet the needs of other family members, such as children or parents for whom they care. There are factors that have been reported to have a significant effect on adherence including: poverty, illiteracy, low level of education, unemployment, lack of effective social support networks, unstable living conditions, long distance from treatment centre, high cost of transport, high cost of medication, changing environmental situations, culture and lay beliefs about illness and treatment, and family dysfunction (Gordillo *et al.*, 1999; Reynolds *et al.*, 2004; Zivin & Kales, 2008; Taylor et al., 2011).

2.3.2.2 Health System Related Factors

The health care delivery system has the potential to affect patients' adherence behaviour. A good patient-provider relationship is one of the factors most likely to improve adherence within the health system (Rose *et al.,* 2000). Factors with negative effect include; poorly developed health services with inadequate or non-existent reimbursement by health insurance plans, poor medication distribution systems leading to shortage of medicines or commodities required for treatment. Factors related to the health provider that may lead to poor adherence include lack of knowledge on managing chronic diseases, overworked health care providers, lack of incentives or feedback on performance and short consultations. The health system may not have capacity to

educate patients or even support their follow-up for managing various health conditions (DiMatteo & DiNicola, 1982; Meichenbaum & Turk, 1987; Friedman *et al.,* 2008).

2.3.2.3 Condition-Related Factors

Condition-related factors represent particular illness-related demands faced by the patient. This may include the severity of symptoms, the level of disability (physical, psychological, social and vocational), the rate of progression and severity of the disease, and the availability of effective treatments. The effect of these factors may influence patients' perception on the importance of following treatment regimen, and the priority placed on adherence. Co-morbidities, such as depression in diabetes or HIV/AIDS (Ciechanowski *et al.,* 2000), and drug and alcohol abuse, are important modifiers of adherence behaviour (Zivin & Kales, 2008).

2.3.2.4 Therapy-related Factors

There are many therapy-related factors that affect adherence. Most notable are those related to the complexity of the medical regimen, duration of treatment, previous treatment failures, frequent changes in treatment, the immediacy of beneficial effects, side-effects, and the availability of medical support to deal with them (Sabaté, 2003).

2.3.2.5 Patient-related Factors

Patient-related factors represent the knowledge, attitudes, beliefs, perceptions and expectations of the patient. Various authors have reported some of the patient-related factors reported to affect adherence which include: forgetfulness; psychosocial stress; anxieties about possible adverse effects; low motivation; inadequate knowledge and skill in managing the disease symptoms and treatment; lack of self-perceived need for treatment; negative beliefs regarding the efficacy of the treatment; misunderstanding and non-acceptance of the disease; frustration with health care providers; anxiety over the complexity of the drug regimen, and feeling stigmatized by the disease (Gordillo *et al.*,

1999; Horne, 1999; Horne & Weinman, 1999; Miller & Rollnick, 2000; Gupta & Horne, 2001; Horne *et al.,* 2001; Webb *et al.,* 2001; Wessely, 2002; Reynolds *et al.,* 2004; Friedman, *et al.,* 2008; Zivin & Kales, 2008, Petrie & Taylor *et al.,* 2011).

2.3.3 Measurement of Adherence

Definitions and measurements of adherence vary widely; this prevents comparisons being made between studies and populations. Commonly used adherence measures in HIV clinical trials and observational studies are such as patient self-report, pill counts, plasma levels, and electronic monitoring (Miller & Hays, 2000). In terms of TB control, adherence to treatment may be defined as the extent to which the patient's history of therapeutic drug-taking coincides with the prescribed treatment (Urquhart, 1996). Adherence may be measured using either process-oriented or outcome-oriented definitions. Outcome oriented definitions use the end-result of treatment, e.g. cure rate, as an indicator of success. Process oriented indicators make use of intermediate variables such as appointment-keeping or pill counts to measure adherence. At population level the success of treatment, that is, the sum of the patients who are cured and those who have completed treatment under the directly observed therapy, short course (DOTS) strategy, is a pragmatic, though proxy, indicator of treatment adherence (Egwaga *et al.,* 2009).

2.3.4 Impact of Adherence

Studies have reported poor adherence to be common among patients with chronic disease both in the developed and developing countries (Sackett *et al.,* 1978, Haynes, 2001). The impact of poor adherence grows as the burden of chronic diseases grows worldwide as reported in Global burden of Disease Report of 2010 (WHO, 2010). Non-communicable diseases, mental health disorders, HIV/AIDS and tuberculosis, combined represented 54% of the burden of all illness worldwide in 2001 (WHO, 2002b). The global burden of disease report of 1996 reported that these conditions will contribute more than 65% of the global burden of disease in 2020 (Murray & Lopez, 1996).

15

Adherence is a primary determinant of the effectiveness of treatment (Cramer, 1998; WHO, 2002b) because poor adherence attenuates optimum clinical benefit (Sarquis *et al.,*1998; Dunbar-Jacob *et al.,*2000). Good adherence improves the effectiveness of interventions aimed at promoting healthy lifestyles, such as diet modification, increased physical activity, non-smoking and safe sexual behaviour (Green, 1987; Rayman, 1988; Clark, 2001). In communicable chronic conditions such as infection with HIV, good adherence to therapies has been correlated with slower clinical progression of the disease as well as lower virological markers (Gifford *et al.,* 2000; Stein *et al.,* 2000). It has been suggested that good adherence to treatment with antiretroviral agents might have an important impact on public health by breaking the transmission of the virus because of the lower viral load found in highly adherent patients (WHO, 2001). The development of resistance to therapies is another serious public health issue related to poor adherence, among other factors. In the treatment of tuberculosis, poor adherence is recognized as a major cause of treatment failure, relapse and drug resistance (Bell & Yach, 1988; Yach, 1988).

In addition to years of life lost due to premature mortality and health care costs attributable to preventable morbidity, the economic consequences of poor adherence include stimulating the need for ongoing investment in research and development of new compounds to fight new resistant variants of the causative organisms. Some of the published research has suggested that when adherence rates are between 50% and 85%, drug resistance is more likely to develop (Chesney, 2000;Wahl & Nowak., 2000). Unfortunately, a significant proportion of treated patients fall within this range (Markowitz, 2000). The "chronic" investment in research and development could be avoided if adherence rates were higher, and the resources could be better used in the development of more effective and safer drugs, or by being directed to the treatment of neglected conditions.

2.3.5 Solutions

The ability of patients to follow treatments in an optimal manner is frequently compromised by more than one barrier. Interventions to promote adherence require several components to target these barriers. There has been a tendency to focus on uni-dimensional factors (primarily patient related factors). All five dimensions (social and economic factors, health care team and systems-related factors, therapy-related factors, condition-related factors and patient-related factors), should be considered in a systematic exploration of the factors affecting adherence and the interventions aimed at improving it. Adherence interventions are categorized according to the underlying mainstream theories, for example, as either behavioural or educational or a combination of both (San Sebastian & Bothamley, 2000; Tuldra *et al.,* 2000; Walsh *et al.,* 2000; Gibson *et al.,* 2002).

When financial incentives are used to improve adherence, the underlying theoretical perspective is behavioural because incentives are considered to act as positive reinforcers. Other interventions focus on persuasive communication to improve adherence, as such, communication theories underpin these interventions.

2.4 Utilisation of Community health workers

Social support (i.e. informal or formal support received by patients from other members of their community), has been consistently reported as an important factor affecting health outcomes and behaviours (MacLean & Lo, 1997; Kyngas, 2001). It has also been reported to improve adherence to prescribed recommendations for treating chronic conditions (Kyngas & Rissanen, 2001), such as diabetes (Pendley, 2002), hypertension (Stanton, 1987; Fishman, 1995), epilepsy (Kyngas, 2000; Kyngas *et al.*, 2000), asthma (Kyngas, 1999) and HIV/AIDS (Catz *et al.*, 2000; Roberts, 2000; Weishut, 1996, Demas *et al.,* 2002; Spire *et al.,* 2002). This social support also promotes some preventive interventions such as breast cancer screening (Katapodi *et al.,* 2002) and follow-up for abnormal pap smears (Crane, 1996; Abercrombie, 2001). So far, social support has not

been shown to affect adherence to smoking cessation therapies (DiIorio *et al.* 1991; Orleans *et al.,* 1991; Owen & Brown, 1991). Good examples of successfully implemented community-based programmes are the medication groups (Guimon, 1995) and the peer/community support groups. The objectives of these programmes were: to promote the exchange of experiences of dealing with a disease and its treatment; to provide comprehensive medical information; and to promote patients' responsibility for their own care.

There is substantial evidence that peer support among patients can improve adherence to therapy (Weishut, 1996; Getahun & Maher, 2000; Broadhead *et al.,* 2002; Magura *et al*., 2002), while reducing the amount of time devoted by health professionals to the care of patients with chronic conditions (Lilja, 1984; Boza *et al.,* 1987; Kulcar, 1991). Many other community interventions have also been shown to result in economic and health benefits by improving patients' self-management capacities (Bermejo & Bekui, 1993; Freudenberg, 1995; Koch *et al.,* 2002) by integrating the interventions with the formal provision of care (Akbar & Al Gamdi, 2000; Gray *et al.,* 2000; Steffens, 2000; Davies M *et al.*, 2001).

2.5 Disability Adjusted Life Years (DALYs)

2.5.1 Definition and Use

Disability Adjusted Life Years (DALYs), is a common measurement unit for morbidity and mortality (Lopez *et al.,* 2006). It is a health gap measure that extends the concept of potential years of life lost due to premature death and also includes equivalent years of healthy life lost by virtue of individuals being in states of poor health or disability (Murray, 1996). One DALY can be thought of as one lost year of healthy life and the burden of disease as a measure of the gap between current health status and an ideal situation where everyone lives into old age free from disease and disability (WHO, 2009). Another description of DALY is that it is a health outcome measure with two main components; Quality of life reduced due to a disability and lifetime lost due to

premature mortality (Burden is measured along two dimensions: time lived with disability and time lost due to premature mortality).

In the DALY, a disability weighted zero indicates perfect health (no disability), and weighted 1 indicates death. Severity weights have been appointed for each disabling condition on a scale from one to zero (Stibich, 2009). The disability severity weight for each disease reflects the average degree of disability a person suffers with each condition. Panels of healthy experts with knowledge about disease conditions have determined the weights. The severity weight is then multiplied by the average time a person is suffering from the disability from each disease (Lindstrand *et al.,* 2006). A measure of years lived in health states less than ideal health is known as "years lived with disability" (YLD).

The DALY facilitates comparisons of all types of health outcomes. DALYs may be used for quantitative analysis of the burden of disease, to analyse the cost-effectiveness of alternative interventions and to help select a package or list of interventions deliverable within an available budget (Janovsky, 1996). It is the primary metric used by the World Health Organization to assess the global burden of disease, and the primary metric used by projects such as the `Disease Control Priorities in Developing Countries' report (Jamison *et al.,* 2006) to quantify the cost-effectiveness of different programs.

The DALY measure was created with intentions of determining the "burden of disease," (BOD) with four key goals, which will help in decisions regarding allocation of resources. It helps to determine health service priorities, assists in establishing primary research concerns, identifies groups in need and offers a common measure of output for interventions (Murray, 1994).

2.5.2 Limitations of DALY

The DALY metric is used to provide a single number to capture all of the health costs caused by a disease (or averted by an aid program). One DALY could represent 1 year

of life lost (due to early death), 1.67 years spent with blindness, 5.24 significant malaria episodes, 41.67 years spent with intestinal obstruction due to ascariasis (an intestinal parasite), or many possible combinations of these and other symptoms (Lopez *et al.*, 2006). There is no way of knowing, from just how many DALYs a program is said to have averted, whether it has saved lives, prevented large numbers of minor health problems, or some combination thereof. This creates a number of problems for donors seeking the charity that best fits their values.

Critics have questioned whether quality of life can be measured in a single and precise number and whether the same health problems have equal impact on different persons or groups. There is no general agreement on the concept of quality of life and how to measure it. Different people as well as different cultures have very different opinions of the main elements of a good life.

While the DALY does take into account many factors necessary for evaluating the "burden of disease," some also argue that it is flawed on a theoretical and technical basis. The DALY does not differentiate between the acts of measuring the burden of disease and the allocation of resources. Additional information could be added to the calculation, such as the amount of support the person is receiving from family and public services, or their financial status. Also, there is a discrepancy between the choice of variables that should be used depending on what is being measured. For example, a person's pre-existing disability separate from the disease would not necessarily guarantee them higher priority for public assistance. (Anand *et al.,* 1997).

2.5.3 Cost-Effect Analysis

Cost-effect analysis is a necessary tool to ensure that resources are being used as wisely as possible. Determining which interventions are the most cost-effective requires an understanding of which programs have worked, how much they cost, and how they were executed. Economic evaluations of health interventions have created a wider knowledge for evaluating the costs and benefits of interventions to enable better use of financial

resources (Jamison & Breman, 2006). The basic concept of the calculation is simple: divide the monetary cost of the intervention by the expected health gain. Cost-effective analysis provides a way to consider the gains of an intervention versus the costs and risks, straightforwardly comparing the economic and scientific consequences of any given program.

Cost-effective analysis can be used to compare different interventions for the same disease or compare different interventions for a certain demographic sector. The cost-effectiveness calculation is particularly useful when relating different interventions that are focusing on the same disease or goal. However, it is also advantageous when looking at interventions that address differing diseases and risk factors. When resources are limited, it is critical that they are used in the most cost-effective interventions possible. Jamison *et al* (2006) gave an example of a cost effect scenario; `*imagine that you have one million dollars and two options on how to spend it: you can either invest the money to increase Hib vaccinations for children and save 10 – 800 lives, or invest the same amount to increase measles vaccinations for children and save 800 – 66,000 lives'.* From this scenario he concluded that the cost-effective analysis highlighted that the second option is the best allocation of resources: if the number of lives saved is the measure of health gain in the analysis calculation, then the best intervention is the one that averts the most deaths (Jamison & Breman, 2006).

Information about cost-effectiveness of past interventions may be used by countries to make decisions on the best value program for the financial resources available for health (World Health Organization. Mental Health Evidence, Research Team, & Disease Control Priorities Project. 2006).

Similarly, as DALY calculation have limitations, cost effect analysis also has drawbacks. Organizations often differ in their ways of performing the calculation. Some studies place the same value on every life regardless of age (i.e. an infant and a middle-aged adult are weighted equally), whereas other studies take into account how many

21

years an individual has left to live (i.e. stopping infant diarrhea is considered largely more successful than rescuing someone older from stroke). Prices also greatly influence cost estimates, which can differ substantially even within a single country. Analysis also depends on the scope of the costs (narrow versus broad definition of "cost"), and additional costs that the researcher has selected to take into account, such as dedication of time and transportation value. Differences in choices of these measurement units significantly impact the interpretation of the analyzed information. (Jamison *et.al.,* 2006). Despite this, cost-effective analysis is an extremely useful tool for comparing interventions and ensuring limitations and flaws can arise, it is important to carefully review all of the factors that were included in the calculation and to consider other possibly influential factors.

CHAPTER THREE

MATERIALS AND METHODS

3.1 Study Area

The current study was undertaken in 2 sub-locations namely Kawangware and Ahero. Kawangware sub-location found in Dagoretti North constituency of Nairobi County represented the urban site for this study. This sub-location is about 15 km west of the city centre of Nairobi. It is between Lavington Estate and Dagoretti. It has a population of 33,707 with an area of 1.20 km^2 (Softkenya, 2013). Ahero sub-location of Nyando Constituency in Kisumu County represented the rural site for the study. It has a population of 31,440 with an area of 39.80 km^2 (Softkenya, 2013).

3.2 Study Design

This was a amphi-directional cohort study which followed up TB patients prospectively and retrospectively. The prospective and retrospective components of the study were used to complement each other. The prospective study ensuring minimum missing of data that would more likely occur in the retrospective study. To enable registration of a large number of TB patients over a spread of time the retrospective study was best suited than the prospective study. Qualitative data was collected from focus group discussions (FGDs), conducted among CHWs to gather views on utilization of CHWs. In-depth interviews were also conducted among health care providers who were directly involved in the supervision of CHWs.

3.3 Study setting

The study was carried out in an urban and rural setting. In these settings, two similar TB treatment health facilities were purposively selected: one engaging CHWs for TB management and the other not. One informal settlement in Nairobi, namely, Kawangware sub-location of Dagoretti North Constituency of Nairobi County

represented the urban set-up, while the rural set-up was in Nyando Constituency of Kisumu County.

Within Kawangware, Riruta Health Centre was enlisted as a facility that had been utilising CHWs from the year 2003 with the support of Malteser, a development partner supporting the Ministry of Health. The support provided to the CHWs included training, supervision, continuous education, monthly meetings and incentives. Another similar facility that had never utilized CHWs was Wema Maternity and Nursing Home found within the same locality as shown in Figure 3.1 was also enlisted. These represented the urban setting.

In the rural setting, Nyando District Hospital was enlisted as the facility that had utilised CHWs from the year 2005 through the support of CDC/KEMRI who provided training, supervision, and incentive to the CHWs, while Nyabondo Mission hospital that had never utilized CHWs was included in the study as the facility for comparison. Both these facilities were found in the same location as indicated in Figure 3.1 (Nyando Constituency, Kisumu County). All these facilities were receiving support from the NTP for TB control. The study collected the records of all TB patients registered in the facility's TB treatment registers and Figure 3.2 describes the distribution of the TB patients enrolled in the study by location and health facility.
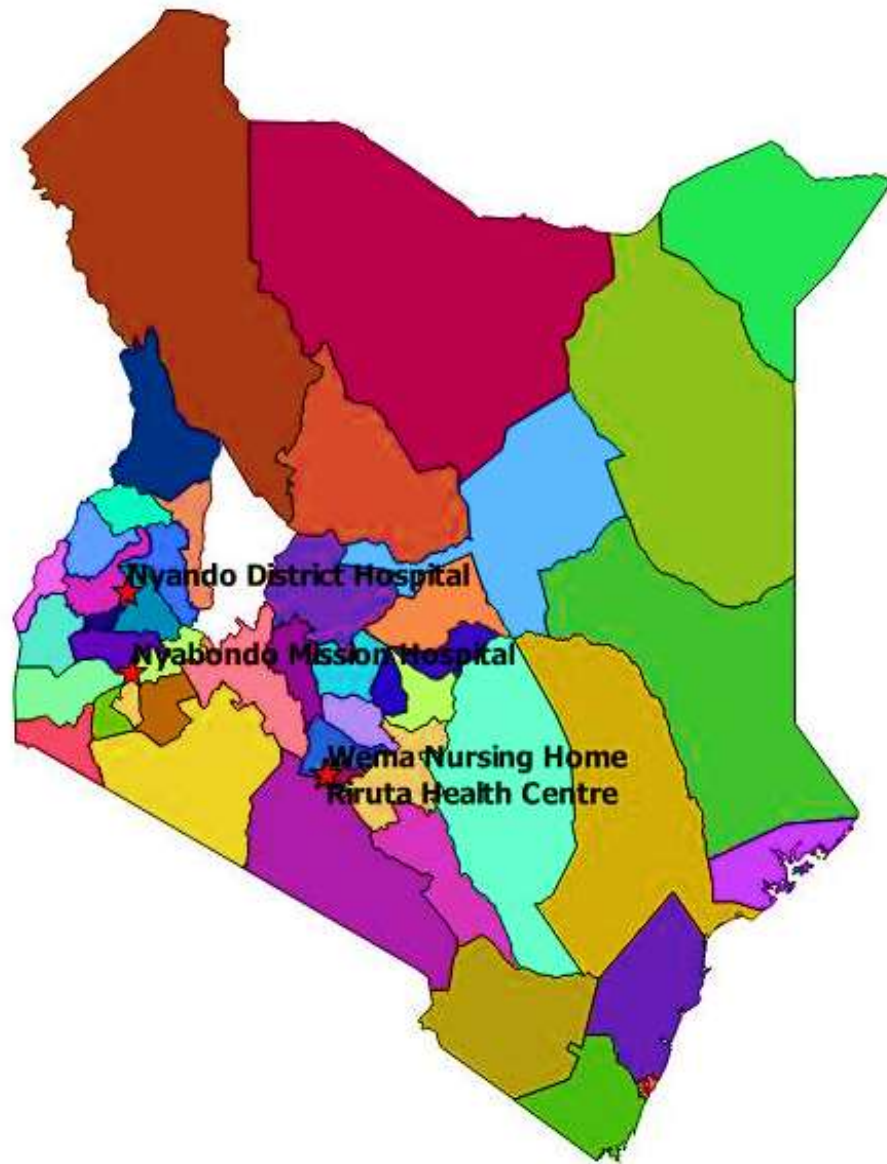
Figure 3.1: **Map of Kenya with the study sites**

```
┌─────────────────────────────────────────────────────────┐
│   NATIONAL TB PROGRAM DATABASE OF 400 HEALTH FACILITIES: │
│        RURAL (Western Kenya) and URBAN (Nairobi)         │
└─────────────────────────────────────────────────────────┘
```

```
┌─────────────────────────────────────────────────┐
│ 1. Public Health facilities supported by the     │
│    Government to provide TB treatment.           │
│                                                   │
│ 2. Facilities utilising CHWs, at least 5 years of │
│ utilization with continuous support of           │
│ implementing partner (training, supervision,     │
│ continuous education, monthly meetings, and      │
│ incentives.                                       │
│                                                   │
│ 3. Annual TB case load urban (350, rural (250)   │
│                                                   │
│ 4. Patients registered to receive treatment at   │
│    the Health Facilities.                         │
└─────────────────────────────────────────────────┘
```

```
┌──────────────────────┐        ┌──────────────────────┐
│ URBAN HEALTH         │        │ RURAL HEALTH         │
│ FACILITIES (HF)      │        │ FACILITIES (HF)      │
└──────────────────────┘        └──────────────────────┘
```

```
┌──────────────┐ ┌──────────────┐  ┌──────────────┐ ┌──────────────┐
│ HF UTILIZING │ │ HF NOT       │  │ HF UTILIZING │ │ HF NOT       │
│ CHWs         │ │ UTILIZING    │  │ CHWs         │ │ UTILIZING    │
│ n = 1051     │ │ CHWs         │  │ n = 465      │ │ CHWs         │
│              │ │ n = 497      │  │              │ │ n = 787      │
└──────────────┘ └──────────────┘  └──────────────┘ └──────────────┘
```

```
┌─────────────────────────────────────────────────┐
│         TOTAL TB PATIENTS n = 2800               │
└─────────────────────────────────────────────────┘
```

```
                              ┌──────────────────────┐
                              │ 22 Patients not      │
                              │ analysed because of  │
                              │ missing data         │
                              └──────────────────────┘
```

```
┌─────────────────────────────────────────────────┐
│         TB PATIENTS ANALYSED n = 2778            │
└─────────────────────────────────────────────────┘
```

Figure 3.2:   Study Participants Registered in the Study from the Urban and Rural Health Facilities

3.4 Study Population

The study enrolled TB patients who were registered to receive treatment at the health facilities between 2005 -2011.

3.4.1 Criteria for inclusion of study subjects

In the prospective study;

- Newly diagnosed TB patients aged 18 years and above.
- Patients on enrollment into the study had to be commencing TB treatment.
- Patients had to be registered to receive TB treatment at the health facilities.
- Patients had to be residents in the locality of the health facilities.
- In the facilities utilising CHWs, the patients had to agree to be supervised by a CHW.
- Patient had to provide informed consent voluntarily.

In the retrospective study;

- All diagnosed TB patients who were registered in the TB treatment facility registers between the years 2005 -2011 were included in the study.

3.4.2 Criteria for exclusion of subjects

In the prospective study;

- TB patients aged below 18 years
- Failure of an eligible TB patient to consent to participate.
- TB patients not registered to receive treatment in the health facility.
- TB patients not resident in the locality of the health facility
- TB patients with on-going TB treatment
- TB patients who declined to receive treatment supervision from CHWs

In the retrospective study;

- All TB patients not registered in the health facility's treatment registers between 2005 -2011 were excluded.

3.5 Sample Size Calculation

The prospective study applied the following formula for sample size calculation for the two populations (Statistics Canada, 2010);

$$n = \frac{(K+1) \{P_1 (1- P_1) + P_2 (1- P_2)\}^2}{(K) \{(P_1 - P_2)^2\}} \times (Z_{\alpha/2} + Z_{\beta})^2$$

n = Minimum sample size

K = Number of groups

P_1 = Defaulter rate in group 1

P_2 = Defaulter rate in group 2

$Z_{\alpha/2}$ = corresponding value at the 95% confidence interval (1.96)

Z_{β} = power of the test (80%)

Considering that default rates were 1% and 20% in the 2 selected urban health facilities, using the above formula, each group required a minimum of 261 TB patients. A design effect factor of 1.2 was applied to compensate for any non-response or missing data of the respondents considering the follow-up nature of the study. The design effect factor also cushioned any effects that would result from the cluster design of the study. The required minimum sample size was 313 for each urban facility. Applying the same formula to the two rural health facilities that had default rates of 1% and 11%; the minimum sample size was 174 and on applying the same design effect, 209 was

considered the minimum sample size for each rural facility. The retrospective study retrieved all records of registered TB patients from the TB treatment facility registers.

3.6 Sampling Design

The prospective study used consecutive sampling until the sample size was attained. This sampling method was used because of the low number of TB cases notified annually in the facilities selected. The urban health facilities in Kawangware had 350 TB patients registered for treatment in 2009 (National Tuberculosis & Leprosy, Programme, 2009), while the rural health facilities in Nyando registered 250 TB patients for the year 2009 (National Tuberculosis & Leprosy, Programme, 2009). The retrospective study used the census method to include all TB patients registered into the study.

3.7 The Study Intervention

The intervention tested in this study was the utilization of CHWs in the management of TB. The utilization of CHWs entailed the following; once a TB patient was registered to start treatment, they were attached to a trained CHW who preferably resided within the same area as the patient. Before initiation of treatment, the TB patient received personalised education from the CHW on TB treatment; risks involved in case of lack of adherence, follow-up schedule and the role of the CHW in his/her treatment. During the intensive phase of treatment, the CHW supervised DOTS at the household level once a week and in the continuous phase, once a month. The TB patients were scheduled to attend follow-up at the health facility weekly during the first 2 months of treatment and monthly in the next 6 months. During follow-up appointment day, each patient received health education from the CHW, received their TB medication and were reviewed clinically by the nurse in charge of TB at the facility. The CHWs and the nurses in charge would meet monthly to review their activities and to refresh their knowledge regarding TB. In the facilities that did not utilise CHWs, TB patients commencing treatment were advised on treatment schedule, treatment adherence and need for family

support by the nurse at the facility. Unlike in the comparison group, these patients did not receive any additional support from a CHW.

3.8 Data Collection

Trained research assistants retrieved clinical records for each of the TB patients from the facility's TB treatment registers. The data collected covered a time period between the years 2005 to 2011. For the years 2005-2010 the data was collected retrospectively, while for the year 2011 data was collected prospectively. A pre-tested data collection tool was used for the prospective study (Appendix 2). The tool gathered information from the patient and also retrieved information from the TB facility treatment registers as the patients were followed while on treatment. The retrospective study retrieved data directly from the TB treatment facility registers and filled in a data sheet that had a record of each patient enrolled (Appendix 3).

Focus group discussions (FGDs), were conducted to explore CHWs' views on the utilization of CHWs. The FGDs were held in venues that were conducive for the process so as to gather all the information from the discussions accurately through digital audio recorders. On average each FGD took a duration of about 1 hour and they were facilitated by a moderator and a secretary to document the proceedings. Two (urban and rural) FGDs for CHWs were held with selected CHWs working at the 2 facilities using the FGD guide (Appendix 5). In-depth interviews were held among 2 health care providers who were directly involved in the supervision of CHWs. In-depth interview guides (Appendix 6) were used to conduct this process.

Costs incurred by CHWs involved in TB management were accessed from the development partners involved in supporting the intervention and also through the FGDs among the CHWs. This included the cost of training the CHWs annually and the total yearly cost of incentives provided. The cost of treating drug sensitive TB was derived from the WHO, Global drug facility product pricing list. The disability weighting of TB (0.3) as provided by the Global burden disease study 2010 (WHO, 2010) was utilised to

30

calculate DALYs. These costings and DALYs were used to analyse the cost effectiveness of utilising CHWs for TB management.

3.9 Variables

The primary outcome variable was TB Treatment adherence which was defined as; patients who were adherent in both treatment phases Intensive Phase (IP) and Continuous Phase (CP). Within the IP; a period equivalent to a minimum 42 days to a maximum of 63 days was considered adherent, while in the CP all patients with the following treatment outcomes; cured, treatment complete, died, and failure were adherent. Patients with outcomes of default and transfer out were non-adherent. The main exposure was utilization of CHWs. Other covariates that were used in this study included, demographics, type of TB defined by diagnosis in the form of pulmonary smear positive (PSP), pulmonary smear negative (PSN) and extrapulmonary TB (EPTB). The rest of the variables were new versus retreatment patients, acceptance of HIV screening, urban versus rural location. Variables for calculating DALY and cost effectiveness analysis included; disability weighting of TB, duration of TB treatment, cost of treating drug sensitive TB, cost of training CHWs, total cost of incentive for CHWs yearly, number of CHWs utilised in the facilities, number of TB patients who were successfully treated and the number of TB patients that died.

3.10 Data Analysis

Statistics and data (STATA) analytic software version 12, (StataCorp. 2011. *Stata Statistical Software: Release 12*. College Station, TX: StataCorp LP.) was used for statistical analysis. Descriptive statistics were used to describe the data. Subjects were classified either as having utilized CHWs or not. These 2 groups were further grouped into adherent or non-adherent based on the study criteria. Statistical significance was considered with p-values < 0.05. The differences between two categorical variables were tested using chi square test. Factors significantly associated with adherence were included in the logistic regression model and the odds ratio (OR) and confidence interval

(95%) was used to determine positive or negative association. Logistic regression procedures were used to adjust for multiple risk factors. The qualitative data was typed into scripts and the information extracted from them was themed and interpreted by guided words, context, internal consistency, frequency and extensiveness of comments, specificity of comments and any important ideas.

3.11 The application of DALY and Cost Effect Analysis in this study

The effectiveness of utilising the CHWs was measured in terms of cost per DALY averted using the number of tuberculosis cases that were successfully treated being considered as averted. In addition, a comparison of mortality of TB patients in the 2 groups was also compared using DALY.

To calculate the cost per DALY averted by successfully treating these patients, the following assumptions were made; that the professional health care provided to these patients was equal in the 2 comparison groups, the only difference being the additional care provided by the CHWs in the intervention group so that this would be an additional cost to be included in the calculation. The additional cost of utilising the CHWs mainly considered the main expenditure that sustains the CHW work which includes; incentive that CHWs receive on a monthly basis (USD 27 per month for each CHW), 3-day training received once per year at a cost of USD 247 per training for each CHW and also the number of CHWs that were utilised in the facilities yearly which was always about 5 for each facility throughout the year. The cost of treating these patients with first line TB regimen for new and retreatment TB patients was also considered. Based on the price list of the Global Drug Facility (GDF) a six-month course of treatment for a newly diagnosed TB patient is approximately USD 30, while an eight-month course of treatment for a retreatment patient is estimated to be USD 50 (Stop TB Partnership, 2014). Infrastructure factors and other logistics were not considered in the calculations.

The calculation of DALY considered the disability weighting of TB (0.3) as provided by the Global burden of disease report of 2010 (WHO, 2010) and time duration (in years)

of treatment of TB which was 6 months for the new TB patients and 8 months for the retreatment TB patients. The total DALYs resulting from TB deaths were calculated using the following recommended formula (Lopez *et al.,* 2006).

(Life expectancy years − Age of person at death) x the weighting of Death [1].

Kenya's 2012 life expectancy at birth of 63 years (CIA, 2013) was used with the disability weighting of death at 1 (WHO, 2010).

3.12 Ethics Statement

The study was approved by the scientific and ethical review committees of KEMRI before implementation. Verbal consent from participants was requested for, before any discussions were initiated for the FGDs and IDIs, while written consent was obtained from the TB patients in the prospective arm.

Efforts were made to maintain confidentiality so that risks of disclosing the information provided by study participants were fully minimized. All data collected was handled confidentially and no names were included in reports or publications. The data was stored in computers while passwords and hard copies were kept in lockable cabinets that had authorised access to the investigators only. Participants were informed that their contribution to the study would help in the understanding and interpretation of issues that would improve the management of TB. All participants received the standard TB treatment with either the support of CHW or without the support of the CHW. Participation was voluntary and study participants had a right to withdraw from the study at any time without any penalty and if so they would still receive their complete TB treatment. In case of any illness other than TB detected on any study participant, appropriate referral for care was provided.

CHAPTER FOUR

RESULTS

4.1 Data Quality

A total of 2,800 TB patient records were collected. The retrospective study collected data from year 2005 to 2009 contributing 2503 (89%) records while the rest 297 was from the prospective study. Twenty-two (22) records of the TB patients from the retrospective study had missing data on follow-up dates and treatment outcomes so that their TB treatment adherence status could not be defined. These TB patients were excluded from the analysis. The prospective study TB patient records were more complete compared to the retrospective ones. Completeness of data between the 2 arms was comparable as shown in Table 4.1. The main differences were noted in the recording of physical measurements of body weight and height with the retrospective study documenting only 2.6% and 0.1% of these variables respectively among the study participants.

Table 4.1:   Comparison of Completeness of Data between the Prospective and Retrospective type of Study

Variable Description	Prospective Study n= 297*	Retrospective Study n=2503*
Age	295 (99)	2492 (99)
Gender	297 (100)	2502 (100)
Body Weight	297 (100)	66 (2.6)
Height	94 (32)	5 (0.1)
Sputum smear examination results on start of treatment	258 (87)	1648 (66)
Chest X-ray done	297 (100)	2503 (100)
Date treatment started	297 (100)	2481 (99)
Disease Classification	295 (99)	2498 (99)
Patient Classification	297 (100)	2500 (100)
Referred for TB screening	262 (88)	1967 (79)
Accepted HIV Screening	297 (100)	2503 (100)
HIV test Results	273 (91)	1628 (65)
Treatment outcomes	296 (100)	2391 (96)
Date of Treatment outcomes	296 (100)	1479 (59)

*All data are frequency (%)

35

4.2 Demographic characteristics of the TB patients

There was more male participation in the urban set up of the study. This was most noted in the urban prospective study with the males from the urban set up contributing 45% of participation compared to the females who contributed 23% in the same set up (Figure 4.1). In the rural set up the females tended to be more likely to participate as demonstrated in the rural prospective study with 20% participation compared to 12% from the males (Figure 4.1).
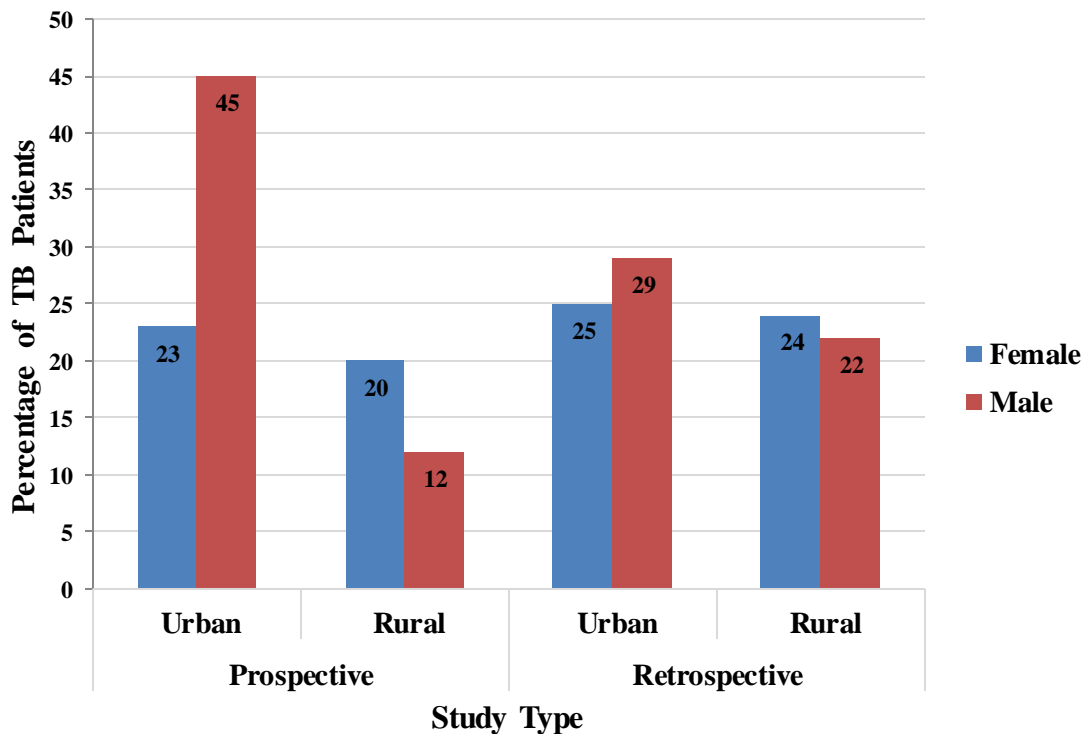
Figure 4. 1: Proportion of males and females enrolled in the study with regard to location and study type

Pulmonary smear positive (PSP) TB patients made up the largest proportion of type of TB disease with rural set up having 30% and the urban 14%, totalling to 44% among all types of TB disease (Figure 4.2). Extrapulmonary TB (EPTB) was the least with urban set up contributing 20%, while rural 4% totalling to 24% (Figure 4.2).
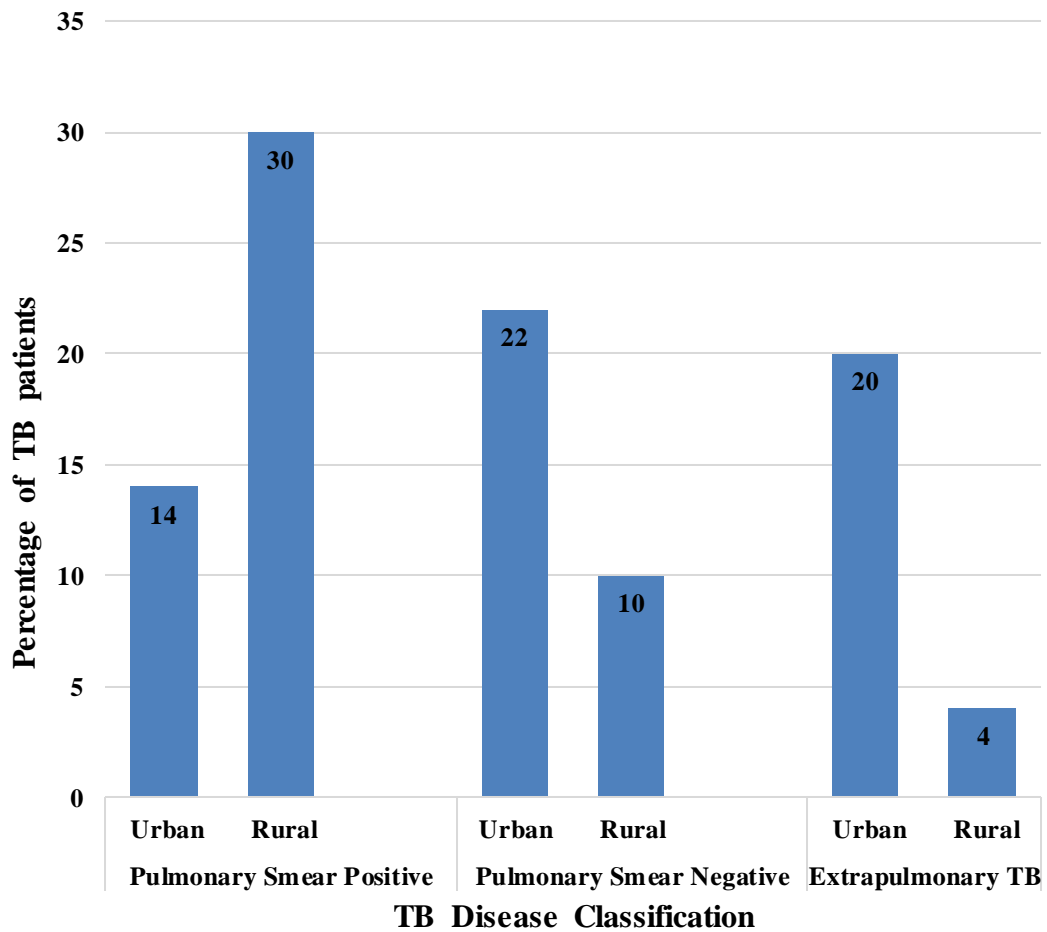
Figure 4. 2: Proportion of TB patients and their disease classification by location

A majority (46% urban and 37% rural) of the TB patients were new TB patients having the disease for the first time (Figure 4.3).
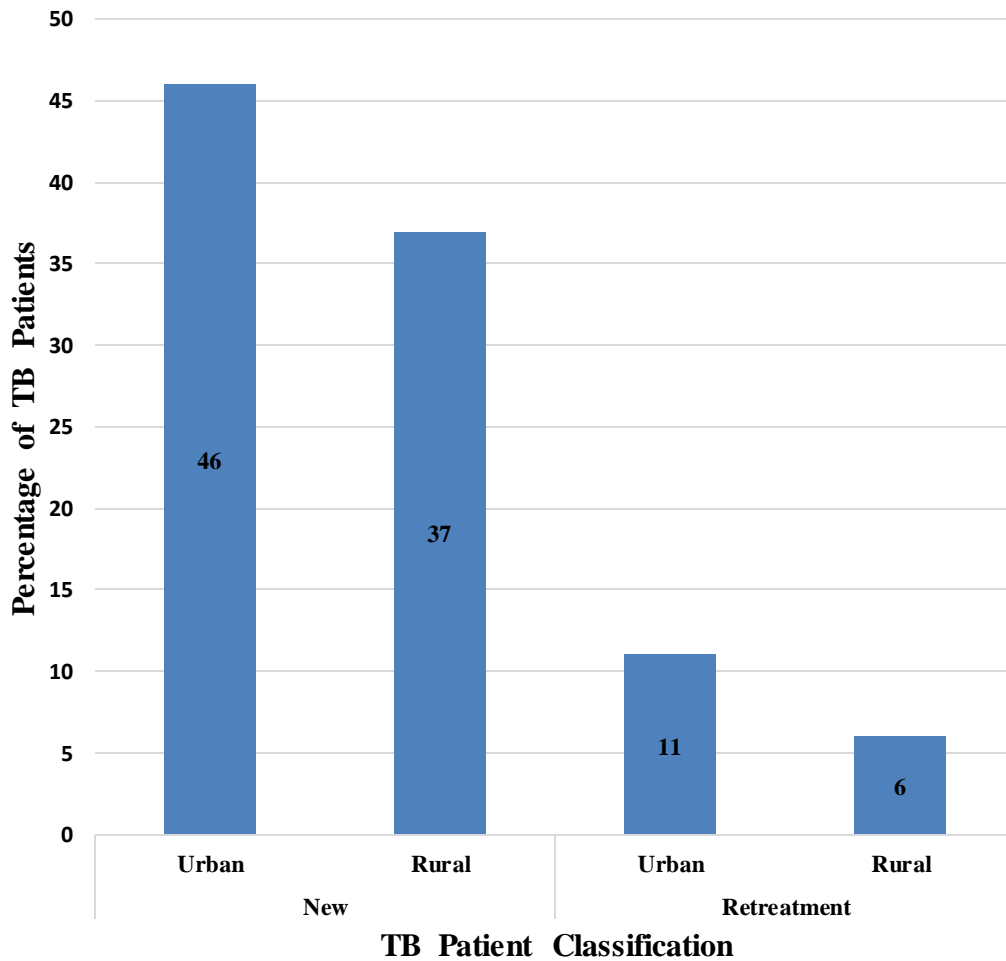
Figure 4. 3:   Distribution of new and retreatment type of TB patients by location

4.3 Characteristics of study participants in relation to utilisation of CHWs

The study enrolled 2778 TB patients and among them 1499 (54%) utilized CHWs for their TB treatment. The proportion of males and females was comparable in both the groups that utilized CHWs and that which did not (Table 4.2). Age group distribution was similar in the 2 groups with mean age and standard deviations falling within the same range. The urban setting in comparison with the rural setting contributed significantly to a higher proportion (70%) of patients utilising the CHWs ($\chi2=277.2324$, df =1, p<0.05). There was also a significantly higher proportion of pulmonary smear negative (PSN) patients (56%) utilizing CHWs for their treatment compared to pulmonary smear positive (PSP) 19% ($\chi2=1100$, df =3, P<0.05). A majority of the patients in this cohort were new TB patients (Table 4.2).

The overall treatment adherence of the cohort as a whole was 79%, on categorizing by use of CHWs, adherence among patients who had utilized CHWs was 83% compared to 68% among those that did not utilize CHWs ($\chi2=76.28$, df =2, p<0.05) (Table 4.2). A comparison between rural and urban set up revealed that adherence was 76% and 81.5% (p <0.05) respectively and when categorized by use of CHWs it was 73% and 90% ($\chi2=76.57$, df =1, p<0.05) for the rural and urban set ups respectively.

Table 4.2: **Characteristics of Study Participants Stratified by use of CHWs**

	CHWs used n= 1499*	CHWs not used n=1279*	$\chi 2$, df, p- value
Age	29.88 (mean) SD 13.39	32.73 (mean) SD 14.24	$\chi 2 = 46.8794$, df =7,p <0.05
Gender			
Male	790 (52.70)	660 (51.60)	$\chi 2=0.3341$, df=1,p= 0.563
Female	709 (47.30)	619 (48.40)	
Disease Classification			
Pulmonary Smear Positive (PSP)	287 (19.15)	936 (73.18)	$\chi 2=1.1e^{+03}$, df=3,p <0.05
Pulmonary Smear Negative (PSN)	839 (56.0)	40 (3.13)	
Extra Pulmonary TB (EPTB)	371 (24.75)	299 (23.38)	
Missing	2 (0.13)	4 (0.31)	
Patient Classification			
New	1128 (75.25)	1106 (86.47)	$\chi 2 =96.8520$, df=2,p <0.05
Retreatment	329 (21.95)	110 (8.60)	
Missing	42 (2.80)	63 (4.93)	
Accepted HIV Screening			
No	87 (5.80)	287 (22.44)	$\chi 2=163.9351$, df=1,p<0.05
Yes	1412 (94.20)	992 (77.56)	
Location			
Rural	448 (29.89)	785 (61.38)	$\chi 2=277.2324$, df=1,p <0.05
Urban	1051 (70.11)	494 (38.62)	
Adherence to treatment			
No	215(14.34)	343 (26.82)	$\chi 2=76.28$, df=2,p <0.05
Yes	1237 (82.52)	875 (68.41)	
Missing	47 (3.14)	61 (4.77)	

All data are frequency (%)

CHW, community health worker, SD Standard Deviation

Tuberculosis patients from the urban set up made up the highest proportion (38%) of patients utilising CHWs for TB management compared to the rural patients with 16% (Figure 4.4). Community Health Workers were mostly not utilised in the rural set up (28%) compared with the urban set up (18%) as demonstrated in Figure 4.4.
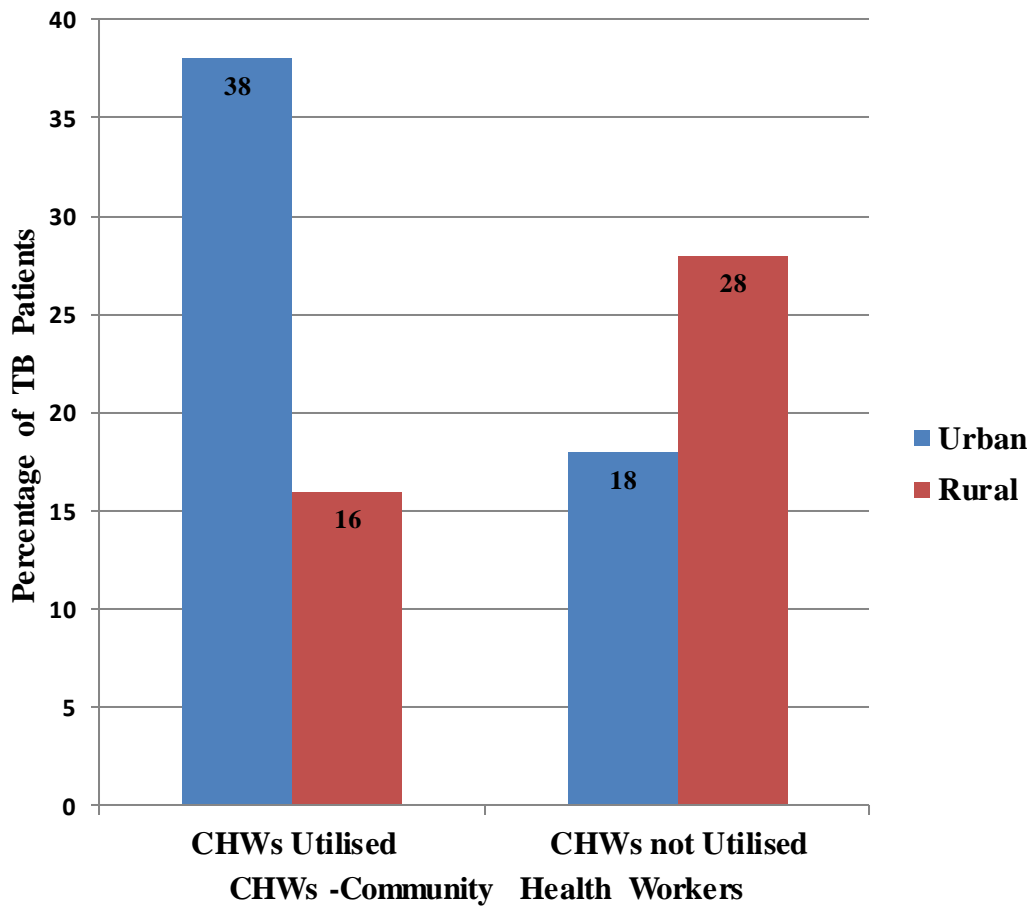
Figure 4. 4:   Proportion of TB patients utilising CHWs by location

New TB patients who utilised CHWs and those who did not utilise CHWs for their treatment were more or less equal in proportion, 43% versus 41% respectively (Figure 4.5).
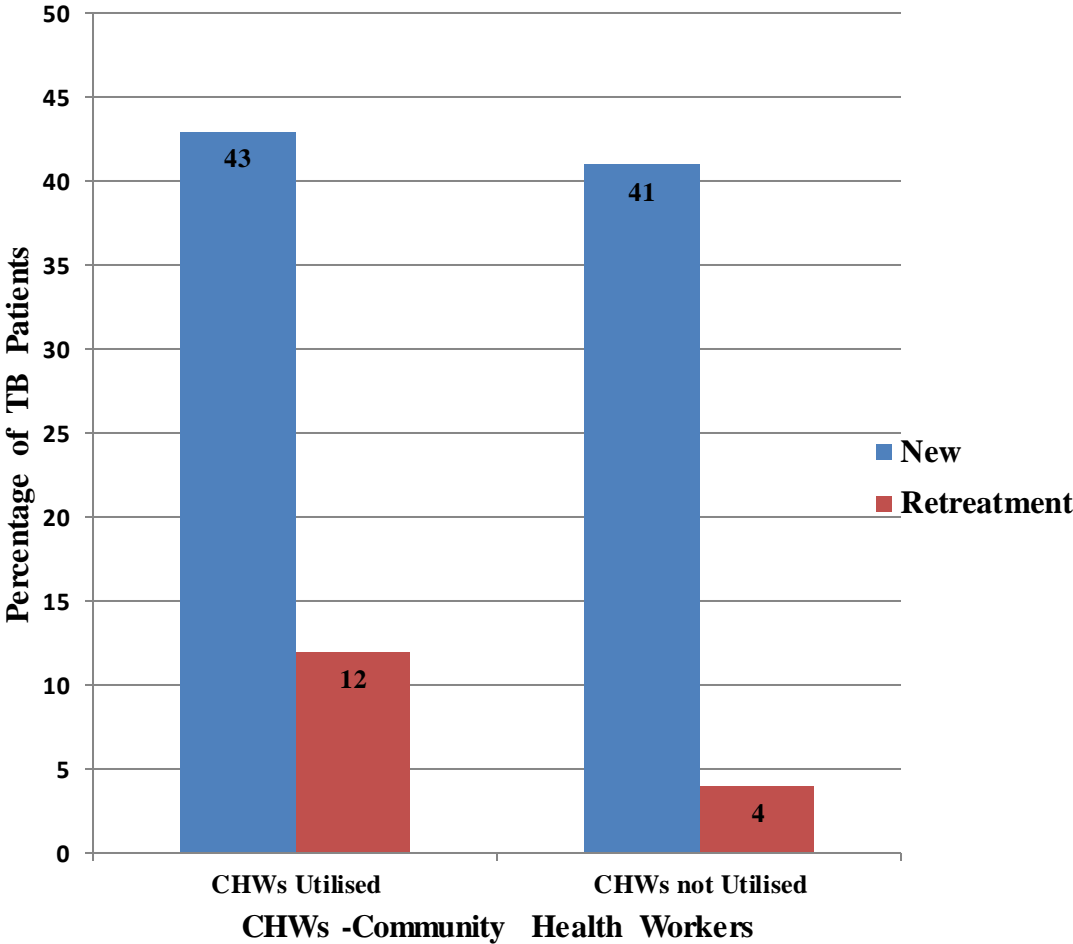
Figure 4. 5:   Proportion of new and retreatment patients utilising CHWs

Pulmonary smear negative (PSN) TB patients had the highest proportion (30%) of those utilising CHWs for their treatment, while PSP patients commonly (34%) did not utilise the CHWs (Figure 4.6).

TB disease classification
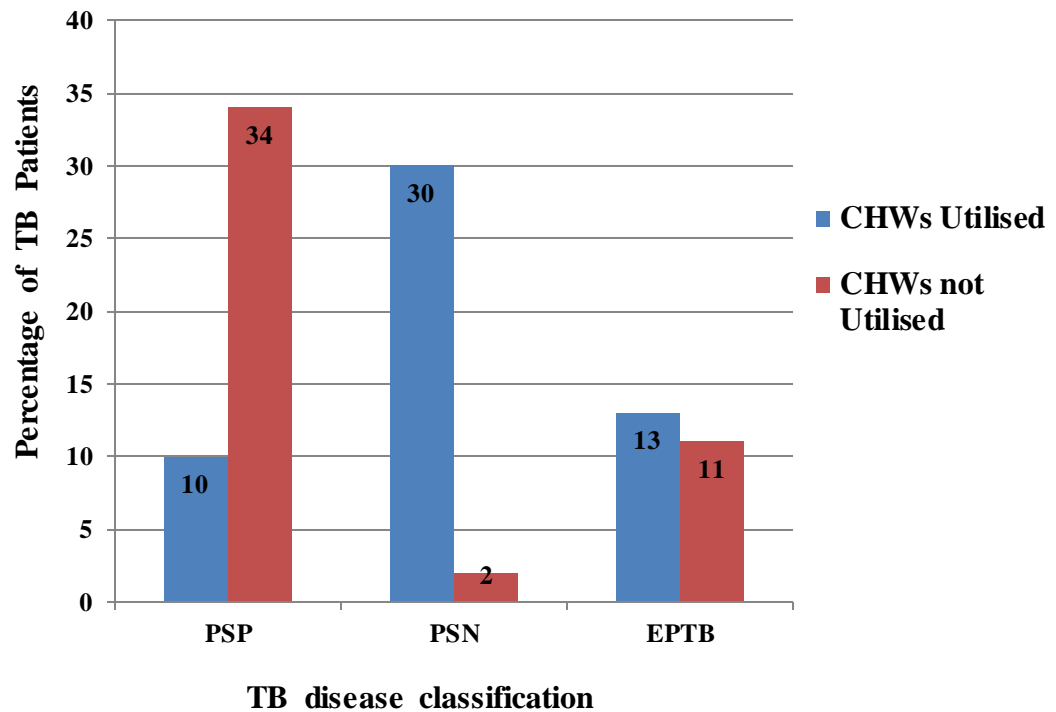
PSP-Pulmonary Smear Positive, PSN-Pulmonary Smear Negative, EPTB-Extra Pulmonary TB, CHWs- Community Health Workers

Figure 4. 6:   Proportion of TB patients utilising CHWs by their disease classification

Acceptance of HIV screening among the TB patients was higher (51%) in those who utilised CHWs compared to those who did not utilise CHWs (36%). This is demonstrated in Figure 4.7.
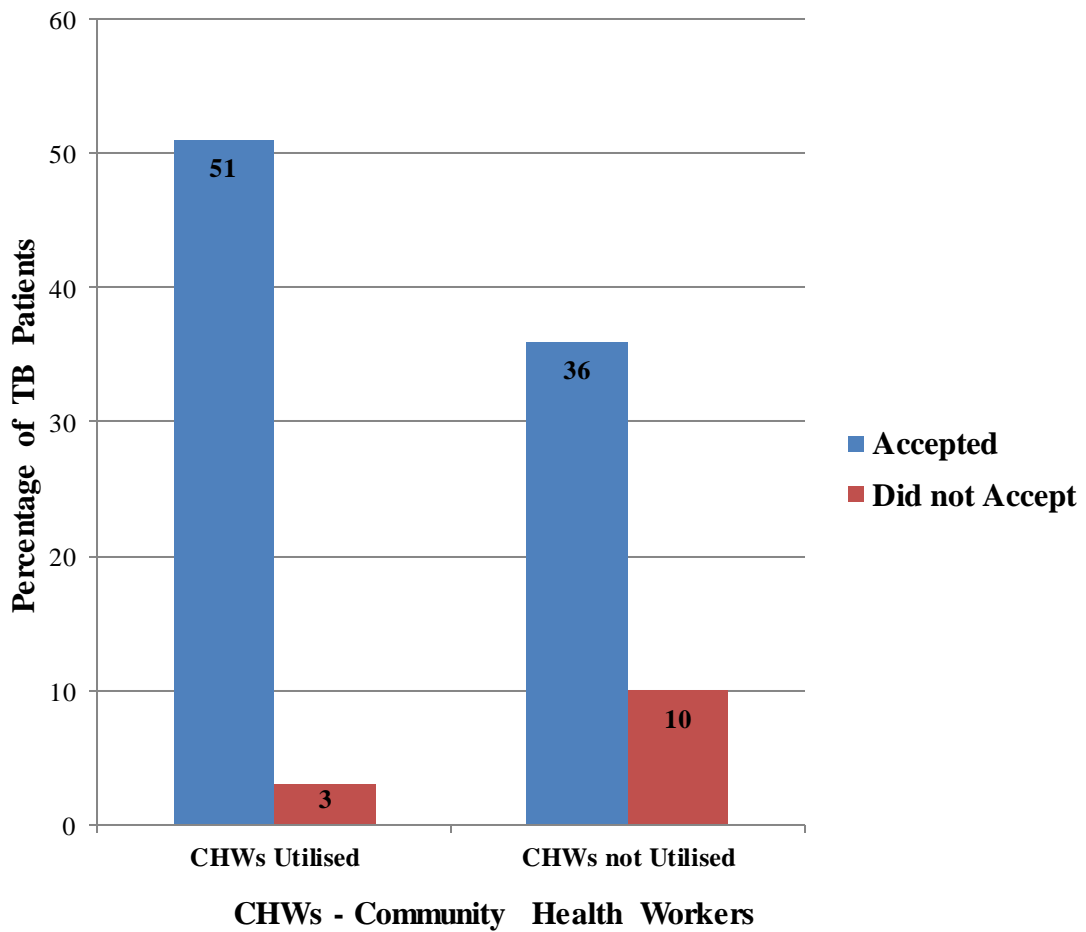
Figure 4. 7:   Proportion of TB patients accepting HIV screening by utilisation of CHWs

4.4 Factors Related to Treatment Adherence

Table 4.3 demonstrates potential factors that may be related to adherence. Among the patients who were adherent, age group 25-34 years made up the highest proportions (38%) of those who were utilising CHWs ($\chi 2$=27.9329, df=14, p<0.05) and similarly contributed to the highest proportion (33%) in the group not utilising CHWs ($\chi 2$=9.4292, df=14, p =0.803). The PSN patients were more likely (56.5%) to be adherent ($\chi 2$=27.9148, df=6, p< 0.05) compared to the other disease classifications among the patients who had utilised CHWs.

In the group that was not utilising CHWs, the PSP were more likely (75%) to be adherent ($\chi 2$=18.2075, df=6, p < 0.05). New TB patients utilising CHWs were significantly likely to be adherent ($\chi 2$=10.5368, df=4, p < 0.05) than those not utilising CHWs. Location and utilization of CHWs combined did have an effect on treatment adherence as demonstrated in Table 4.3. Among the patients who were adherent to TB treatment and utilising CHWs, 75% ($\chi 2$=82.3845, df=2, p<0.05) were residing in the urban set-up compared to the 25% from the rural set up. Not utilising CHWs was associated with higher adherence rates in the rural set up, 68% ($\chi 2$=53.9064, df=2, p< 0.05) compared to 32% in the urban set up.

Table 4.3:　　**Adherence to TB Treatment by Potential Risk Factors, stratified by use of CHWs**

	CHW used n=1237*		CHWs not used n=875*	
	Adherent	χ^2, df, p value	Adherent	χ^2, df, p value
Age				
0-14	158 (12.77)	χ^2=27.9329, df=14,p< 0.05	82 (9.37)	χ^2=9.4292, df=14, p= 0.803
15-24	195(15.76)		126 (14.40)	
25-34	470 (38)		288 (32.91)	
35-44	275 (22.23)		202 (23.09)	
45-54	88 (7.11)		111 (12.69)	
55-64	34 (2.75)		40 (4.57)	
65+	14 (1.13)		20 (2.29)	
Missing	3 (0.24)		6 (0.69)	
Sex				
Female	597 (48.26)	χ^2=2.6379, df=2, p= 0.267	434 (49.60)	χ^2=2.2699, df=2, p= 0.321
Male	640 (51.74)		441 (50.40)	
Disease Classification				
PSP	213(17.22)	χ^2=27.9148,df=6, p< 0.05	654 (74.74)	χ^2=18.2075, df=6,p< 0.05
PSN	699 (56.51)		35 (4)	
EPTB	324 (26.19)		184 (21.03)	
Missing	1(0.08)		2 (0.23)	
Patient Classification				
New	938 (78.83)	χ^2=10.5368, df=4, p< 0.05	749 (85.6)	χ^2=7.4196, df=4, p= 0.115
Retreatment	263 (21.26)		87 (9.94)	
Missing	36 (2.91)		39 (4.46)	
Accepted HIV Screening				
Yes	1162 (93.94)	χ^2=1.4998, df=2, p= 0.472	691(78.97)	χ^2=3.4353, df=2, p= 0.179
No	75 (6.06)		184 (21.03)	
Location				
Urban	928 (75.02)	χ^2=82.3845, df=2,p <0.05	280 (32)	χ^2=53.9064, df=2, p <0.05
Rural	309 (24.98)		595 (68)	

* All data are frequency (%), CHW, Community Health Worker, PSP Pulmonary Smear Positive, PSN Pulmonary Smear Negative, EPTB Extrapulmonary TB

4.5 Logistic Regression

Further analysis by use of bivariable regression was done on the data as a whole and this revealed that other co-variates did not have any additional influence on adherence other than the utilization of the CHWs as demonstrated in Table 4.4 on the unadjusted arm. Multivariable regression revealed that utilisation of CHWs still remained a factor on its own as revealed by the adjusted odds ratios (Table 4.4).

Table 4.4: **Bivariable and multivariable regression analysis of the association between CHWs and TB treatment adherence**

Unadjusted Adherence Exposure Variable	OR	95% CI	p value	Adjusted Adherence OR	95% CI	p value
CHW	2.25	(1.86 -2.73)	<0.05	1.98	(1.51 -2.5)	<0.05
Age	1.00	(0.93-1.07)	0.886	1.00	(0.99 -1.00)	0.71
Male	0.85	(0.70-1.02)	0.095	0.83	(0.68 -1.01)	0.07
TB Disease Classification	1.28	(0.95-1.73)	0.097	1.19	(0.87 -1.63)	0.26
New vs Retreatment	1.21	(0.91-1.62)	0.180	1.26	(0.93 -1.69)	0.12
Accepted HIV Screening	1.20	(0.93-1.57)	0.154	1.20	(0.89- 1.60)	0.21
Location (urban/rural)	1.06	(0.87-1.30)	0.517	1.05	(0.88 -1.38)	0.38

CHW Community Health Worker, OR Odds Ratio, CI Confidence Interval

To further demonstrate the effect of combining location and utilization of CHWs on treatment adherence, logistic regression analysis was done to find out the association. Table 4.5 shows a strong positive effect on combining the use of CHWs and location on treatment adherence, OR 8.02(95% CI 5.43 -11.88, p< 0.05). This revealed that the interaction of location and use of CHWs enhanced effective treatment adherence.

Table 4.5:   The effect of combining location and use of CHWs on TB treatment adherence

Exposure Variable	OR	95% CI	p value
Location	0.45	(0.35 - 0.58)	<0.05
CHW	0.74	(0.56 - 0.97)	<0.05
Location and CHW	8.02	(5.43 -11.88)	<0.05

CHW, Community Health Worker, OR Odds Ratio,
CI Confidence Interval

To define exactly which of the locations either urban or rural, was best suited to have effective treatment adherence with utilisation of CHWs, further analysis revealed that the urban set-up was most effective OR 2.65 (95% CI 2.02-3.48, p<0.05) compared to the rural set up as indicated in Table 4.6.

Table 4.6:   The most effective interaction between various locations and use of CHWs for TB treatment adherence among TB Patients

Exposure Variable	OR	95% CI	p value
Urban and no CHWs	0.45	(0.35-0.58)	<0.05
Rural and CHWs	0.74	(0.56 - 0.97)	<0.05
Urban and CHW	2.65	(2.02 -3.48)	<0.05
Rural and no CHWs	ref = 1		

CHW, Community Health Worker, OR Odds Ratio, CI Confidence Interval

4.6 Results from qualitative data

A majority of the CHWs who participated in the FGDs were between the ages of 25 – 30 years and at least 12 out of a total of 16 were female. They all had received the 3 day basic training on their roles as CHWs for TB care. They were all resident in the communities they served and spoke the same language as the community. They were all literate.

From the discussions, when asked what was their scope of work one said *'we usually look for those who have not come for their appointments, and if we find those who are sick at home we advise them to go to the clinic'*, others said *'on clinic days we give health education to the group'*, *'once in a month we meet with our in-charge to discuss our work'*. This gave a description of their work to include; linking people to health care, providing informal counselling, support and follow-up, making home visits, documenting their activities.

When the CHWs were probed to describe what keeps them to continuing to do the work, these were some of their views; *'I feel strong at doing my work when the nurse allows me to give the morning teaching to the patients who have come to the clinic while she prepares to give them their medication'*, *'people allowing me in their homes to encourage them on health issues makes me happy',' the nurses have shown us what to do'* This indicated that some factors perceived to influence CHWs' performance included: community support and confidence, the continued training and the monthly meetings with their supervisors combined with the cooperation from formal health workers and recognition. The availability of logistics to facilitate their work was reported as an important factor in sustaining them to continue working. This included a monthly allowance of USD 27 and a fee for tracing defaulters of USD 1.4 per traced TB patient.

Comments made by the CHWs on their incentive support included *' at least they give us something, but I wish it could be more, the cost of living is high'* . This expression shows

that they appreciated the incentive provided and there was desire for more to support their daily needs. This may have led to some of them exiting their work whenever another opportunity arose. In the urban set-up the attrition rate among the CHWs over the 5 year period was about 16% compared to the rural set-up of 20%. One major reason that was mentioned for resigning from doing the work despite the continuous availability of support was the opportunity of getting a better source of income.

Factors that may have limited the performance of their work were mentioned and included, coverage of long distances for home visits resulting in lesser visits monthly. This mainly affected the rural site which reported that on average 1 CHW could only manage 20 visits/month while the urban site, a CHW was able to cover 50 home visits/month on average. Sentiments of possible barriers to reach out to people were expressed, *'some homes will not allow you to talk to them' 'people with TB are talked of badly'*. These were other limiting factors mainly from the rural site indicating stigma towards TB from the community and possibly cultural beliefs against the conventional treatment of TB, so that alternative treatments such as traditional medicine were options for use. In the urban site missing clients at home and sometimes insecurity threats were mentioned as factors that could limit their performance. Sentiments on urban home visits included *'during the day we find no occupants in their houses because they have gone to work' 'we could get them in the evening but this may not be safe'*.

Two formal health workers involved in the supervision of the CHWs provided information on the utilization of CHWs through an in-depth interview. They reported that they recognized the importance of the CHWs complimenting their work. They felt the good treatment adherence rates would never have been achieved without the support of the CHWs. In both the rural and urban set up, the recruitment of the CHWs involved the community health committees that were composed of both lay leaders from the community and health workers from the facility.

4.7 The Cost Effect Analysis

Of the enrolled 2,778 patients in the study, 2,669 (96%) had treatment outcomes documented. There was a significant statistical difference in treatment success rate between the cohort that utilised CHWs and that which did not utilise (82.15% vs 72.25% p-value <0.05), Table 4.7.

Table 4.7: **Tuberculosis treatment outcomes stratified by utilisation of CHWs for management of TB**

TB Treatment Outcomes	CHWs utilised n=1451*	CHWs not utilised n=1218*	p-value
Treatment Success	1192 (82.15)	880 (72.25)	<0.05
Died	87 (6)	104 (8.54)	
Failure	2 (0.14)	7 (0.57)	
Lost to Follow-up	86 (5.93)	156 (12.81)	
Transfer Out	84 (5.79)	71 (5.83)	

* All data are Frequency (%), CHW, Community Health Worker

The effectiveness of utilising the CHWs was measured in terms of cost per DALY averted using the number of tuberculosis cases that were successfully treated being considered as averted. In addition, a comparison of mortality of TB patients in the 2 groups was also compared using DALY.

4.7.1 Treatment Success

Among the patients that were successfully treated there were 2 types of patients; the new TB patients (n=1,749) who were having TB disease for the first time and retreatment TB patients (n=323) who previously had TB. The treatment duration of these 2 type of TB patients differed with the new patients receiving treatment for 6 months while the retreatment for 8 months. Table 4.8 summarises the distribution of these patients by use of CHWs.

51

Table 4.8:   Distribution of tuberculosis treatment success by type of patient

Patients treated successfully

Type of Patient	CHWs utilised n=1192*	CHWs not utilised n=880*
New	946 (79)	803 (91)
Retreatment	246 (21)	77 (9)

* All data are frequency (%), CHW, Community Health Worker

To calculate the DALY averted for each TB patient successfully treated, the following formula was used with the assumption that disability was only at the time of TB treatment;

Disability Weighting of TB (0.3) X Time in years on TB treatment (6/12 or 8/12)

Each new TB patient had a DALY 0.15, while a retreatment had a DALY of 0.2. Table 4.9 illustrates the cost of treating TB patients who had a treatment success outcome, the total DALYs averted and the average cost per DALY averted in both the intervention and control group.

Table 4.9:   **Total DALYs averted, and average cost per DALY averted stratified by utilisation of CHWs in tuberculosis treatment**

Intervention	Number of patients with a treatment Success	Total cost of treatment (USD)	Total DALYs averted	weighted Total DALYs averted	Average Cost per DALY averted (USD)
Utilised CHWs	1192	61,211	191	332	184
CHWs not utilised	880	27,940	135	320	87

CHWs, Community Health Workers, DALY Disability Adjusted Life Years, USD United States of America Dollar.

The average cost per DALY averted was higher (184 USD) in the cohort that utilised CHWs compared to the cohort that did not utilise CHWs (87 USD).

4.7.2 Tuberculosis Deaths

A total of 191 deaths among the TB patients enrolled in the study were reported. The total DALYs resulting from these deaths were calculated using the following recommended formula: (Life expectancy years − Age of person at death) x the weighting of Death [1]. Kenya's 2012 life expectancy at Birth of 63 years (CIA, 2013) was used with the disability weighting of death. Table 4.10 summarises the number of deaths and total DALYs resulting from them.

Table 4.10: Number of deaths, total DALYs, stratified by utilisation of CHWs in the treatment of TB

Intervention	Number of Deaths	Total DALYs	Weighted Total DALYs
Utilised CHWs	86	2588	5688
CHWs not utilised	103	3120	5725

CHW, Community Health Worker, DALY Disability adjusted Life Years

Utilising CHWs resulted in less DALYs (5688) from death compared to not utilising CHWs (5725). A majority of patients died in the first 3 months of treatment in both the study cohorts (Figure 4.8). However, of concern was a majority (n=30) who died within the first month in the cohort that did not utilise CHWs.
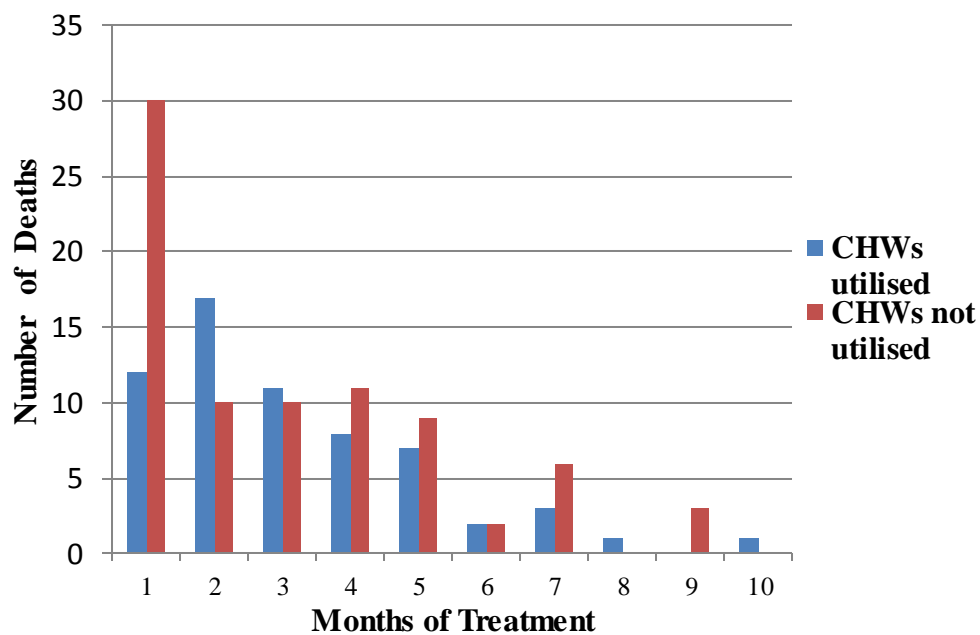
CHWs - Community Health Workers

Figure 4. 8: Time of death of TB patients after initiating treatment

CHAPTER FIVE

DISCUSSION

5.1 Treatment Adherence and use of Community Health Workers

This study showed that treatment adherence among TB patients who had utilized CHWs was higher (83%) than among those that did not utilize CHWs 68% ($p<0.05$). Furthermore, the study revealed that utilising CHWs for TB treatment support was the main enhancing factor among other co-variates considered [OR 1.98 95% CI (1.51-2.5) $p<0.05$]. These findings are similar to what other studies (WHO, 1989; Dick *et al.,* 1996; Kahssay *et al.,* 1998) have shown that use of CHWs can lead to good outcomes of treatment.

There are various factors that may have led to this including; the attitude of both the health facility personnel and the community. In both the situations of the urban and rural settings the CHW programmes were supported by health development partners supporting the Ministry of Health. This programme involved well defined tasks for the CHW, there was provision of capacity building through DOT training and regular refresher training, support supervision and a rewarding and recognition system for tasks done. The health workers in the facility recognized the importance of the CHWs complimenting their work as was revealed in their in-depth discussions. They felt the good treatment adherence rates would never have been achieved without the support of the CHWs.

In both the rural and urban set up the recruitment of the health workers involved the community health committees that were composed of both lay leaders from the community and health workers from the facility. The involvement of this committee indicated community acceptance of the tasks of the CHWs and its positive attitude towards the health services provided by the formal health services. On average the CHWs in the urban and the rural set up had continuously worked for the community for

the 5 years the study analysed. The sustainability of the CHWs may be most attributed to the continuous motivating factors that were mentioned by the CHWs as reasons that encourage them to support TB treatment adherence. This included the continuous support supervision, regular trainings, provision of incentives and recognition of work done well. These findings concur with other studies (Dick *et al.,*1997; Kironde & Klaasen, 2002).

The treatment adherence rate demonstrated in this study of 83% when CHWs are utilised is much lower than that which has been shown by other studies (Mkopi *et al.,* 2012; Nackers *et al.,* 2012). These 2 studies revealed that if adherence is measured by testing isoniazid in the urine of the patients at one point in time of their treatment the rates of adherence were 97.6% and 95.7% respectively. While if adherence was measured also at one point in time by using patient reports the adherence rate was 95.2% [95%CI: 91.3-97.7] (Nackers *et al.,* 2012) and if measured by visual analogue scale (VAS) within this same study the rate was 95.2% [95% CI: 88.0-95.6]. The inconsistence observed is explained by the different methodologies used to determine adherence in this study and the other studies. It may also not be suitable to compare these adherence rates because this study assessed the rate of adherence throughout the full course of TB treatment and not at one point in time as the other studies did.

5.2 Factors Related to Treatment Adherence

This study mainly assessed the effects of a health system related factor towards TB treatment. The support care provided by the CHWs may have had the potential to affect patients' adherence behaviour. A study (Rose *et al.,* 2000) revealed that a good patient-provider relationship is one of the factors most likely to improve treatment adherence. Some of the factors possessed by the CHWs that may have led to good treatment adherence included the knowledge they had on managing TB, incentive for them was available and they had regular feedback on performance. In addition, they had the capacity to educate patients or even support their follow-up.

Other factors that affect treatment adherence other than health system related factors include patient-related factors, social/economic factors, condition–related factors and therapy related factors. Patient related factors represent the knowledge, attitudes, beliefs, perceptions and expectations of the patient. Various authors have reported some of the patient-related factors that affect adherence include: forgetfulness; psychosocial stress; anxieties about possible adverse effects; low motivation; inadequate knowledge and skill in managing the disease symptoms and treatment; lack of self-perceived need for treatment; negative beliefs regarding the efficacy of the treatment; misunderstanding and non-acceptance of the disease; frustration with health care providers; anxiety over the complexity of the drug regimen, and feeling stigmatized by the disease (Gordillo *et al.,*1999; Horne, 1999; Horne & Weinman, 1999; Gupta & Horne, 2001; Horne *et al.,* 2001; Webb *et al.,* 2001; Miller & Rollnick, 2002; Petrie & Wessely, 2002; Reynolds *et al.,* 2004; Friedman *et al.,* 2008; Zivin & Kales, 2008; Taylor *et al.,* 2011). With the use of CHWs some of these factors were overcome through the encouraging counsel that CHWs are trained to provide the TB patients they are following up.

Socioeconomic factors have been reported to have a significant effect on treatment adherence including: poverty, illiteracy, low level of education, unemployment, lack of effective social support networks, unstable living conditions, long distance from treatment centre, high cost of transport, high cost of medication, changing environmental situations, culture and lay beliefs about illness and treatment, and family dysfunction (Gordillo *et al.,* 1999; Reynolds *et al.* 2004; Zivin & Kales, 2008; Taylor *et al.,* 2011). In this study the urban and rural differences in terms of treatment adherence were significant with the urban set up being more adherent on utilising the CHWs. Other factors that could have led to this include the shorter distances to the treatment centres compared to the rural set up and literacy levels which are usually higher in the urban compared to the rural (Bunyi, 2006).

Condition related factors that may affect treatment adherence include the severity of symptoms, the level of disability (physical, psychological, social and vocational), the

rate of progression and severity of the disease, and the availability of effective treatments. The effect of these factors may influence patients' perception on the importance of following treatment, and the priority placed on adherence. TB standard treatment regime has efficacy rate of about 95% (American Thoracic Society, CDC, & Infectious, 2003) so that within 2 weeks from initiation of treatment most patients greatly improve with symptom reduction (American Thoracic Society, CDC, & Infectious, 2003). Co-morbidities commonly like HIV infection in TB patients, depression in diabetes or HIV/AIDS (Ciechanowski *et al.,* 2000), and drug and alcohol abuse, are important modifiers of adherence behaviour (Zivin & Kales, 2008). The patient- provider relationship plays a big role to encourage or discourage the treatment adherence. The use of CHWs enhanced adherence which may be attributed to the continuous motivating relationship they had with the patients assigned to them.

This study assessed treatment adherence among new (first time TB patients) and reoccurrence (retreatment TB patients). The duration of retreatment type of TB is longer than that of new TB patients by 2 months and has injection administered daily in the first 2 months of treatment. This may cause unpleasantness to the patients. The study reported that both these types of patients were significantly likely to be treatment adherent with the use of the CHWs (p<0.05). Possibly the support of CHWs minimized the possible discouragement that may have arisen from the therapy.

5.3 Location and Use of Community Health Workers in treatment adherence

This study showed that utilising CHWs for TB treatment adherence was most effective in the urban set up compared to the rural set up OR 2.65 (95% 2.02-3.48, p< 0.001). This is a similar finding from an evaluation study done by Dick *et al.* (1996) which revealed that using CHWs in the rural set up did not significantly improve treatment adherence (Dick *et al.,*1996). Another study done in Brazil revealed similar findings, that utilising CHWs in certain urban settings enhanced treatment adherence (Cavalcante *et al.,* 2007).

The differences between the rural and urban set ups may be explained by the differences that were described through the discussions from the CHWs and the health workers. In the urban, the CHWs were able to do more home visits compared to the rural because the distances were shorter and the terrain manageable. Though the CHWs in both sites performed the same duties the local and cultural setting varied, possibly the socioeconomic status and cultural beliefs in the rural area may have limited full access to quality health care. In the urban set up communication between clients and CHWs or between CHWs and the formal health care worker was much easier compared to the rural set-up especially with the use of cell telephones.

5.4 Cost Effect Analysis

The average cost per DALY averted for treatment success was higher (184 USD) in the cohort that utilised CHWs compared to the cohort that did not utilise CHWs (87 USD). Valuable resources were allocated for the use of CHWs and this resulted in a better treatment success rate of 82.15% compared to 72.25% (p-value <0.05). This may be considered as a health and economic benefit because life was saved by curing those who had TB and a majority of them were in the productive age group of 25-34 years making up 38% of the cohort that utilised CHWs. This finding is similar to other studies (Islam *et al.,* 2002; Brown *et al.,* 2012) that reported improved quality of life by curing or controlling chronic disease.

Utilising CHWs resulted in less DALYs (5688) from death compared to not utilising CHWs (5725). This finding re-emphasises the outcome of better treatment success rate that prevented the occurrence of death. A majority of patients who died within the first month were in the cohort that did not utilise CHWs. The use of CHWs strongly averted death and this could greatly prevent death in the early months of TB treatment. The results of the cost effect analysis of this study indicated evidence of greater effectiveness with greater cost compared to the control group that did not utilize CHWs. In this situation a judgement that costly intervention was worthwhile in terms of additional

effectiveness was made because of the successful treatment outcomes and the deaths averted. Many examples of cost effect analysis studies fall in similar categories as this study (Neuhauser & Lewicki, 1975; Gould *et al.,* 1999; Kerlikowske *et al.,*1999; El-Serag *et al.,* 2000; Freedberg, *et al.,* 2001; Sonnenberg, 2001).

Disability adjusted life years (DALYs) is a measure of burden of disease. In this study DALY was used to measure the cost effectiveness of utilising CHWs for the management of TB disease. The DALY concept has been used to measure the impact of disease, has helped to choose interventions, and is able to track the success or failure of our intervention (Bobadilla *et al.,* 1994; Foege, 1994). The possible use of DALY to assess the effects of utilising the CHWs should also be applied to other health interventions to evaluate their effectiveness. There are several advantages for using DALY as reported by Yassin (Yassin & Galan, 2004), including; it is a measure that provides information about non-fatal health outcomes, can measure the magnitude of premature death and non-fatal health outcomes attributable to proximal biological causes, including diseases and injuries or attributable to more distal causes such as poor living standards, tobacco use or socio-economic determinants.

In addition, the DALY is a stable measure that can be used for purposes of comparisons either between different communities or between different points of time. Jankovic (2005) emphasized that DALY measurement of clinical outcomes and cost-effectiveness analyses allows existing or prospective interventions to be judged both in terms of cost-effectiveness, and their relative impact in reducing the burden of disease (BOD) and ill-health (Jankovic, 2005). Disability adjusted life years (DALY) as a composite indicator is a useful analytical tool for health policymakers and analysts in priority setting and resource allocation in health systems. It can be used as a measure of trends in disease burden and as a tool for cost-effectiveness studies and priority setting (Lindstrand *et al.,* 2006).

In public health cost effectiveness analysis compares costs and effectiveness of two or more health interventions with effectiveness measured in the same units. In this study the effectiveness was compared using cost per DALY averted. Policy makers can use this information as recommended by WHO's Choosing Interventions that are Cost-Effective project (WHO-CHOICE) which says that a cost/DALY averted less than 3 times the national annual Gross Domestic Product (GDP) per capita is considered effective, whereas one that costs less than once the national annual GDP per capita is considered highly effective (Marseille *et al.,* 2015). The 2014 annual GDP per capita of Kenya as reported by World Bank was 648.84 USD (Trading Economics, 2014). If this is used as a reference this study concludes that these findings make the utilization of CHWs to be highly effective.

The use of cost effect analysis in this study demonstrates one way of conducting a project appraisal and it gives important insights into the economic attractiveness of the intervention of utilizing CHWs for TB management. This intervention had the main health outcome as successful treatment of TB, while the secondary outcome was reduced TB mortality and the non-health outcomes were the economic and welfare gains from improved management of TB. All these outcomes assess the value of the intervention along multiple dimensions.

5.4 Study strengths

This study had various strengths. It used objective procedures (patient treatment records) to define treatment adherence and the data analytic procedures applied, allowed control of various confounding factors. The use of qualitative findings to explain some of the differences found in the urban and the rural set up is an additional strength to this study. Using programmatic data by this study strongly supports the intervention of utilising CHWs in the management of TB treatment. The positive effect of utilising CHWs in a programmatic setting as found in this study can be of value for areas outside the context of TB especially for chronic illnesses.

5.5 Study Limitations

The study was not able to get information on other factors that may influence treatment adherence including level of education, occupation, travel distance and socio-economic status. Cost effective analysis differs in various studies depending on the scope of cost put into the analysis and also pricing differs in different set-ups. The analysis done in this study may have limited application to apply only to the local setting where the data was gathered from.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

1. Utilisation of CHWs in the treatment of TB resulted significantly in better TB treatment adherence (83%) compared to not utilising CHWs (68%).

2. Utilisation of CHWs in the management of TB in an informal settlement within an urban setting resulted significantly in a high rate of TB treatment adherence (90%) compared to the rural setting (73%). The combined effect of utilising CHWs and the urban set up enhanced TB treatment adherence.

3. The use of CHWs was significantly highly cost effective resulting in better treatment success rate (82%) compared to 72% of the cohort that did not use CHWs.

4. More deaths were significantly averted on use of CHWs with death rates of 6% compared to 8.5% without use of CHWs, an indication of health and economic health gain.

5. Utilisation of CHWs for TB treatment adherence was highly cost effective with an average cost per DALY averted at USD 184.

6. Among the TB patients who died while on treatment a majority (30) died in the first month of treatment and were in the cohort that did not utilise CHWs.

7. The null hypothesis of this study was rejected because the findings from this study demonstrated that the use of CHWs in the treatment of TB significantly had better treatment adherence compared to not utilising CHWs

6.2 Recommendations

1. Community Health Workers should be used in the management of TB to enhance treatment adherence and to avert death more so in the early months of TB treatment.

2. The use of CHWs should have a clear plan that supports their sustainability. This would include adequate supervision of CHWs, adequate and appropriate incentives and well described terms of reference for them.

3. Use of CHWs in rural setting will require strategies to improve their mobility and accessibility to patients' homes.

4. Disability Adjusted Life Years (DALYs) is an appropriate tool for evaluation of interventions used in the management of TB. It should be adopted for routine use.

REFERENCES

Abercrombie, P. D. (2001). Improving adherence to abnormal Pap smear follow-up. *Journal of Obstetric, Gynecologic and Neonatal Nursing*, *30*(1), 80-88.

Adatu, F., Odeke, R., Mugenyi, M., Gargioni, G., McCray, E., Schneider, E. and Maher, D. (2003). Implementation of the DOTS strategy for tuberculosis control in rural Kiboga District, Uganda, offering patients the option of treatment supervision in the community, 1998–1999. *The International Journal of Tuberculosis and Lung Disease*, *7*(9s1), S63-S71.

Akbar, D. H. and Al-Gamdi, A. A. (2000). Common causes of admission in diabetics. *Saudi medical journal*, *21*(6), 539-542.

American Thoracic Society. (2000). Diagnostic standards and classification of tuberculosis in adults and children. *Am J Respir Crit Care Med*, *161*, 1376-1395.

American Thoracic Society, CDC, and Infectious. (2003). *Morbidity and Mortality Weekly Report; Treatment of Tuberculosis, June 20, / Vol. 52 / No. RR-11.*

Anand, S. and Hanson, K. (1997). Disability-adjusted life years: a critical review. *Journal of health economics*, *16*(6), 685-702.

Bagchi, S., Ambe, G. and Sathiakumar, N. (2010). Determinants of poor adherence to anti-tuberculosis treatment in Mumbai, India. *International journal of preventive medicine*, *1*(4), 223-232.

Bell, J. and Yach, D. (1988). Tuberculosis patient compliance in the western Cape, 1984. *South African medical journal 73*(1), 31-33.

Bermejo, A. and Bekui, A. (1993). Community participation in disease control. *Social Science and Medicine*, *36*(9), 1145-1150.

Bobadilla, J. L., Cowley, P., Musgrove, P. and Saxenian, H. (1994). Design, content and financing of an essential national package of health services. *Bulletin of the World Health Organization*, *72*(4), 653.

Borgdorff, M. W., Floyd, K. and Broekmans, J. F. (2002). Interventions to reduce tuberculosis mortality and transmission in low-and middle-income countries. *Bulletin of the World Health Organization*, *80*(3), 217-227.

Boza, R. A., Milanes, F., Slater, V., Garrigo, L. and Rivera, C. E. (1987). Patient noncompliance and overcompliance. Behavior patterns underlying a patient's failure to 'follow doctor's orders'. *Postgraduate medicine*, *81*(4), 163-170.

Broadhead, R. S., Heckathorn, D. D., Altice, F. L., Van Hulst, Y., Carbone, M., Friedland, G. H. and Selwyn, P. A. (2002). Increasing drug users' adherence to HIV treatment: results of a peer-driven intervention feasibility study. *Social science and medicine*, *55*(2), 235-246.

Brown, H. S., Wilson, K. J., Pagán, J. A., Arcari, C. M., Martinez, M., Smith, K. and Reininger, B. (2012). Cost-effectiveness analysis of a community health worker intervention for low-income Hispanic adults with diabetes. *Prev Chronic Dis*, *9*, E140.

Brownstein, J. N., Bone, L. R., Dennison, C. R., Hill, M. N., Kim, M. T. and Levine, D. M. (2005). Community health workers as interventionists in the prevention and control of heart disease and stroke. *American journal of preventive medicine*, *29*(5), 128-133.

Bunyi, G. W. (2006). Real options for literacy policy and practice in Kenya. *Paper commissioned for the Education Foundation for Africa, Nairobi, Kenya*.

Byakika-Tusiime, J., Oyugi, J. H., Tumwikirize, W. A., Katabira, E. T., Mugyenyi, P. N. and Bangsberg, D. R. (2005). Adherence to HIV antiretroviral therapy in HIV+ Ugandan patients purchasing therapy. *International journal of STD and AIDS*, *16*(1), 38-41.

Catz, S. L., Kelly, J. A., Bogart, L. M., Benotsch, E. G. and McAuliffe, T. L. (2000). Patterns, correlates, and barriers to medication adherence among persons prescribed new treatments for HIV disease. *Health Psychology*,*19*(2), 124.

Cavalcante, S. C., Soares, E. C., Pacheco, A. G., Chaisson, R. E., Durovni, B. and Team, D. E. (2007). Community DOT for tuberculosis in a Brazilian favela: comparison with a clinic model. *The International Journal of Tuberculosis and Lung Disease*, *11*(5), 544-549.

Centers for Disease Control and Prevention. (2016). *Tuberculosis.* Retrieved from http://www.cdc.gov/tb/.

Chesney, M. (2000). Factors affecting adherence to antiretroviral therapy. *Clinics in Infectious Disease*, *30*, S171-S176.

Central Intellegency Agency. (2013). *World Fact Book*. Retrieved from www.cia.gov/library/publications/the-world-factbook/geos/ke.html.

Ciechanowski, P. S., Katon, W. J. and Russo, J. E. (2000). Depression and diabetes: impact of depressive symptoms on adherence, function, and costs. *Archives of internal medicine*, *160*(21), 3278-3285.

Clark, D. O. (2001). Issues of adherence, penetration, and measurement in physical activity effectiveness studies. *Medical Care*, *39*(5), 409-412.

Clarke, M., Dick, J., Zwarenstein, M., Lombard, C. J. and Diwan, V. K. (2005). Lay health worker intervention with choice of DOT superior to standard TB care for

farm dwellers in South Africa: a cluster randomised control trial. *The international journal of tuberculosis and lung disease*, *9*(6), 673-679.

Cramer, J. A. (1998). Consequences of intermittent treatment for hypertension: the case for medication compliance and persistence. *The American journal of managed care*, *4*(11), 1563-1568.

Crane, L. A. (1996). Social support and adherence behavior among women with abnormal Pap smears. *Journal of cancer education*, *11*(3), 164-173.

Daniel, O. J., Ogun, S. A., Odusoga, O. L., Falola, R. L., Ogundahunsi, O. A., Salako, A. A. and Oluwole, F. A. (2004). Adherence pattern to ARV drugs among AIDS patients on self-purchased drugs and those on free medications in Sagamu, Nigeria. In *XV International AIDS Conference* (pp. 11-16).

Davies, M., Dixon, S., Currie, C. J., Davis, R. E. and Peters, J. R. (2001). Evaluation of a hospital diabetes specialist nursing service: a randomized controlled trial. *Diabetic Medicine*, *18*(4), 301-307.

Delacollette, C., van der Stuyft, P. and Molima, K. (1996). Using community health workers for malaria control: experience in Zaire. *Bulletin of the World Health Organization*, *74*(4), 423-430.

Demas, P. A., Webber, M. P., Schoenbaum, E. E., Weedon, J., McWayne, J., Enriquez, E. and Thea, D. M. (2002). Maternal adherence to the zidovudine regimen for HIV-exposed infants to prevent HIV infection: a preliminary study. *Pediatrics*, *110*(3), e35-e35.

Dheda, K., Schwander, S. K., Zhu, B., Van, Z. S., Richard, N. and Zhang, Y. (2010). The immunology of tuberculosis from bench to bedside. *Respirology*,*15*(3), 433-450.

Dick, J., Clarke, M., Tibbs, J. and Schoeman, H. (1997). Combating tuberculosis--lessons learnt from a rural community project in the Klein Drakenstein area of the Western Cape. *South African medical journal 87*(8 Suppl), 1042-1047.

Dick, J., Murray, E. and Botha, E. (2005). The effectiveness of TB DOTS supporters in South Africa.

Dick, J., Schoeman, J. H., Mohammed, A. and Lombard, C. (1996). Tuberculosis in the community: 1. Evaluation of a volunteer health worker programme to enhance adherence to anti-tuberculosis treatment. *Tubercle and Lung Disease*, *77*(3), 274-279.

Diiorio, C., Faherty, B. and Manteuffel, B. (1991). Cognitive–perceptual factors associated with antiepileptic medication compliance. *Research in nursing and health*, *14*(5), 329-338.

DiMatteo, M. R. and DiNicola, D. D. (1982). Achieving patient compliance: The psychology of the medical practitioner's role.

Division of Leprosy, Tuberculosis and Lung Disease. (2011 -2015). *Strategic Plan.* Kenya.

Division of Leprosy, TB and Lung Disease, MoH, Kenya. (2013). *Guidelines for Management of Tuberculosis and Leprosy in Kenya*. Nairobi: MoH.

Dunbar-Jacob, J. and Mortimer-Stephens, M. (2001). Treatment adherence in chronic disease. *Journal of clinical epidemiology*, *54*(12), S57-S60.

Egwaga, S., Mkopi, A., Range, N., Haag-Arbenz, V., Baraka, A., Grewal, P. and Van Leth, F. (2009). Patient-centred tuberculosis treatment delivery under programmatic conditions in Tanzania: a cohort study. *BMC medicine*,*7*(1), 1.

El-Serag, H. B., Inadomi, J. M. and Kowdley, K. V. (2000). Screening for hereditary hemochromatosis in siblings and children of affected patients: a cost-effectiveness analysis. *Annals of internal medicine*, *132*(4), 261-269.

Fishman, T. (1995). The 90-Second Intervention: a patient compliance mediated technique to improve and control hypertension. *Public Health Reports*, *110*(2), 173.

Foege, W. (1994). Preventive medicine and public health. *Journal of American Medical Association*, *271*(21), 1704-1705.

Freedberg, K. A., Losina, E., Weinstein, M. C., Paltiel, A. D., Cohen, C. J., Seage, G. R. and Goldie, S. J. (2001). The cost effectiveness of combination antiretroviral therapy for HIV disease. *New England Journal of Medicine*, *344*(11), 824-831.

Freudenberg , N. (1995). A new role for community organizations in the prevention and control of tuberculosis. *Journal of Community Health*, *20*, 15-28.

Friedman, I. (2002). In *Community Based Health Workers. SAHR The SEED Trust, Health Programme*.

Friedman, D. S., Hahn, S. R., Gelb, L., Tan, J., Shah, S. N., Kim, E. E. and Quigley, H. A. (2008). Doctor–patient communication, health-related beliefs, and adherence in glaucoma: Results from the glaucoma adherence and persistency study. *Ophthalmology*, *115*(8), 1320-1327.

Getahun, H. and Maher, D. (2000). Contribution of 'TB clubs' to tuberculosis control in a rural district in Ethiopia [Planning and Practice]. *The International Journal of Tuberculosis and Lung Disease*, *4*(2), 174-178.

Gibson, P. G., Powell, H., Coughlan, J., Wilson, A. J., Abramson, M., Haywood, P. and Walters, E. H. (2002). Self-management education and regular practitioner review for adults with asthma. *Cochrane Database Syst Rev*, *3*.

Gifford, A. L., Bormann, J. E., Shively, M. J., Wright, B. C., Richman, D. D. and Bozzette, S. A. (2000). Predictors of self-reported adherence and plasma HIV concentrations in patients on multidrug antiretroviral regimens. *JAIDS Journal of Acquired Immune Deficiency Syndromes*, *23*(5), 386-395.

Gordillo, V., del Amo, J., Soriano, V. and González-Lahoz, J. (1999). Sociodemographic and psychological variables influencing adherence to antiretroviral therapy. *Aids*, *13*(13), 1763-1769.

Gould, M. K., Dembitzer, A. D., Sanders, G. D. and Garber, A. M. (1999). Low-molecular-weight heparins compared with unfractionated heparin for treatment of acute deep venous thrombosis: a cost-effectiveness analysis. *Annals of Internal medicine*, *130*(10), 789-799.

Gray, A., Raikou, M., McGuire, A., Fenn, P., Stevens, R., Cull, C. and Turner, R. (2000). Cost effectiveness of an intensive blood glucose control policy in patients with type 2 diabetes: economic analysis alongside randomised controlled trial (UKPDS 41). United Kingdom Prospective Diabetes Study Group. *Bmj*, *British Medical Journal*, *320*(7246), 1373-1378.

Green, C. A. (1987). What can patient health education coordinators learn from ten years of compliance research?. *Patient education and counseling*, *10*(2), 167-174.

Guimón, J. (1995). The use of group programs to improve medication compliance in patients with chronic diseases. *Patient education and counseling*, *26*(1), 189-193.

Gupta, K. and Horne, R. (2001). The influence of health beliefs on the presentation and consultation outcome in patients with chemical sensitivities. *Journal of psychosomatic research*, *50*(3), 131-137.

Haynes, R. B. (1979). Determinats of compliance. The disease and the mechanics of treatment.

Haynes, R. B., Montague, P., Oliver, T., McKibbon, K. A., Brouwers, M. C. and Kanani, R. (2001). Interventions for helping patients follow prescriptions for medications. The Cochrane Library.

Hill, P. C., Stevens, W., Hill, S., Bah, J., Donkor, S. A., Jallow, A. and Lienhardt, C. (2005). Risk factors for defaulting from tuberculosis treatment: a prospective cohort study of 301 cases in the Gambia. *The International Journal of Tuberculosis and Lung Disease*, *9*(12), 1349-1354.

Horne, R. (1999). Patients' beliefs about treatment: the hidden determinant of treatment outcome?. *Journal of psychosomatic research*, *47*(6), 491-495.

Horne, R. and Weinman, J. (1999). Patients' beliefs about prescribed medicines and their role in adherence to treatment in chronic physical illness. *Journal of psychosomatic research*, *47*(6), 555-567.

Horne, R., Hankins, M. and Jenkins, R. (2001). The Satisfaction with Information about Medicines Scale (SIMS): a new measurement tool for audit and research. *Quality in Health Care*, *10*(3), 135-140.

International Drug Purchasing Facility. (2015). *MDR-TB scale-up initiative*. Retrieved from http://www.unitaid.eu/en/mdr-tb-scale-up

Islam, M., Wakai, S., Ishikawa, N., Chowdhury, A. M. and Vaughan, J. P. (2002). Cost-effectiveness of community health workers in tuberculosis control in Bangladesh. *Bulletin of the World Health Organization*, *80*(6), 445-450.

Jamison, D. and Breman, J. (2006). *Cost–Effectiveness Analysis.* New York: Oxford University Press.

Jamison, D., Breman, J., Anthony, R. and George, A. (2006). *Disease control priorities in developing countries (2nd Edition).* New York: Oxford University Press.

Jankovic, S. (2005). In *Summary measures of population health and their relevance for health policy.* (pp. 190-207). Lage: Hans Jacobs Publishing Company.

Janovsky, K. (1996). *Health policy and systems development: an agenda for research.* Geneva: WHO.

Kahssay, H. M., Taylor, M. E. and Berman, P. A. (1998). *Community health workers: the way forward.* Geneva:World Health Organization.

Kalyango, J. N., Rutebemberwa, E., Alfven, T., Ssali, S., Peterson, S. and Karamagi, C. (2012). Performance of community health workers under integrated community case management of childhood illnesses in eastern Uganda. *Malar J*, *11*(1), 282.

Kangangi, J. K., Kibuga, D., Muli, J., Maher, D., Billo, N., Ng'ang'a, L. and Kimani, V. (2003). Decentralisation of tuberculosis treatment from the main hospitals to the peripheral health units and in the community within Machakos district, Kenya. *The International Journal of Tuberculosis and Lung Disease*, *7*(9s1), S5-S13.

Katabira, C., Casteinuovo, B., Bhushan, A. and Kambugu, A. (2009). Examining Drug Default for Treatment of Tuberculosis in an Urban HIV Clinic in Uganda. *Implementers meeting.*, (p. 117). Windhoek, Namibia.

Katapodi, M. C., Facione, N. C., Miaskowski, C., Dodd, M. J. and Waters, C. (2002). The influence of social support on breast cancer screening in a multicultural community sample. In *Oncology nursing forum* (Vol. 29, No. 5, pp. 845-852). Oncology Nursing Society.

Kawabata, Y. (1998). [Pathogenesis of tuberculosis]. *Nihon rinsho. Japanese journal of clinical medicine*, *56*(12), 3041-3046.

Kerlikowske, K., Salzmann, P., Phillips, K. A., Cauley, J. A. and Cummings, S. R. (1999). Continuing screening mammography in women aged 70 to 79 years: impact on life expectancy and cost-effectiveness. *Jama*, *Journal of American Medical Association 282*(22), 2156-2163.

Kironde, S. and Kahirimbanyib, M. (2002). Community participation in primary health care (PHC) programmes: lessons from tuberculosis treatment delivery in South Africa. *African health sciences*, *2*(1), 16-23.

Kironde, S. and Klaasen, S. (2002). What motivates lay volunteers in high burden but resource-limited tuberculosis control programmes? Perceptions from the Northern Cape province, South Africa. *The International Journal of Tuberculosis and Lung Disease*, *6*(2), 104-110.

Koch, T., Selim, P. A. and Kralik, D. (2002). Enhancing lives through the development of a community-based participatory action research programme. *Journal of clinical nursing*, *11*(1), 109-117.

Kulcar, Z. (1991). Self-help, mutual aid and chronic patients' clubs in Croatia, Yugoslavia: discussion paper. *Journal of the Royal Society of Medicine*, *84*(5), 288.

Kyngäs, H. and Rissanen, M. (2001). Support as a crucial predictor of good compliance of adolescents with a chronic disease. *Journal of clinical nursing*, *10*(6), 767-774.

Kyngäs, H. A., Kroll, T. and Duffy, M. E. (2000). Compliance in adolescents with chronic diseases: a review1. *Journal of Adolescent Health*, *26*(6), 379-388.

Kyngäs, H. A. (1999). Compliance of adolescents with asthma. *Nursing and health sciences*, *1*(3), 195-202.

Kyngäs, H. (2000). Compliance with health regimens of adolescents with epilepsy. *Seizure*, *9*(8), 598-604.

Kyngäs, H. (2001). Predictors of good compliance in adolescents with epilepsy. *Seizure*, *10*(8), 549-553.

Lariosa, T. R. (1991). The role of community health workers in malaria control in the Philippines. *The Southeast Asian journal of tropical medicine and public health*, *23*, 30-35.

Lehmann, U., Friedman, I. and Sanders, D. (2004). Review of the utilisation and effectiveness of community-based health workers in Africa. *Global Health Trust, Joint Learning Initiative on Human Resources for Health and Development (JLI), JLI Working Paper*, 4-1.

Lilja, P. (1984). Recognizing the effect of social support on compliance to medical regimen in the elderly chronically ill. *Home Healthcare Now*, *2*(6), 17-23.

Lindstrand, A., Bergström, S., Rosling, H., Rubenson, B., Stenson, B. and Tylleskär, T. (2006). *Global health: an introductory textbook*. Studentlitteratur. Copenhagen: Narayana Press.

Lopez, A. D., Mathers, C. D., Ezzati, M., Jamison, D. T. and Murray, C. J. (2006). Global Burden of Disease and Risk Factors, Oxford: A copublication of Oxford University Press and The World Bank.

Love, M.B. and Gardner, K. (1992). The emerging role of the community health worker in California. *Health Promotion Section, California Department of Health Services.*

MacLean, D. and Lo, R. (1997). The non-insulin-dependent diabetic: success and failure in compliance. *The Australian journal of advanced nursing: a quarterly publication of the Royal Australian Nursing Federation*, *15*(4), 33-42.

Macq, J. C., Theobald, S., Dick, J. and Dembele, M. (2003). An exploration of the concept of directly observed treatment (DOT) for tuberculosis patients: from a uniform to a customised approach. *The International Journal of Tuberculosis and Lung Disease*, *7*(2), 103-109.

Magura, S., Laudet, A. B., Mahmood, D., Rosenblum, A. and Knight, E. (2002). Adherence to medication regimens and participation in dual-focus self-help groups. *Psychiatric Services, 53*(3), 310-316.

Maher, D., Van Gorkom, J. L., Gondrie, P. C. and Raviglione, M. (1999). Community contribution to tuberculosis care in countries with high tuberculosis prevalence: past, present and future. *The International Journal of Tuberculosis and Lung Disease*, *3*(9), 762-768.

Markowitz, M. (2000). Resistance, fitness, adherence, and potency: mapping the paths to virologic failure. *Jama*, *Journal of the American Medical Association 283*(2), 250-251.

Marseille, E., Larson, B., Kazi, D. S., Kahn, J. G. and Rosen, S. (2015). Thresholds for the cost–effectiveness of interventions: alternative approaches. *Bulletin of the World Health Organization*, *93*(2), 118-124.

Meichenbaum, D. and Turk, D. C. (1987). Facilitation Treatment Adherence. *Plenum.* New York.

Menon, A. (1991). Utilization of village health workers within a primary health care programme in The Gambia. *The Journal of tropical medicine and hygiene*, *94*(4), 268-271.

Menzies, R., Rocher, I. and Vissandjee, B. (1993). Factors associated with compliance in treatment of tuberculosis. *Tubercle and Lung Disease*, *74*(1), 32-37.

Miller, L. and Hays, R. (2000). Measuring adherence to antiretroviral medications in clinical trials. *HIV clinical trials*, *1*(1), 36-46.

Miller, W. R. and Rollnick, S. (2002). Motivational interviewing: Preparing people for change. N.Y: Guilford.

Ministry of Health, (2007). *Community Strategy Implementation Guidelines for Managers of the Kenya Essential Package for Health at the Community Level.*

Ministry of Public Health and Sanitation. (2008). *Tuberculosis Training Curriculum for Community Health Workers.* Kenya.

Mkopi, A., Range, N., Lwilla, F., Egwaga, S., Schulze, A., Geubbels, E. and Van Leth, F. (2012). Adherence to tuberculosis therapy among patients receiving home-based directly observed treatment: evidence from the United Republic of Tanzania. *PloS one*, *7*(12), e51828.

Murray, C. J. (1996). Rethinking DALYs. *The global burden of disease*, *1*, 1-98. Harvard: Harvard University Press.

Murray, C. J. (1994). Quantifying the burden of disease: the technical basis for disability-adjusted life years. *Bulletin of the World health Organization*, *72*(3), 429 -445.

Murray, C. J. and Lopez, A. D. (1996). Evidence-based health policy--lessons from the Global Burden of Disease Study. *Science*, *274*(5288), 740.

Nackers, F., Huerga, H., Espié, E., Aloo, A. O., Bastard, M., Etard, J. F. and Bonnet, M. (2012). Adherence to self-administered tuberculosis treatment in a high HIV-prevalence setting: a cross-sectional survey in Homa Bay, Kenya. *PLoS One*, *7*(3), e32140.

National Tuberculosis and Leprosy, Programme. (2009). *Annual National TB and Leprosy Report.Kenya.*

National Tuberculosis, Leprosy and Lung Diseases Unit. (2013). *The Kenya National Tuberculosis, Leprosy and Lung Disease Unit Annual Report.* Kenya.

Neuhauser, D. and Lewicki, A. M. (1975). What do we gain from the sixth stool guaiac?. *New England Journal of Medicine*, *293*(5), 226-228.

Newell, J. N., Baral, S. C., Pande, S. B., Bam, D. S. and Malla, P. (2006). Family-member DOTS and community DOTS for tuberculosis control in Nepal: cluster-randomised controlled trial. *The Lancet*, *367*(9514), 903-909.

Nuwaha, F. (1999). Control of tuberculosis in Uganda: a tale of two districts. *The International Journal of Tuberculosis and Lung Disease*, *3*(3), 224-230.

Nyirenda, T. E., Harries, A. D., Gausi, F., Van Gorkom, J., Maher, D., Floyd, K. and Salaniponi, F. M. (2003). Decentralisation of tuberculosis services in an urban setting, Lilongwe, Malawi. *The International Journal of Tuberculosis and Lung Disease*, *7*(9s1), S21-S28.

Nyonator, F. K., Awoonor-Williams, J. K., Phillips, J. F., Jones, T. C. and Miller, R. A. (2005). The Ghana community-based health planning and services initiative for scaling up service delivery innovation. *Health policy and planning*, *20*(1), 25-34.

Okanurak, K. and Ruebush , T. K. (1996). Village-based diagnosis and treatment of malaria. *Acta Tropica*, *61*(2), 157-167.

Orleans, C. T., Schoenbach, V. J., Wagner, E. H., Quade, D., Salmon, M. A., Pearson, D. C. and Kaplan, B. H. (1991). Self-help quit smoking interventions: effects of self-help materials, social support instructions, and telephone counseling. *Journal of consulting and clinical psychology*, *59*(3), 439.

Owen, N. and Brown, S. L. (1991). Smokers unlikely to quit. *Journal of behavioral medicine*, *14*(6), 627-636.

Pendley, J. S., Kasmen, L. J., Miller, D. L., Donze, J., Swenson, C. and Reeves, G. (2002). Peer and family support in children and adolescents with type 1 diabetes. *Journal of pediatric psychology*, *27*(5), 429-438.

Petrie, K. J. and Wessely, S. (2002). Modern worries, new technology, and medicine. *BMJ, British Medical Journal 324*(7339), 690-691.

Rand, C. S. (1993). Measuring adherence with therapy for chronic diseases: implications for the treatment of heterozygous familial hypercholesterolemia. *The American journal of cardiology*, *72*(10), D68-D74.

Rayman, R. B. (1988). Health promotion: a perspective. *Aviation, space, and environmental medicine*, *59*(4), 379-381.

Reynolds, N. R., Testa, M. A., Marc, L. G., Chesney, M. A., Neidig, J. L., Smith, S. R. and Robbins, G. K. (2004). Factors influencing medication adherence beliefs and self-efficacy in persons naive to antiretroviral therapy: a multicenter, cross-sectional study. *AIDS and Behavior*, *8*(2), 141-150.

Roberts, K. J. (2000). Barriers to and facilitators of HIV-positive patients' adherence to antiretroviral treatment regimens. *Aids patient care and STDs*,*14*(3), 155-168.

Rose, L. E., Kim, M. T., Dennison, C. R. and Hill, M. N. (2000). The contexts of adherence for African Americans with high blood pressure. *Journal of advanced nursing*, *32*(3), 587-594.

Sabaté, E. (2003). In *Adherence to long-term therapies: evidence for action*. World Health Organization.

Sackett, D. L., Haynes, R. B., Gibson, E. S., Taylor, D. W., Roberts, R. S. and Johnson, A. L. (1978). Patient compliance with antihypertensive regimens. *Patient counselling and health education*, *1*(1), 18-21.

Sarquis, L. M. M., Dell'acqua, M. C., Gallani, M. C., Moreira, R. M., Bocchi, S. C., Tase, T. H. and Pierin, A. M. (1998). Compliance in antihypertensive therapy: analyses in scientific articles. *Revista da Escola de Enfermagem da USP*, *32*(4), 335-353.

San Sebastian, M. and Bothamley, G. H. (2000). Tuberculosis preventive therapy: perspective from a multi-ethnic community. *Respiratory medicine*,*94*(7), 648-653.

Shargie, E. B. and Lindtjørn, B. (2007). Determinants of treatment adherence among smear-positive pulmonary tuberculosis patients in Southern Ethiopia.*PLoS Med*, *4*(2), e37.

Snider Jr, D. E. (1982). An overview of compliance in tuberculosis treatment programmes. *Bulletin of International Union against Tuberculosis and Lung Disease*, 57(3-4), 247-252.

Softkenya. (2013). *Counties in Kenya*. Retrieved from Softkenya All About Kenya: http://softkenya.com/county/counties-in-kenya. Accessed 15 November 2015

Sonnenberg, A. (2001). Cost-Effectiveness of Screening for Colorectal Cancer. *Annals of Internal Medicine*, *135*(3), 219-219.

Spire, B., Duran, S., Souville, M., Leport, C., Raffi, F. and Moatti, J. P. (2002). Adherence to highly active antiretroviral therapies (HAART) in HIV-infected patients: from a predictive to a dynamic approach. *Social science and medicine*, *54*(10), 1481-1496.

Stanton, A. L. (1987). Determinants of adherence to medical regimens by hypertensive patients. *Journal of behavioral medicine*, *10*(4), 377-394.

Statistics Canada. (2010). *Survey Methods and Practices. Statistics Canada,*. Catalogue no. 12-587-X.

Steffens, B. (2000). Cost-effective management of type 2 diabetes: providing quality care in a cost-constrained environment. *The American journal of managed care*, *6*(13 Suppl), S697-703.

Stein, M. D., Rich, J. D., Maksad, J., Chen, M. H., Hu, P., Sobota, M. and Clarke, J. (2000). Adherence to Antiretroviral Therapy Among HIV-Infected Methadone

Patients: Effect of Ongoing Illicit Drug Use*. *The American journal of drug and alcohol abuse*, *26*(2), 195-205.

Stibich, M. (2009). *Disability Adjusted Life Years - DALYs - Measuring Suffering*. Retrieved from URL: http://longevity.about.com/od/longevity101/g/dalys.htm

Stop TB Partnership. (2014). Retrieved August from www.stoptb.org/gdf/drugsupply

Sumartojo, E. (1993). When tuberculosis treatment fails: a social behavorial account of patient adherence. *American Review of Respiratory Diseases*, *147*, 1311-1320.

Taylor, G. H., Wilson, S. L. and Sharp, J. (2011). Medical, psychological, and sociodemographic factors associated with adherence to cardiac rehabilitation programs: a systematic review. *Journal of Cardiovascular Nursing*, *26*(3), 202-209.

Tekle, B., Mariam, D. and Ali, A. (2002). Defaulting from DOTS and its determinants in three districts of Arsi Zone in Ethiopia. *The International Journal of Tuberculosis and Lung Disease*, *6*(7), 573-579.

Tiemersma, E., van der Werf, M., Borgodorff, M., William , B. and Neglekerke, N. (2011). Natural history of tuberculosis: duration and fatality of untreated pulmonary tuberculosis in HIV negative patients: A systematic review. *PLoS ONE, 6*(4), e17601.

Trading Economics. (2014). *Kenya GDP per capita*. Retrieved from http://www.tradingeconomics.com/kenya/gdp-per-capita

Tuldrà, A., Fumaz, C. R., Ferrer, M. J., Bayés, R., Arnó, A., Balagué, M. and Ruiz, L. (2000). Prospective randomized two-Arm controlled study to determine the efficacy of a specific intervention to improve long-term adherence to highly

active antiretroviral therapy. *Journal of acquired immune deficiency syndromes (1999), 25*(3), 221-228.

Urquhart, J. (1996). Patient non-compliance with drug regimens: measurement, clinical correlates, economic impact. *European heart journal*,*17*(suppl A), 8-15.

Wahl, L. M. and Nowak, M. A. (2000). Adherence and drug resistance: predictions for therapy outcome. *Proceedings of the Royal Society of London-Series B: Biological Sciences*, *267*(1445), 835-843.

Walsh, S., Hagan, T. and Gamsu, D. (2000). Rescuer and rescued: Applying a cognitive analytic perspective to explore the 'mis-management'of asthma.*British Journal of Medical Psychology*, *73*(2), 151-168.

Webb, D. G., Horne, R. and Pinching, A. J. (2001). Treatment-related empowerment: preliminary evaluation of a new measure in patients with advanced HIV disease. *International journal of STD and AIDS*, *12*(2), 103-107.

Weishut, D. J. (1996). [Coping with AIDS in a support group--an encounter with the health system]. *[Hebrew] Harefuah*, *130*(8), 521-523

WHO (1994). *Framework for Effective Tuberculosis Control.* Geneva: WHO.

WHO (1989). *Strengthening the performance of community health workers in primary health care. Report of a WHO Study Group. Technical Series 780.* Geneva: WHO.

WHO (2001). *Macroeconomics and Health: Investing in Health for Economic Development – Report of the Commission on Macroeconomics and Health.* Geneva:WHO.

WHO (2002a). *An Expanded DOTS Framework for Effective Tuberculosis Control.* Geneva, Switzerland., WHO/CDS/TB/2002.297.

WHO (2002b). *The World Health Report, Reducing Risks, Promoting Healthy Life.* Geneva:WHO.

WHO (2005). *WHO declares TB an emergency in Africa.* Geneva:WHO.

WHO (2007). *Global tuberculosis control-surveillance, planning, financing.* Geneva:WHO.

WHO (2009). *WHO Disease and Injury estimates.* Geneva:WHO.

WHO (2010). *Global burden of disease (GBD).* Retrieved from http://www.who.int/healthinfo/global_burden_disease/en/index.html.

WHO (2013). *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection.* Geneva:WHO.

WHO (2014). *Global Tuberculosis Report.* Geneva: World Health Organisation.

WHO (2014). *The use of co-trimoxazole prophylaxis.* Retrieved from http://www.who.int/hiv/pub/guidelines/arv2013/December2014-ARVsupplement-chap8.

WHO (2015a). *Global Tuberculosis Report.* Geneva: World Health Organisation.

WHO (2015b). *Multi-Drug Resistance Tuberculosis Update.* Retrieved from http://www.who.int/tb/challenges/mdr/mdr_tb_factsheet.pdf.

WHO (2016). *Tuberculosis.* Retrieved from http://www.who.int/mediacentre/factsheets/fs104/en/.

Winch, P. J., Gilroy, K. E., Wolfheim, C., Starbuck, E. S., Young, M. W., Walker, L. D. and Black, R. E. (2005). Intervention models for the management of children with signs of pneumonia or malaria by community health workers. *Health policy and planning*, *20*(4), 199-212.

World Health Organization. Mental Health Evidence, Research Team, and Disease Control Priorities Project. (2006). *Disease control priorities related to mental, neurological, developmental and substance abuse disorders.* Geneva: World Health Organization.

Yach, D. (1988). Tuberculosis in the Western Cape health region of South Africa. *Social Science and Medicine*, *27*(7), 683-689.

Yassin, K. and Galan, A. (2004). In *Inequalities in Health as Assessed by the Burden of Disease Method -Case Study.* (pp. 163-9). Lage: Hans Jacobs Publishing Company.

Zivin, K. and Kales, H. C. (2008). Adherence to depression treatment in older adults : a narrative review. *Drugs and aging*, *25*(7), 559-571.

Zvavamwe, Z. and Ehlers, V. J. (2009). Experiences of a community-based tuberculosis treatment programme in Namibia: a comparative cohort study. *International journal of nursing studies*, *46*(3), 302-309.

APPENDICES

Appendix 1:   **Informed Consent Explanation for TB Patient**

Title of Study:

Treatment Adherence and Cost Effectiveness of Utilising Community Health Workers in the Management of Tuberculosis in Kenya

Introduction:

My name is _____from KEMRI. I am here to gather information from you, which will help us define the benefit of utilising Community Health Workers (CHWs) during your TB treatment period.

Purpose of Study:

In the provision of TB treatment some health facilities utilize CHWs to support TB patients to adhere to the treatment. The form of support given to the TB patients is in the form of providing health education, supervision of the patient taking the anti-TB drugs and tracing patients who may have defaulted from treatment. In addition to this, when the TB patient attends the TB clinic days, the CHW assists the nurse to efficiently attend to TB patients. This study will assess the cost effectiveness of utilizing the CHWs versus not utilizing them for treatment adherence.

Procedure to be followed:

You have been diagnosed with TB and are commencing treatment. During your treatment you will either have a CHW to support you adhere to treatment or not. If you accept to participate in this study you will be asked a few questions about your condition by the TB nurse. Each time you will be attending your follow-up schedule you will answer a few questions on the same until you complete your treatment.

86

Risks:

Efforts will be taken to maintain confidentiality so that risks of disclosing the information you have given us will be fully minimized. All data collected will be handled confidentially and no names will be included in the report. The data will be stored in computers with passwords and hard copies will be kept in lockable cabinets that have authorised access to the investigators only.

Benefits:

There will be no direct benefit to you for your participation. But your contribution will help us to better understand and interpret issues that will go a long way in improving the management of TB. You will receive the standard TB treatment with either the support of CHW or without the support of the CHW.

Assurance of confidentiality:

All the answers you have provided us will be handled confidentially. Your identity will not be disclosed in any public reports or publications or to any other parties.

Storage of data:

Records relating to your participation in the study will be stored at KEMRI for analysis. Access to these records will only be to the investigators.

Right to refuse or withdraw:

Your participation is voluntary. You may wish to withdraw from this study at any time without any penalty. You would still receive your complete TB treatment.

Subject: If during the course of this study you have any questions concerning the nature of this research you should contact Dr Jane Ong'ang'o, P.O.Box 47855-00100, Nairobi.

Telephone Number: 0202724264 or 0722 733829

If in case you have a question concerning your rights of participation, you should contact; The Secretary, KEMRI/National Ethical Review Committee, P.O.Box 54840-00200, Nairobi.

Telephone Number: 0202722541

I _____ have read/been read to the information shown above and had the opportunity to ask questions and all were answered satisfactorily. I hereby give consent for my participation as explained to me.

Study participant's name: _____

Sign: _____

Date: _____

Name of Investigator/supervisor/nurse: _____

Sign: _____

Date: _____

Maelezo Juu ya Idhini ya Kushiriki kwa Mgonjwa wa Kifua Kikuu

Anwani ya uchunguzi

Utumizi wa wahudumu wa afya wa jamii kwenye usimamizi wa Kifua Kikuu nchini Kenya: Uchunguzi wa Gharama ya uwezekano.

Utangulizi

Jina langu ni Jane Ong'ang'o mkunga wa Kifua Kikuu kutoka KEMRI. Nipo hapa kuchukuwa taarifa kutoka kwako ambayo itatusaidia kutafuta umuhimu wa kutumika kwa wahudumu wa afya kwenye jamii wakati utakaotibiwa kifua kikuu.

Kusudi la uchunguzi

Kwenye matibabu ya kifua kikuu baadhi ya zahanati zinatumia wahudumu wa afya wa jamii kusaidia wagonjwa wa kifua kikuu kufuatilia matibabu. Hali ya usaidizi iliyotolewa kwa wagonjwa wa kifua kikuu iko kwenye kutolewa kwa mafunzo ya afya, usimamizi wa wagonjwa wachukuwe madawa ya kukinga kifua kikuu na kutafuta wagonjwa ambao huenda waliwacha matibabu. Kuongezea hii, wakati mgonjwa wa kifua kikuu anahudhuria siku za kliniki, mhudumu wa afya wa jamii anasaidia mkunga kumhudumia wagonjwa wa kifua kikuu. Uchunguzi huu utabaini uwezekano wa kutumia wahudumu wa afya ya jamii dhidi ya kutowatumia kwa kufuatilia matibabu.

Hatua za kufuatwa

Umechunguzwa kuhusu kifua kikuu na unaanza matibabu. Wakati wa matibabu yako utakuwa na mhudumu wa afya wa jamii kukusaidia ufuatilie matibabu au la. Ukikubali kushiriki kwenye uchunguzi huu utaulizwa maswali chache kuhusu hali yako na mkunga wa kifua kikuu. Kila mara utakapohudhuria utaratibu wako utajibu maswali chache kuhusu hiyo hadi ukamilishe matibabu yako.

Hatari

Hatua itachukuliwa kuhifadhi siri ili hatari ya kutambulika kwa taarifa uliyotupatia itapunguzwa kabisa. Taarifa zote zilizochukuliwa zitachukuliwa kwa siri na hakuna majina yatakayotumika kwa ripoti. Taarifa zitahifadhiwa kwenye tarakilishi zikiwa na hifadhi maalum na nakala ya karatasi zitahifadhiwa kwenye kabati za kufungwa ambazo zitafikiwa na wachunguzi pekee.

Manufaa

Hakutakuwa na manufaa za moja kwa moja kwa kushiriki kwako. Lakini mchango wako utatusaidia kuelewa zaidi na kutafsiri masuala yatakayoelekea kuboresha usimamizi wa Kifua Kikuu. Utapokea matibabu kamili ya Kifua Kikuu kwa ushirikiano wa CHW au bila ushirikiano wao.

Hakikisho la kuhifadhi siri

Majibu uliyotupatia yatachukuliwa kwa siri. Hutatambulika kwa taarifa yo yote ama nakala ama kwa makundi yo yote.

Kuhifadhiwa kwa taarifa

Hifadhi zako zinazohusiana na kushiriki kwako kwenye uchunguzi huu zitahifadhiwa KEMRI kwa uchunguzi zaidi. Kufikiwa kwa hifadhi hizo zitakuwa tu kwa wachunguzi.

Haki yako ya kukataa au kujiondosha

Kushiriki kwako ni kwa hiari. Unaweza kujiondoa kwa uchunguzi huu kwa wakati wo wote bila adhabu yo yote. Utaendelea kupokea matibabu yako yote ya Kifua Kikuu.

Mada

Iwapo kwenye wakati wa uchunguzi huu uko na maswali yo yote kuhusiana na hali ya utafiti huu wapaswa kuwasiliana na Daktari Jane Ong'ang'o, S.L.P. 47855-00100, Nairobi.

Nambari ya simu: 0202724264 au 0722 733829

Iwapo kwa sababu Fulani uko na swali kuhusiana na haki ya kushiriki, wasiliana na: Katibu Mkuu, KEMRI/Kamati Kuu ya Kitaifa ya Uchunguzi wa Masuala ya Siri, S.L.P. 54840-00200, Nairobi.

Mimi _____ nimesoma/kusomewa taarifa iliyo hapo juu na kupata fursa ya kuuliza maswali na yote yakajibiwa yapasayo. Ninatoa idhini ya kushiriki kwangu nilivyoelezwa hapo.

Jina la mshiriki wa uchunguzi: _____

sahihi: _____

Tarehe: _____

Jina la mchunguzi/msimamizi/mkunga: _____

sahihi: _____

tarehe: _____

Appendix 2:   **Data Collection Tool for Prospective Study**

(to be used by the TB nurse to extract information on the TB patient from the TB treatment register)

Date of Enrollment: _____ **Patient Study ID Number** _____

1. Clinic: _____

2. Name: _____

3. Age (years): _____

4. Sex: 1: Male   2: Female

5. Body Weight (Kg): _____

6. Date of start of treatment: _____

7. TB Registration Number: _____

8. Family Treatment Supporter: 1: Yes   2: No

9. Disease Classification: 1: Pulmonary Smear Positive

                            2: Pulmonary Smear Negative

                            3: Extrapulmonary (specify) _____

10. Patient Classification: 1: New   2: Smear Positive Relapse   3: Smear Neg/EP
    Relapse 4: Failure   5: Treatment resumed after default   6: Transfer in.

11. Short Course Chemotherapy Regime: 1: 2RHZE/4RH

                                    2: 2SRHZE/1RHZE/5RHE

12. Sputum Smear examination results on start of treatment: 1: Positive   2: Negative
    3: Not applicable   4: Other (specify) _____

13. Chest x-ray done: 1: Yes   2: No

14. FBC: 1: Yes   2: No

15. Results of FBC: _____

16. Patient referred by: 1. VCT centre   2: HIV care clinic   3: Home Based Care

　　4: Ante-Natal Clinic   5: Private Sector   6: Self- Referral

　　7: Self- Referral   8: Contact Invitation

17. Patient Referred to: 1. VCT centre   2: HIV care clinic   3: Home Based Care

　　4: Ante-Natal Clinic   5: Private sector   6: chemist/pharmacist.

18. Accepted HIV screening: 1: Yes   2: No

19. If Yes to above, what is the HIV test result: 1: Positive   2: Negative

20. If No to Q18 what is the reason for not accepting HIV screening?   1. Will be screened later during TB treatment   2: Not Ready. 3: Other reason (specify) _____

21. If HIV positive, is patient on CPT? 1: Yes   2: No

22. If Yes to Q21, date CPT was started: _____

23. If HIV positive, CD4 count on initiating TB treatment: _____

24. If HIV positive, is patient on ART?   1: Yes   2: No

25. If Yes to Q24, date ART was started: _____

26. ART Regimen: _____

27. Date of next appointment: _____

Data Collection Tool: Follow-up *(to be filled by the TB nurse by asking the TB patient on each follow-up visit)*

Schedule of follow-up: Week: 1, 2, 3, 4, 5, 6, 7, 8, Other(specify) _____

Month: 3, 4, 5, 6 Other (specify) _____

Date: _____

 1. Any current medical signs and symptoms?   1: Yes   2: No

2. If Yes to above, list the signs and symptoms: _____

_____

_____

3. Has the patient missed taking his/her anti-TB drugs in the last seven days?

   1: Yes   2: No

4. If Yes to above, how many days did he/she miss taking the drugs? 1: 1 day

   2: 2 days   3: 3 days   4: 4 days   5: 5 days   6: 6 days

   7: 7 days and above

5. Specify the reason for missing to take drugs: 1: Forgot   2: Felt too ill

   3: Travelled without the drugs   4: side effects   5: Lost his/her medicine
   6: clinic ran out of TB drugs   7: patient ran out of drugs

   8: Other reason (specify) _____

Kiungo cha kuchukua cha Kufuatia (kujazwa na mkunga wa Kifua Kikuu kwa kuuliza mgonjwa wa Kifua Kikuu kila anapozuru)

Utaratibu wa kuzuru: juma: 1, 2, 3, 4, 5, 6, 7, 8, (zingine, taja) _____

mwezi: 3, 4, 5, 6 (zingine, taja) _____

Date (tarehe): _____

1. Kwa sasa zipo ishara au dalili zo zote? 1: Ndiyo   2: La

2. Iwapo ndiyo, taja ishara na dalili zenyewe:

_____

_____

3. Mgonjwa amekosa kuchukua dawa za kukabiliana na Kifua Kikuu kwa siku saba zilizopita?

     1: Ndiyo   2: La

4. Iwapo ndiyo hapo juu, alikosa kwa siku ngapi kuchukua dawa?

     1:siku moja   2: siku mbili   3:siku tatu

     4: siku nne   5:siku tano   6: siku sita

     7: siku saba na kuendelea

5. Taja sababu ya kukosa kuchukua dawa

     1: Kusahau   2: Hisi kuwa mgonja sana   3: Kusafiri bila dawa

     4: Madhara ya kando 5:Kupoteza dawa zake   6: Dawa kuisha kwa kliniki
     7: Kuisha kwa daw kwa mgonjwa

8: sababu nyingine _____

Investigations done in follow-up visit. *(information will be extracted from the TB treatment register by the TB nurse).*

6. Sputum Smear examination: 1: Yes   2: No

7. If Yes to above, result of test: 1: Positive   2: Negative

8. FBC: 1: Yes   2: No

9. Results of FBC: _____

_____

10. HIV screening: 1: Yes   2: No   3. Done in Previous visit

11. If Yes to above, what is the HIV test result: 1: Positive   2: Negative

12.If No to Q10 what is the reason for not accepting HIV screening?

   1: Will be screened later during TB treatment   2: Not Ready.

   3: Other reason (specify) _____

13 If HIV positive, is patient on CPT? 1: Yes   2: No

14 If Yes to Q13, date CPT was started: _____

15.If HIV positive, what is the current CD 4 count? _____ .

16. If HIV positive, is patient on ART?   1: Yes   2: No

17. If Yes to Q16, date ART was started: _____

18. ART Regimen: _____

19. Fill table below at appropriate follow-up schedule

Treatment outcome	Date
Cured	
Treatment Completed	
Failure	
Died	
Defaulted	
Transferred out	

Appendix 3: **Data Collection Tool for Retrospective Study**

(This information will be extracted from the TB treatment registers)

Variable/Measure	
Patient study ID	
Age	
Sex	
Body Weight	
Start of TB Treatment date	
TB registration Number	
Family Rx Supporter Y/N	
Disease Classification	
Treatment Regime	
Sputum Smear result	
CXR done Y/N	
Full Blood count Y/N/ ND	
Referred to clinic by	
HIV Screened Y/N	
HIV Status positive/negative	
CPT Y/N	
ART Y/N/ NA	
ART date of initiation	
Follow-up scheduled appointments as planned; Y/N Weeks 1,2,3,4,5,6,7,8. Months 3,4,5,6	
Treatment outcome;	

Appendix 4:   **Informed Consent for Focus Group Discussion**

Title of Study:

Treatment Adherence and Cost Effectiveness of Utilising Community Health Workers in the Management of Tuberculosis in Kenya

Introduction:

My name is _____ from KEMRI. I am here to gather information from you, which will help us define the benefit of utilising Community Health Workers (CHWs) during the TB treatment period.

Purpose of Study:

In the provision of TB treatment some health facilities utilize CHWs to support TB patients to adhere to the treatment. The form of support given to the TB patients is in the form of providing health education, supervision of the patient taking the anti-TB drugs and tracing patients who may have defaulted from treatment. In addition to this, when the TB patient attends the TB clinic days, the CHW assists the nurse to efficiently attend to TB patients. This study will assess the cost effectiveness of utilizing the CHWs versus not utilizing them for treatment adherence and also through discussion the study will establish some of the processes entailed in utilising the CHWs.

Procedure for group discussion.

A group of 8- 10 CHWs or TB patients shall be gathered together so that a discussion on issues related to utilising CHWs to support TB treatment is held. The discussion will take about 1 hour. As the discussion will be going on it will be audio recorded using a digital recorder and hand written by one of the research assistants. During the discussion you will be encouraged to share out your ideas freely, because all information collected will be treated as group contribution and this may help us in the management of TB.

99

Risks:

Efforts will be taken to maintain confidentiality so that risks of disclosing the information you have given us will be fully minimized. All data collected will be handled confidentially and no names will be included in the report. The data will be stored in computers with passwords and hard copies will be kept in lockable cabinets that have authorised access to the investigators only.

Benefits:

There will be no direct benefit to you for your participation. But your contribution will help us to better understand and interpret issues that will go a long way in improving the management of TB.

Assurance of confidentiality:

All the answers you have provided us will be handled confidentially. Your identity will not be disclosed in any public reports or publications or to any other parties.

Storage of data:

Records relating to your participation in the study will be stored at KEMRI for analysis. Access to these records will only be to the investigators.

Right to refuse or withdraw:

Your participation is voluntary. You may wish to withdraw from the discussion at any time without any penalty.

Subject: If during the course of this study you have any questions concerning the nature of this research you should contact Dr Jane Ong'ang'o, P.O.Box 47855-00100, Nairobi.

Telephone Number: 0202724264 or 0722 733829

If in case you have a question concerning your rights of participation, you should contact; The Secretary, KEMRI/National Ethical Review Committee, P.O.Box 54840-00200, Nairobi.

Telephone Number: 0202722541

I _____ have read/been read to the information shown above and had the opportunity to ask questions and all were answered satisfactorily. I hereby give consent for my participation as explained to me.

Study participant's name: _____

Sign: _____

Date: _____

Name of Investigator/supervisor/nurse: _____

Sign: _____

Date: _____

Idhini ya Kushiriki kwa Mazungumzo ya Kikundi.

Anwani ya uchunguzi

Utumizi wa wahudumu wa afya wa jamii kwenye usimamizi wa Kifua Kikuu nchini Kenya: Uchunguzi wa Gharama ya uwezekano.

Utangulizi

Jina langu ni Jane Ong'ang'o mkunga wa Kifua Kikuu kutoka KEMRI. Nipo hapa kuchukuwa taarifa kutoka kwako ambayo itatusaidia kutafuta umuhimu wa kutumika kwa wahudumu wa afya kwenye jamii wakati utakaotibiwa kifua kikuu.

Kusudi la uchunguzi

Kwenye matibabu ya kifua kikuu baadhi ya zahanati zinatumia wahudumu wa afya wa jamii kusaidia wagonjwa wa kifua kikuu kufuatilia matibabu. Hali ya usaidizi iliyotolewa kwa wagonjwa wa kifua kikuu iko kwenye kutolewa kwa mafunzo ya afya, usimamizi wa wagonjwa wachukuwe madawa ya kukinga kifua kikuu na kutafuta wagonjwa ambao huenda waliwacha matibabu. Kuongezea hii, wakati mgonjwa wa kifua kikuu anahudhuria siku za kliniki, mhudumu wa afya wa jamii anasaidia mkunga kumhudumia wagonjwa wa kifua kikuu. Uchunguzi huu utabaini uwezekano wa kutumia wahudumu wa afya ya jamii dhidi ya kutowatumia kwa kufuatilia matibabu na pia kupitia mazungumzo uchunguzi utabaini baadhi ya hatua zilizoko kwenye utumizi wa wahudumu wa afya wa jamii.

Hatua za mazungumzo ya kikundi.

Makundi ya baina ya wahudumu 8-10 wa afya wa jamii au wagonjwa wa Kifua Kikuu yataletwa pamoja ili mazungumzo ya masuala yanayohusiana na utumizi wa wahudumu wa afya wa jamii kusaidia matibabu ya kifua kikuu yafanyike. Mazungumzo yatachukuwa karibu saa 1. Mazungumzo yakiendelea, yatarekodiwa kutumia chombo

102

maalum na kunakiliwa na mmoja wa wasaidizi wa utafiti. Wakati wa mazungumzo utahimizwa kubadilisha maoni yako bila vikwazo kwa sababu taarifa zote zitakazochukuliwa zitapokelewa kama mchango wa kundi nah ii huenda ikatusaidia kwenye usimamizi wa kifua kikuu.

Hatari

Hatua itachukuliwa kuhifadhi siri ili hatari ya kutambulika kwa taarifa uliyotupatia itapunguzwa kabisa. Taarifa zote zilizochukuliwa zitachukuliwa kwa siri na hakuna majina yatakayotumika kwa ripoti. Taarifa zitahifadhiwa kwenye tarakilishi zikiwa na hifadhi maalum na nakala ya karatasi zitahifadhiwa kwenye kabati za kufungwa ambazo zitafikiwa na wachunguzi pekee.

Manufaa

Hakutakuwa na manufaa za moja kwa moja kwa kushiriki kwako. Lakini mchango wako utatusaidia kuelewa zaidi na kutafsiri masuala yatakayoelekea kuboresha usimamizi wa Kifua Kikuu. Utapokea matibabu kamili ya Kifua Kikuu kwa ushirikiano wa CHW au bila ushirikiano wao.

Hakikisho la kuhifadhi siri

Majibu uliyotupatia yatachukuliwa kwa siri. Hutatambulika kwa taarifa yo yote ama nakala ama kwa makundi yo yote.

Kuhifadhiwa kwa taarifa

Hifadhi zako zinazohusiana na kushiriki kwako kwenye uchunguzi huu zitahifadhiwa KEMRI kwa uchunguzi zaidi. Kufikiwa kwa hifadhi hizo zitakuwa tu kwa wachunguzi.

Haki yako ya kukataa au kujiondosha

Kushiriki kwako ni kwa hiari. Unaweza kujiondoa kwa uchunguzi huu kwa wakati wo wote bila adhabu yo yote. Utaendelea kupokea matibabu yako yote ya Kifua Kikuu.

Mada

Iwapo kwenye wakati wa uchunguzi huu uko na maswali yo yote kuhusiana na hali ya utafiti huu wapaswa kuwasiliana na Daktari Jane Ong'ang'o, S.L.P. 47855-00100, Nairobi.

Nambari ya simu: 0202724264 au 0722 733829

Iwapo kwa sababu Fulani uko na swali kuhusiana na haki ya kushiriki, wasiliana na: Katibu Mkuu, KEMRI/Kamati Kuu ya Kitaifa ya Uchunguzi wa Masuala ya Siri, S.L.P. 54840-00200, Nairobi.

Mimi _____ nimesoma/kusomewa taarifa iliyo hapo juu na kupata fursa ya kuuliza maswali na yote yakajibiwa yapasayo. Ninatoa idhini ya kushiriki kwangu nilivyoelezwa hapo.

Jina la mshiriki wa uchunguzi: _____, sahihi: _____

Tarehe: _____

Jina la mchunguzi/msimamizi/mkunga: _____, sahihi:_____

Tarehe: _____

Appendix 5: Guidelines for Focus Group Discussions (TB Patients and CHWs)

My name is _____ from KEMRI. I would like to welcome you all to this participatory group discussion and thank you all for coming. Our discussion will be about utilising CHWs in providing TB care. I encourage you to share out your ideas freely, because all information collected will be treated as group contribution and this may help us in the management of TB.

With me are _____ and _____ who will help me record the points as you air them. We also have a tape recorder to record the discussion in case any point misses our ears. This will help in the analysis and writing of the report.

Name of assistant moderators;

1. _____

2. _____

Date of FGD _____   Time FGD started _____

Venue _____   Time FGD ended _____

Number recruited for FGD _____   Number attended FGD _____

FGD Target group _____

1. What do you understand by the term Community Health Worker?

    Explore - various definitions

    - recruitment of CHWs or the best candidates for this role.
    - What duties are they expected to do.
    - In which health conditions could they be utilised.

-        How best could they be rewarded or motivated.

2. Are they useful in the management of disease.

Explore – what is considered useful.

-        the benefits in utilising CHWs in TB care.

3. Health Facility TB care and Community TB care.

Explore – the necessity to link health facility care with community care in the management of TB.

4. Costs incurred by CHWs involved in TB care. *(this section will be administered to the FGDs for CHWs only).*

-What kind of incentive is provided to the CHW? What is the cost of this incentive? How frequently is it provided?

- What is the estimated time spent supervising therapy in a home?

- On average how many home visits does each CHW make per month?

- How much time does a CHW spent at the TB clinic day?

- What proportion of a CHW's time is spent on defaulter tracing per month?

- How much time is spent to provide support supervision to the CHWs?

- How much time is spent by a CHW to make monthly reports?

- What proportion of time is spent at DOT training sessions, including continuous education forums?

This will be used to estimate the average cost per patient that a CHW

incurs when they are involved in TB treatment.

Similar questions will be administered to the nurses who supervise the CHWs in the In-depth interviews as a way to verify the answers provided by the CHWs.

Conclusion. It has been a wonderful discussion indeed. I would like to thank you for your contribution which will be helpful in the writing of the research report and in turn in the management of TB. Before we end the discussion, is there anyone who would like to make any final comment?

Mwongozo wa Mazungumzo ya Kikundi. (Wagonjwa wa Kifua Kikuu na Wahudumu wa Afya wa Jamii)

Jina langu ni _____ kutoka KEMRI. Ningependa kuwakaribisha nyote kwa mazungumzo haya ya kushiriki na kuwashukuru nyote kwa kuja kwenu. Mazungumzo yetu yatakuwa juu ya utumizi wa wahudumu wa afya wa jamii kwa kuwapa uangalizi wa kifua kikuu. Nawahimiza kubadilisha maono yenu wazi kwa sababu taarifa yote itakayochukuliwa itapokelewa kama mchango wa kikundi na hii huweza ikatusaidia kwenye usimamizi wa kifua kikuu.

Pamoja nami ni _____ na _____ watakonisaidia kunakili hoja zitakazojitokeza. Pia, tuna chombo cha kunasa sauti cha kunasa mazungumzo endapo hoja itatupita. Hii itasaidia kwenye kutathmini na kwenye kuandika ripoti.

Majina ya wasaidizi wa mjadala;

1. _____
2. _____

Tarehe ya kufanyika kwa mazungumzo _____

Saa ya kuanza mazungumzo _____

Pahali pa kufanyia mazungumzo _____

Saa ya kumaliza mazungmzo _____

Idadi ya watu kwenye mazungumzo _____

Idadi ya waliohudhuria mazungumzo _____

Kundi lililolengwa kwa mazungumzo _____

108

1. Waelewa nini kwa neno mhudumu wa afya wa jamii?
    a. Dadizi - maana tofauti
    b. kusajiliwa kwa wahudumu wa afya au mhudumu mzuri kwa jukumu hili).
    c. Ni wajibu gani wanayotarajiwa kufanya.
    d. Waweza kutumika kwa hali gani za afya.
    e. wawezaje kuwatunuku au kuwatia motisha.
2. Zina manufaa kwenye usimamizi wa ugonjwa?.
    a. Dadizi –kinachotiliwa manufaa.
    b. umuhimu wa utumizi wa wahudumu wa afya wa jamii katika uangalizi wa kifua kikuu.
3. Uangalizi wa kifua kikuu kwenye kituo cha afya na uangalizi wa afya kwenye jamii.
    a. Dadizi –haja ya kujumuisha uangalizi wa kituo cha afya na uangalizi wa jamii kwenye usimamizi wa kifua kikuu.
4. Gharama inayotokana na kushiriki kwa wahudumu wa afya wa jamii katika uangalizi wa kifua kikuu. **(sehemu hii itatumika kwenye mazungumzo ya kikundi cha wahudumu wa afya wa jamii pekee).**

Ni kiinua mgongo gani inayotolewa kwa mhudumu wa afya wa jamii? Ni gharama gani inayotolewa? Huwa inatoloewa mara ngapi?

Huchukuwa takriba muda gani kusimamia huduma hii nyumbani?

Ni kama ziara ngapi za kufuatwa nyumbani hufanywa na mhudumu wa afya wa jamii kwa mwezi?

Ni muda gani unaochukuliwa na mhudumu wa afya wa jamii kwenye siku ya kliniki ya kifua kikuu?

Ni muda gani unaotumika kutoa usaidizi wa kusimamia kwa wahudumu wa afya wa jamii?

Ni muda gani unaochukuliwa na mhudumu wa afya wa jamii kuandika ripoti ya mwezi?

Ni kiasi gani cha muda kinachochukuliwa kwenye kipindi cha mafunzo ya DOT pamoja na fursa ya elimu ya kuendelea?

(Hii itatumika kukadiria gharama ya mgonjwa mmoja ambaye mhudumu wa afya wa jamii anatumia wakati wanashiriki katika matibabu ya kifua kikuu)

Na kufikia hapo ningependa kuwashukuru nyote kwa kushiriki kwenu kwenye mazungumzo haya na kwa kutoa hoja zenu wazi. Asanteni sana.

Appendix 6:   Guidelines for In-Depth Interviews (Nurse)

General Introduction to the interview. My name is _____ from KEMRI. I would like to welcome you to this interview and thank you for coming. Our discussion will be about utilising CHWs in providing TB care. I encourage you to share out your ideas freely, because all information collected may help us in the management of TB.

Name of Respondent _____

Designation of Respondent _____

Date of interview _____

Time started _____   Time ended _____

Interviewer _____

1. What do you understand by the term Community Health Worker?

       Explore - various definitions

      a. recruitment of CHWs or the best candidates for this role.
      b. What duties are they expected to do.
      c. In which health conditions could they be utilised.
      d. How best could they be rewarded or motivated.

2. Are they useful in the management of disease.

       Explore – what is considered useful.

      e. the benefits in utilising CHWs in TB care.

      f.   The experience of the health work if any, working with a CHW. (work definition, reliability, sustainability, documentation of work, achievements, what worked and what did not)

3. Health Facility TB care and Community TB care.

      Explore – the necessity to link health facility care with community care in the management of TB.

      - What supervisory role would you play in guiding a CHW support TB work?

4. Costs incurred by CHWs involved in TB care. *(this section will be administered in the IDIs for Nurses that supervise CHWs only).*

-What kind of incentive is provided to the CHW? What is the cost of this incentive? How frequently is it provided?

- What is the estimated time spent supervising therapy in a home?

- On average how many home visits does each CHW make per month?

- How much time does a CHW spent at the TB clinic day?

- What proportion of a CHW's time is spent on defaulter tracing per month?

- How much time is spent to provide support supervision to the CHWs?

- How much time is spent by a CHW to make monthly reports?

- What proportion of time is spent at DOT training sessions, including continuous education forums?

This will be used to estimate the average cost per patient that a CHW

incurs when they are involved in TB treatment.

Conclusion. This has been a wonderful interview indeed. I have certainly learnt a lot from you and I would like to thank you for sparing your time to attend this interview. Before we end the interview, do you have any final comments to make?

KENYA MEDICAL RESEARCH INSTITUTE

KEMRI/RES/7/3/1   September 23, 2010

TO: DR. JANE ONG'ANG'O,
             PRINCIPAL INVESTIGATOR

THRO':   DR. EVANS AMUKOYE,
             THE DIRECTOR, CRDR,
             NAIROBI

RE: SSC PROTOCOL NO. 1813 (*RE-SUBMISSION*): THE USE OF
             COMMUNITY HEALTH WORKERS IN MANAGEMENT OF
             TUBERCULOSIS IN KENYA: A COST BENEFIT ANALYSIS

Make reference to your letter dated September 7, 2010 received on the same day. Thank you for your response to the issues raised by the Committee. This is to inform you that the issues raised during the 180th meeting of the KEMRI/ERC meeting held on 20th July 2010, have been adequately addressed.

Due consideration has been given to ethical issues and the study is hereby granted approval for implementation effective this **23rd day of September 2010,** for a period of twelve (12) months.

Please note that authorization to conduct this study will automatically expire on **22nd September 2011.** If you plan to continue with data collection or analysis beyond this date, please submit an application for continuing approval to the ERC Secretariat by **4th August 2011**.

You are required to submit any amendments to this protocol and other information pertinent to human participation in this study to the ERC prior to initiation. You may embark on the study.

Yours sincerely,

R. C. KITHINJI,
FOR: SECRETARY,
KEMRI/NATIONAL ETHICS REVIEW COMMITTEE

In Search of Better Health