EFFECTS OF QUALITY MANAGEMENT SYSTEMS ON TREATMENT OF TUBERCULOSIS PATIENTS: A CASE OF KENYA MEDICAL RESEARCH INSTITUTE/CENTRE FOR DISEASE CONTROL AND PREVENTION, KISUMU, KENYA.

BY

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DECLARATION

This research project is my original work and has not been submitted for an award in any other University.

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I dedicate this work to my parents Milka Musau and John Musau for their love and encouragement.

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LIST OF ABBREVIATIONS AND ACRONYMS

CDC – Center for Disease control and prevention

CSO - Civil Society Organization

CTRL- Central Reference Tuberculosis laboratory

DOT - direct observation of treatment

HIV – Human immunodeficiency virus

HMIS- Health Management Information Systems

JOOTRH- Jaramogi Oginga Odinga Teaching and Referral Hospital

KEMRI- Kenya Medical research institute

LQAS - Lot Quality Assurance Sampling

MDGs - Millennium Development Goals

MDR-TB-multidrug-resistant *Mycobacterium tuberculosis*

MTB - Mycobacterium tuberculosis

PDCs - peripheral tuberculosis diagnostic centers

QMS – Quality management systems

RNTCP - Revised National Tuberculosis Control Programme

SLIPTA - Stepwise Laboratory Improvement Towards Accreditation

SPSS- Statistical Package for Social Scientists

STAR-EC - Strengthening TB and HIV & AIDS responses in East Central Uganda

TAT - Turnaround time.

TB – Tuberculosis

WHO - World Health Organization

ABSTRACT

Tuberculosis disease is a global burden ranked eighth highest cause of death and its treatment would be efficient with the presence of Quality management systems in all sectors of Tuberculosis management. It was thus considered important to investigate the effects of Quality management systems on treatment of Tuberculosis. Until 2011, KEMRI/CDC Tuberculosis branch conducted research without clearly outlined quality management systems. The absence of Quality management systems may lead to many challenges like release of delayed results due to inefficient quality systems in diagnosis sector. This may lead to patients going without treatment due to lack of clear diagnosis, unnecessary deaths and continuous infection in the community. The Quality management systems were implemented in the Tuberculosis branch since 2011. The purpose of the study was to investigate the effect of Quality management systems looking at turnaround time, results accuracy, drug inventory, monitoring and evaluation through DOTS and data management on Tuberculosis patient treatment in KEMRI/CDC. Among the objectives that this study investigated included; extent to which Turnaround time, result accuracy, drug inventory, monitoring and evaluation and data management influenced Tuberculosis patient treatment with the research question addressing the level at which they influenced TB treatment. The target population was 200 KEMRI/CDC staff dealing with Tuberculosis patients. The research employed a descriptive cross sectional survey and 133 staff were interviewed. Data was collected using questionnaires administered to the staff dealing with Tuberculosis patients. Pilot-testing was used in making the instrument valid using 13 staff from Jaramogi Oginga Odinga Teaching and Referral Hospital. Data was entered into the computer and analyzed using computer supported software. All questionnaire parameters were entered into the Statistical Package for Social Scientists (SPSS) for results presentation and univariate and bivariate statistics analyzed study data. Study found out time to diagnosis did not affect TB treatment with majority 35(26.3%) taking 3weeks -1 month and completing medication in 6 months. 81(60.9%) of the respondents received smear results in 48 hours, 61(45.9%) received correct results, 76(57.1%) results were complete, 75(56.4%) had routine drug inventory, 72(54.2%) had no expiries in the TB clinics, 85(63.9%) of patients are under follow up, 87(65.5%) are on DOT, 76(57.1%) of the respondents used both electronic and paper or purely electronic and 87(65.4%) were linking patients to the TB registers with all these categories completing TB treatment in a record time of 6 months. The study concluded that a quality management system in KEMRI/CDC TB section had improved treatment of TB patients. The study recommends that other sectors dealing with TB patients especially the public hospital where the TB burden lies, should implement quality management systems to enhance effective TB treatment.

CHAPTER ONE

INTRODUCTION

1.1 Background of the Study

According to World Health Organization`s Global Burden of Disease project, in 2000 TB was the eighth highest cause of death, and the tenth highest cause of disability which adjusted life years (DALYs) (Mathers, 2002). Unlike most other major diseases, with the notable exception of HIV/AIDS, its burden is spread across all age groups and is responsible for the deaths of many productive individuals in the core 15 to 44 age groups (Murray, 1993).More than two billion people, equal to one third of the world population are infected with TB bacilli, and one in ten people infected with TB bacilli become sick with active TB in life (WHO, 2009).

There were 9.4 million new TB cases in 2008 (3.6 million of whom were women), 1.8 million People died of TB in 2008 in which 500,000 people were having HIV-equal to 4,500 deaths a day (WHO, 2009). Twenty two countries were declared as high burdened countries (HBC) with TB, most such Countries are in Africa and Asia, India, China, South Africa, Nigeria and Indonesia which have the highest number of TB cases in the world. Global TB incidence rate was 139 per 100,000 Population in 2008, and Global TB prevalence rate is 164 per 100,000(US Global Health policy, 2010).There were 5.7 million TB case notifications in 2008, and 36 million were cured in DOTS programs (between 1995 and 2008) with as many as 8 million deaths averted through DOTS (WHO, 2008).

According to Brennan *et al* (2009) The U.S. health care system faces significant challenges that clearly indicate the urgent need for reform. There is broad evidence that Americans often do not get the care they need even though the United States spends more money per person on health care than any other nation in the world. Preventive care is underutilized, resulting in higher spending on complex, advanced diseases. Reforming our health care delivery system to improve the quality and value of care is essential to address escalating costs, poor quality, and increasing numbers of Americans without health insurance coverage. Reforms should improve access to the right care at the right time in the right setting. Targeting treatments to the appropriate patients is increasingly important in medical science, and particularly important to promoting quality and value.

As stated by Mori (2009), in Japan health economy, the unprofitability of TB medical services has become more apparent, to the extent that the healthcare community is departing from TB treatment, leading to serious problems such as insufficient beds for TB patients and low clinical capacity levels in some regions. The introduction and expansion of DOTS appears to have improved the quality of TB treatment in Japan. Among other things, the central and local governments should be more clearly committed to the scaling up of quality DOTS in terms of economic incentives to hospitals, as well as the staffing and budgets of Health centers.

As stated by Bhavan (2006), India has a long and distinguished tradition of research in TB. Studies from the Tuberculosis Research Centre in Chennai and the National Tuberculosis Institute in Bangalore provided key knowledge to improve treatment of TB patients all around

the world. Modern anti-TB treatment can cure virtually all patients. It is, however, very important that treatment be taken for the prescribed duration, which in every case is a minimum of 6 months. Because treatment is of such a long duration and patients feel better after just 1-2 months, and therefore, just providing anti-TB medication is not sufficient to ensure that patients are cured. The DOTS strategy ensures that infectious TB patients are diagnosed and treated effectively till cure, by ensuring availability of the full course of drugs and a system for monitoring patient compliance to the treatment. DOTS is a systematic strategy which has various components such as good quality diagnosis and uninterrupted supply of good quality anti-TB drugs.

According to the Service Provision Assessment Survey 2007, 24% facilities in East Central region offered TB diagnostic services and 83% of these had all components needed to conduct TB sputum tests (microscope, glass slides and ZN reagents). Only 28% of facilities had TB treatment and follow-up services. District Reports (Oct – Dec, 2008) to Zonal TB and Leprosy Supervisors indicated a low TB case detection rate within the region (average 35%) and treatment success rate average of 66%. Strengthening TB and HIV & AIDS responses in East Central Uganda (STAR-EC) worked towards improving the strategic information systems of its partners by disseminating results of the Lot Quality Assurance Sampling (LQAS) survey that had been conducted during August/September 2010, conducting district and CSO specific quarterly performance reviews; providing routine HMIS onsite mentorship to various cadres of staff; and performing data quality audits (USAID, 2011).

The Centers for Disease Control and Prevention (CDC) has been collaborating with Kenyan institutions since 1979, including the Ministry of Health, Kenya Medical Research

Institute (KEMRI), and non-governmental institutions. Initially focused on malaria, activities have expanded to include programs like, tuberculosis and others. Kenya conducted a tuberculosis prevalence survey in Nyanza Province that offered testing and treatment referral to 28,000 people and diagnosed 133 persons with active pulmonary tuberculosis (CDC, 2010).

As stated by CDC (2012) the TB incidence in Kisumu is among the highest in country. There is also a lot of HIV, which actually fuels the TB epidemic and makes it more difficult to treat. Kenya has a sizeable problem on its hands with TB, the government has done an excellent job of finding people with TB and treating them, which is the cornerstone of successful TB control. The CDC has been investing in the KEMRI/CDC collaboration for 32 years. So the investments in the buildings, the laboratories, the road network we travel on, the facility upgrades, were all long-term investments over the last 32 years.

Tuberculosis is an important cause of morbidity and mortality in developing countries. It is imperative that Tuberculosis control units maintain accurate, complete and up to date patient records, to ensure patient compliance with treatment, follow up diagnostic tests, and proper documentation of treatment outcomes. The quality of TB registers in most African countries is not known. The review sought to identify published articles from Africa discussing the quality of Tuberculosis patient registers. Manual TB registers are often incomplete. Electronic TB registers may reduce workload and improve quality of data collection, analysis, and report generation. (Nturibi, 2008)

1.2 Statement of the Problem

According to Blaya (2007) Multi-drug resistant tuberculosis patients in resource-poor settings experience large delays in starting appropriate treatment and may not be monitored appropriately due to an overburdened laboratory system, delays in communication of results, and missing or error-prone laboratory data. Electronic laboratory information systems have a large potential to improve patient care and public health monitoring in resource-poor settings. Some of the challenges faced in these settings, such as lack of trained personnel, limited transportation, and large coverage areas, are obstacles that a well-designed system can overcome

In the past years, until 2011, KEMRI/CDC conducted TB research without a clearly outlined quality management system (QMS). The absence of QMS may lead to many challenges in conducting research which include; unmonitored turnaround time, lack of treatment to patients without clear diagnosis, unnecessary deaths and continuous infection in the community. Unmonitored turnaround time may challenge TB treatment in terms of timely diagnosis and lead time for TB treatment.Quality of results may be impacted due to lack of proper quality control in testing and checks to ensure the right result goes to the right patient. This may lead to health people receiving treatment whereas people with TB may go without treatment leading to death or delay in treatment.

Drug inventory may also be a challenge hence running out of stock during treatment and this may lead to MDR-TB as a result of non adherence to the right doses at the right time. Absence of monitoring and evaluation in form of DOTs may lead to relapse cases and drug

resistance due to lack of supervision. Poor data management may affect TB registers and studies leading to lack of follow up, wrong statistics hence misleading the government in policy making and incorrect data. This study was aimed at evaluating the effects of QMS implementation in KEMRI/CDC on TB treatment.

1.3 Purpose of the study

The purpose of the study was to investigate the effects of Quality management systems on Tuberculosis patient treatment in KEMI/CDC.

1.4 Objectives of the study

This study was guided by five objectives;

1. To investigate the extent to which Turnaround time as a component of quality management systems affects treatment of TB patients.
2. To assess the level at which result accuracy as a component of quality management systems affects treatment of TB patients.
3. To investigate how drug inventory as a component of quality management systems affects treatment of TB patients.
4. To determine the level at which monitoring and evaluation as a component of quality management systems affects treatment of TB patients.
5. To assess the level at which data management as a component of quality management systems affects treatment of TB patients.

1.5 Research questions

This study was set to answer the following research questions;

1. To what extent does Turnaround time as a component of quality management systems affect treatment of TB patients?
2. To what level does result accuracy as a component of quality management systems affect treatment of TB patients?
3. How does drug inventory as a component of quality management systems affect treatment of TB patients?
4. How does monitoring and evaluation as a component of quality management systems affect treatment of TB patients?
5. To what level does data management as a component of quality management systems affect treatment of TB patients?

1.6 Significance of the study

It was hoped that the Study may inform TB management team on a quality management systems that could improve TB treatment on the basis of turnaround time, accurate results, drug inventory, monitoring and evaluation and data management.

It was hoped that the findings and recommendations of this study may also be useful to the ministry of health of Kenya to review their policies on TB diagnosis and treatment in the hospitals in Kenya. The study may also form a significant reference material to researchers in conducting their tuberculosis studies.

1.7 Basic Assumptions of the Study

The researcher was aware that some sectors of the TB branch were not fully equipped with the QMS and some data could give misleading information. Some staff or patients may not be sincere in their feedback and problems could arise in accessing all the required data.

However, these issues did not significantly affect the study outcomes since permission was sort to access data and adequate guidance provided to the people involved in data collection.

It was also assumed that the study would be generalized to other parts of the country or projects apart from KEMRI/CDC

1.8 Limitations of the study

The study was limited by incomplete records due to human error and some staff who are not committed to QMS. The study was limited to self reported data which can result to exaggeration and selective memory. People interviewed could be influenced by different personalities and views hence giving contradictory or incorrect information. These limitations were lessened by the researcher administering the questionnaire and clarifying issues that were not clear to the respondent.

1.9 De-limitation of the study

This study was delimited by area of study, which is KEMRI/CDC Kisumu and the areas covered under the research studies which are Siaya and Kisumu. The reason for

choosing KEMRI/CDC is because it's the only area with an established QMS in the TB branch.

1.10 Definitions of the Significant Terms used in the Study

TB treatment – refers to time from diagnosis to exit visit when the patient is cured. This is the lead time for treatment

Turnaround time – Refers to time to diagnosis, time from sample collection to results and Lead time for treatment

Results accuracy - Correctness of results and Quality control in testing to ensure confidence in results

Drug inventory- stock taking to ensure availability of enough stocks, appropriate supply and procurement at the right time to avoid delays and expiries

Monitoring and evaluation- DOTs and follow-up of treatment

Data management- Updating TB registers to ensure proper statistics and follow-up and Proper archival/storage

Quality control - is a process by which entities review the quality of all factors involved in production

Quality management system (QMS) - is a set of interrelated or interacting elements that organizations use to direct and control how quality policies are implemented and quality objectives are achieved.

1.11 Organization of the study

This document consists of three chapters. Chapter one deals with the introduction, background of the study, problem statement, and purpose of the study, objectives, hypotheses, and significance of the study. It also describes limitations, delimitations, assumptions and organization of the Study. Chapter Two reviewed literature related to quality management systems with a particular focus on turnaround time, result accuracy, monitoring and evaluation, drug inventory and data management. Chapter three describes the methodology used to answer the research problem, and justification for the choice of each technique. It deals with the research design, target population, sample size and sampling techniques, validity and reliability and data collection and data analyses techniques to be used.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

The literature review tries to identify what has been written about the area of study. The literature begins with a review of quality management system and its effects to TB patient management based on turnaround time of results, results accuracy, monitoring and evaluation, drug inventory and data management. Thereafter, the literature review evaluates the theoretical framework, conceptual framework and summary of the reviewed literature

2.2 Overview of quality management systems on health services.

Medical dictionary (2009) defines quality management in health care as any evaluation of services provided and the results achieved as compared with accepted standards. In one form of quality assurance, various attributes of health care, such as cost, place, accessibility, treatment, and benefits, are scored in a two-part process. First, the actual results are compared with standard results; then, any deficiencies noted or identified serve to prompt recommendations for improvement. It's a system of review of selected hospital medical and/or nursing records by medical and/or nursing staff members, performed for the purposes of evaluating the quality and effectiveness of medical and/or nursing care in relation to accepted standards

As stated by Brent (1989) Quality Management for Health Care Delivery provides a framework to help hospitals organize for, communicate about, monitor, and continuously

improve all aspects of health care delivery. It also presents evidence to support the proposition that an organized system to achieve high quality care can lead to lower health care costs. In the present national environment a highly structured approach to the pursuit of quality is essential. For the past 10 years American health policy has slowly shifted focus among three areas: access, cost, and quality of medical care. Each area has successively received concentrated attention, often at the expense of the other two.

According to Wagner *et al.* (2006), since the 1990s, there is a general trend for stakeholders to put more pressure on hospitals for accountability, transparency and equity of access to health. The governments of various European countries have, therefore, stimulated the use of Quality Management systems (QMS) and external evaluation in healthcare. Former research has identified four principal models and national variants of external evaluation, e.g. medical speciality-driven visitation, traditional accreditation against explicit standards, European Quality Awards based on the model of the European Foundation of Quality Management (EFQM), and certification using ISO standards (ISO 9000 series).

Although the evaluation models have common roots, their standards have been developed in response to national legislation, economics, culture and demand. The models share common principles and values, but have a different focus and are differently detailed. The perceived appropriateness of every model for hospitals is only one element influencing the prevalence of one approach over another. Legislation also affects the use and development of external evaluation of hospitals. Some countries (e.g. Greece, Portugal and the UK) have no legal requirement for hospitals to meet specific organizational standards, whereas in other

countries (e.g. Germany, France and Austria) governments have legislated some form of internal and/or external assessment of hospital services (Wagner *et al*, 2006).

According to Breckenkamp *et al.* (2007) the interest in quality management in health care has increased in the last decades as the financial crises in most health systems generated the need for solutions to contain costs while maintaining quality of care. In Germany the development of quality management procedures has been closely linked with health care reforms. Starting in the early nineties quality management issues gained momentum in reform legislation only 10 years later. Quality assurance is an integrated part of health professions with a long tradition of developing methods to assess the quality of work. Generally, quality assurance measures aim at maintaining agreed upon standards, quality management consists in prospective strategies for improving quality. In health systems quality strategies aim at optimizing the provision of health care by identifying inadequate delivery of care and ultimately to influence positively the population morbidity and mortality.

Patients and Health Service Stakeholders are becoming increasingly more sophisticated, better informed and more demanding. At the same time, Health Service Providers are faced with ever increasing compliance obligations, for which funding depends. As expectations grow, the only way for Health Service Providers to meet increased demands is to offer a commitment to patient outcomes and quality. Health Service Providers, whatever their size can give themselves a secure future by introducing a Quality Management System (QMS) such as ISO 9001:2008, (Incorporating the Core Standards for Safety and Quality in Healthcare, 2007).

According to Management science for health (2009), Kenya has had the distinction of being the economic and travel hub of East Africa. The promulgation of Kenya's constitution in 2010 was a major milestone in promoting good governance, confidence in the justice system, equitable allocation of resources and devolution of power to the citizens. For the first time in the country's history, health was recognized as a human right. With a population of approximately 40 million, half of which lives in absolute poverty, Kenya is still faced with numerous challenges to root out poverty, provide quality and equitable healthcare to its citizens, sustain economic growth and put in place an infrastructure and systems that are necessary to transform country into a prosperous industrialized nation. Given the correlation between poverty indices of a country and its health indicators, tackling health challenges will contribute to solving poverty issues. Sustainable economic development requires the input of a healthy population. It is within this context that the Kenya Government acknowledges the important role the health sector plays towards the achievement of Kenya's Vision 2030 that states that, "to improve the overall livelihoods of Kenyans, the country aims to provide an efficient and high quality health care system with the best standards.

According to Mwando (2009) the quality of services provided to the public is a big issue within the health sector. Many health facilities are severely substandard: 63 % of hospitals and 64 % of maternities have no regular water supply and 63 % of dispensaries have no regular electricity supply or generator. In addition to infrastructural issues, the poor quality of services is attributable to inadequate supplies and equipment as well as lack of personnel. Moreover, regulatory systems, standards as well as compliance remain poor (Ndavi *et al*, 2009); despite the development of the Kenya Quality Model, its wide spread implementation

through the proposed Kenya Health Services Accreditation Programme still has not taken place.

The laboratory has always played a critical role in diagnosing tuberculosis (TB) and monitoring its treatment. Developed countries have taken advantage of new technologies that provide rapid detection, identification and drug susceptibility testing of *Mycobacterium tuberculosis*, hastening the decline of the prevalence of the disease when combined with good treatment programmes. In contrast, many developing countries are burdened with high rates of TB and struggle to provide good-quality microscopy, with access to culture and drug susceptibility testing (DST) being scarce to non-existent. The Foundation for Innovative New Diagnostics (FIND) is now applying a systematic approach to research and development for new diagnostics. Focusing solely on finance, techniques and new diagnostics, however, often ignores the need for well-trained staff, quality management systems and other prerequisites that underpin the standards of practice in developed countries. Clinicians will continue to forgo existing laboratory testing services and diagnose and treat empirically in situations where there is a lack of trust and credibility concerning the quality of laboratory results. Such failures to have adequate quality standards highlight the urgent need to focus also on strengthening the laboratory system in parallel with efforts to implement new techniques and methods (Ridderhof *et al*, 2007).

Due to these deficiencies in the public health sector, private hospitals are working towards implementing QMS and achieving accreditation for their services and hence providing quality services. This has also contributed to government imitating QMS in various health sectors like the laboratory through the SLIPTA proᴄess. As stated by (Mekonen, 2012)

Guidelines and Policy for implementation of WHO/AFRO SLIPTA was finalized and approved in July 2011 in Nairobi, Kenya.

2.3 Turnaround time and treatment of TB

Based on study conducted by Sreeramareddy *et al.* (2009) a systematic review of literature was carried out. Literature search was done in Medline and EMBASE from 1990 to 2008. They used the following search terms: delay, tuberculosis, diagnosis, and help-seeking/health-seeking behavior without language restrictions. In addition, indices of four major tuberculosis journals were hand-searched. Subject experts in tuberculosis and authors of primary studies were contacted. Reference lists, review articles and text book chapters were also searched. All the studies were assessed for methodological quality. Only studies carried out on smear/culture-positive tuberculosis patients and reporting about total, patient and health-care system delays were included. They revealed that; Delay in diagnosis of pulmonary tuberculosis results in increasing severity, mortality and transmission. The results of this review suggest that there is a need for revising case-finding strategies. The reported high treatment success rate of directly observed treatment may be supplemented by measures to shorten the delay in diagnosis. This may result in reduction of infectious cases and better tuberculosis control.

Silva (2012) indicates that, in Porto Alegre, Rio Grande do Sul State, in southern Brazil, although hospitalization permits a rapid management of the patient and favors a faster diagnosis, we found an unacceptable time delay before the diagnosis of pulmonary TB was made. Future studies should focus on attempt to explain the reasons of diagnostic retard in the patients with the characteristics related to delay in this study. In conclusion, they

demonstrated that the median delay in TB diagnosis in this setting is 6 days, and the factors associated with this delay in multivariate analysis were extra-pulmonary TB and negative sputum smear. Reducing these delays may require increase of diagnostic awareness in health care professionals, and a review of health service practices. Future studies should focus on attempt to explain the reasons of diagnostic retard in the patients with the characteristics related to delay in this study. In addition, studies on health care seeking may be warranted in this setting.

Worrall (2010) did a study on confusion, caring and tuberculosis diagnostic delay in Cape Town, South Africa. The objective was to explore the ways in which provider and patient behaviors interact to exacerbate diagnostic delay in Cape Town, South Africa. The study design included eight focus group discussions which were conducted in four urban communities, all with high tuberculosis (TB) prevalence, including two with high human immunodeficiency virus co-prevalence. Groups were stratified by sex, ethnicity and TB status. Findings were elicited inductively from the dataset using a combination of grounded theory and thematic analysis The results indicated that diagnostic delay was caused by delays in care seeking, provider failure to diagnose TB at first contact, use of the private sector which did not treat TB and multiple care seeking within and between sectors. In conclusion patient behaviour interacts with institutional arrangements in a way that materially exacerbates TB diagnostic delay. Care seeking in pluralistic settings needs to be understood as a complex process involving a range of providers across sectors. Strategies to smooth the flow of patients within and between sectors and improve perceptions of both service quality and

levels of privacy will reduce diagnostic delays and improve both the efficiency and the effectiveness of the current TB treatment programme.

Jacobson *et al.* (2012) in the study conducted in Western Cape Province, South Africa, between 2007 and 2011 revealed that the use of MTBDR*plus* significantly reduced time to MDR tuberculosis treatment initiation. However, DST reporting to clinics was delayed by more than 1 week due, in part, to laboratory operational delays, including dependence on smear and culture positivity prior to MTBDR*plus* performance. In addition, once MDR tuberculosis was reported, delays in contacting patients and initiating therapy require improvements in clinical infrastructure.

A study by Millen (2008) on the Effect of Diagnostic Delays on the Drop-Out Rate and the Total Delay to Diagnosis of Tuberculosis presented an analysis of the factors that contribute to the overall delay in TB diagnosis and treatment, in a resource-poor setting. Impact on the distribution of diagnostic delay times was assessed for various factors, the sensitivity of the diagnostic method being found to be the most significant. A linear relationship was found between the sensitivity of the test and the predicted mean delay time, with an increase in test sensitivity resulting in a reduced mean delay time and a reduction in the drop-out rate. The results show that in a developing country a number of delay factors, particularly the low sensitivity of the initial sputum smear microscopy test, potentially increase total diagnostic delay times experienced by TB patients significantly. The results reinforce the urgent need for novel diagnostic methods, both for smear positive and negative TB, that are highly sensitive, accessible and point of care, in order to reduce mean delay times.

Yimer *et al.* (2005) in his study on diagnostic and treatment delay among pulmonary tuberculosis patients in Ethiopia, found a median total delay of 80 days. The median health-seeking period and health providers' delays were 15 and 61 days, respectively. Conversely, the median patients' and health systems' delays were 30 and 21 days, respectively. Taking medical providers as a reference point, forty eight percent of the subjects delayed for more than one month. Patients' delays were strongly associated with first visit to non-formal health providers and self treatment ($P < 0.0001$). Prior attendance to a health post/clinic was associated with increased health systems' delay ($p < 0.0001$). In conclusion, delay in the diagnosis and treatment of PTB is unacceptably high in Amhara region. Health providers' and health systems' delays represent the major portion of the total delay. Accessing a simple and rapid diagnostic test for TB at the lowest level of health care facility and encouraging a dialogue among all health providers are imperative interventions.

According to Lado Lugga (2008) in his study of factors associated with patient and health service delays in the management of TB in Central Equatoria State(south sudan) in 2008, the median patient's, health provider's and total pre-treatment periods are 4, 10 and 16 weeks respectively. The health care provider delay for patient diagnosis and start of treatment had the greatest contribution to overall total pre-treatment delay .This study indicated the need for strengthening the capacity of health workers for early detection and referral of TB patients. Further research is needed to identify reasons for health provider delay.

A study by Ayuo *et al.* (2008) entitled causes of delay in diagnosis of pulmonary tuberculosis in patients attending a referral hospital in Western Kenya found out that **t**he median patient, health systems and total delays were 42, 2, and 44 days respectively for all the

patients. Marital status, being knowledgeable about TB, distance to clinic and where help is sought first had significant effect on patient delay. In summary, Patient delay is the major contributor to delay in diagnosis and initiation of treatment of PTB among our patients. Therefore TB control programmes in this region must emphasize patient education regarding symptoms of tuberculosis and timely health seeking behaviour.

Ayisi *et al*. (2011) looked at care seeking and attitudes towards treatment compliance by newly enrolled tuberculosis patients in the district treatment programme in rural western Kenya and indicated that most patients initially self-treated with herbal remedies or drugs purchased from kiosks or pharmacies before seeking professional care. The reported time from initial symptoms to TB diagnosis ranged from 3 weeks to 9 years. Misinterpretation of early symptoms and financial constraints were the most common reasons reported for the delay. They also explored potential reasons that patients might discontinue their treatment before completing it. Reasons included being unaware of the duration of TB treatment, stopping treatment once symptoms subsided, and lack of family support.

2.4 Accuracy of results in treatment of TB

According to Cohen & Corbett (2013) accurate diagnosis of disease remains one of the biggest obstacles to global tuberculosis (TB) control. Inadequate diagnosis results in poor patient outcomes and contributes to sustained TB transmission. The majority of national TB control programmes, particularly in low- and middle-income countries, still rely predominantly on sputum microscopy for diagnosis. This is notoriously insensitive, particularly in HIV co-infected patients. Moreover, rapid and accurate diagnosis of drug resistance is required to control multidrug-resistant (MDR-TB) and extensively drug-resistant

TB (XDR-TB). An accurate, quick, and accessible test for the diagnosis of TB and determination of drug resistance is therefore a global priority.

In a press release in Geneva WHO (2011) it was stated that, the use of currently available commercial blood (serological) tests to diagnose active tuberculosis (TB) often leads to misdiagnosis, mistreatment and potential harm to public health. WHO is urging countries to ban the inaccurate and unapproved blood tests and instead rely on accurate microbiological or molecular tests, as recommended by WHO. The research revealed "low sensitivity" in commercial blood tests which leads to an unacceptably high number of patients wrongly being given the 'all clear' (i.e. a false-negative when in reality they have active TB). This can result in the transmission of the disease to others or even death from untreated tuberculosis. It also revealed "low specificity", which leads to an unacceptably high number of patients being wrongly diagnosed with TB (i.e. a false-positive when in reality they do not have active TB). Those patients may then undergo unnecessary treatment, while the real cause of their illness remains undiagnosed, which may then also result in premature death.

In a study conducted by Hawkins (2011) on managing the Pre- and Post-analytical Phases of the Total Testing Process, in Korea, found out that, for many years, the clinical laboratory has been at the forefront of quality improvement activities in the healthcare sector. Its focus on analytical quality has resulted in an error rate of 4-5 sigma which surpasses most other areas in healthcare. However, greater appreciation of the prevalence of errors in the pre- and post-analytical phases and their potential for patient harm has led to increasing requirements for laboratories to take greater responsibility for activities outside their immediate control. Accreditation bodies such as JCI and CAP specifically require healthcare

organizations to have clear and effective procedures for patient/sample identification and communication of critical results and to monitor their performance in these areas. There are a variety of free online resources available to aid in managing the extra-analytical phase and the recent publication of quality indicators and proposed performance levels by the IFCC WG-LEPS provides useful benchmarking data for laboratories embarking on extra-analytical quality improvement programmes. Managing the extra-laboratory phase of the total testing cycle is the next challenge for laboratory medicine. By building on its existing quality management expertise, quantitative scientific background and familiarity with information technology, the clinical laboratory is well suited to play a greater role in reducing errors and improving patient safety.

A study by Rowland (2012) discovery of a deadly form of TB highlights crisis of 'mismanagement' in India, they indicated that, Resistance is man-made, caused by exposure to the wrong treatment, the wrong regimen, the wrong treatment duration. In the management of TB, many factors affect whether the disease is cured or becomes resistant to treatment. Drug misuse or mismanagement can result if a patient does not follow a full course of treatment, or if the correct drugs are not available or patients with undiagnosed resistant TB receive inappropriate therapies. Part of the problem also relates to TB testing. The WHO recommends sputum smear microscopy, a test developed more than one hundred years ago, as the standard diagnosis. Although inexpensive, this method is prone to false negatives, does not provide information on drug susceptibility, and test results can take several weeks — a large window of time for a patient to potentially receive the wrong drugs or transmit the infection.

In a study conducted by Blount *et al*. (2010) on False positives in TB diagnosis lead to real negatives for HIV patients, it was discovered that, Physicians and researchers have long understood that missing a positive diagnosis of tuberculosis in patients who actually have the disease can result in poor outcomes and an increase in mortality rates. But the link between mortality and false positives – diagnosing someone with tuberculosis who does not have the disease – has been less widely understood. In this study, Blount and his colleagues evaluated the outcomes of 600 HIV-infected patients who were treated at Mulago Hospital in Kampala, Uganda, including patients who were incorrectly diagnosed with tuberculosis following rapid testing."Studies tend to emphasize the negative impact of missing the diagnosis of TB," Blount noted. "Our study shows that falsely diagnosing patients with TB who do not actually have TB is also associated with negative outcomes."Blount said the poorer outcomes are likely due to the fact that patients who are misdiagnosed are treated erroneously for tuberculosis while the actual underlying condition remains untreated. Because physicians believe tuberculosis is the culprit, any search for the real underlying disease is delayed, as is proper treatment, he said.

Blount *et al*. (2010) reports that the study's results serve to caution physicians to continue monitoring patients who have been diagnosed with tuberculosis to ensure the treatment is working, and to reassess the diagnosis if patients are not improving."These results remind us as clinicians that diagnostic tests are not 100 percent accurate, and that falsely diagnosing patients with a disease who do not actually have that disease can lead to negative outcomes," he said. "We must continue to re-evaluate a patient's clinical progress. If he or she is not responding as predicted to treatment for a diagnosed disease, we must entertain

alternative diagnoses."Blount also noted that the results indicate a need for further refinement of rapid diagnostic tests for tuberculosis."These rapid tests, however, are not always as sensitive or specific for determining if a person has TB," he said. "Further research should be focused on the development of more sensitive and specific TB diagnostic tests and the clinical impact of these new tests. Ideally, these tests should be affordable enough to be used in low-income countries, where the burden of tuberculosis is high."

Parsons *et al*. (2011) In a study Laboratory Diagnosis of Tuberculosis in Resource-Poor Countries: Challenges and Opportunities summarized their findings as follows; Building capacity and enhancing universal access to rapid and accurate laboratory diagnostics are necessary to control TB and HIV-TB in resource-poor countries. Their paper described several new and established methods as well as some of the issues associated with implementing quality TB laboratory services in resource-limited countries, where there are challenges associated with retaining competent human resources and in establishing adequate infrastructure. Recently, several of these novel methods have been endorsed by the WHO and have been made available at discounted prices for procurement by the public health care sector of high-burden countries. These proven methods have already shown their potential to significantly improve case detection and management of patients, including drug-resistant TB cases, and enhance the identification of the disease in HIV-positive individuals. However, it is important to realize that at present, there is no stand-alone test for the rapid detection of tuberculosis in all patients.

While some new techniques are simple, others have complex requirements, and therefore, it is vital to carefully determine how to link the new laboratory tests together and

incorporate them within a country's national TB diagnostic algorithm, taking into account factors such as the capacity of different levels of the tiered health care system and the opportunity of decentralizing laboratory services that is possible through the recent improvements in integrated molecular testing. In order to implement and maintain the quality of the new diagnostic services, an adequate certification or quality assurance program needs to be inbuilt for all novel tests. Finally, laboratory results alone are not enough to dictate a particular strategy in the TB patient's care. Careful clinical correlation is necessary in determining the clinical significance of laboratory results and making the correct diagnosis or therapeutic decision. Health care providers and laboratory personnel need to communicate and cooperate to bridge any gap between them and thus optimize clinical outcomes (Parsons *et al*, 2011).

Mfinanga *et al*. (2007) in a study on the quality of sputum smear microscopy diagnosis of pulmonary tuberculosis in Dar es Salaam, Tanzania, a study which was carried out to determine the rate of agreement or disagreement of microscopy reading and culture positivity rate among smear positive and negative specimens between peripheral tuberculosis diagnostic centres (PDCs) and Central Reference tuberculosis laboratory (CTRL). In this study 13 PDCs in Dar es Salaam, Tanzania were involved. Lot Quality Assurance Sampling (LQAS) method was used to collect 222 sputum smear slides. A total of 190 morning sputum specimens with corresponding slides were selected for culture. First readings were done by technicians at PDCs and thereafter selected slides and specimens were sent to CTRL for re-examination and culture. Culture results were used as a gold standard. Of 222 slides selected, 214 were suitable for re-examination. Percentage of agreement of smear reading between PDCs and CTRL was

42.9% and 100% for positive and negative slides, respectively. Measure of agreement (Kappa statistic) was 0.5, indicating moderate agreement. Of 190 samples cultured, percentage of agreement between smear reading from PDCs and CTRL was 37% and 88.9% for smear positive and negative slides, respectively. Kappa statistic was 0.3 indicating poor-fair agreements. Comparison of smear reading from PDCs with culture showed sensitivity of 36.9% and specificity of 88.9%. Comparison of smear readings from CTRL with culture results showed sensitivity of 95.6% and specificity of 98.6%. In conclusion there was inadequate performance in diagnosis of TB using smear microscopy among peripheral diagnostic centres in Dar es Salaam. This calls for immediate and rigorous measures to improve the quality of smear microscopy. It is therefore important to strengthen the capacity of laboratory personnel in smear microscopy techniques through supportive supervision and training. It was discovered that, the most important element in the diagnostic test is the accuracy of the test in terms of specificity and sensitivity.

The results of the sensitivity and specificity of smear and culture results between PDCs and CTRL differed from results of a previous study in Dar es Salaam which showed an overall sensitivity and specificity of 88.5% and 100%, respectively (Basra *et al*., 2006). This indicates that there are variations in quality of smear microscopy between tuberculosis laboratories in Dar es Salaam and most likely throughout the country. This is probably due to overwhelming burden of tuberculosis coupled with insufficient staff. The false smear-negative and smear-positive rates observed in this study are higher than that reported from a similar study in Malawi (Mundy, 2002) where false positive and negative rates for AFB microscopy were less than 2%.

Their results indicate that the PDCs are increasingly making incorrect diagnoses. The overall results showed that about one fifth (29/157) of patients were misdiagnosed as non cases and therefore not treated. This under reading has also been reported in other several studies. While a study in Tanzania showed a false negative of 24% that of Kenya showed false negative of about 25% (Basra *et al*., 2006; Hawken *et al.*, 2001). Misdiagnosis contributes to low coverage for early treatment, suffering and ultimate death. This could be one of the reasons for increased transmission of the disease in Dar es Salaam. Misdiagnosis contributes to low coverage for early treatment, suffering and ultimate death. This could be one of the reasons for increased transmission of the disease in Dar es Salaam (Eldholm *et al*., 2006). Moreover, false negative exaggerate a true magnitude of smear negative tuberculosis which is said to be fuelled by HIV/AIDS (Mfinanga *et al*, 2007).

2.5 Drug inventory and treatment of TB

Rookkapan (2005) in a study of deteriorated tuberculosis drugs and management system problems in lower southern Thailand, settings**,** three institutes, 11 hospitals and 38 community hospitals in southern Thailand. The objectives were, to assess the quality of tuberculosis (TB) drugs used in TB treatment facilities in southern Thailand and their TB drug management systems. The study design was a Cross-sectional study utilizing interviews, document review, inspection of drug storage, visual examination of TB drugs, and laboratory analysis of samples of isoniazid (INH), rifampicin (RMP), pyrazinamide (PZA) and ethambutol (EMB). The results indicated that no stock-out of TB drugs was found at any level. Thirteen (25%) hospitals/institutes removed coated EMB tablets from their foil packages for daily dose packing. Eleven (21%) hospitals/institutes bisected 400 mg coated

EMB tablets before dispensing as a non-available 200 mg tablet. On the day of inspection grossly deteriorated EMB was observed in 44% of hospitals/institutes. All samples, except 14% of EMB, passed content assay tests. All INH and EMB samples passed the dissolution tests, but 62% of RMP samples and 26% of PZA samples failed. In conclusion; Sub-standard deteriorated TB drugs are a serious problem for TB control. TB drugs examined in the study area were not managed properly. Education on TB drug packaging and storage, and non-destructive systems in TB drug distribution, storage, inventory control, quality assurance and supervision are essential interventions.

Sianozova (2012) study focused on Strengthening the national capacities for TB drug and health product management; the report includes 7 key findings within the four main functions of the drug management cycle (product selection, procurement, distribution, product use and logistics management information), and 14 recommendations. Among those recommendations, the following are priorities for further strengthening drug management in Armenia:- In order to keep control over forecasting, distribution of drugs, and avoid supply interruptions, the Logistics Management Information System has to be improved through strengthening capacity of central level staff responsible for drug management gathering and interpreting information on drug stocks and managing necessary actions,- Training for drug specialists in forecasting and drug quantification, inventory management and logistics management information is critical.- At the level of SDPs (Service delivery points), review and standardization of reporting-and-recording forms on drug management is needed. To estimate supply and demand for TB drugs, Standard Operation Procedures (SOPs) have to be

developed. Outside assistance is need in development of the monitoring mechanism of stock levels, drug consumption, and tracking expiry dates for drugs.

According to Uchiyama (2006) an assessment survey of anti-tuberculosis drug management in Cambodia, the prescribing practices of the TB service providers were acceptable. The level of new smear-positive TB out-patients' knowledge of TB treatment was high. The storekeepers' inventory practices for TB drugs indicated a need for improvement. Various TB drugs were available in the private pharmacies. TB drug prices in the public sector were similar to international reference prices, although they were higher than the Global TB Drug Facility prices.

Based on Maalaoui (2009) in a research on Strengthening TB Drug Management in the Sudanese National TB Control Program: In-Depth Review of TB Drug Management, they explored several findings in the Sudanese pharmaceutical system institution. These institutions are well established and active, but they lack coordination among themselves. Roles and responsibilities are being redefined to optimize the organizational structure of the pharmaceutical sector. The availability of professionals in the pharmaceutical system is generally not a problem. There are adequate numbers of trained pharmacists and pharmacist's assistants in both the public and private pharmaceutical sectors. He recommends Strengthening of human resources capacity in the area of inventory management at different levels of the programs' pharmaceutical distribution chain, Improvement of the drug management information system and ensuring better control of drug distribution and consumption.

2.6 Monitoring and evaluation in treatment of TB

Establishing a reliable monitoring and evaluation system with regular communication between the central and peripheral levels of the health system is vital. This requires standardized recording of individual patient data, including information on treatment outcomes, which are then used to compile quarterly treatment outcomes in cohorts of patients. These data, when compiled and analyzed, can be used at the facility level to monitor treatment outcomes, at the district level to identify local problems as they arise, at provincial or national level to ensure consistently high-quality TB control across geographical areas, and nationally and internationally to evaluate the performance of each country. Regular programme supervision should be carried out to verify the quality of information and to address performance problems. Both developed and developing countries now have additional diagnostic information at their disposal, including sputum culture, DST and HIV test results, all of which can be used to guide patient management. Use of electronic recording systems will be considered where appropriate (WHO, 2013).

According to Farmer (2005), Factors Influencing Adherence to Tuberculosis Directly Observed Therapy: A Review of the Literature, a methodology consisting of an electronic database search (Cumulative Index of Nursing and Allied Health Literature (CINAHL), Medline, the Cochrane Library, Ingenta Connect, and Webspirs (Social Science Index and General Science Index)) for relevant studies or previous reviews that reported experiences of TB DOT implementation. Various reviews illustrated that intervention directed at staff in TB clinics was a key factor in patient treatment completion. Patients with TB attending health centres with intense supervision of staff were more likely to complete treatment. Management

interventions to motivate staff, lectures and role playing provide staff with in-depth training in communications, confidentiality, outreach techniques and management. External funding was also mentioned as an important and necessary component of effective DOT programs. More instruction on medication techniques, training in patient empathy and communications skills, educational material and a patient-centred approach was identified by school nurses. Nurse case management teams increase TB completion rates by three to six times that of self-administered and DOT alone.

According to Obermeyer (2008) in his assessment on; has the DOTS Strategy Improved Case Finding or Treatment Success? An Empirical Assessment, it was explored by WHO that DOTS programme variables had no statistically significant impact on case detection in a wide range of models and specifications. DOTS population coverage had a significant effect on overall treatment success rates, such that countries with full DOTS coverage benefit from at least an 18% increase in treatment success (95% CI: 5–31%). The DOTS technical package improved overall treatment success. By contrast, DOTS expansion had no effect on case detection. This finding is less optimistic than previous analyses. Better epidemiological and programme data would facilitate future monitoring and evaluation efforts.

Okanurak (2007), a study on Effectiveness of DOT for tuberculosis treatment outcomes: a prospective cohort study in Bangkok, Thailand; and concluded that the pattern of drug administration impacted on treatment success. Centre- + family-based DOT, family-based DOT and centre-based DOT + SAT achieved higher rates of treatment success than the World Health Organization target. Centre-based DOT had the lowest success.

In this study of non-adherence, default and acquisition of MDR among TB patients in Tomsk (western Siberia), substance abuse and in-hospital care were identified as two potential obstacles to effective treatment. These results suggest that DOTS programmes might be more likely to achieve TB control targets if they include interventions aimed at improving adherence by diagnosing and treating substance abuse concurrently with standard TB therapy. They also raise the possibility that some patients with apparent drug-sensitive disease also may be infected with drug-resistant strains that are unmasked upon initiation of therapy (Gelmanova, 2007).

A study conducted by Tumbo *et al*. (2010) on evaluation of directly observed treatment for tuberculosis in the Bojanala health district, North West Province of South Africa, indicated that in this South African rural health district, the DOT utilization rate for TB was 56.8%, mainly for patients on the TB retreatment regimen. Strict implementation of DOT in all patients undergoing TB treatment is a known strategy for improving TB cure rate and preventing recurrence and drug resistance.

Hanson *et al.* (2001) study on Utilization of Tuberculosis control services in Kenya: analysis of wealth inequalities concluded that a disproportionately low number of poor persons utilized DOTS facilities for TB care. The poor may account for a considerable portion of the TB cases not currently being detected. Many of them are utilizing facilities that do not implement DOTS. An interaction with a DOTS provider did not mean the patient was detected, referred for diagnosis or started on treatment. Increased attention is needed to strengthen the identification and referral of poor patients already accessing DOTS facilities.

2.7 Data management and treatment of TB

Vranken (2002) in a study on use of a computerized tuberculosis register for automated generation of case finding, sputum conversion, and treatment outcome reports in South Africa, the setting was based on dramatic increase in the rates of Tuberculosis (TB) in southern Africa in recent years. Provision of accurate data for surveillance, program management, and supervision was increasingly essential. The objective was, to develop software that would provide more efficient collection, compilation, and analysis of TB data on an ongoing basis. Design was based on the 'Electronic TB Register' being a user-friendly, Epi-Info based software program based on the WHO/IUATLD format of recording and reporting. Individual records from the TB registry were entered in a program that provided interactive support. The software provided several patient management and supervision functions, such as lists of defaulters. Finally, it generated standard quarterly and annual reports on case-finding, sputum conversion, and cohort analysis, and provides graphs of trends and maps of TB indicators. Results indicated that the 'Electronic TB Register' software had been successfully implemented in five pilot projects in southern Africa. User acceptance had been high and quality of data had improved, although timeliness remained unchanged. Factors critical for success included a functioning, paper-based system, involvement of staff from the TB program, health information systems, and health facilities, ongoing training, and backup support. In conclusions, the 'Electronic TB Register' was found to be a potentially powerful tool for surveillance, management, and supervision for countries with well-functioning paper-based recording and reporting systems.

According to Deborah *et al*. (2004); Pharmacy Data for Tuberculosis Surveillance and Assessment of Patient Management, a study in Massachusetts highlights that, Controlling and preventing tuberculosis (TB) continue to be major public health challenges in the United States. Information obtained through TB surveillance ensures that TB-control activities are appropriate and can be used to evaluate the effectiveness of public health programs. Because TB surveillance relies heavily on laboratories and providers to report cases to local health departments, surveillance data can be compromised by underreporting, particularly by private-sector clinicians who treat TB infrequently. Pharmacy data, often available in automated form, may supplement traditional TB reporting, especially because anti-TB medications are rarely used to treat other conditions.

The Massachusetts study found that persons with TB who were identified through pharmacy dispensing records and who had not been previously reported to the state health department represented 16% of all new cases. In that study, receipt of two or more anti-TB drugs identified most cases of active TB. These results suggested that pharmacy dispensing information could supplement traditional TB surveillance. In addition, pharmacy dispensing information for persons with active TB provided useful information about appropriateness of prescribed treatment regimens and adherence to therapy (Deborah *et al*, (2004).

Results from Kabongo *et al*. (2010) study on Effectiveness of home-based directly observed treatment for tuberculosis in Kweneng West subdistrict, Botswana indicated that the overall cure rate for smear-positive pulmonary TB patients was 78.5%. Treatment outcomes were not statistically different between FB-DOT and HB-DOT. Contact tracing was significantly better in FB-DOT patients. Interviews revealed advantages and disadvantages for

both FB and HB options and that flexibility in the choice or mix of options was important. A number of suggestions were made by the interviewees to improve the HB-DOT program. They concluded that HB-DOT is at least as good as FB-DOT in terms of the treatment outcomes, but attention must be given to contact tracing. HB-DOT offers some patients the flexibility they need to adhere to TB treatment and community volunteers may be strengthened by ongoing training and support from health workers, financial incentives and provision of basic equipment.

Sharif (2012) in a study on new data system set to radically reduce TB cases in Nairobi, Kenya, indicated tuberculosis incidences could be reduced by 10 per cent every year following the introduction of a digital programme to monitor the treatment of patients. He mentioned that the unique programme dubbed TIBU will help in controlling and managing data of TB patients thereby ensuring zero TB tolerance by the year 2015.He indicated that TIBU is a unique model that specifically addresses challenges of data management that would ensure tracking and monitoring the data of all TB patients countrywide, hence keeping track of their treatment progress. The programme would ensure all the patients complete their treatment. Several cases of patients defaulting on treatment have been reported.

2.8 Theoretical framework

The study is anchored on Juran's (2008) theory known as the "Quality Trilogy." The quality trilogy is made up of quality planning, quality improvement, and quality control. If a quality improvement project is to be successful, then all quality improvement actions must be carefully planned and controlled. Juran believed that there were ten steps to quality improvement. These steps are: An awareness of the opportunities and needs for improvement

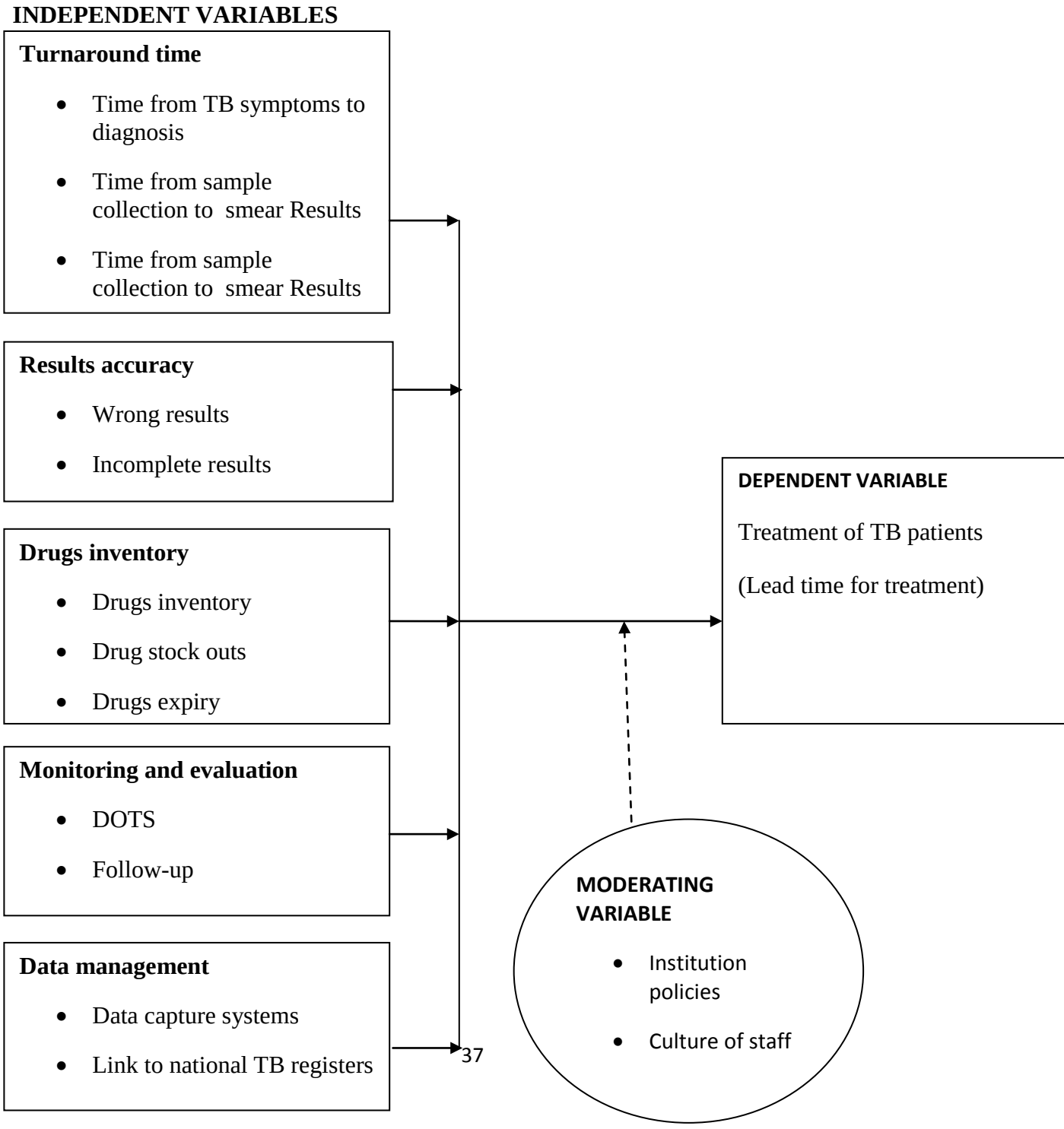
must be created, Improvement goals must be determined, Organization is required for reaching the goals, Training needs to be provided, Initialize projects, monitor progress, Recognize performance, Report on results, Track achievement of improvements and Repeat.

TB patient treatment is directly affected by quality planning to ensure achievement of correct turnaround time, quality control for accurate results and drug inventory, quality improvement in terms of monitoring and evaluation through the DOTS strategy to ensure proper and timely treatment. Planning for data capture tools and management is also vital to ensure follow-up and correct statistics which could assist the country in policy making and implementation. Juran's ten steps apply to implementation, maintenance and improvement of quality management systems.

2.9 Conceptual framework

The study was guided by the following conceptual framework**.**

Figure 2.1 Conceptual Framework



In this study the independent variables which are component of quality management systems include; Turnaround time referring to time to diagnosis, time from sample collection to results and Lead time for treatment, Results accuracy refers to correctness of results and Quality control in testing to ensure confidence in results, Drug inventory includes stock taking to ensure availability of enough stocks, appropriate supply and procurement at the right time to avoid delays and expiries, Monitoring and evaluation inform of DOTs and follow-up of treatment and Data management which involves updating TB registers to ensure proper statistics and follow-up and Proper archival/storage. A measure of treatment of TB patients will be determined by these factors.

On the other hand factors like Institution policies, Culture of staff and Project funding can also influence treatment of TB patients. For example the funding given to a certain project will determine whether funds will be available to implement all aspects of quality management systems which in turn affect treatment of TB patients.

2.10 Summary of literature review

The literature was reviewed to gain more understanding on effects of QMS on TB patient treatment. The QMS was reviewed in terms of turnaround time looking at time to diagnosis, time of diagnosis and lead time for TB treatment; results accuracy looking at Correctness of results and Quality control in testing; Drugs inventory focusing on Supply of drugs and expiry; monitoring and evaluation by DOTS and Follow-up; Data management in terms of Data capture and updating TB registers. . The basis of the literature review was to bring to picture, how these factors as stipulated in the study, impact on TB treatment.

The literature reviewed shows the strategies to smoothen the flow of patients within and between sectors and improve perceptions of both service quality and levels of privacy will reduce diagnostic delays and improve both the efficiency and the effectiveness of the current TB treatment programme (Worrall, 2010) and therefore, an accurate, quick, and accessible test for the diagnosis of TB and determination of drug resistance is therefore a global priority (Cohen & Corbett, 2013)

Establishing a reliable monitoring and evaluation system with regular communication between the central and peripheral levels of the health system is vital (WHO, 2013) and strict implementation of DOT in all patients undergoing TB treatment is a known strategy for improving TB cure rate and preventing recurrence and drug resistance (Tumbo *et al*, 2010). (Rookkapan, 2005) reveals that Education on TB drug packaging and storage, and non-destructive systems in TB drug distribution, storage, inventory control, quality assurance and supervision are essential interventions and Sharif (2012) indicated tuberculosis incidences could be reduced by 10 per cent per year following the introduction of a digital programme to monitor the treatment of patients.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Introduction

This section discusses the research design and methodology that was used in conducting the study. It focuses on the research design applied, target population, sample size and sample selection, research instruments, data collection procedure, data analysis and ethical considerations.

3.2 Research design

This study adopted a descriptive cross sectional survey design which is a one time study with focus or attention on formulation of objectives, designing the data collection instrument, selecting the sample, collecting the data, processing and analyzing the data and reporting the findings (Mugenda & Mugenda, 2003).

Descriptive research design determines and reports the way things are. It attempts to describe such things as possible behaviour, attitudes, values and characteristics. Given the nature of this study, descriptive survey design was the most appropriate in collecting data regarding the QMS and TB treatment.

3.3 Target population

KEMRI/CDC Kisumu has a total population of 1200 staff. The population of the study consisted of staff dealing with TB patients in KEMRI/CDC. At the time of this study, there were 200 staff dealing with TB patients in KEMRI/CDC Kisumu.

3.4 Sampling procedures and sample size

This section describes the sample size, sampling technique and sample selection that was employed by this study.

3.4.1 Sample size

Mugenda and Mugenda (2003) states that the sample size must be large enough to represent the salient characteristics of the accessible population. Generally, the sample size depends on factors such as the number of variables in the research, the type of research design, the method of data analysis and the size of the accessible population. The total population of staff dealing with TB patients was 200. This study therefore used a sample size of 133 respondents randomly sampled from the KEMRI/CDC staff dealing with TB patients.

The sample size was computed using the Yamane, (2007) formula

$$n = \frac{N}{1+N(e)_2}$$

N= Population

n=sample size

e= level of precision/sampling error at 95%confidence level (0.05)

$$n = \frac{200}{1+200(0.05)^2}$$

3.4.2 Sample selection

Simple random sampling method was employed during data collection. In KEMRI/CDC the human resource department has database containing all staff and their different cadres/ profession. From a list of all (200) staff dealing with TB patients, the researcher was able to draw a random sample of 133. Simple random sampling technique was employed where a computer was used to generate a series of random numbers. A list of all the staff dealing with TB patients was entered in an excel sheet. A function =RAND () was used to generate random numbers between 0 and 1. Then, sorted both columns with the list of names and the random number by the random numbers. This rearranged the list in random order from the lowest to the highest random number. Then, the first 133 staff in this sorted list were selected. The study resorted to simple random sampling, since it is easy to use and, generate results of the random numbers very quickly and is not prone to bias.

The Research Assistants approached the sampled staff at their work stations and explained the overall objective of the survey to them then proceeded to interview them after obtaining their consent.

3.5 Research instruments

Mugenda and Mugenda (2003) observed that, the pre-requisite to questionnaire design is definition of the problem and the specific study objectives. The primary data was collected using structured question. The questionnaire provided a more comprehensive view and all the respondents were asked the same questions in the questionnaire considering closed ended questions and it was researcher administered.

The questionnaire was organized into seven sections namely introduction, socio—demographic profile, Turnaround time as a component of quality management systems and TB patient treatment, result accuracy as a component of quality management systems and TB patient treatment, drug inventory as a component of quality management systems and TB treatment, monitoring and evaluation as a component of quality management systems and TB treatment and data management as a component of quality management and TB treatment. Effort was made to ensure that all objectives are addressed and information accurately collected.

3.5.1 Pilot testing

To ensure data collection instruments were reliable pre-testing and practical interviewing was conducted by the researcher with 13 staff who were not part of the sample and dealing with Tb patients at the Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH). The questionnaire was administered to the 13 staff by the researcher and research assistant's .The pilot test was done outside the study area in order to avoid interviewing staff who would later form part of the sample. This was done within a period of one week.

Nachmias and Nachmias (1996) noted that pilot-testing is an important step in the research process because it reveals vague questions and unclear instructions in the instruments. It also captures important comments and suggestions from the respondents that enable the researcher to improve efficiency of instruments, adjust strategies and approaches to maximize response rate.

3.5.2 Validity of the instrument

Validity is the accuracy and meaningfulness of inferences, which are based on the research results. In other words, validity is the degree to which results obtained from the analysis of data actually represent the phenomena under study (Mugenda & Mugenda, 2003). In this study, pilot-testing was used as an important step in making the instrument valid for the purposes of the study. During the pilot testing, vague questions and unclear instructions were noted. Important comments and suggestions were also captured from the respondents that enabled the researcher to improve efficiency of instruments, adjust strategies and approaches to maximize response rate. The responses from different participants were analyzed and came up with a generalized position which stood the validity test.

The study ensured that the questionnaire captured all the intended respondents. The questions were simplified by the study to make all the respondents to comprehend all the questions. The study used a survey method which usually lessens bias hence the study was assured of collecting valid data from the respondents interviewed.

3.5.3 Reliability of the instrument

Reliability is a criterion that refers to the consistency of data from the use of a particular method. A measure of reliability to the extent that repeated application of it under the same condition by different researchers will give the same results (Taylor, 2008).

The reliability of a research instrument concerns the extent to which the instrument yields the same results on repeated trials. Although unreliability is always present to a certain extent, there was generally a good deal of consistency in the results of a quality instrument gathered

at the different times. The tendency toward consistency found in repeated measurements is referred to as reliability (Cook *et al*, 2007).

To measure reliability the study was used the test-retest method which involves selecting 10% of the respondents (13) from JOOTRH and administer the same instrument twice to the same group of participants after some two weeks time lapse.

The results of the test-retest were factored into statistical package for social sciences (SPSS), the results of the first test were correlated with that of the second test. The Karl person's formula for correlation was used as follows;

$$r = \frac{\Sigma\left(X - \bar{X}\right)\left(Y - \bar{Y}\right)}{\sqrt{\Sigma\left(X - \bar{X}\right)^2 \Sigma\left(Y - \bar{Y}\right)^2}}$$

r= Karl persons coefficient of correlation

Y=values of the first test

X=values of the retest

$\bar{Y}$ =Mean of the first test

$\bar{X}$ =Mean of the retest.

3.6 Data collection procedures

The research instrument was a questionnaire. A research permit was obtained from the ministry of higher education under the department of national council for science and technology, which gave an approval for the study to take place. After the permit was acquired, with the assistance of five research assistants, the instruments was administered to the staff

The study sought permission from the study principal investigators and TB branch chief in KEMR/CDC to enable interaction with staff and collecting data.

3.7 Data analysis techniques

Quantitative techniques of data analysis were used to analyze the data gathered from the field. The quantitative data was entered and analyzed using SPSS for windows version 12.0.The analysis employed descriptive statistics, including frequencies and percentage distribution to examine the relation between independent and dependent variables individually.

Descriptive statistics, including frequency and percentages were generated for age, sex, profession and used to analyze the socio-demographic characteristics of the sample. Each and every variable was coded in a database to describe each variable. Univariate and bivariate statistics was used to analyze the data.

3.8 Ethical Issues in Research

Information obtained from other sources or from authors to support the relevance of this research has been acknowledged in the form of references while plagiarism has been minimized as much as possible. The researcher provided adequate and clear explanation on the purpose of the study to each respondent. The researcher sought the respondents consent to participate in the study while assuring them that their participation is voluntary. All the participants were assured of total confidentiality and informed that the information provided would be used for research purposes only.

CHAPTER FOUR

DATA ANALYSIS, PRESENTATION, INTERPRETATION AND DISCUSSIONS

4.1 Introduction

This chapter presents and analyses data in the following themes: response return rate, demographic characteristics of the respondents, the extent to which Turnaround time as a component of quality management systems affects treatment of TB patients, the level at which result accuracy as a component of quality management systems affects treatment of TB patients, drug inventory as a component of quality management systems and how it affects treatment of TB patients, the level at which monitoring and evaluation as a component of quality management systems affects treatment of TB patients and the level at which data management as a component of quality management systems affects treatment of TB patients.

4.2 Questionnaire response return rate

A total of 133 interviews were conducted with the respondents. All interviews were successful and all the questionnaires were returned for analysis forming a return rate of 100%. The study realized this high return rate due the fact that majority of respondents in this category are health workers in KEMRI/CDC who were interviewed at their work stations.

4.3 General information of the respondents

This section described the general information of the respondents. This information was collected on gender, age, years of experience in KEMRI/CDC, profession and lead time for TB treatment. These results were presented as follows in three themes namely; the

respondents gender, respondents age and respondents years of experience in KEMRI/CD, respondents profession and lead time for TB treatment.

4.3.1 Distribution of the respondents by gender

The study found it important to analyze gender distribution of the respondents. This was important to understand the kind of population involved in the study. Due to this the respondents were asked to state their gender and the results were given in table 4.1

Table 4.1: Distribution of the respondents by gender

Gender	Frequency	Percentage
Male	64	48.1
Female	69	51.9
Total	**133**	**100**

Table 4.1 shows that 69(51.9%) of the respondents were the female sex while 64 (48.1%) were males. This is an indication of a balance in gender among the health workers. No policy exists in KEMRI/CDC for gender balance but the study found out that there was a gender balance.

4.3.2: Distribution of the respondents by age

The study sought to establish the ages of the respondents who were interviewed with the essence of understanding the population better. Therefore they were asked to state their ages and the results summarized in table 4.2.

Table 4.2: Distribution of the respondents by age

Age Bracket	Frequency	Percentage
22-30	60	45.1
31-40	62	46.6
41-50	10	7.5
>50yrs	1	.8
Total	**133**	**100%**

Based on the findings in table 4.2, majority of the respondents were 40 years and below which is 91.7%. The nature of KEMRI/CDC projects could have contributed to this since it involves filed work and travelling and that age bracket is suitable for that.

4.3.3 Years of experience in KEMRI/CDC

The study found it important to analyze the years of experience with KEMRI/CDC as a measure TB treatment experience. Due to this the respondents were asked to state their years of experience and the results were given in table 4.3.

Table 4.3: Distribution of respondents by experience

Years of experience	Frequency	Percentage
Less than 4 years	94	70.7
5-10 years	4	3.0
More than 10 years	35	26.3
Total	**133**	**100**

The Findings in table 4.3 show that majority of respondents had an experience of 4 years and below, an indication that majority had not served for long in KEMRI/CDC though they had adequate knowledge on TB treatment**.** The nature of the projects in KEMRI/CDC contributed to this since staffs are recruited on a yearly renewal contact with the studies running for a certain period of time like 3-7 years.

4.3.4 Profession of respondents

The study found it important to analyze the profession of the respondents which could measure the level of contact with the TB patients. Therefore they were asked to state their profession and the information summarized in table 4.4.

Table 4.4: Distribution of respondents by profession

Profession	Frequency	Percentage
Community Interviewers	26	19.5
Clinicians	30	22.6
Doctors	9	6.8
Laboratory staff	16	12.0
Nurses	47	35.3
Pharmacist	5	3.8
Total	**133**	**100**

Table 4.4 indicates nurses as the highest respondents 47(35.3%) followed closely by clinicians 30(22.6%) and Pharmacists were the least 5(3.8%). This met the researcher's target population adequately.

4.4 Turnaround time and TB patient treatment

One of the objectives was to investigate the extent to which Turnaround time as a component of quality management systems affects treatment of TB patients. To achieve this objective respondents were requested to respond to various questions under the following sub-themes: length of time from the time the patient experiences symptoms to the time they seek

medication , turnaround time for smear results, turnaround time for culture results, and time form diagnosis to treatment of TB patients.

4.4.1 Time from TB symptoms to diagnosis and Treatment of TB patients

Early diagnosis of TB disease is vital to ensure timely treatment and prevent chances of infecting the contact people in the community. Therefore in this regard, the respondents were asked to state where majority of patients lie based on the duration from the time the patient experiences symptoms to the time they seek medication out of TB patients contacted in the past 6 months. The summary of the analysis was compared to the time for TB treatment as presented in table 4.5.

Table 4.5: Time from TB symptoms to diagnosis and Treatment of TB patients

Response	Treatment of TB patients							
	6months		7-10 months		11 months and above		Total	
	Frequency	Percentage	Frequency	percentage	Frequency	Percentage	Frequency	percentage
Less than 1 week	12	9.0	4	3.0	0	.0	16	12.0
1-2 weeks	25	18.8	10	7.5	3	2.3	38	28.6
3 weeks-1 month	35	26.3	9	6.8	0	.0	44	33.1
More than 1 month	17	12.8	17	12.8	1	.8	35	26.3
Total	89	66.9	40	30.1	4	3.0	133	100.00

Table 4.5 shows that 12(9.0%) seek medication in less than a week and the treatment completed in 6 months, 4(3.0%) completed treatment in 7-10 months. Out of those who sought medication in 1-2 weeks, 25(18.8%) completed treatment in 6 months, 10(7.5%) in 7-10 months, 3(2.3%) in 11 months and above. Of those who took 3 weeks – 1 month to seek medication,35(26.3%) completed medication in 6 months, 9(6.8%) completed treatment in 7-10 months. 17(12.8%) took More than 1 month to seek medication and treatment was completed in 6 months, 17(12.8%) completed treatment in 7-10 months and only 1(.8%) in 11 months and above. 54(40.6%) seek medication within (2 weeks and below) , 44(33.1%) take 3 weeks – 1 month and 35 (26.3%) taking more than one month to seek medication after onset of TB symptoms. This shows that KEMRI/CDC majority of TB patients seek early TB diagnosis although that doesn't affect TB treatment. The findings can be compared to a study by Ayisi *et. al*.(2011) who looked at care seeking and attitudes towards treatment compliance by newly enrolled tuberculosis patients in the district treatment programme in rural western Kenya and reported time from initial symptoms to TB diagnosis ranging from 3 weeks to 9 years.

4.4.2 Time from sample collection to smear Results and Treatment of TB patients

Smear is the initial diagnosis of TB disease and treatment is initiated with smear results based on the current algorithm in Kenya. According to (McCarthy *et al*, 2010), CDC recommended turnaround time for smear result is 24 to 48 hrs and therefore the respondents were asked to state the time taken to get the smear results. The findings were summarized in table 4.6.

Table 4.6: Time from sample collection to smear Results and Treatment of TB patients

Response	Treatment of TB patients							
	6months		7-10 months		11 months and above		Total	
	Frequency	Percentage	Frequency	percentage	Frequency	Percentage	Frequency	Percentage
Less than 48 hrs	81	60.9	31	23.3	4	3.0	116	87.2
3 days -1 week	8	6.0	8	6.0	0	0.0	16	12.0
2 weeks-1 month	0	0.0	1	.8	0.0	0.0	1	.8
More than 2 month	0.0	.0	0.0	.0	.0	.0	0.0	.0
Total	89	66.9	40	30.1	4	3.0	133	100.00

As indicated in table 4.6, majority of the respondents 81(60.9%) received smear results in 48 hours and completed patient treatment in 6 months, 31(23.3%) in 7-10 months and 4(3.0%) in 11 months and above. 8(6.0%) of them who received smear results in 3 days -1 week completed treatment in 6 months and 8(6.0%) completed in 7-10 months. 1(0.8%) received smear results in 2 weeks -1 month and then treatment was completed in 7-10 months. This clearly shows that majority of the KEMRI/CDC TB patients receive smear results within 48 hours and also treated within 6 months and a few of those are treated in 7-10 months. Lado Lugga (2008) in his study of factors associated with patient and health service delays in

the management of TB in Central Equatoria State(South Sudan) in 2008, found out that the health care provider delay for patient diagnosis and start of treatment had the greatest contribution to overall total pre-treatment delay**.**

4.4.3 Time from sample collection to culture Results and Treatment of TB patients

Due to the low sensitivity and specificity of smear, culture is considered as the gold standard for TB diagnosis and the culture results are confirmatory for a definite case of TB. CDC recommended turnaround time for culture results is less than a month for positives and 2-3 months for negative cultures (McCarthy *et al*, 2010). The respondents were therefore asked to state the time taken to get the culture results. The findings were compared with the TB treatment duration and summarized in table 4.7.

Table 4.7: Distribution of Time from sample collection to culture Results and Treatment of TB patients

Response	Treatment of TB patients							
	6months		7-10 months		11 months and above		Total	
	Frequency	Percentage	Frequency	percentage	Frequency	Percentage	Frequency	Percentage
Less than 1 month	23	17.3	8	6.0	0.0	.0	31	23.3
2-3 months	63	47.4	32	24.1	4	3.0	99	74.4
4 and Above	3	2.3	0.0	.0	0.0	.0	3	2.3
Total	89	66.9	40	30.1	4	3.0	133	100.00

The findings in table 4.7 reveal that 23(17.3%) received culture results in less than 1 month and treated in 6 months, 8(6.0%) were treated in 7-10 months. 63(47.4%) received results in 2-3 months and treated in 6 months, 32(24.1%) were treated in 7-10 months and only 4(3%) were treated 11 months and above. Majority of the results were within the required turnaround time of less than a month for positives and 2-3 months for negative cultures and patients were treated in 6 months or 7-10 months which is within the recommended turnaround time. The findings differ with a study conducted by Jacobson *et al.* (2012) in Western Cape Province, South Africa, between 2007 and 2011 which revealed that DST reporting to clinics was delayed by more than 1 week due, in part, to laboratory operational delays, including dependence on smear and culture positivity prior to MTBDR*plus* performance.

4.5 Results accuracy and TB treatment and Treatment of TB patients

The second objective of the study was to assess the level at which result accuracy as a component of quality management systems affects treatment of TB patients. These were looked at in three categories namely; wrong results received or issued from the laboratories, the number of the wrong results in the past 6 months if any and the number of incomplete results received from the laboratory.

4.5.1 Wrong results received or issued from the laboratories and Treatment of TB patients

Results accuracy is a key aspect of quality management systems and helps to ensure that patients are given the correct results based on identifiers hence the right regimen or treatment is given to the right patient. This was measured by asking the respondents to state if

they have ever received wrong results from the laboratory. The results were summarized in table 4.8.

Table 4.8: Wrong results received or issued from the laboratories and Treatment of TB patients

Response	Treatment of TB patients							
	6months		7-10 months		11 months and above		Total	
	Frequency	percentage	Frequency	percentage	Frequency	Percentage	Frequency	Percentage
NO	61	45.9	28	21.1	2	1.5	91	68.4
YES	28	21.1	12	9.0	2	1.5	42	31.6
Total	89	66.9	40	30.1	4	3.0	133	100.00

Based on the table 4.9, 61(45.9%) who never received wrong received, treated their patients in 6 months, 28(21.1%) in 7-10 months and 2(1.5%) in 11 months and more. 28(21.1%) received wrong results but patients were still treated in 6 months, 12(9.0%) were treated in 7-10 months, 2(1.5%) were treated in 11 months. The results are in line with a study by Rowland (2012) discovery of a deadly form of TB highlights crisis of 'mismanagement' in India, they indicated that, Resistance is man-made, caused by exposure to the wrong treatment, the wrong regimen, the wrong treatment duration.

The 31.6% who had received wrong results were further analyzed to know how many wrong results they actually received as indicated in table 4.9.

4.5.2 Number of wrong results received or issued from the laboratory and Treatment of TB patients

For respondents who indicated that they had received wrong results, there was need to capture the quantity of these wrong results received in the last 6 months to ensure that the number was not high and did not affect the treatment of TB patients. The results were summarized in table 4.10.

Table 4.9: Number of wrong results and Treatment of TB patients

Number	Treatment of TB patients							
	6months		7-10 months		11 months and above		Total	
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
None	15	11.3	2	1.5	0.0	.0	17	12.8
1-5	23	17.3	12	9.0	2.	1.5	37	27.8
6-10	0.0	.0	0.0	.0	0.0	.0	0.0	.0
11 and above	0.0	0	0.0	.0	0.0	.0	0.0	.0
Not Applicable	51	38.3	26	19.5	2	1.5	79	59.4
Total	89	66.9	40	30.1	4	3.0	133	100.00

The findings on the table 4.10 show that only 1-5 wrong results were received with 23(17.3%) completing treatment in 6 months, 12(9.0%) in 7-10months and 2(1.5%) in 11 months and above. Thus the few wrong results did not cause much delay on TB treatment. In

a study conducted by (Blount *et al*.,2010) on how False positives in TB diagnosis lead to real negatives for HIV patients, it was discovered that, Physicians and researchers had long understood that missing a positive diagnosis of tuberculosis in patients who actually have the disease can result .

4.5.3. Number of incomplete results received or issued from the laboratory and Treatment of TB patients

Data completeness is a key indicator of quality and thus the respondents were required to state the number of incomplete results if any received from the laboratory in the past 6 months to represent the current situation. The summary of finding is shown in table 4.10.

Table 4.10: Incomplete results received or issued from the laboratory and Treatment of TB patients

Incomplete results	Treatment of TB patients							
	6months		7-10 months		11 months and above		Total	
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
None	76	57.1	32	24.1	4	3.0	112	84.2
1-5	13	9.8	7	5.3	0.0	.0	20	15.0
6-10	0.0	.0	0.0	.0	0.0	.0	0.0	.0
11 and above	0.0	.0	1	.8	0.0	.0	1	.8
Total	89	66.9	40	30.1	4	3.0	133	100.00

Results in table 4.10 show that 76(57.1%) never received incomplete results and were treated in 6 months, 32(24.1%) were treated in 7-10 months and 4(3.0%) in 11months and above. Generally, 112(84.2%) respondents had never received incomplete results in the last 6 months. Out of staff who received wrong results, 13(9.8%) received only 1-5 wrong results and treatment was completed in 6 months, 7(5.3%) treatment completed in 7-10 months. Only 1(0.8%) received more than 11 wrong results and treatment completed in 7-10 months.

The percentage of none and 1-5 (99.2%) is a clear indication of quality control checks in the laboratory to ensure that results are complete before they are dispatched to the clinic and this also led to timely treatment. This can be compared to a study conducted by (Hawkins.,2011) on managing the Pre- and Post-analytical Phases of the Total Testing Process, in Korea. In this study, it discovered that for many years, the clinical laboratory had been at the forefront of quality improvement activities in the healthcare sector. Its focus on analytical quality had resulted in an error rate of 4-5 sigma which surpassed most other areas in healthcare.

4.6. Drug inventory and Treatment of TB patients

The third objective was to investigate how drug inventory as a component of quality management systems affects treatment of TB patients. The study sought to know if there was routine drug inventory and had the following themes; routine checks of TB drugs and how often inventory was done, drug stock outs and frequency and TB drug expiries and its frequency in the TB clinics.

4.6.1Drug inventory and frequency and Treatment of TB patients

Inventory of drugs is key to TB treatment because inadequate supply leads to non-adherence which may lead to drug resistant TB or prolonged treatment. Routine checks would therefore ensure that there was a constant supply of drugs to the patients and hence the respondents were asked to indicate if there were systems of drug inventory and how often that was done. The results were compared to TB treatment as summarized in table 4.11.

Table 4.11 Drug inventory and Treatment of TB patients

Drug inventory	Treatment of TB patients							
	6months		7-10 months		11 months and above		Total	
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage	Frequency	percentage
No	14	10.5	5	3.8	1	0.8	20	15.0
Yes	75	56.4	35	26.4	3	2,3	113	85
Total	89	66.9	40	30.1	4	3.0	133	100.00

Table 4.11, majority 75(56.4%) of the respondents were performing drug inventory and treatment completed in 6months, 35(26.4%) treated in 7-10 months and 3(2.3%) treated in 11 months and above. 14(10.5%) never conducted drug inventory and treatment completed in 6 months, 5(3.8%) treatment completed in 7-10 months and 1(0.8%) in 11 months and above. The study further sought to establish the frequency of the stock checks as indicated in table 4.12.

Table 4.12: Drug inventory frequency and Treatment of TB patients

Drug inventory	Treatment of TB patients							
	6months		7-10 months		11 months and above		Total	
	Frequency	Percentage	Frequency	percentage	Frequency	Percentage	Frequency	percentage
Monthly	51	38.3	22	16.5	3	2.3	76	57.1
Quarterly	20	15.0	10	7.5	0	.0	30	22.6
Twice yearly	0	.0	0	.0	0	.0	0	.0
Yearly	3	2.3	0	.0	0	.0	3	2.3
No regular pattern	1	.8	3	2.3	0	.0	4	3.0
Not Applicable	14	10.5	5	3.8	1	.8	20	15.0
Total	89	66.9	40	30.1	4	3.0	133	100.00

Table 4.12 shows that the 51(38.3%) had monthly stock checks and treatment was completed in 6 months, 22(16.5%) treated in 7-10 months and 3(2.3%) treated in 11 months and above. frequency of drug inventory is acceptable with majority76 (57.1%) taking stocks monthly and 30 (22.6%) quarterly which also translated to completion of treatment in 6 months and a few in 7-10 months. A small number 7(5.3%) indicated yearly stock check and

other no regular pattern though the treatment was still completed in 6 months and 7-10 months..

This is an indication that KEMRI/CDC has strengthened its inventory system in the pharmacy and clinic which ensures availability of TB regiments hence timely treatment. This echoes Maalaoui,(2009) research on Strengthening TB Drug Management in the Sudanese National TB Control Program: In-Depth Review of TB Drug Management, which explored several findings in the Sudanese pharmaceutical system institution. One of the recommendations was to strengthen human resources capacity in the area of inventory management at different levels of the programs' pharmaceutical distribution chain, Improvement of the drug management information system and ensuring better control of drug distribution and consumption.

4.6.2 TB drugs stock outs and frequency and Treatment of TB patients

Inadequate supply of drugs would lead to interruption of TB treatment or lack of timely treatment of the patients, which directly translates to drug resistance and continuous risk of infection in the community. The respondents were asked to indicate if they ever had drug stock outs and the frequency of such shortages. The summary of the analysis were presented in table 4.13.

Table 4.13: Drug stock outs and Treatment of TB patients

Response	Treatment of TB patients							
	6months		7-10 months		11 months and above		Total	
	Frequency	percentage	Frequency	percentage	Frequency	Percentage	Frequency	percentage
NO	72	54.2	31	23.3	2	1.5	105	79
YES	17	12.8	9	6.8	2	1.5	28	21.1
Total	89	66.9	40	30.1	4	3.0	133	100.00

The findings in table 4.13 are summaries of drug stock outs and it shows that only 28(21.1%) of the respondents had experienced stock outs in the clinics and majority 105(79%) had not. 72(54.2%) had no stock outs with treatment completed in 6 months, 31(23.3%) completed treatment in 7-10 months and 2(1.5) completed in 11 months and above. 17(12.8%) experienced stock outs with treatment completed in 6 months, 9(6.8%) completed in 7-10 months and 2(1.5%) completed in 11 months and above. The study sought to further know the frequency of drug stock outs from the 28 respondents as indicated in table 4.14.

Table 4.14: Frequency of drug stock outs and Treatment of TB patients

Stock outs	Treatment of TB patients							
	6months		7-10 months		11 months and above		Total	
	Frequency	Percentage	Frequency	percentage	Frequency	Percentage	Frequency	Percentage
Daily	0.0	.0	0.0	.0	0.0	.0	0.0	.0
Once a week	0.0	.0	0.0	.0	0.0	.0	0.0	.0
Once a month	2	1.5	4	3.0	2	1.5	8	6.0
Once a year	15	11.3	5	3.8	0	.0	20	15.0
Not Applicable	72	54.1	31	23.3	2	1.5	105	79.9
Total	89	66.9	40	30.1	4	3.0	133	100.00

Results from table 4.14 indicate that stock outs occurred in rare occasions; 8(6.0%) monthly and 20(15.0%) once a year and this did not affect the treatment of TB patients since it was completed in 6 months and 7-10 months. A study conducted by Sianozova (2012) on strengthening the national capacities for TB drug and health product management; it was concluded that, to estimate supply and demand for TB drugs, Standard Operation Procedures (SOPs) have to be developed and outside assistance is needed in development of the monitoring mechanism of stock levels, drug consumption, and tracking expiry dates for drugs.

4.6.3 Expiry of TB drugs and frequency and Treatment of TB patients

Essentially, if there is proper inventory of TB drugs, expiries should not occur in the clinics and if it happens it should be a rare occurrence. Based on this, the respondents were required to indicate if the drugs expire in the clinics and the frequency of this where applicable. The findings were summarized in table 4.15.

Table 4.15: Drug expiry and Treatment of TB patients

Response	Treatment of TB patients							
	6months		7-10 months		11 months and above		Total	
	Frequency	Percentage	Frequency	percentage	Frequency	Percentage	Frequency	percentage
NO	66	49.6	33	24.9	2	1.5	101	76.0
YES	23	17.3	7	5.3	2	1.5	32	24.1
Total	89	66.9	40	30.1	4	3.0	133	100.00

Table 4.15 shows that 66(49.6%) who did not experience drug expiries completed treatment in 6months, 33(24.9%) were treated in 7-10 months and 2(1.5%) were treated in 11 months and above. Out of those who experienced drug expiries, 23(17.3%) completed treatment in 6 months, 7(5.3%) in 7-10 months and 2(1.5%) in 11 months and above. The study further wanted to know the frequency of drug expiries from the 32 respondents and this was analyzed in table 4.16.

Table 4.16: Frequency of drug expiry in the clinic and Treatment of TB patients

Drug Expiry	Treatment of TB patients							
	6months		7-10 months		11 months and above		Total	
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage	Frequency	percentage
Monthly	0.0	.0	0.0	.0	0.0	.0	0.0	.0
Quarterly	1	.8	1	.8	0.0	.0	2	1.5
Twice Yearly	0.0	.0	0.0	.0	0.0	.0	0.0	.0
Once a year (rarely)	22	16.5	6	4.5	3	2.3	31	23.3
Not Applicable	66	49.6	33	24.8	1	.8	100	75.2
Total	89	66.9	40	30.1	4	3.0	133	100.00

Table 4.16 shows that drug expiry was a rare occurrence with majority 29(90.6%) of the respondents only experiencing that once in a year. This revealed a system that was well established to ensure that drugs do not expire in the clinic and only the required amount was supplied to the patients. It also eradicates the possibility of expired drugs being administered to the TB patients leading to serious mutations of the disease or drug resistance.

The findings contradict with(Rookkapan.,2005) study of deteriorated tuberculosis drugs and management system problems in lower southern Thailand, settings**,** three institutes,

11 hospitals and 38 community hospitals in southern Thailand. On the day of inspection grossly deteriorated EMB was observed in 44% of hospitals/institutes. All samples, except 14% of EMB, passed content assay tests. All INH and EMB samples passed the dissolution tests, but 62% of RMP samples and 26% of PZA samples failed. In conclusion; Sub-standard deteriorated TB drugs are a serious problem for TB control. TB drugs examined in the study area were not managed properly. Education on TB drug packaging and storage, and non-destructive systems in TB drug distribution, storage, inventory control, quality assurance and supervision are essential interventions.

4.7. Monitoring and evaluation and Treatment of TB patients

Determining the level at which monitoring and evaluation as a component of quality management systems affects treatment of TB patients was the fourth objective of the study. To achieve this objective, respondents were requested to answer various questions under the following sub-themes: The influence of direct observation of treatment (DOT) on TB treatment, the number of patients on DOT, follow-up of TB patients and how frequently it was done.

4.7.1 Direct observation of treatment (DOT) and Treatment of TB patients

Direct observation of Treatment (DOT) has impacted on the adherence of TB regimens since the patients are observed as they take drugs. This can be achieved through hospital based DOT which happens in the clinic or the community based approach which is done at home. The respondents were asked to state if DOT had any influence on TB treatment and that was based on their opinion. The results were summarized in table 4.17.

Table 4.17: Respondents on DOT and Treatment of TB patients

DOT	Treatment of TB patients							
	6months		7-10 months		11 months and above		Total	
	Frequency	percentage	Frequency	percentage	Frequency	percentage	Frequency	percentage
NO	2	1.5	1	.8	0.0	.0	3	2.3
YES	87	65.5	39	29.3	4	3.0	130	97.8
Total	89	66.9	40	30.1	4	3.0	133	100.00

Table 4.17 shows that 87(65.5%) of the respondents had implemented DOT and treatment completed in 6 months, 39(29.3%) had treatment in 7-10 months, and 4(3.0%) treated in 11 months and above. This was a clear indication that monitoring and evaluation had positively influenced TB treatment through the DOT system. Only 3(2.3%) did not implement DOT. This can be compared to Okanurak.,(2007) study on Effectiveness of DOT for tuberculosis treatment outcomes: a prospective cohort study in Bangkok, Thailand; where it was concluded that the pattern of drug administration impacted on treatment success.

4.7.2 Number of patients on direct observation of treatment (DOT) and Treatment of TB patients

The study sought to find out an approximate figure of the number of patients currently under DOT to establish if the DOT was being implemented. The findings were analyzed in table 4.18.

Table 4.18: Number DOT patients and Treatment of TB patients

Number	Treatment of TB patients							
	6months		7-10 months		11 months and above		Total	
	Frequency	Percentage	Frequency	percentage	Frequency	percentage	Frequency	percentage
None	8	6.0	4	3.0	0.0	.0	12	9.0
Less than 20	43	32.3	16	12.0	2	1.5	61	45.9
21-40	12	9.0	5	3.8	0.0	.0	17	12.8
41-60	6	4.5	5	3.8	0.0	.0	11	8.3
61 and above	19	14.3	10	7.5	2	1.5	31	23.3
Not Applicable	1	.8	0.0	.0	0.0.	.0	1	.8
Total	89	66.9	40	30.1	4	3.0	133	100.00

Table 4.18 shows that majority of the patients were on DOT with only 12(9.0%) respondents indicating that none was on DOT, with 121(81%) under DOT. 59(44.4%) of the

respondents indicated a large number of patients (more than 21) were under DOT. 43(32.3%) indicated less than 20 patients in DOT who completed treatment in 6 months. This reveals the care being provided to majority of the TB patients to ensure drug adherence and hence eventual cure. This is in line with a study conducted by Tumbo *et al*. (2010) on evaluation of directly observed treatment for tuberculosis in the Bojanala health district, North West Province of South Africa, which indicated that in this South African rural health district, the DOT utilization rate for TB was 56.8%, mainly for patients on the TB retreatment regimen. Strict implementation of DOT in all patients undergoing TB treatment is a known strategy for improving TB cure rate and preventing recurrence and drug resistance.

4.7.3 Follow-up of TB patients and frequency and Treatment of TB patients

Follow-up of the patients also gives an indication that there was a way of ensuring that the TB patients took drugs and were properly cured. Based on that, the respondents were asked if follow-up was done and how often that was done. The results were summarized in table 4.19.

Table 4.19: Follow-up and Treatment of TB patients

Response	Treatment of TB patients							
	6months		7-10 months		11 months and above		Total	
	Frequency	percentage	Frequency	percentage	Frequency	percentage	Frequency	percentage
NO	4	3.0	0.0	.0	0.0	.0	4	3.0
YES	85	63.9	40	30.1	4	3.0	129	97.0
Total	89	66.9	40	30.1	4	3.0	133	100.00

Table 4.19 shows that 129(97%) of the respondents were doing follow-up on the TB patients and only 4(3%) were not doing that. 85(63.9%) of those doing follow-up completed treatment in 6 months, 40(30.1%) in 7-10 months, and 4(3.0%) in 11 months and above. Only 4(3.0%) were not doing follow-up. The study further analyzed the patterns of follow-up, based on the number of patients under follow up. As indicated in table 4.20.

Table 4.20: Follow up frequency and Treatment of TB patients

follow up	Treatment of TB patients							
	6months		7-10 months		11 months and above		Total	
	Frequency	Percentage	Frequency	percentage	Frequency	percentage	Frequency	Percentage
Less frequently (less than 50%)	10	7.5	1	.8	0.0	.0	11	8.3
Frequently (over 50%)	17	12.8	16	12.0	0.0	.0	33	24.8
More Frequently (90% and above)	60	45.1	23	17.3	4	3.0	87	65.4
Not Applicable	2	1.5	0.0	.0	0.0	.0	2	1.5
Total	89	66.9	40	30.1	4	3.0	133	100.00

Majority of the respondents 87(65.4%) in table 4.20 indicated that over 90% of the patients were under follow-up and also led to completion a big percentage 45.1% completing treatment in 6 months.

4.8 Data management and TB management and Treatment of TB patients

The fifth objective was to assess the level at which data management as a component of quality management systems affects treatment of TB patients. This was considered under the following themes; Data capturing systems available, link of TB patients to national TB registers and how often the link was done.

4.8.1Data capturing systems and Treatment of TB patients

Effective data capture is a quality indicator which translates to proper statistics hence efficient TB treatment. Capturing data on paper alone has proved to be ineffective due to factors like slow data transfer and natural calamities like fire. Both paper and electronic or purely electronic capture ensures data is secure, can be easily transferred and analyzed. The respondents were asked to state the system in place and results are as stipulated in table 4.21.

Table 4.21: Data capture systems and Treatment of TB patients

Data capture	Treatment of TB patients							
	6months		7-10 months		11 months and above		Total	
	Frequency	percentage	Frequency	Percentage	Frequency	percentage	Frequency	percentage
Electronic	16	12.0	3	2.3	0.0	.0	19	14.3
Paper	13	9.8	5	3.8	0.0	.0	18	13.5
Paper and electronic	60	45.1	32	24.1	4	3.0	96	72.2
Not Applicable	2	1.5	0.0	.0	0.0	.0	2	1.5
Total	89	66.9	40	30.1	4	3.0	133	100.00

Table 4.21 shows that majority of the respondents 96(72.2%) had paper and electronic systems of data capture, 19(14.3%) captured electronically and only 18(13.5%) were only using paper only. This reveals 86.5% of adequate data capture, a system which led to completion of treatment in 6 months and a few in 7-10 months. Vranken (2002) in a study on Use of a computerized tuberculosis register for automated generation of case finding, sputum conversion, and treatment outcome reports in South Africa, the 'Electronic TB Register' was found to be a potentially powerful tool for surveillance, management, and supervision for countries with well-functioning paper-based recording and reporting systems.

4.8.2 Link of TB patients to national TB registers and frequency and Treatment of TB patients

The study sought to find out if the TB patients were linked to the TB register as this forms a basis of policy formulation by the government thereby leading to the right decisions on treatment of TB and its management. The respondents were therefore asked to state if they linked the patients to the TB registers and how often that was done and the findings were summarized in table 4.22.

Table 4.22: Link to national TB registers and Treatment of TB patients

Response	Treatment of TB patients							
	6months		7-10 months		11 months and above		Total	
	Frequency	percentage	Frequency	Percentage	Frequency	percentage	Frequency	percentage
NO	2	1.5	4	3.1	0.0	.0	6	.4.6
YES	87	65.4	36	27.1	4	3.0	127	95.5
Total	89	66.9	40	30.1	4	3.0	133	100.00

From the findings in table 4.22, 127(95.5%) respondents indicated that TB patients were linked to the TB registers and only 6(4.5%) thought they were not linked. The study sought to further establish how often the link is done for adequate statistics as indicated in table 4.23.

Table 4.23: Frequency of linking TB patients to the TB registers and Treatment of TB patients

Frequency	Treatment of TB patients							
	6months		7-10 months		11 months and above		Total	
	Frequency	percentage	Frequency	Percentage	Frequency	percentage	Frequency	percentage
Daily	49	36.8	15	11.3	0.0	.0	64	48.1
Weekly	15	11.3	5	3.8	0.0	.0	20	15.0
Monthly	19	14.3	11	8.3	4	3.0	34	25.6
Quarterly	4	3.0	3	2.3	0.0	.0	7	5.3
Yearly	0.0	.0	2	1.5	0.0	.0	2	1.5
Not Applicable	2	1.5	4	3.0	0.0	.0	6	4.5
Total	89	66.9	40	30.1	4	3.0	133	100.00

Table 4.23 shows the frequency as follows, daily 64(48.1%), weekly 20(15.0%), monthly 34(25.6%), 7(5.3%) and yearly 2(1.5%). The frequency of daily to monthly was quite adequate and that translated to 88.7%. Correct data capture therefore translates to proper policy formulation on the TB patients hence proper treatment and management. This is line with Sharif (2012) study on new data system set to radically reduce TB cases in Nairobi, Kenya, which indicated that tuberculosis incidences could be reduced by 10 per cent every year following the introduction of a digital programme to monitor the treatment of patients.

He mentioned that the unique programme dubbed TIBU will help in controlling and managing data of TB patients thereby ensuring zero TB tolerance by the year 2015.

CHAPTER FIVE

SUMMARY OF FINDINGS, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

In this section the sub topics were discussed as: summary of findings, conclusions of the study and recommendations for further research for both policy and contribution to knowledge.

5.2 Summary of Findings

This study had five major themes namely; to investigate the extent to which turnaround time as a component of quality management systems affects treatment of TB patients, to assess the level at which result accuracy as a component of quality management systems affects treatment of TB patients, to investigate how drug inventory as a component of quality management systems affects treatment of TB patients, to determine the level at which monitoring and evaluation as a component of quality management systems affects treatment of TB patients and to assess the level at which data management as a component of quality management systems affects treatment of TB patients.

The findings show that of those who took 3 weeks – 1 month to seek medication,35(26.3%) completed medication in 6 months, 9(6.8%) completed treatment in 7-10 months. Only 17(12.8%%) sought medication in one months and above and this didn't affect the treatment duration since in occurred in 6 months and 7-10 months. This is an indication that time to diagnosis does not affect TB patient treatment. 81(60.9%) received smear results in 48 hours and completed treatment in 6 months.31(23.3%) also received

results in 48 hours and treatment completed in 7-10 months. Only 1(0.8%) received smear results in 2 weeks -1 month and then treatment was completed in 7-10 months. This clearly shows that majority of the KEMRI/CDC TB patients receive smear results within 48 hours and also treated within 6 months and a few of those are treated in 7-10 months. The findings reveal that 63(47.4%) received culture results in 2-3 months treatment completed in 6 months. Majority of the results were within the required turnaround time of less than a month for positives and 2-3 months for negative cultures and patients were treated in 6 months or 7-10 months which is within the CDC recommended turnaround time according to (McCarthy *et al*, 2010).

On the objective to assess the level at which result accuracy as a component of quality management systems affects treatment of TB patients, the results show that 61 (45.9%) had never received wrong results with treatment completed in 6 months, 28(21.1%) also received correct results and treatment completed in 7-10 months. Only 1-5 wrong results were received and that did not affect TB patient treatment. Results also show that 76(57.1%) respondents never received incomplete results in the last 6 months and treatment completed in 6 months. The percentage of correct and complete results is an indication of quality control checks in the laboratory to ensure that results are complete before they are dispatched to the clinic. This is a confirmation that the Quality management system in the laboratory has minimized transcription errors and quality results are generated hence TB patients receiving timely treatment.

Drug inventory as a component of quality management systems and how it affects treatment of TB patients; Majority 75 (56.4%) of the respondents were performing drug

inventory with treatment completed in 6 months. Results also show that the frequency of drug inventory is acceptable with majority 51 (38.3%) taking stocks monthly treatment completed in 6 months. Summaries of drug stock outs show that 72 (54.2%) had never experienced drug stock outs in the clinics with treatment completed in 6 months. Of the respondents experiencing stock outs 28, majority 20 (71.4%) occurred in rare occasions which is yearly and that did not affect the length of treatment. 66 (49.6%) had not experienced drug expiries in the clinic and treatment completed in 6 months. The quality management systems have enhanced implementation of proper inventory checks to ensure that clinics don't run out of stocks and only few expiries are experienced in the clinics. Adequate and quality drugs were therefore available to ensure proper treatment of the TB patients.

Another objective was to determine the level at which monitoring and evaluation as a component of quality management systems affects treatment of TB patients. Based on the respondents opinion, 87 (65.5%) felt that DOT had improved TB treatment and treatment completed in 6 months. Results also indicate that 85 (63.9%) of the respondents were doing follow-up on the TB patients and treatment completed in 6 months. 60 (45.1%) indicated that over 90% of the patients were under follow-up and treatment also completed in 6 months. The summary of the results reveal a good monitoring and evaluation system through the DOT and patient follow-up hence benefiting the TB patients by ensuring that they are closely monitored when taking their drugs and follow-up till they are completely cured.

The last objective was to assess the level at which data management as a component of quality management systems affects treatment of TB patients. Results show that majority of the respondents 60 (45.1%) had both paper and electronic data capture and treatment was

completed in 6 months. More findings show that 87 (65.4%) of respondents link TB patients to national registers and treatment completed in 6 months. 49 (36.8%) were linking TB patients to the national registers on a daily basis and treatment completed in 6 months. Correct data capture and link therefore translates to efficient data analysis, transfer and proper policy formulation on the TB patient's hence proper treatment and management.

5.3 Conclusions

From the present research findings there is sufficient evidence that the quality management systems implemented in KEMRI/CDC since 2011 have improved the treatment of TB patients. The turnaround time for smear and culture results have met the CDC standards according to (McCarthy *et al*, 2010), patients are seeking medication in good time with a slight sensitization required and the lead time for TB patients is 6 months hence timely treatment of TB patients. Results accuracy has enhanced release of correct and complete results following the constant quality checks in the laboratory translating to correct diagnosis and appropriate treatment of TB patients.

Routine inventory of drugs has enhanced adequate supply of drugs with rare cases of expiries in the TB clinics. The TB patients are therefore given the right regimens and doses leading to effective treatment and cure of TB disease. TB patients are not exposed to inconsistent supply of drugs which may eventually lead to drug resistance.

Monitoring and evaluation through the DOT systems and follow-up has also proved effective in ensuring that TB patients are monitored closely as they take their drugs. Follow-up is also vital to capture progress and end points of the patients. Data capture is key in TB treatment and has ensured fast analysis and data transfer. This enables KEMRI/CDC to get a

true picture of TB burden in the country and thereby assisting the government to make the right decisions and formulate policies towards eradication of TB disease.

5.4 Recommendations

Having looked at the theoretical framework, the conceptual framework alongside the literature review and the study findings, the following recommendations were made:

KEMRI/CDC has managed to provide proper and effective treatment of TB patients through implementation of quality management systems but there are a few cases of drug stock outs and expiries, wrong results, long turnaround time for some results and paper only data capture systems which should be addressed for effective treatment of TB patients.

Other sectors dealing with TB patients should embrace quality management systems which have resulted to successful TB treatment in KEMRI/CDC. TB patients received timely results and timely treatment which ensured proper cure.

Monitoring of TB patients is essential since it ensured adherence to drugs and reduced chances of multi-drug resistance and relapse cases. DOT and follow-up of patients enabled proper monitoring of TB patients in KEMRI/CDC and should be implemented in other sectors for proper management of TB patients.

Proper drug inventory ensured availability of drugs and this led to successful treatment of TB patients in KEMRI/CDC. This ensured that patients access quality and adequate drugs to enable completion of treatment within the required 6 months.

Electronic data capture should be implemented in other sectors since it enhanced fast data capture, analysis and transmission. Patients in KEMRI/CDC were able to access timely treatment and proper management due to efficient and fast data transfer.

5.4.1 Recommendations for Policy issues and Practice

KEMRI/CDC has a record of an effective quality management system on the TB sector with 116(87.2%) smear turnaround of 48 hours and 130 (97.7%) turnaround times of less than 3 months for culture results. The highest burden of TB lies in the public hospitals and hence the Ministry of Health is encouraged to enforce quality management systems to ensure timely and effective care of TB patients.

Quality management systems should be a key factor in allocation of health budgets not only in Kenya but also globally. KEMRI/CDC has 115(86.5%)of adequate data capture systems, electronic and paper or purely electronic which enhance proper decisions and may assists the government of Kenya in policy formulation toward eliminating TB disease.

5.4.2 Suggestions for further Research

This study did not explore certain areas that were equally important. Such areas were left out because they were beyond the scope and limitation of this study warranted and also due to a limitation in time and other resources.

In view of this, the study recommends the following areas for further research. There is need for a comparative study to investigate other TB sectors outside KEMRI/CDC who have implemented similar quality management systems to find out whether different results can be

generated. In the current study, this is not possible as the study had limited resources and tight time schedules.

There is need to conduct a similar study in the public hospitals to identify the gaps in pursuit of enlightening or advising the policy makers on the action plans. This would help to relieve the country of the TB disease burden.

Table 5.1 Contribution to body of Knowledge

Objectives	Contribution to body of knowledge
1. To investigate the extent to which Turnaround time as a component of quality management systems affects treatment of TB patients.	Majority of the respondents received smear results in 48 hours which is an indication of efficiency in KEMRI/CDC labs which can provide mentorship to other laboratories.
2. To assess the level at which result accuracy as a component of quality management systems affects treatment of TB patients.	A few respondents received some wrong results from the laboratory and hence measures should be put in place to ensure that no wrong results are released from the laboratory.
3. To investigate how drug inventory as a component of quality management systems affects treatment of TB patients.	Some clinics experienced drug stock outs occasionally and also drug expiries and hence inventory should be improved to eliminate these occurrences.
4. To determine the level at which monitoring and evaluation as a component of quality management systems affects treatment of TB patients.	Majority of the TB patients are under DOT which is good indication that the programme has been successfully implemented
5. To assess the level at which data management as a component of quality management systems affects treatment of TB patients.	A few health sectors are still using paper only as a data capture system and efforts should be put to ensure they embrace electronic data capture as well.

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APPENDIX I

LETTER OF TRANSMITTAL

UNIVERSITY OF NAIROBI

P.O. BOX 30197-00100

NAIROBI, KENYA

18 FEB 2012

TO…….

RE: EFFECTS OF QUALITY MANAGEMENT SYSTEMS ON TREATMENT OF TB PATIENTS IN KEMRI/CDC, KISUMU

I am currently a student pursuing a Masters of Arts Degree in Project Planning and Management at the University of Nairobi. I am carrying out the above study in KEMRI/CDC, Kisumu as part of the requirements for the fulfillment of Masters of Arts Degree. The purpose of this letter is to request your participation in the study.

All information collected will be treated as strictly confidential.

Your cooperation and support in this study will be highly appreciated.

Yours faithfully,

Susan Kalondu Musau.

APPENDIX II

Questionnaire for KEMRI/CDC staff

Introduction

I am Susan Musau, a student from the University of Nairobi pursuing a master's degree in project planning and management. Thank you for agreeing to participate in filling up this questionnaire. You have been identified as one of the KEMRI/CDC staff who has the opportunity to contribute to the study which tries to get effects of quality management systems on treatment of TB patients in KEMRI/CDC, Kisumu, Kenya.

Before we begin, I'd like to reassure you that your identity and the information you provide will be kept strictly confidential and for the research purposes only.

Do you have any questions at this point?

A. General information

1. What is your Gender? Male □ Female □

2. What is your Age? Below 20 □ 22-30 □ 31-40 □

41-50 □ Above 50 □

3. What are your years of Experience in KEMRI/CDC?

Less than 4 years □ 5-10 □ More than 10 □

4. What is your Profession?

Doctor □ Clinician □ Nurse □ Laboratory staff □

Community interviewer □ Pharmacist □

B. Turnaround time and TB treatment

1. Out of TB patients contacted in the past 6 months, what is the length of time from the time the patient experiences symptoms to the time they seek medication?(tick where most of the patients lie)

Less than One week ----------Patient/s

1-2 weeks ----------Patient/s

3 weeks -1 month ----------Patient/s

More than one month ----------Patient/s

2. How long do the smear results take currently (2011-Present)?

Less than 48 Hrs □

3 days -1 week □

2wks- 1month □

2 months and above □

3. How long do the culture results take currently (2011-Present)?

Less than 1 month □

2-3 months □

4 and above □

4. Out of the total TB patients who have completed TB treatment since January 2011 to end January 2013.

How long does it take to treat a TB patient –from time of diagnosis to exit visit? (tick where most of the patients lie)

6 months ----------Patient/s

7-10 months ----------Patient/s

11 and above months ----------Patient/s

C. Result accuracy and TB treatment

1. **Have you ever received or issued a wrong result from the laboratories in the last 6 months?** Yes □ No □

   (If No, skip to question 3)

2. **If yes, how many wrong results have you received or issued in the last 6 months?**

   None□ 1-5 □ 6-10 □ 11and above □

3. **For the last 6 months how many incomplete results have been received or issued from the laboratory?**

None □ 1-5 □ 6-10 □ 11and above □

D. Drug inventory and TB treatment

1. Do you have routine stock checks of your TB drugs? Yes □ No □

(If No, skip to question 3)

2. If yes how often is this done?

Monthly □ Quarterly□ Twice yearly □ Yearly □ No regular pattern □

3. Do you ever experience TB drugs stock outs? Yes □ No □

(If No, skip to question5)

4. If yes, how often does that happen?

Daily □ Once a week □ Once a month □ Once a year □

5. Do TB drugs expire in the clinic? Yes □ No □

(If No, skip to section E)

6. If yes, how often do drugs expire in the clinic?

Monthly□ Quarterly □ Twice yearly □ Once a year □

E. Monitoring and evaluation and treatment

1. In your own opinion do you think direct observation of treatment (DOT) influence TB treatment Yes □ No□

(If No, skip to question 3)

2. If yes how many patients **are currently on Direct observation of treatment (DOT)?**

None □ Less than 20 □ 21-40 □ 41-60 □

61 and above □

3. Do you do follow-up on the TB patients? Yes □ No□

4. If yes how frequently does it happen?

Less frequently (less than 50%) □ frequently (over 50%) □

More frequent (90% and above) □

F. Data management and TB treatment

1. How is patient Data captured in your system?

Electronic □ Paper□ Paper and electronic□ Other……

2. In your own opinion, do you think patients are linked to the national TB registers?

Yes □ No □

3. If yes, how often do you do that?

Daily □ Weekly □ Monthly □ Quarterly □ Yearly □ Other ……

APPENDIX 111

Letter of Research Authorization

REPUBLIC OF KENYA

NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

Telephone: 254-020-2213471, 2241349, 254-020-2673550
Mobile: 0713 788 787 , 0735 404 245
Fax: 254-020-2213215
When replying please quote
secretary@ncst.go.ke

P.O. Box 30623-00100
NAIROBI-KENYA
Website: www.ncst.go.ke

Our Ref: **NCST/RCD/12A/013/56**

Date: **20th May 2013**

Susan Kalondu Musau
University of Nairobi
P.O Box 30197-00100
Nairobi.

RE: RESEARCH AUTHORIZATION

Following your application dated **6th May, 2013** for authority to carry out research on ***"Effects of quality management systems on treatment of tuberculosis patients at the Kenya Medical Research Insitute/Centre for Disease Control and Prevention, Kisumu, Kenya."*** I am pleased to inform you that you have been authorized to undertake research in **Kisumu District** for a period ending **31st August, 2013.**

You are advised to report to **the Chief Executive Officer, KEMRI/CDC** before embarking on the research project.

On completion of the research, you are expected to submit **two hard copies and one soft copy in pdf** of the research report/thesis to our office.

DR. M. K. RUGUTT, PhD, HSC.
DEPUTY COUNCIL SECRETARY

Copy to:
The Chief Executive Officer
Kenya Medical Research Institute/CDC

"The National Council for Science and Technology is Committed to the Promotion of Science and Technology for National Development".

APPENDIX 1V

Research Permit

PAGE 2

THIS IS TO CERTIFY THAT:
Prof./Dr./Mr./Mrs./Miss/Institution
Susan Kalondu Musau
of (Address) University of Nairobi
P.O Box 30197-00100, Nairobi.
has been permitted to conduct research in

Kisumu — Location
Nyanza — Province

on the topic: Effects of quality management systems on treatment of tuberculosis patients at the Kenya Medical Research Insitute/Centre for Disease Control and Prevention, Kisumu, Kenya

for a period ending: 31st August, 2013.

PAGE 3

Research Permit No. NCST/RCD/12A/013/56
Date of issue 20th May, 2013
Fee received KSH. 1,000