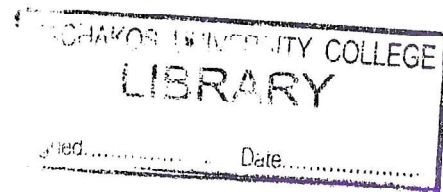


**FACTORS AFFECTING IMPLEMENTATION OF ISO  
9001:2008 QUALITY MANAGEMENT SYSTEM IN  
HOSPITALS: THE CASE OF THE MATER HOSPITAL,  
NAIROBI**

**CAROL MORAA MITAKI**



**A PROJECT REPORT SUBMITTED TO THE SCHOOL OF HUMAN  
RESOURCE DEVELOPMENT IN PARTIAL FULFILMENT OF THE  
REQUIREMENTS FOR THE AWARD OF THE DEGREE OF  
EXECUTIVE MASTER OF BUSINESS ADMINISTRATION OF JOMO  
KENYATTA UNIVERSITY OF AGRICULTURE AND TECHNOLOGY**

**JUNE, 2011**

## DECLARATION

This project report is my original work and has not been presented for a degree in any other university.

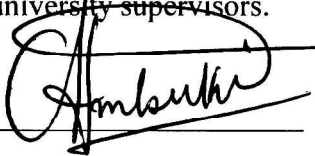
Signature ..... Carol Mitaki .....

Date ..... 22/06/2011 .....

Carol Mitaki

Reg. No. HD334-033-0768/2010

This project report has been submitted for examination with our approval as the appointed university supervisors.

Signed: 

Date: 22/06/2011

Dr. Ombuki Charles

Signed: 

Date: 22.06.2011

Mr. Sang' Paul



## DEDICATION

*This project is dedicated to my late father, who did not live long enough to be part of my achievements; yet would have been immensely proud of me.*

## **ACKNOWLEDGEMENT**

I want to acknowledge my dear friend and husband, Patrick, my number one fan, for his unwavering support - moral and material - during my research journey. I also acknowledge my sons, Marvin and Samora, for their support and patience when I had to put in long hours of work hence deprived them of a mother's care.

To my supervisors, Dr. Charles Ombuki and Mr. Paul Sang', this project could not be completed without your guidance. I appreciate your support and your patience. May the Lord expand your horizons.

## ABSTRACT

The aim of this study was to establish the factors affecting implementation of the ISO 9001:2008 quality management system (QMS) in hospitals, with a focus on The Mater Hospital. To establish the factors, the study aimed at addressing the following objectives: determining the effects of training on implementation of ISO 9001:2008 QMS at The Mater Hospital; assessing the effect of availability of resources on implementation of ISO 9001:2008 QMS at The Mater Hospital, and to establish the extent to which top management support affects implementation of ISO 9001:2008 QMS at The Mater Hospital. The study limited itself to The Mater Hospital, Nairobi, since it was the first hospital in East and Central Africa to be ISO 9001:2000 certified. The study adopted a descriptive design method because it describes the factors affecting implementation of ISO 9001:2008 QMS at The Mater Hospital. The target population for the study was The Mater Hospital staff. 50 employees out of the target population of 500 employees were selected, using stratified random sampling technique, to represent the sample size from the Heads of Departments, Section Managers and non-management staff. The data collection tool used was the questionnaire due to its convenience and cost effectiveness. Finally, the data collected was analyzed using the Statistical Package of Social Sciences (SPSS) version 17.0 and the data presented in tables and graphs.

The study found out that all staff should be trained on ISO 9001:2008 QMS, and attend training related to their function in the hospital. Staff should also have regular departmental awareness sessions in ISO 9001:2008 QMS. The effects of training on implementation of ISO 9001:2008 QMS include enhanced knowledge and skills of the people involved in offering services, standardization of healthcare processes and practices at the hospital, and enhanced customer focus. The study also found that availability of resources encourages innovation and creativity in service delivery, and enhances team work, while minimizing individuality. The study findings depict that a hospital's top management should support the ISO 9001:2008 QMS by organizing awareness sessions, appointing a manager to be in charge of the system, and using the system as a management tool. Further, to support the QMS, the study found that non-conformities should be addressed in consultation with the Heads of Department (HODs), follow up actions should be done by management, the HODs should be responsive to departmental needs, and they should frequently hold departmental meetings on the QMS. The study concluded that training, availability of resources and top management support are factors that affect implementation of the ISO 9001:2008 in hospitals.

## TABLE OF CONTENTS

<b>DECLARATION</b> .....	<b>ii</b>
<b>DEDICATION</b> .....	<b>iii</b>
<b>ACKNOWLEDGEMENT</b> .....	<b>iv</b>
<b>ABSTRACT</b> .....	<b>v</b>
<b>TABLE OF CONTENTS</b> .....	<b>vi</b>
<b>LIST OF TABLES</b> .....	<b>ix</b>
<b>LIST OF FIGURES</b> .....	<b>x</b>
<b>ABBREVIATIONS / ACRONYMS</b> .....	<b>xi</b>
<b>DEFINITION OF TERMS</b> .....	<b>xii</b>
<b>CHAPTER ONE</b> .....	<b>1</b>
<b>INTRODUCTION</b> .....	<b>1</b>
1.1 Introduction .....	1
1.2 Background to the Study .....	1
1.2.1 ISO 9001:2008 Standard .....	6
1.2.2 The Mater Hospital .....	7
1.3 Statement of the Problem .....	8
1.4 General Objective.....	9
1.4.1 Specific Objectives .....	10
1.5 Research Questions .....	10
1.6 Justification of the Study.....	10
1.7 Scope of the Study.....	12
1.8 Limitations of the Study .....	12
<b>CHAPTER TWO</b> .....	<b>13</b>
<b>LITERATURE REVIEW</b> .....	<b>13</b>
2.1 Introduction .....	13
2.2 QMS Concept.....	13
2.2.1 ISO Standards .....	13
2.2.2 Quality Management Principles .....	14
2.2.3 Organizational Performance .....	15

2.3. Quality of Nursing Care .....	18
2.4 Effect of Training on Implementation of ISO 9001:2008.....	23
2.5 Effect of Availability of Resources on Implementation of ISO 9001:2008	23
2.6 Effect of Top Management Support on Implementation of ISO 9001:2008	24
2.7 Operational Efficiency .....	25
2.8 Amount of Time Taken for Service Delivery .....	29
2.9 Empirical Studies .....	31
2.10 Benefits of ISO 9001:2008.....	33
2.11 Critique of Literature Review and Research Gaps.....	33
2.12 Conceptual Framework .....	34
<b>CHAPTER THREE .....</b>	<b>36</b>
<b>RESEARCH METHODOLOGY .....</b>	<b>36</b>
3.1 Introduction .....	36
3.2 Research Design.....	36
3.3 Target Population .....	36
3.4 Sampling Design .....	37
3.4.1 Sampling Frame.....	37
3.4.2 Sample Size .....	38
3.4.3 Sampling Procedures .....	39
3.5 Data Collection Instruments.....	39
3.5 Data Collection Procedures.....	40
3.6 Data Analysis .....	41
<b>CHAPTER FOUR.....</b>	<b>42</b>
<b>DATA ANALYSIS, PRESENTATION AND INTERPRETATION .....</b>	<b>42</b>
4.0 Introduction .....	42
4.1 Background Information of the Respondents.....	43
<b>CHAPTER FIVE .....</b>	<b>62</b>
<b>SUMMARY OF FINDINGS, CONCLUSION, AND</b>	
<b>RECOMMENDATIONS.....</b>	<b>62</b>
5.0 Introduction .....	62

5.1 Summary of Findings .....	62
5.2 Conclusions .....	64
5.3 Recommendations .....	65
5.4 Suggestions for further studies.....	66
<b>REFERENCES.....</b>	<b>67</b>
<b>APPENDIX I: LETTER OF INTRODUCTION .....</b>	<b>75</b>
<b>APPENDIX II: QUESTIONNAIRE .....</b>	<b>76</b>



## LIST OF TABLES

Table 3.1: Target population for the study.....	38
Table 3.2: Sample frame for the study.....	38
Table 4.1: Distribution of respondents by gender.....	43
Table 4.2: Distribution of respondents by departments .....	44
Table 4.3: Distribution of the respondents by education level .....	46
Table 4.4: Training in ISO 9001:2008 QMS .....	47
Table 4.5: Training relevant to function .....	48
Table 4.6: Effects of training on implementation of ISO 9001:2008 .....	51
Table 4.7: Availability of resources to support service delivery at The Mater Hospital .....	52
Table 4.8: Effects of availability of resources on implementation of ISO 9001:2008 QMS .....	53
Table 4.9: Effects of top management support on implementation of ISO 9001:2008.....	55
Table 4.10: Effects of ISO 9001:2008 QMS on organizational performance .....	56
Table 4.11: Factors associated with the success or failure of ISO 9001:2008 quality management systems.....	58
Table 4.12: Suggestions on how ISO 9001:2008 QMS can contribute to enhancing organizational performance at The Mater Hospital.....	60

## LIST OF FIGURES

Figure 3.1: Conceptual Framework .....	35
Figure 4.1: Years worked with the organization.....	45
Figure 4.2: Last training.....	49
Figure 4.3: Frequency of Training.....	50

## **ABBREVIATIONS / ACRONYMS**

**CQI** : Continuous Quality Improvement

**EHRs** : Electronic Health Records

**HIM** : Health Information Management

**HODs** : Heads of Department

**IT** : Information Technology

**JIT** : Just-in-Time

**KEBS** : Kenya Bureau of Standards

**TQM** : Total Quality Management

**KPIs** : Key Performance Indicators

**QMS** : Quality Management System

## **DEFINITION OF TERMS**

- Just-in-time:** A production strategy that strives to improve a business' return on investment by reducing in-process inventory and associated carrying costs. (<http://en.wikipedia.org>)
- Quality:** The extent of resemblance between the purpose of healthcare and the truly granted care (Donabedian, 1986).
- Total Quality Management:** A system of management based on the principle that every staff member must be committed to maintaining high standards of work in every aspect of a company's operations.
- Standard:** Is a pre-determined baseline condition or level of excellence that comprises a model to be followed and practiced.
- Nursing audit:** May be defined as a detailed review and evaluation of selected clinical records in order to evaluate the quality of nursing care and performance by comparing it with accepted standards

## **CHAPTER ONE**

### **INTRODUCTION**

#### **1.1 Introduction**

This chapter presents the background to the study and the statement of the problem. It also presents the objectives of the study, research questions, significance and scope of the study.

#### **1.2 Background to the Study**

Countries around the world today have been focusing on healthcare as one of their key national agenda due to, among other reasons, their growing aging populations and a high percentage of chronic disease patients. Access to the right and accurate information delivered to the right place at the right time, providing the right level of quality of care and reducing healthcare cost are the challenges faced by not only the local governments but by many of the healthcare institutions in both developed and developing countries (Fisher *et al*, 2003).

Over the last 50 years, the medical field has made incredible advances in increasing life expectancy dramatically, and turning many diseases that once were fatal, into chronic conditions that can be successfully managed for a lifetime (Gabbitas and Jeffs, 2007).

Despite tremendous advances in medicine, healthcare innovation is falling dangerously short of delivering consistent quality and accessing accurate

information largely due to an inability to connect isolated islands of information throughout the healthcare systems. As healthcare is an information-intensive endeavor, pervasive information disconnects are extremely costly, both economically and in terms of human life (Hollingsworth, 2003).

Studies by Private Health Insurance Administration Council (2008) clearly indicate that countries with high maternal, prenatal, and neonatal mortality have inadequate and poor quality health services and this can be associated with reduced utilization of health care services. As such, increased emphasis is being placed on the need for standards of care, as well as mechanisms which address the barriers to provision and use of quality care. Evidence also suggests that explicit, evidence-based guidelines improve the process and outcomes of health care when appropriately implemented. Experience from countries indicates that the characteristics of the guidelines, the process used in their development and a clear implementation strategy supported by effective monitoring and supervision influence the impact of practice guidelines (Joumard *et al.*, 2008).

A quality management system can be described as a set of key quality elements that must be in place for an organization's work operations to function in a manner as to meet the organization's stated quality objectives. Such a system provides the means to direct and control the organization with regard to quality (Carla *et al.*, 1996). The increasing complexity of today's healthcare services emphasizes the need for a systematic approach that both promotes and provides

for the highest level of service quality and patient safety. A healthcare quality management system describes, documents, implements, measures, and monitors the implementation and effectiveness of the work operations of any organization, service unit, or support operation in the organization. The establishment of policies and procedures that increase quality of life of patients define quality health care management. Quality healthcare management is also cost effective and generates a profit (Adongo *et al.*, 1996).

The worldwide healthcare industry is highly attuned to defining and enforcing standards for its medical professionals. Businesses worldwide use established standards to reduce time, effort and money they have to invest in the research and development of new products, while increasing their likelihood of success in the market place (Verhoeven, *et al.*, 2007). By providing best – practice guidance, standards help businesses to assess their processes, allowing them to take steps to increase efficiency and become more profitable. Standards also provide a reliable benchmark against which performance can be judged, enabling businesses to demonstrate product performance. Introducing standards can help businesses to retain existing clients and generate sales from new customers. (World Health Organization, 2004)

The healthcare industry is like any other industry: success is identified by how well an organization manages its resources, how successful that organization is in meeting the goals it sets; and how the organization compares to its competitors.

The difference between a healthcare organization that represents quality and a competitor is the bottom line. The bottom line in healthcare is measured by life and death. Quality healthcare management results in healthier patients (World Health Organization, 2004).

The ISO 9001:2008 standard requires an organization to establish, document, implement, and maintain a quality management system and continually improve its effectiveness. Specifically, quality management system documentation should include but not be limited to: documented statements of a quality policy and quality objectives, a quality manual, documented procedure required by this International Standard, documents needed by the organization to ensure the effective planning, operation and control of its processes. Where the standard specifically requires a “documented procedure”, the procedure has to be established, documented, implemented, and maintained (Onditi, 2009). It also emphasizes that the extent of the QMS documentation may differ from one organization to another due to: the size of organization and type of activities, the complexity of processes and their interactions, and the competence of personnel. All the documents that form part of the QMS have to be controlled in accordance with clauses of ISO 9001:2008.

The provision of high-quality, affordable, health care services is an increasingly difficult challenge. Due to the complexities of health care services and systems, investigating and interpreting the use, costs, quality, accessibility, delivery,



organization, financing, and outcomes of health care services is key to informing government officials, insurers, providers, consumers, and others making decisions about health-related issues (Reerink and Sauerborn, 2006). Since organizations depend on their customers, therefore they should understand current and future customer needs, should meet customer requirements and try to exceed the expectations of customers. An organization attains customer focus when all people in the organization know both the internal and external customers and also what customer requirements must be met to ensure that both the internal and external customers are satisfied (Heras *et al*, 2002).

As customers' expectations grow, it is essential that businesses continually improve to provide products and services of the highest quality (Hakes, 1991). Gopal (1996) notes that quality is a continual process that doesn't just happen but evolves over time and with experience. Quality standards have been used over the years to improve the quality of products and services in the increasingly competitive marketplace. Organizations can help secure their future by committing to a process of continual improvement and introducing a quality management system (QMS) or by adopting the process of conformity assessment (Brocka, 1992).

Docteur and Oxley (2003) admit that healthcare executives and managers are always searching for better ways to improve production capacity for medical treatment and thereby, improving operational efficiency. Many times, capacity in a health care organization is a vague, hard-to-measure concept which varies over

time and with local economic conditions. In any hospital, Duckett (2008) reports that resources are limited and they are mostly dissimilar in nature. Considering the limited resources, it is essential to find the optimal way to admit patients in order to maximize efficiency and productivity. This could directly affect the bottom line – maximizing revenue or profit. Typically the resources in any hospital are: doctors, nurses, operating rooms, waiting rooms, number of beds, laboratory, etc. The awareness of public authorities, industry and other economic players in developing countries of the importance of international standards is important to their economic development.

#### **1.2.1 ISO 9001:2008 Standard**

Lai (1996) defines a standard as a document approved by a recognized body, which recommends voluntary rules and guidelines concerning the characteristics of products, processes or methods. Standards facilitate trade and commerce by transmitting information in a consistent way and permitting comparisons of products and services. They allow for economies of scale, promote the efficient use of parts and components in production, facilitate the diffusion of technology and promote product quality, safety and environment cleanliness. By providing solutions to common problems they also make life simpler.

ISO 9001:2008 is the standard that provides a set of standardized requirements for a quality management system, regardless of what the user organization does, its size, or whether it is in the private, or public sector (Cianfrani, 2009). According

to Hakes (1991), the ISO quality management tool was designed to help an organization achieve its Total Quality Management (TQM) goals. ISO 9001:2008, the more recent version of ISO 9000, consists of a series of quality management standards aimed to standardize work processes and promote quality production throughout a variety of industries which it achieves through regularly analyzing conformance to customer requirements, characteristics of planning, construction implementation processes, and supplier performance data (Cianfrani, 2009).

### **1.2.2 The Mater Hospital**

The Mater Hospital was opened in 1962 by the Sisters of Mercy, a Catholic Order of Nuns originating from Ireland to cater mainly for poor, indigenous Kenyans, with the primary mission being general healthcare (Mater, 2009).

The hospital's mission is to deliver timely and compassionate medical services to patients and their families to the highest possible standard through the provision of staff, the most appropriate equipment and staff training programmes. It also seeks to contain its cost of operation such that the cost of medical care charged to patients remain as low and affordable as possible to as many patients as possible and such that the viability of the hospital, employment and investment are maintained in line with the ethos of the Sisters of Mercy Kenya. The Mater Hospital is committed to be a leading healthcare provider in East and Central Africa and benchmark itself against the highest attainable world standards seeking continuous improvement (Mater, 2009).

The Mater Hospital objectives are to continually improve the satisfaction of its patients with regard to effectiveness of service in meeting the needs of its patients and timeliness with which services are offered. The objectives are evaluated through analysis of data obtained through patient evaluation, process performance and service non conformance. The hospital is committed to excellence in providing the highest quality of healthcare and services to its customers. The hospital understands what timeliness and efficiency of service delivery means to its customers and believes that there is always room for improvement in the never-ending search for quality. To deliver this promise, the hospital has established and implemented a quality management system in line with ISO 9001:2008 (Mater, 2009).

### **1.3 Statement of the Problem**

Economic uncertainty has forced companies to find ways to become more efficient in order to maintain profitability and be globally competitive. Formal performance improvement programs like ISO 9000 help to improve quality, operational efficiency and a company's competitive edge. Healthcare executives and managers are always searching for better ways to improve production capacity for medical treatment and thereby improving operational efficiency.

Various strategic advantages arise from the use of the ISO 9001:2008 quality management system such as creation of a more efficient value chain system,

increased market access, increased customer satisfaction and retention because of production of quality products and services (Lai, 1996). However, despite these seemingly guaranteed advantages of implementing the ISO 9001:2008 QMS, organizations still face challenges in implementation and maintenance of the system, thus end up not reaping its benefits. The Mater Hospital, certified to ISO 9001:2000 in 2002, has not been spared from these challenges. According to findings of an audit of the hospital in 2009, despite renewal of the ISO 9001:2000 certificate, the hospital's overall performance remained low, as did customer satisfaction levels to the extent that the stakeholders wondered whether it had been worthwhile to adopt the system in the first place (Mater, 2009). In 2008, the hospital's management made a strategic decision to apply for recertification to the then newly revised standard, ISO 9001:2008. With a deliberate focus on process improvement and service delivery, the management decided to use the revised standard to improve its performance. This study therefore aimed to establish the factors affecting implementation of ISO 9001:2008 in hospitals, with a focus on The Mater Hospital, Nairobi

#### **1.4 General Objective**

The general objective of the study was to establish the factors affecting implementation of ISO 9001:2008 quality management system at The Mater Hospital.

#### **1.4.1 Specific Objectives**

- i) To determine the effect of training on implementation of ISO 9001:2008 at The Mater Hospital.
- ii) To assess the effect of availability of resources on implementation of ISO 9001:2008 at The Mater Hospital.
- iii) To establish the effect of top management support on implementation of ISO 9001:2008 at The Mater Hospital.

#### **1.5 Research Questions**

- i) What is the effect of training on implementation of the ISO 9001:2008 QMS at The Mater Hospital?
- ii) How does availability of resources affect implementation of the ISO 9001:2008 QMS at The Mater Hospital?
- iii) To what extent does top management support affect implementation of the ISO 9001:2008 QMS at The Mater Hospital?

#### **1.6 Justification of the Study**

Many organizations have recognized the importance of quality management in service delivery. The research work shall offer a basis for further development of the knowledge on the Kenyan health industry and the role of various stakeholders in regulating the health care industry for better services and vibrant industry growth.

The Kenya Government, as part of its strategy to achieve Vision 2030, requires its various departments Kenya to be ISO certified as a part of the strategic plan to attain Vision 2030 goals. The study will assist in show casing to firms that are not certified the benefits attached to being certified, which will in turn assist the government achieve vision 2030 objectives.

The study will bring out the benefits of having ISO certification programs in place in terms of the impact the system has on organizations performance. Kenyan hospitals already certified will learn of the various opportunities to use due to their certified status, while those not certified will appreciate the benefits of implementing the QMS.

The Mater Hospital's top management will also gain from the study in terms of getting researched feedback on the impact of QMS on performance, as well as the attendant challenges of maintaining it. The employees, especially newer ones, will gain by understanding that the quality management system is not a threat to them but a supporting framework to be used in improving their clinical and business processes.

Academicians taking quality assurance and management as a unit of study will gain in reference from the study. For quality assessors and certification bodies, the study will serve as feedback, as well a reference they can use to demonstrate to

other organizations that any organization in any industry can implement the ISO 9001:2008 QMS and reap the attendant benefits.

### **1.7 Scope of the Study**

The focus of this study was the factors affecting implementation of ISO 9001:2008 quality management systems at The Mater Hospital. The hospital was selected since it is among the largest private hospitals in Kenya and East Africa, and was the first to implement the ISO certification in the region. The study focused on the impact that the system has on performance of the hospital, the value the system has on enhancement of customer satisfaction and the challenges the quality management is facing years after implementation.

### **1.8 Limitations of the Study**

Some respondents were unable, due to the nature of their work in a healthcare institution, to fill the questionnaire within the time frame agreed on with the researcher. However this was overcome by the researcher working irregular hours to ensure that all the questionnaires were filled and returned.



## **CHAPTER TWO**

### **LITERATURE REVIEW**

#### **2.1 Introduction**

This chapter presents an analysis of the QMS concept, the ISO standards, the conceptual framework, the principles and requirements of the ISO system, organizational performance and the research gaps.

#### **2.2 QMS Concept**

In the healthcare industry, quality of care is more than a concept. It has become essential to patient well-being and financial survival. The complexity of medical processes makes healthcare work processes variable and prone to error. Thus process-based quality management system standards, applicable to the healthcare industry provide the opportunity to reduce errors, rework, and inefficiencies that jeopardize patient safety. According to Pyzdek (2003) a quality management system (QMS) can be expressed as the organizational structure, procedures, processes and resources needed to implement The elements of a Quality Management System include; quality management, organizational structure, responsibilities, methods, data management, processes, resources, customer satisfaction, continuous improvement and product quality.

##### **2.2.1 ISO Standards**

ISO standards are voluntary. As a non-governmental organization, ISO has no legal authority to enforce the implementation of its standards. ISO does not

regulate or legislate. However, countries may decide to adopt ISO standards - mainly those concerned with health, safety, or the environment - as regulations or refer to them in legislation, for which they provide the technical basis. ISO only develops standards for which there is a market requirement. The work is mainly carried out by experts from the industrial, technical and business sectors which have asked for the standards and which subsequently put them to use ([www.wikipedia.org](http://www.wikipedia.org)).

ISO standards are based on international consensus among the experts in the field. Consensus, like technology, evolves and ISO takes account both of evolving technology and of evolving interests by requiring a periodic review of its standards at least every five years to decide whether they should be maintained, updated or withdrawn. In this way, ISO standards retain their position as the state of the art. ISO standards are technical agreements which provide the framework for compatible technology worldwide. They are designed to be globally relevant - useful everywhere in the world (Chow-chua *et al*, 2002).

### **2.2.2 Quality Management Principles**

There are eight quality management principles on which the quality management system standard of the ISO 9000 series is based. These principles can be used by management as a framework to guide their organizations towards improved performance. The principles are derived from the collective experience and knowledge of the international experts who participate in ISO Technical

Committee ISO/TC 176, *Quality Management and Quality Assurance*, which is responsible for developing and maintaining the ISO 9000 standards (Buttle, 1997).

### **2.2.3 Organizational Performance**

Organizational performance comprises the actual output or results of an organization as measured against its intended outputs or goals and objectives. According to Richard (2009), organizational performance encompasses three specific areas of firm outcomes: 1. financial performance in profits, return on assets, return on investment and others; 2. product market performance of sales, market share and others; and 3. total shareholder return of total and economic value added.

The Key Performance Indicators, also known as KPIs or Key Success Indicators (KSI), help an organization define and measure progress toward organizational goals. Once an organization has analyzed its mission, identified all its stakeholders, and defined its goals, it needs a way to measure progress toward those goals. KPIs are those measurements. They are quantifiable measurements, agreed to beforehand, that reflect the critical success factors of an organization. They will differ depending on the organization. A business may have as one of its KPIs the percentage of its income that comes from return customers. A school may focus its Key Performance Indicators on graduation rates of its students, while a hospital may focus its KPIs on the length of stay for inpatients, or time

taken to serve outpatients. A Customer Service Department may have as one of its KPIs, in line with overall company KPIs, percentage of customer calls answered in the first minute. A KPI for a social service organization might be number of clients assisted during the year (Carol, 1990). Whatever KPIs are selected, they must reflect the organization's goals, they must be key to its success, and they must be quantifiable and measurable. KPIs usually are long-term considerations. The definition of what they are and how they are measured do not change often. The goals for a particular KPI may change as the organization's goals change, or as it gets closer to achieving a goal.

The overall organizational performance construct can be categorized into several distinct groupings. The four primary categories of overall organizational performance variables are: accounting measures; operational measures; market-based measures; and survival measures. In addition, measures of economic value creation are popular in practice but are not frequently used in strategic management or entrepreneurship research. Accounting measures are those that rely upon financial information reported in income statements, balance sheets and statements of cash flows. Accounting measures can be further subcategorized into profitability measures, growth measures, leverage, liquidity and cash flow measures, and efficiency measures (Kaplan and Norton, 1992).

Operational measures include variables that represent how the organization is performing on non-financial issues. Measuring performance on non-financial

dimensions has received renewed attention over the past many years as corporations have adopted a 'balanced scorecard' approach for the integration of strategy and performance measurement (Kaplan and Norton, 1992). These variables include market share, changes in intangible assets such as patents or human resources, customer satisfaction and stakeholder performance. Most of the measures in this category require primary data from management in the form of their assessment of their own performance, which may lead to questions of the validity of the responses. Market-based measures of performance include ratios or rates of change that incorporate the market value of the organization. These variables include return to shareholders, market value added, holding period returns, Jensen's alpha and Tobin's Q. The calculation of these variables requires a market valuation for the company and is generally only available for publicly traded companies.

Survival measures of performance on the other hand simply indicate whether the organization remained in business over the time period of interest. Drucker (1989) proposed that survival is the ultimate measure of long-term performance. However, since most empirical research in entrepreneurship and strategic management addresses time horizons of five years and less, survival is rarely used as a measure of overall organizational performance. Economic value measures of performance are adjusted accounting measures that take into consideration the cost of capital and some of the influences of external financial reporting rules. These measures have rarely been used by researchers in strategic management or

entrepreneurship empirical studies because the values are not generally reported and most companies do not even calculate them internally. Typical economic value measures include residual income, economic value added and cash flow return on investment (Bernard, 1993).

### **2.3. Quality of Nursing Care**

A systems analysis of healthcare organizations demonstrates that methods for improving quality involve the effective feedback regulation of key organizational performance parameters. Information flow is impaired in dysfunctional healthcare organizations, which often disregard significant clinical problems while preferentially tracking nonclinical indicators and clinical data considered most likely to meet the organization's standards (Davis, Schoen, 2007). Such organizations thus achieve "pseudocompliance" with external requirements, but do not systematically work to improve the quality of clinical care or their performance as organizations.

Efforts by government agencies and national organizations to foster quality improvement activities have had limited success precisely because local organizations perceive these efforts as externally imposed. (Dunne *et al.* 2002). Leaders' anxieties about their own and their organizations' autonomy, control, and performance can cause unwillingness to review data indicating performance problems, oversimplification of decision making criteria, and reluctance to formulate meaningful conclusions and act on them. Contemporary quality

improvement models, such as Continuous Quality Improvement (CQI) and Total Quality Management (TQM), are indeed suppose to reconnect leaders to their organizations' quality processes by emphasizing the leaders' roles in promoting quality as an organizational value, setting meaningful quality goals, and actively using information to improve organizational effectiveness (Edinger, 2000).

A key function of quality healthcare management is being able to provide quality healthcare that the average person can afford. If in a given community most of the residents cannot afford to visit the doctor or pay for necessary laboratory test or prescription drugs, then there is inadequate access to quality affordable healthcare (Holcik, 2000). Where there is an absence of quality affordable healthcare there is a void in quality healthcare management. When healthcare facilities report a decrease in premature or preventable death, it means that the quality of healthcare management is high. Quality healthcare management controls every aspect of patient care and directly affects patient mortality. Healthcare organizations that successfully practice preventive medicine realize a reduction in premature death, preventable death, accidental death and hospital-acquired infections (Hussey *et al.*, 2004). Quality healthcare management initiates and enforces policies and procedures that are designed to improve the quality of health of the patients it serves.

Quality healthcare management includes the financial growth and viability of the healthcare organization. A healthcare organization can realize quality healthcare management only when it is fully staffed with medical and managerial

professionals and is able to invest in the most advanced equipment (IOM, 2001). Without financial viability a healthcare facility cannot practice quality healthcare management. No healthcare facility can spend more than it earns and still succeed. If a healthcare organization or facility is unsuccessful, patients may be dying prematurely and may be receiving inadequate healthcare. Healthcare standards and expected patient outcomes cannot improve without substantial changes in the management of the healthcare facility. Quality healthcare management will drive changes that result in more favorable patient outcomes. The exception would be healthcare facilities for the terminally ill (HOPE, 2003).

ISO 9001:2008 QMS requires production of better data as a key objective of an organizations information management strategy. Sound health care planning decisions require accurate, timely and accessible data. Quality information is essential to making effective evidence-based decisions, which ultimately impact on an organizations ability to adequately meet the health care needs of its customers (ICH, 2005). Health information management (HIM) is the practice of maintenance and care of health records by traditional (paper-based) and electronic means in hospitals, physician's office clinics, health departments, health insurance companies, and other facilities that provide health care or maintenance of health records. With the widespread computerization of health records and other information sources, including hospital administration functions and health human resources information, health informatics and health information



technology are being increasingly utilized in information management practices in the health care sector (IOM, 2002).

Proper collection, management and use of information within healthcare systems determine the system's effectiveness in detecting health problems, defining priorities, identifying innovative solutions and allocating resources to improve health outcomes. For example, health information administrators have been described to "play a critical role in the delivery of healthcare in the United States through their focus on the collection, maintenance and use of quality data to support the information-intensive and information-reliant healthcare system". As the field grows and information technology becomes a more crucial part of the medical world, health information management is experiencing a transition from traditional managing practices with paper to more efficient electronic management, such as Electronic Health Records (EHRs). But the main goal is still to analyze, manage, and utilize the information that is essential to patient care and making sure the providers can access the information when necessary. (Barnes, 1998)

A health institution can assure quality nursing care by providing the mechanisms to effectively monitor patient care provided by health care professionals using cost-effective resources. Nursing programmes of quality assurance for example, are concerned with the quantitative assessment of nursing care as measured by proven standards of nursing practice. In addition, they motivate practitioners in nursing to strive for excellence in delivering quality care and to be more open and

flexible in experimenting with innovative ways to change outmoded systems. Even though defining quality is difficult, the expense of quality is an interactive process between customer and provider. The customer does not receive anything tangible, mostly only a piece of paper with a promise for a better future e.g. doctors writing prescriptions. Donabedian (1986) defined quality as the extent of resemblance between the purpose of healthcare and the truly granted care. In an economic dimension quality is the extent of accomplished relief case with a justified use of means and services (Williamson 1999). Government and those who pay of the care will see quality as a weighing out between results and costs to fulfill certain expectations in health care.

Quality standards make life safer, healthier and easier for people, organizations and enterprises all over the world. They enable communication and trade, while allowing resources to be used more efficiently. Thus the plan of nursing care as a standard includes priorities and the prescribed nursing approaches or measures to achieve the goals derived from the nursing diagnoses. Nursing actions provide for patient participation in health promotion, maintenance, and restoration- indeed nursing actions assist the patient to maximize his health capabilities, the patient's progress or lack of progress towards goal achievement is determined by the patient and the nurse. In other words, the patient's progress or lack of progress towards goal achievement directs re-assessment, re-ordering of priorities, new goal setting, and a revision of the plan of nursing care. Quality nursing requires an audit to be carried out regularly (Martin, *et al.*, 2007).

#### **2.4 Effect of Training on Implementation of ISO 9001:2008**

According to Pyzdek (2003), an organization should determine the necessary competence for personnel performing work affecting conformity to product requirements, where applicable provide training or take other actions to achieve the necessary competence, evaluate the effectiveness of the actions taken, ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and maintain appropriate records of education, training, skills and experience.

ISO 9001: 2008 should provide the leadership, structure and resources, and establish the quality policy for the entire health care quality system. To check process effectiveness, hospitals should audit all their documented processes at least twice a year through training a sufficient number of auditors to meet that internal goal audit (Pyzdek, 2003).

#### **2.5 Effect of Availability of Resources on Implementation of ISO 9001:2008**

An organization should determine and avail resources needed to implement and maintain the QMS and continually improve its effectiveness, and enhance customer satisfaction by meeting customer requirements (Pyzdek, 2003). Since quality is the degree to which a set of inherent characteristics fulfils requirements, then product/service quality would be the degree of conformity to product/service requirements.

Organizations must dedicate resources (staff, equipment, tools, materials, information and money) in a reasonable timeframe to establish and improve the QMS and enhance customer satisfaction by meeting customer requirements. While this may seem like an easy concept to follow, it often proves to be one of the most difficult for an organization to implement because the extent to which the resources should be provided is not defined, and it is a costly undertaking for any organization. For hospitals, medical personnel and equipment are capital intensive because of the specialized nature of the services they provide.

## **2.6 Effect of Top Management Support on Implementation of ISO 9001:2008**

An organization should ensure that the senior management team completely supports the ISO 9001:2008 QMS. This is so because of the advantages ISO 9001:2008 compliance will bring to an organization: competitive advantage, improved business performance, enhanced reputation, saving organization money, streamlined operations, and reduced waste. Top management should appoint a Management Representative, who is responsible for the ISO 9001:2008 QMS implementation. The person will need to have a thorough understanding of the principles of the standard, so will have to be qualified and/or trained. Senior management should also identify a steering team for the project, preferably made up of managers from the different areas of the organization. The purpose of this team will be to assign resources and responsibilities for the project as well as providing leadership for the project (Pyzdek, 2003).

Top management should review the organization's QMS, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. The input to management review shall include information on: results of audits, customer feedback, process performance and product conformity, status of preventive and corrective actions, follow-up actions from previous management reviews, changes that could affect the quality management system, and recommendations for improvement (Chow-chua *et al*, 2002).

## **2.7 Operational Efficiency**

Operational efficiency deals with minimization of waste and maximization of resource capabilities, in order to deliver quality products and services to customers. It is concerned with identifying wasteful processes and resources that drain the organization's profits (Afonso and Aubyn, 2006). Operational efficiency is also involved with designing new work processes that improve quality and productivity. For example, the "Just-in-time" process emerged as a result of the focus on improving operational efficiency by reducing inventory to the bare minimum. The supply of inventory in JIT is delivered just when it is needed for a process thus eliminating holding costs of inventory.

Operational efficiency has a distinct significance in any organization whether the organization exists for commercial or non-commercial purpose. Ideally improving

operational efficiency has a direct impact on the company's profit margins. Assuming the overall quality is standard, in order for businesses to profit, they have to either raise the price of their product or service, sell more of their products or lower the costs involved in making the product (Hollingsworth, 2003). Raising the selling price and increasing the market share are both inhibited by increased global competitive market. However lowering costs is a viable option because internal wastage contributes to increased cost.

The organizational structure and the internal processes of an organization affect its operational efficiency. It is also affected by the company culture and employee morale. Companies that have very rigid hierarchical structures have more inefficiency due to duplication of efforts. Several government structures suffer from this kind of organizational structure. The communication in such organizations tends to suffer, leading to disparate teams or departments working for their personal objectives (Macinko *et al*, 2003). Thus there is a systematic buildup of wasted resources at every level.

Besides organizational structure, the supply chain of an individual company also affects its operational efficiency. The supply chain network involves suppliers, distributors and consumers of the company's products and services. The overall operational efficiency can only be improved when these links are efficient. For example if a supplier is unreliable, then the company has to deal with the cost of missed opportunities, lack of quality and unsatisfied customers. Therefore,

improving operational efficiency should also involve improving the "value chain" (Momany *et al*, 2006).

It does suffice to consider improving operational efficiency as a system wide effort. Improving operational efficiency involves adopting flexible organization structures that allow for a network flow of information. The focus is on horizontal organizations and network structures. Involving other stakeholders, such as the suppliers, distributors and customers in improving the supply chain also translates to greater operational efficiency (Richardson, 2005). Adopting established processes such as Six Sigma and Total quality Management (TQM) is another route to improving operational efficiency. Companies that adopt these processes are able to access prevalent benchmarks and also invest heavily in employee training. Qualified employees and common standards all contribute to greater operational efficiency.

Healthcare executives and managers are always searching for better ways to improve hospital operational efficiency and the subsequent value of care to patients. Treatment capacity in a health care organization does not have a clear, universal definition. The term "capacity" is generally used to refer to the sustainable maximum output that is produced in an organization, depending on factors such as labor and technology availability (Schoen *et al*, 2007).

Most of these resources are expensive for a hospital to maintain and one of the major problems is to be able to maximize the utilization of each of these

resources. One of the problems commonly faced while trying to maximize utilization and throughput is the difficulty in comparing capacities of different types of resources and identifying the bottleneck. When any single resource's capacity is increased, the bottleneck seems to shift to another resource. Similarly, if we increase the capacity of this bottleneck resource now, a brand new bottleneck may appear elsewhere. It is very difficult to find a balance in the resources where each one of them is performing to maximum capacity and thus the resources as a whole generate the maximum throughput for the entire system to be operationally efficient (Scott *et al.*, 2008).

An integrated QMS provides an opportunity to deliver consistent, high quality, and cost-effective health care in any healthcare organization. In healthcare service areas where governmental and accreditation compliance apply, a QMS will simplify the process. In most of the world, healthcare organizations and services are operating at or below the stage of quality assurance. Although some healthcare organizations or services are working successfully at the level of a quality management system, many are not. Thus, the need to upgrade to a quality management system approach is becoming evident from groundbreaking reports that describe medical errors in present day healthcare systems (Starfield, and Shi, 2002).

The best contribution a healthcare organization can make to reducing medical errors that harm patients is to understand and document its processes, train people



to be competent in following those processes, identify problematic processes, and improve processes where problems exist. The foundation of a quality management system, with operations under control, provides a platform for continuous improvement and further transition up the quality hierarchy. If a healthcare organization implements proper quality management system models then its ability to reduce or eliminate medical error, the likelihood of meeting customer requirements and sustainable attainment of quality objectives are likely to be greatly enhanced (Tieman, *et al.*, 2006). This, with leadership commitment to building a quality management system, will establish a platform for continuous improvement and further progress toward overall Total Quality Management. In general, the application of comprehensive quality management tools significantly contributes to the achievement of the strategic objective of efficiency, and swiftly leads to the development of optimally regulated and reliable processes and well-balanced product and service quality, supported by operational efficiency improvements and cost-reductions (Gopal, 1996).

## **2.8 Amount of Time Taken for Service Delivery**

ISO 9001: 2008 provides a company with a framework and set of principles to ensure a common sense approach to the management of business activities and to consistently achieve higher customer satisfaction. According to Bart (2011), there are ten statistical predictors of satisfaction in any customer–supplier relationship for any product or service, Timeliness being a key one. The others include Quality, Value, Ease of Access, Efficiency, Environment, Teamwork,

Commitment, Self Management, and Innovation. As the world continues to globalize and speed up, customers have less time than ever to deal with suppliers of products and services. Customers want what they want and they want it fast. Customers want product and service delivery to take the minimum amount of time possible. As the complexities in the modern life of customers increase, the corresponding demand for precision from suppliers requires that products and services be delivered on or before the agreed upon time. Customers want suppliers they can depend upon, who can deliver when they say they will. Customers don't like to wait, and have little patience for suppliers that make them do so (Berry, 2011).

Stauss and Neuhaus (1997) also agree that certain aspects of customer satisfaction, though qualitative in nature, are still accepted by the vast majority of customers. Timeliness is an issue throughout the entire experience from waiting in line to be seated to waiting for the bus person to serve beverages, to waiting for the food server to take the order, deliver the appetizers, salads, soups, entrees, deserts, coffee, and finally, the check. Bell and Zemke (1992) posit that, when delivering exceptional service, firms need to fulfill the customer's wants and expectations, be flexible with the service, treat the customer as a partner not an adversary and make it easy for them to do business with you. They also stress the importance of identifying customer values, setting standards and monitoring results. For instance timeliness, accuracy and responsiveness were identified as

the most important service values to a surveyed group of bank customers (Liswood, 1990).

Zero-time companies that can respond instantly to requests of their customers know what drives them. It's their customers' needs/ values and attitudes that drive the service process (Yeh *et al*, 2000). The customer focused organization principle as defined by ISO 9001 aids in such focused service delivery trends which result in timely and satisfactory service delivery.

## **2.9 Empirical Studies**

The global adoption of ISO 9001 may be attributable to a number of factors. A number of major purchasers require their suppliers to hold ISO 9001 certification. In addition to several stakeholders' benefits, a number of studies have identified significant financial benefits for organizations certified to ISO 9001. Corbett *et al* (2005) showed that certified organizations achieved superior return on assets compared to otherwise similar organizations without certification. Heras *et al* (2002) found similarly superior performance and demonstrated that this was statistically significant and not a function of organization size. Naveh and Marcus (2007) showed that implementing ISO 9001 led to superior operational performance. Sharma (2005) identified similar improvements in operating performance and linked this to superior financial performance. Chow-Chua *et al* (2002) showed better overall financial performance was achieved for companies in Denmark. Rajan and Tamimi (2003) showed that ISO 9001 certification

resulted in superior stock market performance and suggested that shareholders were richly rewarded for the investment in an ISO 9001 system.

While the connection between superior financial performance and ISO 9001 may be seen from the above, there remains no proof of direct causation, though longitudinal studies, such as those of Corbett *et al* (2005) may suggest it. Other writers such as Heras *et al* (2002) have suggested that while there is some evidence of this, the improvement is partly driven by the fact that there is a tendency for better performing companies to seek ISO 9001 certification.

The mechanism for improving results has also been the subject of much research. Lo *et al* (2007) identified operational improvements (cycle time reduction, inventory reductions, etc.) as following from certification. Buttle (1997) and Santos (2002) both indicated internal process improvements in organizations leading to externally observable improvements. Hendricks and Singhal (2001) results indicate that firms outperform their control group during the post implementation period and effective implementation of total quality management principles and philosophies leads to significant wealth creation. The benefit of increased international trade and domestic market share, in addition to the internal benefits such as customer satisfaction, interdepartmental communications, work processes, and customer/supplier partnerships derived, far exceeds any and all initial investment according to (Alcorn, 1995).

## **2.10 Benefits of ISO 9001:2008**

It is widely acknowledged that proper quality management improves business, often having a positive effect on investment, market share, sales growth, sales margins, competitive advantage, and avoidance of litigation (Dalglish, 2005; Barnes, 2000). The quality principles in ISO 9001:2008 are also sound, and the ISO 9000 guidelines provide a comprehensive model for quality management systems that can make any company competitive (Wade, 2002 and Barnes, 1998). Barnes (1998) further cites a survey by Lloyd's Register Quality Assurance which indicated that ISO 9001 increased net profit, and another by Deloitte-Touche which reported that the costs of registration were recovered in three years.

## **2.11 Critique of Literature Review and Research Gaps**

Previous researches have been able to look at the concept of ISO 9001:2008 but not wholly. Some or most of the studies were able to analyze ISO 9001:2008 in organizations but this research will add information, especially to the healthcare industry. From the studies described above no clear conclusions on the factors affecting implementation of ISO 9001:2008 quality management systems in organizations can be drawn, as some results are in favor of some effects while others favor other effects over others.



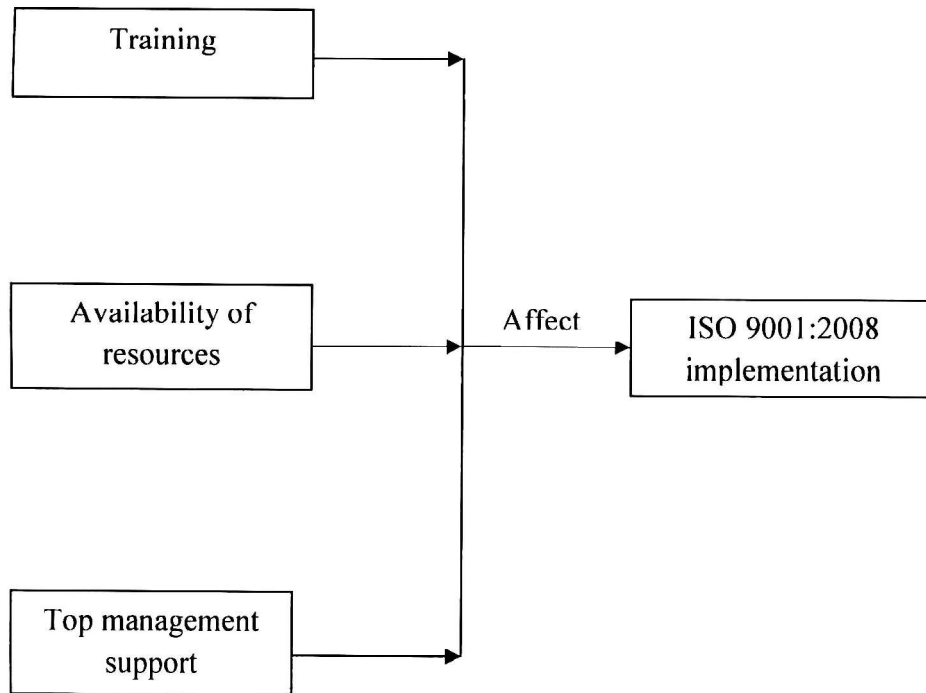
## **2.12 Conceptual Framework**

Mugenda and Mugenda (2003), define a conceptual framework as a hypothesized model identifying the concepts under study and their relationships. In this framework, there are certain requirements that are mandatory for an organization to meet for successful implementation of the ISO 9001:2008 QMS. These requirements include but are not limited to management commitment – clause 5.1, provision of resources – 6.1, and competence, training and awareness – clause 6.2.2. The standard specifies several requirements but for purposes of this study, only these three will be considered as the independent variables. Implementation of ISO 9001:2008 is the dependent variable that is affected by the independent variables.

Considering that fulfillment of the identified requirements determines successful implementation of the QMS, the requirements then also stand out as the challenges that the QMS would face, should they not be met. The following diagram 1 shows the perceived interrelationship between these variables.

**Independent Variable**

**Dependent Variable**



**Figure 2.1: Conceptual Framework**

## **CHAPTER THREE**

### **RESEARCH METHODOLOGY**

#### **3.1 Introduction**

This chapter describes the method that was used to collect data pertinent in answering the research questions. It provides an overview of research design, target population, sampling design, description of research instruments, description of data collection procedures and data analysis procedures.

#### **3.2 Research Design**

This study aimed at establishing the factors affecting implementation of ISO 9001:2008 at The Mater Hospital. The study adopted a descriptive design. According to Kombrabail (2009), descriptive design exhaustively describes a variable under test. Through Correlation Studies, descriptive design method determines the extent of relationship between variables (Key, 1997) without influencing them in any way.

#### **3.3 Target Population**

The study targeted the top management (Heads of Departments), middle level managers, as well as the non-management staff of The Mater Hospital, who total 500 (Mater, 2011) as illustrated in the following table:



**Table 3.1: Target Population for the Study**

<b>Department</b>	<b>Total Target Population</b>	<b>Sample Size</b>	<b>Percentage of the Sample Size (%)</b>
Heads of Departments (HODs)	12	1	10
Section Heads (middle level managers)	50	5	10
Non-management	438	44	10
<b>Total</b>	<b>500</b>	<b>50</b>	<b>10</b>

### **3.4 Sampling Design**

#### **3.4.1 Sampling Frame**

The sampling plan describes the sampling unit, sampling frame, sampling procedures and the sample size for the study. The sampling frame describes the list of all population units from which the sample will be selected. Where external validity is important, one needs to carry out random sampling from properly defined population. In this view stratified random sampling whose logic lies in selecting a truly random and representative sample that permits confident generalizations from the sample to a larger population is done. Using stratified random sampling each population member has a known chance of being included in the sample. Statistically, in order for generalization to take place, a sample of at least 30 must exist.

Stratified random sampling technique is used when population of interest is not homogeneous and can be subdivided into groups or strata to obtain a representative sample. From the population of 500 staff working at The Mater Hospital, a sample of 10% was taken using stratified random sampling which gives each item in the population an equal probability chance of being selected. Wiersma (2005) observed that due to limitation in time, funds and energy, a study could be carried out from a carefully selected sample of 10% of the total to represent the entire population. This generates a sample of 50 respondents for this study. The characteristic of the sample size is given in the following table 3.2.

**Table 3.2: Sample frame for the study**

<b>Department</b>	<b>Total Target Population</b>	<b>Sample Size</b>	<b>Percentage of the Sample Size (%)</b>
Heads of Departments (HODs)	12	1	10
Section Heads (middle level managers)	50	5	10
Non-management	438	44	10
<b>Total</b>	<b>500</b>	<b>50</b>	<b>10</b>

### **3.4.2 Sample Size**

The total sample size for the study was 50 employees from the selected strata in The Mater Hospital as shown in table 3.2 above. A sample of 1 HOD, 5 Section

Heads and 44 non- management staff was used for the study. The researcher believed that the sample was representative enough to lead the research to informed and accurate findings. Ritchie and Lewis (2005) argue that the frame should not be so small that it fails to present a good number of subjects from which a representative sample size is to be collected.

### **3.4.3 Sampling Procedures**

The study stratified the sample size as shown in table 3.2 systematic random sampling was used to sample both the section heads and the non-management staff to participate in the study. Since the number of non-management staff at The Mater Hospital is large, random sampling made it possible to cover as many departments as possible, and made it possible to include all cadres of staff for more representative findings.

### **3.5 Data Collection Instruments**

According to Dörnyei and Taguchi (2010), a questionnaire is a data collection instrument that best collects relevant information from a large group of people, at a reduced cost and within the time convenience of the respondents. This study adopted a questionnaire as the tool for data collection because the researcher aimed to collect information from a large group of people who have different working time frames. The questionnaire was self administered, and was collected by the researcher after being duly filled.

Validity indicates whether the items measure what they are designed to measure (Borg and Gall, 1989). The researcher used content validity to examine whether the instruments answer the research questions. Adjustments and additions to the research instruments consultations and discussions with the supervisor were done to *establish content validity*.

Instrument reliability is the dependability, consistency or trustworthiness of a test (Cohen *et al*, 2007). For this study the Pearson Product Moment Correlation coefficient was used. The researcher employed self administration approach of data collection and monitored the process to ensure that the unintended people did not fill the questionnaire. The questionnaires were filled and assistance was sought where possible thus raising the reliability.

### **3.5 Data Collection Procedures**

The researcher first visited The Mater Hospital to seek permission to conduct an academic research. After being granted the permission, the researcher then booked appointments with the respondents, during which she explained to them the purpose of the study, its importance, and the ethical standards it was going to meet, such as confidentiality/privacy.

Data was obtained from the identified respondents, who were the primary source, through the chosen data collection tool. Further data was obtained by the researcher from secondary sources in the form of audit reports and other records

kept by the hospital. The researcher employed self-administration approach of data collection and monitor the process to ensure that unintended people did not fill the questionnaire or were not interviewed. The questionnaires were filled and assistance provided to respondents where necessary, thus raising the reliability of the data collected.

### **3.6 Data Analysis**

The process of data analysis involved several stages namely; data clean up and explanation. Data clean up involves editing, coding, and tabulation in order to detect any anomalies in the responses and assign specific numerical values to the responses for further analysis. The questionnaires were edited for completeness and consistency. The data was then coded and checked for any errors and omissions (Kothari, 2004). Frequency tables, percentages and means were used to present the findings. Responses in the questionnaires were tabulated, coded and processed by use of a computer Statistical Package for Social Science (SPSS) version 17.0 programme to analyze the data.

## CHAPTER FOUR

### DATA ANALYSIS, PRESENTATION AND INTERPRETATION

#### 4.0 Introduction

This chapter is presented in four sections: part A, part B, part C and part D. Part A is *the demographic* information of the respondents. The second section, part B, looks at the effect of training on implementation of ISO 9001:2008, part C looks at the effect of availability of resources on implementation of ISO 9001:2008, while part D looks at the effect of top management support on implementation of ISO 9001:2008.

The data has been presented in tables, pie charts and bar graphs. The responses were analyzed using computer Statistical Package for Social Science (SPSS). Out of 50 questionnaires which were administered to the interviewees, all of them were returned for data analysis. This translates to 100.0 percent return rate of the respondents. Overall, the response rate can be considered to have been very high.

#### 4.1 Background Information of the Respondents

The researcher sought to find out the distribution of the respondents by gender to know which gender is the majority as the hospital staff. The findings are presented in the table below:

**Table 4.1: Distribution of respondents by gender**

<b>(Gender)</b>	<b>Frequency</b>	<b>Percent</b>
Male	18	36.0
Female	32	64.0
<b>Total</b>	<b>50</b>	<b>100.0</b>

From table 4.1 above, it is evident that majority of the respondents, represented by 64.0% are females while 36.0% are males. This is so because the hospital provides nursing care, a profession that is generally dominated by females. However, this is a general finding that has no implications whatsoever to the study.

The researcher sought to find out which department the respondents were from.

The results are tabulated below:

**Table 4.2: Distribution of respondents by departments**

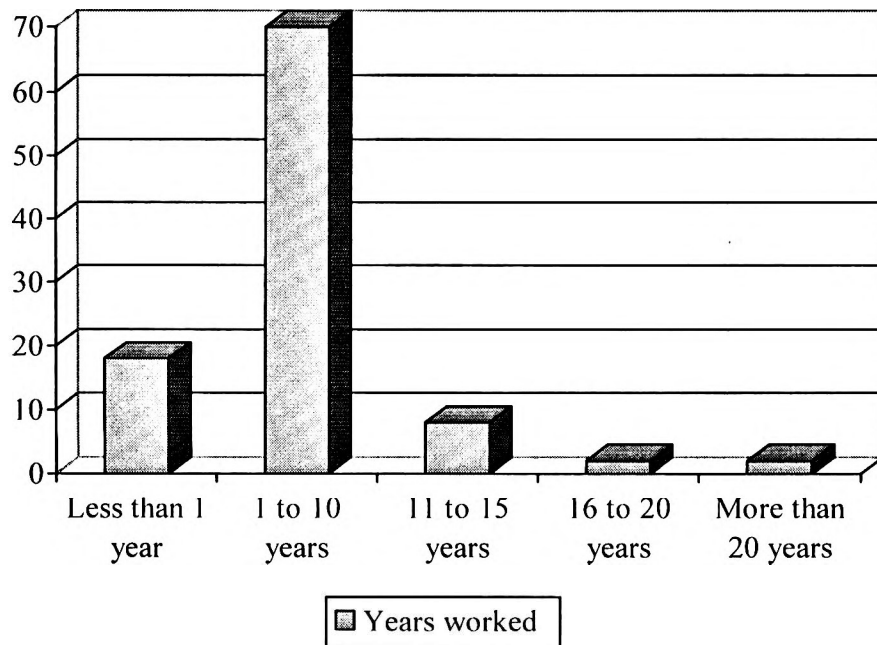
<b>DEPARTMENT</b>	<b>Frequency</b>	<b>Percent</b>
Admin	5	10.0
Finance	7	14.0
Nursing	13	26.0
Marketing	5	10.0
Medical	8	16.0
Procurement	4	8.0
Pharmacy	3	6.0
Maintenance	5	10.0
<b>Total</b>	<b>50</b>	<b>100.0</b>

From the table 4.2 above, majority of the respondents were from Nursing (26.0%), Medical (16.0%), Finance (14.0%) and Maintenance (10.0%) departments. The highest number of respondents was from the Nursing department, which is the largest department by virtue of its function being the core business of the hospital.

This implies that successful implementation of ISO 9001:2008 QMS requires inclusion of all staff, more so those in the core function of the organization.



The researcher sought to find out years of experience the respondents had in the hospital. The results are presented in the figure below:



**Figure 4.1: Years worked with the organization**

Figure 4.1 above reveals that majority of the respondents (70.0%) have worked at The Mater Hospital for a period of between 1-10 years, 18.0% have been in the hospital for less than a year, while 12.0% have been in the hospital for 11-15 years. Of the respondents sampled, none of them had worked at the hospital for more than 16 years. This is indicative that the staff turnover at the hospital is not high, and majority of staff put in at least 10 years of service to the hospital. Successful implementation of ISO 9001:2008 heavily depends on continuity, not interruptions occasioned by high staff turnover.

The researcher sought to find out the respondents' level of education. The results are presented in the table below:

**Table 4.3: Distribution of the respondents by education level**

<b>LEVEL OF EDUCATION</b>	<b>Frequency</b>	<b>Percent</b>
O-Level	1	2.0
Diploma	30	60.0
Degree	14	28.0
Postgraduate	5	10.0
<b>Total</b>	<b>50</b>	<b>100.0</b>

Table 4.3 above shows that majority of the respondents (60.0%) have attained diploma level of education. A small proportion (28.0%) have attained undergraduate degree, and an even smaller proportion ((10%) have attained post graduate training.

The findings imply that the hospital hires professionals, for whom a tertiary level of education is a minimum requirement. This is critical for the implementation of ISO 9001:2008, which requires a high degree of understanding, and which can be possible only with a certain minimum level of education.

## **SECTION B: EFFECT OF TRAINING ON ISO 9001:2008**

### **Training in ISO 9001:2008**

The researcher sought to find out whether the respondents had been trained in ISO 9001:2008 QMS. The results are presented in the table below:

**Table 4.4: Training in ISO 9001:2008 QMS**

<b>TRAINING IN ISO 9001:2008</b>	<b>Frequency</b>	<b>Percent</b>
Yes	42	84.0
No	8	16.0
<b>Total</b>	<b>50</b>	<b>100.0</b>

Table 4.4 above depicts that majority of the respondents (84.0%) had been trained on the ISO 9001:2008 QMS, and only a small proportion (16%) had not been trained. This indicates that the hospital ensures that all staff are trained in the QMS; those that had not been trained were mostly the newly employed staff. Further, training in the QMS is an important factor in the implementation of the QMS; hence the efforts to ensure all staff are trained.

### **Training Relevant to Function**

The researcher sought to find out whether the respondents had attended training relevant to their functions in the hospital. The results are presented in the table below:

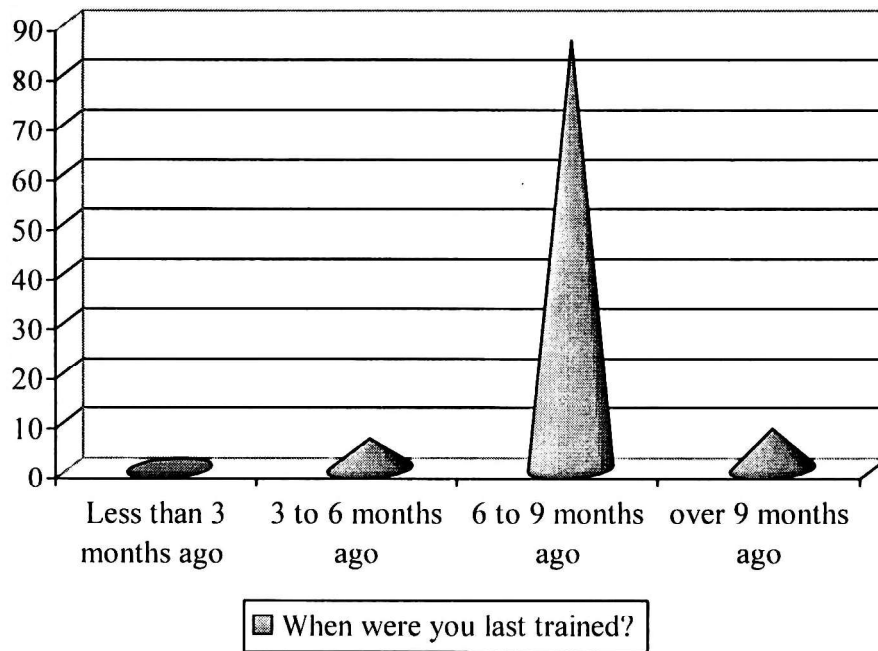
**Table 4.5: Training relevant to function**

<b>FUNCTIONAL TRAINING</b>	<b>Frequency</b>	<b>Percent</b>
Yes	46	92.0
No	4	8.0
<b>Total</b>	<b>50</b>	<b>100.0</b>

Table 4.5 depicts that 92.0% of the respondents had attended training related to their function at the hospital, while 8.0% indicated had not. This is an indicator that the hospital ensures that all staff are trained in the function for which they are employed at the hospital. Those that had not been trained were mostly the newly employed staff.

### Last Training

The researcher sought to find out when the respondents had received their last training. The results are presented in the figure below:

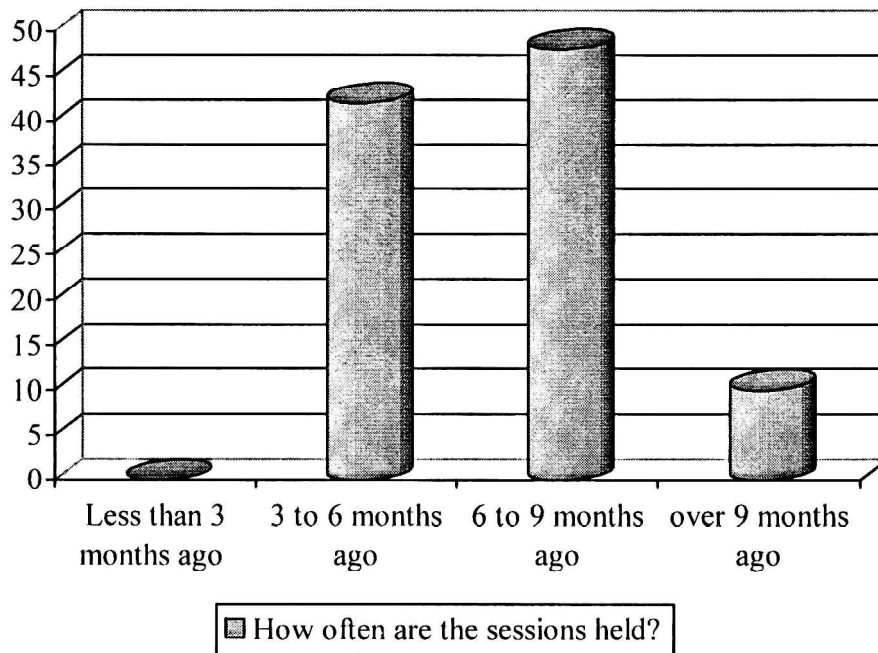


**Figure 4.2: Last Training**

Figure 4.2 above reveals that majority of the respondents (86.0%) had attended training in the last 6-9 months. The figure further reveals that 8.0% had attended training in the last 9 months, while 6.0% had attended training in the last 3-6 months. This indicates that the hospital facilitates regular training for most of its staff, at least every 3-9 months. Those who had been trained within the last 3-6 months were be newly employed staff, while those who had been trained within the last 9 months and more could be in highly specialized fields, whose training is probably also very costly.

### Frequency of Training

The researcher sought to find out how often the QMS awareness sessions were held. The results are presented in the figure below:



**Figure 4.3: Frequency of Training**

Figure 4.3 reveals that almost half of the respondents (48.0%) indicated that departmental awareness sessions were held in the last 6-9 months, 42.0% indicated the last 3-6 months, while 10.0% indicated over the last 9 months. The 10% who indicated the last awareness session to have been over the last 9 months were from Administration department, which is responsible for training and so does not need to have the departmental sessions as frequently as the rest of the departments. This indicates that QMS awareness is conducted regularly, every 3-9 months.

**Table 4.6: Effects of training on implementation of ISO 9001:2008**

TRAINING	Strongly agree		Agree		Undecided		Disagree		Strongly disagree	
	No.	%	No.	%	No.	%	No.	%	No.	%
Adoption of ISO 9001:2008 has enhanced knowledge and skills of the people involved in offering services at The Mater Hospital	49	98	1	2	0	0	0	0	0	0
Continuous training has led to standardization of healthcare processes and practices at the Mater Hospital	38	76	11	22	1	2	0	0	0	0
Continuous training has enabled The Mater Hospital to adopt health and safety measures, thereby raising the confidence of staff in service delivery.	15	30	35	70	0	0	0	0	0	0
Continuous training has enhanced customer focus	50	100	0	0	0	0	0	0	0	0

Table 4.6 reveals that 98% (49) of the respondents strongly agreed that continuous training has enhanced knowledge and skills of the people involved in offering services, has led to standardization of healthcare processes and practices (76.0%), and enhanced customer focus (100.0%), all of which are indicators of a successfully implemented ISO 9001:2008 QMS.

However, only 70% (35) of the respondents agreed that continuous training has enabled The Mater Hospital to adopt health and safety measures, thereby raising the confidence of staff in service delivery. The fact that they did not strongly agree to this aspect of training is an indicator that the training has not had as much impact on the staff as expected, yet the institution is a healthcare provider.

**SECTION C: EFFECT OF AVAILABILITY OF RESOURCES ON ISO  
9001:2008**

The researcher sought to establish the availability of resources to support service delivery at The Mater Hospital. The results are tabulated as follows:

**Table 4.7: Availability of resources to support service delivery at The Mater  
Hospital**

<b>AVAILABILITY OF RESOURCES</b>	<b>Yes</b>	<b>No</b>	<b>Total</b>
Efficient working tools	100.0	0.0	100.0
Timely supply of requested resources	92.0	8.0	100.0
Timely repair & maintenance of working tools	86.0	14.0	100.0
Training on use of working tools	90.0	10.0	100.0

From table 4.7, it is evident that all respondents (100.0%) had efficient working tools to support service delivery at The Mater Hospital. A large proportion of the respondents agreed that supply of requested resources was timely (92.0%), repair and maintenance of working tools was also timely (86.0%), and they were trained on use of working tools (90.0%), which support service delivery at The Mater Hospital.

This indicates that while the working tools available were efficient, there were delays experienced in the provision of requested resources in the repair and



maintenance of the same. Majority of staff were also trained in the use of working tools; those not trained as at the time of the study were newly employed staff.

**Table 4.8: Effects of availability of resources on implementation of ISO 9001:2008 QMS**

The researcher sought to find out the effects of availability of resources on implementation of the ISO 9001:2008 QMS. The findings are tabulated as follows:

AVAILABILITY OF RESOURCES	Strongly agree		Agree		Undecided		Disagree		Strongly disagree	
	No.	%	No.	%	No.	%	No.	%	No.	%
Adoption of ISO 9001:2008 encourages innovation and creativity in service delivery at The Mater Hospital.	42	84.0	3	6.0	5	10.0	0	0.0	0	0.0
Adoption of ISO 9001:2008 has enhanced team work and minimized individuality.	50	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Adoption of ISO 9001:2008 has created a culture of customization of services in order to meet clients' preferences better, thus enhancing efficiency.	16	32.0	34	68.0	0	0.0	0	0.0	0	0.0
There are no staffing inadequacies in our department	10	20.0	40	80.0	0	0.0	0	0.0	0	0.0

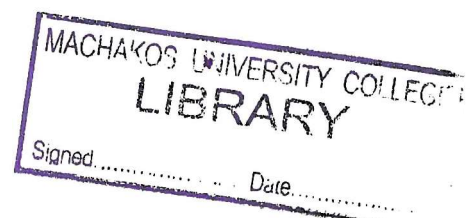


Table 4.8 shows that majority of the respondents strongly agreed that implementation of ISO 9001:2008 encourages innovation and creativity in service delivery (84.0%) and has enhanced team work and minimized individuality (100.0%) as effects of availability of resources on implementation of ISO 9001:2008 at The Mater Hospital.

A relatively large proportion of the respondents agreed that implementation of ISO 9001:2008 has created a culture of customization of services in order to meet clients' preferences better, thus enhancing efficiency (68.0%) and there is no staffing inadequacy in their department (80.0%) as being effects of availability of resources on ISO 9001:2008 implementation at The Mater Hospital.

Considering that all respondents agreed that adoption of ISO 9001:2008 encourages innovation and creativity in service delivery at The Mater Hospital, it is indicative that the culture is strongly entrenched in the hospital, to the extent that even new employees are able to appreciate it. Overall, availability of resources is appreciated and all staff agree that availability of resources affects implementation of the ISO 9001:2008 QMS.

## SECTION D: EFFECT OF TOP MANAGEMENT SUPPORT ON ISO

### 9001:2008 QMS

The researcher sought to find out if the hospital management supports the ISO 9001:2008 quality management system. All respondents (100.0%) agreed that the hospital management supports the ISO 9001:2008 quality management system. The reasons they gave were that the hospital organizes awareness sessions, it has appointed a Quality Assurance Manager in charge of the system, the management use the system as a management tool and the hospital management goes for certification every 3 years.

**Table 4.9: Effects of top management support on implementation of ISO**

### 9001:2008

TOP MANAGEMENT SUPPORT	Strongly agree		Agree		Undecided		Disagree		Strongly disagree	
	No	%	No	%	No	%	No	%	No	%
Head of Department frequently holds departmental meetings on the QMS	0	0.0	100	100.0	0	0.0	0	0.0	0	0.0
Follow up of agreed on actions is done by management	40	80.0	0	0.0	0	0.0	10	20.0	0	0.0
The head of department is responsive to departmental needs	31	62.0	6	12.0	0	0.0	8	16.0	5	10.0
Non-conformities in the department are addressed in consultation with the head of department	40	80.0	3	6.0	0	0.0	7	14.0	0	0.0

From table 4.9 on the previous page, it can be seen that all respondents agreed to HODs frequently holding departmental meetings. A large percentage (80%) of respondents strongly agreed that actions agreed on were followed up by management and that non-conformities in the departments were addressed in consultation with the HODs. 20% of respondents disagreed that follow up of agreed on actions is done by management, an indicator that there were issues arising from some departments on which action was yet to be taken. A total of 74% of the respondents agreed to HODs being responsive to departmental needs, with the rest disagreeing. This could be an indicator that in some departments or for some requisitions, the HODs are not as responsive as their staff expect.

All respondents agreed that the ISO 9001:2008 QMS has an effect on organizational performance. The respondents indicated the following outcomes of ISO 9001:2008 QMS to be influencing organizational performance.

**Table 4.10: Effects of ISO 9001:2008 QMS on organizational performance**

	Strongly agree (%)	Agree (%)	Undecided (%)	Disagree (%)	Strongly disagree (%)
Customer focus	100.0	0.0	0.0	0.0	0.0
Involvement of people	80.0	0.0	0.0	20.0	0.0
Process approach	84.0	16.0	0.0	0.0	0.0
Continual improvement	100.0	0.0	0.0	0.0	0.0

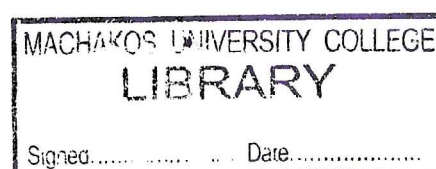
Table 4.10 reveals that all respondents strongly agreed that customer focus and continual improvement are effects of ISO 9001:2008 QMS on organizational performance. A significant proportion indicated involvement of people (80.0%) and process approach (84.0%) as effects of ISO 9001:2008 QMS on organizational performance.

**Table 4.11: Factors associated with the success or failure of ISO 9001:2008 quality management systems**

The researcher felt the need to find out the factors associated with the success or failure of ISO 9001:2008 QMS. The response was as follows:

<b>Factors</b>	<b>Frequency</b>	<b>Percent</b>
<b>Success</b>		
Support by management	43	86.0
Continuous system review	40	80.0
Quality and well structured internal audits	34	68.0
Continuous training of staff	45	90.0
<b>Failure</b>		
High staff turnover	36	72.0
Lack of proper procedure	6	12.0
Lack of understanding of QMS by employees	12	24.0
Lack of employee involvement in decision making	3	6.0
Inadequate resources	12	24.0
Poor staff motivation	10	20.0

Table 4.11 above reveals that majority of the respondents associated support by management (86.0%), continuous system review (80.0%), quality and well structured internal audits (68.0%) and continuous staff training on the QMS as success attributes of ISO 9001:2008 quality management systems in the hospital.



On the other hand, a relatively large number of the respondents associated high staff turnover (72.0%), lack of proper procedure follow up (12.0%), lack of understanding of the QMS by employees (24.0%), inadequate resources (24.0%) and poor staff motivation (20.0%) as failure attributes of ISO 9001:2008 quality management systems at the hospital.

This indicates that support by management, continuous system review, quality and well structured internal audits and continuous staff training on the QMS are factors associated with successful implementation of the ISO 9001:2008 QMS. On the other hand, staff turnover, lack of proper procedure follow up, lack of understanding of the QMS by employees, inadequate resources and poor staff motivation are factors associated with failure of ISO 9001:2008 QMS.

**Table 4.12: Suggestions on how ISO 9001:2008 QMS can contribute to enhancing organizational performance at The Mater Hospital**

The researcher sought, from the respondents, suggestions on how the ISO 9001:2008 QMS can contribute to enhancing organizational performance at The Mater Hospital. The results are tabulated below:

<b>Suggestions</b>	<b>Frequency</b>	<b>Percentage</b>
Continuous audits of the system to enhance effectiveness	44	88.0
Continuous training of staff on QMS values and benefits	39	78.0
Redesign organization and work processes to ensure adherence	2	4.0
Involvement of staff who directly deal with customers	40	80.0
Staff motivation	27	54.0
Staff to be given feedback from meetings	19	38.0
Quality management board to visit hospital regularly	6	12.0

Table 4.12 above reveals that the respondents indicated continuous audit of the system to enhance effectiveness (88.0%), involvement of staff who directly deal with customers (80.0%), continuous training of staff on QMS values and benefits (78.0%), staff motivation (54.0%), staff to be given feedback from meetings



(38.0%), quality management board to visit hospital regularly (12.0%) and redesign organization and work processes to ensure adherence (4.0%) as suggestions on how ISO 9001:2008 QMS can contribute to enhancing organizational performance at The Mater Hospital.

Continuous audit of the system, involvement of staff who directly deal with customers, continuous training of staff on QMS values and benefits, staff motivation, and feedback to staff from management deliberations are recommendations on how ISO 9001:2008 QMS can contribute to enhancing organizational performance.

**CHAPTER FIVE**  
**SUMMARY OF FINDINGS, CONCLUSION, AND**  
**RECOMMENDATIONS**

**5.0 Introduction**

The basic purpose of this chapter is to give the summary, conclusions and recommendation of the study. This was based on the research findings that is presented and discussed in the previous chapters.

**5.1 Summary of Findings**

This study aimed at establishing the factors affecting implementation of the ISO 9001:2008 in hospitals, with a focus on The Mater Hospital, Nairobi. The task included determining the effects of training on implementation of ISO 9001:2008 QMS at The Mater Hospital; assessing the effect of availability of resources on implementation of ISO 9001:2008 QMS at The Mater Hospital, and establishing the extent to which top management support affects implementation of ISO 9001:2008 QMS at The Mater Hospital.

The researcher reviewed previous studies with a view to establishing academic gaps which the present study could bridge. This was done through library research. The procedure included reading, evaluating the methodology employed in terms of design choice, target population, sample and sampling procedure data collection instruments (that is suitability, validity and reliability), data collection procedures, data analysis, findings and recommendations. The researcher

benefited immensely from the literature review for it guided the present study by pointing to areas that needed to be investigated.

The findings depict that almost all the respondents have been trained on the ISO 9001:2008 QMS, have attended training related to their function at The Mater Hospital. Majority of the respondents last attended training 6-9 months ago and had regular ISO 9001:2008 QMS awareness sessions in their departments. The study findings reveal that continuous training affected implementation of the ISO 9001:2008 QMS by enhancing knowledge and skills of the staff involved in offering services, standardization of healthcare processes and practices, and enhancing customer focus. Further, HODs frequently hold departmental meetings.

The findings reveal that efficient working tools are made available in a timely manner at The Mater Hospital. Staff are also trained on the use of working tools to support service delivery at The Mater Hospital. Availability of resources in implementation of ISO 9001:2008 QMS encourages innovation and creativity in service delivery and enhances team work, as well as minimizes individuality.

Finally, the study findings reveal the hospital management supports the ISO 9001:2008 QMS. This is evidenced by regular awareness sessions, appointment of a Quality Assurance Manager in charge of the system, and use of the QMS as a management tool, which is renewed every 3 years. Non-conformities in the departments are addressed in consultation with the HODs, and follow-up of agreed on actions is done by management. The ISO 9001:2008 QMS has an effect

on organizational performance through customer focus and continual improvement.

## **5.2 Conclusions**

Based on the findings of the study, the following main conclusions were made for factors affecting implementation of the ISO 9001:2008 in hospitals.

From the findings of the study, continuous training of staff, both in their functions and in the ISO 9001:2008 QMS enhances their knowledge and skills in service delivery, leads to standardization of healthcare processes and practices, and enhances customer focus. The aspects of training that are prioritized seem to have a greater impact than those that are not, as evidenced by the responses to effects of training on adoption of health and safety measures.

Efficient working tools, timely supply of requested resources, timely repair and maintenance of working tools and training on use of working tools enhance service delivery in hospitals. As a result of resources being made available to users for the implementation of the ISO 9001:2008, the QMS encourages innovation and creativity in service delivery, and enhances team work while minimizing individuality.

The findings indicate that a hospital's management should support the ISO 9001:2008 QMS through organizing awareness sessions, appointing a manager to be in charge of the system and management should use the system as a

management tool. Under effects of top management support on ISO 9001:2008 implementation, the study found that non-conformities in the department should be addressed in consultation with the HOD, follow up actions should be done by management, the HOD should be responsive to departmental needs, and HODs should frequently hold departmental meetings on the QMS.

The study also found that the ISO 9001:2008 QMS has effect on organizational performance. Specifically, customer focus and continual improvement are effects of ISO 9001:2008 QMS on organizational performance. Success attributes of ISO 9001:2008 QMS in hospitals are associated with support by management, continuous system review, quality and well structured internal audits, and continuous staff training on the QMS.

From the study findings it can be concluded that training, availability of resources and top management support are factors affecting implementation of the ISO 9001:2008 QMS in hospitals.

### **5.3 Recommendations**

On the basis of the above conclusions, the following recommendations were made for factors affecting implementation of the ISO 9001:2008 QMS in hospitals.

Hospitals should do continuous audits of their systems to enhance effectiveness, involve staff who directly deal with customers, motivate staff by giving feedback from QMS meetings, and carry out continuous staff training on QMS system

values and benefits. New employees should be brought on board as soon as they join the hospital to be at par with the rest in enhancing service delivery.

The quality management board should visit hospitals regularly and redesign organization and work processes to ensure adherence. This will assist the hospitals to have more customer focus and people involvement.

#### **5.4 Suggestions for further studies**

This study sought to assess the factors affecting implementation of the ISO 9001:2008 QMS in hospitals, attempting to bridge the gap in knowledge that existed. Although the study attained these, it mainly focused on The Mater Hospital in Nairobi. There is need to conduct a similar study which will attempt to find out the employees' perception of the ISO 9001 QMS, as well as the role of ISO 9001:2008 certification in developing competitive advantage for Kenyan organizations.

## REFERENCES

- ACG (Allen Consulting Group) (2008). *Economic Impacts of a National Individual Electronic Health Records System*, Academy of Management Review, Vol. 15 No.1, pp.72-79.
- Afonso, A. and St. Aubyn, M. (2006). Relative Efficiency of Health Provision: a DEA Approach with Non-discretionary Inputs, *ISEG-UTL Economics Working Paper*, No. 33,  
<http://pascal.iseg.utl.pt/~depeco/wp/wp332006.pdf>
- AGWA (Auditor General of Western Australia), (2007). *Auditor General's Report: Performance Examination - First Do No Harm: Reducing Adverse Events in Public Hospitals*, Report 10, October. Australian Prudential Regulation Authority (2008) *Insight*, Issue 3.  
[http://www.apra.gov.au/Insight/upload/Insight\\_Issue\\_3\\_2008.pdf](http://www.apra.gov.au/Insight/upload/Insight_Issue_3_2008.pdf)
- Alcorn, J. E. (1995). Benefits of ISO 9000 Certification, *Ceramic Engineering and Science Proceeding*. Gordon Patzer, Westport, (pp.14-21).
- Badri M. (1999). The Effect of Quality Management on Firm Performance in the UAE: *An Empirical Study Using Path Analysis*, *Dirasat: Management Science*. (pp.130-132).
- Barnes, F. C. (1998). ISO 9000 Myth and Reality: *A Reasonable Approach to ISO 9000*. S.A.M. Advanced Management Journal. Cincinnati. Spring 1998, (pp.14-21).
- Barnes, F. (2004). Good Business Sense is the Key to Confronting ISO 9000, *In Review of Business*, Spring. (pp.130-132).
- Bart, I.H. (2011). "Quality of Primary Health Care in Developing Countries," *International Journal for Quality in Health Care* 4 131-39.
- Bernard, T. (1953). Executive Functions, *From Aristotelian to Reaganomics*. Greenwood Publishing Group. p.40
- Berry R. (2011). "Quality of Primary Health Care in Developing Countries," *International Journal for Quality in Health Care* 8, no. 2 (2006): 131-39.

- Berwick D.M. (1996). Quality of Health Care. Part: Payment by Capitation and the Quality of Care. *N Engl J Med*; 335, (pp.1227-1231).
- Borg C and Gall V. (1989) *Business Research Methods*, Fifth edition, McGraw-Hill Inc. (pp. 43-50).
- Bruce Brocka (1992). *Quality Management: Implementing the Best Ideas of the Masters*. V (1), (pp. 23-30).
- Buttle, F. (1997). "ISO 9000: Marketing Motivations and Benefits", *International Journal of Quality and Reliability Management*. ISBN, USA (pp. 102-110).
- Carla AbouZahr *et al.*, (1996). Quality Health Care for Women: A Global Challenge, *Health Care for Women International* 17: (pp449-67).
- Carol, T. (1990). Performance Indicators, *BERA Dialogues* (2), ISBN 9781853590924, (pp. 102-110).
- Charles A. C, (2009). ISO 9001:2008 Explained. William Troy, USA. (pp. 23-30).
- Chow-chua *et al* (2002). Does ISO 9000 Certification Improve Business Performance? *The International Journal of Quality and Reliability Management*. 5<sup>th</sup> Edition, Amacom, NY, (pp.12-15).
- Chris, H. (1991). Total Quality Management: The Key to Business Improvement. Chapman & Hall, Australia, (pp. 45-70).
- Churchill, L. (1991). Research Design: *Qualitative, Quantitative, and Mixed Methods Approaches*, ISBN, USA, (p.130-132).
- Cohen B, Manion C and Morrison A, (2007). *Essentials of Education and Social Science Research Methods*. Canada: Masolp publishers. (pp. 45-50).
- Commonwealth Fund Commission on a High Performance Health System (2008). *Why Not the Best? Results from the National Scorecard on U.S. Health System Performance*. Amacom, Kindle Edition, 1601Broadway, New York. NY, (pp.54-75).



- Cooper V and Schindler K, (2003). Research Design: *Qualitative, Quantitative, and Mixed Methods Approaches*, Economic Research, Inc., Cambridge (p.130-132).
- Corbett, C.J. Montes-Sancho, M.J. & Kirsch, D.A. (2005), The Financial Impact of ISO 9000 Certification in the United States: An empirical analysis, *Management Science*. London, Panos. Upper Saddle River, NJ: Prentice Hall. (pp. 61-75).
- Dalgeish S, (2005). Probing the Limits: ISO 9001 Proves Ineffective, *Quality Magazine*. (pp. 23-26).
- Davis, K, and Schoen, C (2007). State Health System Performance and State Health Reform: *Health Affairs (Millwood)*, 26(6):664–666.
- Docteur E. and Oxley H. (2003). *Health Care systems: Lessons From the Reform Experience*, OECD Economics Department Working Paper no. 374.
- Donabedian, A (1988). The Quality of Care: How Can it be Assessed? *Journal of the American Medical Association*, (pp1743–1748).
- Dörnyei, Z. & Taguchi, T. (2010). *Questionnaires in Second Language Research: Construction, Administration and Processing*. 2<sup>nd</sup> Ed. New York: Routledge, (pp.12-15).
- Drucker, P. F., (1989). The Practice of Management, *International Journal of Quality and Reliability Management*. Amacom, Kindle Edition (pp.54-75).
- Duckett, S. (2008). Design of Price Incentives for Adjunct Policy Goals in Formula Funding for Hospitals and Health Services, *BMC Health Services Review*, vol. 8, no. 72.
- Dunne, HF *et al.* (2002). Quality in Irish Health Care (2000–2002): *The Consumer Perspective*. Amsterdam, ISQua's 21st International Conference, (pp.32-45).
- Edinger, S (2000). *The Definitions of Quality of Care – Measurement and Applications to the Clinical and Public Health Laboratories*. Boston, MA, American Public Health Association (APHA). (Abstract #1357, 128th Annual Meeting of the APHA, 12–16 November 2000).

- Fisher, E., Wennberg, D., Stukel, T., Gottlieb, D., Lucas, F., and Pinder, E. (2003b). The Implications of Regional Variations in Medicare Spending Part 2: Health Outcomes and Satisfaction with Care, *Annals of Internal Medicine*, vol. 138, pp. 288- 298.
- Gabbittas, O., and Jeffs, C. (2007). Assessing Productivity in the Delivery of Health Systems in Australia: Some Experimental Estimates, *Paper presented to the ABS-PC Productivity Perspectives 2007 Conference*, <http://www.pc.gov.au/research/conference-papers/health-service-productivity>
- Gay, J. (1992). Research Design: *Qualitative, Quantitative, and Mixed Methods Approaches*. 5<sup>th</sup> Edition, Amacom, NY, (pp.12-15).
- Godfrey, A. B., (1999). "*Juran's Quality Handbook*", ISBN, (pp. 42-48).
- Gopal K. Kanji (1996). 100 Methods for Total Quality Management. Sage Publications, London. (pp. 44-45).
- Hendricks, K.B. and Singhal, V.R. (2001). The Long-Run Stock Price Performance of Firms with Effective TQM Programs, *Management Science*, (pp.12-15).
- Heras, I. Dick, G.P. M. & Casadesus, M. (2002). ISO 9000 Registration's Impact on Sales and Profitability - A Longitudinal Analysis of Performance Before And After Accreditation, *International Journal of Quality and Reliability Management*. Amacom, Kindle Edition, 1601 Broadway, New York. NY, (pp.54-75).
- Holcik, J (2000). Primary Health Care in the Czech Republic: Brief History and Current Issues. *International Journal of Integrated Care*, 1:1–10.
- Hollingsworth, B. (2003). Non-parametric and Parametric Applications Measuring Efficiency in Health Care, *Health Care Management Science*, vol 6, pp 203-219.
- HOPE, (2003). *The Quality of Hospital Care in the European Union*. Leuven, Standing Committee of the Hospitals of the European Union (pp23).

- Hussey, PS *et al.* (2004). How Does the Quality of Care Compare in Five Countries? *Health Affairs (Millwood)*, 23(3): pp89–99.
- I.H. Reerink and R. Sauerborn. (2006): “Quality of Primary Health Care in Developing Countries,” *International Journal for Quality in Health Care* 8, no. 2 (2006): 131-39.
- ICH (2005). *The Irish Clearing House on Health Outcomes*. Limerick, Irish Clearing House (<http://www.healthintelligence.ie/articles.htm>, accessed October 2005).
- IOM (2001). *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC, National Academy Press.
- IOM (2002). *Medicare: A Strategy for Quality Assurance*, Vol.1. Washington, DC, National Academy Press.
- Joumard, I., Christophe, A., Nicq, C., and Chatal, O. (2008) *Health Status Determinants: Lifestyle, Environment, Health-care Resources and Efficiency*, Economics Department Working Papers no. 627. [http://www.oalis.oecd.org/oalis/2008doc.nsf/LinkTo/NT0000363E/\\$FILE/JT03249407.PDF](http://www.oalis.oecd.org/oalis/2008doc.nsf/LinkTo/NT0000363E/$FILE/JT03249407.PDF)
- Kaplan, R. S. & D. P. Norton. (1992). *The Balanced Scorecard - Measures that Drive Performance*. Harvard Business Review (January-February)
- Key, J., P. (1997). *Research Design in Occupational Education*. Oklahoma State University
- Kombrabail, H. (2009). *Research Designs*. TYBMS. Retrieved from <http://www.scribd.com/doc/18132239/Research-Design>
- Khan, P. (1993). *Research Methodology: A Step-by-Step Guide for Beginners*, Qounte, Mumbai (pp. 21-33).
- Kishore, S. & Naik, R. (2003). *ISO 9001:2000 for Software Organizations*, Tata McGraw-Hill, New Delhi, (pp.14-21).
- Kothari, C. R. (1990). *Research Methodology: A Step-by-Step Guide for Beginners*, vol 5, New Age International. New Delhi, (Pp.45-56).

- Lo, Chris K.Y.; Yeung, Andy C.L.; Cheng, T.C. Edwin (2007). Impact of ISO 9000 on Time-Based Performance: An Event Study, *World Academy of Science, Engineering and Technology*, ISBN, USA, (p.130-132).
- Macinko, J. *et al* (2003). The Contribution of Primary Care Systems to Health Outcomes within Organization for Economic Cooperation and Development (OECD) Countries, 1970–1998, *Health Services Research*, vol. 38, no. 3, June.
- Mark L. Blazey (2009). Insights to Performance Excellence 2009-2010: Sage Publications, London, (pp.23-45).
- Martin, AB *et al*. (2007). Health Spending by State of Residence, 1991–2004. *Health Affairs (Millwood)*, 26(6):651–663.
- Momany *et al* (2006). A Cost Analysis of the Iowa Medicaid Primary Care Case Management Program, *Health Services Research*, vol. 41, no. 4 (Part I), pp. 1357-1371.
- Mugenda, O.M. & Mugenda, A.G. (2003). Research Methods: *Quantitative and Qualitative Approaches*. 2<sup>nd</sup>. Rev Ed. Act Press, Nairobi.
- Naveh, E.; Marcus, A. (2007). Financial performance, ISO 9000 standard and safe driving practices effects on accident rate in the U.S. motor carrier industry, *Accident Analysis & Prevention*. 2<sup>nd</sup> Edition, Hodder, Western Cape, (pp.42-44).
- Oakland, J.S. (2004). *Oakland on Quality Management*, Elsevier Butterworth-Heinemann, Oxford, (pp 56-89).
- Onditi, P. (2009). The Factors Affecting Adoption of ISO Certification in Public Sector Organizations. Research project submitted for Executive Masters in Business Administration, Jomo Kenyatta University of Agriculture and Technology, (pp. 5-17).
- Parvathi S.J. *et al* (2006). Why Hospitals Should go in for ISO Certification, Qunte, Mumbai (pp. 21-33).
- Philip B. Adongo *et al.*, (1999). Qualitative Research on Perceptions Toward Health Services and Contraceptives, *Survey Research Indonesia* (Jakarta

- and Baltimore: Johns Hopkins University.School of Public Health, Population Information Program, 1996).
- Poksinska, B. *et al* (2002). The State of ISO 9000 Certification: A Study of Swedish Organizations, *The TQM Magazine*, (pp. 15-17).
- Private Health Insurance Administration Council (PHIAC) (2008). *Operations of the Private Health Insurers Annual Report 2007–08*, PHIAC, Canberra.
- Pyzdek, T, (2003). *Quality Engineering Handbook*, ISBN 0824746147, (pp. 33-40).
- Richard, D. (2009). Measuring Organizational Performance: *Towards Methodological Best Practice. Journal of Management*.
- Richardson, J. (2005). Priorities of health policy: cost shifting or population health, *Australia and New Zealand Health Policy*, vol. 2, issue 1.
- Ritchie, J and Lewis, J. (2005). Qualitative research practice: *A guide for social science students and researchers. London: Sage Publications Ltd*.
- Schoen, C. *et al* (2007). Towards Higher-performance Health systems: *Adults' Health Care Experiences in Seven Countries, 2007, Health Affairs online*, vol. 26, no. 6 pp.w717-w734.
- Scott, A. *et al*, (2008). The Effects of Financial Incentives on Quality of Care: *The Case of Diabetes*. Working Paper no. 12/08. Melbourne Institute of Applied Economic and Social Research, University of Melbourne.
- Sharma, D.S. (2005). The association between ISO 9000 certification and financial performance, *The International Journal of Accounting*. Oxford University Press, Oxford, (pp.32-38).
- Starfield, B. and Shi, L. (2002). Policy Relevant Determinants of Health: An International Perspective, *Health Policy* vol. 60, pp.201–218.
- Stauss *et al* (1997). The Qualitative Satisfaction Model. *International Journal of Service Industry Management*. Sage Publications: Croom Helon, London, (pp. 42-48).
- Tieman J. *et al*. (2006). *Integration, Coordination and Multidisciplinary Approaches in Primary Care: A Systematic Investigation of the Literature*,

Canberra: Australian Primary Health Care Research Institute.  
[http://www.anu.edu.au/aphcri/Domain/MultidisciplinaryTeams/Final\\_25\\_Currow.pdf](http://www.anu.edu.au/aphcri/Domain/MultidisciplinaryTeams/Final_25_Currow.pdf)

Verhoeven, M., Gunnarsson, V., and Carcillo, S. (2007). Education and Health in G7 countries: Achieving better outcomes with less spending, *International Monetary Fund (IMF) working paper*, WP/07/263.

World Health Organization (2004). Global strategy on diet, physical activity and health, Resolution WHA57.17,  
<http://www.who.int/dietphysicalactivity/strategy/eb11344/en/index.html>

Web addresses sited are:

[http:// www.iso.org/iso/survey2007.pdf](http://www.iso.org/iso/survey2007.pdf) -

[http:// www.materkenya.com](http://www.materkenya.com)

[http://en.wikipedia.org/wiki/ISO\\_9000](http://en.wikipedia.org/wiki/ISO_9000)"

<http://www.iso.org/iso/en/iso9000-1400/certification/isosurvey.html>

[http://www.iso.org/iso/iso\\_catalogue/management\\_standards/iso\\_90001:2008.html](http://www.iso.org/iso/iso_catalogue/management_standards/iso_90001:2008.html)

## APPENDIX I: LETTER OF INTRODUCTION

Carol Mitaki,  
P.O. Box 21900-00400  
Nairobi, KENYA.

Dear Respondent,

### **RE: DATA COLLECTION**

I am a student at the Kenya Institute of Management. Currently I am doing a research study on the **FACTORS AFFECTING IMPLEMENTATION OF ISO 9001:2008 IN HOSPITALS: THE CASE OF THE MATER HOSPITAL, NAIROBI** to fulfill the requirements for the award of the degree of Executive Master of Business Administration.

You have been selected to participate in this study and I would highly appreciate if you assisted me by responding to all questions in the attached questionnaire as completely, correctly and honestly as possible. Your response will be treated with utmost confidentiality and will be used only for research purposes of this study.

Thank you in advance for your co-operation.

Yours faithfully,



Carol Mitaki,  
Researcher

## APPENDIX II: QUESTIONNAIRE

**Instructions:** *Kindly complete the following questionnaire using the instructions provided for each set of question. Tick appropriately.*

**Confidentiality:** *The responses you provide will be strictly confidential. No reference will be made to any individual(s) of the organization in the report of the study.*

### SECTION A: GENERAL INFORMATION

1. Gender                      Male    [   ]                      Female    [   ]
2. Department/section \_\_\_\_\_
3. Position held in the organization (optional) \_\_\_\_\_
4. How many years have you worked with the organization? (Please tick)  
  
Less than 1 year            [   ]  
  
1 – 10 years                    [   ]  
  
11 – 15 years                   [   ]  
  
16 – 20 years                   [   ]  
  
More than 20 years        [   ]
5. What is your level of education? Tick where appropriate  
  
O –Level                      [   ]  
  
Diploma                        [   ]  
  
Degree                         [   ]  
  
Post graduate                [   ]  
  
Other(s) – Specify.....



**SECTION B: EFFECT OF TRAINING ON IMPLEMENTATION OF ISO**

**9001:2008**

6. Have you been trained in ISO 9001:2008 quality management system?

Yes [ ]      No [ ]

7. Have you attended any training related to your function at The Mater Hospital?

Yes [ ]      No [ ]

If yes, please indicate when you were last trained.

Less than 3 months ago      [ ]

3-6 months ago      [ ]

6-9 months ago      [ ]

Over 9 months ago      [ ]

8. Do you have regular ISO 9001:2008 QMS awareness sessions in your departments?

Yes [ ]      No [ ]

9. If yes to Q. 8 when was the last session held?

Less than 3 months ago      [ ]

3-6 months ago      [ ]

6-9 months ago      [ ]

Over 9 months ago      [ ]

10. To what extent would you agree/disagree with the following listed statements as effects of training on implementation of ISO 9001:2008?

**Key:** 5- Strongly Agree 4-Agree 3-Undecided 2-Disagree 1-Strongly Disagree

	<b>TRAINING</b>	Strongly agree	Agree	Undecided	Disagree	Strongly disagree
		5	4	3	2	1
1.	Adoption of ISO 9001:2008 has enhanced knowledge and skills of the people involved in offering services at The Mater Hospital					
2.	Continuous training has led to standardization of healthcare processes and practices at the Mater Hospital					
3	Continuous training has enabled The Mater Hospital to adopt health and safety measures, thereby raising the confidence of staff in service delivery.					
4	Continuous training has enhanced customer focus					

**SECTION C: EFFECT OF AVAILABILITY OF RESOURCES ON IMPLEMENTATION OF ISO 9001:2008**

11. Do the following statements apply to availability of resources to support service delivery at The Mater Hospital?

Efficient working tools Yes [ ] No [ ]

Timely supply of requested resources Yes [ ] No [ ]

Timely repair & maintenance of working tools Yes [ ] No [ ]

Training on use of working tools Yes [ ] No [ ]

12. To what extent would you agree/disagree with the following listed statements as effects of availability of resources on implementation of ISO 9001:2008? Key: 5- Strongly Agree 4-Agree 3-Undecided 2-Disagree

1-Strongly Disagree

AVAILABILITY OF RESOURCES		Strongly agree	Agree	Undecided	Disagree	Strongly disagree
		5	4	3	2	1
1.	Adoption of ISO 9001:2008 encourages innovation and creativity in service delivery at The Mater Hospital.					
2.	Adoption of ISO 9001:2008 has enhanced team work and minimized individuality.					
3	Adoption of ISO 9001:2008 has created a culture of customization of services in order to meet clients' preferences better, thus enhancing efficiency.					
4	There are no staffing inadequacies in our department					

**SECTION D: EFFECT OF TOP MANAGEMENT SUPPORT ON  
IMPLEMENTATION OF ISO 9001:2008**

13. Does the hospital management support the ISO 9001:2008 quality management system?

Yes [    ]                  No [    ]

Briefly explain your choice .....

.....

.....

14. To what extent would you agree/disagree with the following listed statements?

Key: 5- Strongly Agree 4-Agree 3-Uncecided 2-Disagree 1-Strongly Disagree

	<b>TOP MANAGEMENT SUPPORT</b>	<b>Strongly agree</b>	<b>Agree</b>	<b>Undecided</b>	<b>Disagree</b>	<b>Strongly disagree</b>
		5	4	3	2	1
1.	Head of Department frequently holds departmental meetings on the QMS					
2.	Follow up of agreed on actions is done by management					
3	The Head of Department is responsive to departmental needs					
4	Non conformities in the department are addressed in consultation with the Head of Department					

15. Do you think the ISO 9001:2008 QMS has any effect on organizational performance? Please tick one.

Yes [ ] No [ ]

16. If yes to Q 15, please indicate to what extent the following effects of ISO 9001:2008 quality management systems are applicable to The Mater Hospital. Key: 5- Strongly Agree 4-Agree 3-Undecided 2-Disagree 1-Strongly Disagree

	1	2	3	4	5
Customer focus	[ ]	[ ]	[ ]	[ ]	[ ]
Involvement of people	[ ]	[ ]	[ ]	[ ]	[ ]
Process approach	[ ]	[ ]	[ ]	[ ]	[ ]
Continual improvement	[ ]	[ ]	[ ]	[ ]	[ ]

16. What do you think are the factors associated with the success or failure of the ISO 9001:2008 quality management system at The Mater Hospital?

.....  
.....

17. Please give any suggestions on how the ISO 9001:2008 quality management system can contribute to enhancing organizational performance at The Mater Hospital. ....

.....

**THANK YOU FOR YOUR TIME AND COOPERATION**