

**EFFECT OF IMPLEMENTING QUALITY MANAGEMENT SYSTEMS
ON SURGICAL PATIENT CARE: EXPERIENCE OF MOI TEACHING
AND REFERRAL HOSPITAL.**

BY

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Date of Submission

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DECLARATION

I declare that this thesis is my original work and to the best of my knowledge has not been presented in any other institution for award of any degree.

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ABSTRACT

Background. There is pressure for hospitals to adopt tool that can help them address the challenges facing the delivery of health care services. Quality management systems (QMS) are being adopted for this purpose. However, there is limited studies' on their effect on patient care.

Objectives. To establish the determinants of quality management system uptake in hospital setting and effect of implementing QMS on patient care at MTRH, Eldoret.

Methods. This was a cross sectional research which utilized quantitative and qualitative research methods. A sample of 96 nurses chosen by simple random and purposeful sampling and working in a surgical unit were involved. Data was collected using 5 point Likert scale questionnaires, key informants guide and documentary reviews.

Results. The aim for ISO certification was to standardize (mean 4.47, $p=0.000$) and to improve the quality of care (4.25, $p=0.000$). Critical factors to consider were staff commitment (4.16, $p = 0.000$) and understanding of ISO standard (4.00, $p=0.000$). The main challenge faced was increased amount of documentation (4.11, $p=0.000$).

Efficiency in provision of care had improved (mean 3.88, CI 3.75-4.02) especially retrieval of records (mean 4.26, $p=0.00$), clear work instruction (mean 4.24 $p=0.000$) and improved documentation (mean 4.13, $p=0.00$). Patient centered care improved through provision of feedback to clients (3.89, $p=0.000$) and responding to clients (3.73, $p=0.000$). Patient safety improved (3.77, CI 3.63-3.90), while there was reduction in medication errors (4.06, $p=000$) and surgical site infections (4.04, $p=0.000$). Accessibility (mean 3.27, CI 3.10-3.43) and equity (3.6, CI 3.47-3.75) in provision of care also increased. Documentary review indicated a

consistent customer satisfaction of 75%, an increase in bed occupancy of 10% but no change in length of stay.

Conclusion and recommendations Quality Management system was implemented in a public hospital with the aim of improving service delivery. Understanding requirements of QMS are critical in its implementation, though one need to overcome increased documentation which is seen as a major challenge. Implementation of QMS improved aspects of care but others had not improved significantly. Use of performance indicators may provide reliable measure of the effect of QMS on quality of care.

Key words. Quality management systems, ISO 9001; 2008, quality of care.

TABLE OF CONTENTS

DECLARATION	i
SUPERVISOR’S APPROVAL	ii
ACKNOWLEDGEMENT	iii
ABSTRACT	iv
LIST OF TABLES	x
LIST OF FIGURES	xi
LIST OF ACRONYMS	xii
OPERATIONAL DEFINITIONS	xiii
CHAPTER ONE: INTRODUCTION	1
1.1. Background information	1
1.2. Problem statement.....	3
1.3 Justification of the study.	3
1.4. Hypothesis.....	4
1.5. Research questions.....	4
1.6 Research Objectives.....	4
1.6.1 Broad objectives.....	4
1.6.2. Specific objectives.	4
1.7 Significance of the study.....	4
1.8 Theoretical framework.....	4
1.9. Conceptual Framework	5
CHAPTER TWO: LITERATURE REVIEW	6
2.1 Introductions to literature review.....	6

2.2. ISO 9001 Standard.....	6
2.3. Factors influencing implementation of ISO standard.	6
2.3.1. ISO 9001 Implementation Motives.....	6
2.3.2. Critical factors in ISO Certification.....	7
2.3.3. Benefits of implementing ISO standard.....	7
2.3.4. Barriers to successful implementation of ISO 9001	9
2.4. Issues in quality of patient care.....	9
CHAPTER THREE: METHODOLOGY	11
3.1. Study Design.....	11
3.2. Study Setting.....	11
3.3. Study population:	11
3.4. Eligibility.	12
3.4.1. Inclusion criteria.	12
3.4.2. Exclusion criteria.	12
3.5 Sample size calculation.....	12
3.6. Sampling methods.....	13
3.7. Recruitment and consenting procedure.....	13
3.8. Data collection procedure.	14
3.9. Variables and their measurements.	15
3.9.1. Predictor variables.	15
3.9.2. Outcome variables.	15
3.10. Quality assurance procedures.	15
3.10.1. Pretesting.....	15

3.10.2. Research assistant.....	15
3.11. Data collection instruments.....	16
3.12. Ethical consideration.....	16
3.13. Data management and analysis.....	17
CHAPTER FOUR: RESULTS.....	18
4.1 Response rate.....	18
4.2 Reliability Scores.....	18
4.3 Characteristics of the respondents.....	18
4.4 Motives for ISO Certification.....	21
4.5. Critical Factors in Implementing QMS.....	23
4.6. Challenges to Implementation of QMS.....	24
4.7. Effect of implementing QMS on quality of care.....	26
4.7.1. Efficiency and effectiveness.....	26
4.7.2. Patient Centered Care.....	30
4.7.3 Patient safety.....	33
4.7.4. Accessibility.....	33
4.6.5 Equity.....	34
CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATION.....	36
5.1. Introduction.....	36
5.2. Motives for seeking ISO certification.....	36
5.3. Critical factors in Implementing QMS.....	36
5.4. Challenges in Implementing QMS.....	37
5.5. Effect of Implementing QMS on Patient Care.....	37

5.6. Conclusions.....	40
5.7. Recommendations.....	41
5.8. Future research.....	41
5.9. Study limitations.....	41
APPENDICES.....	45
Appendix 1: Informed Consent.....	45
Appendix 2. Questionnaire.....	47
Appendix 3: Key Informant Guide.....	52
Appendix 4- Data Extraction Sheet.....	54
Appendix 5: Ethical Approval from KNH/UON ERC.....	55
Appendix 7: Approval from the Director, MTRH.....	58

LIST OF TABLES

Table 1: Reliability Scores (Cronbach’s Alpha).....	18
Table 2: Characteristics of the Respondents.....	19
Table 3: Motives for ISO Certification.....	22
Table 4: Critical Factors in ISO Implementation.....	24
Table 5: Challenges in Implementing ISO.....	25
Table 6: Mean scores for Efficiency and Effectiveness.....	27
Table 7: Mean scores for Patient Centered Care	31
Table 8: Mean Scores for Patient Safety.....	33
Table 9: Mean scores for Accessibility of care.....	34
Table 10: Mean scores for Equity.....	35

LIST OF FIGURES

Figure 1: Number of Admissions, Operations and Theatre Cancellations	28
Figure 2: Length of Hospital Stay.....	29
Figure 3: Trends in Bed Occupancy	30
Figure 4: Compliments and Complaints	32
Figure 5: Customer Satisfaction Levels	32

LIST OF ACRONYMS

BScN	:	Bachelor of Science in Nursing.
IREC	:	Institutional Research and Ethics Committee.
ISO	:	International Organization for Standardization
KEBS	:	Kenya Bureau of standards
KECHN	:	Kenya Enrolled Community Health Nurse
KEN	:	Kenya Enrolled Nurse
KNH	:	Kenyatta National Hospital.
KRCHN	:	Kenya Registered Community Health Nurse
KRN	:	Kenya Registered Nurse
MTRH	:	Moi Teaching and Referral Hospital
MU	:	Moi University
NHSSP	:	National Health Sector Strategic Plan
QMS	:	Quality Management System.
SD	:	Standard Deviation
SEM	:	Standard error of the mean
WHO	:	World Health Organization.

OPERATIONAL DEFINITIONS

Accessibility:	Availability of doctors, specialists and diagnostic services on 24 basis.
Acceptability:	Provision of care that is relevant to the client's needs
Bed occupancy rate:	Number of occupied beds versus empty beds in a year
Clause:	Subsection of the ISO standard.
Clinical indicator:	Characteristic of care that is subject to measurement.
Customer:	A recipient of care.
Effect:	Change in the status of services
Effectiveness:	The ability to achieve the desired results.
Efficiency:	Utilization of human resources, time and wards and operating rooms.
Equity:	Provision of care devoid of variability and discrimination
Implementation:	Execution of procedures as outlined in ISO 9001:2008 standard.
Length of stay:	Time taken by a patient from admission to the time of discharge.
Medical error:	Harm to a recipient of care resulting from an intervention during care
Quality:	Service that is deemed to satisfy the customer.
Re-operation rates:	Second operation within 3 months for same condition
Readmission rate:	Admission with same diagnosis of a patient 28 days after discharge.
Safety:	Care that does not result in a client getting harm while in the hospital
Standard:	Refers to ISO 9001:2008 standard
Satisfaction:	Being contented with the quality of care

CHAPTER ONE: INTRODUCTION

1.1. Background information

In today's world, delivery of health care is under immense pressure to improve efficiency and competitive advantages in relation to cost effectiveness and quality of care (Al-Najjar and Jawad, 2011, Wardhani *et al*, 2009). The reasons behind this movement are the increasing complexity of health care institutions, competition in the healthcare market, the ongoing process of (sub-) specialization of health care providers, strengthening of the client position and increasing awareness on patient safety (Wardhani *et al*, 2009). These processes have resulted in the adoption of quality management system (QMS) in hospitals (van den Heuvel *et al*, 2005).

In Kenya, health care access, efficiency and quality of service delivery is a big issue and a challenge to many Kenyans (Mwando *et al*, 2009). The National Health Sector Strategic Plan, 2005 (NHSSP 1) objective was to improve access, service quality, responsiveness, efficiency and effectiveness of the health care services. Evaluation of the NHSSP 1 indicated a decline in the utilization of public health facilities leading to decline in national health indicators (Mwando *et al*, 2009). Access to care especially for the poor and vulnerable who makes up 46% of the population was found to be poor. Consequently, the second National Health Sector Strategic Plan 2005-2010 (NHSSP II) is aptly titled "reversing the trends".

To address the problems of health care delivery, a system approach and orientating system to the delivery and improvement of quality is recommended to meet the expectation of both the patients and healthcare workers (WHO, 2006). The International Organization of

Standardization (ISO) 9001:2008 standard is a Quality Management System that utilizes systemic approach to quality improvement. Hence, the ISO standard is finding application in health care.

The ISO 9001:2008 standard has eight principles. These are: customer focus, Leadership, Involvement of people, Process approach, System approach to management, continual improvement, factual approach to decision making and mutually beneficial supplier relationships. ISO 9001:2008 standard is premised on continuous quality improvement. It involves documenting best practices that an institution commits to deliver to its customers. These practices are then audited internally and externally to evaluate the degree to which the institution is implementing quality management systems.

While the quality management concept and tools are being widely accepted in hospitals (Cerrillo *et al*, 2012), various reports on their success and failure have been noted. It is generally accepted that the failure is not due to the principles of QMS itself, but mainly due to ineffective implementation steps or strategies (Durai, 2011).

A study conducted at Red Cross hospital in the Netherlands, showed implementation of ISO 9000 standard resulted in increased patients focus, improved quality of care and improved patient safety (van den Heuvel *et al*, 2005). In another study conducted in Egypt (Magd, 2010) it was found that ISO helped manufacturing firms to meet and exceed quality levels of competitors. However, there was difficulty in implementing the standard due to lack of understanding of the standard.

There is lack of data on implementation of ISO in health care setting in developing countries (Wardhani, 2009). This is because the implementation of QMS originated in the manufacturing industry (Al-Najjar, 2011). However, Kenya is undergoing a quality revolution with an increasing awareness of competition worldwide, regionally and locally. In this regard, a few hospitals in Kenya have adopted quality management systems. This includes Nairobi, Mater, Gertrude, Karen, Moi and KNH hospitals.

1.2. Problem statement.

Implementation of QMS concepts in health care, are with few exceptions a recent development .The number of ISO certified hospitals is also very low compared to manufacturing industries and thus limited empirical studies on the effectiveness of QMS in health care setting(Wardhani *et al*,2006) . This is particularly so in Kenya and especially in public hospitals. MTRH was the first of the only two public hospitals to implement QMS. It set the pace for other public hospitals which intends to adopt quality management systems. This study provides knowledge on the outcome of implementing quality management system on patient care in public hospitals in Kenya. It also addresses the determinants of quality management system in hospital settings.

1.3 Justification of the study.

The purpose of this study is to establish the outcome of implementing QMS on patient care and the factors associated with the uptake of QMS in ward setting.

1.4. Hypothesis

Implementation of quality management systems is associated with an improvement of quality of patient care.

1.5. Research questions.

1. What is the effect of implementing quality management systems on quality of patient care?
2. What are the factors associated with the uptake of quality management systems in surgical wards at MTRH?

1.6 Research Objectives

1.6.1 Broad objectives

To determine the factors that influences the uptake of the quality management system in surgical wards and the effect of implementing the standard on the quality of patient care.

1.6.2. Specific objectives.

1. To establish effect of implementing quality management systems on quality of s patient care.
2. To determine factors associated with implementing QMS in surgical ward setting.

1.7 Significance of the study.

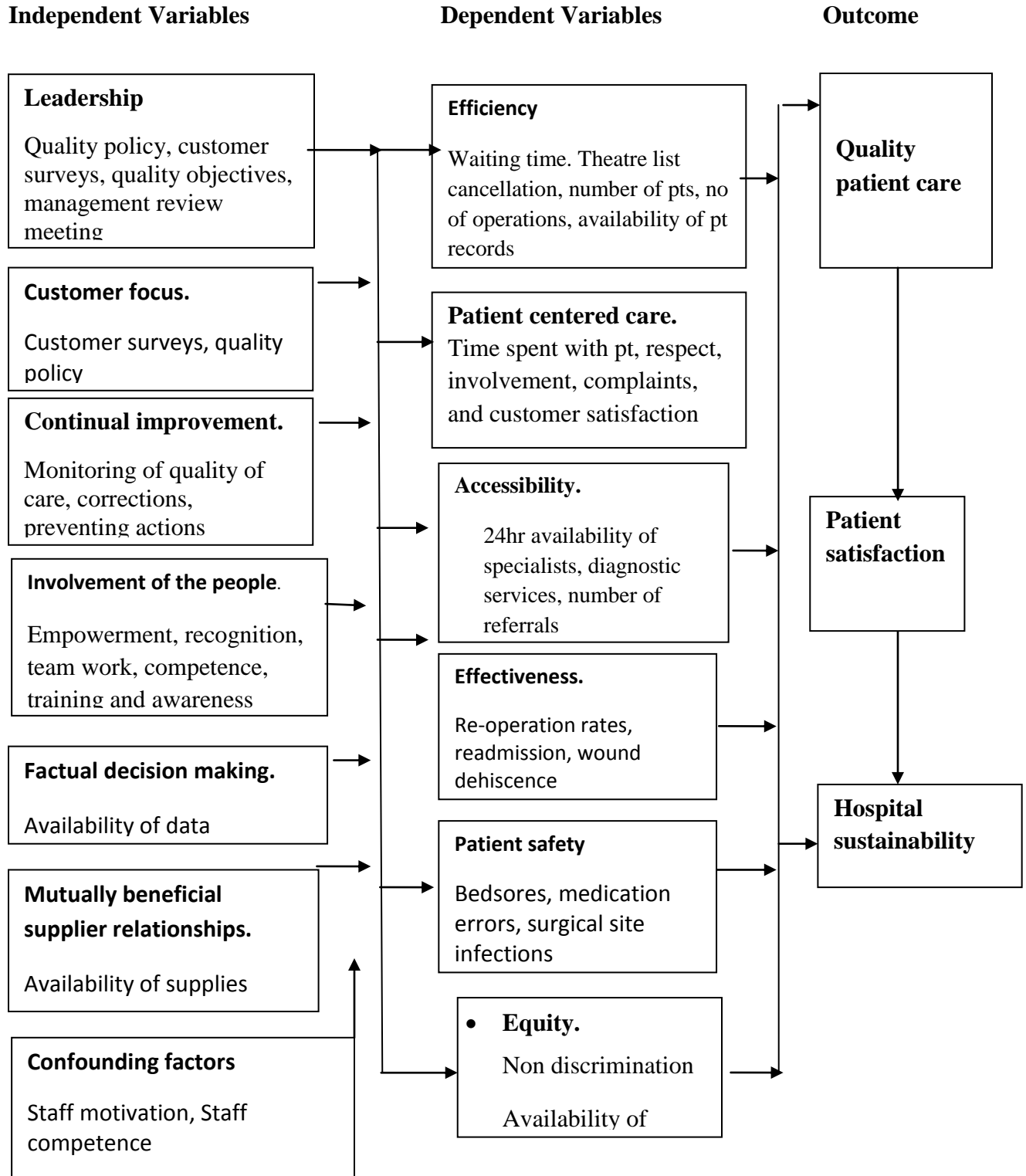
This study has contributed knowledge to the application of quality management systems in surgical wards in particular and in hospital setting in general.

1.8 Theoretical framework.

This study utilizes theoretical framework suggested by WHOM (2006). This framework suggests the use of effectiveness, efficiency, patient centeredness, equity, accessibility and patient safety to assess the quality of care.

1.9. Conceptual Framework

1.9. Conceptual Framework



CHAPTER TWO: LITERATURE REVIEW.

2.1 Introductions to literature review.

This chapter presents literature review from previous studies addressing the effects of ISO standard and the determinants of implementing QMS.

2.2. ISO 9001 Standard

The ISO 9001 standard was first issued by the International Standardization for Organization (ISO) in 1987 (Simeri, 2010). It has since been revised in 1994, 2000 and in 2008. The ISO standard is an international standard in which an organization needs to demonstrate a consistent ability to meet customer requirements, regulations and legislation requirements. The aim of the standard is to enhance customer satisfaction through effective system including processes for quality improvement (Simeri, 2010). To be ISO certified, organizations need to meet requirements set in the standard. There are five main requirements namely clause 4 (quality management), clause 5 (management responsibility), clause 6 (resource management), clause 7 (product realization process) and clause 8 (measurement, analysis and improvement). Clause one through clause 3 provides scope and explanation of the ISO standard

2.3. Factors influencing implementation of ISO standard.

2.3.1. ISO 9001 Implementation Motives.

The reasons for adopting ISO 9001:2008 have been identified as: Customer requesting an institution to be certified, as a means to increase market share and as a means to improving internal processes, product or services (Durai, 2011). The motives of seeking ISO certification have been summarized into two categories (Sampaio, 2009). The categories are internal and external

motives. The internal motives relates to the desire to achieve improvement of the organization. On the other hand, external motives relate to the issues of promotion and marketing, customer pressure or increase in market share. The reason to adopt ISO standard appears to influence the degree to which ISO 9000 meets organizational expectations. In Canada, companies that implemented the ISO standard due to customer and market influences experienced high levels of benefits than companies that did so for the purpose of making internal performance improvement (Bhuiyan and Alam, 2005). Hospitals are implementing the ISO standard as a means of improving quality of patient care (van den Heuvel *et al*, 2005).

2.3.2. Critical factors in ISO Certification.

Wahid and Corner (2009) indentified critical factors in the implementation of ISO standard as senior management involvement and commitment, involvement of employees, training to understand the ISO standard, commitment to continuous improvement, team work and positive attitude and behaviour. In hospital setting, physician involvement is considered an important factor (Wardhani *et al*, 2009).

2.3.3. Benefits of implementing ISO standard.

Implementation of the ISO standard has been associated with improvement of processes and procedures and increase in employee awareness about quality (Zaramdini, 2007). Institutions that have implemented ISO standard have benefitted from improved documentation, improved perception on quality and creation of disciplined work environment (Simedi, 2010, Buciuniene *et al*, 2006). Implementation of QMS is associated with better service quality, high patient

satisfaction, and stronger sense of security among patients, more effective communication, safer work environment and improved work organization (Buciuniene *et al*, 2006).

The implementation of the quality management system in hospitals has led to development of admission criteria, development of protocols, periodic checking of medication, calibration of equipments, development of disease specific care maps, and performance of preventive maintenance (Cerrillo, *et al* 2012) .The study showed improved customer satisfaction, improved consultations, no complaints, no medical equipment failures, reduced readmission, improved supplies and increased compliance to protocols.

ISO 9001 standard improves major hospital performance indicators (van den Heuvel *et al*, 2006). This included growth in catchment area, increased admissions, reduction on hospital length of stay, reduction on waiting periods, and increased number of surgical operations, increased efficiency, reduction of absenteeism and a consistently high performance of patient satisfaction surveys. Tsai *et al* (2012) studied the effect of implementing QMS in medical setting. He reported fewer customer complaints, increased productivity and greater degree of quality control. He noted that standardization of procedures avoids variability in the provision of care. Rouzbahani *et al* (2013) studied the effect of ISO in health services. He reported increased patient satisfaction; reduction in work related mistakes and improved work process in the wards.

2.3.4. Barriers to successful implementation of ISO 9001

Barriers to successful implementation of ISO standard have been identified as the cost of training (Al-Najjar, 2011). Other challenges and barriers identified includes lack of management involvement, high implementation and maintenance cost, perceived decreased value of attaining ISO certification and excessive auditors support of paperwork as well as lack of knowledge concerning specific industries (Simeri, 2010, Francois et al, 2003).

Other impediments to successful implementation of the standard are management commitment (Al-Najjar, 2011, Wahid and Corner, 2009) and employee resistance (Wahid and Corner, 2009). In hospitals the problems of implementing the quality management systems are related to process of developing procedures, cost, lack of information and the development of work instructions (Buciuniene *et al*, 2006, Wahid and Corner, 2009). The health care system is composed of health professionals who value their authority and freedom to carry out their functions. This makes the introduction of changes in health care particularly prone to resistance and possible rejection (Kamenade *et al*, 2011). The hospital environment is not particularly favourable terrain for profound changes (Francois *et al*, 2003).

2.4. Issues in quality of patient care.

Health care is faced by serious quality problems and skyrocketing cost (van den Heuvel et al , 2006) and is consistently unable to meet patients need (WHO, 2006).Most complaints and dissatisfaction are related to waiting time, interdepartmental consultations, length of hospital stay and lack of explanations by health care providers (Saleh *et al*, 2012)..In a study conducted in India, reported inequality between the locals versus the non locals, educated versus the non

educated and the rich versus the poor (Puri *et al*, 2012). Lack of fast response and adequate time to provide care have contributed to poor quality of care (Shirley and Norazliah, 2012). Hospitals pose threats to patients in terms of, patient suffering from surgical site infections, catheter infections, drug reactions and development of pressure ulcers (Sandra *et al*, 2012). Inefficiency is manifested when theatre cases start late; inadequate patient preparations and coordination of services among the various departments, surgical delays, theatre cancellations and slow turnover of patients in the operating room (British Columbia Medical Association, 2011).

CHAPTER THREE: METHODOLOGY

3.1. Study Design.

This study was a cross-sectional design utilizing qualitative and quantitative research methods. Cross sectional design is chosen because it gives a snapshot of what is happening at a given time.

3.2. Study Setting.

The study was conducted in surgical wards of the Moi Teaching and Referral Hospital, Eldoret. The hospital has seven hundred and fifty beds and a daily inpatient number of close to eight hundred patients. It serves the western Kenyan region which has an approximately fifteen million people. The hospital serves as a training hospital for Moi University College of health sciences and three other middle level medical colleges. It was the first public hospital to be ISO certified in March 2009 and has been recertified since then.

The surgical units of MTRH comprises of female, male and paediatrics general surgical wards, burns unit, neurosurgical ward, the eye ward, the operating theatres, central supplies sterilizing unit(CSSD) and the orthopedic ward. There are 125 beds in the unit distributed as follows: female ward 48; male 55 and eye ward 22. Bed occupancy in the unit averages between 95 and 120%. The major objective of the unit is to provide quality patient care.

3.3. Study population:

The study population comprised one hundred and twenty five (125) nurses working in the surgical unit. The study population included nurses offering directly patients care as well as

ward in charges and nurse managers. Nurses have a twenty four hour contact with the patients. At the ward level, nurses coordinate the provision of patient care and are the patients' advocates. The nurse in charge is the custodian of records and reports generated in the wards. Nurses form large homogenous health care providers.

3.4. Eligibility.

3.4.1. Inclusion criteria.

Data was collected from nurses who had worked in the surgical wards for at least twelve months and were willing to consent and participate in the study.

3.4.2. Exclusion criteria.

Nurses who have worked in the hospital for more than a year but declined to consent and those who were off when data was collected.

3.5 Sample size calculation.

Sample size was calculated using Yamane's formula (1967:886) as follows

$$n = \frac{N}{1 + N(e)^2}$$

95% confidence level and $P = 0.05$ are assumed for Equation

Where n is the sample size,

N is the population size, =125

e is the level of precision.0.05.

Substituting

$$n = \frac{125}{1+125(0.05)^2}$$

$$n= 96$$

96 participants were invited to participate in the study.

Seven key informants were purposefully selected from the five surgical wards.

3.6. Sampling methods.

This study utilized both probability and non-probability sampling methods. Non-probability sampling utilized purposeful sampling for key informant. This method is chosen because the respondents have in-depth information about the quality management system and the effect on the quality of care. In addition, the ward in charges and nurse managers, apart from being the senior most, are the custodians of the wards records and hence are likely to be more informative. Although this type of sampling is not generalizable and may introduce personal bias, it is nevertheless utilized because it provides rich information that enriched the data collected by the questionnaire. The probability sampling method used for respondents of structured questionnaires was simple random sampling. This is a sampling method that provides an equal chance to all the nurses in the surgical wards to participate in the study. This sampling method enables the generalization of the research findings.

3.7. Recruitment and consenting procedure.

The sampling frame was the nurses' duty rosters of the respective wards. Each nurse on duty was allocated a number which was then entered in an excel worksheet. Using excel worksheet, random numbers equivalent to the sample size of ninety six (96) were generated. The numbers

picked formed the participants who were to respond to the questionnaire. The principle investigator directly contacted the participants through face to face meetings. Verbal and written explanations of the objectives of the study were explained to the participants. If a member so selected was unavailable or unwilling to participate in the study, the next number was picked and included in the study. The replacement of participant was chosen by simple random sampling of the remaining nurses not chosen in the initial selection. This was achieved by generating random numbers using excel. Key informants who are the ward in-charges were contacted directly by the researcher and their participation obtained using the same approach.

3.8. Data collection procedure.

Those who consented to participate were provided by the researcher and the assistant with the questionnaires to fill. The participants were directed where to place the completed questionnaires in a sealed box within the wards. The questionnaires were collected daily by the researcher for analysis. The researcher conducted five key informant interviews each lasting about forty minutes. This was conducted in areas of work to enable retrieval of documents where appropriate. The researcher took notes during the interviews while tape recording using a Sony, ICD BX132,2GB tape recorder. Immediately at the end of the interviews, the tape recordings were transcribed verbatim.

Documentary review involved reviewing hospital statistics, internal and external audits, incident reports, customer satisfaction surveys, non- conformity registers, compliments and complaint registers and annual reports. Relevant data was entered in a data abstraction sheet.

3.9. Variables and their measurements.

3.9.1. Predictor variables.

The independent /predictor variables in this study were the eight principles of ISO namely customer focus, Leadership, Involvement of people, Process approach, System approach to management, continual improvement, Factual approach to decision making and mutually beneficial supplier relationships. These principles are supported by the clauses of the ISO 9001:2008 standard.

3.9.2. Outcome variables.

The outcome variables included waiting time, length of stay, theatre cancellation, pressure ulcers, urinary catheter infections, surgical site infections, duration of interaction with patients, respect for patient ,number of complaints, patient satisfaction level etc.

3.10. Quality assurance procedures.

3.10.1. Pretesting.

The data collection tools were pretested to test their validity and reliability. The tools were pretested with a sample size of ten staff for the questionnaire and the ward in charge and nurse manager as the key informants. This represents ten per cent of the study population.

3.10.2. Research assistant.

One research assistant was trained by the principal researcher. The research assistant was holder of Bachelor of Science in nursing and had working experience of at least five years at MTRH. The training took three days and consisted of training in data collection procedures. The assistant was utilized in data collection phase.

3.11. Data collection instruments.

Data was collected using standardized questionnaire, data abstraction form and a key informant guide. The questionnaire was divided into three sections. Part one contained demographic data of the respondents. There were six (6) items in this section covering the age, gender, marital status, professional qualification, years of experience as a nurse and the duration they had worked at MTRH. Part two consists of twenty five (25) items. These items are focused on the determinants of ISO uptake and include motives (9 items), critical factors (8 items) and challenges (8 items). The last part contained thirty two (32) items which measured the effect of the ISO standard on the quality of patient care: The questionnaire was in form of a five point Likert scale ranging from strongly agrees to strongly disagree. The internal consistency and reliability of the questionnaire was determined by Cronbach's alpha. A range of 0.6 to 0.90 was considered adequate (Hair et al, 2006).The key informant interview guide had five questions which elicited information about the motives for seeking ISO certification, the critical factors, challenges and effect of implementing QMS in surgical wards.

Document analysis for the period 2009-2012 was used to collect data that was related to the effect of implementing quality management system in surgical wards. These documents included customer satisfaction surveys, complaints and compliments registers, critical incident reports, and ISO audit reports.

3.12. Ethical consideration.

Ethical approval was obtained from KNH-UON ethical and research committee while the permission to collect data was obtained from the director, MTRH. Participants gave written

consent after being assured of confidentiality, privacy, anonymity and voluntary participation. Data was kept under lock and key and was only accessible to the researcher.

3.13. Data management and analysis.

The raw data was edited to detect errors and omissions and to correct these when possible. This included tracing the respondent immediately and seeking clarifications. Where this was not possible, data that was missing from a given section of the questionnaire was not included in the analysis of those particular sections. Data coding involved assigning numerals to answers. This enabled them to be put into a limited number of categories. Coding for the key informant interviews was done using colored pencil on the margin of the field notes and transcription notes. During data classification, the coded data was arranged in groups on the basis of common characteristics. Descriptive statistics included measures of central tendency such as mean, percentages and median. Categorical data such as gender was analyzed using chi square test while continuous data was analyzed by t- test and correlation coefficient Quantitative data is presented in percentages, and frequency tables, bar graphs and time- series graphs. Qualitative data is presented according to themes.

CHAPTER FOUR: RESULTS.

4.1 Response rate.

A total of eight five questionnaires were distributed in the surgical wards during a two week period in June 2013. Sixty eight questionnaires were returned which gave a gross response rate of 80%. Five of the proposed seven key informants (71%) were interviewed.

4.2 Reliability Scores.

The reliability scores of the questionnaire were determined by calculating the Cronbach's alpha. The scores ranged from 0.662 to 0.855 and an overall score of 0.831. This was within the recommended range by Hair et al (2006).

Table 1: Reliability Scores (Cronbach's Alpha)

Category	Cronbach's Alpha	Number of items
Motivation for certification	0.762	9
Critical factors	0.662	7
Challenges	0.855	9
Perceived effect on quality care	0.797	32
Overall	0.831	57

4.3 Characteristics of the respondents

Majority of the respondents 92.6% (n=63) were female. Majority 65.7% (n=44) Kenya Registered Community Health Nurses, married 74.6% (n=50) aged 31 to 40 years 47% (n=31) with a mean of 36 ± 8.6 years. Majority 42.6% (n=29) had worked at MTRH for 5 to 10 years.

Table 2: Characteristics of the Respondents

Demographics	Variables	Frequency	Percentage	P-value
Sex	Male	5	7.4	0.000
	Female	63	92.6	
Age	20-30	19	28.8	0.004
	31-40	31	47	
	41-50	10	15.2	
	.> 50	6	9	
Marital status	Single	13	19.4	0.000
	Married	50	74.6	
	widowed	4	6	
Years of experience as nurse	<5 years	14	20.9	0.271
	5-10 years	25	37.3	
	11-15 years	11	16.4	
	16-20 years	5	7.5	
	21-25 years	4	6	
	26-30 years	8	12	
Years of service at MTRH	<5 years	21	30.9	0.001
	5-10 years	29	42.6	
	11-15 years	14	20.6	
	16-20 years	1	1.5	
	21-25 years	3	4.4	
Professional qualifications	KECN	11	16.5	0.000
	KRN	3	4.5	
	KRCHN	44	65.7	
	BSc.Nursing	9	13.4	

Association between age, motives and challenges

A Pearson correlation test was done to compare the effect of age on the perception of certification motives and challenges. The correlation tests did not yield significant differences between age and motivation. There was a negative relationship between a person's age, and perceived challenges. ($r = -.106$, $p = .427$). There was also a negative relationship between a person's age and motivation mean score ($r = -.01$, $p = .945$). This indicates, as the respondent's age increased the motives were seen as external. It also means that respondents with many years experienced more difficulty in implementing ISO

Association between Years of experience, motives and challenges

A test of association between years of experience and motive scores yielded weak association. There was a weak negative relationship between a person's years of experience, and their motive mean score ($r = -.039$, $p = .773$). This was also the case for the person's years of experience, and their mean score for challenges ($r = -.147$, $p = .270$). This indicates that the more years of experience the less the person perceived the motive of seeking ISO as intended for quality improvement. It also means staff with over ten years' experience perceived more challenges than those with less than ten years' experience.

Association between professional qualification, motives and challenges

A test of association was done to reveal whether there is a difference in the qualification of the respondents and their perception of motivation and challenges faced in implementing QMS. The test yielded weak associations that were not significant. The motivation mean score for KRCHN was 3.6 ± 0.54 compared to 3.4 ± 0.89 for BScN. This difference in means was not

significant $t(41) = 0.734, p=0.467$). This was also the same for challenge mean score for KRCHN (2.2 ± 0.81) compared to 2.6 ± 0.1 for BScN. This difference in means was not significant $t(46) = -1.295, p=0.202$. However it indicates that the degree holders did not perceive the implementation of ISO as a strategy to improve quality of care. The degree holders also experienced difficulties than the diploma holders.

4.4 Motives for ISO Certification

Fifty eight out of the 61 respondents (95%) identified the need to develop work procedures as the main motive for seeking ISO certification. This motive had a mean score of 4.47($P=0.000$). Other motives that received high scores were to improve the quality of care- means score of 4.25 ($P=0.000$) and to be internationally recognized mean score of 4.02($P=0.000$). Those motives that received low scores were Government directive-mean score 2.84($P=0.520$) and to wade of competitors-mean score 2.75($P=0.227$).

Table 3: Motives for ISO Certification

Opinion on motive for ISO certification	Mean	Sd	SEM	P-value
Hospital wanted to standardize work procedure	4.47	0.854	.107	.000
To improve the quality of service	4.25	1.049	.128	.000
Hospital wanted to be recognized internationally	4.02	1.157	.146	.000
Hospital wanted to improve its image	3.79	1.065	.134	.000
Hospital wanted to reduce medical errors	3.35	1.175	.149	.104
Government directives to be ISO certified	3.00	1.403	.175	.520
Suppliers required the hospital to be ISO certified	2.84	1.293	.166	.303
To wade off competitors and remain in business	2.75	1.309	.164	.227
Customer required our hospital to be ISO certified	2.73	1.405	.177	.257

A paired t test was performed to establish whether there was a difference between the motives for seeking ISO certification. The external motives had a mean of 2.8 ± 1.1 , while internal motives had a mean of 3.99 ± 0.77 . The two mean were significantly different $t(55) = 6.936, p = .000$.

Key informant's perception on the motives for ISO certification

The key informants were asked the motive for seeking ISO certification. They were also asked whether it was the hospital initiative or it was a requirement from other stakeholders. When asked this question Key informant R4 said:

“I think mainly to improve the quality of care for our clients. If the hospital is ISO certified it attracts many clients to come to the hospital”

R3 said *“raising the quality of care, that could be the prime reasons”*

Asked where the idea came from R3 said *“not aware but internal initiative”*

However, there were those who thought otherwise.

R5 had this to say:

“The hospital felt it needed to match internationally with other hospital in the care of patients for the purposes of customer satisfaction”

R1 said *“may be to meet international standard which are required of referral hospitals. Also a requirement set by the ministry of health and government as a whole”*.

4.5. Critical Factors in Implementing QMS.

Descriptive statistics was used to determine the relative importance of critical factors for successful implementation of QMS. Most staff considered full commitment (mean score 4.16, P=0.00) and understanding of ISO standard (mean score of 4.00, P=0.00) as the main factors to consider in implementation QMS. Top management commitment and involvement (3.97, P=0.00) and staff involvement in all stages of ISO implementation (3.63, P=0.00) were also considered critical. The factors that were least considered critical included doctors' active participation (3.38, P=0.032), staff training on ISO (2.8, P=0.399) and reward and recognition (2.27).

Table 4: Critical Factors in ISO Implementation.

Critical factors	Mean score	Sd	SEM	p-value
I am committed to the implementation of ISO	4.16	0.745	.094	.000
I understand the ISO standard fully	4.00	1.00	.124	.000
Top management committed to ISO	3.97	1.237	.153	.000
I am fully involved in ISO implementation	3.63	1.245	.154	.000
Doctors participate in implementation of ISO	3.38	1.31	.165	.032
I was trained on ISO prior to the certification	2.80	1.372	.170	.399
There was reward and recognition for staff	2.27	1.3	.163	.002

Key informants were to large extent in agreement with the questionnaire respondents in the critical factors.

Employee and management commitment

Key informant R2 had this to say:

“For ISO to be implemented, personally I think commitment from management and employee. If employees are not committed to the implementation of this standard it may not work” Asked why management commitment was important R2 said: “Very important because they need to support staff and even capacity building and because it is a new concept and carries the objective of the management...”

4.6. Challenges to Implementation of QMS.

The major challenges encountered were: ISO decreases the amount of documentation (mean 4.11, p=0.00), ISO is not well understood (3.78, p=0.00) top management commitment (3.77, p=0.00). The challenges considered least were: Staff do not take ISO seriously (means 3.17

p=0.520), time spent implementing QMS would best be utilized in caring for patients (mean 3.25, p=0.189), failure by doctors to participate in the implementation (mean 3.57, p= 0.004).

Table 5: Challenges in Implementing ISO

Perceived challenges	Mean	Sd	SEM	P-value
ISO decreases amount of documentation	4.11	1.002	.124	.000
ISO standard is not well understood to me	3.78	1.142	.144	.000
Hospital management are not committed to ISO	3.77	1.225	.151	.000
Auditing process add no value to patient care	3.71	1.250	.157	.000
ISO standard is not applicable to patient care	3.67	1.257	.155	.000
It is difficult to develop work instructions	3.65	1.234	.152	.002
Doctors do not participate in implementing QMS	3.57	1.38	.171	.004
Time spent on QMS could best be used pt care	3.25	1.358	.168	.189
Staff do not take implementation seriously	3.17	1.330	.165	.520

Key informants expounded on the challenges faced on the implementation of ISO. Respondent

Lack of knowledge/ understanding of the ISO standard

R1 said: *“the expectations are high. Most staff may or may not be acquitted of what is required of them so there is lack of knowledge and hence the output is less than what is expected”*.

R4 commented: *“not all staff understands ISO, some are ignorant, and others don’t bother they think it is a nursing issue”*.

Lack of team work/staff resistance

R2 said: *“there are many challenges in ward set up where there are a whole lot of people yet ISO is left to the nursing officer in charge. The rest are not participating”*. This was shared by respondent R3 who said: *“lacks of staff participation- doctors are retreating leaving the implementation of ISO to become a nursing duty”*.

Doctors were pinpointed as the least likely to participate in ISO. R5 said:

“If I can rate the doctors participation in percentage, I would give them 30% they are usually busy and committed (in other duties), if they participate they would not remain there fully”

While R6 said: *“they are asking me what is this thing called ISO, a few (the auditors) participate but others are negative”*.

Other challenges identified by key informants were increased workload and the language used by auditors and that its implementation consumes a lot of time.

4.7. Effect of implementing QMS on quality of care.

4.7.1. Efficiency and effectiveness.

Staff strongly disagreed that ISO had resulted in an increase in the number of patients with bedsores (mean 4.32) and increase in medical mistakes (mean 4.27). However, respondents agreed that ISO improved documents retrieval (4.26), provided for clear work instructions (mean 4.24) and improved documentation (4.13).

Reduction of average length of stay received a score of 3.09 while reduction of waiting time (3.54) and theatre cancellation (3.44) had the least scores. All statements were significant ($p < 0.004$) except the average length of stay ($p = 0.750$).

Table 6: Mean scores for Efficiency and Effectiveness

Efficiency and effectiveness	Mean	Sd	SEM	P-value
Number of patients with bed sores have increased	4.32*	0.668	.084	.000
Medication errors have increased	4.27*	0.833	.103	.000
Patient records can easily be retrieved	4.26	0.871	.108	.000
ISO provides clear work instruction/procedures	4.24	0.805	.099	.000
ISO improves documentation of nursing care	4.13	1.072	.131	.000
Peri-operative mortality rate has declined	3.84	0.931	.114	.000
I have Cared for indwelling catheter that is infected	3.70*	1.231	.150	.001
unplanned readmission of patients has increased	3.68*	1.161	.144	.004
Waiting time for operations have increased	3.54*	1.187	.147	.004
Cancellation of theatre list has increased	3.44*	1.165	.143	.008
Average length of stay has been on the decline	3.09*	1.262	.155	.750

Mean improvement in efficiency and effectiveness-3.88, CI 3.75-4.02

Improved Efficiency

Key informants agreed that the efficiency and effectiveness of care had increased since the introduction of QMS. R5 said:

“Care has improved. When a patient is admitted the patient is seen immediately. There is less loss of lab results and we have set times when operations start and end which is followed”.

However, asked about efficiency R5 said: “*theatre should start at 8.00am but sometimes that does not occur. However turnover is poor because of rising emergencies*”.

The number of admissions, operations; length of stay is depicted in figure 1. It indicates these parameters remained almost constant during the period 2009-2012. There was no significant difference in the number of surgeries cancelled in 2011 (2224 surgeries) compared to those cancelled in 2012(2027 surgeries) OR: 0.99, CI: 0.93 – 1.06 (p=0.86). The number of admissions decreased by 11% between 2009 and 2012 while the number of operations decreased by 0.09%.

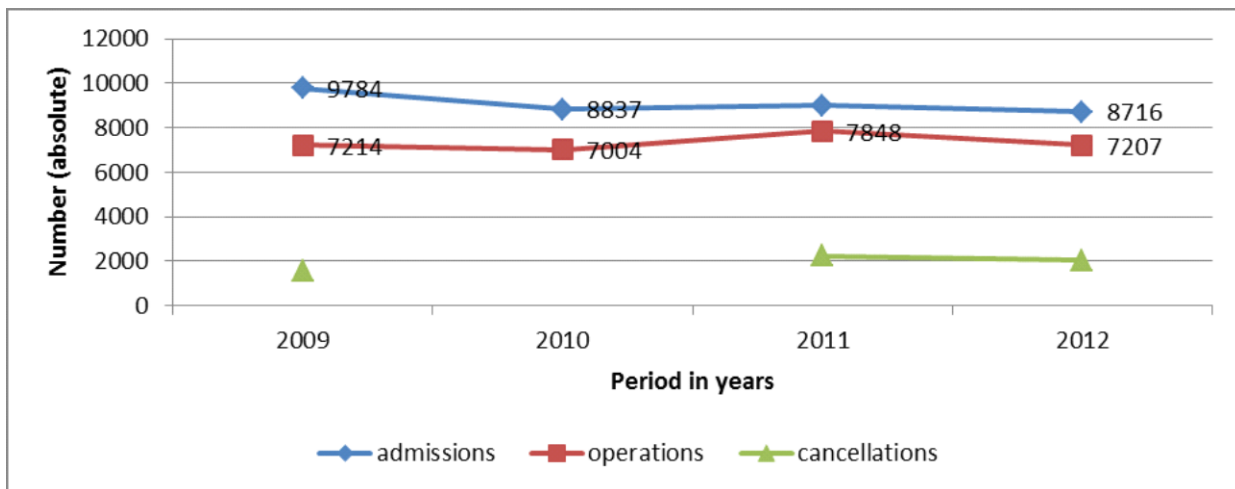


Figure 1: Number of Admissions, Operations and Theatre Cancellations

Figure 2 shows average length of stay in the surgical wards. It indicates an increase in the length of stay from 8.97 days to 11.72 days between 2009 and 2012. However, this could be due to inaccurate data availability initially which could be improving with time.

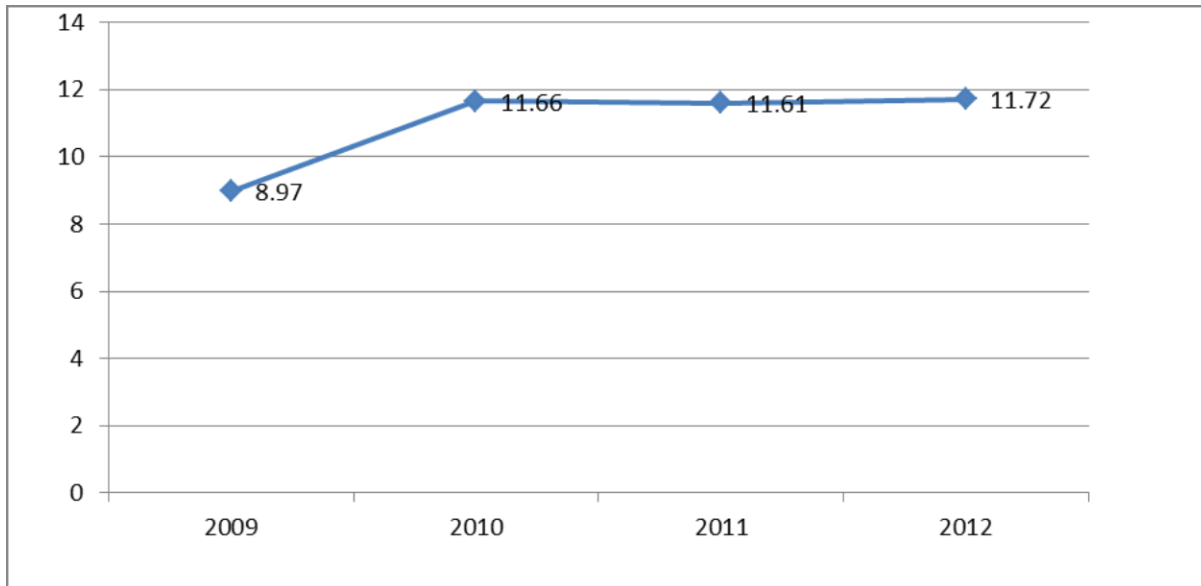


Figure 2: Length of Hospital Stay

Trends in Bed Occupancy

Figure 3 indicate the average bed occupancy rates in the surgical units. There was a 20% increase in bed occupancy between 2009 and 2010. However the bed occupancy has reduced by 10% between 2010 and 2012. This may indicate a level of increased efficiency aimed at reducing congestion in the wards following implementation of ISO. The decrease could also be related to industrial action that occurred in 2012. In total however, there was an increase in bed occupancy of 8% between 2009 and 2012.

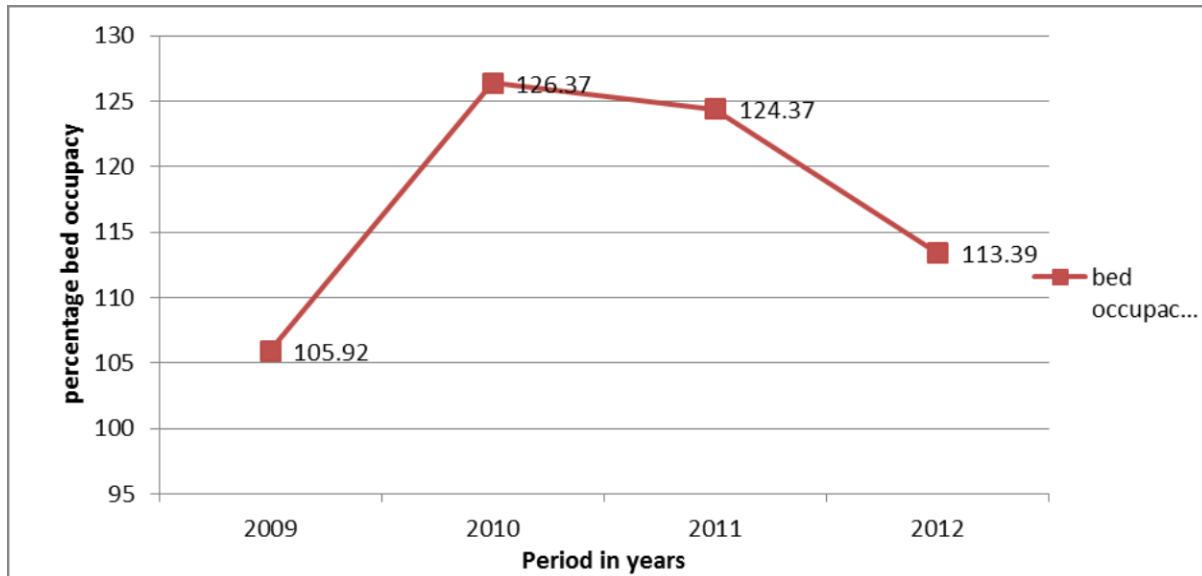


Figure 3: Trends in Bed Occupancy

4.7.2. Patient Centered Care.

Providing feedback (3.83) analyzing root causes of complaints (3.73) and responding to clients within a given period of time (3.64) received high scores respectively. Engaging clients in the provision of care received a score of 3.48 while the adequacy of time to health educate the clients received a low approval of 2.76. Generally 74.5 % of the respondents agreed with an increased focus on the patients following the implementation of the quality management system. All statements were significant ($p < 0.003$) except statements about ability to address client complaints.

Table 7: Mean scores for Patient Centered Care

Patient centered care	Mean	Sd	SEM	P-value
I always provide feedback to my clients	3.89	0.918	.116	.000
I respond to patient within reasonable time	3.73	1.053	.129	.000
I am satisfied with time I interact with patient	3.64	1.132	.139	.000
I analyze patients complaints to find root causes	3.57	0.941	.115	.000
Number of patients complaints has reduced	3.46	0.91	.111	.002
I engage my patients in planning their care	3.42	1.124	.138	.003
I address patients complaint within given time	3.38	0.958	.121	.008
I have adequate time to health-educate clients	2.76	1.116	.136	.312

Key informant R2 had this to say about patient focus: *“Privacy is not up-to-date sometimes we have ten patients in a room which is separated by curtains, sometimes patients share beds”*.

Asked about patient centered care, R3 said:

“Our target was to improve the customer satisfaction level from 73 -87%. We capture customer complaints by use of complaint registers and suggestion boxes”.

Complaints and Compliments

The number of compliments rose from 25 in 2009 to 59 in 2012, an increase of 136 % (p=0.002, OR 2.36, CI 1.356-4.12). The number of complaints dropped from 40 to 32 in 2011

(7.5%, $p=0.780$) before rising sharply to 207 in 2012. This was attributed to a change in the method of collecting information.

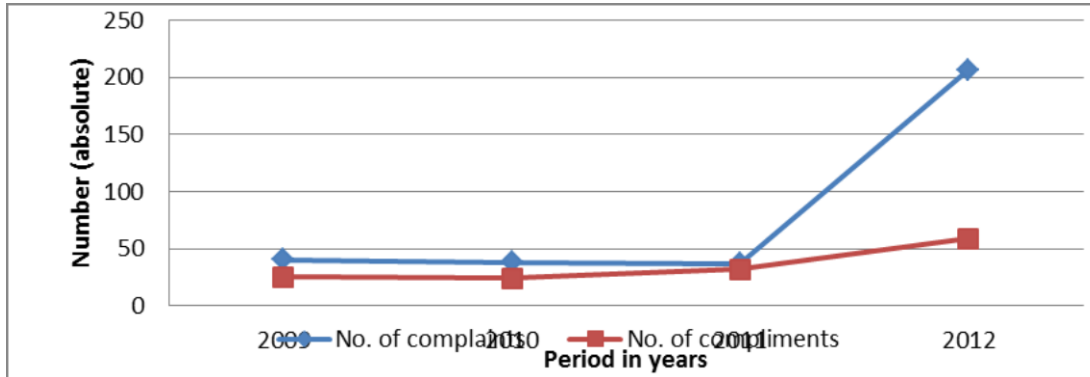


Figure 4: Compliments and Complaints

Customer satisfaction levels

There rate of customer satisfaction levels remained almost constant at 75% and then dropped to 61% in the first quarter of 2012, then rose to 69% in the third quarter of 2012. This could be due to change of management that occurred in march 2012 and industrial action that occurred in September in year 2012.

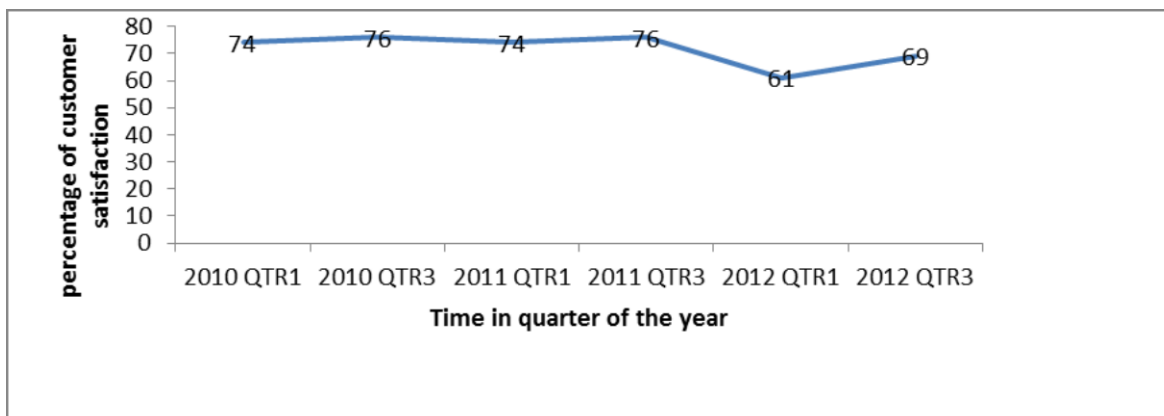


Figure 5: Customer Satisfaction Levels

4.7.3 Patient safety

Table 8 indicates that respondents disagreed with increased levels of medication errors (4.06) and increased levels of surgical sites infection (4.04). The respondents scored the legibility of treatment sheets (3.88), calibration (3.66), preventive maintenance (3.6) and a safer working environment (3.39) above three which indicate agreement. All statement were significant ($p < 0.007$). The average mean was (Mean 3.766, CI 3.10-3.43)

Table 8: Mean Scores for Patient Safety

Safety	Mean	Sd	SEM	P-value
ISO has resulted in increased level of medical errors	4.06*	1.099	.134	.000
There is an increased rate of surgical site infections	4.04*	0.787	.096	.000
Treatment sheets are legible and contains right dosage	3.88	1.108	.135	.000
Medical equipments are periodically calibrated	3.63	1.112	.136	.001
There is routine preventive maintenance of equipments	3.60	1.06	.129	.000
Working environment has become safer	3.39	1.1	.134	.007

* reversed scores

4.7.4. Accessibility

Table 9 indicates patients being seen by specialists (3.96, $p=0.000$) and resolution of interdepartmental consultation within 24 hrs (3.13 $p=0.283$) had a mean score above three, indicating agreement. However, the respondents also agreed there had been an increase in patients unable to pay the cost of services (2.54, $p=0.109$). The average mean was (Mean 3.27 CI 3.10-3.43)

Table 9: Mean scores for Accessibility of care

Accessibility	Mean	Sd	SEM	P-value
All patients are managed by the respective specialists	3.95	1.133	.142	.000
Number of patients referred to other hospitals has increased	3.39*	1.487	.186	.011
Interdepartmental consultations are completed within 24hrs	3.13	1.048	.133	.283
Number of patient unable to pay has increased	2.54*	1.058	.135	.109

Key informants views on accessibility of care.

Availability of specialists

Asked about accessibility of surgeons R1 said: *“yes they are available on phone at night and weekend we call and they come”*. R3 said: *“we have 24 hour coverage by (specialist) according to the rota. Patients are reviewed daily”*. While R2 said:

“What is happening in (ward) we have a doctor who covers from 8.00am to five and then at night ... where we have challenges is in the night shift. Sometimes the doctor is held in an operation, if an emergency arises there is a slight delay”.

4.6.5 Equity.

Respondents disagreed that patient’s are discriminated on ability to pay or according to ethnic group (mean 4.42, P=0.000). Majority agreed that work instructions ensured procedures do not vary among staff (3.62, p=0.00). There was almost an equal number of respondents who reported that performance of procedures depended on ones experience (mean 2.8, p=1.00).

Table 10: Mean scores for Equity

Equity	Mean	Sd	SEM	p-value
Patients are discriminated according to their ethnic group or ability to pay	4.42	0.94	.117	.000
Work procedure and work instructions ensure services offered do not vary among the staff	3.62	1.04	.137	.000
Performance of procedures depends on one's experience	2.80	1.249	.160	1.00

The average mean was (Mean 3.6 CI 3.47-3.75)

Key informants views on equity of care.

Asked about if there is discrimination of patients in the hospital, respondent R3 said:

“I would not say there is any. We have male and female from all regions and we extend to southern Sudan. The issue with payment like those with cover or ability to pay May distinguishes where to be care for”.

In general the respondents were clear that there was no form of discrimination in the provision of care.

CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATION.

5.1. Introduction.

In this chapter, the main findings of the study are discussed in relation to previous studies and possible implications. The chapter ends with conclusion and recommendation derived from the study.

5.2. Motives for seeking ISO certification.

There are many reasons why institutions seek to be ISO certified. Sampaio (2010) classified the motives for seeking ISO certification as internal or external. He concluded that internal motivations are related to genuine desire to improve the organization performance. Organizations that seek ISO certification due to external motives have a limited view of the QMS scope and are unlikely to achieve improvement. Organizations that seek ISO certifications as internal motives are committed to continual improvement of their internal process and thus achieve success. In this study, just like previous studies by Heuvel (2005, 2006) and Cerrillo (2012), the motives for ISO certification were internal. However, respondents who had worked for more than ten years and those with basic degree perceived the motives to be external. This was similar to previous study by Othman and Abdullah (2007) who found that those with less than ten years experience had positive perception while those with more than ten years had a negative perception

5.3. Critical factors in Implementing QMS

The main critical factors identified in this study are staff commitment, understanding of the ISO and management involvement. This is similar to previous studies that have identified

management commitment and people involvement (Wahid and corner, 2009). Others have been the size of the organization, training, physician involvement and availability of resources (Wardhani et al, 2009). The staff at MTRH did not think that recognition and reward were critical factors while Tsai et al (2012) suggested that the results of providing incentives and rewards could result in better results for the implementation of QMS.

5.4. Challenges in Implementing QMS.

This study identified increased amount of documentation lack of understanding of the standard as the main challenges. This may be related to ISO requirements on documentation. Lack of training was responsible for the lack of understanding of the standard. These findings support the work of Simedi (2010), Wahid and Corner (2009) and Francois et al, (2003) who found lack of understanding of ISO which was related to lack of training as the main challenge. Previous study (Heras et al, 2008) identified management involvement and commitment, training, staff involvement and availability of resources as the main challenges to implementing of QMS.

5.5. Effect of Implementing QMS on Patient Care.

The current study indicates improved quality of care following implementation of QMS. There was improved efficiency as a result of improved documentation and retrieval of records. Consequently there was no loss of patient's records which is a recognized cause of delays and inefficiency (Puri et al, 2012). Similar studies by Tsai et al (2012) and van den Heuvel *et al* (2005) have reported improved efficiency following implementation of QMS in hospitals. Proper documentation and record keeping is one of the requirements of ISO standard (clause 4.2 of ISO 9001:2008).

This study also shows improved effectiveness as measured by decreased number of unplanned readmissions, unplanned referrals, reoperations and surgical sites infections. Lack of proper diagnosis, poor initial treatment and misdiagnosis are major causes of readmissions, reoperations and unplanned referrals (Cerrillo, 2012). Improvement on effectiveness may be related to QMS that requires personnel to be competent on the work they do (ISO 9001; 2008 clause 6.2.1)

Patient satisfaction is important in health care. This is because it increases patient's compliance to treatment and also the likelihood of return visits. Hospitals may spend a lot of time and money addressing patients' complaints. Previous studies by van den Heuvel *et al*, (2005), Tsai *et al*, (2012) showed improved patient satisfaction following implementation of QMS. ISO requires organizations to monitor and act on customer complaints and take corrective and preventive action (ISO 9001:2008).

This study has shown increases accessibility of care following implementation of QMS. Patients are seen by respective specialist. The ISO standard requires personnel performing work to have necessary training and competence (clause 6.2.1). Interdepartmental consultations are completed within 24hrs which ensures no delays and that care is continuous. Delays in interdepartmental consultation are a cause of low patient satisfaction. (Saleh and Hatan, 2012).

This study indicated improved patient safety. Hospitals pose threat to patient safety when there are surgical sites infections and bed sores (Sandra et al, 2012). Improved patient safety in ISO certified institutions is related to documented procedure that ensures there is no variability of provision of care hence reduced risk. These procedures define and control the work to be done

and identify who and how it should be done (Cerrillo, 2012). This is also attributed to periodic maintenance and calibration of equipments which are requirements of ISO 9001:2008 (clause 7.6). Previous studies by Cerrillo et al (2012) and Buciuniene *et al* (2006) reported improved patient safety after implementation of QMS.

Mwando et al (2009) noted a greater access and utilization of health services by the wealthy more than the poor. Puri et al (2012) studied out patient satisfaction and quality of care in India. He found the poor had a longer waiting time than the rich while the educated were able to get faster consultation than the uneducated. This study showed that the very poor have their cost for services waived. While this is a government requirement, QMS requires institution to meet the statutory requirements (clause 1.1a). The use of work procedures ensured that provision of services did not vary according to ones experience. By emphasizing documented procedures, QMS eliminates the likelihood of variability in quality of care provided.

While respondents in this study rated the effects of QMS highly, the data from document reviews showed parameters such as patient satisfaction levels, complaints, compliments, admissions length of stay and the number of operations had not significantly improved. This was contrary to previous studies by van den Heuvel *et al* (2005) and Cerrillo *et al* (2012) who reported improvement in customer satisfaction and the number of admissions. However reduced admissions in surgical wards in the current study could be related to reduction in the number of unnecessary admissions and increased day care surgeries.

This study indicates that the effect of QMS was affected by change in management and industrial action. This is reflected by drop in the customer satisfaction levels, increase in complains among other indicators in 2012. None of the previous studies that were reviewed had noted external forces that may influence the implementation of QMS. However its known management commitment is critical to the implementation of QMS and lack of resources may hinder implementation of the standard.

The benefits of ISO are both tangible and intangible and may take several years to manifest (Baric *et al*, 2007). Zaramdini notes that the benefits of ISO relate to internal operations and include improvement to quality of processes and procedures.

5.6. Conclusions

The following conclusions were made from this study:

1. Quality management systems were implemented at MTRH with the aim of improving the quality of patient care.
2. The critical factors that were considered in implementing QMS were staff understanding the ISO standard.
3. The main challenge faced in implementing quality management system was increased documentation.
4. There was improved documentation, patient centered care accessibility and safety of patients. However, the number of admissions, operations and length of stay had not significantly improved.

5. Quality management system can be successfully implemented in public hospitals in Kenya.

5.7. Recommendations.

A larger study using performance indicators and involving entire hospital is needed. This would give more generalizable results than this study that has used one unit in the hospital. A detailed review of events that may have resulted in decline in unit performance is needed to evaluate and take preventive actions.

5.8. Future research.

Studies may be conducted to compare hospitals implementing QMS and those that have not. Other studies may compare hospitals that have implemented ISO and those that have implemented other standards such as the Gold Standard.

5.9. Study limitations.

The study is limited to surgical wards of a single hospital hence making it difficult to generalize the findings. Being cross-sectional, it is difficult to establish causal- effect. The study relied on self-reported findings which depended on recall. To mitigate the limitations, data was collected from different sources and means i.e. questionnaire, key informant guide and documentary review. The sample was selected by simple random to avoid bias.

References

1. Al-Najjar,S.A. And Jawad,M.K. "ISO 9001:Implementation,Barriers And Misconception; An Empirical Study." *International Journal Of Business Administration* 2, No. 3 (2011): 121-131.
2. Baric,D.,Brkic,K.,Satlic,Z. et al."Implementation and Further Development of Quality Management System According to ISO 9001:2000 Standard at the Department of Cardiac Surgery", Duprava University Hospital,*Poslovnalzvorst Zagreb God I (2007)Br 1*.
3. Bhuiyan,N. and Alam, N. "An Investigation Into Issues Related to the Latest Version of ISO 9000." *Total Quality Magazine* 16, No. 2 (2005): 199-213.
4. British Columbia Medical Association."Enhancing Surgical Care in British Columbia:Improving Perioperative Quality, Efficiency and Access." June (2011). www.Bcma.Org (Accessed December 11, 2012).
5. Buciuniene I, Malciankina S, Lydeka Z, Kazlauskaite R. "Managerial Attitude to the Implementation of Quality Management Systems in Lithuanian Support Treatment and Nursing Hospitals." *Biomedical Central* 6, No. 120 (2006).
6. Cerrillo, M.R., Diaz,E.F., Romero,A.I. and Ana-Poza,M. "Implementation Of Quality Management System According to ISO 9001 Standard in a Hospital-Changes and Achievements".*International Journal of Health Care Quality Assurance* 25, No. 6 (2012): 498-508.
7. Durai A.K. And Balashkrinan V. "A Study on ISO 9001 Quality Management System Certification-Reasons Behind Failure of ISO Certified Organizations." *Global Journal of Management And Business Research* 11, No. 9 (2011).
8. Francois,P., Peylin,J.C.,Toubal et al. "Evaluating Quality Manangement Systems In A Teaching Hospital Clinical Departments." *International Journal For Quality In Health Care* 15, No. 1 (2003): 47-55.
9. Hair,J.,Anderson,R.,Tatham,R.,et al *Multivariate Data Analysis* N.J. Pearson/Prentice Hall Inc,2006.
10. Heras,I, Cilleruelo,E. And Iradi,J. "ISO 9001 and Residential Homes for the Elderly: A Delphi Study." *Managing Service Quality* 18, No. 3 (2008): 272-283.
11. International Organization for Standardization. "ISO" (2007). www.iso.Org (Accessed July 11, 2012).

12. Kamenade, E.A., Hardjono, T.W. And De Vries, H.J. "The Willingness of Professionals to Contribute to their Organization Certification." *International Journal Of Quality And Reliability Manangement* 25, No. 1 (2011): 27-42.
13. Magd,H."Quality Management Standard Implementation in Egypt:ISO 9000 Perspectives." *Global Business and Management Research, An International Journal* 2, No. 1 (2010): 57-68.
14. Mwando, A., Rukwaro, E.,Onguti, E.et al. *Improving Access ,Quality and Efficiency of Health Care Using Capitation As The Payment Mechanism for Outpatient Services in Kenya*. Nairobi: Morans Publishers, (2009).
15. Othman, R., Abdullah, M. 2007. *ISO standard's implementation at private colleges: academics and non-academics' perspectives*. The 1st International Conference on Educational Reform,Mahasarakham University, Thailand.
16. Puri, N., Arun, A.,K. and Kaushal,V. "Outpatient Satisfaction and Quality of Health Care in a North Indian Medical Institute"." *International Journal of Haelth Care Quality Assurance* 25, No. 8 (2012): 682-297.
17. Rouzbahani, M.T.,Min, B., Soleimani,E. "Studying the Effects of Implementing QMS of ISO 9000:2000 on Improvemnet of Health Services." *Journal of Basic And Applied Scientific Research* 3, No. 3 (2013): 931-936.
18. Saleh, M. Hatam, A., Alturki, H. et al. ""Determinants of Patient Satisfaction In The Surgical Ward at a University Hospital In Saudi Arabia"." *Journal of Life Sciences* 9, No. 1 (2012): 277-280.
19. Sampaio,P.,Pedro,S.and Rodriques A.G. "ISO 9000 Certification Research:Questions, Answers And Approaches".*International Journal of Quality and Reliability Manangement* 26, No. 1 (2009): 38-58.
20. Sandra, V. Jacques,J., Koen, H. et al. "Retrospective Medical Evaluation:Reliability In Assessing Causation,Preventability and Disability of Adverse Events." *International Journal of Health Care Quality Assurance* 23, No. 8 (2012): 649-662.
21. Shirley And Norazliah,S. "Surgical Patients Satisfaction of Nursing Care at The Orthopaedic Wards in Hospital Universiti Sains,Malaysia(HUSM)." *Health and The Environmental Journal* 3, No. 1 (2012).

22. Simerdi, S. "ISO 9001 Implementation Studies on Small Medium Enterprises, Motives, Problems And Benefits." *Standardisasi* 12, No. 13 (2010): 197-201.
23. Tsai, T., P., Chen, H., C., Pai, J., Y. "The Evaluation of Implementing ISO 9000 Quality Management System in Medical Setting- A Study from Teaching Hospital. *African Journal of Business Management* Vol 6 No 6 (2012) 7779-7787.
24. Van Den Heuvel, J. Bogers, J.J.C., Does, R.J.M.N et al. "An ISO 9001 Quality Management System In A Hospital: Bureacracy or Just Benefits?" *International Journal of Healthcare Quality Assurance*, Vol. 18 No. 5, (2005): 361-369.
25. Van Den Heuvel, J., Bogers, J.J.C. And Does, R.J.M.N et al. "Quality Manangement: Does It Pay Off ?" *Quality Management In Healthcare* 15, No. 3 (2006): 137-149.
26. Wahid, R. And Corner, J. "Critical Successful Factors and Problems in ISO." *International Journal of Quality And Reliability Management* 26, No. 9 (2009): 881-893.
27. Wardhani, V., Utarini, A., Van Dijk, J.P. Et Al. "Determinants of Quality Management Systems In Hospitals." *Health Policy* 89 (2009): 239-251.
28. WHO. *Quality of Care: A Process of Making Strategic Choices In Health System*. Geneva: WHO, 2006.
29. Zaramdini, W. "An Empirical Study on the Motives and Benefits of ISO 9000 Certification: The UAE Experience." *International Journal Of Quality And Reliability Manangement*, 24, No. 5 (2007): 472-491.

APPENDICES

Appendix 1: Informed Consent.

TITLE OF STUDY: Effect of Implementing Quality Management Systems on Patient Care in Surgical Wards: Experience of Moi Teaching and Referral Hospital.

INVESTIGATOR: Michael. M. Njenga. Tel: 0721564783.

School of Nursing Sciences,

University of Nairobi

Po Box 19676, Nairobi.

Hello,

I am Michael M. Njenga, a Master of Science in nursing student at the School of Nursing Sciences, University of Nairobi. I am conducting a research study on “**Effect of Implementing Quality Management Systems on Patient Care in the Surgical Wards of Moi Teaching and Referral Hospital**”. The purpose of this study is to establish the motives, critical factors, challenges and perceived effect of implementing the ISO standard in patient care activities.

I am requesting you to participate in this study. Your part requires you to complete a questionnaire which will take you not more than thirty (30 min) minutes. I am requesting you to complete the questionnaire as honestly and openly as possible.

Confidentiality

Your name will not appear on the questionnaire .What you tell me will be treated confidentially and will only be between you and me. At no time will you be identified by name or your opinion is shared with anybody else.

Risks

There are no perceived risks for your participation in this study. However, if a question makes you uncomfortable, you may decide not to answer it.

Voluntary

Participation in this study is voluntary. You are free to decline or withdraw from the study any time. Refusal to take part will not attract any penalty. You retain the right to withdraw from the study without any consequences.

Participation or non participation does not come with any financial cost. Equally, there is no compensation for participating in the study.

Information from this study will establish a basis of enhancing the quality of patient care and the implementation of ISO standard both in this hospital and in hospitals intending or implementing the ISO 9001 standard.

The findings of this research study will be available from the author. They will be published in scientific journals. In all cases your participation will be treated with outmost confidentiality.

Should you have any concerns do not hesitate to contact me on the above contacts or the following chairpersons;

Chairperson,

KNH/UON ERC
(IREC)

TEL +254-02726300-9

P. O Box 20723 CODE 00202

Nairobi.

The chairperson,

Institutional Research and Ethics Committee

TEL +254-020-334 extension 3008

P.O Box 3.

Eldoret.

Declaration

This consent process has been explained to me by the researcher. All my queries have been addressed. I agree to participate in the study out of my own will.

.....

Informant signature

.....

Date

.....

Investigator

.....

date

Appendix 2.Questionnaire

Dear respondent,

My name is Michael Njenga, a Master of Science nursing student at the school of nursing sciences, University of Nairobi. Currently, I am conducting a study on the provider perceived effect of implementing QMS on the quality of patient care in the surgical unit of Moi teaching and referral hospital. I am requesting you to be a respondent in the study.

Your help and cooperation in answering this questionnaire is very important in order for me to be able to collect relevant data and carry out this research.

Should you require further information, please do not hesitate to email me at mbuguaanne20@yahoo.com or call me at 0721564783.

Thank you for your time and cooperation.

Respondent number

Ward

Number of beds in the ward

Number of patients in the ward today.....

Part 1: Demographic data of respondent.

1. What is your gender? Male Female
2. What is your age in years? 0-30 31-40 41-50 51-60
3. What is your current marital status? Single Married separated
Widowed Separated Divorced.
4. What is your cadre KEN KECHN KRN KRCHN? BScN OTHERS

5. What are your years of experience as a nurse?.....

6. For how many years have you worked at MTRH?

Part II. Motivation for certification

In your opinion, what led the hospital to seek ISO certification? Please tick against SA=strongly Agree, A= Agree, N=Neutral, D= Disagree or SD= strongly disagree

	Item	SA	A	N	D	SD
1	Following government directive.					
2	Our customers required our hospital to be ISO certified					
3	Our suppliers required the hospital to be ISO certified					
4	To improve the quality of services					
5	The hospital wanted to improve its image					
6	The hospital wanted to reduce medical errors					
7	The hospital wanted to standardize work procedures					
8	The hospital wanted to be recognized internationally					
9	To wade off competitors and remain in business					

Do you have other reasons why you think the hospital adopted quality management systems? YES NO

PLEASE EXPLAIN.....

PART III Critical factors in the Implementation of QMS

To what extent do you agree with the following statements? Please tick against SA=strongly Agree, A= Agree, N=Neutral, D= Disagree or SD= strongly disagree

		S A	A	N	D	S D
10	I am fully involved in all stages of ISO implementation					
11	I was trained on ISO prior to the certification of the hospital.					
12	Top management are fully involved and committed to ISO					
13	There was reward and recognition for staff who embraced ISO.					
15	Doctors actively participate in of ISO.					
16	I am fully committed to the implementation of ISO					
17	I understand the ISO standard fully.					
What other factors do you consider to be critical in implementing quality management systems?						
	Part iv. Challenges in implementing QMS	S A	A	N	D	S D
18	The hospital management are not committed					
19	Many staff do not take the implementation of ISO seriously					

20	The ISO standard is not well understood to me					
21	The ISO standard is not applicable to patient care setting.					
22	The auditing process add no value					
23	Time spent implementing QMS could best used to care for patients.					
24	ISO decreases the amount of documentation required of my work					
25	Doctors do not participate in the implementation of QMS					
26	It is difficult to develop procedures and work instructions					

What other challenges do you face in implementing quality management systems?

PART V Perceived effect of implementing quality management systems on quality of patient care Please tick against SA=strongly Agree, A= Agree, N=Neutral, D= Disagree or SD= strongly disagree against the following statements concerning the effect of implementing quality management systems on patient care.

	Efficiency and effectiveness	SA	A	N	D	SD
27	Average length of stay has declined					
28	Waiting time for different operations have increased					
29	ISO provides for clear work instruction/procedures					
30	Peri-operative mortality rate has declined					
31	The cancellation of theatre list has increased					
32	Patient records can easily be retrieved					
33	Medication errors have increased					
34	I have cared a patient with infected indwelling catheter					
35	There is increased unplanned readmission of patients					
36	The numbers of patients with bed sores have increased.					
37	ISO improves the documentation of nursing care					

	Customer focus					
38	I am satisfied with the time I interact with my patients					
39	I am respond to my patient call within reasonable time.					
40	I engage my patients in planning their care					
41	I have adequate time to health -educate my clients					
42	I am address my patients complaint within given time					
43	There has been reduction of patients complaints					
44	I analyze patients complaints to find the root causes					
45	I always provide feedback to my clients					
	SAFETY					
46	The treatment sheets are legible, contain right dosage					
47	The working environment has become safer					
48	ISO has resulted in increased level of medical errors					
49	Most medical equipments are periodically calibrated.					
50	There is a routine preventive maintenance of equipments					
52	There is increased rate of surgical site infections					
	Accessibility					
52	There is an increase in patients referred to other hospitals.					
53	All patients are managed by the respective specialists.					
54	There is increase in patient unable to pay cost of services					

55	Interdepartmental consultations completed within 24 hrs.					
	Equity					
56	Patients are discriminated according to their ethnic group or ability to pay.					
57	Work procedure /work instructions ensure services offered do not vary among staff.					
58	Our performance of procedures depends on experience.					

Appendix 3: Key Informant Guide.
Title of the Study

Effect of Implementing Quality Management Systems on surgical patient care: Experience of Moi Teaching and Referral Hospital”.

Preliminaries

Hello. My name is Michael M. Njenga, a master’s student at the University of Nairobi pursuing a master’s degree in nursing.

I am conducting a study on the effect of implementing ISO 9001:2008 on the quality of patient care in the surgical wards of MTRH.

I have invited you to this interview because of your involvement in the implementation of quality management system.

Part 1: Demographic data of respondent.

Sex -----

Date of birth-----

Marital status-----

Professional qualification-----

Years of experience as a nurse-----

Years of service at MTRH-----

Duration of service in the surgical unit-----

B. Motivation to seek certification

Why do you think the hospital sought ISO 9001:2008 certification?

Probes: internal and external motives.

C.CRITICAL FACTORS IN THE IMPLEMENTATION OF ISO

What do you consider to be the critical factors in the certification and implementation of ISO standard?

Probes mgt commitment and involvement, training, physicians involvement,

D. CHALLENGES IN IMPLEMENTING ISO

What challenges do you face in implementing quality management systems?

Probes: staff attitude, lack of mgt Commitment and support/, language of the standard, time,

E. EFFECTS OF IMPLEMENTING ISO ON QUALITY OF PATIENT CARE

How has certification and implementation of ISO standard affected the quality of patient care?

Probes

Efficiency When are admission of elective cases admitted, Time of starting first case, patient turnover in theatre, availability of lab results, investigations of elective cases before admission

Effectiveness- perioperative mortality, wound dehiscence, reoperation rates

Safety, preventive maintenance, calibration of equipments, availability of wrinkle mattresses, airings and Use of preop checklist.

Accessibility- 24hr ward coverage, referrals, frequency of equipment failures, availability of specialists, frequency of patient reviews.

Patient focus- confidentiality, privacy, patient involvement, customer surveys, individualized care plans, complaint handling

Equity- waiver policy, discrimination policy, admission procedure

Do you have any other comments on the effect of ISO?

Closing

Thank you for sharing with me on the impact of ISO certification on the patient care.

Appendix 4- Data Extraction Sheet

	2009		2010		2011		2012	
Customer satisfaction levels								
Number of patients complaints								
Number compliments								
Number of non conformities								
Number of incident reports								
Number of patients admitted								
Number of operations								
pts with pressure ulcers								
Number of adverse events								
Number of pts fall								
Number of patients abscodees								
Number of medication errors								
Number of theatre cancellations								
Number of reoperations'								
Number of peri-operative deaths								
Bed occupancy rate								
Number of re-admission								
Average length of stay								
Referrals to other hospitals(NO)								

Appendix 5: Ethical Approval from KNH/UON ERC



UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254-020) 2726300 Ext 44355

Ref: KNH-ERC/A/139

Michael M. Njenga
School of Nursing Sciences
College of Health Sciences
University of Nairobi

Dear Michael

RESEARCH PROPOSAL: EFFECT OF IMPLEMENTING QUALITY MANAGEMENT SYSTEMS ON SURGICAL PATIENT CARE: EXPERIENCE OF MOI TEACHING AND REFERRAL HOSPITAL (P95/03/2013)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above revised proposal. The approval periods are 30th May 2013 to 29th May 2014.

This approval is subject to compliance with the following requirements:

- a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
- c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
- d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
- e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
- f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
- g) Submission of an *executive summary* report within 90 days upon completion of the study
This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.



KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi


30th May 2013

Link: www.uonbi.ac.ke/activities/KNHUoN

Protect to Discover

For more details consult the KNH/UoN ERC website www.uonbi.ac.ke/activities/KNHUoN

Yours sincerely


31/5/2013
PROF. M. L. CHINDIA
SECRETARY, KNH/UON-ERC

c.c. Prof. A.N. Guantai, Chairperson, KNH/UoN-ERC
The Deputy Director CS, KNH
The Principal, College of Health Sciences, UoN
The Director, School of Nursing Sciences, UON
The HOD, Records, KNH
Supervisors: Kivuti Bitok L., Samuel Kimani

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Appendix 6 Ethical Approval from IREC



MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

Reference: IREC/2013/84
Approval Number: 000999

Michael M. Njenga,
School of Nursing Sciences,
College of Health Sciences,
UNIVERSITY OF NAIROBI.



MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET
Tel: 33471/2/3
6th June, 2013

Dear Mr. Njenga,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has received your request for approval of your study titled:

"Effect of Implementing Quality Management Systems on Surgical Patient Care: Experience of Moi Teaching and Referral Hospital".

On the basis of your study review and approval by the KNH/UoN – Ethics and Research Committee (ERC), IREC is glad to inform you that your study has been granted a Formal Approval Number: **FAN: IREC 000999** on 6th June, 2013. You are therefore permitted to continue with your study.

Note that this approval is for 1 year; it will thus expire on 5th June, 2014. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

Arusasa 06/06/2013
DR. W. ARUASA
VICE-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE



cc: Director - MTRH
Principal - CHS
Dean - SOM
Dean - SPH
Dean - SOD
Dean - SON

Appendix 7: Approval from the Director, MTRH



MOI TEACHING AND REFERRAL HOSPITAL

Telephone: 2033471/2/3/4
Fax: 61749
Email: director@mtrh.or.ke
Ref: ELD/MTRH/R.6/VOL.II/2008

P. O. Box 3
ELDOR ET

6th June, 2013

Michael M. Njenga,
School of Nursing Sciences,
College of Health Sciences,
UNIVERSITY OF NAIROBI.

RE: APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled:-

"Effect of Implementing Quality Management Systems on Surgical Patient Care: Experience of Moi Teaching and Referral Hospital."

You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.



DR. J. KIBOSIA
DIRECTOR
MOI TEACHING AND REFERRAL HOSPITAL

- CC - Deputy Director (CS)
- Chief Nurse
- HOD, HRISM