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

November 2013
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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To all my respondents and informants and the management of MTRH, I thank you sincerely for your assistance. To Nyamwata, Nancy, Sagala and Cherotich, your support was very encouraging.

God bless you all

Thank you all.
ABSTRACT

Background. There is pressure for hospitals to adopt tools 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=0.000), clear work instruction (mean 4.24 p=0.000) and improved documentation (mean 4.13, p=0.000). 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.
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<th>Meaning</th>
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<tr>
<td>BScN</td>
<td>Bachelor of Science in Nursing.</td>
</tr>
<tr>
<td>IREC</td>
<td>Institutional Research and Ethics Committee.</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
</tr>
<tr>
<td>KEBS</td>
<td>Kenya Bureau of standards</td>
</tr>
<tr>
<td>KECHN</td>
<td>Kenya Enrolled Community Health Nurse</td>
</tr>
<tr>
<td>KEN</td>
<td>Kenya Enrolled Nurse</td>
</tr>
<tr>
<td>KNH</td>
<td>Kenyatta National Hospital.</td>
</tr>
<tr>
<td>KRCHN</td>
<td>Kenya Registered Community Health Nurse</td>
</tr>
<tr>
<td>KRN</td>
<td>Kenya Registered Nurse</td>
</tr>
<tr>
<td>MTRH</td>
<td>Moi Teaching and Referral Hospital</td>
</tr>
<tr>
<td>MU</td>
<td>Moi University</td>
</tr>
<tr>
<td>NHSSP</td>
<td>National Health Sector Strategic Plan</td>
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<tr>
<td>QMS</td>
<td>Quality Management System.</td>
</tr>
<tr>
<td>SD</td>
<td>Standard Deviation</td>
</tr>
<tr>
<td>SEM</td>
<td>Standard error of the mean</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization.</td>
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</table>
# OPERATIONAL DEFINITIONS

**Accessibility:** Availability of doctors, specialists and diagnostic services on 24-hour 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.
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 influence 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 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

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Dependent Variables</th>
<th>Outcome</th>
</tr>
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<tbody>
<tr>
<td><strong>Leadership</strong></td>
<td><strong>Efficiency</strong></td>
<td>Quality patient care</td>
</tr>
<tr>
<td>Quality policy, customer surveys, quality objectives, management review meeting</td>
<td>Waiting time. Theatre list cancellation, number of pts, no of operations, availability of pt records</td>
<td></td>
</tr>
<tr>
<td><strong>Customer focus.</strong></td>
<td><strong>Patient centered care.</strong></td>
<td>Patient satisfaction</td>
</tr>
<tr>
<td>Customer surveys, quality policy</td>
<td>Time spent with pt, respect, involvement, complaints, and customer satisfaction</td>
<td></td>
</tr>
<tr>
<td><strong>Continual improvement.</strong></td>
<td><strong>Accessibility.</strong></td>
<td>Hospital sustainability</td>
</tr>
<tr>
<td>Monitoring of quality of care, corrections, preventing actions</td>
<td>24hr availability of specialists, diagnostic services, number of referrals</td>
<td></td>
</tr>
<tr>
<td><strong>Involvement of the people.</strong></td>
<td><strong>Effectiveness.</strong></td>
<td></td>
</tr>
<tr>
<td>Empowerment, recognition, team work, competence, training and awareness</td>
<td>Re-operation rates, readmission, wound dehiscence</td>
<td></td>
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<tr>
<td><strong>Factual decision making.</strong></td>
<td><strong>Patient safety</strong></td>
<td></td>
</tr>
<tr>
<td>Availability of data</td>
<td>Bedsores, medication errors, surgical site infections</td>
<td></td>
</tr>
<tr>
<td><strong>Mutually beneficial supplier relationships.</strong></td>
<td></td>
<td></td>
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<tr>
<td>Availability of supplies</td>
<td><strong>Equity.</strong></td>
<td></td>
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<tr>
<td><strong>Confounding factors</strong></td>
<td>Non discrimination</td>
<td></td>
</tr>
<tr>
<td>Staff motivation, Staff competence</td>
<td>Availability of</td>
<td></td>
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</tbody>
</table>
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 (Simedi, 2010). It has since been revised in 1994, 2000 and in 2008. The ISO standard is an international standard in which an organization need 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 (Simedi, 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 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 (Simedi, 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 roasters 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)**

<table>
<thead>
<tr>
<th>Category</th>
<th>Cronbach’s Alpha</th>
<th>Number of items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Motivation for certification</td>
<td>0.762</td>
<td>9</td>
</tr>
<tr>
<td>Critical factors</td>
<td>0.662</td>
<td>7</td>
</tr>
<tr>
<td>Challenges</td>
<td>0.855</td>
<td>9</td>
</tr>
<tr>
<td>Perceived effect on quality care</td>
<td>0.797</td>
<td>32</td>
</tr>
<tr>
<td>Overall</td>
<td>0.831</td>
<td>57</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Variables</th>
<th>Frequency</th>
<th>Percentage</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>Male</td>
<td>5</td>
<td>7.4</td>
<td>0.000</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>63</td>
<td>92.6</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>20-30</td>
<td>19</td>
<td>28.8</td>
<td>0.004</td>
</tr>
<tr>
<td></td>
<td>31-40</td>
<td>31</td>
<td>47</td>
<td></td>
</tr>
<tr>
<td></td>
<td>41-50</td>
<td>10</td>
<td>15.2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt; 50</td>
<td>6</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Marital status</td>
<td>Single</td>
<td>13</td>
<td>19.4</td>
<td>0.000</td>
</tr>
<tr>
<td></td>
<td>Married</td>
<td>50</td>
<td>74.6</td>
<td></td>
</tr>
<tr>
<td></td>
<td>widowed</td>
<td>4</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Years of experience as nurse</td>
<td>&lt;5 years</td>
<td>14</td>
<td>20.9</td>
<td>0.271</td>
</tr>
<tr>
<td></td>
<td>5-10 years</td>
<td>25</td>
<td>37.3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>11-15 years</td>
<td>11</td>
<td>16.4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>16-20 years</td>
<td>5</td>
<td>7.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>21-25 years</td>
<td>4</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td></td>
<td>26-30 years</td>
<td>8</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Years of service at MTRH</td>
<td>&lt;5 years</td>
<td>21</td>
<td>30.9</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5-10 years</td>
<td>29</td>
<td>42.6</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>11-15 years</td>
<td>14</td>
<td>20.6</td>
<td></td>
</tr>
<tr>
<td></td>
<td>16-20 years</td>
<td>1</td>
<td>1.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>21-25 years</td>
<td>3</td>
<td>4.4</td>
<td></td>
</tr>
<tr>
<td>Professional qualifications</td>
<td>KECN</td>
<td>11</td>
<td>16.5</td>
<td>0.000</td>
</tr>
<tr>
<td></td>
<td>KRN</td>
<td>3</td>
<td>4.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>KRCHN</td>
<td>44</td>
<td>65.7</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BSc.Nursing</td>
<td>9</td>
<td>13.4</td>
<td></td>
</tr>
</tbody>
</table>
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. \( r = -0.106, p = 0.427 \). There was also a negative relationship between a person’s age and motivation mean score \( r = -0.01, p = 0.945 \). 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 \( r = -0.039, p = 0.773 \). This was also the case for the person’s years of experience, and their mean score for challenges \( r = -0.147, p = 0.270 \). 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

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

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.

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

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

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

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”.

25
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

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

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”.

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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.
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.

Figure 3: Trends in Bed Occupancy
Table 7: Mean scores for Patient Centered Care

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

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

The 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

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

* 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

<table>
<thead>
<tr>
<th>Accessibility</th>
<th>Mean</th>
<th>Sd</th>
<th>SEM</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients are managed by the respective specialists</td>
<td>3.95</td>
<td>1.13</td>
<td>.142</td>
<td>.000</td>
</tr>
<tr>
<td>Number of patients referred to other hospitals has increased</td>
<td>3.39*</td>
<td>1.48</td>
<td>.186</td>
<td>.011</td>
</tr>
<tr>
<td>Interdepartmental consultations are completed within 24hrs</td>
<td>3.13</td>
<td>1.04</td>
<td>.133</td>
<td>.283</td>
</tr>
<tr>
<td>Number of patient unable to pay has increased</td>
<td>2.54*</td>
<td>1.06</td>
<td>.135</td>
<td>.109</td>
</tr>
</tbody>
</table>

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

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

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.

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 complaints 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


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.  


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 utmost confidentiality.

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

Chairperson, 
KNH/UON ERC or Institutional Research and Ethics Committee (IREC) 
TEL +254-02726300-9 TEL +254-020-334 extension 3008 
P. O Box 20723 CODE 00202 P.O Box 3. 
Nairobi. 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

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

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

<table>
<thead>
<tr>
<th>Item</th>
<th>SA</th>
<th>A</th>
<th>N</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 I am fully involved in all stages of ISO implementation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11 I was trained on ISO prior to the certification of the hospital.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 Top management are fully involved and committed to ISO</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13 There was reward and recognition for staff who embraced ISO.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15 Doctors actively participate in ISO</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16 I am fully committed to the implementation of ISO</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17 I understand the ISO standard fully</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

What other factors do you consider to be critical in implementing quality management systems?

<table>
<thead>
<tr>
<th>Part iv. Challenges in implementing QMS</th>
<th>SA</th>
<th>A</th>
<th>N</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 The hospital management are not committed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19 Many staff do not take the implementation of ISO seriously</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th></th>
<th>Efficiency and effectiveness</th>
<th>SA</th>
<th>A</th>
<th>N</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>27</td>
<td>Average length of stay has declined</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28</td>
<td>Waiting time for different operations have increased</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>29</td>
<td>ISO provides for clear work instruction/procedures</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>30</td>
<td>Peri-operative mortality rate has declined</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31</td>
<td>The cancellation of theatre list has increased</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>32</td>
<td>Patient records can easily be retrieved</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>33</td>
<td>Medication errors have increased</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>34</td>
<td>I have cared a patient with infected indwelling catheter</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35</td>
<td>There is increased unplanned readmission of patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>36</td>
<td>The numbers of patients with bed sores have increased.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>37</td>
<td>ISO improves the documentation of nursing care</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Customer focus</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>38</td>
<td>I am satisfied with the time I interact with my patients</td>
<td></td>
<td></td>
<td></td>
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<td>39</td>
<td>I am respond to my patient call within reasonable time.</td>
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<td>40</td>
<td>I engage my patients in planning their care</td>
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<tr>
<td>41</td>
<td>I have adequate time to health -educate my clients</td>
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<tr>
<td>42</td>
<td>I am address my patients complaint within given time</td>
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<tr>
<td>43</td>
<td>There has been reduction of patients complaints</td>
<td></td>
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<td>44</td>
<td>I analyze patients complaints to find the root causes</td>
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<td>45</td>
<td>I always provide feedback to my clients</td>
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<td></td>
<td><strong>SAFETY</strong></td>
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<tr>
<td>46</td>
<td>The treatment sheets are legible, contain right dosage</td>
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<tr>
<td>47</td>
<td>The working environment has become safer</td>
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<td>48</td>
<td>ISO has resulted in increased level of medical errors</td>
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<td>49</td>
<td>Most medical equipments are periodically calibrated.</td>
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<td>50</td>
<td>There is a routine preventive maintenance of equipments</td>
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<tr>
<td>52</td>
<td>There is increased rate of surgical site infections</td>
<td></td>
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<tr>
<td></td>
<td><strong>Accessibility</strong></td>
<td></td>
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<td>52</td>
<td>There is an increase in patients referred to other hospitals.</td>
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<tr>
<td>53</td>
<td>All patients are managed by the respective specialists.</td>
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<tr>
<td>54</td>
<td>There is increase in patient unable to pay cost of services</td>
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<td>55</td>
<td>Interdepartmental consultations completed within 24 hrs.</td>
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<td><strong>Equity</strong></td>
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<tr>
<td>56</td>
<td>Patients are discriminated according to their ethnic group or ability to pay.</td>
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<td>57</td>
<td>Work procedure /work instructions ensure services offered do not vary among staff.</td>
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<td>58</td>
<td>Our performance of procedures depends on experience.</td>
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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.
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<th>2009</th>
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<th>2011</th>
<th>2012</th>
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<tr>
<td>Customer satisfaction levels</td>
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<tr>
<td>Number of patients complaints</td>
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<td>Number compliments</td>
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<td>Number of non conformities</td>
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<td>Number of incident reports</td>
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<td>Number of patients admitted</td>
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<td>Number of operations</td>
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<td>pts with pressure ulcers</td>
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<tr>
<td>Number of adverse events</td>
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<td>Number of pts fall</td>
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<td>Number of patients abscodees</td>
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<td>Number of medication errors</td>
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<td>Number of theatre cancellations</td>
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<tr>
<td>Number of reoperations’</td>
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<tr>
<td>Number of peri-operative deaths</td>
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<tr>
<td>Bed occupancy rate</td>
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<tr>
<td>Number of re-admission</td>
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<td>Average length of stay</td>
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<td>Referrals to other hospitals(NO)</td>
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</table>
Appendix 5: Ethical Approval from KNH/UON ERC

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegram: MEDSUP, Nairobi

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

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.
(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.

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

Yours sincerely

[Signature]

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

C.C. Prof. A. N. Guntai, 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
Appendix 6 Ethical Approval from IREC

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI Teaching and Referral Hospital
P.O. BOX 3
Eldoret
Tel: 334712123

Reference: IREC/2013/84
Approval Number: 000999

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

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,

DR. W. ARUASA
VICE-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

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

APPROVED
06 JUN 2013
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
ELDORET
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.

12 JUN 2013

DR. J. KIBOSIA
DIRECTOR
MOI TEACHING AND REFERRAL HOSPITAL

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