

A study on Nurses Perception Towards Iso 9001:2008 quality Management System introduction in a Ward Setting at Kenyan Hospital

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Abstract: Background: ISO certification in health institutions enhances quality of care delivered to patients and efficiency. For ISO 9001:2008 quality management system (QMS) standard implementation to be successful the perception of the organization has to be taken into consideration. To identify nurses perception towards ISO 9001:2008 Quality Management System. The study adopted a descriptive cross-sectional design. The study was carried out in orthopedic wards at Kenyatta National Hospital, Kenya (KNH). To realize the goal a sample consisting of 75 nurses representing Nurse Managers and nurses was selected in orthopedic wards at KNH. Stratified sampling and purposive methods were used to sample the respondents. Data was gathered using self-administered questionnaire and Key informant guide. Measures of central tendency were used to determine the motives of seeking ISO certification. Chi-square was used to measure the significance on improvement of patient care in orthopedic wards at KNH. The main motivating factors behind the implementation of ISO 9001:2008 quality management system for KNH were to achieve quality improvement followed by improvement of the hospital image. Parameters analyzed for improvement of patient care in relation to ISO 9001 quality management systems were statistically significant. The decision to seek ISO certification at KNH had improved patient care in orthopedic wards. The study reveals that KNH as an organization did well to seek certification irrespective of being a public hospital. This research is vital for making policy decisions of the Hospital operations in the future.

Key words: ISO 9001:2008, Quality Management Systems, Motives, Nurses perception, efficiency,

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I. Background

International Organization for Standardization (ISO) is a network of national standards of bodies. ISO gives state of the art specifications for products, services and good practices, making organizations more efficient and effective. ISO started in 1946 in London and has published more than 18000 standards. ISO 9000 has been revised thrice latest being 2008. ISO also provides a framework to establish document and maintain an effective Quality Management System in order to meet client requirements [1]

ISO 9001 establishes a basic set of quality system requirements necessary to ensure that the process is capable of consistently producing products that meet the customer's expectations. Products and services are the result of activities or processes that transform inputs into outputs and the quality of products and services is directly related to the quality of the process that produces them. Most organizations seek ISO certification in the hope of improving the quality of their product or service so as to satisfy their customers.

ISO 9001 being a series of QMS standard helps an organization to understand its processes of delivering products or services to its customers [2]. The leading reasons for implementing QMS included qualifying for tenders, improving customer service, improving organizational efficiency and marketing benefits [3]. To measure the improvements quality management system provided a benchmark. ISO defined goals and objectives, stressed the process approach, provided for work performance consistency and discovered the causes of poor performance [4].

Simpao et al classified motives for seeking ISO certification as internal or external, concluding that internal reasons were related to genuine desires to improve the organization performance [5]. Organizations that seek ISO certification due to external reasons had limited view of the QMS scope. They were unlikely to achieve improvement. Institutions that seek ISO certification as internal motives were committed to continual improvement of their internal process and thus achieved success [6], [7].

ISO 9001 quality management systems deals not only with improvement in quality levels of products and services, but also provide the means and guidelines to achieve it. It's broadened to include components of QMS such as customer satisfaction, top management commitment, ISO auditing, quality assurance,

productivity, and benefits and cost. Customer satisfaction is the final intangible product that any ISO 9001 certified organizations seeks to deliver to its customers after the delivery of the product. ISO 9001:2008 standard document explains how it is important for the ISO 9001 certified firms to continually keep their customers satisfied[8]

Magd analyzed implementation of ISO: 2000 in the Egyptian manufacturing sector and indicated Egyptian manufacturing organizations were aware of ISO: 2000 and considered it relevant. The study concluded that the main motives for seeking ISO 9000 certification were the improvement of the efficiency of quality systems and the achievement of customers' satisfaction [9]

Tsai et al studied the effect of implementing QMS in medical setting and reported fewer customer complaints, increased productivity and greater degree of quality control. That study noted that standardization of procedures avoids variability in the provision of care[10] .A study on effects of ISO in health services showed increased patient satisfaction; reduction in work related mistakes and improved work process in the wards [11].

II. Methods

This was a mixed method whereby both quantitative and qualitative cross sectional descriptive study carried out within orthopedic wards at Kenyatta National Hospital, Nairobi, Kenya.

This is a National Referral Hospital with a bed capacity of 2000, located in Nairobi, the country's capital city. It offers both surgical and curative services for a variety of illnesses to patients from all over Kenya with an average of 600,000 outpatient visits and 89,000 inpatients annually. The department is composed of four inpatient wards and one outpatient orthopedic clinic. The Orthopedic wards have a capacity of 226 beds and bed occupancy of not less than 170%.Conditions admitted in orthopedic wards included acute orthopedic trauma injuries, chronic orthopedic conditions and cancers for both adults and children. This area was selected because the hospital was ISO Certified and implementing QMS. The study area provided varied view of the problem under study.

The study participants consisted of nurses giving direct care to patients. The sample size was calculated using the formula of Fishers et al. (1998):

$$n = Z^2 \cdot P \cdot (1 - P) / d^2 = (1.96)^2 (0.5)(0.5) / (0.05)^2 = 385$$

Where Z = standard normal distribution curve value for 95 % CI which is 1.96

P = proportion of nurses giving direct care to patients was taken as 50%

d = absolute precision (0.05)

However, sample size adjustment was made since the target population was <10,000 using the following formula: $nf = n / (1 + n/N) = 385 / (1 + 385/145) = 75$

Where: nf = the desired sample size for population <10,000; N = Total population (number of nurses giving direct care to patients in orthopedic wards at KNH were about 91); n= the calculated sample size (75).

Therefore, the minimum sample size of the study was 75 respondents.

Stratified Random Sampling was used to select the sample size for the nurses giving direct care to patients. Purposive sampling was used for the key informants who were the nurse managers. Stratified Random Sampling method was used to select the study sample. Nurses from each ward were selected separately. In ward 6A, the researcher wrote 75 papers yes and 16 papers written No. Those who picked "Yes" from a container were recruited. The same was repeated in every ward. A pretested semi structured questionnaire was used to collect information in the same orthopedic wards on nine (10) nurses who worked directly with the patients. The data collected was divided into three sections. Part one described demographic data of the respondents. There were eight items in the section covering age, gender, professional qualification, years of experience as a nurse and duration they had worked in orthopedic wards at KNH, whether they had been trained as ISO auditors and whether they had participated in auditing in the hospital.

Part two consisted of items focused on the motives for seeking certification of ISO (9) items,. The last part contained eight (8) items which measured the effects (efficiency and effectiveness) of the existing ISO standard on the quality of patient care. The semi- structured questionnaire was in form of a five point Likert's scale.

The study instrument was pre-tested with 10% of the study's sample size in the same orthopedic wards. Reasons for choosing the same unit was because KNH is the only ISO certified hospital with an orthopedic unit. There is no other orthopedic unit in Kenya like in Kenyatta National Hospital

One research assistant who was a registered BscN nurse was trained on data collection process. Moreover, the principal investigator was monitoring the data collection on daily basis. Data collected was entered into a Microsoft excel spread sheet and analyzed using Statistical Package for social sciences (SPSS) version 24. Descriptive statistics were analyzed using measures of central tendency such as mean and standard deviation and also frequency distribution. Correlation coefficient was used to test whether there was positive or negative relationship between factors affecting implementation of QMS. Analysis of variance (ANOVA) and log linear regressions assisted in determining if there was a change in patient outcomes before

and after implementation of QMS. A P-value less than 0.05 was considered statistically significant. Study approval was sought from the Kenyatta National Hospital/ university of Nairobi Ethics and Research committee (KNH/UON-ERC). Written informed consent was sought from all study participants after they were given participant information, before they were interviewed. Participation was purely on voluntary bases. Privacy and confidentiality were maintained while handling participants' information.

III. Results

Characteristics of respondents

The majority 48 (63.2%) of the respondents working in the orthopedic wards were female. The population of male nurses in these wards was twenty eight (36.8%). It was established that nurses who held diploma certificate made the highest proportion (76.32%) of the respondents. Big proportions (36.8%) of the nurses were aged between 31-40 years and the majority had between 11-20 years of experience at KNH. The rate of retention in the orthopedic ward was low since the majority (82.7%) had 0-10 years' experience in these wards. There was a higher representation (41.7%) of senior nursing officers than any other cadre in the study. Among the study population sixty two nurses (87%) had not trained at any Level of ISO 9001:2008 and forty eight (64%) of them said they had not participated in auditing in the wards (**Table 1**)

Table 1: Characteristics of Respondent

Serial No.	Demographic characteristics	Variables	Frequency	Percentage
1.	Gender	Male	28	36.8
		Female	48	63.2
2.	Level of qualifications	Certificate	4	5.3
		Diploma	58	76.3
		Degree	14	18.4
		Master	0	0
3.	Age in years	<30	17	22.4
		31-40	28	36.8
		41-50	23	30.3
		51-60	8	10.5
4.	Years of service at KNH	1-10	36	48
		11_20	22	29.3
		21-30	14	18.7
		31-40	3	4
5.	Years worked in orthopedic ward	0-10	62	82.7
		11_20	12	16
		21-30	0	0
		31-40	1	1.3
6.	Job group	SEN	4	5.3
		NOIII	7	9.3
		NOII	11	14.7
		NOI	20	26.7
		SNO	31	41.3
		CAN	2	2.7
7.	Level of ISO 9001:2008 Training	No Training	62	87.3
		Certified internal auditor	9	12.7
8.	Participation in auditing your ward	Yes	22	64
		No	48	29.3
		Not sure	5	6.7

The Motives for Implementing QMS at KNH

The mean score for the nine statements set to identify the motives for seeking ISO certification ranged between 2.92 and 4.32. The main motive for seeking ISO certification was to improve quality of service. This motive had a (Mean score=4.32, SD = 1.104), other motives that received high scores were to improve hospital image (Mean score=4.16, SD = 1.223) and to standardize work procedures in the hospital (Mean score=4.11, SD = 1.184). Those motives that received low scores were customers' demands (Mean score=3.20, SD = 1.336), and suppliers requirement (Mean score=2.92, SD = 1.269)(Table 2).

Table 2: Motives for seeking ISO Certification QMS

Reasons for seeking ISO Certification	Scale (%)					Item Statistics			
	Strongly Agree (5)	Agree (4)	Neutral (3)	Disagree (2)	Strongly Disagree (1)	N	Mean	Std. Error	Std. Deviation
A Directive from Government	28.9	31.6	11.8	9.2	18.4	75	3.43	0.168	1.464
Following Customers Demand Our hospital to be ISO certified	20	28	16	24	12	75	3.20	0.154	1.336
Suppliers required the hospital to be ISO certified	13.5	21.6	21.6	29.7	13.5	74	2.92	0.147	1.269
Improve Quality Services	61.6	21.9	8.2	2.7	5.5	73	4.32	0.129	1.104
Improve Hospital Image	55.3	25	7.9	3.9	7.9	75	4.16	0.140	1.223
Reduce Medical errors in the hospital	34.7	32	18.7	5.3	9.3	75	3.77	0.144	1.247
Standardize Work procedures in the hospital	51.3	25	13.2	3.9	6.6	75	4.11	0.136	1.184
The Hospital Wanted to be Recognized Internationally	40.5	31.1	12.2	5.4	10.8	74	3.85	0.152	1.310
To wade off competitors and remain in business	14.7	30.7	16	22.7	16	75	3.05	0.154	1.335

Note: The mean score was based on participants' level of agreement with each scale of 5=strong agree=to 1=strongly disagree a mean score above 4 indicated high, 3 indicated moderate and a score less than 2 indicated a low level of agreement. SD=standard deviation

The effects of the existing Quality Management System on patient care in orthopedic ward at Kenyatta National Hospital

Efficiency and effectiveness

The mean score for the eight statements set to determine the efficiency and effectiveness of existing QMS on patient care ranged between 2.39 and 3.91. The key statements that effectively and efficiently improved patient care were ISO improved the documentation of nursing care (Mean score=3.91, SD = 1.176). Others with high mean scores were ISO provided clear work instructions/ procedures (Mean score=3.77, SD = 1.130), patients records were easily retrieved (Mean score=3.73, SD = 1.138) and average length of stay had declined (Mean score=3.43, SD = 1.283). However medication errors had increased (Mean score=2.39, SD = 1.244) and bedsores had increased (Mean score=2.39, SD = 1.283) contributing the lowest mean score (Table 3).

Table 3: Effectiveness and efficiency of the improvement of ISO in nursing care

Effects	Scale (%)					Item Statistics			
	Strongly Agree (5)	Agree (4)	Neutral (3)	Disagree (2)	Strongly Disagree (1)	N	Mean	Std. Error	Std. Deviation
Average length of stay has declined	20.3	37.8	20.3	8.1	13.5	74	3.43	0.149	1.283
ISO provides clear work instructions/procedures	26.7	44	16	6.7	6.7	75	3.77	0.130	1.122

The cancellation of theatre list has decreased	15.8	14.5	23.7	27.6	18.4	76	2.82	0.153	1.334
Patients Records are easily retrieved	23	48.6	16.2	2.7	9.5	74	3.73	0.132	1.138
Medication errors have decreased	9.2	10.5	17.1	36.8	26.3	76	2.39	0.143	1.244
There is increased unplanned readmission of patients	7.9	17.1	19.7	28.9	26.3	76	2.51	0.146	1.270
Bedsore have decreased	8	16	12	34.7	29.3	75	2.39	0.148	1.283
ISO improves the documentation of nursing Care	36	40	9.3	8	6.7	75	3.91	0.136	1.176

Bed sores incidence showing patient outcome with QMS

After doing variance of analyses using chi square, it showed that there was improvement on incidence of bedsore with a P<0. 001. Incidence of bedsore reduced showing improvement was statistically significant (Table 4).

Table 4: Bed sores incidence showing patient outcome with QM

Summary of analysis					
Source	d.f.	Deviance	mean deviance	deviance ratio	approx. chi pr
Regression	1	32.99	32.9907	32.99	<.001
Residual	22	14.73	0.6694		
Total	23	47.72	2.0747		

Dispersion parameter is fixed at 1.00.

Mortality rates analysis showing patient outcome with QMS

Provided details on the mortality rates, after regression analysis was done the P =0.52 meaning Mortality rate improvement was not statistically significant. (Table 5).

Table 5: Mortality rates analysis showing patient outcome with QMS

Summary of analysis					
Source	d.f.	Deviance	mean deviance	deviance ratio	approx. chi pr
Regression	1	0.41	0.4133	0.41	0.52
Residual	22	14	0.6366		
Total	23	14.42	0.6269		

Dispersion parameter is fixed at 1.00.

Association of Patients' outcomes in relation to introduction of QMS

To test the null hypothesis, a number of performance indicators (bed sores incidence, mortality rates, theatre cancellation rate and surgical site infections) were extracted from the patients' documents and hospitals dataCentre. The difference between the rate of infections at the surgical site before and after implementation of QMS was statistically significant (F=235.48, def. = (1, 23), p<0.001). The change between the rate of theatre cancellation in the two years was statistically significant (F=92.63, def. = (1, 23), p<0.001). The change between the mortality rates before and after implementation was not statistically significant ($\chi^2=0.41$, def. = (1, 23), p<0.52). The difference between the incidence of bedsore in 2011 and 2016 was significantly different ($\chi^2=32.99$, p<0.001). Since implementation of QMS three of the four interventions mentioned above led to significant change in patient outcomes. (Table 6)

Table 6: Association of Patients' outcomes in relation to introduction of QMS

Variable	def.	Test statistic	P-Value
Surgical site infections	(1,23)	F=235.48	<0.001
Theater cancellation rate	(1,23)	F=92.63	<0.001
Mortality rates	(1,23)	$\chi^2=0.41$	0.52
Bed sores incidence	(1,23)	$\chi^2=32.99$	<0.001

IV. Discussions

Demographic results of the respondents

The majority 48 (63.2%) of the respondents working in the orthopedic wards were female. It was established that nurses who held a diploma certificate made the highest proportion (76.32%) of the respondents. This meant they had enough knowledge to embrace ISO. Large proportions (36.8%) of the nurses were aged between 31 – 40 years with between 11-20 years of experience at KNH (29. 3%).The rate of retention of nurses in orthopedic ward was low since the majority (82.7%) had 0-10 years' experience in these wards.

There was a higher representation (41.7%) of senior nursing officers than any other cadre in the study. Among the respondents 62 (87%) had not been trained on ISO 9001:2008. Majority 48 (64%) of respondents said they had not participated in auditing in the wards. This was likely to hamper or slow down the successful implementation of QMS. Once the staffs are trained they are empowered with skills and knowledge, which was in agreement with a study done in who argued thatonce the staffs are trained in ISO, they are empowered with skills and knowledge.The researchers in Indonesia concluded that training help staffs to understand ISO standard and get commitment to continuous improvement[11].

Motives for seeking ISO certification

It was found out that six out of the nine items listed as motives for seeking certification of ISO were internal reasons led by, to improve quality of service. The main motive for seeking ISO certification was a genuine desire to improve organization performance, improve service delivery of care and commitment to continual improvement of their internal process and thus achieve success. Organizations that seek ISO certifications due to internal motives are committed to continual improvement of their internal process and thus achieve success .This agrees with previous study done in Netherlands and Kenya which argued that internal motives are related to genuine desire to improve the organization performance in Netherlands, Kenya and Portugal[5],[6],[7].

External motives for seeking certification in this study were a directive from Government to implement QMS at the Hospital. This was followed by customer demand and suppliers' requirement to seek ISO certification. Organizations that seek ISO certification due to external reasons have a limited view of the QMS scope. They tend not to be committed to continual improvement of their internal process and thus not achieve success. Another study previously done in Greece stated otherwise, that most organizations seek ISO certification in the hope of improving the quality of their product or service so as to satisfy their customers [2].

Respondents in this study disagreed that KNH motives for seeking certification were due to customer demand and suppliers' requirement. This was supported by the low mean scores.It could be concluded that the two items were not key motives for seeking ISO as they scored mean score of two which is lowest mean score of disagreement.

KNH implemented ISO standard as a means of improving delivery of quality services. Quality Management System standard helps an organization to understand its processes of delivering products or services to its customers. In regard to the inferential statistics the results showed that there was a positive and significant association. This was between motives for seeking ISO certification and effects of implementing QMS in orthopedic wards at KNH. The correlation results showed that there was a correlation of 0.074.motives ($t=6.646$, $p\leq 0.014$,). These finding indicated that there was a positive and significant influence in motives for seeking ISO certification in orthopedic wards at KNH.

Effects of the existing QMS on patient care in orthopedic ward at Kenyatta National Hospital:

Effectiveness and Efficiency

This study showed improved quality of care in orthopedic wards at KNH following implementation of QMS. The eight statements set showed improved efficiency and effectiveness as result of improvement of documentation of nursing care, provision of clear work instructions/ procedures and easy retrieval of patients records .Consequently there was no loss of patient's records. The documents were readily available thus patients were not delayed.This was in agreement with a similar Kenyan study which reported improved efficiency resulting from implementation of QMS [9].Proper documentation and record keeping is one of the requirements of ISO standard [8]. The study results showed QMS implementation had reduced patient's hospital length of stay and waiting periods.In regard to the statistics on association of Patients outcomes with Quality Management System, the results showed that there was a positive and significant association between efficiency and QMS implementation.

Association of Patients' outcomes in relation to introduction of QMS

A number of performance indicators (bed sores, mortality rates, theatre cancellation rate, average length of stay, level of customer satisfaction, bed occupancy, and surgical site infections). They assisted in inferring if there was significant change in patient outcomes before and after implementation of QMS. After being analyzed independently using variance of analyses , chi square, it showed that there was reduction in

incidence of bedsores with a $P < 0.001$, reduction in theatre cancellation with a $P < 0.001$ and mortality rates with a $P = 0.52$. This meant mortality rate improvement was not statistically significant. The study results showed all performance indicators outcomes were statistically significant except in mortality rates which held constant $P = 0.52$. Implementation of QMS in Orthopedic wards at KNH did in-fact influence patient outcomes.

These findings supported another study in Kenya which found out that ISO 9001 standard improved major hospital performance indicators [10]. The study concluded that there were improved patients outcomes as a result of improved documentation and retrieval of records. A similar study done in Turkey also reported improved patients outcome following implementation of QMS in hospitals [6]. Proper documentation and record keeping was one of the requirements of ISO standard [7].

V. Conclusion

A strong interdependence between the hospitals certification motives and the results obtained exists in orthopedic wards at Kenyatta National Hospital. Effects of existing QMS was reflected through improved care as shown in most evaluation indicators analyzed in this study apart from mortality rates which had not statistically significantly improved. Thus holding mortality rates constant. The main motives for seeking ISO certification were to achieve quality improvement and improvement of the hospital image which are internal motives. Organizations that seek certification as an opportunity to improve internal processes and systems will get broader positive results from ISO

VI. Recommendations

This research is vital for making policy decisions of the Hospital operations in the future

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