

Evaluation of nurses' compliance with standards of quality management system

Elham Youssef Elhanafy

Lecturer of Nursing administration- Faculty of Nursing-Damanhour University

Abstract:

Background: Quality management system (QMS) incorporates quality planning, provide framework for managing the activities that enable the health organization to create items and services which consistently satisfy the patient and regulatory requirements. **Aim of the study:** Evaluate the nurses' compliance with standards of quality management system. **Design;** descriptive explorative design was used. **Sample & setting:** convenience sample consisted of (40) nurses working in critical care units. **Tools:** Data was collected through observational form of standards of quality management system, and divided into two parts, the first part was concerned with demographic characteristics of the health care providers (age, unit, qualification, etc.) and the second part included 184 items. **Results;** Nurses working in high risk unit reported the highest mean score in relation to the total implementation of nursing care standard while nurses working in intensive care unit (ICU) reported the lowest mean score in relation to the total implementation of nursing care standard. Statistically significant difference among nurses in all items except for items of critical care unit (CCU) and item of infection control. Also, the result revealed that there was no significant statistically difference in total and all items of nursing care standard. The 72.5% of studied nurses were moderately implemented standards of quality management system. **Conclusion;** the study findings revealed that there more than two third of studied nurses are moderately implemented standards of quality management system. **Recommendation;** planning workshops for manager and staff nurses about quality management system to be effectively communicated to them, Continuous follow up and supervision for staff nurses to firmly implementation of standards of quality management system and, In-service training and education programs about applying infection controls measures should be conducted to staff nurses.

Keywords: Evaluation – Quality- Management –System- Critical area.

Introduction:

Healthcare Institutions took up the challenge of improving the quality of care and services offered to the customers "Patients" and satisfying their requirements. Indeed, the quality of care has become a world concern and an essential criterion in the assessment of healthcare institutions performance and governments' programs of public health. Avedis DONABEDIAN has been conscious that it is important to assess the quality of care and services offered to "Patients" in order to improve the healthcare quality. In the sixties, DONABEDIAN has introduced the principles of his model: "Structure Process-Results". This model presents

a multidimensional framework for quality of care and services in health institutions and is still considered as a reference in this field. ^(1,2)

Quality management is profound change in hospital that leads to transformation of its organization; this transformation concerns every actor within the organization. It implies a change in culture, habits and behaviour ⁽³⁾ and it disrupts the sociological hierarchy and power systems, setting up quality management should take into account these obstacles which implies leading the organizations culture and management, as well as its actors, to evolve, the quality management

system is broadly defined as all the procedures explicitly designed to monitor, assess and improve the quality of care.⁽⁴⁾

Quality management system (QMS) incorporates quality planning, provide framework for managing the activities that enable the health organization to create items and services which consistently satisfy the patient and regulatory requirements.⁽⁵⁾ The QMS also provides for the continual improvement of the quality management system by monitoring processes based on their significant, measuring their effectiveness against objectives, and management selection of processes for improvement, the QMS includes monitoring, supervision and problem solving by the governorate health office and by the ministering of health quality program.^(6, 7)

Quality management process is a critical process within any health care organization, as it will help to improve the quality of team deliverables, implement a quality assurance process, to boost confidence in the quality of outputs, set quality targets to be team, define how those quality targets will be measured, take the actions needed to measure quality, identify quality issues and improvement report on the overall level of quality achieved.^(8, 9)

Mover over, an effective quality management process support for rapid adoption and consistent and repeatable application of quality improvement methodologies, as manufacture across the globe are experiencing increased competitive pressure, price erosion and shorter time-to-market requirement.⁽¹⁰⁾

Additionally, the purpose of quality management system is to ensure that the health care providers learn and follow standards which are thought to ensure quality care to patients, and that management at

different levels monitor supervise and support these actions, hospital management was supportive and encouraging, promising action to help meet standards which were not being met, and carrying out these action where it was within their powers to do, so the quality management system is not just the standards and supervision at the hospital, but includes respected credible external expert support, supervision and follow up.⁽⁶⁾

Angus and Black⁽¹¹⁾ state that institutional and healthcare system approach complement bedside strategies to improve care of the critically ill'. Various clinical practice guidelines have been developed internationally to facilitate the implementation of both medical and nursing practice that is evidence-based. Ultimately, the aim of these measures is to ensure that quality patient care is provided to critically ill patient, which each of these tools having a place in the care provision tool.⁽¹²⁾

Measuring the quality of nursing care by systematic process in a particular unit or institution is called quality assurance. It involves setting standards. Determining criteria to meet those standards, evaluating how well the criteria have been met, making for change based on the evaluation. Monitoring nursing care is component of quality assurance. Several methods are used to monitor nursing care including nursing audit, peer review, utilization review and patient satisfaction.⁽¹³⁾

A regional or national hospital quality strategy is a long-term (2-5 year) programmer to increase patient and personnel safety and improve hospital quality services. This synthesis searched for evidence about the nature, implementation and results of both specific strategies in one hospital and strategies to improve

quality in many hospitals. ⁽¹⁴⁾ A quality strategy differs from a quality tool in being an overall approach an organization takes over a period of time, rather than a specific method for a particular purpose. Thus, a programme for external inspection of hospital of hospitals is strategy. A particular method for carrying out inspection is referred to by quality specialists as a tool. It is possible to pilot- test a tool, but not a strategy. Benchmarking is a tool and strategy. ⁽¹⁵⁾

In evaluating strategies, it is necessary to identify alternatives and judge their effects, using evidence and clear criteria. Evidence in relation to the following criteria were sought to assess quality strategies ease and cost of implementation, impact on health personnel, patient outcomes and cost saving. ⁽¹⁶⁾ Finally, quality management system is composed of basic elements which affect a system that promotes the best clinical standards and ensures the highest quality of patient care. ⁽¹⁷⁾

Significant of the study:

Implementing a Quality Management System helps an organization and nurses' to become more efficient and productive, which not only improves an organization's standards internally, it also benefits customer relations. Existing customers gain confidence and will soon realize that orders are met consistently on time and to the correct specifications. New customers will place initial orders with confidence and this can help open up the marketplace and increase opportunities and company growth. ^(1,8)

Aim of the study:

The aim of current study was to evaluate the nurses' compliance with standards of quality management system.

Research question:

Is the quality management system applied at critical care units at Damanhur National Medical Institute?

Subjects and methods:

Design:

A descriptive Explorative design was used to carry out the study.

Setting:

The study was conducted at Damanhur National Medical Institute in three critical care units, intensive care unit (ICU), coronary care unit (CCU) and high risk unit. This institute is the largest governmental medical institute that provides health care services for the population of El Beheira Governorate (n= 564 beds). Damanhur National Medical Institute establishes internal quality system and applying it since 2006.

Subjects:

A convenience sample of the study included all nurses who working in the critical care units in Damanhur National Medical Institute and all data collected by the researcher (40 nurses) divided to 3 groups. Group (1)14 nurses from ICU- Group (2) 17 nurses from CCU and group (3) 9 nurses from high risk unit.

Tool of the study:

One tool was used to collect data, evaluation observational form of standards of quality management system. It was checklist developed by Ministry Of Health ⁽¹⁸⁾ to assess level of quality management system. It consisted two parts.

- **Part (A):** Include data about socio demographic characteristics of nurses such as, age, department, qualifications and years of experience.
- **Part (B):** Standards of quality management system: to assess health team performance according to standards of quality management system, it included

(176 items) subdivided into seven main subscales

- ✓ (36 items) for nursing intervention standard
- ✓ (18 items) for infection control standard
- ✓ (12 items) for sterilization standard
- ✓ (13 items) for hygiene standard.
- ✓ (22 items) for kitchen standard
- ✓ (35 items) for waste disposal standard
- ✓ (40 items) for standards that necessary for nursing care.

Scoring:

Three points Likert scale was used. Response for this scale was implemented (3 score) Partial implemented (2 score) and not implemented (1 score). Range of score toward quality standards: low = 184:305, moderate = 306:427 and high = 428: 552

Content Validity and reliability:

Content validity was used for the modified tools and to determine whether the tools cover the aim of the study. The stage developed by a Jury of seven experts (professors, assistant professors of medical-Surgical nursing and nursing administration) from the Faculty of Alexandria, Damanhur, Mansoura, and Ain Shams University. Test reliability of the proposed tools was done by cronbach's alpha test, showed a strong significant positive correlation between test (A) and retest (B).

Pilot study:

A pilot study was carried out on 4 nurses (10%) of the total sample in order to test the clarity of the checklist. Nurses who were included in the pilot study were excluded from the main study sample. The pilot study was conducted to test applicability, clarity of the checklist, identify obstacles and problems that may be encountered during data collection and estimate the time needed to fill the questionnaire.

Field work:

Data were collected after a meeting with the nurses in each unit, by the researcher on individual basis to inform them about the aim of the study and to gain their cooperation. Nurses and head nurses were approached while they were in their work area. The researcher remained with the nurse or the head nurse until the checklist was completed. Time needed to fill the questionnaire was 20-30 minutes. Data was collected in the period from March 2013 to August 2013.

Administrative and ethical considerations:

An official letter was issued from Faculty of Nursing, Damanhour University to get permission from the administrators of the previously mentioned units; for gathering research's data. Oral consent was insured from each study's participant, after explaining the study, its purpose, confidentiality of information, anonymity and some instructions.

Statistical design:

After data were collected it was revised, coded and fed to statistical software SPSS version 11.0. Data were presented using descriptive statistics as mean, standard deviation test of significant (ANOVA test), number, percentage, chi- square test and t test, and Pearson correlation coefficients implementation standards of quality management system. Statistical significant was considered at $p = \leq 0.05$ was used for analyzing data and obtaining results.

Results:

According to the distribution of studied nurses according to their demographic characteristics, **table (1)** shows that, the total study sample was 40 nurses, 42.5% of them working in intensive care unit, 70.0% of studied nurses aged between 20 to less than 30 years with mean age (27.98 ± 7.65) as

regarding to their education, and 75.0% of studied nurses have bachelor degree in nursing degree and 10.0% had a diploma degree in nursing while 52.5% of studied nurses have experience from 3 to 6 years.

The mean scores of nurse's implementation standard of nursing care at **table (2)**, it clearly show the result revealed that there was no significant statistically difference in total and all items of nursing care standard. Nurses working in high risk unit reported the highest mean score in relation to the total implementation of nursing care standard while nurses working in intensive care unit (ICU) reported the lowest mean score in relation to the total implementation of nursing care standard.

Table (3): Clarifies that there was no statistically significant difference among nurses in all items except for items of critical care unit (CCU) and item of infection control. Nurses working in high risk unit reported the highest mean score of total infection control and sterilization standard while nurses working in intensive care unit (ICU) have the lowest mean score and respectively of total infection control sterilization standard.

Table (4): Illustrates mean score of nurse's implementation of waste disposal Standards. The result revealed that there is no statistically significant difference among studied nurses in total and all items of nurse's implementation of waste disposal standards. Nurses working in high risk care unit reported the highest mean score while, nurse's working in intensive care unit (ICU) reported the lowest mean score in implementation of waste disposal standards.

The result of **table (5)** clearly shows that there was statistically significant difference in total and all items, except the item of (preparation

of burns). But nurses working in intensive care unit reported the lowest mean score in implementation of standards that necessary for nursing care.

Mean scores of nurses' implementation standards of quality management system at **table (6)** revealed that there was no statically significant difference between studies units in total and all items except for item of "Standard that necessary for nursing care". Nurses working in high risk unit reported the highest mean score, while nurses working in intensive care unit reported the lowest mean score in implementation of total standards of quality management system.

Figure (1): Illustrates the level of implementation of standard of quality management system. The result revealed that 72.5% of studied nurses moderately implemented standard of quality management system.

Table (7): Shows that, there is no statistically significant correlation between nurses' implementation of standard of quality management system, age and years of experience.

Discussion:

Today quality is emerging as a dominant and complex theme in today's competitive health care environment; it plays an important role in patient's choice of hospital. Quality orientation is an integral part of patient care. Total quality management therefore, is essential to judge the appropriateness and effectiveness of medical care. Quality of service offered, result of intervention and treatment, undesirable outcomes, and other managerial and treatment related processes can be analyzed to define the scope of improvement. Quality indicators help in achieving these objectives, quality of care is partly a function of the need for care and includes patient's satisfaction which is

a function consistent with scientific knowledge and generally accepted professional standards. ⁽¹⁸⁾ This study aims to evaluate the nurses' compliance with standards of quality management system.

The result of the present study revealed that the more than third of studied sample nurses were moderately implemented standards of quality management system. This result might be due to majority of studies nurses were not follow completely standards of quality management system, and standards of quality management system not effectively communicated to nurses and not continuous follow up by quality assurance team in the hospital. This result supported by Vergil ⁽¹⁹⁾ who revealed that, each organization should develop a policy and procedures manual that outlines its specific standards. These standards allow the organization to measure unit and individual more objectively. However these results disagree with, Abd El-fatah ⁽²⁰⁾ who found at his study at Tanta University hospital that the most of the nurses were aware regarding developing the quality assurance standards for the nursing performance at each unit . This support research question "Is the quality management system followed at Critical care units department at Damanhur National Medical Institute?"

The finding of the present study revealed that: nurses' implementation of standards of quality management system arranged according to scoring system as follow: firstly sterilization standard, followed by nursing intervention standard, hygiene standard, infection control standard, resources that necessary for nursing care, food standard, waste disposal standard and lastly Landry standard.

Regarding to sterilization standard the result of the present study indicated that it was the first standard. This might be due to the nurses depending on themselves on sterilization and following prevention measures and aseptic techniques especially in the high risk unit to ensuring providing safe from acquiring infection. This result supported by Tafreshi ⁽¹⁶⁾ who stated that the application of aseptic techniques is related to knowledge and this lead to high quality of performance of skills and prevent transmission of microorganisms and this reduce risk of infection. While this result disagree with Mohamed ⁽²¹⁾ who stated that most of nurses did not flow prevention measures and aseptic technique and nursing performance is inadequate at Ain Shams University hospitals.

Regarding to nursing intervention standards were the second level of nurses' implementation of standards of quality management system. This result might be due to nursing care is the most important role of nurses in critical care units and it is daily routine work. This result supported by Ahmed ⁽²²⁾ who said that continuity of care is one dimension of quality of care according to his study at Benha University hospitals. .

The result of the present study revealed that hygiene standard were the third level of nurses' implementation of standards of quality management nursing care this result might be due to critical care nurses aware to keep good hygiene level in intensive care unit to maintain clean and safe environment for them and to their patients. This result supported by Mitchel ⁽²³⁾ which stated that there were good hygiene level should be available in each unit at any health care organization and considered it important item from the patient right.

The result of the present study relieved that infection control standard was the fourth level of nurses' implementation of standards of quality management system. This result might be due to lack of supervision from infection control unit no established infection control principles. This result supported by Ebrahim and Abd El Galil^(24, 25) who stated that the highest percentage of nurses had poor performance, that explained by lack of in-service education courses and lack of supervision from infection control committee rendered in Sues Canal and Mansura Universities hospitals.

Regarding to resources that necessary for nursing care the present study relieved that it was the fifty level of nurses; implementation of standards of quality management system. The lowest related to inadequate equipment of each department that used in providing nursing care, this resources and supplies are important indicators of quality care and this care cannot be delivered without adequate resources. This result agreed with Tabolli et.al.,⁽²⁶⁾ who mentioned that, the structure standards regulate the environment to ensure quality and the good structure that is a sufficiency of resources and proper system design is probably the most important means of protecting and promoting the quality of care. This finding was parallel with finding of Evans⁽²⁷⁾ who found that poor structure contributes to poor quality of care.

On the other hand, the food standard, finding of the present study indicated that; a highly level of nurses' implementation of standards of quality management system. The lowest related to lack of supervision, neither shortage of good kitchen 'supplies and essential equipments as (safe food containers, type of food and methods to storage the food), nor invalidity of standards from the hospital polices to

guide and evaluate worker performance. This result supported by Diab⁽²⁸⁾ who has stated that in order to provide quality patient services, nurses require a support system that includes appropriate equipment, also, Kenny and Christeney⁽²⁹⁾ who mentions that the physical resources and supplies important indicators of quality care and this care cannot be delivered without adequate staff and resources were ranked as the first, and second influential factors affecting quality of care.

Regarding to waste disposal standard, finding of the present study indicated it was the seventy level of nurses; implementation of standards of quality management system. The lowest neither related to lack of nurses' knowledge and practices about waste disposal standard this due to the majority of them nor receive any training courses related to infection control and waste disposal measures. This result supported by Abd El Galil⁽²⁵⁾ who found at his study at Mansura University hospitals, the majority of nurses not attends training in this respect.

As regarding to Landry standards which have the last level of nurses' implementation of standards of quality management system, the lowest related to defect in hospital managers to established system to organized work with the Landry, as well as lack and shortage of supplies and equipment which create a barrier hindering the application of nursing care standard. This finding supported by Ahmed⁽³⁰⁾ study at Alexandria University hospital who mentioned that, physical, financial resources and supportive services were consider to be most important factors affecting on quality care, and this was supported by Chitty⁽³¹⁾ who stated that there were standardized equipment specification should be available in each unit at any

health care organization.

The result of the present study relieved that nurses working in high risk unit were reported the highest mean score, in relation to nurses' implementation of standards of quality management system. This finding supported by Nour ⁽³²⁾ who reported that, medical surgical nurses at Malysian Public Hospital, care for adult patients; understand the importance of measuring and improving the quality of care delivered which provide comfort and individual attention to patient at the moment.

Conclusion:

The current study findings revealed that there more than two third of studied nurses are moderately implemented standards of quality management system.

Recommendations:

1. Planning workshops for nursing management and staff nurses about quality management system to be effectively communicated to them.
2. Continuous follow up and supervision for staff nurses to firmly implementation of standards of quality management system.
3. In-service training and education programs about applying infection controls measures should be conducted to staff nurses.
4. Replication of the study on a large probability sample is recommended to achieve more generalization.
5. Assess barriers that hinder effective application of quality management system.

Table (1): Demographic characteristics of the study sample (N=40)

Items	N=40	
	No	%
Age:		
▪ 20<30	28	70.0
▪ 30<40	8	20.0
▪ >40	4	0.0
Mean ± SD	27.98±7.65	
Units		
▪ Intensive care unit	17	42.5
▪ Coronary care unit	14	35.0
▪ High risk unit	9	22.5
Educational qualifications		
▪ Bachelor	30	75.0
▪ Diploma	10	25.0
Years of experience		
▪ 1<3	15	37.5
▪ 3<6	21	52.5
▪ >6	4	10.0

Table (2): Mean score of nurses implementation of standards of nursing care in the studied units (n=40)

Items	Maximum score	ICU	CCU	high risk unit	F	P-value
		n=14	n=17	n=9		
		Mean ±SD	Mean ±SD	Mean ±SD		
Nursing station	15	8.71 ± 1.38	9.17±1.07	9.11±2.62	0.336	>0.05
Nursing staff	18	12.93±3.09	14.18±2.98	15.0±2.12	1.547	>0.05
Policies & procedures	12	6.86±1.79	6.18± 1.59	6.44 ±2.60	0.484	>0.05
Distribution of the work	21	13.79 ± 3.19	15.47 ± 2.94	15.22 ± 5.31	0.881	>0.05
Continuing education & Training program	30	14.36±4.55	6.94±3.42	17.56±4.72	2.140	>0.05
Nursing uniform	12	7.00 ±1.88	7.76 ±3.39	7.89± 1.69	1.116	>0.05
Total	108	63.64±10.99	69.71± 8.99	71.22 ± 14.77	1.639	>0.05

Table (3): Mean score of nurse's implementation of infection control sterilization standards in the studied units (n=40)

Items	Maximum score	ICU	CCU	High risk unit	F	P-value
		n=14	n=17	n=9		
		Mean ±SD	Mean ±SD	Mean ±SD		
Infection control committee	12	8.36 ± 4.03	8.71±2.23	9.11±1.54	0.188	>0.05
Policies & procedure	33	16.57± 4.07	16.82 ± 3.91	17.89 ± 4.78	0.293	>0.05
Critical care measures	9	5.14±1.51	5.29± 2.20	7.44± 1.33	5.256	>0.05*
Infection control measures	6	3.86 ± 1.09	4.29 ± 1.53	5.33 ± 0.71	3.921	>0.05*
Policies & procedure	30	0.00 ± 5.99	22.59 ±7.34	23.22 ± 3.46	0.963	>0.05
Total infection	54	30.07 ±7.76	30.82 ±6.45	34.44 ± 5.53	1.243	>0.05
Total sterilization	36	23.86±6.81	26.88 ± 8.43	28.56 ± 4.03	1.331	>0.05

* Statistically significant difference $P \leq 0.05$

Table (4): Mean score of nurse's implementation of waste disposal standards in the studied units (n=40)

Items	Maximum score	ICU	CCU	high risk	F	P- value
		n=14	n=17	unit n=9		
		Mean \pm SD	Mean \pm SD	Mean \pm SD		
Infectious wastes	21	14.36 \pm 5.09	15.59 \pm 5.57	17.33 \pm 2.29	1.026	>0.05
Sharp waste	18	10.86 \pm 3.76	11.47 \pm 4.58	14.44 \pm 2.61	2.460	>0.05
Pharmaceutical Wastes	9	5.64 \pm 2.31	5.82 \pm 2.65	6.11 \pm 2.32	0.099	>0.05
Radioactive wastes	12	7.07 \pm 3.12	8.24 \pm 3.17	7.44 \pm 2.51	0.596	>0.05
Separation & circulation	12	7.00 \pm 2.39	8.12 \pm 2.64	8.11 \pm 2.03	0.958	>0.05
Storage of waste	12	6.21 \pm 2.19	6.82 \pm 2.24	7.44 \pm 2.29	0.845	>0.05
Safe disposal	21	10.71 \pm 3.60	11.35 \pm 4.65	13.11 \pm 1.83	1.105	>0.05
Total	105	61.86 \pm 18.86	67.41 \pm 20.91	74.00 \pm 12.61	1.169	>0.05

Table (5): Mean score of Nurse's Implementation of Structure that Necessary for Nursing Care in the Studied Units (n=40)

Items	Maximum score	ICU	CCU	high risk	F	P- value
		n=14	n=17	unit n=9		
		Mean \pm SD	Mean \pm SD	Mean \pm SD		
Preparation of nursing station	69	47.29 \pm 6.83	50.12 \pm 6.79	55.56 \pm 3.71	4.785	>0.05*
Preparation of intensive care	33	23.14 \pm 3.78	25.24 \pm 2.84	28.22 \pm 3.15	6.636	>0.001**
Preparation of burns;						
▪ Infection control.	18	10.43 \pm 2.24	9.24 \pm 1.71	10.67 \pm 2.50	1.877	>0.05
▪ Sterilization standard						
▪ Standards that necessary for nursing care						
Total	120	80.85 \pm 10.96	84.59 \pm 9.33	94.44 \pm 7.42	5.643	>0.001

* Statistically significant difference $P \leq 0.05$ ** statistically significant differences $P \leq 0.01$ **Table (6): Mean scores of Nurses' Implementation Standards of Quality Management System in the study units (n=40)**

Items	Maximum score	ICU	CCU	High risk	F	P value
		n=14	n=17	unit n=9		
		Mean \pm SD	Mean \pm SD	Mean \pm SD		
Nursing intervention standard	108	63.64 \pm 10.99	69.71 \pm 8.99	71.22 \pm 14.77	1.639	>0.05
Infection control standard	54	30.07 \pm 7.76	30.82 \pm 6.45	34.44 \pm 5.53	1.243	>0.05
Sterilization standard	36	23.86 \pm 6.81	26.88 \pm 8.43	28.56 \pm 4.03	1.331	>0.05*
Waste disposable standard	105	61.86 \pm 18.86	67.41 \pm 20.90	74.00 \pm 12.61	1.169	>0.05*
Landry standard	24	11.79 \pm 3.47	14.12 \pm 3.79	15.00 \pm 2.32	3.060	>0.05
Hygiene standard	39	21.64 \pm 5.15	20.94 \pm 3.94	22.22 \pm 4.02	0.262	>0.05
Kitchen standard	66	37.07 \pm 7.97	34.35 \pm 9.33	38.44 \pm 11.50	0.644	>0.05
Standard that necessary for nursing care	120	80.86 \pm 10.96	84.59 \pm 9.33	94.44 \pm 7.42	5.643	<0.001**
Total	552	330.79 \pm 53.89	348.82 \pm 55.45	378.44 \pm 50.26	2.149	>0.05

* Statistically significant difference $P \leq 0.05$ ** statistically significant differences $P \leq 0.01$

Table (7): Correlation Coefficient between Nurses' Implementation Standards of Quality Management System, Their age and Years of Experience (n=40)

Variables	Nurses Implementation Standards of Quality Management System Standards	
	r	P
▪ Age	0.108	>0.05
▪ Years of experience	0.308	>0.05

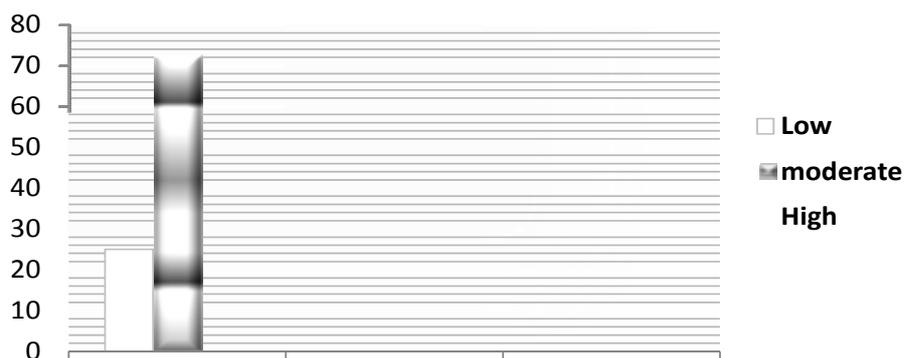


Figure (1): level of nurses' implementation of standard of quality management system

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