

Benefits of ISO 9001-2008 Quality Management System on the Change of Quality Indexes Effectiveness in the Case of Three Iranian Regional Hospitals

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ABSTRACT

At present time, the competition in the health care market intensifies, and health care institutions have tried to improve the efficiency and competitive advantages of their institutions by improving the cost-effectiveness and quality of care. Here, we aimed to determine the relationship between the levels of ISO 2008 - 9001 quality management system with change of indicators of quality effectiveness from the provision of staff in hospitals of Rasht. This cross-sectional study was performed in three ISO-certified hospitals of Rasht, 352 people were considered in current study, during 2014. The data of this research was collected through self-regulation questionnaire, by measuring its criterion related validity and content validity. In addition, Cronbach coefficient alpha was applied to confirm the reliability of the given data. Data of quality effectiveness indicators were compared by using T-test before and after the implementations. Furthermore, analysis was followed by Pearson correlation coefficient. There was a significant relationship between the implementations and some indicators of quality effectiveness ($r = 0.58, p < 0.05$). No significant differences were observed between the length of stay of patients in hospitals before and after the deployment ($p > 0.05, t = 0.08$). We found that 72.4% of the staff disagrees with the impact of implementations on bed occupancy, while 83.8% of the staff disagrees with average length of patients stay. Using an integrated quality management model which can offer a program for the continuous improvement of quality in addition to being able to identify the exact quality needs in medical and healthcare fields would impact on medical indicators of the quality effectiveness in hospitals.

Key words: ISO 9001-2008, effectiveness, quality.

INTRODUCTION

As competition in the health care market intensifies, health care institutions have tried to improve the efficiency and competitive advantages of their institutions by improving the cost-effectiveness and quality of care¹. So, many efforts have been employed for concentration on multiple performance measures to assess the quality level reached^{2, 3}. It is noteworthy to mention that not only

patient outcome measures, but also workers satisfaction and organizational and financial performance have to be managed and improved³. The purpose of quality management in hospital is to establish a system that measure and manage patient care in a way that provide the optimal medical service for patient. These programs include developing a competent staff, investing in advanced technology, promoting information analysis, and improving interdepartmental communications. Up

to date, a number of empirical studies have reported the positive effects of applying the QM paradigm in the service and manufacturing settings⁴. To facilitate the improvement of health care quality and performance, a large range of quality management and organizational models have been yet developed³. The Institute of Medicine (IOM), however, states that health care harms too frequently and routinely fails to deliver its potential benefits. The IOM also emphasized the necessity to redesign the health care delivery system to improve the quality of care, because it is highly fragmented and care processes are poorly designed⁵. The ISO 9000, which describes a set of standards that a quality system should match, is now widely spread throughout industries and has entrenched itself in services⁶. ISO takes a systems and process approach to improve organizational and financial performance with a specific focus on quality management. By using process control and quality assurance techniques, it enables us to achieve planned outcomes and prevent unsatisfactory performance or non-conformance⁵. As previously mentioned, more than 982,832 conformities to ISO 9000 standards have been issued in 176 countries at the end of December 2008 which showed an increase of more than 3 percent compared to previous year, 2007⁷. In order to keep pace with the rapid changes of today's world, leaders must equip themselves with new management theories⁸. Among the sectors that have recently begun to implement quality systems, we can name department of Health⁹. In the health sector in terms of the types of services and dealing with the health status and lives of people, improving quality and ensuring that for public health system is increasingly considered as a continuous matter of fact¹⁰. There are several studies reporting positive effects of applying ISO 9000 series to health care services^{6, 11, 12}. Many authorities previously stated a higher patient satisfaction level in ISO 9000 certified hospitals, by a 60.32 to 47.32 ratio, than in hospitals without certification¹³. The current study aimed to determine the relationship between the levels of ISO 2008 - 9001 quality management system with the indicators of quality effectiveness from the staff perspectives in hospitals of Rasht, Guilan province of Iran.

MATERIALS AND METHODS

This study is analytical and descriptive on which the selection of effectiveness index is based on relevant literature and determination of the relations to the standard requirement of ISO quality management system according to objectives the directors of implementation ISO quality management system in their hospitals¹⁴. Using *t*-test technique, mean effectiveness index data of pre- and post-confirmation has obtained and then coefficient of variation of these indexes were also analyzed. To confirm the hypothesis of the current study, two questionnaires followed as; a questionnaire contained 13 items, considered as researcher's self-regulation questionnaire responded by researcher itself, and another questionnaires with 24 items were designated, including 12 questions related to investigation of the situation of quality management system of the hospital and rest related to indexes in hospitals which answered by staffs of three different hospitals with total the sample size of 352 individual and calculated by the use of Kookran formula. Contents of this questionnaire have been validated by the experts and in accordance to ISO 9001 requirement, Reliability were calculated alpha cronbakh test. To test the hypotheses, SPSS software ver. 21 has been used. After analysis of discretional statistics of the gathered information, hypotheses were tested by Pierson correlation coefficient test.

RESULTS

Results of demographic analysis showed that 38.6% of the respondents were nurses in the range of 36 years old and more. Most of them had bachelor degree with 11-15 years of working experience as formal employment. The average pair *t* test, showed a meaningful difference between most of the effective indexes, with exception of mean index of length of stay before and after of the system implementation. According to the research's data analysis, there is a meaningful correlation between ISO quality management system confirmation and effectiveness of quality indexes ($p < 0.05$, $r = 58\%$). It was demonstrated that the most satisfying indexes were related on the field of work style documentation, codification and prophecy of job

description. The highest level of dissatisfaction with the ISO quality management system effect on hospital bed occupancy (72.4 %) and the reduction of mean length of stay rate with 83.8%, respectively.

DISCUSSION

At present study we securitized the mean effective variation of indexes pre and post the ISO quality management system confirmation in three hospitals located in Rasht, Gilan province, north of Iran. The survey on the workers viewpoints about some kinds of variations and their relationship with quality management system confirmation revealed positive effects. In order to verify the survey hypothesizes; items were adapted from the previous work by Staines in a Swiss regional hospital⁶. In addition to investigation of the confirmation steps, he also has delivered a report about the positive results of using ISO 9002 in the hospital⁶. Beholz and colleagues declared that certification of separate departments could contribute to a consciousness of quality on the way to total quality management¹⁵. Moreover, in a study by Gaillard-France and Bouliethe application of a methodology for implementation of a quality system in a therapeutic drug monitoring laboratory accepted to improve the laboratory organization and management¹⁶. Similar to current study findings, by investigating of viewpoints of executors showed profound positive effects the confirmation of ISO in Europe radiotherapy division⁸.

Heuvelet *et al.* also observed a vast number of advantages such as continuous improvement of quality of care and system performance during implementation of ISO quality system management programs which targeted and reviewed all of the processes of the hospital with identification and documentations capability⁵. In support of Heuvel and colleague's work, we also founded the levels of satisfaction staff in field of documentation process and communication of work duties in hospitals which was recorded 77.6 % and 75.6%, respectively. In accordance to high satisfaction levels from the speed of handling the complaints (89%) and an increase in handling variations coefficient (36.8%) of current study, it is deducible that our design is suitable for the recognition and confirmation of a beneficial documentary system to responsibility.

Unfortunately, manager's opinion about the impossibility of taking advantage of ISO quality management systems in the current condition are the reasons of disagreement with ISO system quality management impact on hospital bed occupancy rate and the mean length of stay of the survey in Esfahan¹⁷. As it previously mentioned in a survey on a cement company in Shahrood city, located in center of Iran, the application of improvements methods like ISO quality management system, with implementing these techniques, has a few impact on job satisfaction and manager's viewpoints pre- and post-implementation. Interviewing with this group

Table 1: Significant level of quality effectiveness of indexes before and after ISO confirmation

	Significant level	T statistics	Mean differences
Bed occupancy	0	-6.8	6.1
Mean hospitalization	0.42	0.8	1.2
Resolved non-compliance	0	-8	10.8
Release with personal desire	0.02	2.3	6.2
Bed operation	0.03	-2.2	4.2
The percentage of handled compliance	0	-12	10.3
Staffs satisfaction	0	-8	9.9
Patience satisfaction	0	-8	8.9
The percentage of identified processes	0	-12	7.8
The percentage of resolutions achieved	0.05	-2	14.3
The ratio of calibration	0	-8	38.8
The percentage of trained programs	0.02	-3	5.6
Evaluation purchase decision	0	-16	17.4

Table 2: The scores of each item of the questionnaire

Scores	Under investigation indexes	Scores	Under investigation items
1211	Improvement of quality	799	ISO effect on increase of bed occupancy confident
1452	Documentation of how to do works	697	Effect on reduction of mean hospitalization
1461	Job description of staffs	1232	ISO effect on report and handling of the problems
1163	Determination of getable goals and act to them	1301	ISO effect on patience satisfaction and his attendant
1122	Optimum usage of hospital sources	1068	ISO effect on staffs satisfaction
1367	Providing maintenance program for equipment	1215	ISO effect on saving drug costs and medical equipment
1102	Providing suitable working area	1288	ISO effect on report andpursuitof training classes
1389	Customer centric actions of hospital	1347	ISO effect on rate of handling compliances
1294	Description of services and their availability	1274	ISO effect on reduction of the number ofcompliances
1307	Investigating the internal processes of the organization	1179	ISO effect on quality of goods
1104	Finding the reasons of the problems and do the corrective action	1350	Reduction of destruction of medical equipment because of pm
976	Control of the effectiveness of the corrective actions	1200	Increase of the fulfilled legislations

revealed it presumably related to factors such as specific expectations of managers from improvement procedures¹⁸.

Moreover, in the area of health these expectations may relate to remedial and hospitalization parameter such as occupancy rate and average length of stay. However, Schonherr stated that the main motivation of most of organizations and companies to obtaining ISO is originated presumably from external pressures in a manner that specific obligations can stimulate the implementation of QM-activities more than general, framework legislation^{19, 20}.

CONCLUSION

According to the survey results from staff's viewpoints, it is deducible that there is a meaningful relation between score of ISO quality management system confirmation and some of the modal indexes such as the speed of investigating to complaints, following approvals, cost savings and etc. Although,

despite the fact that ISO quality management system had shown enhanced positive results in documentation processes, but it was affectless in the determination of the practical actions for reduction of length of stay patients and bed occupancy rate from the staffs viewpoints. According to staffs disagreements and lack of authentic evidences pertaining to literature to confirm the relationship between bed occupancy rate and average length of stay with the evaluation of the ISO quality management system, it is logical that the increase in the coefficient of variation could be correlated to other factors such as improvement techniques and quality systems like EFQM, clinical governance, population increase and seasonal diseases outbreak. These results suggested health care services to attempt in achieving high quality in management and performance²¹.

By using of an integrated package of quality which enable us to identify the quality requirements of health area but also deliver a program to recover the quality, could contributed to

impact the health quality effectiveness indexes. With consideration of current results and to ensure the effectiveness of quality systems accomplishment of researcher, we suggest following parameters; comparative investigation of indexes in the hospitals with ISO certificate and the hospitals without this quality management systems and investigation of managers motivation from choosing the kind of quality system for a special hospital and the estimation of their organizational results expectations.

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