

The Effects of Quality Management System on Patient Safety Culture in Hospitals

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Abstract

Among the important indicators of efficiency and effectiveness in providing health services, it is essential, on one hand, to have a level of services in a minimum acceptable level for the viewpoints of all stakeholders and, on the other hand, not to harm patients except for some predetermined certain risks in medical interventions.

This situation makes quality and patient safety practices in hospitals imperative. Quality management systems set out minimum standards in hospitals as it does them in other institutions and can generate positive impacts on patient and employee safety in providing services. With a carefully planned study from this viewpoint, opinions of health care workers of a hospital on patient safety and quality management systems were taken and a relationship between these two concepts and status of this relationship were presented. The samples of this study contain a total of 253 hospital employees regardless of professional differences. The evaluation of the data received from 253 healthcare workers of the hospital through surveys, frequency tables, center and spread with Pearson's correlation test and linear regression analysis were also used.

When examining the effects of Quality Management System to Patient Safety Culture, analyses were conducted to determine the relationship between Quality Management System and Patient Safety Culture. Significant/Meaningful relationships between the sub-dimensions of Quality Management System and that of PSC were determined statistically.

The results of this study reveal that Quality Management System predicts 44% of variations in Patient Safety Culture. In addition, There is a significant/meaningful regression model ($F=193.753$; $p<0.05$). As a result, the regression equation is to be

found as “Patient Safety Culture =1.588+0.43 Quality Management System”. Therefore, according to the results of analyses, it is found out that Quality Management System affects Patient Safety Culture with a coefficient of 0.43.

Key Words: Patient safety culture, quality management systems, hospital management, healthcare workers.

Hastanelerde Kalite Yönetim Sisteminin Hasta Güvenliği Kültürüne Etkisi⁴⁹

Özet

Sağlık hizmetlerinin sunumunda verimlilik ve etkinliğin önemli göstergeleri arasında, bir yandan hizmetin tüm paydaşlar açısından asgari kabul edilebilir düzeyde olması, diğer yandan ise tıbbi müdahalelerde önceden belirli riskler dışında hastaya zarar verilmemesi gelmektedir. Bu durum da hastanelerde kalite ve hasta güvenliği uygulamalarını önemli hale getirmektedir. Kalite yönetim sistemleri en basit anlamıyla tüm örgütlerde olduğu gibi hastanelerde de minimum standartları ortaya koymakta, hizmetin sunumunda hem çalışanın hem de hastanın güvenliği üzerinde olumlu sonuçlar doğurabilmektedir. Buradan hareketle planlanan araştırmada bir üniversite hastanesinde çalışan sağlık personelinin hasta güvenliği ve kalite yönetim sistemi konusundaki görüşleri alınmış ve iki kavram arasındaki ilişki ve ilişkinin durumu ortaya konulmuştur. Araştırmanın örneklemini meslek farkı gözötilmeksizin araştırmaya alınan toplam 253 hastane çalışanı oluşturmaktadır.

Araştırmada, 253 sağlık çalışanına uygulanan anketle alınan verilerin değerlendirilmesinde, sıklık tabloları, merkezi ve yaygınlık ölçütleri ile Pearson korelasyon testi ve doğrusal regresyon analizi kullanılmıştır.

Kalite Yönetim Sisteminin Hasta Güvenliği Kültürüne etkisi incelenirken öncelikle, Kalite Yönetim Sistemi ile Hasta Güvenliği Kültürü arasındaki ilişkiyi belirlemeye dönük analizler yapılmıştır. Kalite Yönetim Sisteminin alt boyutları ile Hasta Güvenliği Kültürünün alt boyutları arasında istatistiksel olarak anlamlı ilişkiler belirlenmiştir.

Araştırma bulgularına göre, Kalite yönetim sistemi hasta güvenliği kültürünün % 44'lük bölümünü açıklamaktadır. Ayrıca, regresyon modeli anlamlıdır ($F=193,753$; $p<0,05$). Araştırmada regresyon denklemi “Hasta güvenliği kültürü=1,588+0,43Kalite yönetim sistemi” olarak ortaya çıkmıştır. Regresyon analizi sonuçlarına göre kalite yönetim sistemi hasta güvenliği kültürünü 0,43'lük katsayı ile etkilemektedir.

Anahtar Kelimeler: Hasta güvenliği kültürü, kalite yönetim sistemleri, hastane yönetimi, sağlık çalışanları.

JEL Classification Codes: I10, I18, I19.

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Introduction

Quality Management System and Patient Safety Culture are crucial issues for hospitals. There are so many factors affecting patient safety. Providing for health services vary for every culture, every institution and every ambient. Quality management system, since it complies with the standards which do not change from culture to culture, from one person to another and from an ambient to another, is closely related with providing for health services and patient safety. Furthermore, there is the effect of the quality management system on patient safety culture.

Hospitals Patient Safety Quality Management System Before examining the issue of the impact of culture in the literature on hospital quality management system and explanations are given to the patient safety culture.

Hippocrates was the first person to describe the term "patient safety". This term exists in a general principle of medicine, "do not harm the patient". However, all medical practices and initiatives in health care brings in its own risks. Today, in order to mitigate or control these risks, a precise and detailed approach, which is patient safety concept, is more dominant.

Before analyzing the effect of Quality Management System on Patient Safety in Hospitals, there are explanations on hospital quality management system and patient safety culture in literature.

1. Quality Management System In Hospitals

There is a growing interest to improve the work on the quality of health services in Turkey, as it is in the other parts of the world. The Ministry of Health, as well as the hospital authorities, conduct the work to establish quality management systems in hospitals and improve the quality of service. Quality Management System Efforts are underway in many health institutions. "Quality Management Services Inpatient Treatment Institutions" Directive was enacted by the ministry enact on October 30, 2001 to establish Total Quality Management into the structure of the health organizations (Kaya, 2003).

It is essential to define and explain the concept of quality before making statements about the quality management system in hospitals. According to Quality Control Union of the European Union (EOQC), quality is defined as; "The degree of compliance with the consumer's request of the specific goods or services". The American Society for Quality Control (ASQC) defines quality as; "all the features of a good or a service that demonstrates its ability

to meet a specific requirement/need". On the other hand, A quality specialist, Jura, defines quality as; "Suitability for the use". By using the common features of all these definitions, quality can be defined as; the level of a product or a service to meet customers' expectations and requirements (Soylu and Suer, 1998: 150).

Quality assurance in health services is the establishment of standards, reviewing these standards in a periodic manner and continually improving medical processes standards proper to these standards. The followings are the three key elements of quality assurance: reaching a consensus on standards, comparing the current situation with these standards, correction of activities that do not meet these standards (Drucker, 1995: 202).

Hospitals adopting the "Total Quality Management" (TQM), a contemporary form of management, has been making efforts on ensuring an increase in quality during providing services and on patient satisfaction oriented service approach. It is essential to increase the staff's competence, to get their thoughts on decision making and process improvement activities in order to be quality oriented institutions. TQM assumes that a staff who does a work has best knowledgeable on that work and also signifies the teamwork (Kavuncubaşı, 2000:285).

The quality management systems (QMS) adopt the principles of continuous improvement and development, on the job training of workers, the leadership of senior management, teamwork and customer orientation (Simsek, 2001: 134). According to Donabedian, there are three important elements of quality in health care: First one is to have good quality of the technical service, and second one is to have a good relationship between health service provider and patient, and the third is to provide convenience and comfort during providing health care (Donabedian, 1995: 32).

The quality of health care is to deliver services on diagnosis, treatment and care based on internationally recognized standards and the patient expectations and needs on health care service related processes. Health care in an excellent quality is to deliver services to the right person on exact time in a rightful manner using right tools and to achieve best possible results. (Tengilimoglu et al, 2012: 487). As a result, objectives of the establishment of quality management system are to provide high quality health care, to focus on continuous improvement and to ensure patient safety and staff safety (Ministry of Health, 2011: 7).

2. Patient Safety Culture

Patient safety culture concept in hospitals are inseparable from organizational culture. Therefore, the issue of organizational culture is primarily identified and explained. Organizational culture is simply defined as "how things work roll in an institution". In other words, it can be defined as "the work is done this way in this institution" (Lowery, 1997: 1-14). Members of an institution show new members how to conduct a task properly. Organizational culture consists of its own beliefs, values, customs, practices and procedures. Organizational culture is not a value that can be changed easily. As there are members who can adopt themselves to a change, but some members may show resistance to the change. In some institutions, the latter can be majority. In organizational culture, it is important to recognize and support of a change by senior management and the management should share this change with the staff.(O'Connor and Fiol, 1997: 39-60).

What is important is the organizational leadership before it is important how these changes he accepts, then all the organizations of the need for this change and what it is to tell a clear and sharing will bring (O'Connor and Fiol, 1997: 39-60).

While Organizational culture is defined as values, attitudes and a set of behaviors that holds the organization together, the patient safety culture is defined as the acceptance of patient safety as top priority and a common value of the institution (Dursun et al, 2010: 2). Patient safety culture is a part of the organizational culture and consist of attitudes, beliefs, perceptions and values of individuals in the organization, (Kaya, 2009: 32-34). In hospitals, during the creation of PSC, it is also necessary to raise awareness of hospital employees and managers and, as well as, awareness of patients (Akalin, 2004: 13).

Significant Factors that affect and contribute the development of PSC in Turkey are the followings; (Ozmen and Bason, 2010: 81-97);

1. Increase in awareness and expectations of society,
2. Increase in health care demands,
3. Technological developments and the risks created by them,
4. Increase in the costs of service provisions and burden of these costs to the social security system,
5. Rise in Service quality standards,
6. Increase in competition

7. Legal responsibilities decreed

8. Continuous improvements on health care policies.

There are studies on patient safety, prevention of errors related to health care and the diminishing injury and death due to these errors (Akalin, 2010: 10). According to National Patient Safety Agency (National Patient Safety Agency), patient safety is hospitals risk assessment, risk management and risk identification associated with patients, risk reporting to reduce recurrent risks and their analysis and finally the process of making safer care to patients as a result of the implementation of the solutions developed (Gözlü and Kaya, 2012: 175).

Patient safety and medical errors is one of the most intensively studied subjects in healthcare services in the last few years. Every year, a large number of patients lose their lives as a result of medical errors in the health sector. Incidences of errors due to medication side effect or during medical care of patients hospitalized in the United States was found to be 2.9% and 3.7%, respectfully and at least half of them are avoidable. Medical errors, thus, patient safety, are related to the quality management system. This is because a significant portion of medical errors are caused by system related problems such as organizational structure, technical infrastructure, manpower shortage and etc., rather than individual mistakes (Dursun et al, 2010: 3).

Medical errors that affect patient safety negatively can occur at every stage of health care. This medical errors can be classified as medication errors, surgical errors, errors in diagnosis, errors due to system failures and errors other (TMA, 2011: 17):

- **Medication errors:** these errors, which can mostly be prevented, are about the medication of patients. Errors such as wrong dose, wrong way of administration, the interaction with other medications, unintentionally administering a drug to a patient who has a known allergy history of this drug are in this group. Between 34% and 56 % of the errors can be prevented.

- **Surgical mistakes:** Studies reveals that a surgical malpractice occurs in one of every 50 patients hospitalized.

- **Errors in diagnosis:** Misdiagnosis can lead to inaccurate and inadequate treatment or unnecessary additional tests to be done. Incorrect implementation or interpretation of laboratory tests is among common medical errors. There are many diagnostic error caused by inexperienced personnel's diagnosis.

- **Error depending on the system deficiencies:** It is the errors occurring in the system while providing health services and they are quite difficult to find out. Among these are faults in instruments, such as

defibrillator, ventilator, intravenous fluid pumps, etc., which are determined when it happens, but cause significant consequences. Vast majority of the malpractices occurring during medical treatment are defined as system errors.

- Other important issues: These include medical malpractices such as hospital infections and blood transfusion errors.

Patient safety is a safeguard preventing the conditions that may harm patients due to a malpractice and negligence. In recent studies, it was found out that medical errors due to malpractices are more than that of negligence (Henneman, 2010: 8).

There are significant/meaningful correlations/relations between deficiency in the number of personnel in terms of quantity as well as quality, which is an issue in QMS, and medical malpractice or patient safety. (Mayo and Duncan, 2004: 209-217).

3. Patient Safety Culture Effect Of Quality Management System In Hospitals

It is important to set a patient safety culture and quality management system in hospitals. Therefore, there are many domestic and foreign organizations working on issues related to quality and developing standards and programs. One of these organizations, the Joint Commission International (JCI), set some basic standards to reduce the risks that might occur during the provision of services of doctors and nurses in hospitals. These standards include risk management and use of resources to ensure quality improvement and patient safety (Goktas, 2007: 3).

Standard is defined as completing a task in a way determined before. In medical practices, medical failure means causing an injury of a patient, a failure to conform to minimum health care standards and skills and malpractice means failure to act correctly according to minimum standards. Thus medical malpractice means not complying with minimum standards. QMS is closely related with patient safety since it contains most comprehensive standards. Hence, it is possible to state that there is a close relationship between medical malpractice or patient safety and quality management system, which is the most comprehensive definition (Pakiş, 2006: 4).

Patient safety culture of a hospital's health not only shows the approach and competence level in the management of both health and safety, but also reflects values, attitude, perception, skill and behavior of an individual, a group or an institution determining the commitment in this field. Patient safety culture is concerned with not only clear rules on manager's commitment on safety, style of communication and reporting errors, but also

the motivation of employees, their morale, the way they perceive the error and attitudes towards the management and factors affecting errors, such as fatigue, risk-taking, violation of processes (Tütüncü et al, 2006: 288).

It is clearly understandable from the experiences shared by Johns Hopkins Hospital on what can be done to set up and improve patient safety culture in healthcare organizations, and how to reach to success. The outlines of the program started in May 2001 are as follows (Pronovost PJ, Weast B Bishop N, et al, 2004: 59-68):

1. Measurement of patient safety culture of all employees in the unit that the study was carried out,
2. Training of all employees on patient safety,
3. Determination of concerns of employees on Patient safety culture in accordance with the Patient safety culture measurement results,
4. Conducting weekly patient safety inspections in units under supervision of Senior leaders,
5. The implementation of the improvement process,
6. Reporting of results,
7. Widely sharing Information and developing new success stories,
8. Repetition of patient safety culture measurement.

Presence of patient safety culture yields improvement opportunities to provide better quality services, thus contributes to quality management system. Effective and efficient implementation of the quality management system also causes an increase in patient safety. Therefore, the quality management system has a positive relationship with patient safety culture. As a result, the quality management system in hospitals affects patient safety culture.

4. A Research To Determine The Effect Of Quality Management System To Patient Safety Culture

4.1. Purpose of the Research

The aim of this study was to determine the effect of Quality Management System to Patient Safety Culture in Research and Practice Hospital of Kocaeli University.

4.2. Population, Sample and Data Collection Tool

In this study, which is conducted to determine the effect of QMS to PMS, the universe of the study constitutes 817 hospital employees, including physicians, nurses / health officer and technicians. To collect data, a permission was obtained from the Chief of Staff of the Hospital and it was aimed to reach the entire universe in the hospital. 253 of 817 questionnaires distributed were returned back by the hospital staff. Some of the employees

did not participate in this survey because of their heavy workload as well as some thinking that the subject was not relevant to them, and the rate of return is 30.96%.

In this study, a measurement tool prepared by Research and Quality Agency in Healthcare services prepared and measured its validity and reliability by Ali Çakır was used (Çakır, 2007: 151). Yet, since the reliability and validity of the scale had already been made, this was not repeated again, however, Cronbach's alpha value was calculated to determine the internal consistency for reliability. According to patient safety, alpha value is found to be 0.86; The scale for quality management system has been identified as a 0.96. There is no substance detected in both scale showing negative effects. The scale for quality management system consists of 39 items in 5 sub-dimensions while the scale of patient safety consists of 34 items in 10 sub-dimensions. Scales are Likert-type 5scales and scale "1" is worst case while "5" represents the best condition.

The data obtained in this study have been transferred to electronic media and analyzed using SPSS 13.0 statistical software package. First, compliance of data with the normal distribution is analyzed using the One Sample Kolmogorow - Smirnow test and Histogram plotting and a normal distribution is found out. Therefore, parametric statistical analysis tests were used in this study. Frequency tables, measures of central and prevalence with Pearson correlation test and linear regression analysis in the analysis and the evaluations were used.

4.3. Results

Demographic data of participants of this research conducted in Research and Practice Hospital of Kocaeli University, values for sub-dimensions of QMS and PSC and results showing the effect of QMS on PSC are presented in tables below.

The values related to the classification of samples based on their socio-demographic and occupational characteristics are presented in Table 1.

Table 1. Socio-Demographic And Occupational Characteristics

Variables	Features	Numbers	%
Age Group	18-25	37	14.6
	26-33	137	54.2
	34-41	53	20.9
	42-49	17	6.7
	50 +	9	3.6
Gender	Women	181	71.5
	Men	72	28.5
Marital Status	Married	163	64.4
	Single	90	35.6
Educational Status	Lycee	29	11.5
	Short Cycle	55	21.7
	Degree	113	44.7
	Graduate	56	22.1
Titles	Physician	52	20.6
	Nurse	155	61.3
	Health Technician	32	21.6
	Other	14	5.5
Seniority	Less Than A Year	24	9.5
	1-5 Year	87	38.3
	6-10 Year	79	31.2
	11-15 Year	29	11.5
	16 +	24	9.5
Weekly Hours	0-39	17	6.7
	40-49	138	54.5
	50-59	56	22.1
	60-69	12	4.7
	70-79	3	1.2
	80 +	27	10.7
Work Unit	Emergency/ Operating Room/ Intensive care	73	28.9
	Clinics	117	46.2
	Polyclinics	63	24.9
Income Group	1501-2000	78	30.8
	2001-3000	126	49.8
	3001-4000	31	12.2
	4001-5000	5	2
	5001-6000	3	1.2
	6001 +	10	4
	Total	253	100.0

The 71.5% of those surveyed in this study are women, 54.2% are in the age range of 26-33, 64.4% are married, 44.7% have bachelor's degree, 61.3% are

nurses / health officer, 38.3% work in the hospital between 1 and 5 years, 54.5% work between 40 and 49 hours a week, 46.2% work in clinics, and 49.8% have income levels between 2001 TL and 3000 TL.

As a result of the analysis of the data obtained in the study, and the values for the QMS and its sub-dimensions are presented in Table 2.

Table 2. The Values for QMS and Its sub-dimensions

Variables	n	Mean	Standard Deviation	Min.	Max.
General Conditions	253	2.82	0.78	1	5
Management Responsibility	253	2.78	0.81	1	4.88
Implementation Services	253	3.06	0.71	1	4.58
Resource Management	253	2.52	0.76	1	5
Measurement Analysis and Improvement	253	2.82	0.75	1	5
General Evaluation	253	2.76	0.65	1,05	4.42

As a result of the analysis of the data obtained in the study, and the values for the PSC and its sub-dimensions are presented in Table 3.

Table 3. The Values for PSC and Its sub-dimensions

Variables	n	Mean	Standard Deviation	Min.	Max.
The Incidence of Reported Events	253	2.61	1.05	1	5
Management and Communication	253	2.44	0.93	1	5
General Security Perception	253	3.14	0.70	1	5
Organizational Learning	253	3.33	0.85	1	5
Teamwork	253	2.75	0.97	1	5
Evaluation of Error	253	2.45	0.81	1	5
Personel Proficiency	253	1.77	0.76	1	3.67
Approach of Hospital Management	253	2.83	0.78	1	5
Relations Between Units	253	2.65	0.78	1	5
Task Change	253	3.30	0.82	1	5
General Evaluation	253	2.77	0.43	1.38	4.42

In the literature, when investigating effect of any variable to a dependent variable, it is, first, investigated if there is a relation between them. In this study, before determining the effects of QMS to PSC, it is investigated

whether there is a relationship between QMS and PSC. Values indicating the relationship between the general and sub-dimensions of QMS and those of PSC are given below in Table 4.

Table 4. The relationship between the general and sub-dimensions of QMS and those of PSC Sub-Dimensions of Patient Safety Culture

Dimensions of QMS		1	2	3	4	5	6	7	8	9	10	11*
General Conditions	r	,124	,312	,293	,307	,343	,046	,045	,366	,282	-	,419
	p	,049	,000	,000	,000	,000	,470	,480	,000	,000	,832	,000
Management Responsibility	r	,143	,452	,312	,311	,376	,046	,142	,462	,342	-	,522
	p	,023	,000	,000	,000	,000	,470	,024	,000	,000	,692	,000
Implementation Services	r	,076	,412	,412	,294	,281	,038	,115	,485	,259	,054	,495
	p	,227	,000	,000	,000	,000	,544	,069	,000	,000	,391	,000
Resource Management	r	,050	,420	,252	,200	,415	,092	,360	,392	,400	-	,481
	p	,425	,000	,000	,001	,000	,145	,000	,000	,000	,119	,000
Measurement Analysis and Improvement	r	,166	,447	,350	,413	,413	,108	,117	,494	,369	,104	,621
	p	,008	,000	,000	,000	,000	,088	,063	,000	,000	,100	,000
General Evaluation	r	,182	,516	,416	,426	,470	,065	,190	,580	,443	-	,660
	p	,004	,000	,000	,000	,000	,302	,002	,000	,000	,529	,000
	n	253	253	253	253	253	253	253	253	253	253	253

* Pearson correlation test were used.

* Sub-Dimensions of Patient Safety	
1. PS The Incidence of Reported Events	7. PS Personnel Proficiency
2. PS Management and Communication	8. PS Approach of Hospital Management
3. PS General Security Perception	9. PS Relations Between Units
4. PS Organizational Learning	10. PS Task Change
5. PS Teamwork	11. PS General Evaluation
6. PS Evaluation of Error	

When correlation table of general and sub-dimensions of quality management system and of patient safety culture, there are statistically significant/meaningful relationship among QMS and PSC at various dimensions, except the dimensions for the evaluation of errors and change

Table 5. The Effect of Quality Management System to Patient Safety Culture

	Fixed	B	β	t	R ²	Rest.R ²	F	P
Independent Variable								
Quality Management System	1.588	0.430	0.660	13.920	0.436	0.433	193.753	0.000

* *Dependent Variable "Patient Safety Culture", $p < 0.05$*

Quality management system describes 44 % of the patient safety culture. In addition, the regression model is significant($F = 193.753$, $p < 0.05$). The regression equation emerges as " patient safety culture = 1.588 + 0.43 Quality management system". According to regression analysis results, Quality management system affect patient safety culture by a factor of 0.43.

5. Conclusion

There are key roles of quality management system and patient safety culture in providing health services in hospitals efficiently and effectively. Patient safety culture, which is part of the organizational culture, consists of employee attitudes, their beliefs, perceptions and values. Therefore, it is necessary to raise awareness of all employees and patients, including managers.

Patient safety and medical errors in providing health care has a very essential place. A significant part of medical errors, accordingly a significant part of patient safety stems from systems such as organizational structure, the number of employees and lack of technical infrastructure rather than individual mistakes. Therefore, the quality management system is related with medical errors and patient safety.

Proper diagnosis, treatment and care of the internationally recognized standards in providing quality health care in hospitals is crucial. In addition, it is also imperative to fully satisfy patient needs and expectations in the entire processes of health services provided. It is an important managerial tool to boost the information system and ensure its widespread use to reduce medical errors and thus, improve patient safety. Use of computerized decision support systems in the patient treatment causes increased treatment reliability and thereby, increased patient safety by providing significant support on drug interactions and allergic reactions (Bates, 2000: 788-791).

Quality management system contains continuous development and improvement, on job training of employees, leadership of senior management, teamwork and principles of customer. The internalization of

hospital quality management system is only possible with the attitude, beliefs, perceptions and values of the staff, in other words, with the change of the organizational culture. Quality management system, which is part of the organizational culture, is associated with Patient safety culture.

It is found out that there is a strong correlation between patient safety and quality management system ($p < 0.05$; $r = 0.66$). This situation reveals that development of implementation of quality management system in hospitals affects patient safety positively. As a result of regression analysis, the exposition is found to be 0.43 and this reveals that the implementation of quality management system has an impact on almost half of the patient safety. This is an enormous value for in terms of the exposition of a single variable.

This study cannot be generalized since it is conducted with the results obtained only in Kocaeli University Research Hospital. In order to generalize the results, it is recommended that a further study be carried out in a broader universe which includes samples of employees of other state university hospitals.

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