THE ROLE OF QUALITY MANAGEMENT SYSTEM IN PATIENT SAFETY CULTURE FOR CENTRAL STERILIZATION UNITS

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INTRODUCTION

Total Quality Management (TQM) is based on the premise that customers should be the focus of the organization. All the studies and improvements should aim the customer satisfaction (Tutuncu & Dogan, 2005; Tutuncu & Dogan, 2004). The term customer reflects both internal and external customers (Tutuncu, et al., 2005). The ISO 9001: 2000 certification has its own chapter due its strong emphasis in customer satisfaction and the importance of quality management systems to improve organizational performance in all aspects (Chan, 1998). The ISO 9000 series of standards is a non-governmental organization established to promote the development of standardization and related activities. The goal is to facilitate the international exchange of goods and services, and to develop cooperation in the spheres of intellectual, scientific, technological and economic activity (Bhuiyan & Alam, 2005).

Accidents and complications are common in health care and can be deadly. Only in the 1990s did errors in health-care settings begin to draw public attention. Adverse medical events, as injuries to patients that arise from mistakes and accidents during medical treatment are called, can be result of human errors, technological errors, or a system that failed to detect these mishaps and prevent them (Bernstein, et al., 2003). Two landmark studies, one in New York and the other in Utah and Colorado (Brennan et al., 1991; Thomas et al, 2000), estimated that 44,000 to 98,000 Americans die every year as a result of adverse medical events. The Washington, D.C. based Institute of Medicine came out with a study in 1999 designed to raise awareness among the public and key stakeholders of the scope of the problem; it was followed with studies by the United Kingdom and Australia, which tried to get a complete picture of the inconvenience, morbidity, extended stays, or death resulting from adverse events in hospitals (Wong & Beglaryan, 2004).

There are many proposed definitions of safety culture. One of the more concise definitions was presented in a report by ACSNI (1993) stating that "it is the product of individual and group values, attitudes, perceptions, competencies and patterns of behavior that determine the commitment to the and the style and proficiency of an organization's health and safety management".

Disinfection and sterilization failures may cause some negative patient safety results. Patients depend on the science of sterilization and the application of surgical asepsis as the primary method of protection from potentially devastating infections (Vane, 2005). It is important for CSUs. Events that may contribute to failure of sterilization and disinfection include (NSW Health Department Newsletter, 2002):

✓ inadequate reprocessing of 'loan' instruments because staff were unaware of the internal structure or mechanisms of individual instruments or the recommended practice for a specific disinfectant or sterilising process,
✓ confusion regarding packaging and labelling,
✓ inappropriate use of automated machines,
✓ insufficient periods of time for reprocessing,
✓ inability of staff to check physical, chemical or biological indicators for sterilisation,
✓ use of an unregistered solution for disinfection,
✓ use of inexperienced or untrained staff,
✓ inadequate training regarding the introduction of new instruments, equipment or methods of work,
✓ absence of the appropriate operating manual for specific instruments, equipment or machinery,
✓ disregard or deviance from manufacturers' instructions.

Quality Management System (QMS) is identified as an important factor in implementing continuous quality improvement and total quality management and in promoting integration in health care systems. QMS has also been identified as an important factor in promoting patient safety and error reduction in health care organizations. The pressing need to increase the reliability of health care systems to reduce frequency of adverse events-both negligent and other types-has placed a renewed focus on the role of QMS in promoting patient safety. This study aims to improve the measurement of and characterize the role of QMS in increasing the reliability of patient care systems to reduce adverse events in central sterilization units (CSU).

RESEARCH METHODOLOGY

The survey was conducted among the related higher (directors, microbiologists, surgeons, hygienists, infection control nurses) of sterilization units of 59 Turkish hospitals. Questionnaire was applied in the First National Sterilization Conference (March 2006). In total, 200 questionnaires distributed by the researchers and usable 130 questionnaires were returned, with a response rate of 65%, which is statistically acceptable for data analysis.

Data was obtained by administrating a structured-questionnaire survey consisting two parts. The first part of the survey inquired 40 statements about organizational commitment under five dimensions. The second part of the survey inquired demographic and nominal questions about the employees and safety culture. The total 41 items which have been resulted in 5 independent factors and 3 dependent variables are rated on a five-point scale (1= strongly agree; 2=agree; 3=neither agree nor disagree; 4=disagree; 5=strongly disagree). The employees were asked to state these statements. Data was analyzed by using SPSS 13.0 program. Data analysis consisted of frequency distribution, descriptive statistics, factor analysis, and regression analysis at the base of descriptive and inferential statistics.

RESEARCH FINDINGS

Demographic dispersion and profile of employees under the base of descriptive statistics are stated in Table 1. 130 sterilization unit staff has gone under the research.

Table 1. Numerical and Percentage dispersion of sample profile

	Number	%		Number	%
Sex			**Education**		
Female	62	47,7	High school	54	41,5
Male	59	45,4	University	66	50,8
Missing	9	6,9	Missing	10	7,7
Total	130	100,0	Total	130	100,0
Age			**Profession**		
18-25	16	12,3	Nurse	61	46,9
26-33	55	42,3	Technician	31	23,8
34-41	37	28,5	Other	29	22,3
42 and above	13	10,0	Missing	9	6,9
Missing	9	6,9	Total	130	100,0
Total	130	100,0			
Freq. of event reports in the last 12 months			**Direct communication with patients**		
0	55	42,3	Yes	23	17,7
1-2	24	18,5	No	90	69,2
3 and above	27	20,8	Missing	17	13,1
Missing	24	18,5	Total	130	100,0
Total	130	100,0			
Working years in sterilization unit					
Less than 40 hrs	19	14,6			
41 and more	85	65,4			
Missing	26	20,0			
Total	130	100,0			

The reliability tests have been implemented on data at the base of derivative statistics. To increase the reliability coefficient of the test, two data have been taken out of study. As a result of the test, the general Cronbach's alpha of data is found to be as 0,98. This result is within the acceptable limits (Nunnaly, 1978).

In accordance with Cronbach's alpha result obtained, the factor analysis has been implemented on data. The Barlett Test result is realized as the value of 3325,739 and p<,001 level and Kaiser-Meyer-Olkin illustration value as 0,908 and this value is within the acceptable limits. In the principal component analysis implemented on data, the varimax alternative is used up and in accordance with scree plot dispersion obtained; data of which Eigenvalue (main value) is above one is taken under consideration.

The variables of which loading rates are less than 0.30 have been taken out of evaluation so as to have the topic be presented much more clearly. Together with it, there is no expression of which factor load is below 0.30. In the light of this data, it is found that 34 variables are formed under five factors and with total difference (variance) in the rate of 73,364. In other words, 7 out of 41 expressions are taken out of study with data reduction. Together with it, the explanation rate of total difference (variance) obtained in factor analysis is realized in an acceptable rate such as 73,364. The reason for taking this data out of concept is finding out single and dual data to be found out as a factor from analysis result. Thus, totally 9 data with 2 data which is omitted in reliability analysis has been taken out of evaluation to increase the meaningfulness of the study. The summary results of factor analysis are presented in Table 2. The participants have given the lowest average as 3,58 to the fourth factor which represents resource management (5 as the highest and 1 as the lowest). Together with it, they have given the highest average rate with 4,09 to the factor of service realization, which may mean that staff working in sterilization units believe that they are giving service systematically and carefully. This factor is followed by the management responsibility with the average of 4,00. Indeed, all the factor averages are representing that staff have positive approach and perception about all the dimensions of quality management system as a whole.

Table 2. Results of Factor Analysis

	Factor Loading	Eigen-value	Mean	Variance Explained	F value	alpha	p
FACTOR 1 – General Requirements		18,01	3,96	55,314	59,757	,89	,0001
Processes are defined	,642						
System is documented	,535						
Quality Manual is easily accessible	,581						
Documents are controlled	,796						
Records are controlled	,792						
FACTOR 2 – Management Responsibility		2,137	4,00	61,599	9,689	,92	,0001
Management is customer oriented	,560						
We have quality policy	,905						
We have quality goals	,792						
Quality system is planned	,727						
There is a staff in charge of quality system	,820						
Our responsibilities are well defined	,644						
Management reviews quality system periodically	,639						
FACTOR 3 – Service Realization		1,534	4,09	4,513	4,7446	,94	,0001
Service is realized within a plan	,511						
All official and other requirements are realized about sterilization	,627						
Services are reviewed and recorded	,518						
Comm. is well established btw. units	,712						
Purchasing is done appropriately	,666						
Products are inspected after purchase	,713						
Sterilization is controlled	,750						
Validation of sterilization process is ensured	,580						
Observation of sterilized products are ensured	,590						
Borrowed materials are secured	,605						
Sterilized materials are packaged and stored conveniently	,745						
FACTOR 4 – Resource Management		1,365	3,58	4,013	4,8132	,89	,0027
Necessary resources are provided for a high quality system	,603						
We have a competent, conscious, and trained personnel	,531						
We have infrastructure of high quality	,797						
We have a good working atmosphere	,804						
FACTOR 5 – Measurement, analysis, and Improvement		1,101	3,85	3,240	10,0209	,94	,0001
The satisfaction levels of served units are evaluated	,547						
Inside evaluations are made within quality system	,616						
Sterilized products are controlled and recorded	,560						
Inappropriateness of sterilized materials are under control	,640						
Data collected during sterilization is analyzed	,737						

Kaiser-Meyer-Olkin Illustration Measurement = 0,908; Total Variance Explained =73,364

In order to analyze the relationship among independent variables, correlation coefficient values were calculated. As Table 3 shows, there is a positive and strong relationship between almost all the factor attributes. All the correlations are significant between the variables and correlation coefficients exceed 0,650.

Table 3. Correlation Matrix

		Gen Req	Mgt Resp	Service Realz	Resource Mgt	Measurmt, Analy,& Impr
Gen Req	Pearson Correlation	1				
	N	121				
Mgt Resp	Pearson Correlation	,658(**)	1			
	Sig. (2-tailed)	,000				
	N	108	115			
Service Realz	Pearson Correlation	,704(**)	,740(**)	1		
	Sig. (2-tailed)	,000	,000			
	N	111	105	120		
Resource Mgt	Pearson Correlation	,677(**)	,623(**)	,715(**)	1	
	Sig. (2-tailed)	,000	,000	,000		
	N	112	106	114	120	
Measurmt, Analy,& Impr	Pearson Correlation	,689(**)	,650(**)	,830(**)	,747(**)	1
	Sig. (2-tailed)	,000	,000	,000	,000	
	N	113	109	115	117	122

Note : Multiple R=,834; R square =,696; Adjusted R Square =,686 F=64,970; Signif F=,0001

In order to analyze the difference between nominal questions and independent variables, One-way ANOVA Analysis is made. According to ANOVA results, there is a significant difference between number of event reports within last 12 months and Management Responsibility (F=3,476 and p=0,035) and Service Realization (F=4,273 and p=0,017). Management responsibilities represent the systematic and well organized quality system and management approach to it. More adverse events are reported when quality system is applied successfully and when the service in the unit is systematically operated.

There is significant difference between the total working years in sterilization unit and the dimensions of quality management system. The difference is also significant between the professions and the quality dimensions (p≤0,05). For instance, nurses rate Service Realization (F=7,593 and p=0,001) as 3,80 while technicians rate that dimension as 4,31.

Regression analysis is made to determine the importance of independent variables on dependant variables (Table 4). There are five dependent variables. In other words, the expression of 'Overall, I believe that quality system is applied in sterilization unit ' given with the circular expression is involved. However this expression is considered as dependant variable, due to the findings obtained in factor analysis. Especially 3 factors of quality system as Management Responsibility, General Requirements and Resource management have strong effect on this dependent variable. When we look at Table 4 it is seen that the F value is realized as meaningful in the level of 64,970, p=,0001. In connection with it, Multiple R=,834 and R Square=,696 is realized. It is examined that R square value is in the sufficient level for the researches made in social sciences. It is needed to assess the Beta values to determine the importance levels of independent variables in connection with the dependant variable parallel with the knowledge gained from regression analysis. When we examine the importance of Beta values obtained from regression analysis, it is seen that the variable of Management Responsibility has become meaningful in the level of ,462. Another variable which is meaningful is General Requirements, it is seen that the variable is meaningful in the level of ,341. Also, Resource Management is the third factor that affects the dependent variable with the value of ,250. It is understood that, this three factors affect the dependent variable approximately 70 %.

Table 4. Regression Analysis of the Factors Affecting the Existence of Quality Management System in the Sterilization Unit

VARIABLES	β	T	Sig T
Management Responsibility	,462	4,302	,0001
General Requirements	,341	3,221	,002
Resource Management	,250	2,943	,004
Constant	-,174	-,549	,584

Note :Multiple R=,822; R square=,676; Adjusted R Square=,668 F=89,540; Signif F=,0001

There is another dependent variable expressed as 'Overall, I believe that qualified service is given in sterilization unit'. A second regression analysis is made to determine the effects of dependent variables of quality system on the dependent variable. In Table 5, it is seen that the F value is realized as meaningful in the level of 89,540, p=,0001. In connection with it, Multiple R=,822 and R Square=,676 is realized. It is examined that R square value is in the sufficient level for the researches made in social sciences. When Beta values are examined to determine which factor has stronger effects on dependent variables, it is seen that Service Realization has the highest Beta value of ,841. The other important factor is Resource Management with the Beta value of ,200.

Table 5. Regression Analysis of the Factors Affecting the Existence of Service Quality in Sterilization Unit

VARIABLES	β	T	Sig T
Service Realization	,841	-,536	,591
Resource Management	,200	7,466	,0001
Constant	-,181	2,504	,014

Note :Multiple R=,822; R square=,676; Adjusted R Square=,668 F=89,540; Signif F=,0001

CONCLUSION

The results of this study supports that dimensions of QMS have strong affects in patient safety perception in sterilization units. Management Responsibility is realized as the key factor in implementing and empowering the quality management system in sterilization units. Also General Requirements representing documentation, processes and evaluation have also strong effect on quality system. Resource Management has been realized another important factor in all dependent variables, meaning all the measures like financial resources, human resources and physical infrastructure and working conditions affect both quality management system, service quality and patient safety issues.

One of the most important factors of quality management system that affects patient safety perception is Service Realization. Quality management system ensures that product or service is realized with a planned, systematic and analytical approach in sterilization units. The sub-dimensions of Service Realization which are stated in factor analysis reflect the critical points of sterilizing and controlling the process. Thus, Service Realization has been perceived the most important factor among other dimensions. Sterilization staff believes that effective resource management also has salient importance on patient safety.

Cleaned and sterilized equipment can be obtained by comprehensive policies and procedures within the context of quality management system. Quality management system and documents can be audited on a regular basis. These audits and reviews identify opportunities for improvement. CSUs employees should pay more and special attention to the processes. These processes will require standardized/validated cleaning and decontamination procedures, labeling of items, packaging criteria, loading of sterilizers, sterilization processes (i.e., equipment, sterilant quality, and quantity), controlled quarantine, storage sites, transportation, documentation of the above, and a method of recall if the manufacturing system fails.

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