TOTAL QUALITY MANAGEMENT IN SURGICAL AND MEDICAL EQUIPMENT MANUFACTURING INDUSTRY IN PAKISTAN

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Abstract

Total quality management (TQM) is an approach in which all the people in an organization are involved in constantly improving the quality of product, service and business process. The functioning of surgical and medical equipment manufacturing industry is much dependent upon TQM. The purpose of this study is to examine the level of adoption of TQM practice in surgical and medical equipment manufacturing industry in Pakistan. A questionnaire based survey was conducted among 200 organizations. The study revealed that 52 percent organizations have implemented TQM, but deficiencies have been found in implementation of required management methods, evaluation of customer satisfaction and application of seven quality control / quality improvement techniques. This does not allow to consider the organizations as perfect TQM organizations. The findings may help organizations to focus on efforts required for implementation of TQM system perfectly. The research and findings are limited to a specific segment of manufacturing industry, so findings cannot be generalized to the whole manufacturing industry in Pakistan.

Keywords: Total Quality Management, Quality Control, Medical Equipment Manufacturing, Customer Satisfaction.

JEL Classification: Z000

Introduction

Pakistan and Germany are the largest centers around the globe for the production of surgical and medical instruments. This is the sector where quality holds pivotal position. As per report published by Rawalpindi Chamber of Commerce and Industry (RCCI, 2010), Pakistani surgical instruments industry is in a serious confrontation with German industry which is excellently equipped with quality processes and systems. In the last decade, China, Malaysia, Korea, Poland, Hungry, and India have entered the international market as growing surgical instruments manufacturers. The issue of quality

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is further becoming more serious with the entry of new entrants from other countries. Conformance to standards, testing and certifications will become more critical for surgical and medical equipment manufacturing industry to move up the value chain. Rapidly changing global medical requirements and protectionist policies of the developed world also stands in the way of Pakistani industry.

As per Surgical Instrument Manufacturers Association of Pakistan (SIMAP, 2016), about 100 Million surgical instruments are manufactured annually in Pakistan and $80-90\,\%$ of production is exported to over 140 countries. The value of this export for financial year 2014-2015 was US \$ 339 Million. This sector comprises of approximately 2500 production units including large, medium and small sized manufacturing units. As the industry is flexible in following American, German, British or any international standards/ specifications, the United States and European countries are the leading buyers of Pakistan made surgical instruments.

With reference to quality management, most of the organizations in Pakistan claim that they practice total quality management (TQM). Here arises the question that up to what extent for management of the organizations understand the TQM principles and practices, whether a complete understanding exists and the tools and techniques that are considered essential for qualification are implemented. TQM principles and practices encompass commitment of top management towards quality, focus on customer satisfaction, employee involvement and their training and application of quality control / quality improvement techniques (Yusof & Aspinwall, 2000; Dale, 2003). Seven quality control / quality improvement techniques include check sheet, histogram, flow chart, control chart, scatter diagram, Pareto analysis and cause-and-effect diagram (Evans & Lindsay, 2011). No research is available on this aspect; therefore, it was appropriate to set the objective of the research as to evaluate the level of adoption of TQM in surgical and medical equipment manufacturing industry in Pakistan.

Literature Review

Quality management evolved in manufacturing environments and finds its roots in early 1930s as discussed by American industrial thinkers (Huggins, 1998). Statistical quality control introduced by Shewhart showed to be a narrow approach which has now been expanded to more wider holistic approach with the name Total Quality Management (TQM) (Dahlgaard-Park, Bergman, & Hellgren, 2001). After W. Shewhart and Huggins (1998) identifies W. Edwards Deming, Joseph M. Juran, A.V. Feigenbaum, Kaoru Ishikawa, and Philip Crosby as pioneering and renowned theorists in the field of TQM. He further credits A. V. Feigenbaum as the originator of the term "Total Quality Control" which was the title of his book published in 1961. The Japanese adopted Feigenbaum's concept with the name as "companywide quality control". U.S. Naval Air Systems Command developed the term "total quality management" parallel to Japanese-style approach to quality improvement that is based on participation of all employees of an organization in improving goods, services and the organizational culture. Theoretical and practical application of work by above mentioned management scientists

led to the development of strategies which enable firms to achieve quality products. These strategies include Total Quality Management (TQM), benchmarking, business process reengineering (BPR), Just-in-Time (JIT), and Six Sigma among others. According to Karia and Asaari (2006), the TQM presented itself as a dominant strategy with worldwide acceptance and adoption to ensure business excellence and quality improvement. This statement receives a good countenance by a number of studies published (Lee, 2002; Beheshti & Lollar, 2003; Hung, 2004; Yeung & Armstrong, 2005).

For a TQM approach, Dale (2003) articulates that superior level of quality can be achieved with the implementation of the principles for quality management in all functions of an organization. It should include the higher level of customer integration with the business. He further elaborates the main elements of TQM as the commitment of top management towards quality, application of quality management techniques, employee involvement, training, feedback from customers, measurement the results and building the culture in organization for continual improvement. Jablonski (1991) has identified six elements of TQM as customer focus, process and result focus, prevention focus, mobilization of expertise of workforce, fact based decision-making and feedback. Martins and Toledo (2000) are of similar opinion.

Talha (2004) views TQM encompassing managerial approaches incorporating product quality, quality improvement, quality assurance and process control through involvement of total organization and its employees. Homologous to this approach Evans (2005) describes TQM as a people focused holistic approach that necessitates continually increasing the customer satisfaction while continually lowering the real cost by involvement of all employees, departments and suppliers of the organization. Bergman and Klefsjo (2007) express fairly similar structure of the concept meaning TQM as a constant endeavor to fulfill, and preferably exceed the customer needs and expectations at the lowest cost, by continuous improvement work, to which all involved are committed, focusing on the process in the organization. Dean and Brown (1994) have characterized total quality by its principles, practices and techniques. They emphasize on principles as foundation of the philosophy, practices as activities by which the principles are implemented, and techniques as tools and approaches that help managers and employees make the practices effective. In the similar context, TQM can be seen comprising three core elements described in the research work as fundamental principles, tools and result (Ciampa, 1992); principles, procedures and tools (Shea & Gobeli, 1995); core values, techniques and tools (Hellsten & Klefsjo, 2000).

By reviewing the available literature, it can be understood that at present there is generally a similar opinion about basic principles and techniques for implementation of TQM in an organization. In the retrospect, the need for adoption of quality, quality management and the total quality management in Japanese organizations arose due to serious competition in markets and rejection of their products. Success of Japanese organizations created a threat to the Western organizations and this led the West to recognize the need for quality management (Evans, 2005).

Mellahi and Eyuboglu (2001) are of the opinion that popularity, adoption and implementation of the concept of TQM seem to be limited to firms of developed countries of the West and Japan, and with a little emphasis on firms in developing and third world countries. However, many organizations throughout the world have had very positive experiences and benefits from adopting quality management. Much can be learned from those which have enjoyed sustainable benefits (Brown, 2013).

Example of Turkey is worthy of consideration. Research by Mellahi and Eyuboglu (2001) revealed that Turkish firms decided to implement TQM due to volatile and uncertain operating environment prevailing in the country after the trade liberalization era in the 1980s. In 1989, the entry of Turkish firms into European Common Market was faced with severe competition and difficulties in achieving customer satisfaction and this became an important drive for implementation of quality management (Turker, 2008).

The literature reviewed led in developing research methodology and the questionnaire for the purpose of study.

Methodology

The objective of the research was to analyze and determine the level of adoption of TQM practice among the surgical and medical instrument manufacturing industry in Pakistan, the research necessitated a survey-based data collection. Zikmund (2003) is of opinion that among several research methods, survey-based research discloses that what is actually happening in a business activity and what are the reasons for any deficiency.

Pakistan surgical instrument manufacturing industry is divided into four major segments depending upon the organization's annual revenue and investment in production equipment as shown in Table 1 (RCCI, 2010). The sample for the survey was taken from 2300 firms registered with Surgical Instrument Manufacturers Association of Pakistan (SIMAP) in the year 2013. As the objective was to study a large sized industry, judgment sampling method was considered appropriate. According to Saunders, Lewis, and Thornhill (2011) purposive or judgmental sampling enables a researcher to select cases that best enables him to answer his research question and to meet his objectives. Neuman (2005) suggests that this type of sampling is used when researcher wishes to select the cases that are particularly informative. 200 organizations were taken as sample for study. Number of organizations representing all the four segments of population are shown in Table 2. Furthermore, the study was only to determine the level of adoption of TQM practice in this sector of manufacturing industry, there was no requirement for hypothesis and its testing.

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Table 1
Segmentation of surgical and medical equipment manufacturing industry in Pakistan

Type of organization	Annual Revenue Rs. Mil.	Investment in Equipment Rs. Mil.		
Large	60 - 100	50 - 100		
Medium	10 - 60	10 - 25		
Small	1 - 10	1 - 5		
Vendors	1 - 1.5	Up to 1		

Table 2
Segment-wise composition of the sample

Type of Organization	No. of Registered Organizations	Sample for Study	%	
LARGE: High sales segment	30	20	10	
MEDIUM: Medium sales segment	50	30	15	
SMALL: Low sales segment	150	40	20	
VENDOR Segment	2000	110	55	
Total		200	100	

A comprehensive questionnaire was developed to obtain information from the sample firms. The construct of the questionnaire is shown in Table 3. Questionnaire was arranged in five sections. General information about company is recorded in the first section and the second section aimed at evaluating the extent of adoption of quality management systems and approaches. The third section was to study the commitment of top management towards quality, the fourth section to estimate the study of customer satisfaction by organizations and the fifth section evaluated the level of implementation of quality control / quality improvement techniques. A pilot survey among a few firms helped in administering the minor changes in the questionnaire. A questionnaire was given to each firm.

Table 3
Construct used for development of questionnaire for survey

Section	Element of TQM	Description
1	Information about company	Name, type and size
2	Adoption of quality management system	Formal QA department, quality manual,ISO 9001 certification,TQM, benchmarking, six sigma.
3	Commitment of top management	-Quality circles, training, preventive maintenance, employee suggestion scheme, quality cost Communication to all employees emphasizing on product quality.
4	Customer satisfaction	Frequency of surveys to get customer feedback.
5	Use of quality control/ quality management techniques	Seven statistical techniques as check sheet, histogram scatter diagram, flowchart, control chart, Pareto analysis, cause and effect diagram.

Survey Results

With reference to the construct of the questionnaire, results of data collected against each question are analyzed. This analysis of survey results will provide basis for discussion and conclusions.

Organization's intention towards TQM

ISO 9000: 2005 defines quality management as coordinated activities to direct and control an organization with regard to quality. The foundation for an effective quality management system is the establishment of a document named as "quality manual" (Lo, Humphreys, & Sculli, 2001). It outlines the organization's quality policy and practices directed towards achieving the improvement in customer satisfaction. ISO 9001 standards is to assist organizations of all types and sizes to implement and operate an effective quality management system (Wahid & Corner, 2009). The qualification of an organization for ISO 9001 certificate indicates its commitment to the implementation of TQM. Data analysis presented in Table 4 and Table 5 exhibit that a formal TQM is in place in 52 percent organizations, out of which 20 percent are ISO 9001 certified. In 35 percent organizations, ISO 9001 Standards are under implementation. Further 18 percent organizations have recognized the necessity of TQM for future. Presently 55 percent of the surveyed organizations have developed a quality manual.

Table 4
Level of adoption of quality management systems

Quality Management System	Yes %	No %
Established QC / QA department	52	48
Established quality Manual	55	45
Obtained ISO 9001 certification	20	80
In the process of obtaining ISO 9001 certification	35	65

Table 5
Level of adoption of quality related approaches

% of organizations							
Quality Management Approach	Not heard about	Heard about	Thinking about	Started	Established		
TQM	5	14	18	11	52		
Benchmarking	12	8	10	32	38		
Six Sigma	57	33	10	0	0		

Commitment of top management

Research work on TQM reveals that commitment of top management towards quality is one of the essential characteristics of the quality focused organizations (Witcher, 1994; Tari, 2005; Fotopoulos & Psomas, 2009). In their research work, Boon, Arumugam, and Hwa (2005) articulate that complete involvement of top management in the TQM programme of an organization ensures better business performance. Along with quality improvement and customer satisfaction, the organization achieves improved level of motivation and morale of employees, cost efficiency, productivity and competitiveness and financial benefits (Beheshti & Lollar, 2003).

Jablonski (1991) expresses that committing a subordinate's time and corporate funds to TQM initiative are inadequate. Management commitment concerns with committing organization's resources and executive's own time. Top management has to necessarily allocate a considerable amount of time for a successful TQM programme.

Survey results reveal that top management of 64 percent organizations has verbally or in written form communicated to its employees about the quality of their product and satisfaction of

customer during last one year. Survey results shown in Table 6 further endorse this figure that 68 percent organizations emphasize on training of employees and 74 percent organizations encourage the contribution of employee's suggestions.

Table 6
Level of application of different management methods

Management Method	Yes %	No %	Management Method	Yes %	No %
Quality circles	18	82	Employee Suggestion Scheme	74	26
Training of Employee	68	32	Analysis of quality Costs	6	94
Preventive Maintenance	45	55			

Customer satisfaction

The success of an organization largely depends upon the degree of its ability to satisfy its customers. Deming (1986) placed the customer satisfaction as an important parameter to measure the outcome of TQM practice in an organization. This theory has been corroborated by Sandholm (2000) and Bergman and Klefsjo (2007). A customer feels satisfied or dissatisfied by a product or service, and he develops these feelings during or after the usage of that product or service (Kotler & Armstrong, 2001; Kotler & Keller, 2006). Focus on customer satisfaction is an essential element of TQM principles (Yusof & Aspinwall, 2000). Measurement of customer satisfaction holds an important position in determining the status of TQM in an organization.

The frequency of survey by the sample organizations for assessing customer satisfaction is shown in Table 7. Organizations which have reported that they conduct this survey twice a year are 43 percent of sample. However, 25 percent organizations conduct customer satisfaction survey more frequently, i.e., after every three months or after every transaction.

Table 7
Frequency of surveys conducted by organizations to get feedback about customer satisfaction

Frequency of Survey	%
No survey	22
Survey after every year	10
Survey after every 6 month	43
Survey after every 3 month	9
Feedback collect after every transaction	16

Implementation of quality control / quality improvement techniques

Implementation of seven statistical techniques is considered as a common characteristic of a TQM organization (Al-Khalifa & Aspinwall, 2000; Dale, 2003; Fotopoulos & Psomas, 2009). These techniques are check sheet, histogram, flow chart, control chart, scatter diagram, Pareto analysis and cause-and-effect diagram. Japanese call them 'Seven QC Tools', and they have been used for decades to support quality improvement efforts (Evans & Lindsay, 2011). Table 8 presents the percentage of organizations applying quality control/quality improvement techniques. The check sheet and flow chart have been found as the most popular techniques with 58 percent and 51 percent applicability respectively. Control chart is the technique which has got 33 percent applicability. It is evident from the data that only a few organizations are familiar with the usage of cause-and-effect diagram.

Table 8

Percentage of organizations applying quality control / quality improvement techniques

Technique	Yes %	No %	Technique	Yes %	No %
Check Sheet	58	42	Control Chart	33	67
Histogram	23	77	Pareto Analysis	13	87
Scatter Diagram	12	88	Cause-and-effect Diagram	6	94
Flow Chart	51	49			

Discussion

Results of survey analysis exhibit a good scenario of TQM awareness among surgical and medical equipment manufacturing industry in Pakistan. At present 52 percent organizations have established formal TQM including 20 percent organizations having ISO 9001 Standards certification. Further 35 percent organizations are in the process of obtaining ISO 9001 Standards certification. Although these are quite encouraging figures and show a fairly good percentage of organizations implementing TQM, but more than half the organizations are ignoring ISO 9001 Standards certification which is a reliable indication of the organization's intention and commitment towards TQM.

In 64 percent organizations employees are communicated about product quality and customer satisfaction. Although it is a reasonable figure, but it also reveals that 36 percent organizations are lacking this essential element of a TQM organization. However, cross analysis of data also shows good popularity of employee suggestion schemes and employee training programs.

Customer satisfaction can be determined by the feedback provided by the customers who are real judges for quality of product. 78 percent of the organizations collect feedback from their

customers at different frequencies. But worthy of attention are those 22 percent organizations which do not conduct any survey to get customer feedback, which in turn means organization's poor inclination to enhance customer satisfaction.

With respect to implementation of quality control / quality improvement techniques, the check sheet and flow chart have been found commonly used techniques. The other five useful techniques are practiced by fewer organizations. This can be due to unawareness of management about the advantages of these techniques, or managers have not understood the necessity of these techniques. Specifically, managers are not familiar with usage of Pareto Analysis and cause-and-effect diagram which usually result 50 to 80 percent improvement in any quality problem. Training of employees can help in resolving this issue. The contents of training programme for employees need major changes giving more focus on quality control / quality improvement techniques among other elements of training.

Conclusion and Managerial Implications

Pakistan is one of the two largest centers in the world for production of surgical and medical equipment. The other center is Germany, to which Pakistan faces an intense competition in quality. The objective of research was to examine the level at which the quality management is being practiced in surgical and medical instrument manufacturing industry in Pakistan. Present scenario of TQM in this sector in Pakistan in encouraging. Out of 2500 large, medium and small production units, 52 percent organizations are practicing a formal TQM. This portrait a reasonable intention, enthusiasm and commitment to TQM. This level can be good at the moment to sustain the share in global market, but cannot be considered as a holistic approach to quality management, so called TQM.

Organizations have been found aware of the importance of customer satisfaction. Management communicates to the employees of the organization about their product quality and customer satisfaction. Implementation of seven quality control / quality improvement techniques is the essential element of an organization adopting TQM. These include check sheet, histogram, flow chart, control chart, scatter diagram, Pareto analysis and cause-and-effect diagram. The results of survey shown that only two techniques, check sheet and flow chart, have got reasonable acceptance among the organizations. The usage of other five techniques, which are histogram, scatter diagram, control chart, Pareto analysis and cause-and-effect diagram, is also an essential element of a TQM organization, but the data reveal a small percentage of sample organizations applying these techniques. Specifically, the small degree of application of control chart and Pareto analysis cannot be considered as satisfactory. Although, 68 percent organizations arrange training for their employees, the low percentage of usage of seven quality control/quality improvement techniques exhibits a lack of complete understanding and rather ignorance of TQM principles among the management of organizations. Top management should arrange training programs for employees which necessarily include exercises on quality control / quality improvement techniques.

In the years to come, the surgical and medical equipment manufacturing industry in Pakistan will face higher requirements for quality, especially when it is trying to diversify into more value added products and enter into more sophisticated markets. The issue of quality will become more serious with the entry of manufacturers from other countries such as Malaysia, Poland, Hungry, China, Korea and India.

In order to meet the present as well as future requirements of quality, it is of great value that the management of the industry must have a strong affiliation with TQM principles and practices. Managers should understand the TQM principles and have a proper knowledge and skills required to manage TQM in changing scenario. They must be committed and provide necessary resources for implementation of TQM. Organizations which are lacking quality management systems in any way, must understand the necessity of TQM to maintain their share in global market.

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