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Association of
Healthcare Providers
(India)

HANDBOOK OF HEALTHCARE QUALITY & PATIENT SAFETY



Editors
GIRDHAR J GYANI
ALEXANDER THOMAS

Foreword
Carsten Engel

3rd Edition

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Contents

Section 1: Healthcare Quality Management

1. **An Overview of Quality in Healthcare** 3
   Girdhar J Gyani

2. **The Basics of Quality Management** 16
   Ajit Singh, Girdhar J Gyani

3. **Quality Management Tools** 33
   Akhilesh N Singh

4. **Healthcare and Climate Change: Implementing Green Practices in Hospitals** 58
   Divya Alexander, Shriram Manogaran

5. **Effective Communication for Quality Healthcare** 69
   Alexander Thomas, Divya Alexander

Section 2: Quality Assurance in Hospital Functions

6. **Quality Assurance in Medical Laboratories** 87
   CV Anand, Jayaram N Iyengar, Venkatesh Thuppil

7. **Quality Assurance in Diagnostic Imaging Centers** 98
   Poonam Narang

8. **Quality Assurance in Hospital Facilities and Engineering Services** 109
   Col Dr Sunilkumar M Rao, Deepak Venkatesh Agarkhed

9. **Quality Assurance in Emergency Departments** 128
   Saravana Kumar S, Tamorish Kole

10. **Quality Assurance in Critical Care** 139
    Binila Chacko, JV Peter

Section 3: Patient Safety Management

11. **Patient Safety Framework** 153
B Krishnamurthy, Renuka Vidyashankar

12. **Infection Control** 167
Sanjeev Singh

13. **Medication Safety** 193
Sangeeta Sharma, Subhrojyoti Bhowmick

14. **Monitoring of Clinical and Managerial Indicators** 215
Parag Rashmikant Rindani, Natasha Bhasin

15. **Standard Treatment Guidelines** 230
Sangeeta Sharma

16. **Clinician Engagement in Patient Safety and Quality** 242
Badari Datta, Girdhar J Gyani

Section 4: Clinical Governance

17. **An Introduction to Clinical Governance** 253
Vinit Raj

18. **Education and Training** 260
Naresh Shetty

19. **The Role of Leadership in Quality Healthcare and Patient Safety** 267
Girdhar J Gyani, Pawan Kapoor, Anupam Sibal

20. **Health Informatics and Health Information Management** 274
Suptendra Nath Sarbadikari, S Murali

21. **Clinical Audit** 287
Anand R

22. **Clinical Effectiveness** 302
Narayan Pendse

23. **Risk Management in Healthcare** 310
Badari Datta, Sunny Kuruvilla

Section 5: Management of Healthcare Organizations

24. Planning and Designing of Patient-centric Hospitals 327
Vivek Desai

25. Complying with Legal and Statutory Requirements in Hospitals 345
Suganthi Iyer

26. Managing the Quality and Cost of Healthcare 358
Vijay Agarwal

27. Patient and Family Engagement 368
Anuradha Pichumani

28. Implementing and Sustaining the Quality Journey in a Healthcare Organization 379
Girdhar J Gyani, Lallu Joseph

29. Healthcare Quality during Pandemics 387
Alexander Thomas, Badari Datta, Umashankar Raju D

30. Emerging Trends in Healthcare 406
Sanjeev Singh, Girdhar J Gyani

Index 417

CHAPTER 2

Ajit Singh, Girdhar J Gyani

The Basics of Quality Management

ABSTRACT

Quality is a timeless concept. It has been an inherent part of human society right from creation. Somewhere down the line, quality was identified only with the manufacturing sector and accordingly linked quality evolution with the industry. Today, quality is inseparable from everything we do, and hence it has truly become a way of life.

Quality can be attributed to a product, a process, system or even an organization. Quality, or satisfying customers on a continuous basis, has become an integral part of an organization's policies and objectives. It has become a corporate strategy and drives most businesses. It is said that quality permeates to a nation by thought and actions. Japan transformed the whole concept of quality and geared the quality vision to masses. In Japan, the quality vision became more relevant with its application in the service industries such as hospitals, education, municipal corporations, and other general services.

The International Organization for Standardization (ISO), a worldwide federation of National standard bodies, developed over 18,000 quality standards of which the ISO 9000 series of standards have found vital applications in the healthcare industry. The ISO 9001:2015 is the latest revised standard for quality management system.

LEARNING OBJECTIVES

- To learn the various definitions of the term "Quality"
- To understand customer focus and the process approach as a quality management principle
- To learn the historical perspectives of the emergence of quality
- To understand the constituents of total quality management (TQM)
- To learn about the various series of International Organization for Standardization (ISO), with emphasis on a few important series standards
- To learn about the quality movement in India

INTRODUCTION

The term "quality" in some form or the other has been known to human race from times immemorial. Quality can be regarded as both art and science. It means different things to different people. Technical people evaluate quality by way of conformance to the specified requirements as recommended by a given standard or as specified by the client organization. Quality relates to perception when viewed by the customer or user. For

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instance, a person may go to a restaurant and appreciate the food served on the first visit, but may not like it as much on the next visit, even though the same quality food was served both times. The cleanliness or orderliness and hygiene practices assume as much importance as the food. This kind of perception gave birth to the description of quality as "satisfying customers continuously."

Customer needs and requirements are ever-changing. What was satisfying in the past may be the basic minimum requirement now. This means that quality cannot be static. It is dynamic and should keep on improving continuously.

Quality, at times, is defined as value for money. This definition is linked with the perception of an individual, but at the same time, considers the importance of cost or affordability.

Dr Juran defines quality as "fitness for purpose."[1] The meaning of fitness has changed now. Let us look at the example of an automobile. Previously, it was a basic requirement solely for the transportation of people. But today, the aspects of comfort, and emission/environment safety features are also included as well as fitness for purpose.

CUSTOMER FOCUS

The ISO is a worldwide federation of national standard bodies and has developed over 18,000 standards. One such standard that has taken the world by storm is the ISO 9000 series of standards. The ISO 9001:2015 is the latest revised standard for quality management system (QMS). Within the framework of this standard, quality is defined as "degree to which a set of inherent characteristics fulfills requirements."[2] The requirements in this definition could be specified by the supplier or by the customer, or it may also be legal/regulatory. Looking from the customer's perspective, this definition simply means that a product must have features that meet the customer's needs and thereby provide customer satisfaction. Another simpler definition of quality is "satisfying/delighting customers on a continuous basis." The onus is entirely on the supplier to keep on assessing the customer's dynamic needs and make sure that products/services meet the needs. Mere conformance to specifications may not satisfy the customer's needs, and hence quality departments cannot relax by declaring that their products conform to the specifications. A continuous lookout and assessment of varying needs or aspirations of the customers is essential to incorporate them in the products.

Customer focus is one of the most important quality management principles published by ISO/TC 176 Committee, responsible for ISO 9001:2015 standard on QMSs. The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations.[2]

Sustained success is achieved when an organization attracts and retains the trust of customers and other interested parties on whom it depends. Every aspect of customer interaction provides an opportunity to create more value for the customer. Understanding current and future needs of customers contributes to the sustained success of an organization.

Quality, or satisfying customers on a continuous basis, needs to be an integral part of an organization's policies and objectives. Systems and processes design should focus on the customers. Leadership needs to play a key role in institutionalizing customer focus at all levels in the organization. This can best be achieved through empowering general and particularly, frontline staff. Finally, the organization needs to have a strong feedback system in place for promoting, receiving, analyzing, and acting on feedback received from customers.

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PROCESS APPROACH

Quality can be attributed to a product, a process, or even an organization. An organization broadly consists of a number of departments or functions where one department receives goods/services from another department. Every process will have a supplier and a customer, who are termed as internal supplier and internal customer. Inputs are also received from external suppliers. Each process feeds its output to another department before it finally goes to the external customer. This is termed as the process approach.

A quality organization will have an established network of quality processes and activities to deliver quality products. The treatment of internal supplier–customer relationship and external supplier–customer relationship is balanced. The processes, inputs, and outputs are controlled, monitored, and measured at different process stages to ensure quality. **Flowchart 2.1** defines the relationship between customers, suppliers, and the process.[2]

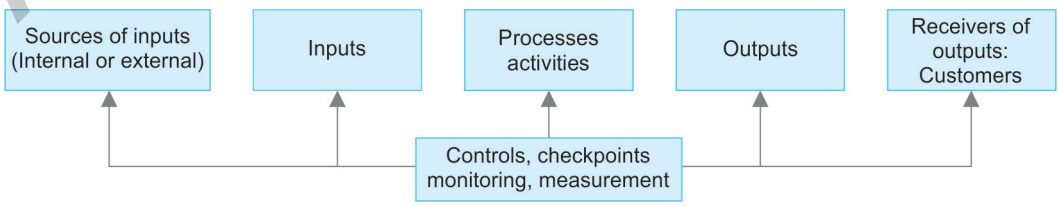
Quality can be qualitative, quantitative, or both, and hence it is described on the basis of the domain under consideration. For example, quality healthcare means correct diagnoses, good communication, informed consent, respect for patient rights, and finally, patient safety. Quality airline service requires on-time performance as the basic criteria. Similarly, a quality catering service needs to demonstrate hygiene followed by courtesy. A good academic institution should demonstrate an effective teaching–learning process capable of delivering competency-based education.

QUALITY: THE HISTORICAL PERSPECTIVE

Cavemen are the earliest example of the concept of quality. As loners, they were the sole makers and users of their stone tools. With evolution and the development of the tribal system, people started specializing as potters and blacksmiths, providing their products to the community. In the middle ages, skill-based crafts required well-experienced craftspeople such as artisans, goldsmiths and weavers. The goods made by them were priced on the basis of their quality or the reputation of the individual artisan who created them. These confident craftspeople ensured customer satisfaction and had higher job satisfaction as their products were appreciated in the community. The competition among them soon resulted in the formation of craft unions called guilds. During the late 13th century, these guilds began to formally look into establishing the end-of-line concept, in which the final products were checked based on the predetermined product specifications and inspection methods.

Quality through Inspection

The industrial revolution began in Europe during the mid-18th century and gave birth to factories that soon outperformed the artisans and the guilds. The craftspeople became factory workers, and the quality was managed through their skills and supplemented by



FLOWCHART 2.1: Customers, suppliers, and process relationship.

Source: Reference 2. ISO 9001:2015 standard

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in-house supervisory inspection, which is termed as "first-party inspection." Late in the 19th century, the United States broke the European tradition and adopted the concept of the Taylor system of scientific management by separating planning from execution.[3] The emphasis on productivity had a negative effect on quality. To restore the balance, a central inspection department came into being. For example, the Hawthorne Works of the Western Electric Company employed 40,000 people in 1928, out of which more than 5,000 people were in the inspection department.[4]

Emergence of Quality Control

It was realized that the inspection method of quality is costly, as it relied on rejection and rework if the quality was not good or acceptable. All the costs were incurred in labor, materials, and work, and if work was rejected, it added to waste, thereby increasing the cost. So inspection was moved from "after work" to "during work," giving rise to quality control (QC). The introduction of "scientific management of quality" in the early 1900s led to well-defined QC as a discipline. It helped the workers to achieve the desired quality without rejection of the product. Control using statistical techniques also became popular during this phase.

Emergence of Quality Assurance

Quality cannot be sustained over the long term just by inspection. It has to be institutionalized by adopting a management system where the fundamentals of quality are integrated into a system which also improves continuously. Experience is channeled back into the system for continual improvement. Inspection starts at the end of line or process, whereas assurance starts before the line or at beginning of the process. The process approach is inbuilt into the quality assurance. Inspection is a part of quality assurance. A system consisting of all interrelated processes and responsibilities and authorities is documented for implementation. It also addresses customer-related processes and handles complaints.

Emergence of Quality Management

The post-World War II period witnessed dramatic developments of quality tools and techniques, more predominantly in Japan. Companies converted their activities to "quality assurance," which finally led to the development of quality management, with the realization that quality has to be managed at the top level. It provided planned and systematic actions required to ensure adequate confidence to a customer that a product or service would satisfy the given quality requirements. In Japan, company-wide QC emerged and later became popular under the term TQM.

Emergence of Total Quality Management

Total quality management requires the creation and maintenance of an environment focused on total customer satisfaction in order for an organization to achieve complete quality credibility. There are no quick fixes, no shortcuts, and no magic formulas. TQM requires many years of dedicated hard work. TQM cannot be borrowed, but needs to evolve from within an organization based on certain proven principles. It must be led by top management and should be based on a systematic, consistent, organization-wide perspective that is manifested in every aspect of an organization. Equally essential are the involvement of everyone and everything and the continuous improvement of all systems and processes.[1] TQM is defined as an ongoing journey of continuous, measurable improvements, championed by empowered individuals at all levels of the organization. It is driven by leadership,

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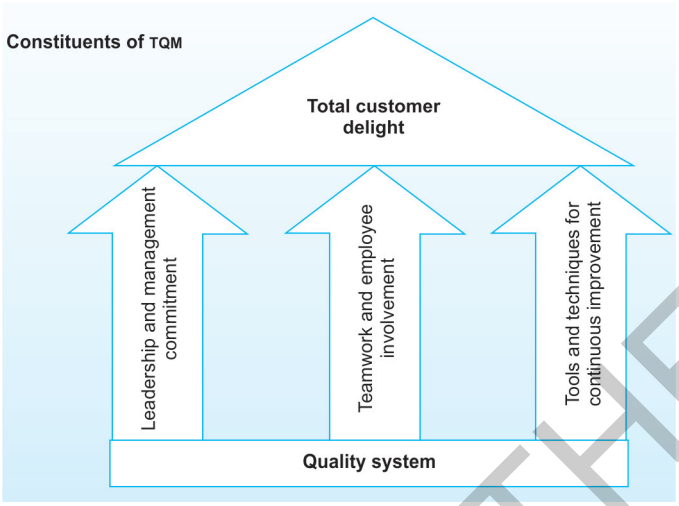

FIG. 2.1: Constituents of total quality management (TQM).

which inspires teamwork, trust, and belief among people, which results in an enjoyable and productive workplace, dedicated to the highest level of customer satisfaction. The principal constituents of TQM are depicted in **Figure 2.1**.

Leadership

A vision developed by the top management of an organization should indicate the future of the organization. The organization will achieve the vision of this top management by plan or by default. This vision must be shared with everyone in the organization. A thorough communication process must be established for this purpose to create oneness in the organization. The TQM philosophy and guiding principles can be instituted in the organization only by the actions of management and not by slogans.

Teamwork and Employee Involvement

Involvement will not happen on its own; efforts will be required to involve suppliers, customers, operations, technology, public affairs, and all functions. It has been seen that when the top management is involved, workers are focused without neglecting the middle and lower management. Initial enthusiasm may die down soon and, therefore, the middle management should carry forward the routine activities, otherwise urgencies will take over. The entire management must work together.

Ownership

Ownership is a must to ensure pride of ownership. Right from the start of a process, the output and workmanship, satisfaction of internal customers, and empowerment should be owned by individuals or groups. Team work and team ownership are equally important in TQM. The organization must give opportunity to experiment, which may sometimes lead to mistakes; and one must then learn from these mistakes.

Reward and Recognition

Rewards and recognition are a part of any organization. In TQM, it is very important for group or individual contributions, customer focus, and improvement activities.

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TABLE 2.1: A comparison of traditional management and total quality management.[5]

Traditional management	Total quality management
Looks for quick fixes	Adopts a new management philosophy
Fire-fights	Uses structured, disciplined operation methodology
Operates the same old way	Promotes breakthrough thinking
Random improvement efforts	Continuous improvement
Focuses on short term	Stresses on long term
Inspects for errors	Prevents errors
Decides using opinions	Decides using facts
Throws resources at a task	Uses people as primary means to add value
Is motivated by profit	Is motivated by customer satisfaction
Focuses on Individuals	Focuses on group
Strong management	Strong leadership

Continuous Improvement

A continuous improvement system gears the organization toward the attainment of the vision. It is a fundamental aspect of TQM primarily based on a system to involve people who are working in improvement teams, quality circles, kaizen teams, or any other indigenously developed teams by the organization. It should be understood that people are not the problem but the solution. Almost all root causes of problems or variation in the process can be traced to the system or process itself. Measurement and quantitative techniques are the principal means for improvement.

Training and Education

Training and education are an investment and should be a never-ending activity. It provides the necessary skills and knowledge—the ability to make a process happen. In addition to providing job skills, process understanding, and improvement, customer orientation must be a part of the training and education activity.

Customer Orientation

The ultimate result of all the processes in an organization should be achieving customer satisfaction or delight. In case of any confusion while working on the TQM, it is essential to cross-check whether customer satisfaction is achieved and that continuous improvement is institutionalized in the organization.

Table 2.1 shows a short comparison between traditional management and TQM.[5]

Quality and Costs

It is a general belief that high quality costs more, which is a big misconception. When the focus is on quality improvement, rejections, customer returns, warranty claims, material savings, waste and scrap, and many other types of wastes are reduced directly or indirectly. The implementation of TQM saves costs, improves profitability, and gives a competitive position.

Cost of Poor Quality

Car makers, television manufacturers, banks, hospitals, airlines, couriers, electricity boards, and municipalities afflict the public with poor quality and high costs. Frequent failures to do things correctly the first time adds to this situation. The burden that poor quality imposes on the society is probably incalculable. Companies estimate that poor quality costs them about 3% or 5% of sales;

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however, it is actually calculated at around 20–30% of the cost. In addition to costs, failures also impact company image and customer confidence leading to market share reduction.

According to Dr JM Juran, the costs of poor quality (**Fig. 2.2**) can be generally classified into four broad categories.[1,5]

1. *Internal failure costs*: Scrap, rework, failure analysis, reinspection, retesting, avoidable process losses, and down-grading.
2. *External failure costs*: Warranty charges, complaint adjustment, returned material, and concessions.
3. *Appraisal costs*: Incoming inspection and testing, in-process inspection and testing, final inspection and testing, product quality audits, maintaining accuracy of testing equipment, and evaluation of stocks.
4. *Prevention costs*: Quality planning, new-product review, process control, quality audits, supplier quality evaluation, and training. Prevention costs are incurred to keep failure and appraisal costs to a minimum.

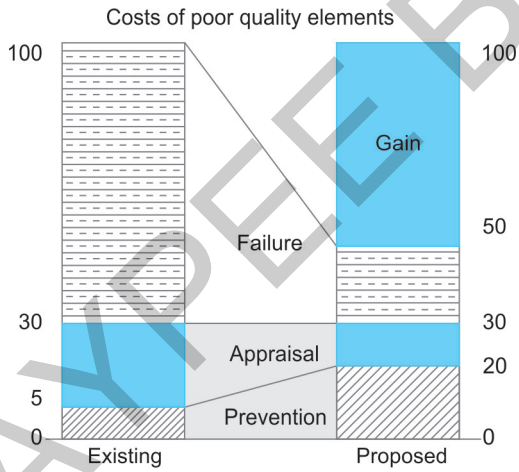

FIG. 2.2: Costs of poor-quality elements.

Source: World Class Quality by Ajit Singh, published by ASSOCHAM.

Quality and Productivity

Productivity is defined as a ratio of output to input. When the quality of output improves, its value becomes higher, leading to increased productivity. When rejections, rework, and waste are reduced, inputs are reduced. This action also leads to enhancement of productivity.

$$\text{Productivity} = \frac{\text{Output}}{\text{Input}}$$

The value of output is higher when quality improves, and input (costs) is reduced by reducing rejection, rework, and waste. Waste in any form is the prime enemy of quality and productivity.

Role of Technology in Quality

Technology has become an integral part of medicine today. The right *technology* can assist with increased efficiency and *improved quality*. Technology has played a vital role in quality initiatives as follows:

- The surgeon requires precision in his or her hands while performing an operation. Today, the quality of the operation can be improved by robot-assisted surgery. The surgeon can carry out a surgery with more precision than before, leading to better quality surgery and increased patient safety.
- Robots can perform processes in hazardous working conditions which are unfavorable for humans. Drones can be used for fumigation and delivery of medicines in critical situations.
- Technology increases access to care, improves safety, makes test results more reliable, and helps teams communicate

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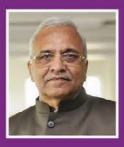

Girdhar J Gyani PhD FIE MCSI is the Director General of Association of Healthcare Providers - India (AHPI) with over five decades of experience in administration, research, and quality. He is widely recognized as the founder of healthcare quality in India. During his tenure as Secretary General of the Quality Council of India, Dr Gyani played a pivotal role in the creation of National Accreditation Board for Hospitals and Healthcare Providers (NABH). He also pioneered quality accreditation in varied disciplines such as public services, school education, environment, food safety and the manufacturing sector. SME World Magazine in the cover story of its June 2012 issue, described Dr Gyani as the "Quality Man of India."



Alexander Thomas MS (Orth) MPhil PGDMLE President of AHPI, President of the Association of National Board Accredited Institutions (ANBAI), and Founder-President (2012-2017) and Patron of the Consortium of Accredited Healthcare Organizations (CAHO), has effected far-reaching policy changes within the healthcare landscape. He led the expert group on medical education for the National Education Policy 2019 headed by Dr Kasturirangan, created national coalitions [with the Indian Medical Association (IMA)], the think tank on health (with NLSIU), and liaised between government and health stakeholders during the COVID-19 pandemic. He has served on committees of the Union Health Ministry, NABH, HSSC, CII, FICCI, UNESCO, PHFI, and NBE. He has several publications to his credit, including *Communicate. Care. Cure. A Guide to Healthcare Communication*, India's first book on the subject.

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