Chapter-1

INTRODUCTION

Good health, responsiveness to the expectations of its people, and financial contribution to the nation are the goals for health care systems of a country (WHO, 2000). An overview of the health scenario all over the world indicates that despite having numerous excellent health care facilities, there exists a sufficiently large gap between the demand and delivery. In India, for example, nearly one million people die every year due to inadequate health care and two-third population is deprived of specialist care (Article 1, 2009). The healthy life expectancy at birth in India is reported to be 58 years, whereas, the general life expectancy at birth has been 64 years. According to the latest data available, India spends US$ 29 per capita on health with only 6 physicians available per 10,000 persons (GHO, 2009).

In the United States of America too the health care systems do not deliver equivalent to what is spent on them. The issues like right to health care, access, fairness, efficiency, cost, and quality are still being debated in the country (Article 2, 2010). A sum of US$ 6719 per capita is being spent on health in the USA and 26 physicians are serving per 10,000 population. On an average people live a healthy life for 70 years in this country, whereas, the life expectancy at birth is worked out as 78 years (GHO, 2009). The Islamic Republic of Iran, another country under study, lies in between India and the USA on these health indicators. The global health observatory (GHO, 2009) reports a per capita expenditure of US$ 215 on health in Iran. The life expectancy at birth and that for healthy people have been 72 years and 61 years, respectively. There are nine physicians working for every 10,000 persons (GHO, 2009).

With increasing competition, advances in medical sciences, and rising patient expectations, the health care systems have become complex organizations. They need to obtain an optimum balance between the resources and patient satisfaction. Total quality management (TQM) has shown a great potential to solve quality problems and make
health care more affordable. Experiences from all over including the United States and Europe are evidence to this fact (Øvretveit, 2000).

In this chapter, an introduction of total quality management, organizational excellence, ISO 9000, and health care systems of the three countries is presented to develop an understanding of the theme of this thesis.

1.1 Total Quality Management

Total quality management (TQM) is a philosophy aimed at continuously improving the quality and process to achieve customer satisfaction. Simply stated, it is the building of quality into products and process making quality a concern and responsibility for everyone in the organization (Stevenson, 2005; www.tqe.com). TQM provides a framework (Figure-1.1) to integrate the principles, methods, and best practices for organizations to strive for excellence in everything they do (www.tqe.com). Customer is the focal point of any TQM approach. Processes are designed and improved to build the required quality into the product. As the customer requirements and expectations are not stationary, TQM emphasizes on periodic reviews and improvements. The following definition of TQM (Juran, 1995) further describes its focus and approach: the system of activities directed at achieving delighted customers, empowered employees, higher revenues, and reduced costs.

![TQM Model](image)

[Figure-1.1: TQM Framework]

The customer-supplier interfaces at different stages of purchasing, manufacturing, and selling are the core of TQM (www.businessballs.com). A supplier is the one who supplies goods, services, parts or materials to someone who is referred to as the
customer-internal or external. TQM integrates the key components of an organization-people, processes, and systems to achieve quality interfaces between suppliers and customers. TQM is described as a culture which needs commitment at all levels, particularly at the top management level, and an effective communication channel to operate within and outside the organization (Figure-1.2).

TQM is an approach to improving the competitiveness, effectiveness and flexibility of an organisation for the benefit of all stakeholders. It is a way of planning, organising and understanding each activity, and of removing all the wasted effort and energy that is routinely spent in organisations. It ensures the leaders adopt a strategic overview of quality and focus on prevention not detection of problems (www.businessballs.com). Whilst it must involve everyone, to be successful, it must start at the top with the leaders of the organisation.

All senior managers must demonstrate their seriousness and commitment to quality, and middle managers must, as well as demonstrating their commitment, ensure they communicate the principles, strategies and benefits to the people for whom they have responsibility. Only then will the right attitudes spread throughout the organisation.

A fundamental requirement is a sound quality policy, supported by plans and facilities to implement it. Leaders must take responsibility for preparing, reviewing and monitoring the policy, plus take part in regular improvements of it and ensure it is understood at all levels of the organisation.
Effective leadership starts with the development of a mission statement, followed by a strategy, which is translated into action plans down through the organisation. These, combined with a TQM approach, should result in a quality organisation, with satisfied customers and good business results. The 5 requirements for effective leadership are given below.

- Developing and publishing corporate beliefs, values and objectives, often as a mission statement.
- Personal involvement and acting as role models for a culture of total quality.
- Developing clear and effective strategies and supporting plans for achieving the mission and objectives.
- Reviewing and improving the management system.
- Communicating, motivating and supporting people and encouraging effective employee participation.

Everything we do is a Process, which is the transformation of a set of inputs, which can include action, methods and operations, into the desired outputs, which satisfy the customers’ needs and expectations. In each area or function within an organisation there will be many processes taking place, and each can be analysed by an examination of the inputs and outputs to determine the action necessary to improve quality.

In every organisation there are some very large processes, which are groups of smaller processes, called key or core business processes. These must be carried out well if an organisation is to achieve its mission and objectives. The section on processes discusses processes and how to improve them, and Implementation covers how to prioritise and select the right process for improvement.

The only point at which true responsibility for performance and quality can lie is with the people who actually do the job or carry out the process, each of which has one or several suppliers and customers.

An efficient and effective way to tackle process or quality improvement is through teamwork. However, people will not engage in improvement activities without commitment and recognition from the organisation’s leaders, a climate for
improvement and a strategy that is implemented thoughtfully and effectively. The section on people expands on these issues, covering roles within teams, team selection and development and models for successful teamwork.

An appropriate documented quality management system will help an organisation not only achieve the objectives set out in its policy and strategy, but also, and equally importantly, sustain and build upon them. It is imperative that the leaders take responsibility for the adoption and documentation of an appropriate management system in their organisation if they are serious about the quality journey. The Systems section discusses the benefits of having such a system, how to set one up and successfully implement it.

Once the strategic direction for the organisation’s quality journey has been set, it needs performance measures to monitor and control the journey, and to ensure the desired level of performance is being achieved and sustained. They can, and should be, established at all levels in the organisation, ideally being cascaded down and most effectively undertaken as team activities and this is discussed in the section on performance.

Organisations operating at international levels, particularly in the manufacturing sector, have used quality as a vital factor to success (Zakuan et al., 2010). Service sector, on the other hand, is found lagging behind in effectively implementing the TQM practices (Yasin et al., 2004; Samat et al., 2006). The situation worsens further when we look at the services, like health care, that are directed at customers (Khamalah and Lingaraj, 2003). Apart from various industry-specific factors, Yasin et al. (2004) have found lack of commitment towards TQM implementation as a major factor responsible for poor results of TQM in service industries. Samat et al. (2006) have conducted a study on service organizations in Malaysia to explore the relationship between total quality management (TQM) practices and service quality. They report that employee empowerment, information and communication, customer focus, and continuous improvement had a significant effect on service quality.
Total quality management has been considered as one of the models for operational excellence. Organizations are reported to implement TQM as a strategy to achieve competitive advantage.

1.2 Organizational Excellence (OE)
The term organizational excellence appears to be used as a synonym of business excellence in the quality-related literature. Tracing the evolution of organizational excellence as a concept, McAdam (2000) reports that activities directed towards organisational excellence gained momentum in the early 1990s after the advent of quality awards like European Quality Award and Malcolm Baldrige Award. This has been defined as a key stage on the TQM journey and measures the effectiveness of TQM implementation (McAdam, 2000).

The Pillars of Organizational Excellence

Value to all Stakeholders

Performance Excellence

Structured, Innovative Management

[Figure-1.3: Five Pillars of Organisational Excellence]

The European Foundation for Quality Management (EFQM) describes excellent organizations as the ones which achieve and sustain superior levels of performance that meet or exceed the expectations of all their stakeholders (www.efqm.org). Innovation, systems, technology, benchmarking, leadership, people, and culture form the foundation for achieving such excellence (Law, 2003). Harrington (2005) has
proposed five pillars (Figure-1.3) to support organizational excellence. He argues that organizations must manage these pillars simultaneously in order to excel in their operations.

Organizational excellence is designed to permanently change an organization by focusing on the five important business pillars. Learning to manage them together is the key to success in the endless pursuit of improved performance (Harrington, 2005).

**Process management:** The process management concept certainly is not new to management professionals; it is the basis of most improvement methodologies. A process is a series of interconnected activities that take input, add value to it and produce output. It is how organizations do their day-to-day routines. Your organization's processes define how it operates. In order to manage a process, the following must be defined and agreed on.

(a) An output requirement statement between process owners and customers.
(b) An input requirement statement between process owners and suppliers.
(c) A process that is capable of transforming the suppliers' input into output that meets the customers' performance and quality requirements.
(d) Feedback measurement systems between process and customers, and between process and suppliers.
(e) The process must be understood.
(f) A measurement system within the process.

These six key factors should be addressed when designing a process. However, the problem facing most organizations is that many of their support processes were never designed in the first place. They were created in response to a need without really understanding what a process is. There are two basic approaches to managing processes.

(a) The micro-level approach that is directed at managing processes within a natural work team or an individual department.
(b) The macro-level approach that is directed at managing processes that flow across departments and/or functions within the organization.
Most of the work that quality professionals do is related to continuously improving our processes. Some of the tools we use include design of experiments, process capability studies, root cause analysis, document control, quality circles, suggestions, Six Sigma, Shewhart's cycles, ISO 9000, just-in-time manufacturing and supplier qualification, among many others.

Management in excellent organizations requires each natural work team (department) to continuously improve (refine) the processes they use. Refining the process is an ongoing activity. If the refinement process is working, as it should, the total process' efficiency and effectiveness should be improving at a rate of 10 to 15 percent a year. In most cases the process team focuses on the broad problems that reflect across departments and reap this harvest within two to three months. At that time the process team can be disbanded and the process refinement activities turned over to the natural work teams that are involved in the process.

**Project management**: Processes define how organizations function and projects are the means by which organizations improve those processes. A project is defined as a temporary endeavor undertaken to create a unique product or service. There are endless numbers of examples of poor project management.

Projects in most organizations are mission-critical activities and delivering quality products on time is non-negotiable. Even in IT projects, things have changed. The benchmark organizations are completing 90 percent of their projects within 10 percent of budget and on schedule. Information systems organizations that establish standards for project management, including a project office, cuts their major project cost overruns, delays, and cancellations by 50 percent.

Process redesign and process reengineering are two of the most important projects that organizations undertake. Even so, these types of projects have a failure rate estimated to be as high as 60 percent. There are two main causes for these high cost failures: poor project management and poor change management. Following points describe the reasons for project failure.

(a) Failure to adhere to committed schedule caused by variances, exceptions, poor planning, delays, and scope creep.
(b) Poor utilization of resources like time and skills.
(c) The portfolio of projects were not managed correctly, e.g., the wrong projects selected, high risk projects were not identified, and poor control over interdependencies between projects.
(d) Loss of intellectual capital/knowledge capital, like lack of the means to transfer knowledge, and people leave the organization.
(e) Not preparing the people who will use the output from the project.

The project management body of knowledge (PMBOK) defines 69 different tools that a project manager needs to master. Few of the project managers that I have come in contact with over the past fifty years have mastered all of these tools. In today's complex world most organizations have numerous projects going on at the same time. Many of these projects are interlinked and interdependent. Their requirements and schedules are continuously changing, causing a chain reaction through the organization. As a result, the organization cannot afford to manage each project one at a time. They have to manage their portfolio of projects, making the proper trade off of personnel and priorities.

Change management: Change is inevitable and we must embrace it if we are going to be successful in this challenging world we live in. Change management system is made up of the following three distinct elements.
   (a) Defining what will be changed.
   (b) Defining how to change.
   (c) Making the change to happen.

Most of the books written to date about change management have been theoretical in nature. They talked about black holes, cascading sponsorships, and burning platforms, but that is only the last phase of the change process. Most organizations have not understood or followed a comprehensive change management system.

An effective change management system requires that the organization step back and define what will be changed. By that, we are not talking about reducing stock levels, increasing customer satisfaction, or training people; we are talking about the very fundamentals. Which of the key business drivers need to be changed and how do they need to be changed? That means that you need to develop very crisp vision statements that define how the key business drivers will be changed over time. This requires that
the organization have an excellent understanding of what its business drivers are and how they are operating today. Then the organization must define exactly how it wants to change these key business drivers over a set period of time.

Once the organization has defined what it wants to change, then it can define how to change. During this stage the organization looks at the more than 1,100 different improvement tools that are available today and determines which tools will bring about the required changes to these key business drivers and schedule the implementation of these tools and methodologies. This schedule will make up a key part of the organization's strategic business plan.

The last phase in the change management process is making the change happen. This is the area where the behavioral scientists have developed a number of excellent approaches to breakdown resistance and build up resiliency throughout the organization. It is this phase that most change management books have concentrated on, but it is the last phase in the total change management system.

**Knowledge management:** Today, more than ever, knowledge is the key to organizational success. In order to fulfill this need, the Internet and other IT technology have provided all of us with more information than we can ever consume. Instead of having one or two sources of information, the Internet provides us with hundreds, if not thousands, of inputs, all of which need to be researched to be sure you have not missed a key nugget of information. We are overwhelmed with so much information that we don't have time to absorb it.

To make it worse, most of the organization's knowledge is still not documented; it rests in the minds and experiences of the people doing the job. This knowledge disappears from the organization's knowledge base whenever an individual leaves an assignment. Effective corporations define how to establish a knowledge management system designed to sort out unneeded information and capture the "soft" knowledge needed to run the organization. With the almost endless amount of information that clouds up our computers, desks, and minds, a knowledge management system needs to be designed around the organization's key capabilities and competencies.
Knowledge is defined as a mixture of experiences, practices, traditions, values, contextual information, expert insight, and a sound intuition that provides an environment and framework for evaluation and incorporating new experiences and information. There are two types of knowledge—explicit and tacit. Explicit knowledge is defined as knowledge that is stored in a semi-structured content such as documents, e-mail, voicemail, or video media. I like to call this hard or tangible knowledge. It is conveyed from one person to another in a systematic way.

Tacit knowledge is defined as knowledge that is formed around intangible factors embedded in individual's experience. It is personal, content-specific knowledge that resides in an individual. It is knowledge that an individual gains from experience or skills that he or she develops. It often takes the form of beliefs, values, principles, and morals. It guides the individual's actions. I like to call this soft knowledge. It is embedded in the individual's ideas, insights, values, and judgment. It is only accessible through the direct corroboration and communication with the individual that has the knowledge.

Knowledge management is defined as a proactive, systematic process by which value is generated from intellectual or knowledge-based assets and disseminated to the stakeholders. There are six phases required to implement an effective knowledge management system. These phases are as follows.

(a) Phase I - Requirements definition.
(b) Phase II - Infrastructure evaluation.
(c) Phase III - KMS design and development.
(d) Phase IV - Pilot.
(e) Phase V - Deployment.
(f) Phase VI - Continuous improvement.

One of the biggest challenges related to implementing a knowledge management system is transferring knowledge held by individuals, including processes and behavioral knowledge, into a consistent format that can be easily shared within the organization. But an even bigger challenge is changing the organization's culture from a knowledge-hoarding one to a knowledge-sharing culture.
The true standard of success for knowledge management is the number of people who access and implement ideas from the knowledge networks. Those bring state of the art ideas and/or best practices into one place and time, thereby collapsing the organization into areas of critical mass that imply standardization for ideas that work, and everyone can make comments to improve those standards. Even the newest novice to the organization can look at the materials and make recommendations based on personal insight, creativity, and experience.

A big challenge related to implementing a KMS is in transforming knowledge held by individuals, including processes' and behaviors' knowledge, into a consistent technology format that can be easily shared with the organization's stakeholders. But the biggest challenge is changing the organization's culture from a knowledge hoarding one to a knowledge sharing culture.

**Resource management:** Even the best ideas need resources to transform them into Profit. Nothing can be accomplished without resources. Resources are at the heart of everything we do - too little and we fail, too much and there is waste, making our organization not competitive. Too many organizations limit their thinking about resources to people and money. These two are important, but they are only a small part of the resources that an organization needs to manage. Effective corporations look at all of the resources that are available to an organization and how to manage them effectively.

In its broadest sense, resource management includes all the resources and assets that are available to the organization. It will include stockholders, management, employees, money, suppliers, inventory, boards of directors, alliance partnerships, real estate, knowledge, customers, patents, investors, good will, and brick and mortar. It is easy to see that when you consider all of the resources that are available to the organization, effective resource management is one of the most critical, complex activities within any organization.

Each of these resources needs to be managed in their own special way in order to become an excellent organization. The big question is, “How do you pull all these different activities and improvement approaches together and prioritize them?”
In order to answer this question, companies must adopt a total involvement approach to strategic planning one that involves everyone from the chairman of the board to the janitor, from sales to personnel, from development engineering to maintenance. Yes, this is a total involvement approach to strategic planning; it is both bottom up and top down.

Resource management cannot be an after thought. It must be the basis that all executive decisions are based on. It requires a lot of planning, coordination, reporting, and continuous refining to do an excellent job at resource management. Too many organizations manage the operations by throwing more resources into the pot. They may be very successful with this approach as long as they have very little competition, but even the giants fall if they do not do an outstanding job of resource management.

While we looked at the five pillars that must be managed to achieve excellence, there are a number of things that run across all of them. For example, communication, teamwork, empowerment, respect for one another, honesty, leadership, quality, fairness, and technology.

All of the key factors are built into the word management. It is all the things that turn an employee into an individual that own his or her job, thereby bringing satisfaction and dignity to the individual for a job well done. According to Jack Welsh, former CEO of General Electric, “The essence of competitiveness is liberated when we make people believe that what they think and do is important and then get out of their way while they do it”.

In today's worldwide marketplace customers do not have to settle for second best. Overnight mail brings the best to everyone's doorstep. The Internet lets your customers shop internationally so it is easy for them to get the best quality, reliability, and price, no matter who is offering it. Customers are concerned about the products they purchase, but they are equally or more concerned about dealing with organizations who care, who are quick to respond, and who will listen and react to their unique needs. This demands that, in order to succeed in the twenty-first century,
organizations need to excel in all parts of their business. You must have an organization that excels at what it is doing, but also is recognized for its excellence to win today's savvy customers.

1.3 TQM and Organisational Excellence in Health Care
Kelley and Hurst (2006), in their project on health care quality indicators, refer to the manual of Organisation for Economic Cooperation and Development (OECD) and Institute of Medicine (IOM) to define the quality of health care as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge”. Donabedian (2003) has proposed the following three categories of various quality indicators pertaining to health care.

(a) **Structure indicators** (such as whether doctors are suitably qualified and whether hospitals are appropriately equipped) represent indicators of the characteristics of, or inputs to, health care. They may represent necessary conditions for the delivery of a given quality of health care but they are not sufficient. Their presence does not ensure that appropriate processes are carried out or that satisfactory outcomes are achieved by the health system.

(b) **Process indicators** (such as whether children are immunised appropriately, whether, for those at risk, patients’ blood pressure is checked regularly by a physician) represent measures of the delivery of appropriate (or inappropriate) health care to the relevant population at risk – where appropriateness should be based on clinical evidence of the effectiveness of the process concerned and ‘consistent with current professional knowledge’ (IOM, 2001). Of concern with process indicators is the degree to which these measures are related to clinically desirable outcomes. In addition, there is some concern that process indicators are more vulnerable to gaming than outcome or structure measures. However, process measures represent the closest approximation of actual health care offered and are the most clinically specific of the three types of indicators.

(c) **Outcome indicators** (such as rates of hospital-acquired infections or rates of 1 year survival following acute myocardial infarction) seek to represent
measures of health improvements (or deterioration) attributable to medical care. The main challenge to outcome indicators is that they may be influenced by other factors but quality of care.

With particular reference to the health care organizations, quality has contributed positively in improving the performance. While analyzing the hospital performance, Prior (2006) finds an improvement in the productivity index and technical change when quality is introduced in the analysis as a variable. The literature pertaining to quality in health care reveals that management support was the prime reason for success of TQM in health care, and lack of such support was the usual reason for its failure. Other important factors for TQM implementation include resources, training, reward programs, and involvement of all employees (Reeves and Bednar, 1993). The study by Reeves and Bednar (1993) also identifies unclear TQM goals and inadequate training in TQM as additional barriers to TQM implementation and its success in health care organizations.

The Malcolm Baldrige criteria for performance excellence in health care organizations define (NIST, 2010) performance excellence as an integrated approach to organizational performance management that results in (a) delivery of ever-improving value to patients and stakeholders, contributing to improved health care quality and organizational sustainability, (b) improvement of overall organizational effectiveness and capabilities as a health care provider, and (c) organizational and personal learning.

This criteria address four types of performance- health care processes and outcomes; patient- and stakeholder-focused; financial and marketplace; and operational. The health care process and outcome performance refers to performance relative to measures and indicators of health care delivery important to patients and stakeholders. Examples of health care performance include reductions in hospital admission rates, mortality and morbidity rates, nosocomial infection rates, length of hospital stays, and patient-experienced error levels, as well as improvements in functional status. Other examples include increases in outside-the-hospital treatment of chronic conditions, culturally sensitive care, and patient compliance and adherence. Health care performance might be measured at the organizational level, the DRG-specific level,
and the patient- and stakeholder-segment level. The patient- and stakeholder-focused performance refers to performance relative to measures and indicators of patients’ and stakeholders’ perceptions, reactions, and behaviors. Examples include patient loyalty, complaints, and survey results. The third component of performance, financial and marketplace performance refers to performance relative to measures of cost, revenue, and market position, including asset utilization, asset growth, and market share. Examples include returns on investments, value added per staff member, bond ratings, debt-to-equity ratio, returns on assets, operating margins, performance to budget, the amount in reserve funds, days cash on hand, other profitability and liquidity measures, and market gains. The operational performance refers to workforce, leadership, organizational, and ethical performance relative to effectiveness, efficiency, and accountability measures and indicators. Examples include cycle time, productivity, waste reduction, workforce turnover, workforce cross-training rates, accreditation results, regulatory compliance, fiscal accountability, community involvement, and contributions to community health. Operational performance might be measured at the department and work unit level, key work process level, and organizational level (NIST, 2010).

The American Hospital Association (AHA, 2009) provides a framework “Hospitals in Pursuit of Excellence” (HPE) for hospitals to excel in their performance that also includes a few successful cases of such hospitals. The case studies in this guide illustrate that applying the principles of performance excellence can produce substantial patient and operational value and help hospitals deliver care that meets the six aims of for Improvement - care that is safe, timely, effective, efficient, equitable and patient-centered. These six aims evolved by the Institute of Medicine (IOC) are popularly known as the 6 IOM aims and are abbreviated as STEEEP.

Hospitals in Pursuit of Excellence is a permanent activity of the American Hospital Association. It provides an ever-expanding portfolio of resources to help hospital leaders, clinicians and staff accelerate the transformation of care and support processes to meet the 6 IOM aims. The mission is to bring field-tested practices, proven strategies, tools and education to engage, support and advance hospital leaders’ ongoing efforts to improve the patient experience and outcomes. The goal is to smooth the path for hospitals to achieve excellence in clinical, operational and
financial performance. This effort brings to bear the power of the AHA’s connection to its more than 5,000 member hospitals, health systems and other health care organizations; its partners, such as state and allied hospital associations; and its 38,000 individual members. With these resources at hand, Hospitals in Pursuit of Excellence will shine the light on practices that have proven successful in helping hospital leaders transform their organizations into high-performing, highly reliable providers of care. Hospitals in Pursuit of Excellence is NOT about adding more requirements for hospitals and health systems. Rather, it is designed to enable hospital leaders to easily understand and access coherent and proven strategies for implementing systemic improvements and for advancing specific practices in clinical and operational areas that have already been identified as keys to progress. It IS about building hospitals’ capacity to internally improve and bring better results to their patients and communities. The cornerstone of Hospitals in Pursuit of Excellence is the 6 IOM aims. With an approach that emphasizes systems thinking and process management, this effort seeks to help hospitals reduce waste and inefficiency, optimize the use of resources, and enhance their ability to deliver safe, high-quality and affordable patient care. Hospital leaders can achieve these goals by applying the following principles of performance excellence.

(a) **Perfect the patient experience**: Care must be respectful of, and responsive to, individual preferences, needs and values.

(b) **Create a high-reliability culture**: Organizational cultures must embrace the transformation of hospitals into places where each patient receives the best quality care, every single time.

(c) **Manage organizational variability**: Some variables, such as scheduling of elective surgery, can be smoothed out to achieve more even patient flow.

(d) **Remove waste**: This includes removing inefficiencies, such as unnecessary process steps, and can have a direct, positive impact on the bottom line.

(e) **Eliminate defects**: Finding and resolving problem points will result in greater efficiency and better health outcomes.

(f) **Reduce process variation**: Using quality tools and frameworks can increase consistency and reduce errors in both the clinical delivery of care and the policies and procedures that support care.
Applying these principles to specific areas that have proven to have a significant impact on the patient experience and outcomes can help hospitals and health systems provide care that meets the 6 IOM aims.

A hospital’s efforts to improve quality, safety, service and overall organizational performance are measured in years, not weeks or months. It is a journey that never ends. The ultimate goal never changes—care that is safe, timely, effective, efficient, equitable and patient-centered. Successful improvement efforts focus on specific areas of hospital care and operations that have proven to yield some of the greatest opportunities for improvement.

1.4 ISO 9000 and Health Care

The International Organization for Standardization (ISO) was established in 1947 and is a network of the national standards institutes of 163 countries, one member per country, with its central secretariat in Geneva, Switzerland, that coordinates the system. ISO is a non-governmental organization that forms a bridge between the public and private sectors. On one hand, many of its member institutes are part of the governmental structure of their countries, or are mandated by their government. Moreover, other members have their roots uniquely in the private sector, having been set up by national partnerships of industry associations. Therefore, ISO enables a consensus to be reached on solutions that meet both the requirements of business and the broader needs of society (www.iso.org).

The goal of the ISO is to facilitate the international exchange of goods and services, and to develop cooperation in the spheres of intellectual, scientific, technological and economic activity. The work of ISO results in international agreements, which are published as International Standards. ISO 9000, the first international quality management system standard with a registration scheme, was issued in 1987. It has had a great impact on manufacturing industries, establishing the framework required for effective and efficient quality assurance and quality management systems. It does not apply to any specific technical specification for products, but does apply to every type of industry and service. As a result of its applicability to a variety of organizations, it has also gained widespread attention in service organizations.
ISO 9000 family of standards demonstrates how, collectively, they form a basis for continual improvement and business excellence.

The ISO Series can form the means by which a holistic management system can be implemented, into which quality, health and safety and environmental responsibility can be integrated, with the audits carried out either separately or in combination. The ISO Standard is also now more closely aligned with the requirements of the EFQM excellence model (www.businessballs.com). ISO 9000 contains the following eight quality management principles, upon which to base an efficient, effective and adaptable quality management system (QMS). They are applicable throughout industry, commerce and the service sectors- customer focus, leadership, involving people, process approach, systems approach, continual improvement, factual decision making, and mutually beneficial supplier relationships.

The latest version of the standards (ISO 9000:2008) consists of the following three documents.

- ISO 9000:2008 – Fundamentals and vocabulary
- ISO 9001:2008 – Requirements
- ISO 9004:2008 – Guidelines for performance improvement

ISO 9001 is used when an organisation is seeking to establish a quality management system that provides confidence in the organization’s ability to provide products that fulfil customer needs and expectations. ISO 9004 is used to extend the benefits obtained from ISO 9001 to all parties that are interested in or affected by your operations. Interested parties include your employees, owners, suppliers, partners and society in general.

ISO 9001 and ISO 9004 are compatible and can be used separately or in combination to meet or exceed expectations of customers and interested parties (www.iso.org). Both standards apply a process approach. Processes are recognized as consisting of one or more linked activities that require resources and must be managed to achieve predetermined output. The output of one process may directly form the input to the next process and the final product is often the result of a network or system of
processes. The eight quality management principles provide the basis for the performance improvement.

To provide additional guidance to the health care industry, a document known as IWA-1, was published by the ISO International Workshop Agreement in the year 2001. The objective of this additional ISO standard is the systematic pursuit of process improvement in order to attain continual improvement, the prevention of error and other adverse outcomes, and the reduction of variation and organizational "waste", such as non-value added activities (Frost, 2006). This has been found that the generalized implementation of ISO 9001 quality management systems by health care establishments is seen as an opportunity to improve the quality of health care while reducing the costs. The IWA-1 includes much of the text ISO 9004 supplemented by text specifically aimed at assisting health service organizations to implement a QMS, regardless of whether they decide to pursue certification to ISO 9001. The major outcomes of implementing the IWA-1 in conjunction with ISO 9000, as reported by different health care organizations include the following (Frost, 2006).

- Fewer patient requests to meet the patient counsellor
- A largely positive attitude to quality among personnel
- Less variation in work practices, treatment methods and services
- Fewer national insurance compensation claims against treatment errors
- Improved statistical follow-up on quality indicators
- Better control and calibration of measurement devices
- Elimination of redundancies and improved efficiency
- Improved employee satisfaction
- Increased performance and service quality.

1.5 Health Care in India, Iran and the United States

This section presents an overview of the health care policies, networks and infrastructure of India and Iran, the two countries under study, as well as that of the United States of America, the benchmark for the present work.

Health Care in India: The National Health Policy 2002 aims at achieving an acceptable standard of health for the general population of the country. Keeping in
line with this broad objective, the Eleventh Five Year Plan had set upon itself the goal of achieving good health for the people, especially the poor and the underprivileged. To achieve the objective, a comprehensive approach was advocated, which included improvements in individual health care, public health, sanitation, clean drinking water, access to food and knowledge of hygiene and feeding practices. Importance was accorded to reducing disparities in health across regions and communities by ensuring access to affordable health (Rao, 2010).

An assessment of the performance of the country’s health related indicators depicts that significant gains have been made in them e.g. life expectancy at birth, child and maternal mortality, among others.

There has been a steady increase in the allocations made for the Health Sector. The allocations for Ministry of Health & Family Welfare registered substantial step up during the 11th Plan with an outlay of Rs. 140135 crore as against the actual expenditure of Rs. 36079 crore during the 10th Plan, registering nearly a 4 fold increase.

Conscious and vigorous efforts continued to be made during the current year to step up funding of the health sector as part of our endeavor to ensure that allocations for health in the public domain reach 3 per cent of the GDP by 2012.

Keeping in view the federal nature of the Constitution, areas of operation have been divided between Union Government and State Governments. Seventh Schedule of Constitution describes three exhaustive lists of items, namely, Union list, State list and Concurrent list. Though some items like Public Health, hospitals, sanitation, etc. fall in the State list, the items having wider ramifications at the national level like population control and family welfare, medical education, prevention of food adulteration, quality control in manufacture of drugs etc. have been included in the Concurrent list.

The country has a well structured 3-tier public health infrastructure, comprising Community Health Centres, Primary Health Centres and Sub- Centres spread across
rural and semi-urban areas and tertiary medical care providing multi-Speciality hospitals and medical colleges located almost exclusively in the urban areas.

The Ministry of Health & Family Welfare is instrumental and responsible for implementation of various programmes on a national scale in the areas of Health & Family Welfare, prevention and control of major communicable diseases and promotion of traditional and indigenous systems of medicines. Apart from these, the Ministry also assists States in preventing and controlling the spread of seasonal disease outbreaks and epidemics through technical assistance.

Ministry of Health & Family Welfare incurs expenditure either directly under Central Schemes or by way of grants-in-aid to the autonomous/statutory bodies etc. and NGOs. In addition to the 100% centrally sponsored family welfare programme, the Ministry is implementing several World Bank assisted programmes for control of AIDS, Malaria, Leprosy, Tuberculosis and Blindness in designated areas. Besides, State Health Systems Development Projects with World Bank assistance are under implementation in various states. The projects are implemented by the respective State Governments and the Department of Health & Family Welfare only facilitates the States in availing of external assistance. All these schemes aim at fulfilling the national commitment to improve access to Primary Health Care facilities keeping in view the needs of rural areas where the incidence of disease is high. The Ministry of Health & Family Welfare comprises the following departments, each of which is headed by a Secretary to the Government of India.

- Department of Health & Family Welfare
- Department of AYUSH
- Department of Health Research
- Department of AIDS Control

Directorate General of Health Services (Dte.GHS) is an attached office of the Department of Health & Family Welfare and has subordinate offices spread all over the country. The DGHS renders technical advice on all medical and public health matters and is involved in the implementation of various health schemes (Rao, 2010).
The Indian healthcare industry is seen to be growing at a rapid pace and is expected to become a US$280 billion industry by 2020. The Indian healthcare market was estimated at US$35 billion in 2007 and is expected to reach over US$70 billion by 2012 and US$145 billion by 2017. According to the Investment Commission of India, the healthcare sector has experienced phenomenal growth of 12 percent per annum in the last 4 years. Rising income levels and a growing elderly population are all factors that are driving this growth. In addition, changing demographics, disease profiles and the shift from chronic to lifestyle diseases in the country has led to increased spending on healthcare delivery (www.wikipedia.org).

Even so, the vast majority of the country suffers from a poor standard of healthcare infrastructure which has not kept up with the growing economy. Despite having centers of excellence in healthcare delivery, these facilities are limited and are inadequate in meeting the current healthcare demands. Nearly one million Indians die every year due to inadequate healthcare facilities and 700 million people have no access to specialist care and 80% of specialists live in urban areas.

In order to meet manpower shortages and reach world standards India would require investments of up to $20 billion over the next 5 years. Forty percent of the primary health centers in India are understaffed. According to WHO statistics there are over 250 medical colleges in the modern system of medicine and over 400 in the Indian system of medicine and homeopathy (ISM&H). India produces over 250,000 doctors annually in the modern system of medicine and a similar number of ISM&H practitioners, nurses and para professionals. Better policy regulations and the establishment of public private partnerships are possible solutions to the problem of manpower shortage.

India faces a huge need gap in terms of availability of number of hospital beds per 1000 population. With a world average of 3.96 hospital beds per 1000 population India stands just a little over 0.7 hospital beds per 1000 population. Moreover, India faces a shortage of doctors, nurses and paramedics that are needed to propel the growing healthcare industry. India is now looking at establishing academic medical centers (AMCs) for the delivery of higher quality care with leading examples of The Manipal Group & All India Institute of Medical Sciences (AIIMS) already in place.
As incomes rise and the number of available financing options in terms of health insurance policies increase, consumers become more and more engaged in making informed decisions about their health and are well aware of the costs associated with those decisions. In order to remain competitive, healthcare providers are now not only looking at improving operational efficiency but are also looking at ways of enhancing patient experience overall.

**Health Care in Iran:** The Ministry of Health and Medical Education (MOHME) has executive responsibility for health and medical education within the Iranian government (MOHME, www.wikipedia.org).

Iran's health system is highly centralized, and almost all decisions regarding general goals, policies and allocation of resources are made at the central level by MOHME. The Ministry has the legal authority to oversee, license and regulate the activities of the private health sector.

An elaborate system of health network provides Primary Health Care (PHC) to the vast majority of the Iranian public. MOHME owns and runs Iran's largest health care delivery network of health establishments and medical schools. MOHME is in charge of provision of healthcare services through its network, medical insurance, medical education, supervision and regulation of the healthcare system in the country, policymaking, production and distribution of pharmaceuticals, and research and development.

MOHME has a mission to provide access to sufficient quantities of safe, effective and high quality medicines that are affordable for the entire population. MOHME is the main stakeholder of pharmaceutical affairs in the country. However, the Social Security Investment Co. (SSIC), Iran's largest holding company, which owns and controls 22 pharmaceutical manufacturing companies with a 40% share of total pharmaceutical production in Iran, is affiliated to the Ministry of Welfare.

In 2006, 55 pharmaceutical companies in Iran produce more than 96 percent (quantitatively) of medicines on the market, worth $1.2 billion annually in a total market worth $1.87 billion (2008) and $3.65bn by 2013 (projected). Although over 85
percent of the population use an insurance system to reimburse their drug expenses, the government heavily subsidises pharmaceutical production/importation.

The MOHME Department of Medical Equipment supervises imports of medical equipment, its import and distribution is mostly handled by the private sector.

Health care in Iran and medical sector's market value was almost US $24 billion in 2002 and was forecast to rise to US $31 billion by 2007. With a population of almost 70 million, Iran is one of the most populous countries in the Middle East. The country faces the common problem of other young demographic nations in the region, which is keeping pace with growth of an already huge demand for various public services. The young population will soon be old enough to start new families, which will boost the population growth rate and subsequently the need for public health infrastructures and services. Total healthcare spending is expected to rise from US$24.3bn in 2008, to US$50.0bn by 2013, reflecting the increasing demand on medical services. Total health spending was equivalent to 4.2% of GDP in Iran in 2005. 73% of all Iranians have health care coverage.

The World Health Organization in the last report on health systems ranks Iran's performance on health level 58th, and its overall health system performance 93rd among the world's nations. The health status of Iranians has improved over the last two decades. Iran has been able to extend public health preventive services through the establishment of an extensive Primary Health Care Network. As a result child and maternal mortality rates have fallen significantly, and life expectancy at birth has risen remarkably. Infant (IMR) and under-five (U5MR) mortality have decreased to 28.6 and 35.6 per 1,000 live births respectively in 2000, compared to an IMR of 122 per 1,000 and a U5MR of 191 per 1,000 in 1970. Immunization of children is accessible to most of the urban and rural population.

Ministry of Health and Medical Education (MOHME) through its network of health establishments and medical schools in the country. MOHME is in charge of provision of healthcare services through its network, medical insurance, medical education, supervision and regulation of the healthcare system in the country, policymaking, production and distribution of pharmaceuticals, and research and development. Additionally, there are other parallel organisations such as Medical Services
Insurance Organizations (MSIO) that have been established to act as a relief foundation as well as an insurance firm. Some hospitals, such as Mahak for children's cancer, are run by charitable foundations.

According to the last census that Statistical Centre of Iran undertook in 2003, Iran possesses 730 medical establishments (e.g. hospitals, clinics) with a total of 110,797 beds, of which 488 (77,300 beds) are directly affiliated and run by the MOHME and 120 (11,301 beds) owned by the private sector and the rest belong to other organisations, such as the Social Security Organization of Iran (SSO). There were about seven nurses and 17 hospital beds per 10,000 population.

An elaborate system of health network has been established which has ensured provision of Primary Health Care (PHC) to the vast majority of public. However, access and availability of health care continues to be somewhat limited in lesser developed provinces where the health indices are also lower as compared to national averages. The country is in an epidemiologic transition and faces double burden of the diseases. New emerging threats should also be considered. The demographic and epidemiological transition underway will have a significant effect on the pattern of morbidity and mortality in the near and distance future, especially as it affects the emergence of chronic non-communicable diseases and the health problems of an aging population.

**Health Care in the United States of America:** The Department of Health and Human Services (HHS) is the United States government’s principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves (www.hhs.gov).

HHS represents almost a quarter of all federal outlays, and it administers more grant dollars than all other federal agencies combined. HHS’ Medicare program is the nation’s largest health insurer, handling more than 1 billion claims per year. Medicare and Medicaid together provide health care insurance for one in four Americans.

HHS works closely with state and local governments, and many HHS-funded services are provided at the local level by state or county agencies, or through private sector grantees. The Department’s programs are administered by 11 operating divisions.
including eight agencies in the U.S. Public Health Service and three human services agencies. The department includes more than 300 programs, covering a wide spectrum of activities. In addition to the services they deliver, the HHS programs provide for equitable treatment of beneficiaries nationwide, and they enable the collection of national health and other data.

Departmental leadership is provided by the Office of the Secretary. Also included in the Department is the Office of Public Health and Science, the Office of the HHS Inspector General and the HHS Office for Civil Rights. In addition, the Program Support Center, a self-supporting division of the Department, provides administrative services for HHS and other federal agencies.

Health care in the United States is provided by many separate legal entities. Health care facilities are largely owned and operated by the private sector. Health insurance is primarily provided by the private sector, with the exception of programs such as Medicare, Medicaid, TRICARE, the Children's Health Insurance Program and the Veterans Health Administration (www.wikipedia.org).

In the United States, ownership of the health care system is mainly in private hands, though federal, state, county, and city governments also own certain facilities. The non-profit hospitals share of total hospital capacity has remained relatively stable (about 70%) for decades. There are also privately owned for-profit hospitals as well as government hospitals in some locations, mainly owned by county and city governments.

More money per person is spent on health care in the United States than in any other nation in the world, and a greater percentage of total income in the nation is spent on health care in the U.S. than in any United Nations member state except for East Timor. Despite the fact that not all citizens are covered, the United States has the third highest public healthcare expenditure per capita. A 2001 study in five states found that medical debt contributed to 62% of all personal bankruptcies. Since then, health costs and the numbers of uninsured and underinsured have increased.

Active debate about health care reform in the United States concerns questions of a right to health care, access, fairness, efficiency, cost, and quality. Many have argued
that the system does not deliver equivalent value for the money spent. The US pays twice as much yet lags behind other wealthy nations in such measures as infant mortality and life expectancy, though the relation between these statistics to the system itself is debated. Currently, the U.S. has a higher infant mortality rate than most of the world's industrialized nations. The United States life expectancy lags 42nd in the world, after most rich nations, lagging last of the G5 (Japan, France, Germany, UK, USA) and just after Chile (35th) and Cuba (37th).

The USA's life expectancy is ranked 50th in the world after the European Union (40th). The World Health Organization (WHO), in 2000, ranked the U.S. health care system as the highest in cost, first in responsiveness, 37th in overall performance, and 72nd by overall level of health (among 191 member nations included in the study). The Commonwealth Fund ranked the United States last in the quality of health care among similar countries, and notes U.S. care costs the most by far.

The Institute of Medicine report notes that “Lack of health insurance causes roughly 18,000 unnecessary deaths every year in the United States”, while a 2009 Harvard study published in the American Journal of Public Health found a much higher figure of more than 44,800 excess deaths annually in the United States due to Americans lacking health insurance. More broadly, the total number of people in the United States, whether insured or uninsured, who die because of lack of medical care was estimated in a 1997 analysis to be nearly 100,000 per year. On March 23, 2010, the Patient Protection and Affordable Care Act became law, providing for major changes in health-insurance procedures (www.wikipedia.org).

Different regions in the world have understood and practiced the TQM philosophy with a different pace. Countries and regions like Japan, America, and Europe have taken a lead, whereas, the developing countries like India and Iran are following them. This study is about the TQM practices being implemented in the health care organizations in these two countries for the purpose of organizational excellence. The TQM scenario in the health care of the United States of America has been the benchmark for the study. The chapter that follows (Chapter-2) presents the literature review on the subject.
In this thesis the terms patient, customer, health care services, and performance of health care services shall mean the following as per the Health Care Criteria for Performance Excellence 2009-10, National Institute of Standards and Technology (NIST, 2010, www.baldrige.nist.gov)

**Patient:** Refers to the person receiving health care, including preventive, promotional, acute, chronic, rehabilitative, and all other services in the continuum of care.

**Customer:** Refers to actual and potential users of your organization’s services or programs. Patients are the primary customers of health care organizations. The Criteria address customers broadly, referencing current and future customers, as well as the customers of your competitors and other organizations providing similar health care services or programs.

**Health care services:** Refers to all services delivered by the organization that involve professional clinical/medical judgment, including those delivered to patients and those delivered to the community.

**Performance:** Refers to outputs and their outcomes obtained from processes, health care services, and patients and stakeholders that permit evaluation and comparison relative to goals, standards, past results, and other organizations. Performance can be expressed in non-financial and financial terms. The Baldrige Health Care Criteria address four types of performance: (1) health care processes and outcomes, (2) patient- and stakeholder-focused, (3) financial and marketplace, and (4) operational.

Also, the terms like health care organization, hospital, clinic, health care system, etc. are being used interchangeably in this thesis and they all refer to a single unit providing health care services of inpatient and emergency type.