

# **Chapter –I**

## **Introduction**

This chapter is divided into three sections, the first section introduces the main domain of the research that focuses on quality in healthcare and includes definitions of quality, quality management systems in healthcare and its evolution as a management system for hospitals. The second section describes the significance of quality management system specific to the operation theatre complex and its background. The third section outlines the framework and structure of the thesis.

### **Section- 1**

#### **1.1 Overview of Quality and Quality Management System**

Deregulation and global competition in a number of industries is forcing institutions to turn to quality in order to satisfy their customers. Like other industries hospitals across the globe are also striving for higher quality in their all operational areas. Establishment of quality in hospitals require a robust quality management system that has long term sustainability. However the implementation of a robust Quality Management System is a challenging task in a complex setting like hospital .Even more problematic to sustain the system in the longer term because quality is a very subjective term and must alter with time. Every individual has his or her own meaning of quality. Individualized expectations of stake holders in hospital make the meaning of quality more complicated at the ground level and are specific to the needs of a wide variety of stakeholders. Added to this is the question of focusing on the more critical locations in a hospital such as the Operation Theatres (OT), Intensive care units (ICUs) these are the hot spots in the gamut of management for a safe and quality oriented hospital.

### **1.1.1 Meaning of Quality**

Quality is like beauty that is in the eyes of beholders. Every individual has different meanings and ways of defining beauty, likewise meaning of quality is also highly individualized. Different stake holders perceive quality differently. Care receivers' e.g. patients, care providers, i.e. healthcare providers or healthcare facilities, care givers i.e. healthcare professionals, others e.g, insurance companies, government bodies, accreditation bodies etc. define quality differently. Care receivers or patients and their relatives tend to define quality as affordable clear and simple access to almost everything in the hospital and the ability to see these efforts made to provide care to patients.

The concept and vocabulary of quality is hard to pin down. The Oxford dictionary defines quality as “the degree of excellence of a thing” or “a distinctive attribute or faculty”. The vocabulary jargon associated with Quality is complex. Dictionary definitions are usually inadequate in helping a quality professional to understand the concept. Quality is a very subjective attribute and its interpretation may differ from person to person. For example, purchasers of a product or service may focus on the specifications or how it compares with similar products in the marketplace. Manufacturer of a product/ service might measure the degree to which it was produced correctly. Maintenance personnel may measure quality in the degree that a product / service is dependable or sustainable.

### **1.1.2 Definitions of quality**

The business meanings of quality have developed over time. As per the American Society for Quality (ASQua), “quality is a subjective term for which each person or sector has its own definition”. In technical usage, quality can have two meanings, firstly it defines the characteristics of a product or service that bear on its ability to satisfy stated or implied needs and the second is. a creation of product or service free of deficiencies “Deficiencies in the product

or service causes dissatisfaction among customers. According to Joseph Juran quality means “fitness for use or purpose” this definition of quality evaluates how well the product or service performs for its intended use.” Whereas Philip Crosby means quality as “conformance to requirements”(Divya Singhal &Keshav Ram Singhal, 2012).According to ISO 9000:2005, Quality management systems -- Fundamentals and vocabulary “quality is the degree to which a set of inherent characteristics fulfils requirements."Peter Drucker has described "Quality in a product or service is not what the supplier puts in. It is what the customer gets out and is willing to pay for."According to the Six Sigma philosophy, quality is "Number of defects per million opportunities” whereas lean philosophy defines quality as elimination of waste. The following definition is often used in the quality related literature:

- Quality is a predictable degree of uniformity and dependability at low cost and suited to the market. - Deming (1982 cited in Flood 1993:42)
- Quality is in its essence a way of managing an organisation. – Feigenbaum(1983:6)
- Quality is meeting customer requirements. - Oakland (1989:3)
- Quality is the totality of characteristics of an entity that bear on its ability to satisfy stated or implied needs. - International Standard Definition (ISO8402, 1994: viii)
- Quality is a system of means to economically produce goods or services,which satisfy customer requirements. Japan Industrial Standards (Z8101-1981)

David Gravin potted five principle approach to defining quality as mentioned below (Poornima M. Charantimath,Total Quality Management ,second edition,2011)

1. The transcendent approach
2. The product based approach
3. The user based approach

4. The manufacturing based approach
5. The value based approach

**1. The Transcendent approach:** David Gravin(1984) has explained that as per this approach 'quality is synonymous with innate excellence'. Followers of this approach cannot define the quality of a product or service but they share their experience. Means a product or service possesses a standard characteristics but that is subjective and can be only experienced. Due to the subjective nature of quality of services this approach is very important.

**2. The product based approach:** According to this approach quality is precise and measurable. Quality is amalgamation of all the features or characteristics of the product that describe the degree of excellence of the product. This approach was also illustrated by a draft of ISO 8402

**3. The User based approach:** This approach incorporates the voice of customer during product design. This is based on individual idea about the features of a service. But this approach has two drawbacks. First one is that every user has different view about the features of a product means customer preferences vary widely and second that the aggregation of this wideness is not easy.

**4. The manufacturing based approach:** This approach of defining quality is based on manufacturing practices of a product. This follows the universally accepted definition of quality –“conformance to requirement”. Every product or service should have basic specification and able to fulfil the basic requirement. Any deviation from these specifications results in reduction in quality of a product or service. According to this approach quality of products not necessary will be according to the customers' requirements, but that it will be according to standards set by the organization.

**5. The value based approach:** In this approach quality is defined in terms of costs and prices. According to this a product will be considered a quality product if it gives performance at acceptable cost. Cost associated with the product is one of the main factors for decision making for purchase of a product. Philip Crosby also supported this approach. Different authors had proposed a variety of definitions of quality and they are applicable in different circumstances. The term quality is open to a range of interpretations and the formation of a standard definition thus remains elusive (*Dale and Plunkett, 1990*).

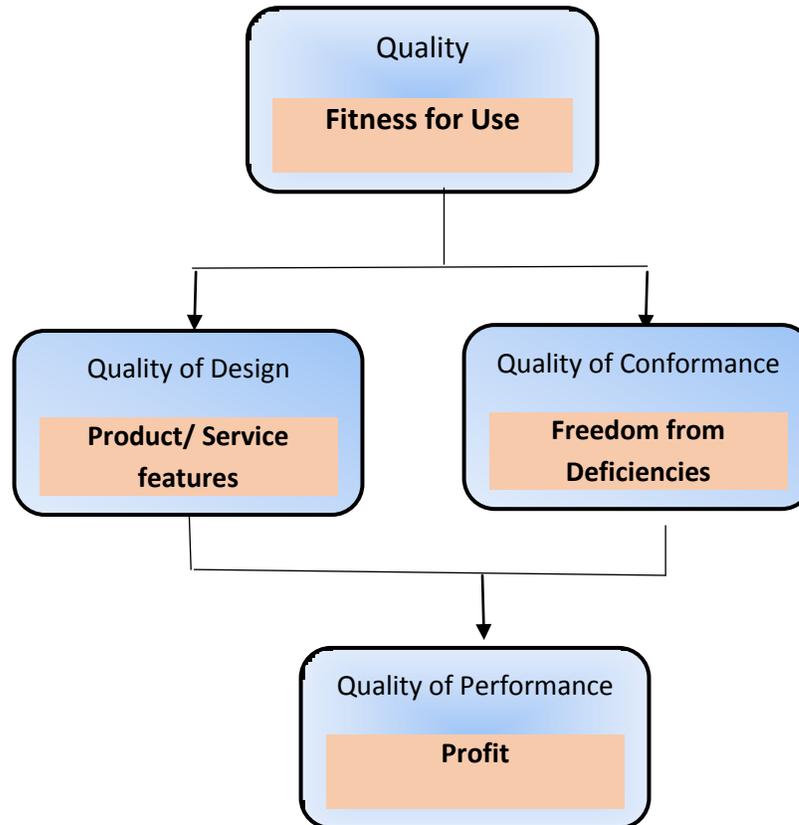
### 1.1.3Types of Quality

Poornima M.M Charanthimath (2011,page no,8) cited in her Total Quality Management book and also described by Devbashish Sarkar(1998) three types of quality to produce a product or service. These types are ;Quality of Design, Quality of Conformance, Quality of Performance.

**Quality of Design:**This type of quality is based on the characteristics of a product of service identified by the market research. This type of quality incorporates features of the product or service those represent the current and future needs of the consumer.

**Quality of Conformance:**Michael Milakovich(1995) explained that the quality of conformance can be defined as the degree to which a product of service are consistent with the intent of design. Capability of equipment, Training and skill of employees, process monitoring to assess conformance, employees motivation, and management commitment.

**Quality of Performance:** Michael Milakovich(1995)Devbashish Sarkar(1998)Poornima M.M Charanthimath (2011,page no,8) explained that quality of performance incorporates the reliability and consistency of the product or service. Promptness of employees and support services are also a component of quality of performance



**Figure No 1 : Types of Quality**

(Source : Adopted from Poornima M. Charantimath, Total Quality Management ,2011Pearsons, Publication)

#### **1.1.4 Quality in Healthcare:**

Quality in healthcare service is a unified effort between the healthcare provider and the patient in a conducive atmosphere. Individual characteristics of the care givers, patient, and elements linked with the healthcare organisation, healthcare system, and the broader environment affect healthcare service quality. Healthcare quality can be improved by supportive visionary leadership, proper planning, education and training, availability of resources, effective management of resources,

employees and processes, and collaboration and cooperation among provider (Mosadeghrad, 2014)

Unlike the manufacturing sector, the quality of healthcare service is difficult to define and measure. The unique characteristics of the healthcare industry such as intangibility, heterogeneity and simultaneity make it challenging to define and quantify quality. Healthcare service is an intangible product and cannot physically be touched, felt, viewed, counted, or measured like manufactured goods. When tangible goods are manufactured, they can be sampled and their quality can be inspected at several points during the manufacturing process and also in use afterwards. In contrast, some quality traits relating to healthcare service such as dependability, promptness of service and accuracy are subjective and difficult to measure in quantitative terms. They depend on the perception of the patients and their exchanges with the service provider. (Mosadeghrad, 2014) It is often difficult to reproduce consistent healthcare services. Healthcare services can differ between producers, customers, places. This 'heterogeneity' can occur because different professionals (e.g. physicians, nurses, paramedics etc.) deliver the service to patients with varying needs. Quality standards are more difficult to establish in services offered in the healthcare settings. Healthcare professionals are different as they differ in terms of experience, individual expertise, and temperaments. Healthcare services are produced and consumed at the same time and cannot be retained for use later on. As a result, it becomes cumbersome to keep a check on the quality as the client cannot judge 'quality' prior to purchase and consumption (Lee, et al., 2002). Unlike manufactured goods, it is less likely to have a final quality check. Therefore, healthcare outcomes cannot be guaranteed.

The Institute of Medicine has equated quality of care with the avoidance of medical errors (adverse events), patient safety and the pursuit of ways to improve these. Physicians tend to define quality not just in terms of outcomes but also with having happy patients, Insurance agencies have focused on those things which they could count and measure, often based on claims data – such as treatment and prescribing patterns and the use of generics. The concept of comparative

effectiveness (or better still, cost-effectiveness) appeals to them. ( *Humphrey Taylor,2011*)Institute of Medicine describes six important dimensions of a health care system that provides high quality care to individuals.

1. **Safety:**The healthcare environment should be safe for patients. It should be free from accidental injury for all patients, in all process and all the time.

2. **Patient-Centred or acceptability:** A high quality health care system is patient-centred. This concept encompasses respect for patients' values, preferences, and expressed needs; coordination and integration of care; information, communication, and education; physical comfort; emotional support (i.e., relieving fear and anxiety); and involvement of family and friends.

3. **Effective :** A high quality health care system provides care that is effective (i.e., care that, wherever possible, is based on the use of systematically obtained evidence to make determinations regarding whether a preventive service, diagnostic test, therapy, or no intervention would produce the best outcomes).



Figure No 2 : Dimensions of Quality of Care : Proposed by Institute of Medicine

4. **Efficient:** A high quality health care system is efficient (i.e., uses resources to obtain the best value for the money spent). Waste, including equipment, supplies, ideas, and energy, should be avoided.

**5. Equitable :**A high quality health care system is equitable (i.e., care should be based on an individual's needs, not on personal characteristics--such as gender, race, or insurance status-- that are unrelated to the patient's condition or to the reason for seeking care)

**6. Timely:** A high quality health care implies care that is delivered in a timely manner (i.e., without long waits that are wasteful and often anxiety-provoking episode).

The notion of quality healthcare is multi-faceted and subjective. Deming (1986) cites Donabedian's definition of healthcare quality as 'the application of medical science and technology in a manner that maximises its benefit to health without correspondingly increasing the risk'(Deming, 1986)

Juran (1989) cites Øvretveit's definition of quality care as the 'Provision of care that exceeds patient expectations and achieves the highest possible clinical outcomes with the resources available'(Juran, 1989) Weiner et al (1997) cites Schuster et al. who define good healthcare quality as "providing patients with appropriate services in a technically competent manner, with good communication, shared decision making and cultural sensitivity" (Weiner, et al., 1997). Kralovec (1990) cites Lohr's definition of quality as "the degree to which healthcare services for individuals and population increases the likelihood of desired healthcare outcomes and is consistent with the current professional knowledge" (Kralovec, 1990). Meyer et al (2004) cited Mosadeghrad's (2014) definition of quality healthcare as "consistently delighting the patient by providing efficacious, effective and efficient healthcare services according to the latest clinical guidelines and standards, which meet the patients needs and satisfies providers".

As it is evident from the various definitions given above, the criteria of quality are nothing more than value judgments that are applied to several aspects, properties, ingredients or dimensions of a process called medical care. As such, the definition of

quality may be almost anything anyone wishes it to be, although it is, ordinarily, a reflection of values and goals current in the medical care system and in the larger society of which it is a part (Donabedian, 2005).

### **1.1.5 Quality Management System and Hospital as a service Industry**

By definition a service industry is a business that provides services rather than products. Though Total Quality Management or Quality Management Systems was originally developed for the manufacturing industry, its appropriateness and usefulness was recognised by highly customer-centric service industries such as retail, hospitality, telecom or banking. In service organisations, the aim is to interlink business processes in such a smooth manner that the focus on client is retained. An approach of quality control which envisages all the processes of an organisation is required. As people or employees are the service providers in a service industry, every facet of quality is linked with each and every employee and quality control department plays a major role. Setting up quality management system machinery that is effective, asks for the pledge and patience of the management and the employees in an equal measure, in order to appease the client.

A WHO report on Patient Safety emphasizes the importance of *systems approach* in healthcare. Health services involve infrastructure such as buildings, equipment, instrument required to provide care to patients as well as people and processes. Unless the people concerned realise and understand the collective objective, the system will fail to work in a coherent manner. People are an important entity responsible for the proper function of the system. Health professionals come across many challenges in the execution of their duties and are aware of the situations where errors are most likely to occur. But they have not been taught or accustomed to think in terms of concepts of systems theory. A systems approach compels us to look at health care as a whole system, with all its intricacies and interdependence, diverting the attention from the individual to the organization as a whole. It trains us to shift away from the blame game towards a transparent process

of care. The organisational factors that lead to accidents or errors in a healthcare system such as suboptimal designs, flawed processes, un-coordinated teamwork, monetary restrictions etc. are identified and addressed to find a resolution. (WHO, 2012)

The layman trusts healthcare professionals like doctors, nurses and other hospital staff to possess the knowledge and skill sets required to perform their assigned duties. All the healthcare professionals are bound by ethics and legal responsibilities for which they are accountable. These legal responsibilities may differ in different countries, but they have a unified aim of instilling confidence in the community at large in healthcare professionals. Answerability is a professional commitment and it is expected that health-care are answerable. But healthcare professionals are not solely answerable as they are working in a system. The system accountability includes mechanisms that are unbiased, see-through and foreseeable in a way that health-care providers are informed of the types of matters for which they will be held personally responsible for, and will be supported to provide optimal health-care services.(WHO, 2012)

By nature, human beings dislike being told that their behaviour is improper or shown their mistakes. The solution to this problem lies in using a systems approach to healthcare. The systems should be designed in such a way that there is minimal scope for human errors to occur. A systems approach requires an in-depth understanding of the various issues involved in the multiple areas that together constitute the health-care system. (WHO, 2012)J. Reason delineated the essentials of the system that should be considered as part of a “systems-thinking” approach: patient factors, provider factors, task factors, technology and tool factors, team factors, environmental factors and organizational factors.(WHO, 2012)

### 1.1.6 Evolution of Quality & Quality Management Systems

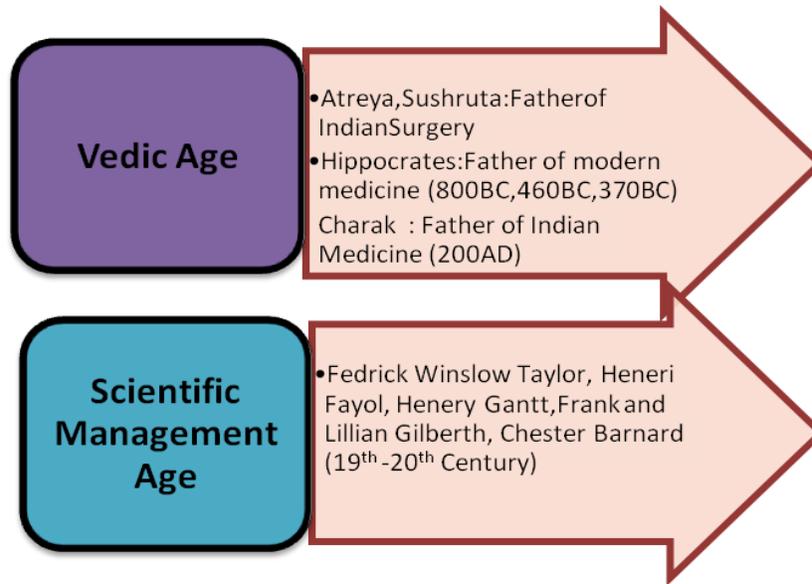
The concept of quality and quality management is not new. The evidence of the concept of quality and quality management were found / have been found in the vedic period. The contribution of the pioneers in the field of ancient science of medicine e.g. Atrya (about 800 BC) Sushruta (Father of Indian Surgery) Charak (200 AD) and Hippocrates (Father of Modern Medicine 430-370 BC) is remarkable. In the 19<sup>th</sup> and 20<sup>th</sup> century management gurus like Fredrick Winslow Taylor, Henry Fayol, Henry Gantt, Frank and Gilbreth, Chester Barnard, Henry Ford have found different scientific ways to improve the productivity of the organization by using various techniques and tool to reduce the wastes. Indirectly these gurus are the precursors of the modern concept of the quality.

As per the World Health Organisation's guidelines on Patient Safety the word *system* describes any collection of two or more interacting parts or "an interdependent group of items forming a unified whole". and, "A *complex system* is one in which there are so many interacting parts that it is difficult, if not impossible, to predict the behaviour of the system based on knowledge of its component parts. The delivery of health care fits this definition of a complex system." (WHO, 2012).

According to the American Society of Quality, a quality management system (QMS) is a validated system that records processes, procedures, and responsibilities of each individual for achieving the objectives of quality. A QMS helps to synchronise an organisation's efforts and activities to meet consumer needs as well as regulatory requirements and improve the value and competence of an organisation on an on-going basis. (ASQ, American Society for Quality, 2016) ISO 9001:2015 is an international standard stipulating requirements for quality management systems and it is a major pathway leading to quality management systems. (ISO, 2016).

Quality management systems result in the achievement of a multitude of objectives like streamlining of processes in order to reduce wastage of material as well as

manpower, cutting costs, pinpointing and enabling coaching prospects, involving staff and providing a direction for the advancement of the organisation. (ISO, 2005)



**Figure No 3: Evolution of Quality in Healthcare**

Quality management System is explained by various definitions. ISO describes process approach as an essential component of quality management system. Quality Management System intends to provide a process approach to improve quality of service by the integration of organizational process. This integration looks very simple but it is little complex and depends on the organizational values. Quality management System establishment requires structured organizational framework and resource planning and documented policy and protocols, monitoring system to evaluate the adherence to policy and protocols. Thus a Quality management System can be defined as an integration of planning, policy and practices.

The history of quality management system can be traced to the Industrial Revolution. Due to the need for mass production, huge teams of people worked together on different stages of production. One person or team would not necessarily complete a product from start to finish as was the practice earlier. Towards the end of the 19th century, forerunners such as Frederick Winslow Taylor and Henry Ford realised that the methods being used in mass production had their own limitations and would invariably lead to differing quality of output. Ford laid stress on the standardization of design and components to ascertain that a standard product was produced, Birland set up Quality Departments to supervise the quality of production and fixing of errors. Management of quality was the responsibility of the Quality Department and was carried out by Inspection of the product to 'catch' defects.(MSGExperts, 2008).Over a period of time, by experience, best methods for monitoring product and process outcomes were ascertained and recorded. These recorded best methods came to be known as standard practices for quality management systems.

Quality became more important during the Word War II, for example, when ammunition produced in one place had to match with arms which were made at some other place. In the beginning, the armed forces carried out 100 per cent inspection of its procurement. Later on, in order to make the procurement process easier and faster, without compromising on safety, the military published specifications for the procurement of each and every item they needed. They also started the practice of using methods of sampling for inspection and brought into use the statistical process control techniques proposed by Walter Shewhart.(ASQ, 2016)

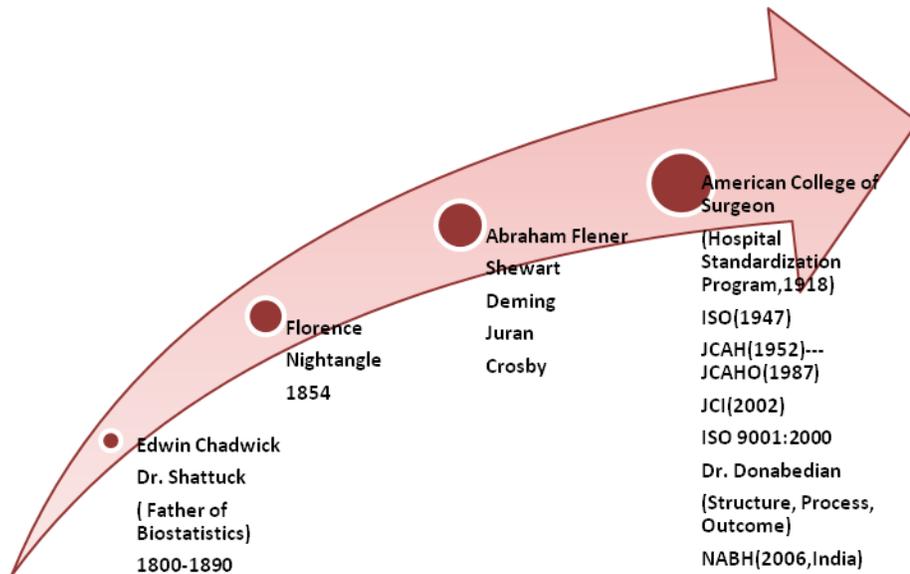
The concept of quality gained further importance after the war. American quality gurus like Joseph M. Juran and W. Edwards Deming took the message of quality from the Japan in early 1950 Japanese people completely understood and implemented their inputs and brought about a quality revolution. Instead of carrying out 100% inspection of products, the Japanese started improving all the processes which went into the manufacture of a product by involving the people who used them. The Japanese reputation for shoddy exports was replaced by high-quality

exports. As a result, by the 1970s the industrial sectors such as electronics and automobiles in which the U.S. had monopoly earlier were side tracked by Japan's competition based on the high- quality of the product.(ASQ, 2016) As an answer to the revolution in Japan based on quality of product, the Americans gave birth to the concept of total quality management (TQM), a quality management method that emphasized the approaches that involved the entire organization. (ASQ, 2016)

In the late 20th century, independent organisations began turning out standards to aid in the development and implementation of quality management systems. The phrase "Total Quality Management" gave way to the term "Quality Management System" or "QMS". The word 'Systems' was preferred due to the variety of unique systems that it can be applied to.(ASQ, 2016)

At the start of the 21st century, QMS had begun to fuse with the concept of sustainability and transparency in operations, as these topics gained importance in the ultimate goal of customer satisfaction.(ASQ, 2016)

Ernest Codman ( A surgeon from Boston,1914) realized the significance of the assessment of surgical outcome while working with Massachusetts Hospital, Boston, USA a century ago (Weiser T.G. et al, 2013). He had developed a system called" End Result System" to measure the outcome of surgery. He contributed in establishment of American College of Surgeon (ACS). This step of Codman has initiated the standardization of surgical care. Codman's contribution is remarkable in the conduct of first conference on mortality in USA.



**Figure No 4: Development of concept of Quality in Healthcare**

A WHO report on Patient Safety highlights the importance of *systems approach* in healthcare. Health services present as a system—buildings, people, processes, desks, equipment, telephones—yet unless the people involved understand the common purpose and aim, the system will not operate in a unified fashion. People are the glue that binds and maintains the system. Although health professionals face many challenges in their workplaces and understand the multiple components that are prone to dysfunction, they often have difficulty in thinking in terms of systems, because they have not been trained to think in the concepts of systems theory, nor do they use its tools to make sense of the systems in which they work. A systems approach requires us to look at health care as a whole system, with all its complexity and interdependence, shifting the focus from the individual to the organization. It forces us to move away from a blame culture towards a systems approach.

A systems approach examines the organizational factors that underpin dysfunctional health care and errors (poor processes, poor designs, poor teamwork, financial constraints and institutional factors), rather than focus on the people who are blamed for an error. This type of approach helps to move away from blaming, towards understanding and improving the transparency of the processes of care. All

health professionals have ethical and legal responsibilities for which they are accountable. While these requirements may vary from country to country, they aim to give confidence to the community that the health professionals can be trusted to have the knowledge, skills and behaviours set by the relevant professional body (Accreditation Bodies or Quality Organization). According to experts, although it is hard to change the aspects of complex systems, it is even harder to change the behaviour of human beings, in terms of errors. Therefore, the foremost response to health-care errors should be making changes to the system using a systems approach. A systems approach requires an understanding and action on the multiple factors involved in each of the areas that make up the health-care system. The intention of a systems approach is to improve the design of the system so that errors are prevented from occurring and/or their consequences minimized. Reason outlined the elements of the system that should be considered as part of a “systems-thinking” approach: patient factors, provider factors, task factors, technology and tool factors, team factors, environmental factors and organizational factors.

## **Section-II: Operation Theatre**

### **1.2.1 The Importance of Operation Theatre in a hospital setup**

The operation theatre is a special environment within a healthcare facility, where surgical procedures are performed on patients in a sterile environment to diagnose and treat disease or injury. A surgical procedure requires the complex coordination of surgeons, anaesthesia providers, nurses, and support staff to provide timely and effective care; heightened patient acuity and time pressure increase the potential for critical errors and omissions in established standards of care.

An operation theatre is one of the most complex units in a hospital due to its in numerous processes and sub-processes directly or indirectly connected to the production of surgeries. (American Society of Quality) The extra ordinary complexity of an operation theatre is manifested not only in the patient and their condition but also in the sophistication of instrumentation, the high volume of information that must be processed, the nature of communication and team co-ordination and the urgency

and occasional uncertainty with which decisions and interventions must be made. This complexity, combined with heavy workloads, fatigue and production pressures makes surgical care particularly vulnerable to adverse drug reaction. (Charles Vincent) This makes the operation theatre more important in a hospital set up.

### **1.2.2. Operation Theatre and Quality Management System**

Infections at the surgical site are the most common of the health care associated infections. The initial introduction of microbial pathogens occurs most often during the surgical procedure performed in the Operating Theatre (OT). The source of pathogens in such infections is the endogenous flora of the patient's skin, mucous membranes, or hollow viscera. Exogenous sources of surgical site infection pathogens include surgical personnel (especially members of the surgical team), the operating room environment (including air), and all tools, instruments, and materials brought to the sterile field during an operation. Interventions to prevent surgical site infections therefore are aimed at reducing or preventing microbial contamination of the patient's tissues or of sterile surgical instruments besides other interventions such as preoperative antibiotic prophylaxis, careful surgical technique, adequate ventilation of the OT, etc. It is important to have a quality management system that effectively addresses the issue of infection control in the operation theatre as the aforesaid variables are easier to control than patient risk factors such as presence of underlying diabetes, age, smoking, history, and obesity.

### **1.2.3. Background of the study**

Conceptually, the Quality Management literature would lead to some notion that Quality Management could increase performance in the healthcare industry. Deming (1986) and Juran (1995) specifically mentioned healthcare as a major industry that could benefit from using Quality Management principles. Yet, how this actually occurs is perhaps less clear than the connection between Quality Management and quality goods and services. The complexity of the healthcare profession healthcare delivery system at the hospital level and technological advancement has created the need to synchronize the quality management system(QMS) with the changes

occurring at the various levels of every hospital. QMS in hospital (QMS-H) is a mechanism or work procedure that ensures a consistently high quality of healthcare. Studies conducted in the various type of the healthcare facilities across the globe (Lin & Clousing, 1995, Shortell et al, 1995, Carman et al, 1996, Kennedy et al, 1997, Clare & Goh M, 1999-2000, Badrick & Preston, 2003) were carried out in developed countries like, USA, Australia, France and those only focus the culture, climate and the significance of involvement or leadership of top management or involvement of clinicians in QMS implementation, but do not suggest all related factors and the strategies to sustain a QMS. In this study researcher tried to explore the factors responsible to sustain the quality management system that will help the teaching hospitals to develop a strategy for overcoming the barriers to sustain a QMS implementation in the hospitals.

### **Section-III**

#### **1.3. Structure of thesis**

This thesis is consisted of the total eight chapters including the introduction chapter. Chapters are in the following order

Chapter number two is Literature review, Chapter number three is Aim(s) & Objective(s), Chapter number four is Materials and Methods, Chapter Number five is Observations and Results Chapter number six is Discussion, Chapter number seven is Summary, Chapter number eight is Conclusion and at the end Bibliography- reference etc. and annexure.

Literature review chapter describes the existing knowledge about the quality management system in hospital and operation theatre and the gaps related to quality management system. Next chapters explain about the aim(s), objective(s) and research. Materials and method chapter explains about the methodology of research, sample, sampling techniques, setting, inclusion and exclusion criteria. Observation and result chapter describes the observations and data analysis.

Discussions chapter explains about the interpretation of data and major findings. Summary of the thesis is presented in the summary chapter. Research conclusion is reported in the last chapter of the thesis.