CHAPTER ONE

INTRODUCTON

Health service quality is in serious crisis. The frequency and magnitude of avoidable adverse patient events was not well known and recognized until the 1990s. Many countries reported staggering numbers of patients harmed and killed by medical errors. In 1999, the Institute of Medicine (IOM) released a report entitled "*To Err is Human: Building a Safer Health System*" (IOM, 1999). The report stated that medical errors cause as many as 98 000 deaths every year in American hospitals, and over one million injuries. Medical errors cost the U.S. $29 billion a year (IOM, 1999).The WHO reported that 1 in every 10 patients is a victim of medical errors in hospitals around the world (WHO, 2006). The majority of medical errors result from faulty systems and processes, not individuals (IOM, 1999).

A recent study on medication errors in King Abdulaziz Medical City (KAMC) in Riyadh, Saudi Arabia, revealed a medication error rate of 560 per 1,000 medication order. 78.8% were classified as potentially harmful. While the international figure is 3.5 per 1,000 medication orders (Al-Jeraisy et al., 2011).

Despite rapid advances in medical science and technology, the healthcare delivery system has failed to provide consistently high quality care to all (IOM, 2001). This implies that increased know-how and increased resources will not, in themselves, translate into the high quality of healthcare which populations and individuals rightly expect (WHO, 2006). It is important to adopt various process-improvement techniques to identify inefficiencies, ineffective care, and preventable errors to then influence changes associated with systems (McNally, 1997). Both the Joint Commission International (JCI) and the Central Board for

Accreditation of Healthcare Institutions (CBAHI) have encouraged hospitals to use quality improvement models (Weiner, et al., 2006).

Quality Improvement Models are systemic approaches to planning and implementing continuous improvement in performance (WHO Europe 2008). They focus in improving work processes by teams trained in basic statistical techniquesand problem solving tools and empowered to make decisions based on their analysis of the data (Powell, et al., 2009). Healthcare systems around the world have used a variety of models to improve quality and safety. Many of these models have drawn on quality improvement models which originated outside the healthcare industry. Foremost among these are: Total Quality Management (TQM)/Continuous Quality Improvement (CQI); Business Process Reengineering (BPR); The Model for Improvement (MFI); Triology of Juran, Lean Thinking and Six Sigma (Powell, et al., 2009).

Although, each of the above mentioned leading models claims to provide solutions to the problems of healthcare delivery, hospitals that adopt them often struggle with their implementation (Powell, et al., 2009; Shortell, et al., 1998). There is lack of sustainability of improvements in the long term (Maher, et al., 2010). Health care organizations have experienced the fact that complex systems tend to evolve or revert back to previous iterations organically **(**Hovlid et al., 2012), they often cycle through the multiple QI initiatives without sustained improvement (Morrissey, 2004; Alexander, et al., 2007; Shortell, et al., 2005; Ferlie and Shortell, 2001). It is estimated that fewer than 40 percent of health care initiatives successfully transition from adoption to long-term, sustained implementation (Counte and Meurer, 2001). The results of lack of effective sustainability caused many problems to the health care system such as: waste of resources, increased staff fatigue, more stressful work environment, increased

patient care costs, increased resistance to later initiative to improve care (Hovlid et al., 2012; Klein and Sorra, 1996). However, as quality improvement continues to be a major focus in healthcare, there is growing interest in developing strategies to ensure sustained improvement in the long term (Maher, et al., 2010).

Importing quality improvement techniques from manufacturing industry may have the benefit that the tools and approaches have been tested to some degree, but the complexity of health care systems and delivery of services, the unpredictable nature of healthcare, and the occupational differentiation and interdependence among clinicians and systems make the use of these models difficult (Ferlie, 2005; Glouberman and Mintzberg, 2001; Degeling, et al., 2001; Gaba 2000).

Moreover, the contingencies of the particular local and organizational circumstances in developing countries can combine to overwhelm the potential advantages of these models. Even while viewing quality as systemic approaches as conceptualized in these models, developing and developed countries have different contexts and might need to focus on different dimensions of quality (Ramani, 2009).

In industrialized countries, quality of care is widely debated in the context of health sector reform. The literature reflects the progress made in these countries in developing tools to monitor and improve the quality of health care. On the other hand, hospitals in developing countries rely primarily on traditional tools and hard work to improve the care given to patients. However, it is difficult for traditional tools and hard work to create reliable and sustained improvements considering the complexity of health care systems and delivery of services (Varkey, et al., 2007).

The importance of using a systemic organization-wide approach to improve healthcare in developing countries cannot be understated. However, developing

countries cannot blindly employ the same models that are used in developed countries without adaptation to local circumstances, since improving processes and outcomes may prove impractical bearing in mind the differences in structural competence.

As the successful implementation is more about the interaction between any given quality improvement model and its implementation in the local context(Powell, et al., 2009), this study aims to develop a quality improvement model that fits the local circumstances of Saudi hospitals. The proposed model draws on a wide range of effective tools and principles from different approaches as well as the researcher's work experience. It will take into consideration the cognitive, emotional, and other factors that are known to impede sustained improvements in healthcare services in Saudi Arabia and suggest a framework to optimize sustainability of quality improvement initiatives. The effectiveness of the suggested model on a group of prioritized quality measures will be empirically evaluated through multiple experiments in the local circumstances of Saudi hospitals.

1.1 Research Problem:

The healthcare system in Saudi Arabia has serious problems with quality and safety that can be reduced through systematic quality improvement (QI) activities (Al-Jeraisy et al. 2011; Almalki et al. 2011). There is evidence that Saudi Arabia has used Total Quality Management (TQM) philosophy to improve healthcare services during the last two decades. However, the results are still far beyond expectations (Alaraki, 2013). Healthcare organizations face several challenges in sustaining and spreading good ideas, including the characteristics of the innovation itself; the willingness or ability of those making the adoption to try the new ideas;

and characteristics of the culture and infrastructure of the organization to support change ((Al-Jeraisy et al. 2011; Almalki et al. 2011). This is despite the fact that Saudi Arabia spends more than many other nations on improving the quality and safety of patient care. The poor results of quality initiatives in Saudi hospitals raise the need for a comprehensive and well defined quality model that takes into consideration the local political, cultural, social, and institutional factors that are unique to the country. This needs considerable adaptation of a range of approaches and tools to suit the local circumstances and to respond to emerging developments.

1.2 Research Questions

1. What are the organizational characteristics that make Saudi hospitals particularly challenging for quality improvement implementation?
2. How a model derived from the existing quality improvement models in healthcare overcomes the challenges that impede quality improvement in Saudi hospitals?
3. What is the effect of the proposed quality improvement model on a group of quality indicators?

1.3 Objectives

1) To develop a quality improvement model to address the organizational characteristics that impede quality improvement implementation in Saudi hospitals.

2) To apply the model in real life settings.

3) To evaluate the impact of the proposed model on a group of randomly selected quality indicators.

1.4 Hypotheses

1. *Hypothesis 1*: The proposed QI model is comprehensive, well defined, easy to learn and applicable in the local context of Saudi hospitals.
2. *Hypothesis 2*: The proposed QI model will produce measurable improvements to quality indicators.
3. *Hypothesis 3*: Improvements attributable to the proposed model will continue at or above the rate after application of the model.

1.5 Significance of the Study

The aggressive competition among healthcare providers, increasing costs of health services and continuously rising patients' expectations have forced healthcare institutions to focus on quality improvement. To this day for the healthcare service market in Saudi Arabia, there is a need for a quality improvement model that takes into consideration the local circumstances and a complete coverage of the practices that researchers consider necessary for effective healthcare quality improvement.

Quality improvement models have been researched extensively for many industries and briefly for the healthcare industry and there is substantial proof that in the multi-service healthcare industry the dimensions identified are quite different than those used for other industries and are yet to be uncovered. Moreover, although modern approaches to improving quality are increasingly used globally, their adoption remains sporadic in Saudi Arabia and other developing countries. Health systems in Saudi Arabia and developing countries are undergoing rapid change. The requirements for conforming to the new challenges of changing demographics, disease patterns, emerging and re-emerging diseases coupled with rising costs of healthcare delivery have forced Saudi hospitals to focus on

comprehensive review of health systems and their functioning. Healthcare quality in the Kingdom has to be addressed in a comprehensive model that incorporates all practices and dimensions of modern quality.

The proposed model could be the first comprehensive formalization of the healthcare quality practices local perspective and provides a creative approach to quality improvement that is not only applicable to Saudi Arabia but to developing countries as a whole. The model takes into consideration the local political, cultural, social, and institutional factors that are unique to Saudi Arabia and to some extent to other developing countries.

The proposed model is a system-wide top-down and bottom-up approach fitting local context and at the same time is based on the generic principles and practices of quality improvement. It focuses on systems and emphasizes incremental quality improvement achievements that might be more effective in yielding sustainable improvements in healthcare quality at the national or regional level.

Moreover, the model identifies and explains the key factors underpinning successful sustainability of quality improvement in Saudi hospitals. It provides effective change management practices through focusing on the people side of change including the cognitive and emotional factors that are known to impede sustained improvements in healthcare services in Saudi Arabia.

The suggested model will assist Saudi Arabia as well as developing countries in the process of choosing the best interventions to increase quality in healthcare systems and to successfully overcome numerous barriers to sustaining improvements.

CHAPTER TWO

LITERATURE REVIEW

2.0 THE KEY MODELS FOR QUALITY IMPROVEMENT

Over the past few decades, an understanding of healthcare quality as a system property has emerged (Berwick, 2003; Batalden and Stoltz, 1993; IOM, 2001). Accordingly, the quality of health care primarily depends on the function of the system and to a lesser degree on the skills of individuals (Berwick, 2003). Changing the system is therefore the most effective route to improvement; i.e., an organization needs to change its way of operating to produce improved outcomes, and these changes must be maintained to sustain the improvements (Berwick, 2003; Shojania and Grimshaw, 2005).

Recognition of actual and potential deficits in quality in healthcare in the past two decades has prompted health care organizations to introduce a wide range of initiatives and programs. There is a large and sprawling literature on quality improvement approaches. In part, this reflects the very broad range of activities and interventions aimed at quality improvement in health care.

This literature review focuses on those strategies adopted at organizational level, namely: Total Quality Management (TQM)/ Continuous Quality Improvement (CQI); Business Process Reengineering (BPR); The Model for Improvement (MFI); Lean thinking; and Six Sigma.

The review considers each of these models individually, while recognizing that the approaches are not always well defined and those healthcare organizations often draw on a range of tools and principles from different approaches. The five models will be described and evaluated separately in order to bring out some important conceptual similarities and differences between them. This will include

the identification and comparison of their strengths and weaknesses. The broad set of core conditions for successful implementation will also be explored and identified from the broader literature on health service change.

After reviewing the background and evidence for each of the five models, the review considers the evidence internationally on the multi-factorial challenges that surround any plans to spread and sustain the gains in quality improvement work. These factors as well as strategies, frameworks and guides to overcome them will be described and explained through review of both systematic and non-systematic reviews.

2.1 TOTAL QUALITY MANAGEMENT

2.1.1 Origin of Total Quality Management (TQM)

It can be argued that many of the TQM practices were being applied by organizations before the TQM movement appeared; consequently, it is not easy to establish the exact date of birth of the term TQM. However, many authors in this field believe that, TQM originated in manufacturing industry from the thoughts and practices pioneered by quality management experts such as Deming, Juran, Crosby, and Ishikawa (Khan, 2010). Deming's 14 points, Juran's trilogy and 10 steps, Crosby's 14 steps to quality improvement, are essential elements of TQM philosophy (Brocka and Brocka, 1992). Many authors claim that, TQM was developed by the US statistician Deming in Japan in the 1950s and became more prominent outside Japan from the late 1980s and from the early 1990s in health care (Gann and Restuccia 1994; Schiff and Goldfield 1994; Trisolini 2002; Grol et al. 2007). It has been suggested that TQM was in part a reaction by Deming to Taylor's 'Scientific Management' of the 1910s and 1920s and its perceived emphasis on profit-driven management rather than on quality (Schiff and Goldfield 1994) and that Deming recognised that putting quality first could reduce costs and

improve productivity (Roberts 1993). In contrast to Taylorist ‘minimum specifications’ and the concept of workers as ‘shirkers’, Deming’s approach emphasized continuous ongoing improvement and enabling staff to participate in producing a quality product or service (Schiff and Goldfield 1994).

The increasing use of TQM in US healthcare organizations is said to result from increased consumerism, competition and institutional pressures on organizations (e.g. from accrediting bodies and from other hospitals) and from the growing emphasis in the health care literature on the need to move from quality assurance to industrial quality management approaches (Berwick 1998; Bigelow and Arndt 1995; Gann and Restuccia 1994).

2.1.2 Definition of Total Quality Management (TQM)

The terms Total Quality Management (TQM) and Continuous Quality Improvement (CQI) are often used interchangeably in the healthcare quality literature (Gustafson and Hundt 1995). However, some authors maintain that, what was originally called total quality management (TQM) in the manufacturing industry evolved into continuous quality improvement (CQI) as it was applied to healthcare administrative and clinical processes (Sollecito and Johnson 2012). To keep with previous editions and to focus on the unique challenges within healthcare, the term TQM will be used primarily throughout this research as an umbrella term which includes CQI.

Despite the large amount of literature on quality issues, there is surprisingly no global definition of TQM (Lau and Anderson, 1998; Dale and Plunkett, 1990).When asked by Journal of Organizational Change Management, Deming refused to define TQM indicating that TQM had many meanings for researchers (Boje, 1993). Crosby, argues that the word quality should have no qualifiers. He maintains that quality 'control' and quality 'assurance' help to disguise a simple message that 'every time you see the word "quality", read conformance to

requirements'. That is why TQM has been defined and represented in a variety of ways, for example: fitness for use (Juran, 1979**);** conformance to requirement (Crosby, 1979); a way of managing an organization (Feigenbaum, 1983); meeting customer requirements (Oakland, 1989**);** a search for excellence, creating a “right first time” attitude and delighting the customer (Moore and Brown, 2006).

TQM can be defined as: an organization-wide process, where employees are motivated and empowered to do the right things, right first time and every time, to reflect on what they do and to improve what they do (Mohanty and Behera, 1996). It is a systematic approach to the practice of management, requiring changes in organizational processes, strategic priorities, individual beliefs, individual attitudes, and individual behaviors (Spencer 1994). It is both a philosophy and a set of guiding principles for managing an organization (van der Wiele et al. 1997).

In healthcare TQM is a continuous effort by all the members of an organization to meet and exceed the needs and expectations of the patients and other customers. The goal is to not merely meet standards of care or to see them as ceilings to which we strive, but to exceed these standards (Al-Assaf and Schmele, 1993; MxGlynn, 1996). Deming (1994) said, “a product or service possesses quality if it helps somebody and enjoys good sustainable market” (Deming, 1994). In healthcare, it refers to the care that meets the expectations of patients and supports the competitive position of the organization (Laffel and Blumenthal, 1989). Juran and De Feo (2010), in their book "Juran's Quality Handbook", defined quality as both: “product features that meet customer needs and freedom from deficiencies” (Juran and De Feo, 2010). In healthcare “freedom from deficiencies” means freedom from any avoidable intervention (Brown, 2012).

The problem in defining TQM results in another problem of establishing a clear-cut boundary to distinguish “TQM” from “not TQM”, and what belongs to TQM and what does not. Indeed some authors (e.g. Shojania and Grimshaw 2005)

argue that in practice TQM has become not so much a specific intervention but a more general approach to improving quality and different organizations use different approaches under an overall heading of TQM.

2.1.3 Total Quality Management Concepts and Practices

In practice TQM has become not so much specific intervention as different organisations use different approaches under an overall heading of TQM (Grimshaw 2005). Several variants of TQM have been identified by the 'gurus' (Pollitt 1996). Quality gurus place strong emphases within TQM on quality as an integral part of everyday work rather than an isolated project, on continuous improvement (with the aim of 'getting it right first time') rather than on inspection, on the active involvement of senior managers in leading quality improvement, and on systems and teams rather than on individuals (Arndt and Bigelow 1995).

As there are few analytical or agreed definitions of TQM: the concepts of the approach tend to be defined by a list of practices held to be essential for its implementation (Pollitt 1993; Roberts 1993; Gann and Restuccia 1994; Arndt and Bigelow 1995; Ovretveit 2000; Grol et al. 2007). TQM concepts and practices (Table 2-1) are not objectives, but are the actions and processes that can be controlled by management to achieve the organization's goals. They are those vital few requirements that must be present in an organization to be able to attain its mission, and to be guided towards its vision (Wali*et al.*, 2003).

Table 2-1: TQM concepts and practices.

SN	Practice	Description
1	Leadership	TQM strongly emphasizes leadership and the need for management involvement on project teams. Leadership provides guidance and direction for the entire organization to adopt and implement any quality improvement program.

2	Continuous Improvement	TQM sees quality improvement as a normal and integrated ongoing activity within the organization to find innovative or improved methods to increase the quality of care, and focus on improving outcomes and overall patient safety. This requires that employees acquire and apply new knowledge, skills and values to continuously improve the organization's performance and respond to changing customers' preferences.
3	Focus on processes and systems	TQM focuses attention on systems rather than individuals and emphasizes continuous improvement and avoiding mistakes before they happen ('getting it right first time') rather than on inspection. The concept that quality is the end result of complex but understandable processes that either enhance or detract from quality. It is a systematic approach to identify causes of variation/defect and effectively manage systems and processes to control cost, improve productivity, effectiveness and patient safety.
4	Measurement	TQM emphasizes the importance of measurement: data are a key tool for the analysis of variability in work processes and outputs. Carefully designed data collection and appropriate analysis support decision making to improve patient outcomes, healthcare documentation, patient safety, and overall organizational performance.
5	Focus on customer	The notion that as 'goods' or 'services' move along a process, different stakeholders and 'customers' emerge. A focus on these internal and external customers with whom

		one works in cooperation to meet their needs and enhance their satisfaction with goods and services. The customer is the center of all health services, so customers' satisfaction must be the basic principle for any health system and a key characteristic of organizations with high employee and patient satisfaction. The quality of service delivered by a hospital can be measured by determining the difference between what the patient needs (patient expectations) and how the patient experiences the service (patient perceptions).
6	Employee management and Teamwork	The concept that most people are intrinsically well motivated to work hard and do well. The focus is on involvement and participation of all employees at all levels in the organization to improve the quality of the current and future product or service. The emphasis on empowered cross-functional teams to identify and solve quality improvement problems for and by themselves.
7	Training and Education	TQM emphasises the importance of promotion and development of employees' skills related to problem solving and organization's beliefs to change to a culture that places high value on quality. Training and education maintain high quality level and induces a positive culture to warrant a sustainable TQM climate.
8	Supplier Management	The concept that a comprehensive approach to systematically managing an organization's interactions with the firms that supply the products and services it uses

		contributes to knowledge acquisition, costs reduction, enhancement of quality of service delivery, and brings sustainable benefits.

Adapted from: Alaraki, 2013; Ali et al., 2012; Talib et al., 2011; Sadikoglu and Zehir, 2010; Talib et al., 2010; Talib and Rahman, 2010; *Gann and Restuccia 1994; Arndt and Bigelow 1995; Ovretveit 2000; Grol et al. 2007*

2.1.4 TQM Tools and Techniques

TQM uses a range of tools and approaches including cause and effect diagrams, statistical methods (e.g. statistical process control) to assess and compare processes, and the Plan-Do-Study-Act cycle (Roberts 1993; Gann and Restuccia 1994; Arndt and Bigelow 1995; Lilford et al. 2003). Scheuermann and Scheuermann (1997) identified 15 most often used tools that they divided into qualitative and quantitative tools. Qualitative tools incorporate flow charts, cause-and-effect diagrams, multi-voting, affinity diagram, process action teams, brainstorming, election grids, and task lists. Quantitative tools include Shewart cycle (PDCA), control charts, scatter diagrams, Pareto charts, sampling, run charts, histograms. Psychogios and Priporas (2007) proposed the following TQM tools that were most frequently mentioned in Quality Management Literature: Statistical Process Control, Pareto analysis, matrix diagram, histograms, tree decision diagram, Critical Path Analysis, cause-and-effect diagrams (Fishbone or Ishikawa Diagram). Gunther and Hawkins (1999); after reviewing the works of Deming and Shewhart; identified the following tools: PDCA, force field analysis, consensus model, cause and effect diagram, five whys, work process measurement, flowcharting, brainstorming, scatter diagram, nominal group technique, Pareto chart or analysis, focus groups, decision matrix, customer-needs mapping, activity-based cost accounting, customer service loss calculation, benchmarking.

Each of the above mentioned tools has some specific characteristics and can find its application in different areas of quality management, namely for defining the problem, analyzing the problem, solving the problem and evaluating performance. (See Appendix 1, for more details on quality tools).

2.1.5 Empirical Evidence of TQM in Healthcare

Although the industrial environment is different from that of healthcare, studies have shown that TQM can be used in a healthcare setting (Hyer et al., 2003; Lindgaard Laursen, 2003; Spear, 2005). Many authors believe that TQM offers a method for solving quality problems of healthcare, even in the context of weak health systems facing severe material and human resource constraints (Zeitz et al., 1993; Loevinsohn et al., 1995; Heiby 1998; Massoud et al., 2001; Kelley et al., 2001; Hermida and Robalino, 2002; Berwick 2004; Rowe et al., 2005; Rennie et al., 2007; Dickson et al., 2007). TQM, as a model for organizational change, is culturally compatible with the values of health professionals because it emphasizes determining and meeting the needs and wishes of patients; it aims at a holistic approach to quality improvement based on identifying the underlying causes of poor performance; it emphasizes fact-based management and the need to improve quality on a daily basis (Shortell et al., 1998; Thompson, 1996).

TQM appears to have been widely used, at least in name, in health care in Europe, US and in many other countries around the world. There are numerous published papers describing its application in hospitals and in individual departments. Previous research on the transfer of TQM from industry to healthcare shows that the adoption of the ideas is not unproblematic. In most cases, TQM is implemented partially, rarely delivering the improved organizational performance wished for (Yasin et al., 2002). In the early years when TQM was used in health care, it was mainly in administrative areas; it was only applied in clinical areas

from around the mid 1990s (Shortell et al., 1998). According to Ovretveit (2000), it is difficult to categorise and evaluate the large number of projects and programs that claim to be carrying out TQM as many hospitals adopt some of the principles of the approach and apply the approaches in a piecemeal way.

Reviews of published research (e.g. Bigelow and Arndt, 1995; Shortell et al., 1998; Ovretveit, 2000; Shojania and Grimshaw, 2005) conclude that there is limited evidence about whether TQM works and whether it is more or less successful than other quality improvement approaches such as Lean thinking and Six Sigma. In part this is because TQM is more susceptible to being used as a general 'catch-all' label than Lean thinking or Six Sigma and it is difficult to define what is done under this overall 'heading'. In addition, it is difficult to assess whether reported improvements are attributable to, or merely contemporaneous with, the TQM interventions (Shortell et al., 1998).

The extensive review of the literature shows that organizations which have implemented TQM have achieved mixed results. Many recent empirical studies suggest that the successful implementation of TQM can improve hospital performance in terms of increased economic efficiency (i.e., length of stay, costs, and labor productivity), improved clinical outcomes (i.e, medical errors, mortality and readmission rates), improved customer satisfaction, and increased market acceptance (Alaraki, 2013; Ali et al., 2012; Irfan et al., 2012; ul Hassan et al., 2012; Malik et al., 2010;Talib et al., 2010; Zakuan et al., 2009; Kumar et al., 2009). While other authors argue that, despite the substantial resources invested by many organizations to adapt and implement TQM programs, many of them did not achieve any improvement and some only a little (Øvretveit, 2000; Parry, 1993; Schaffer, 1993; Hansson and Ericsson, 2002; Hari, 2004; Boaden, 1997; Hellsten and Klefsjo, 2000; Harari, 1997; Ugboro and Obeng, 2000). According to Øvretveit (2000), of those hospitals and services which have implemented TQM,

few have had great success and many have found difficulties sustaining their programs. In fact, it has been suggested that the number of successful implementations of TQM programs may be insignificant when compared with the number of failed implementations (Parry, 1993). Schaffer (1993) claims that, later surveys have suggested that over 80 percent of organizations implementing TQM programs have failed to achieve measurable, let alone positive results.

Despite this lack of success, many researchers found that TQM is still a very important source for improving the organizational performance of hospitals (Yang, 2003; Eggli and Halfon, 2003; Andaleeb, 2001; Ovretveit, 2001; Kunst and Lemming, 2000; Butler, Leong, 2000; Kenagy et al., 1999; Yasin et al., 1998; Brashier et al., 1996; McAlexander et al., 1994). Swinehart and Green (1995), state that TQM can provide an environment that will focus on quality of patient care and continuous quality improvement at all levels of the organization including the governing body, the administrative, managerial, and clinical areas. The failure of most organizations in achieving their expected target from implementing this approach has been attributed by many researchers to the lack of compliance with the practices and principles of TQM implementation (Ugboro & Obeng, 2000; Alaraki, 2013; Ali et al., 2012; Irfan et al., 2012; ul Hassan et al., 2012; Malik et al., 2010;Talib et al., 2010; Zakuan et al., 2009; Kumar et al., 2009).

Other researchers who explored the unsuccessful TQM efforts in healthcare organizations have identified two main problems. The first was the uncertain definition of TQM, and the second was the inappropriate implementation of TQM (Hansson and Ericsson, 2002). Specifically, due to the presence of a multitude of barriers, many healthcare organizations utilize only a partial implementation of TQM, and hence are unable to achieve continuous and systematic improvement (Nwabueze and Kanji, 1997; Zabada et al., 1998).

According to Mosadeghrad (2013), unsuccessful implementation of TQM in healthcare sector can be attributed to the strongly departmentalized, bureaucratic and hierarchical structure, professional autonomy, tensions between managers and professionals and the difficulties involved in evaluating healthcare processes and outcomes. Other barriers to TQM success include lack of: leadership commitment and support; poor leadership and management; insufficient training and education; lack of a quality culture; inadequate resources; and lack of employees' involvement and commitment to TQM implementation (Mosadeghrad, 2013).

Johnson and Omachonu (1995), maintain that the greatest challenge for top management is to make TQM a part of corporate strategy and to create an organization in which every employee, department and function is linked to the organization's mission and vision. It is believed that TQM is most likely to be successful when it is integrated into the organization's structures and processes and not seen as a separate activity or one-off project (Shortell et al 1998; Jackson 2001) and when senior managers and physician leaders are actively involved in the TQM program on an ongoing basis (Gann and Restuccia 1994; Carman et al. 1996; Ovretveit 1997; Weiner et al. 1997; Trisolini 2002).

A study in one US hospital reported that TQM style techniques had been used for several years and had now become an integral part of the organization, although some senior staff remained unconvinced of its value; the hospital used a range of approaches including interchange of jobs (in which medical and nursing teams spent time in administrative offices, in the kitchens and in the laundry) (Roberts 1993). However, interviews with 19 prominent TQM thinkers and activists in the US in the mid 1990s found that the basic principles of TQM had yet to diffuse deeply through most healthcare organizations especially on the clinical side: many doctors were sceptical about the approach or did not know about it, few patients were involved (despite the emphasis on 'consumer' definitions of quality)

and not all senior leaders were directly involved in the TQM projects running in their organisations (Blumenthal and Kilo 1998).

As in the US, European hospitals introducing TQM found that it was very difficult to secure doctors' leadership and involvement (Ovretveit 1997). Many health professionals were resistant to working in teams and feared loss of autonomy. They were reluctant to take time from high patient care workloads to adopt these new methods in the absence of strong evidence that they were more effective than any alternatives. There was a lack of emphasis on producing demonstrable results and many employees viewed work on quality as separate to their everyday work, in part because quality approaches were largely being applied to more peripheral activities (e.g. diagnostic and administrative support services).

There is substantial evidence relating to TQM in the United Kingdom from a major evaluation of TQM at a range of NHS units in 8 health authorities from 1990-1993 (Joss and Kogan 1995). The study covered 38 different hospitals and community service units as well as two newly privatized industries. In relation to health care, the study concluded that many cost savings resulted but that there were significant problems.

Table 2-2: Summary of experience of implementing TQM in eight NHS

.SN	Practice	Problems
1	Corporate approach to quality	There was a lack of corporate approaches e.g. there was no undue concern with quality generally and only superficial diagnosis of the situation at the outset; planning for quality mainly took place separately from mainstream business planning; implementation plans rarely contained detailed objectives and targets/ monitoring plans

2	Measurement	Much of the information needed to provide evidence of quality of processes was unavailable and/or not integrated; much was quantitative; qualitative data were crude. Individual performance measurement was rudimentary although measures of service provision were improving.
4	Empowerment of staff	Staff empowerment was low and improved little over the 3 year period. Few doctors were involved. Some progress was made in involving patients and carers in quality improvement. They also had significantly less involvement of senior managers: many NHS quality managers lacked sufficient authority to monitor action or to influence other staff. Furthermore, in the NHS, the lack of participation by doctors in TQM training and activities presented a great contrast to the involvement of staff groups in industry.
5	TQM structures	Other structural changes going on at the time were in conflict with the structures needed for TQM e.g. the development of clinical directorates or of other quality related groups or the preparation of bids for trust status; quality managers were too junior in many cases; TQM was poorly integrated with medical and other audit
6	Integration	TQM activities were poorly integrated with other activities like audit
7	Training	There was little training in TQM tools; very few doctors attended any training

		There was significantly less pre-TQM planning and design of initiatives in the NHS compared to industry and significantly less training for staff. Some health care organisations only provided initial TQM awareness events lasting two or three hours in contrast to the considerable training provided to staff in TQM tools and techniques in the private sector.
8	Leadership support	The NHS organisations had much lower funding for the TQM initiatives and lacked the support that the commercial organisations received from their marketing and operational research departments but many cost savings resulted.
9	Change	The NHS organisations struggled with the ongoing turbulence of NHS change and with a range of different quality initiatives that were not integrated with TQM (e.g. Patients Charter groups, medical audit groups, resource management groups) whereas the commercial organizations appeared to have a clearer sense of the purpose of TQM and the links between quality, a successful business and security of employment. In contrast, in the NHS, TQM (with its focus on aggregates of cases and on systems) seemed to sit uneasily with health professionals' training which had traditionally schooled them to make individual judgements on individual cases.

Source: Joss and Kogan 1995

The researchers found that those NHS organisations that appeared to have made more progress with TQM shared a number of key characteristics (Table 2-3) including a strong focus on training individuals in the tools and techniques of process improvement, and providing sufficient funding for the program both at the start and throughout the three year period of its implementation.

Table 2-3: Characteristics of NHS organizations that made progress with TQM

SN	Practice	Characteristics
1	Focus on process	A strong focus on process improvement
2	Data management	Attention to robust data collection and analysis before making changes
3	Efficiency	Attention to cost and waste reduction as well as to improving patient satisfaction
4	Cross-functional activity	Attention to organisational-wide issues through cross-functional activity
5	Patient-centred	A move away from strong dependence on technical and professional definitions of quality to more holistic and patient-centred definitions
6	Training	A strong emphasis on providing training and support for individuals in the tools and techniques of process improvement
7	Teamwork	The establishment of quality improvement structures including groups and teams at middle management and front line staff levels
8	Funding	Realistic start-up funding and sustained funding over the three years
9	Leadership	Senior management understanding of and commitment

		to TQM
10	Empowerment of staff	An emphasis on engaging the active commitment of front line staff to carrying out TQM as part of their daily working practices

Source: Joss and Kogan 1995

Recent empirical studies in developing countries show similar findings. Organizations that successfully implemented TQM practices appeared to have made more progress with TQM (Alaraki, 2013; Ali et al., 2012; Irfan et al., 2012; ul Hassan et al., 2012; Malik et al., 2010;Talib et al., 2010; Zakuan et al., 2009; Dilber et al., 2005). These studies show that successful implementation of TQM practices support to reduce service time, increase flexibility, improve efficiency, improve involvement of staff, improve the communication and result in better collaboration and coordination of services.

What the review of TQM studies suggest is that there is evidence of some successes when TQM principles are applied to some administrative processes and support services (e.g. discharge processes, recruitment, medical records) that more closely resemble those in industry (Powl et al., 2009; Arndt and Bigelow 1995) and that in Europe at least, both small hospitals and large complex hospitals had more difficulties introducing TQM than did medium sized hospitals (around 2000 employees) (Powl et al., 2009; Ovretveit 1997).

2.1.6 Strength and Weaknesses of TQM

In summary, the strengths of TQM are that: it emphasizes determining and meeting the needs and wishes of patients or customers; it aims at a holistic approach to quality improvement based on identifying the underlying causes of poor performance; it emphasizes fact-based management and scientific methodology and may therefore be culturally compatible with the values of health

professionals; and it emphasizes the need to improve quality on a daily basis (Shortell et al 1998).

However, significant challenges have also been identified, particularly in adopting TQM in the public sector (Morgan and Murgatroyd 1994). It is argued that much of the literature on TQM is based on assumptions that do not apply in many organizations, particularly in health care: the assumptions that decision-making in hospitals is a technical rational process; that managers have hierarchical control over technical core processes; and that there are no significant conflicts between the needs of internal and external customers (Bigelow and Arndt 1995).

It is also argued that most models of TQM start from the assumption that the staff are naïve about most matters of quality, when in fact many healthcare professional and technical staff already view technical quality as of prime importance and may therefore be resistant to what appears to be a patronizing approach (Joss 1994). Further weaknesses of TQM (which are also shared by other quality improvement approaches) are that it seeks to achieve what is in effect wholesale cultural change but appears to underestimate how long such change takes to achieve in practice, thus raising unrealistic expectations on the part of organizations and health care funders (Counte and Meurer 2001). Like other approaches, it is also highly demanding in time and money: the work needed to redesign systems of care is very labour-intensive and prolonged (Blumenthal and Epstein 1996; Trisolini 2002).

2.2 LEAN THINKING

2.2.1 Origin of Lean Thinking:

The concept called “lean thinking” was developed by Toyota Motor Company as Toyota Production System (TPS) in the 1950s based largely on the work of quality guru W. Edwards Deming (Institute for Healthcare Improvement 2005).

The Toyota Production System (TPS) aimed to achieve quality by focusing on waste reduction and efficiency while simultaneously improving product quality. TPS led Toyota to increase its competitive edge by using fewer employees to produce more cars with fewer defects (Westwood and Silvester 2006).

The principles originating from the Toyota Production System (TPS) have led to a set of ideas that are commonly grouped under the name ‘lean thinking’ (‘lean production’ or sometimes just ‘lean’). Toyota’s manufacturing approach soon developed into a new paradigm and became a model for many companies in many different industries (Womak et al, 1990; Koskela, 2004; Al-Najem et al., 20 12).

The term ‘Lean’ was first used by John Karfcik in 1988 to describe the methods used in the Toyota Production System (TPS) (Krafcik, 1988). The term ‘Lean’ production was popularized by Womak et al. (1990) in their book, “The Machine that Changed the World”, revealing the practices of the Toyota Motor Company implemented by Taiichi Ohno. In Ohno‘s TPS both the production system and the qualitative experiences of the employees are considered important for the achievement of quality improvement (Shah & Ward, 2007).

2.2.2 Definition of Lean

A precise definition of lean thinking may not exist (Dennis, 2002; Ohno, 1988). However, several lean definitions are available in the literature. Lean Thinking is a systematic approach to identifyingand eliminating waste (non-value-added activities)through continuous improvement by flowing theproduct (process, information, service, patients) at the pull of the customer in pursuit ofperfection. It is not a manufacturing tactic, nor a cost-reduction program, but rather a management strategy that is based on improving processes in a system (Nelson-Peterson & Leppa, 2007). Lean thinking is an approach to the redesign of complex processes derived from methods developed in the manufacturing sector (Womack and Jones, 1998). Calderone (2008) defined Lean thinking as: aquality focused

concept that concentrates improvement initiatives within the workflow in an effort to identify and drive out waste and variability within processes.

Definitions stated in references such as (Shingo & Dillon, 1981; Dennis, 2002; Detty& Yingling, 2000; Chalice, 2007; Rooney & Rooney, 2005; Alukal & Chalice, 2007) are all common in describing lean as a way of using all available resources (i.e. man, machine, material, space, and time) in their minimum possible levels to fulfill customer defined needs; with the objective of decreasing these levels while pursuing perfection through continuous improvement.

Lean Thinking in healthcare is about simplifying processes by understanding what adds value and eliminating waste (Fillingham, 2007; Jimmerson et al., 2005; Endsley et al., 2006; Dickson et al., 2008). Lean is an integrated system of principles, practices, tools, and techniques that are focused on reducing waste, synchronizing work flows, and managing production flows (Koninget.al. 2010). Lean thinking is the efficient use of staff, resources, and technology to provide the highest level of service possible to the healthcare customer (Campbell, 2009).

2.2.3 **Lean Thinking Concepts and Practices**

The key concept in lean thinking is ‘value’. Value is defined as the capability to deliver exactly the product or service a customer wants with minimal wasted time, effort and cost (Wormack and Jones, 2003; UK). Customers are defined as all those outside the organization who use or depend on the products or services provided by the organization or vendors. Primary processes serve the external customer (e.g. patients and their families) and internal processes serve internal customers in support of the process (Brown, 2014). By defining ‘what customers want’, process-steps can be divided into value-adding and non-value adding.

Value adding activities contribute directly to creating a product or service a customer wants while non-value adding activities do not. Those actions or processes which do not create value are called waste and need to be identified and

eliminated (Wormack and Jones, 2003; Joosten et al., 2009).The value of any given process is determined by distinguishing value-added steps from non-value-added steps and eliminating waste so that ultimately every step in the process adds value to the customer. Removing 'waste' in the system is intended to create additional capacity and increase customer satisfaction(IHI, 2005).

Researchers identified five key concepts in lean thinking: value, the value stream, flow, pull, and perfection (Womack and Jones 1996; Young et al. 2004; Radnor et al. 2006; NHS Institute for Innovation and Improvement 2007; UK 2009; Wanga and Chenb, 2011). Below is a brief description of each:

2.2.3.1 Value (Specify the value)

The question of value is the most important concern within the lean thinking paradigm. This value must be defined by the end customer. Only what the customer perceives as value is important. The customer, depending on the process, can be a patient, a physician, or an administrator. So this value could be varying from different customer perspective about the same product or the same service.

In healthcare, value is any activity that improves the customer's experience: the patient's health, wellbeing and experience. Each step in a process should produce value for the customer. If it does not then it must be re-engineered or eliminated.

Patients routinely get stuck in processes that do not add value to their care. They wait for long time to see their treating physician, or they complete a medical history form multiple times within the same medical encounter. Those processes were designed to add value to the healthcare professional, not the customer. In lean thinking, a first step in evaluating value is determining who the customer is and looking from his or her point of view (Campbell, 2009).

2.2.3.2 Value Stream (Identify the 'value stream)

The value stream is the steps required to complete a process or service (or in manufacturing, to create a product). Having understood the value for the

customers, the next step is to analyze the business processes to determine which ones actually add value. Waste can be uncovered with value stream and process mapping tools (Rother and Shook, 1999; NHS Institute for Innovation and Improvement, 2005). Examining the value stream helps to identify waste within a process. If an action does not add value, it should be modified or eliminated.

Each step within a process will have one of three outcomes: it will create clear value (value added step); create no value but be unavoidable due to configuration of the current process (non-value added step type 1); or create no value (non-value added step type 2) and the later must be eliminated immediately. Returning to the example of seeing one's treating physician, the step of being examined by the physician adds clear value to the patient. The step of filling out a medical history form multiple times is a step that adds no value but which is unavoidable due to current processing requirements. Finally, the step of waiting long time to see the physician adds no value and should be removed immediately (Campbell, 2009).

There is a tremendous amount of waste occurring in the healthcare industry. The majority of waste encountered by healthcare organizations occurs in flow and throughput. As a result, Lean implementations in this field are primarily focused on the elimination of waste in staffing and staff/patient processes. Unlike manufacturing industries most healthcare organizations have very little inventory. Thus, some of the Lean concepts related to inventory control are less applicable to healthcare. Healthcare organizations typically spend a larger percentage of operating expenses on overhead and labour costs. This can account for 50 percent of the operating costs while inventory is in the range of 2 percent (Caldwell, 2005). However, Jimmerson (2004) suggests waste can be reduced inhealthcare by focusing on inventory and the overstocking of supplies from linens to drugs.

Taiichi Ohno (1988) states seven types of waste (Muda) for manufacturing that describe all activity that adds cost but not value. These are: transportation, inventory, motion, waiting, over-processing, over-production and defects (TIMWOOD).The term "waste" encompasses an array of definitions for hospitals and health systems, including wasted time, finances, steps and human potential, to name a few. The patient journey is the process and value streams that typically group patients together by similarity of process rather than by the traditional grouping by condition or specialty (Jones and Mitchell 2006). Recently researchers in lean healthcare added (underutilized intellect) as the eights waste. This refers to non-utilization of human potential (Poole et al, 2010). Graban (2012) defined human potential as waste and loss due to not engaging employees.

The eight types of waste in healthcare are: defects, over-production, waiting, non-utilization of human potential (employee's talent), transportation, inventory, motion, and excess processing (DOWNTIME). Table 2-4 lists the eight lean thinking categories of 'waste' with examples in healthcare.

Table 2-4:Lean thinking categories of waste and health care examples

SN	Waste (Muda)	Brief description	Hospital examples
D	Defect	Work that contains errors or lacks value	- Adverse drug reactions - Readmission because of inappropriate discharge - Repeating tests because of incorrect information
O	Over-production	Redundant work. Doing more than what is needed by customer or doing it sooner than needed.	- Requesting unnecessary diagnostic procedures - Duplicate charting

			- Multiple forms with same information
W	Waiting	Idle time created when people, information, equipment or materials are not at hand	- Waiting for doctors to discharge patients - Waiting for test results - Waiting for other workers at meetings, surgeries, procedures, reports
N	Non utilization of human potential	Waste and loss due to not engaging employees, listening to their ideas, or supporting their careers. People doing the work are not confident about the best way to perform tasks.	- Employees get burned out and quit giving suggestions for QI - Same activities being performed in different ways by different people - Unclear medical orders or route for drug administration
T	Transportation	Unnecessary movement of patients, specimens, and materials in a system. Required relocation or delivery of patient, materials or supplies to complete a task	- Central equipment stores rather than ward based stores for commonly used items - Delivery of medication from central pharmacy - Staff travel to a remote storage room to retrieve supplies
I	Inventory	More materials on hand than are required to do the work. Excess	- Waiting lists - Excess stock in stockrooms - Overstocked medications on

		inventory cost through financial cost, storage and movement cost, spoilage, wastage.	units - Overstocked supplies on units and in warehouses
M	Motion	Unnecessary movement by employees in the system. Movement of people that does not add value	- Unnecessary staff movement to obtain information or supplies - Materials, tools located far from the work
E	Excess Processing (Over-processing)	Doing work that is not valued by the customer or aligned with patient's needs. Activities that do not add value from the /customers perspective.	- Asking patients for the same information several times - Clarifying orders - Redundant information gathering/charting - Missing medications - Regulatory paperwork

Adapted from NHS Institute for Innovation and Improvement: Going lean in the NHS (2007); Healthcare Performance Partners (2008); Steed, 2012; Belter et al,2012; Radnor et al, 2012; O'Neill et al, 2011; Poole et al, 2010; Graban (2012).

2.2.3.3 Flow

Make value flow continuously without interruptions. Processes need to be aligned so that the system flows efficiently with materials, information and services available as and when they are needed without intermediate storage.

In healthcare, this means facilitating the smooth continuous flow of patients and information across different departments and services (e.g. wards, operating theatres, imaging departments).

To make the value flow continuously it is important to eliminate the use of batching and queuing within a process. Processes that use batches and queues produce multiple wait times and interruptions. The ultimate goal of flow is to ensure that a process is continuously worked on until it is complete. For the patient, this means receiving the care he or she needs without waiting, interruptions, and suffering unnecessary pain.

Zimmerman (2004) proposes that studing and improveing flow leads to a need to consider alignment within the whole system and goals withing the system, especially between healthcare organization and clinitions. This should lead to whole system approaches to improvement. One quality improvement approach that focuses on flow is Theory of Constraints (TOC). The basic concepts of the theory of constraints are: every system has at least one constraint – anything that limits the system from achieving higher performance – and that the existence of constraints represents opportunity for improvement (Walshe and Smith, 2011).

2.2.3.4 Pull (Let the customer pull the value from producer)

Pull has been described as: performing work as it is requested or needed by a step in a value stream (Bushell and Becky. 2002). This is the opposite of push system, where a product can be created when there is little or no demand. Push processes can lead to large inventories and related costs to maintain them.

In health care, this means that, for example, demand for ward beds for postoperative patients is led by the completion of theatre and recovery procedures.

The difference between Pull & Push is that in push work is completed based on a planning system while in pull system work is finished based on downstream needs.

Push leads to steps in a service being performed out of order if a next step in the process is not ready. For example, during the transfer of a baby from a surgical suite to a neonatal intensive care unit (NICU), if the baby arrives at the NICU and the respirator and the respiratory therapist are not waiting for the patient, there is a problem. The baby has been pushed to the NICU without the appropriate services and staff on hand to provide appropriate care (Campbell, 2009). Pull works to ensure that the respirator, the respiratory therapist, and charge nurse are ready and waiting when the baby arrives in the NICU.

2.2.3.5 Perfection (*Pursue perfection)*

A key tenet in lean thinking is that no matter how many times a process is improved, it can be further enhanced. Implementation of the first four principles is not the end of the process for reducing waste, time, cost and mistakes. Actually it is the beginning of a long time improvement through incremental change based on outcomes (Tsasis and Cindy, 2008).

This means that processes are continuously developed and amended in pursuit of the ideal: reducing the number of steps and the amount of time and information needed to serve the customer. Lean thinking does not involve implementing a one-off solution to a problem; instead the aim is to create an environment of constant review, emphasising suggestions from the ‘floor’ and learning from mistakes.

2.2.4 Lean Tools and Techniques

Implementation of Lean needs some tools that must be applied in the right time and right place. It starts by defining the purpose of the process (value for the customer) and then redesigns the process to deliver that value with minimum

wasted time, effort and cost. It then organises people and organisations to manage that process. In analysing processes and redesigning them, lean thinking uses tools from other approaches e.g: (theory of constraints; 5 whys; PDSA and Six Sigma) (Powell, et al., 2009).

Whilst many researchers caution that Lean should not be seen as a set of tools (Bhasin, 2008; Emmiliani, 2008; Schönberger, 2007; Holweg, 2007; Womack and Jones, 2006; Roth 2006; Spear 2004), tools do help organizations to identify and eliminate waste when they are used correctly and built on strong foundations that consist of leadership, alignment with strategy, learning and training, and engagement of staff (Bicheno, 2004; Hines et al, 2008; Radnor 2010b).

Many of the Lean tools that are utilized in health care are aimed at eliminating waste, though it should be noted that tool-based implementation may lead to initial gains and quick wins but is unsustainable without staff engagement (Radnor et al, 2012). Researchers mentioned several Lean tools and techniques that can be utilized in health care such as value stream maps, standardized work, gemba walks, 5S, continuous flow, waste reduction, pull, kanban, changeover reduction, and visual control, among others (Poksinska, 2010, Belter et al, 2012, Poole et al, 2010). Powell, et al. (2009) identified six most used tools in healthcare: 5S or CANDO, rapid improvement events (kaizen), value stream mapping, 5 Whys, statistical process control, and PDSA.Zidel (2006) presented 5 simple Lean tools and techniques as the basic tools used in Lean transformation for a healthcare setting: 5 why‟s, 5S, Kanban, visual controls and standard work which can help any healthcare organization to launch its Lean transformation. Bicheno (2004) differentiates between tools that identify ‘value’, tools that prepare for ‘flow’, tools for mapping and analysis, tools for ensuring quality (reducing defects) and tools for continuous improvement. Below are some of the most commonly used tools in the healthcare sector with a brief description of their use**.**

2.2.4.1 5S or CANDO

5S (also known as 5C or CANDO) is a common starting point for organisations in implementing lean principles. The process encourages workforce teams to critically evaluate the environment they work in (e.g. accessibility of supplies, typical daily movements of staff and information, hazards in the environment) and to start a process of improvement at their level of operation by following five steps (sort, straighten, sweep, standardise and sustain). The objective is keeping everything in order to reduce time wasted looking for things and to improve visibility at a glance. This exercise will prompt staff to think about the department or unit's processes and that it will act as a catalyst in identifying and addressing current blocks to process flow (e.g. defective equipment, supplies in the wrong place, delays in obtaining information).

2.2.4.2 Rapid improvement events (kaizen)

Kaizen is a Japanese word that has become common in many western companies. The word indicates a process of continuous improvement of the standard way of work (Chen et al., 2000). It is a compound word involving two concepts: Kai (change) and Zen (for the better) (Palmer, 2001). The term comes from Gemba Kaizen meaning 'Continuous Improvement' (CI). It calls for endless effort for improvement involving everyone in the organization (Malik and YeZhuang, 2006).A kaizen event or a rapid improvement event (RIE) as it is frequently known refers to a short burst of improvement activity with a cross section of worker involved in a particular process. Key participants in a particular process are brought together in an intensive four or five day event aimed at analysing current processes and identifying changes needed.

2.2..4.3 Value Stream Mapping

Value Stream Mapping is a tool that helps to map all the actions in process (both value-added and non-value added) by analyzing the flow in order to identify

and reduce non value added activities (Kollberg, *et al.*, 2006; Manos, *et al.*, 2006; Powell, et al., 2009). This map helps people identify the waste that occurs within the process and look at the bigger picture of material and information flow within the whole organization (Morrow & Main, 2008; Rother and Shook, 2003).

2.2.4.4 Process Mapping

Process mapping focuses on actions at the level of the process. A process map shows the complete picture of the process flow starting from the input to all the steps that will lead to outcomes. It provides the information about the main steps and it helps to expose the bottlenecks to improve the process (Anjard, 1998). It is particularly applicable in hospital setting where waiting time is the most frequent problem from patients' perspectives. Process mapping helps to identify activities which are non value added or create a bottleneck (Staccini, et al., 2005).

2.2.5 Empirical Evidence of Leant Thinking in Health Care

Lean management principles have been used effectively in manufacturing companies for decades, particularly in Japan. Karlsson et al. (1995) argue that Lean product development, supply chain management, and Lean manufacturing are important areas also in healthcare. The focus on zero defects, continuous improvements and JIT in healthcare makes Lean concepts especially applicable. The establishment of customer interaction is equally important in the manufacturing industry as it is in the healthcare sector. Womack and Jones (2003) advocate the application of Lean thinking in the medical systems. They argue that the first step in implementing Lean thinking in medical care is to put the patient in the foreground and include time and comfort as key performance measures of the system. Having multi-skilled teams taking care of the patient and an active involvement of the patient in the process is emphasized.

Young et al. (2004), see an obvious application of Lean thinking in healthcare in eliminating delay, repeated encounters, errors and inappropriate procedures.

Similarly, Breyfogle and Salveker (2004), advocate Lean thinking in healthcare and give an example of how Lean management principles can be applied to health care processes through the use of the Six Sigma methodology, which in many ways resemble the Lean production techniques. Several case stories on Lean thinking initiatives in healthcare sector can be found in Miller (2005), and Spear (2005).

Compared to other sectors, application of lean thinking in health care is still in its infancy (Antony et al. 2007b). Lean in healthcare is mostly used as a process improvement approach and focuses on three main areas: defining value from the patient point of view, mapping value streams and eliminating waste to create continuous flow (Poksinska, 2010). Although there is a growing interest in applying lean in healthcare, yet, there is little evidence of the Lean philosophy being applied in the healthcare (Hines et al., 2004; Radnor and Boaden, 2008).

When reviewing literature on the use of Lean in healthcare, one underlying theme becomes apparent: Lean is often perceived as a set of tools and techniques for improving processes. The words “process”, “value stream” and “continuous flow” appear in almost all papers that discuss the application of Lean in healthcare (Poksinska, 2010). It is often emphasized that current healthcare systems consist of fragmented process which require a shift in how the flow of patient care delivery is perceived and organized (Kim et al., 2007).

Lean thinking philosophy, which includes employee involvement, customer involvement, pull systems and continuous flows has been used successfully in healthcare environments over the past decade (Shah & Ward, 2007). There is a growing endorsement of lean thinking in health policy initiatives in many countries across the world. The US Institute for Healthcare Improvement (IHI) believes that lean principles can be successfully applied to the delivery of healthcare. According to the (IHI), the application of lean thinking is one way for organisations to improve processes and outcomes at reduced cost and with greater patient and staff

satisfaction (IHI, 2005). The US Institute of Medicine (IOM) concluded “the waste and inefficiency in the current delivery system is substantial” and there are strategies, including Lean, to “lower expenditures over the short- and long-term (Young and Olsen, 2010).

In terms of evidence, there are reports from the US and the UK (e.g. Institute for Healthcare Improvement 2005; Radnor et al. 2006; Papadopoulos and Merali 2008; Radnor and Walley 2008) of substantial reductions in waste in health care organizations, with lower inventory levels, reduction in waiting time to first appointment or to diagnosis following tests, and people and supplies travelling shorter distances. Lean implementations in health care are reported to deliver substantial operational benefits including reduced waste and a more responsive service (Papadopoulos and Merali 2008).

The IHI’s ‘White Paper’ on lean thinking refers to the example of Virginia Mason Medical Center in Seattle which after two years of lean implementation and 175 Rapid Improvement Events had increased productivity and had achieved reductions of around 40% or higher in a range of measures including inventory, lead time and the distances travelled by people and products (IHI, 2005). Other examples include: Denver Health System (LaGanga, 2011), Intermountain Healthcare (Jimmerson, Weber, & Sobek, 2005), Johns Hopkins (Herzer et al., 2008) and ThedaCare (de Souza, 2009) have shown how Lean projects have been used to increase clinical quality, throughput, and efficiency, while also decreasing costs. Dickson et al. (2009) followed Lean implementation in the emergency departments of four hospitals and concluded that Lean implementation had the most immediate benefit when the frontline caregivers were actively involved in the process improvement efforts.

In the UK the NHS has been using elements of lean thinking in its approach to service redesign for several years: it forms part of the body of knowledge they

refer to as clinical systems improvement (Crump 2008; Rogers et al. 2004) and is incorporated within the current 'Productive Time' programme which brings together process redesign, workforce management and technology to improve performance (Shannon 2006). Lean thinking is also endorsed by the NHS Confederation (Jones and Mitchell 2006). Nevertheless, despite considerable activity in some areas (e.g. national programs in NHS Scotland), overall implementation in health settings has so far been relatively limited.

Certainly the potential does seem to exist to reduce waste and improve treatment processes. Walley (2003), used two years activity data from two health care communities, and extensive observation of activities over a six week period by seven researchers to identify patient flows that could be used to re-design treatment processes around the patient using lean principles. The study found that there was potential to reduce some queues by redesigning processes and that waiting times in A & E were to some extent attributable to capacity imbalances rather than capacity shortages.

An overview of the use of lean thinking in eight public sector organizations including two health care organizations showed that organizations tended just to use a few tools and approaches (e.g. value stream mapping). One of the health care organisations in the study was taking a long-term approach to lean and emphasizing sustainable change (incorporating lean principles into strategy formulation and policy development) while the other health care organization was taking a more short-term approach to generating process improvement through PDSA cycles carried out by multi-functional teams (Radnor et al. 2006; Radnor and Walley 2008). The two health agencies in this study reported process improvements (e.g. reducing the number of steps in a process, reduction in time to first appointment from 23 days to 12 days) and reduction in time to diagnosis (the percentage of patients diagnosed in two weeks increased to 92% from 45%)

(Radnor and Walley, 2008). The more tactical adoption of lean thinking in problem areas was the more common approach in the eight public sector organisations than full implementation. The aspects of lean thinking that some organisations were using were too advanced for the organization's stage of readiness and a common problem was difficulty in sustaining the changes made (Radnor et al. 2006).

Recognition of the extent of the organization's problems in one French hospital led to the deliberate decision to concentrate on improving the stability of basic processes through lean principles before attempting mapping processes or rapid improvement events (Balle and Regnier 2007). A 5S process was used to address basic processes (e.g. ward and corridor tidiness) before addressing more technical processes involving patient care, and this was done through small pilot projects in specific areas of the hospital rather than attempting hospital-wide initiatives. This approach resulted in a calmer working environment where staff were better able to focus on what they needed to do and where problems could be more easily identified at an earlier stage (Balle and Regnier 2007). However, experience of using even this initial and limited approach to lean in health care settings is challenging: four change agents who were responsible for running 16 initial CANDO (5S) projects over four hospitals within one trust over 18 months encountered a range of problems including resistance to change; inertia and lack of motivation; lack of management support; and problems in sustaining changes made (Massey and Williams 2005; Massey and Williams 2006).

There is only one organisation (Bolton Hospitals NHS Trust) reported in the UK literature to have attempted to apply lean principles across a whole NHS hospital, with mixed results (Fillingham 2007). Most reports of the use of lean in health care settings describe its partial application, both in terms of the selective use of certain lean tools and approaches to achieve changes rather than adoption of the overall 'whole system' philosophy and in terms of its use in individual

departments within hospitals, including support and administration departments (Esain et al. 2008). For example, the pathology department at one trust improved the turnaround time for pathology specimens to be received, analyzed and reported on (Westwood and Silvester 2007). Another trust which applied lean techniques to achieve the national target in radiology waiting times developed an intranet-based waiting list for radiology services and achieved significant reductions in waiting times: the longest waiting time decreased by 30% in all areas of radiology; the inpatient waiting time for imaging reduced to a maximum of 72 hours (Lodge and Bamford 2008). Other improvements followed: a single waiting list was developed across the four hospital sites and DNA rates halved to 4% after patients were given a choice of appointments (Lodge and Bamford 2008).

In NHS Scotland, the Improvement and Support Team (IST) of the Scottish Government's Health Delivery Directorate has applied lean thinking to a number of national redesign programs, with achievements in assessment processes, in bed availability and occupancy rates and in patient waiting times from referral to diagnosis (Scottish Government Directorate of Health Delivery 2008).

A review of seven lean-inspired projects in Swedish health care (Tragardh and Lindberg 2004) found that although some of the projects led to improvements in the quality of patient care, in some organizations staff used the process of examining existing activities to justify the status quo, arguing that existing processes were already as 'lean' as they could possibly be and that only substantial increases in resources would lead to any improvement.

Dickson et al (2009), described the effects of Lean on quality of care in 4 emergency departments (EDs). The results showed that length of stay was reduced in 3 of the EDs despite an increase in patient volume in all 4. The immediate results were also greater in the EDs in which the frontline workers were actively participating in the Lean-driven process changes.

Erfan, (2010) found that Value Stream Mapping tool showed significant improvements in the overall performance of the health care system in Libya, leading to increased productivity, flexibility, smooth flow and high quality service.

Mazzocato et al. (2010)systematically reviewed empirical studies of lean applications in healthcare from January 1998 to February 2008. They concluded that Lean has been applied successfully in a wide variety of healthcare settings.

Glasgow et al. (2010) conducted A systematic literature review to determine whether Lean has been effectively used to create and sustain improvements in the acute care setting. They concluded that Lean can aid institutions in tackling a wide variety of problems encountered in acute care. However, the true impact of this approach is difficult to judge, given the lack of rigorous evaluation or clearly sustained improvements provides little evidence supporting broad adoption.

Mazzocato et al. (2012) conducted a case study of lean-inspired intervention at the Astrid Lindgren Children's hospital, Stockholm, Sweden. Their study revealed improvements in waiting and lead times (19-24%) that were sustained in the two years following lean-inspired changes to employee roles, staffing and scheduling, communication and coordination, expertise, workspace layout, and problem solving. These changes resulted in improvement because they: (a) standardized work and reduced ambiguity, (b) connected people who were dependent on one another, (c) enhanced seamlessflow through the process, and (d) empowered staff to investigate problems and to develop countermeasures using a “scientific method.

In conclusion, Lean principles adapted to local culture of care delivery can lead to behavioral changes and sustainable improvements in quality of care metrics in the ED. These improvements are not universal and are affected by leadership and frontline workforce engagement (Dickson et al., 2009).

2.2.6 Strengths and Weaknesses of Lean Thinking

Lean thinking has several strengths. It encourages staff to look at processes in a customer- or patient- focused way, which fits well with other policy initiatives. Its main focus (on value for the customer) can be addressed in conjunction with other tools and approaches; and it is seen as a bottom-up change process, which is more conducive to staff involvement.

Moreover, lean can assist in identifying and addressing different types of 'waste' in processes and thus make health care delivery more streamlined and more pleasant for patients and for staff.

Like other quality improvement approaches, lean thinking in health care faces the challenge of defining 'the customer' when there are multiple internal and external customers, whose interests may conflict. A particular challenge for implementing lean thinking is that many staffs are suspicious of the concept: lean thinking is perceived to emphasize cost cutting and staff reduction ('lean and mean'). Indeed one NHS Confederation document explicitly advises that applying lean methods cannot be used as a short term crisis measure to balance budgets, and warns that *"long experience suggests that lean initiatives rarely succeed unless staff employment is guaranteed in advance"* (Jones and Mitchell 2006:21).

Lean is also challenging in health care for several other reasons: its 'Just-In-Time' thinking requires that demand can be accurately predicted, which may be hard in some health care fields (e.g. psychiatric and emergency care), and making processes 'lean' is difficult in health care settings when many patient pathways are complex and when current processes are department- or specialty- based (UK). Just-In-Time production may prove more difficult and risky in health care due to the unpredictable volumes during infection outbreaks or natural disasters. For example, during the 2003 SARS outbreak a Just-In-Time inventory, of masks and

other infection control inventory, may have led to the supply being unable to meet the demand (O'Neill, 2014).

In summary, on the evidence available to date, lean thinking may provide a useful approach to looking at processes in organizations and particularly in streamlining processes in individual support departments (e.g. pathology, radiology). 5S type tools may help with initial 'ground-clearing' prior to more detailed examination of processes or prior to implementing other quality improvement approaches (Radnor et al 2006: 5).

2.3 SIX SIGMA

2.3.1 Origin of Six Sigma

Six Sigma was originally developed by Bill Smith of Motorola in 1986 as a way of eliminating defects in manufacturing, where a defect is understood to be a product or process that fails to meet customers' expectations and requirements. Motorola is one of the world's leading manufacturers of electronic equipment, systems and components for both United States and international markets.

Six Sigma has its roots in Statistical Process Control (SPC), which first appeared in 1920s. In 1922, Walter Shewhart introduced 'Three Sigma' as a measurement of output variation (Chakrabarty and Tan, 2007). Shewhart's observation in the 1920s was that three standard deviations from the mean is the point where a process requires correction. He stated that process intervention is needed when output went beyond this limit. The three sigma (standard deviations) concept is related to a process yield of 99.973 percent or 2,600 Defect Per Million Opportunities (DPMO). A Six Sigma opportunity is the total quantity of chances for a defect to occur in a product. Three sigma was adequate for most manufacturing units at that time (Raisinghani, 2005).

In the 1970s, Motorola encountered intense competition from their global competitors, especially the Japanese. During this period, Japanese industries possessed strong competitiveness based on their ability to develop higher quality products with lower costs compared to their American competitors. The threats caused Motorola to execute the benchmarking from the Japanese electronics industry and found out that many Japanese electric products were with six sigma (6σ) quality level (3.4 DPMO), but Motorola's products were with four sigma (4σ) quality level only (6.210 DPMO). The weakness in quality led Motorola to initiate the Six-Sigma improvement program as a systematic method for eliminating defects in manufacturing, where a defect is understood to be a product or process that fails to meet customers' expectations and requirements. The aim of Motorola was to achieve six sigma (6σ) quality level (2.33 DPMO) in a 5-year period.

The successful implementation of the Six Sigma program in Motorola resulted in huge benefits. Within four years, the Six Sigma programs saved the company $2.2 billion (Harry and Schroeder, 2000). Only two years after launching Six Sigma, Motorola was honored with the Malcolm Baldrige National Quality Award (MBNQA) in 1988 (Klefsjö and Edgeman, 2001). The MBNQA is presented annually by the President of the United States to organizations that demonstrate quality and performance excellence.

Allied Signal followed Motorola in successfully implementing the Six Sigma program in the early 1990s. Allied Signal (now Honeywell) attained savings of US$2 billion during a five-year period (Klefsjö and Edgeman, 2001). Such impressive results induced General Electric (GE) to undertake a thorough implementation of the Six-Sigma program (GE-6σ) since 1995 (Pande, et al., 2000). GE implemented 6σ programs and reaped huge financial benefits. The 1999 annual report of GE showed that the implementation of GE-6σ produced more than US$2 billion in benefits in that year (Slater, 2001; Schweikhart and Dembe, 2010).

The impressive benefits of implementing Six Sigma programs in Motorola and high profile companies such as Allied Signal and General Electric (GE) encouraged many industries and organizations throughout the world to adopt Six Sigma (Schweikhart and Dembe, 2010). Within a decade the Six Sigma mindset had traveled across the globe to become one of the world's most important methods in quality management (Caulcutt, 2001; Goh, 2002; George, 2002;Thawani, 2004; Chakrabarty and Tan, 2007; Nakhai and Neves, 2009).

2.3.2 Definition of Six Sigma

Sigma (σ) is a Greek letter used in statistics as a symbol to represent standard deviation (Park, 2003). Standard deviation is a statistical way to describe how much variation exists in a set of data or a process. It measures the amount of variation or dispersion from the average. Low standard deviation means that a set of scores is not very widely dispersed around the mean, while a high standard deviation indicates the scores are more widely dispersed (Singleton, 2010).

Six Sigma is a statistical concept that measures a process in terms of defects (Snee, 2010; Kumar et al., 2011). The output of a process is expected to meet specifications, which can be determined according to the customer requirements.Any variation outside of the customer specifications for quality is considered a defect and is seen as a failure to meet the customer expectations. Six sigma is therefore used to denote 'perfection' and is usually defined for practical purposes as achieving a rate of only 3.4 defects per million opportunities (DPMO) or almost free-error (Wears 2004; Young et al. 2004; (Pande et al., 2000; Pandey, 2007; Llyod and Holsenback, 2006; Jenicke et al., 2006). An 'opportunity' is defined as a chance for nonconformance, or not meeting specifications.

The importance of a precise definition to rigorous research can never be overstated (Wacker, 2004). What is surprising, however, is that even after three

decades in practice, a commonly agreed definition of Six Sigma Model is yet to be developed (Schroeder et al., 2008). There are various definitions because Six Sigma means different things to different people (Jiju, 2004). From a business perspective, Six Sigma may be defined as: a formal methodology for measuring, analyzing, improving, and then controlling processes to improve business profitability, effectiveness and efficiency to meet or exceed customer needs and expectations (Kwak and Anbari, 2006; Bolze, 1998; Goh, 2002; Paul, 1999; Harry and Schroeder, 1999). Paul (1999), defined Six sigma as a comprehensive, statistics-based methodology that aims to achieve nothing less than perfection in every single company process and product. Six Sigma is often defined as: a quality improvement program with a goal of reducing the number of defects to as low as 3.4 parts per million opportunities (DPMO) or 0.0003% (Chakrabarty and Tan, 2007). It is a business strategy used to improve business profitability, effectiveness and efficiency of all operations to meet customer needs (Kwak and Anbari, 2006).

Incorporating elements from the work of many quality pioneers, Six Sigma aims for virtually error free business performance. Hayler and Nichols define Six Sigma as an "application of scientific management methods, but it actually integrates many different creative, technical, and change management methods, tools, and techniques to improve business processes", (Hayler and Nichols, 2007).

Paul (1999), defined Six sigma as a comprehensive, statistics-based methodology that aims to achieve nothing less than perfection in every single company process and product. For many organizations Six Sigma simply means an information-driven methodology for reducing defects, increasing customer satisfaction, and improving processes, with a focus on financially measurable results (Goh, 2002; Paul, 1999; Harry and Schroeder, 1999).

The statistical focus of various six sigma definitions reflects its basic philosophy. Fundamentally, it is an organisation wide quality improvement

approach that uses statistical and quality management tools for implementing organization change, dramatically reducing defects, optimizing processes and producing measurable financial results (Snee 2004; Harry and Schroeder 2000; Goh et al., 2003; Calia, et al., 2009; Chua, 2001).

2.3.3 Six Sigma Concepts and Practices

The objective of Six Sigma is to reduce defects so that virtually all the products or services provided meet or exceed customer expectations (Mahdi and Almsafir, 2012). This means Six Sigma is strongly supported by the theoretical notion of zero defects. According to Crosby (1979), defects cause waste, rework, or scrap, and eventually lead to customer dissatisfaction. If a process can achieve Six Sigma quality level, it will literally produce no defective product. This will not only reduce waste and cost but also improve customer satisfaction.

The level of quality depends on the level of sigma as an indicator of the number of defects in a process. Higher sigma values indicate better performance, while lower values indicate a greater number of defects per unit (Chakrabarty and Tan, 2007). For instance, at a three sigma level defects are 66,800 per million opportunities while at Six Sigma level defects are limited to just 3.4 per million opportunities (Schweikhart and Dembe, 2010; Henderson and Evans, 2000; Bolze, 1998). A Six Sigma level is determined by random sampling then calculating a statistical reading from the sample to estimate the defects of the entire population of goods and services. From this random sampling and estimate of the population, the organization gains an understanding of the level of quality it is producing at. This level of quality is the sigma level which again is an indication of the number of defects per million opportunities (Hayler and Nichols, 2007).

In healthcare, Six Sigma aims to eliminate defects and reduce variation in processes in order to improve output and outcomes from the system to meet customer requirement (Khaidir et al., 2014; Westwood and Silvester 2006). The

key methods to achieve this are statistical tools and analysis to identify the root cause of variation (Schweikhart and Dembe, 2009; Catherwood, 2002; Henderson and Evans, 2000; Hahn et al., 1999). A process is “an organized group of related activities that work together to transform one or more kinds of input into outputs that are of value to the customer” (Hammer, M. 2001). In healthcare a process refers to the procedures, methods, means and sequence of steps for providing or delivering care and producing outcomes (Brown, 2012).

Process variation refers to the way the performance of a process changes over time. There will be fluctuations in all processes over time (e.g., day-to-day, week-to-week, month-to-month, etc.). This variation occurs naturally in all processes and should be expected. Six Sigma identifies two causes of variation: ‘common’ or 'random' causes that result in minor fluctuations in the data, and ‘special’ or ‘assignable’ causes that result in the data showing an unusual pattern (compared to that normally displayed by random causes) and to which a cause can be assigned (Naslund 2008; Taylor and Shouls 2008). Common-cause variation appears as random variation in all measures from healthcare processes (Lighter,2011). Special-cause variation appears as the effect of causes outside the core processes of the work. Management can reduce this variation by enabling the easy recognition of special-cause variation and by changing healthcare processes—by supporting the use of clinical practice guidelines, for example—but common-cause variation can never be eliminated (Neuhauser, at al., 2011). The magnitude of common-cause variation creates the upper and lower control limits in Shewhart control charts (Berwick, 1991; Moen et al., 1998; Nolan and Provost, 1990).

The goal of statistical thinking in quality improvement is to make the available statistical tools as simple and useful as possible in meeting the primary goal, which is not mathematical correctness, but improvement in both the processes and outcomes of care (Neuhauser, at al., 2011). In Six Sigma, the aim is primarily to

address the second type of variation (special or assignable causes of variation), although if a process has a significant amount of common variation, then action may be needed to change the process itself (Naslund 2008).

Some variation in healthcare is desirable, even essential, since each patient is different and should be cared for uniquely. New and better treatments, evidence-based practice and improvements in care processes result in beneficial variation. Special-cause variation should lead to learning (Neuhauser, at al., 2011).

A crucial differentiator of Six Sigma from other quality improvement methods is intensive technical training and coaching by experienced so-called 'master black belts' (Proudlove et al. 2008). Quality improvement projects are led by so called Black Belts (BBs) and Green Belts (GBs), typically selected from middle management. To guide Black Belts and Green Belts through the execution of an improvement project, the program provides a collection of long standing management and statistical tools and a problem solving methodology.

Statistical process control (SPC) is a key tool used in Six Sigma; SPC can also be used independently of a Six Sigma approach. SPC uses statistically based rules to interpret any unusual patterns in plotted data of events or other system parameters. SPC charts enable retrospective analysis of the state of the process, but also prospective analysis that allows dynamic monitoring to detect any shifts in the process (Taylor and Shouls 2008; Schleicher 2008).

Because variation exists in all processes, statistical thinking can be used to monitor and improve the processes in any business environment (Schleicher, 2008). There are three principles of statistical thinking: (i) all work is a process, (ii) all processes have variability and (iii) all processes create data that explains variability. Consequently, a helpful preliminary step in statistical thinking is to diagram the various steps in creating a product or a service (Hoerl and Snee, 2002).

In manufacturing applications, the goals of statistical process control are to create a stable, predictable process by eliminating special causes of variation and then to achieve a process that is capable of meeting customer requirements by reducing common cause variation (Wheeler 2000). In health care applications, special causes can often be eliminated through corrective action such as redesigning procedures and training staff. SPC control charts can be used in healthcare improvement to visualize and analyze organizational processes over time to determine whether the process is stable and predictable or whether there is unwarranted variation (Thor et al. 2007).

2.3.4 Six Sigma Tools and Techniques

Over time, many tools and techniques have been developed to help organizations improve their processes to achieve Six Sigma level quality (See Appendix 1, for more details on quality tools). The most used tools are DMAIC (Define, Measure, Analyze, Improve, and Control) and DFSS (Design for Six Sigma) (Antony et al. 2007b; Naslund 2008; Pulakanam and Voges, 2010).

2.3.4.1 DMAIC Methodology

The DMAIC (duh-may-ick) is a data-driven quality strategy that guides practitioners through problem-solving steps and gives a structure for the use of tools like process mapping and statistical process control. It is an integral part of a Six Sigma initiative, but in general can be implemented as a standalone quality improvement procedure or as part of other process improvement initiatives such as Lean. Six Sigma also uses the theory of constraints: this provides a set of steps to identify and address any constraint (bottleneck) that impacts on the whole system (Hines et al. 2004; Young et al 2004; Pulakanam and Voges, 2010). The DMAIC methodology and the objectives in different phases are shown in table 2-5.

Table 2-5: The DMAIC Methodology.

Step	Description	Objectives
Define	Define the problem within a process	The Define phase includes defining the defect, forming the team, defining the project's goals, mapping the process, identifying customers, and identifying the characteristics that have the most impact on quality "Critical to quality" (CTQs) or "Vital Few" and separating them from the "Trivial Many" ((Mandahawi et al., 2011).
Measure	Measure the defects	The next step is to collect data to find out why, how, and how often this defect occurs. Baseline data is collected on the process performance and its impact. Once the reasons for input failures are determined, preventive action plans are put into place. The big part of this phase begins with establishing valid and reliable metrics to monitor the progress of the project are established during the Measure phase (Antony and Banuelas, 2002).
Analyze	Analyze the causes of defects	The team analyzes data collected in previous steps to identify the causal factors using analytical tools like root cause analysis or cause and effect analysis. The team learns how to eliminate the gap between existing performance and the desired performance.

Improve	Improve the process performance to remove causes of defects	The team changes the process to address the root causes identified. Resources are allocated so that changes needed for improvement can be implemented. Several rounds of improvement may be necessary.
Control	Control the process to ensure that defects do not recur	The team determines the control plans that will ensure that the defects will not recur; a statistical process control chart is commonly used to monitor the process and alert the team to special variation that requires remedial action. Success in this phase depends upon how well things are done in the previous four phases. The team shares the gains with the organization as a whole. (Desai and Shrivastava, 2008; Bandyopadhyay and Coppens, 2005).

Source: adapted from Antony et al. 2007b

2.3.4.2 Design for Six Sigma (DFSS)

Another Six Sigma methodology, *Design for Six Sigma* (DFSS), is used to systematically design new products and services that meet customer expectations and can be produced at Six Sigma quality levels (Kwak and Anbari, 2006). Unlike the DMAIC methodology, the phases of DFSS are not universally recognized or defined — almost every company or organization will define DFSS differently. Many researchers agree that DFSS is a proactive approach and focuses on design by doing things right the first time (El-Haik and Roy, 2005; Treichler et al, 2002;

De Feo and Bar-El, 2002). The major focus of DFSS approach is to look for inventive ways to satisfy and exceed the customer requirements. This can be achieved through optimization of product or service design function and then verifying that the product or service meets the requirements specified by the customer (Antony and Coronado, 2002; De Feo and Bar-El, 2002).

The literatures also concentrate on the differences between DMAIC and DFSS approach. The DFSS involves designing processes to reach Six Sigma levels while the DMAIC methodology is excellent when dealing with an existing process in which reaching a defined level of performance will result in the benefits expected (Hoerl, 2004; Ferryanto, 2005). The projects improved through DMAIC methodology are constrained by the assumptions made during the development and design stages, whereas DFSS builds quality into the design by implementing preventive thinking and tools in the product development process (Smith, 2001). The tools and techniques involved in the DFSS methodology are also somewhat different from those of the DMAIC methodology (El-Haik and Roy, 2005). DFSS includes innovation tools such as the theory of inventive problem solving, axiomatic design, and quality function deployment, which DMAIC does not (Kwak and Anbari, 2006; Hendry and Nonthaleerak, 2005; El-Haik and Roy, 2005; Goel, et al., 2005; Raisinghani et al., 2005; Basu, 2004; Antony and Coronado, 2002; Stamatis, 2002 (a and b); Harry and Schroeder, 1999).

2.3.5 Empirical Evidence of Six Sigma in Healthcare

The use of Six Sigma in health care is relatively recent (Revere et al. 2004). Most of healthcare organization focused on direct care delivery, administrative support and financial administration *(*Khaidir et al., 2014).

One of the first health care organizations to implement Six Sigma was the US Commonwealth Health Corporation in Kentucky, which achieved improvements in throughput and reducing costs in radiology (Heuvel et al. 2005). Other US hospitals reported successes from Six Sigma. Major benefits realized at Mount Carmel Health System, a three hospital organization in the US, were a financial return of $3.1 million and increased employee satisfaction and retention as a result of addressing problems with daily operational processes (Sehwail and DeYong 2003). Revere et al. (2004) lists applications of Six Sigma in Scottsdale Healthcare resulting in reduced variation in length of stay, reduced times for transferring patients from the emergency room to the ward and gained profits at $600,000.

Eldridge et al. (2006) explored the effect of Six Sigma in the implementation of the Centers for Disease Control and Prevention (CDC) guidelines for hand hygiene in four intensive care units in three hospitals. Their study revealed significant increase in the compliance rate from 47% to 80%.

In the UK, studies in the NHS have reported quality improvements in healthcare when Six Sigma tools are applied to particular processes e.g. reducing turnaround time for pathology specimens (Westwood and Silvester 2006). The NHS Modernisation Agency set up a Six Sigma pilot project in 2004 to test its viability in the NHS. This was in part a response to concerns that few hospitals were carrying out measurement as part of their quality improvement initiatives, despite the Agency's promotion of the PDSA approach (with its strong emphasis on measurement as part of the improvement cycle) (Proudlove et al. 2008).

The NHS Institute for Innovation and Improvement has designed an integrated Lean Six Sigma approach (NHS Institute for Innovation and Improvement, undated) with the intention that organizations can draw on a range of tools and make use of facets of both approaches. This integrated approach was developed because early NHS experience with Six Sigma found that sigma scores were so far

from the Six Sigma proposition that the processes required extensive redesign (NHS Institute for Innovation and Improvement undated).

Antony et al (2007b) review Six Sigma programs in health care organizations in the US and Europe. The use of Six Sigma in health care has produced benefits in some organizations in terms of reducing errors, reducing length of stay and improving patient satisfaction. However, application in healthcare is in its infancy and the use of Six Sigma is highly demanding (e.g. training staff in the methods, obtaining high quality data regularly, accurately identifying processes).

The Skaraborg Hospital Group (SkaS) in Sweden is the first hospital group in the Nordic Countries that has added Six Sigma on a large scale to its quality program to improve care processes. Unlike many change efforts in the healthcare sector that are neither successful nor sustainable the success rate of improvement projects in the program was 75%, in some respects due to lessons learned from this particular project (Lifvergren et al., 2010).

Through a range of Six Sigma projects supported by structured training, the Red Cross Hospital in the Netherlands achieved savings from 2002-2004 of around 1 million Euros and improved efficiency in a range of areas including waiting times, length of stay and distribution of supplies (Heuvel et al. 2005).

DelliFraine and Langabeer (2010) conducted a structured systematic review of articles on the use of Six Sigma in healthcare settings that were published between 1999 and 2009. The authors found that the level of evidence supporting a positive relationship between the use of Six Sigma and performance improvement was weak. They also found that most studies focused on Six Sigma to improve processes of care, while few studies focused on Six Sigma to improve clinical outcomes. The authors also found limited literature on the failures of Six Sigma.

Charles et al., (2012) examined how Performance Improvement (PI) initiatives mediate the effect of medical error sources to enhance three hospital outcomes

(patient safety, operational effectiveness, and competitiveness). They concluded that Six Sigma was significant in improving organizational effectiveness and achieving superior sustainable competitive advantage.

DelliFraine et al (2013) conducted a comprehensive literature review to assess the correct use and implementation of Six Sigma and the empirical evidence demonstrating the relationship between Six Sigma and improved quality of care in health care organizations. This review demonstrates very weak evidence that Six Sigma is being used correctly to improve health care quality.

Chakraborty and Chuan (2013) investigated the applicability of Six Sigma in services. They concluded that, despite the availability of much theoretical description of Six Sigma, its implementation in service organizations is not yet mature. Matthew (2013)conducted a comprehensive review and assessment of the extant Six Sigma healthcare literature, focusing on: application, process changes initiated and outcomes, including improvements in process metrics, cost and revenue. While 67 percent of the applications had initial improvement in the key process metric, only 10 percent reported sustained improvement. Only 28 percent reported cost savings and 8 percent offered revenue enhancement.

Miguel and de Carvalho, 2014reported case studies conducted in services organizations including healthcare that apply Six Sigma in an emerging economy in Brasil. They verified that Six Sigma was successfully implemented in those organizations, however with some drawbacks. Six Sigma implementation in a short span of six months in Zahra Hospital in Libya had resulted in reduced risk factors, significant improvement in almost all infections, reduced utility consumption without any compromise on patient care and patient satisfaction (Elsagri, 2014).

Statistical process control (SPC) is a key tool used in Six Sigma. Studies that have looked at the use of statistical process control (SPC) in healthcare have found that SPC has the potential to improve a range of processes at the individual patient

level (e.g. in an individual patient's control of their diabetes) and at the organizational level (e.g. bed occupancy, medication errors), but that effective use of SPC depends on the existence of a number of conditions which are difficult to achieve in a typical health setting (e.g. high quality routine data, statistical expertise, robust and comprehensive IT infrastructure) (Thor et al., 2007).

More recently there has been increasing pragmatic use of a combination of lean thinking and Six Sigma under the name Lean Six Sigma (Hines et al. 2004; Antony et al. 2007b). As it is mentioned earlier, lean has a focus on product flow and elimination of waste, while six sigma aims to reduce variability. Using either one of the philosophies in isolation may create diminishing returns at some point, when the combination may bring improvements in productivity (Arnheiter and Maleyeff, 2005) since Lean Six Sigma aims to capitalize the strengths of the two philosophies and avoid the weaknesses of them.

When six sigma is used in isolation, the focus is reducing the variation which may be the reason for losing the customer-oriented approach. On the other hand, being too lean may force organizations to lose the producers' point of view. Therefore, the balance should be creating customer value, while simultaneously reducing variation to acceptable levels (Pepper and Spedding, 2010).

2.3.6 Strength and Weaknesses of Six Sigma

With the implementation of Six Sigma, organizations can achieve significant benefits. Those benefits may turn into competitive advantages for organizations because Six Sigma integrates the process knowledge with statistics, engineering and project management. (Kwak and Anbari, 2006). Besides, with Six Sigma, organizations learn to change their problem solving approach from reactive to proactive (El-Haik and Roy, 2005; Treichler et al, 2002; De Feo and Bar-El, 2002).

Six Sigma and its associated tools enables prospective and retrospective analysis of variations in a process and can enable identification of unwarranted

variation and the impact of subsequent interventions (Powell et al., 2008). Six Sigma was reported to have been successfully used to decrease defects/variations and operating costs and improve outcomes in a variety ofhealthcare settings (Printezis et al., 2007; Guinane and Davis, 2004; Jimmerson et al., 2005). It was found to be a detailed process that clearly differentiated between the causes of variation and outcome measures ofprocess (Printezis et al., 2007).

Six Sigma makes reworkdifficult because the root causes of the pre-implementation processes are targeted to achieve more effective results ((Printezis et al., 2007; Jimmerson et al., 2005) Thompson et al., 2003). Commitment of leadership time and resources contributes to effective use of this strategy and is associated with improved patient safety, lowered costs, and increased job satisfaction (Thompson et al., 2003). Six Sigma is also an important strategy for problem-solving and continuous improvement; communicating clearlyabout the problem; guiding the implementation process; and producing results in a clear, concise and objective way (Endsley et al., 2006).

Despite its scientific approach, the use of Six Sigma in healthcare is challenging. Patient care significantly involves human element as compared to machine elements, in which the variability is subtle and very difficult to quantify. Therefore, the challenge in adopting Six Sigma approach to healthcare is to find a way to leverage the data from Six Sigma to drive human behavior. Success will come only when the Six Sigma technical strategy is combined with a cultural strategy for change acceleration (Lasarus et al., 2003).

Six Sigma is often criticized for not considering system interaction and coordination of projects. Becausethereisnoimplementationmodel,practitionershaveencounteredtremendousdifficultyinimplementingtheseprograms,andtherearereportsofwide-spreadSixSigmafailures (Fursule, et al., 2012) .According to Hines et al., (2004),

Six Sigma lack consideration for human factors, processes improved independently, significant infrastructure investment required, and the goal of Six Sigma (3.4 DPMO) is absolute – but this is not always an appropriate goal and does not need to be adhered to rigorously.

In addition, Six Sigma does not in itself address the cultural or interpersonal aspects of quality improvement and it is limited further in that it looks at individual processes rather than taking a system-wide approach and looking additionally at the interaction between processes (Westwood and Silvester 2006; Klefsjo, et al., 2001). It may therefore encourage a single hit' approach rather than continuous improvement across a range of aspects of care (Proudlove et al. 2008). It is also problematic in that it emphasizes requires investment in training and the use of a cadre of experienced experts (Black or Green Belts) who are 'parachuted in' in contrast to the bottom up improvement process of other quality improvement approaches (e.g. TQM). This particular feature would discourage many small and medium size enterprises from the implementation of Six Sigma strategy.

Six Sigma may be less suitable for use in healthcare settings than in industry because many health care processes are complex and subject to more 'noise' or uncontrollable factors (e.g. interactions between health professionals and sick patients) than manufacturing processes are (Antony et al. 2007a; Antony et al 2007b; van Iwaarden et al., 2008). Similarly, the measurement of patient satisfaction is more difficult than customer satisfaction in industry because of the human interaction aspects: it is easier to change machine parameters than it is to adjust staff or work processes (Antony et al., 2007a; Antony et al., 2007b).

To be effective, Six Sigma is dependent on high quality data, clearly defined outcomes, agreement on what constitutes a defect and on statistical expertise, all of which are often lacking in healthcare settings (Young et al. 2004; Ovretveit 2005). It also requires substantial investment in training (Ovretveit 2005; Antony et al.

2007b). Front line clinicians must therefore have access to appropriate systems and support (both technical and statistical) so that they can easily collect robust appropriate data for analysis. Six Sigma may therefore be useful in analysing variation in relatively stable processes in organisations providing high quality data and robust ongoing support for clinical teams to enable them to collect, analyse and use the data effectively.

2.4 Business Process Reengineering (BPR)

2.4.1 The Origin of the BPR

Some researchers argue that the original concept of reengineering can be traced back to the management theories of the nineteenth century and the classical school of strategic thinking popularized in the 1960s (Galliers, 1998). However it is commonly agreed that BPR originated in the US in the 1950s and drew on older ideas including scientific management, operational research, function-cost analysis and organisation and methods (Packwood et al. 1998).

BPR has gained currency on the back of the idea that there was an urgent need for US firms to change radically in order to remain competitive: that there was a need for a radical shift away from the marginal incremental improvements of TQM and away from an excessive focus on the efficiency of each task towards focusing on the processes and reengineering them (Arndt and Bigelow 1998). It is based on the assumption that change in business processes should generate radical improvements in critical performance measures (such as cost, quality, service and speed) (Hammer and Champy 1995). Unlike any continuous improvement program, the processes are not merely improved, they are restructured and redrawn. Direction for this radical shift would come from the top: from a visionary leader who would mobilize and motivate employees.

BPR is commonly linked with authors Hammer and Champy who claim to have defined, clarified and systematized the work that was already being done under the title of reengineering (Hammer and Champy 1995).

The early 1990s saw many companies around the world, especially in the United States, implementing Business Process Reengineering (Chan and Land, 1999; Hammer and Champy, 1990). BPR has been recognized as a powerful approach to radically change and improve business processes (Davenport & Stoddard 1994); attracting both executives and academics, and also being explored in several books (Grover & Malhotra 1997; Melão & Pidd 2000).

2.4.2 Definition of the BPR

BPR is known by many names, such as 'core process redesign', 'new industrial engineering' or 'working smarter'. The term Business Process Improvement (BPI) is also used interchangeably with Business Process Re-engineering (BPR) (Adesola and Baines, 2005). All of these terms imply the focus on integrating both business process redesign and deploying IT to support the reengineering work.

Researchers and practitioners have defined BPR in a variety of ways (Al-Mashari and Zairi, 2000). This lack of a commonly agreed definition of BPR makes it difficult to assess the overall success or failure of its concept (Peltu et al., 1996; van Meel et al., 1994; MacIntosh and Francis, 1997; Peltu et al., 1996).

BPR encompasses the envisioning of new work strategies, the actual process design activity, and the implementation of the change in all its complex technological, human, and organizational dimensions" (Thomas H. Davenport, 1993). Hammer and Champy (1993), defined business process reengineering (BPR) as: *"the fundamental rethinking and radical redesign of business processes to achieve dramatic improvements in critical, contemporary measures of performance, such as cost, quality, service, and speed."* (Hammer and Champy

1993: 32)". Ovenden (1994, p.56) defined reengineering as "a fundamental re-appraisal of the purpose of the processes involved, with no holds barred, and putting in place what might be radically changed organization and operations".

BPR can also be defined as a total transformation of a business, an unconstrained reshaping of all business processes, technologies and management systems, as well as organizational structure and values, to achieve quantum jumps in performance throughout the business (Crowe, Fong and Zayas-Castro, 2002). This involves throwing away the old processes and starting anew (Aalst and Hee, 1995; Hammer, 1990).

BPR as an integrated and systematic approach enhances analysis and re-design of the functions, workflows and structure of the organization to improve service quality and cause cost and time reduction (Khodambashi, 2013). Muthu et al. (1999) pointed out that organizations need to backtrack and reexamine their very roots before starting a BPR project. Stoica et al., (2004) stressed that BPR is the evaluation and amendment of strategy, process, technology, organization, and culture. The emphasis in all the definitions is on redesigning business processes using an enabled approach to organizational change (Johansson et. al., 1993). The definitions suggest that organisations should concentrate on processes rather than functions (or structures) as the focus of business activity.

2.4.3 **BPRConcepts and Practices**

BPR is based on the belief that implementing radical changes in business processes is the way to achieve dramatic and satisfactory results. One reason the change in BPR is radical rather than incremental is "to avoid being trapped by the way things are currently done" (Vidgen et al., 1994).

According to Hammer (1990), reengineering is not automation of an existing system (i.e. computerization) or doing less with less (i.e. downsizing). It is the

obliteration of what now exists completely and starting over with the design of a process on a clean sheet of paper. This involves the development from an ‘as-is’ process to the development and implementation of an actual ‘to-be’ process (Randor, 2010). Robinson (1994), claims that radically re-versioned processes drive the shape of the organization, rather than current structures.

In BPR, the process to be reengineered is called ‘business process’. Hammer and Champy (1993) define a business process as: a collection of activities that takes one or more kinds of input and creates an output that is of value to the customer. (p. 35). Davenport (1993), defined a business process as: ‘a structured, measured set of activities designed to produce a specified output for a particular customer or market. It implies a strong emphasis on how work is done within an organization’. Business processes are characterized by three elements: the inputs, (data or materials), the processing of the data or materials, and the outcome (the delivery of the expected result). The problematic part is processing.

Business process reengineering mainly intervenes in the processing part, which is reengineered in order to become less time and money consuming. BPR emphasizes radical rethinking: starting afresh and designing processes anew from the ground up. The key question is *‘Why do we do what we do at all?’* It is an ‘all or nothing’ approach which avoids incremental changes that leave basic structures and processes intact. The keywords for BPR are `fundamental’, `radical’, `dramatic’, `change’ and `process’. A business process has to undergo fundamental changes to improve productivity and quality.

Compared to other quality improvement models, BPR offered a more aggressive approach aimed at attaining radical and not marginal improvement or incremental changes. Reengineering is about making substantial changes to achieve significant performance improvements. It attempts to improve underlying

process efficiency by applying fundamental and radical approaches by either modifying or eliminating non-value adding activities and redeveloping the process, structure, culture" (Patwardhan and Patwardhan, 2008). BPR can be achieved by identifying the critical business processes, analyzing these processes and redesigning them for efficient improvement and benefit. This requires an information system to support process reengineering. The restructuring of an information system should support functional integration to improve supply chain management and improve productivity and quality (Soliman and Youssef, 1998).

The degree of BPR change is determined by the level of change occurring in seven aspects of re-engineering: process work flows, roles and responsibilities, performance measurements and incentives, organizational structure, IT culture and skill requirements (Chang 2006; Childe et al. 1994, Morris and Brandon 1993).

BPR is a top-down, process-driven approach managed by senior executives, which aims to improve the performance by radical changes in the system over the short term (Ardhaldjian and Fahner 1994). Companies have to meet three goals to achieve effectiveness: (i) a process, not product perspective, (ii) cross-functional coordination or integration, and (iii) consistency between goals and improvement plans (Wickens 1995, Jones et al. 1997; Lockamy and Smith 1997).

The basic aim of BPR is to deliver quality goods and services at competitive prices in a timely fashion. Therefore, a manufacturing system as well as a service organization should be modified emphasizing coordination of the basic business processes in the chain, from suppliers to customers, as opposed to the existing complex structures of the functional hierarchies. The behavioral changes should precede the reengineering. Therefore, issues such as training and education, employee empowerment, teamwork and incentive schemes should be given priority in BPR (Gunasekaran and Kobu, 2002).

Hammer and Champy suggested seven reengineering principles to streamline the work process: (i) organize around outcomes, not tasks; (ii) identify all the processes in an organization and prioritize them in order of redesign urgency; (iii) integrate information processing work into the real work that produces the information; (iv) treat geographically dispersed resources as though they were centralized; (v) link parallel activities in the workflow instead of just integrating their results; (vi) put the decision point where the work is performed, and build control into the process; (vii) capture information once and at the source.

Adesola and Baines (2005), stated that there are five key principles of BPR: (i) understand the business needs and the processes; (ii) model and analyse processes; (iii) benchmark business processes and their outcomes; (iv) use the information to redesign and implement the new processes; and (v) review and assess new process performance to feedback into further redesigns.

Grover (1993) has identified the following as common features of BPR programs: involves the radical redesign of business processes; typically employs Information Technology as an enabler of new business processes; attempts to achieve organizational level strategic outcomes; and tends to be inter-functional in its efforts. Vidgen et al. (1994) define the central tenets of BPR as: radical change; process and goal orientation; organizational re-structuring; and the exploitation of enabling technologies, particularly information technology. That is, by focusing on business objectives, analysing the processes of the organisation, eliminating non-essential or redundant procedures, and then using IT to redesign (and 'streamline') organizational operations.

Powel et al. (2009) stated that the key themes of BPR are: change is driven from the top by a visionary leader who sets the direction for the requisite radical rethinking; organisations should be arranged around key processes, not around specialist functions; tasks and functions are aggregated and narrow specialists are

replaced by multi-skilled workers in self-managed teams which are collectively responsible for designing work processes and delivering performance; change is continual and may be radical if necessary; the focus on what is produced and adds value for the customer requires objective scrutiny uncontaminated by existing functional or political interests (so external facilitation is likely to be needed); and the nature of the work is likely to alter (e.g. aggregated roles).

Davenport and Short (1996), suggest that the redesign effort of an organization involve five major steps: (i) develop business vision and process objectives; (ii) identify processes to be redesigned; (iii) understand and measure existing processes; (iv) identify IT levers; (v) design and build a prototype of the process. In the first step (define the vision), the objective of BPR should be identified based on customer needs. In "identify the process" step, organisations declare which process should be redesigned based on cost analysis or revenue generation of process. Some methods such as High-Impact and Exhaustive approaches could help in selection of the process. The high-Impact approach focuses on the most important process which are necessary to be re-designed based on selected criteria. In the Exhaustive approach, organisations should first identify all of the processes and then prioritize them to be redesigned (Malhotra, 1998). The "understanding the process" step aims to prevent repetitive and old mistakes based on measurement of the current process and providing a baseline for future improvement. In the next step (identify IT levers), it is essential to select a methodology to do the re-design process (Malhotra, 1998; Nonaka and Takeuchi, 1995). After selecting a methodology organizations should design a prototype for the new process. It means that the organization should design a prototype of the future process before implementation (Malhotra, 1998).

When comparing Business Process Reengineering and Total Quality Management, Childe et al. (1994) claim that, TQM helped incremental process improvements in manufacturing/service organizations in the 1980s, but in the 1990s it was replaced by BPR using advanced IT for improving the effectiveness of organizations. Despite some common themes, like a strong focus on the customer, proponents of BPR argue that it cannot be equated with other quality improvement programs (e.g. TQM/CQI) which aim for incremental improvement of *existing* processes (Steinberger 1994). BPR is different from TQM in that BPR concentrates on major discrete changes to business processes, whereas TQM concentrates on minor continuous improvement to business processes. That is, the improvements in TQM are smaller than the ones in BPR (Butler, 1994).

Furthermore, whereas BPR is commonly viewed as a top-down solution from management, TQM involves staff from all levels for problem solving and suggests bottom-up improvement. Employees' resistance to change has been identified as one major barrier to the success of BPR. MacIntosh and Francis (1997) claim that these two approaches are compatible and propose a concept of 'participative BPR' which combines both of them. They justify the claim that TQM addresses the human aspects of change while BPR highlights the delays, errors and inefficiencies which are introduced when passing information from one function to another.

2.4.4 BPR Tools and Techniques

There are some tools and techniques that can be used to assist the re-design process such as: problem analysis, solution testing and workflow diagram. (Malhotra, 1998; Nonaka and Takeuchi, 1995). BPR tools are computer-aided tools that support diagrams, analysis, reports and design documents that are often created and generated by BPR tools. There are many tools available to facilitate BPR process. These tools vary from the simplest flowcharting software to the most

complex data modeling applications. These tools assist analysis, redesign and modeling of the process. Organizations can classify these tools to static modeling and dynamic modeling. Example of static modeling is flowcharting and for dynamic modeling is simulation of the process.

None of the tools can completely support BPR and cover all the aspects. In addition, process control flow is a tool used in BPR and addresses the flow of information as well as task and activity optimization (Bertoni et al., 2009). These tools help people to elicit, formalize and share their process in order to help decision making (Bertoni et al., 2009). BPR concentrates on core business processes, and uses the specific tools and techniques within the JIT and TQM (Johansson et. al., 1993).Many authors recognized that business process improvement methodologies; such as BPR; are based on established tools and techniques, and therefore could be argued to merely draw on *"any good practice of process/operations improvement that allows reduction of waste, improvement of flow and better concept of customer and process view"* (Radnor et al., 2006).

It could be argued that the tools within the methodologies are used for three reasons: (i) assessment: to assess the processes at organisational level e.g. value stream mapping, process mapping; (ii) improvement: tools implemented and used to support and improve processes e.g. structured problem solving; (iii) monitoring: to measure and monitor the impact of the processes and their improvement e.g. control charts, visual management (Radnor, 2010; Radnor et al., 2006). According to Radnor (2010), evidence was found that assessment tools focused at organisational or departmental level, while the improvement and monitoring tools usually focused at individual processes rather than system or organisation level.

2.4.5 Empirical evidence of BPR in healthcare

The most important driver for hospitals to implement BPR in their processes as reported in USA in 1996 and 1997 was cost reduction (Walston and Bogue, 1999; Albery, 2001). In its application in healthcare, BPR has evolved in different ways but in practice it has always been applied partially rather than comprehensively (Willcocks et al. 1997; Packwood et al. 1998).

Indeed, some authors distinguish between business reengineering (strategic redesign of the whole organisation) and process reengineering (applied to key processes only). The literature notes that there is considerable confusion about whether and how patient-focused care, with its emphasis on redesigning processes around the patient, differs from BPR (Hurst 1995; Newman 1997; Arndt and Bigelow 1998; Powell and Davies 2001);one author suggests that patient-focused care is a health care variant of BPR (Edmonstone 1997).

The studies that focused on successful application of BPR in healthcare found that the impact of BPR was classified into time, cost, quality and flexibility. BPR was found to decrease cycle time, reduce execution cost, improve quality of care and increase flexibility that enable the organization to react effectively to changes in patients' demands ((Netjes et al., 2010; Jansen-Vullers and Reijers, 2005; Brand and Van der Kolk, 1995). Elkhuizen et al. (2006), investigated available evidence on patient care redesign process in hospitals and found that the most frequently mentioned benefits of BPR were reduced length of stay, increased quality, and cost reduction. Patwardhan et al.(2008), examined BPR as a quality management method in healthcare systems and concluded that BPR led to reduced waiting times and length of stay, faster diagnostic and increased flexibility. Bertolini et al. (2011) found that BPR tools enhanced the analysis and simulation of the existing processes to design the future state to improve efficiency of surgical ward.

In the United Kingdom, there was a strong emphasis on BPR in the 1990s. The Department of Health gave substantial financial support to two three-year reengineering pilot sites (King's Healthcare Trust, London and Leicester Royal Infirmary) (Packwood et al. 1998), which were evaluated by independent evaluators (Packwood et al. 1998; Bowns and McNulty 1999; McNulty and Ferlie 2002). There was also a major BPR programme at the John Radcliffe Hospital in Oxford (Willcocks et al. 1997). Although the proponents of BPR strongly differentiate it from the incremental improvement of other quality approaches like TQM, the NHS Executive policy documents on BPR published in the late 1990s appear to play down the emphasis on radical change and present a more modest vision of the potential of BPR.

The evaluators who studied the two NHS BPR pilot sites in the 1990s found that at neither site was the radical reengineering vision realised in practice. Instead the initiatives went through several redefinitions and ended up being 'watered down' into more modest changes and more limited improvements. There were some pockets of change but no overall organisational transformation; change was patchy, difficult and took longer than anticipated (Leverment et al. 1998; McNulty and Ferlie 2002). Reengineering was varied in pace and rate in different parts of the hospital, with progress and effects very variable in different clinical settings (McNulty and Ferlie 2002: 273). A crucial factor affecting BPR implementation at each of the sites was resistance from medical staff, who retained a high degree of control over clinical work practices and made it very difficult for the reengineers (who lacked the medical staff's detailed specialty-specific knowledge) to reshape these core processes over the short timescales available (Buchanan 1997; Willcocks et al. 1997; McNulty and Ferlie 2002). The lack of managerial control over health professionals and in particular medical staff and the contrast this

presents with managerial power in some other types of organisation has been noted (Arndt and Bigelow 1998; McNulty and Ferlie 2002).

The John Radcliffe Hospital, Oxford, UK, conducted a BPR pilot project in late 1990 facilitated by external consultants. This pilot study was successful and BPR concepts and the pilot study ways of working were therefore rolled out across the whole hospital (Willcocks et al. 1997). The main emphasis of the change was to move from separate vertical hierarchies for nurses, doctors and managers to a more horizontal, multi-disciplinary team culture. The BPR program was successful in part: by 1993 the new process-based structure was in place and working, on the whole, clinicians were positive about running their own service groups, forward planning had become more accurate and the new arrangements were held to be more efficient despite increasing pressure, financial constraint and unprecedented demand in terms of patient numbers. However, the changes had taken significantly longer than the 12 months the BPR literature suggests for core process reengineering and the trust did not attempt radical reengineering but had to use a more evolutionary approach that took account of the existing culture and the diverse professional and organizational groups. Despite this more modest approach, significant challenges remained. The implementation plans were not well communicated to all staff and there were major problems around the use of IT. Many staff lacked experience in rolling out information systems, many nurses remained sceptical about the use of IT systems in their work, and funding problems meant insufficient time for training, insufficient terminals and too few IT support staff to remedy these problems.

Evidence is also lacking of successful implementation of BPR in other contexts. The bulk of the literature on the application of BPR to healthcare either provides snapshots of stages in the reengineering process, which make it difficult to assess the success of the initiative as a whole (Iles and Sutherland 2001), or describes

cautious and diluted attempts to implement BPR, initiatives which should perhaps not be classified as BPR at all. Experience in applying BPR in health care outside the UK is very mixed. A nationwide study in the US found that reengineering did not appear to improve a hospital's overall cost position (Walston et al. 1999). A questionnaire study of more than 200 US and Canadian hospital chief executives (Ho et al. 1999) found that only around two-thirds of hospitals had attempted to measure the results of their BPR activities. The executives acknowledged that many employees were unconvinced about BPR and were concerned about job security; many executives thought that hospitals ought to carry out successful CQI activities before attempting the more intense activity of reengineering.

Reengineering in a large Canadian teaching hospital had significant adverse effects on staff morale and motivation, with perceptions of decreased support from colleagues and supervisors and increased confusion about roles (Woodward et al. 1999). One of the facets of BPR is aggregation of tasks and streamlining of roles, but one US hospital found that the plan to reduce the number of job categories from 250 to 12 was particularly contentious for staff and prompted widespread concerns about job security; the hospital cancelled its reengineering programme in an attempt to restore staff morale (Trisolini 2002). Outside health care, BPR has been used in the private sector in the UK but high risk radical approaches are rare compared to reengineering of existing processes (Willcocks et al. 1997).

One review of the literature on BPR in health care concluded that there was little evidence of impact, that many of the activities that were being classed as reengineering were closer to TQM (e.g. they only involved one department and not the whole organization), that the term BPR was being used interchangeably with 'patient focused care' and that overall *"the evidence is grounded more in fervor than in hard data"* (Arndt and Bigelow 1998: 61). A more recent systematic

review of the literature on BPR in hospitals confirmed these findings: the methodological quality of studies was highly variable, there was a wide range of definitions and programs, and few comparisons between studies could be drawn (Elkhuizen et al. 2006).

More recently, redesign has evolved into a form that has been described as building on the earlier experience of the challenging and largely unsuccessful attempts at implementing BPR and combining the more gradual approach of TQM with the more radical organization-wide perspective of BPR (Locock 2003). There is increased emphasis within this later approach to redesign on the need to address the human aspects of change, and to involve senior managers and clinicians in actively leading the redesign initiatives. These initiatives have shown some successes (e.g. Spaite et al. 2002; McGrath et al. 2008), but they share the common challenges of other quality improvement initiatives including the need for leadership by senior managers and clinicians and problems of sustaining improvements. Role redesign has its own challenges and requires attention to a range of human resources issues including remuneration, management and accountability arrangements and education and training needs (Hyde et al. 2005). Studies of NHS redesign initiatives suggest that the changes achieved have not been as extensive as intended (Locock 2003).

2.4.6 Strengths and Weaknesses of BPR

A key strength of Business Process Reengineering is its emphasis on processes. This focus on processes is the most enduring healthcare legacy from BPR and may have contributed to the interest in many health care systems in examining patient care pathways as part of patient centred care (Newman 1997; Powell and Davies 2001). The aim being to reduce duplication and delays and to make the individual patient the centre of health care services (Buchanan and Wilson 1996; Crass and Munro 1997). Advocates of BPR argue that the scope of BPR's ambition may

stimulate more creative and bold thinking about existing ways of organising care than other more incremental QI methods (Hammer and Champy 1995).

Despite the advantages of the approach, strong advocates of BPR like Hammer and Champy were cautious about the scope for implementing reengineering in public sector organizations. They pointed to the difficulty of measuring performance there, and suggested that public sector organizations may find it hard to balance between improving services and reducing costs. Further barriers in the public sector include deficits in IT infrastructure and capacity, which is risky for an approach like BPR which is so dependent on IT (Willcocks et al. 1997), the emphasis on changing employees' roles, which is likely to prompt resistance in the settled occupational groups of the public sector, and the lack of power that public sector managers have over some staff groups compared to their managers in industry (Halachmi 1995; Arndt and Bigelow 1998).

Other researchers have argued that the barriers to implementing BPR in the service sector are much more fundamental and widespread. These include the presence of multiple stakeholders, a culture which tends to be evolutionary rather than radical (Halachmi 1995).

Researchers have identified a range of other interconnected barriers to implementing BPR in healthcare systems. These include the scope and complexity of patient processes and the challenge of carrying out radical redesign while continuing to provide a year-round service. In addition, radical innovation may be precluded by several factors: the range of multiple stakeholders with competing perspectives, the high visibility of the service sector to those stakeholders (e.g. to communities and the media) and a culture which tends to be evolutionary rather than revolutionary (Packwood et al. 1998; Bowns and McNulty 1999).

BPR appears to disregard organizational history and culture, aspects which much of the organizational literature emphasizes as pivotal in organizational

change particularly in a complex and highly politicized setting like healthcare (Pollitt 1996; Buchanan 1997; Willcocks et al. 1997; Leverment et al. 1998). BPR has been widely criticized for reasons as diverse as its lack of conceptual rigor, its mechanistic view of organizations and its aggressive approach to downsizing and job loss (Holtham 1994; Buchanan and Wilson 1996).

Classic reengineering methodology reflects a top down model of change management based on assumptions of clear line management and relatively uncontested managerial control, conditions which do not apply in healthcare organizations (Patwardhan and Patwardhan, 2008; Jones, 1995; McNulty and Ferlie 2002), particularly in relation to medical staff: *"…many of the claims made on behalf of reengineering do not make sense for hospitals and…important assumptions underlying reengineering do not apply to hospitals"* (Arndt and Bigelow1998: 64). Instead, health care organizations are made up of diverse professional groups, some of which (particularly the medical profession) have high levels of knowledge, skills and other resources to adopt or adapt change initiatives in the light of their own preferences and interests (Pollitt 1996; Leverment et al. 1998; McNulty and Ferlie 2002; Nayak et al., 1995; Bernonville et al., 2010). These professional groups are well used to competing for 'territory' and control over work processes and are largely resistant to the multiskilling demanded by BPR (Pollitt 1996; Leverment et al. 1998; McNulty and Ferlie 2002).

BPR in its pure form appears to have little applicability to healthcare organizations: *"Re-engineering is revealed as an idea and rhetoric for change undermined by its contextual insensitivity and overconfident assumptions about managerial agency"* (McNulty and Ferlie 2002: 331). Health service developments such as the increasing emphasis on vertical structures of performance management and the shift towards increasing medical specialization (McNulty and Ferlie 2002) (together with the programs of undergraduate and postgraduate medical training

that underpin such specialization) are at odds with the horizontal structures and aggregated roles of BPR.

In summary, the literature suggests that the radical abrupt change of BPR is unlikely to be feasible or desirable in health care settings and certainly the successful implementation of a TQM program within an organization is likely to be an important prerequisite for any organization contemplating the more intensive process of reengineering (Trisolini 2002; Patwardhan and Patwardhan, 2008; Jones, 1995). However, although radical BPR is not well suited to health care, redesign principles can be applied in more modest and incremental ways.

2.5 THE MODEL FOR IMPROVEMENT

2.5.1 ORIGIN OF THE MODEL FOR IMPROVEMENT (MFI)

The Model for Improvement (MFI) was developed by Associates in Process Improvement (API) in the late 1980's and early 1990's based on Deming's Plan-Do-Study-Act (PDSA) cycle (Moen et al. 2010). API has partnered with the US Institute for Healthcare Improvement (IHI) to support IHI's innovation and improvement programs. The model has become popular when the IHI started using it as the framework to guide innovation and improvement work in healthcare through their 'Breakthrough Series' collaborative approach (Langley et al. 2009; Ketley and Bevan 2007; Kilo 1998).

The Plan-Do-Study-Act (PDSA) originates as a method for achieving efficiency in Japanese car manufacturing, and was influenced by earlier work on industrial statistical quality control. Deming adapted the (PDSA) from Shewhart's Plan-Do-Check-Act (PDCA) (Kilo 1998; Ketley and Bevan 2007). Both PDSA and PDCA terms are often used interchangeably in reference to the method in the literature. However, Deming was cautious over the use of the 'PDCA' terminology and

warned it referred to an explicitly different process, referring to a quality control circle for dealing with faults within a system, rather than the PDSA process, which was intended for iterative learning and improvement of a product or a process. This subtle difference in terminologies may help to explain studies that refer to the method as 'PDSA' (Moen, 2010).

2.5.2 DEFINITION OF THE MFI

The Model for Improvement is a simple yet powerful tool for accelerating improvement. The model is not meant to replace change models that organizations may already be using, but rather to accelerate improvement. This model has been used very successfully by hundreds of healthcare organizations in many countries to improve healthcare processes and outcomes (Langley *et al.*, 2009).

2.5.3 MAIN CONCEPTS AND PRACTICES

The Model for Improvement has two parts (Figure 2-1): the first part is the thinking part which poses three fundamental questions and the second one is the Plan-Do-Study-Act (PDSA) cycle, by which these questions are put into action and tested in the clinical environment (Langley *et al.*, 2009).

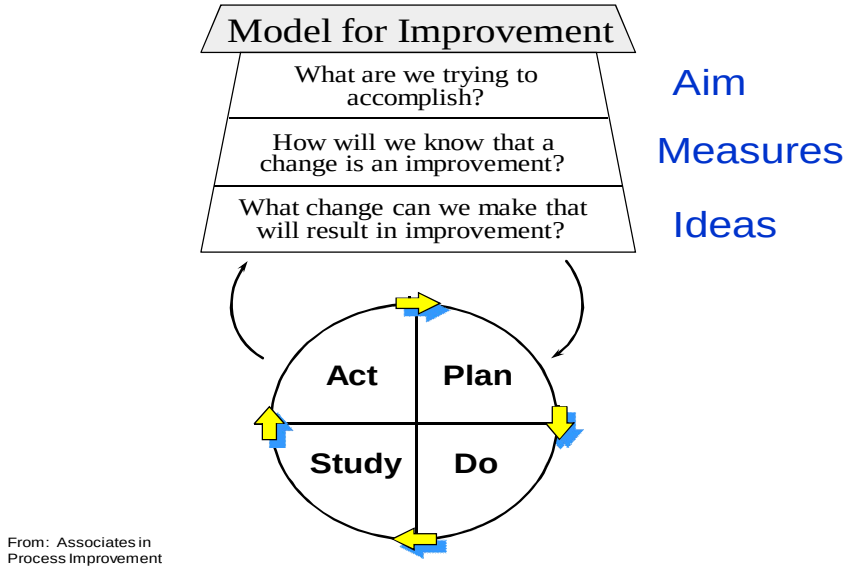

Figure 2-1: The Model for Improvement (MFI)

The three fundamental questions in the thinking part are: 1) what are we trying to accomplish?; 2) how will we know that a change is an improvement?; and 3) what changes can we make that will result in improvement? The thinking part involves gathering evidence and ideas for improvement projects.

Question 1: is designed to help the team build knowledge about current practice. Improvement begins with setting aims. Starting with a clearly stated, mutually agreed-upon aim will help teams stay on track throughout their improvement efforts. An organization will not improve without a clear and firm intention to do so. The aim should be expressed in specific terms—for example, reduce operating room costs by 30%, reduce time on mechanical ventilation to 6 hours or less, or reduce the 30- day readmission rate by 50%. Agreeing on the aim is crucial; so is allocating people and resources necessary to accomplish the aim.

Question 2 helps teams to choose measures to check whether planned changes do result in improvement. Teams use qualitative measures to determine if a specific change actually leads to an improvement—for example, is ICU length of stay decreasing? Is median ventilator time decreasing? Are operating room costs for DRGs 106 and 107 being reduced? Define the measures that will be used to monitor the impact of this improvement effort: Identify outcome measures (minimum of 1), process measures (minimum of 2), and balancing measures (minimum of 1) for the project. This is called family of measures. Connect measures to the goals and outcomes of the charter (Tip: Consider qualitative feedback as well as quantitative measures).

Question 3 focuses on selecting the change that can lead to improvement. All improvement requires making changes, but not all changes result in improvement. Organizations must, therefore, identify the changes that are most likely to result in improvement. Ideas for change can come from a variety of sources: critical thinking about the current system, creative thinking, observing the process, a

hunch, an idea from the scientific literature, or an insight gleaned from a completely different situation. This Guide refers to good ideas for change as "change concepts." A change concept is a general idea—with proven merit and a sound scientific or logical foundation— that can stimulate specific ideas for changes that lead to improvement. Using change concepts and combining them creatively can inspire new ways of thinking about how to improve processes. Teams need to make sure that changes designed to improve one part of the system are not causing new problems in other parts of the system. For example, teams working to reduce ventilator times should also measure to make sure re-intubation rates are not increasing. Teams working to reduce length of stay should also measure to make sure readmission rates are not increasing.

The Plan-Do-Study-Act (PDSA) cycle is by which these questions are put into action and tested in the clinical environment. **P**lan: Plan the change to be tested or implemented; **D**o: Carry out the test or change; **S**tudy: Study the data before and after the change and reflect on what was learned; **A**ct: Act on the information and plan the next change cycle. The aim of PDSA is to pursue, sustain and rollout effective changes in care processes that favourably affect outcomes, using rapid small-step change cycles. The model involves four cyclical stages (Figure 2-2): hypothesis formation (Plan); implement the new process with data collection (Do); interpreting the results (Study); and a decision as to what to do next (Act) (Langley et al. 2009).

Thus, the Model for Improvement identifies four key elements of successful process improvement: specific and measureable aims, measures of improvement that are tracked over time, key changes that will result in desired improvement, and a series of testing 'cycles' during which teams learn how to apply key change ideas to their organisation. The model supports the idea of the 'trial and learning' approach to close the gap between evidence of the best way to do things and how

things actually need to be done in practice. The approach also draws from the Institute for Healthcare Improvement's Breakthrough Series Collaborative Model which is founded on the premise that health care outcomes are the result of processes (Kilo 1998).

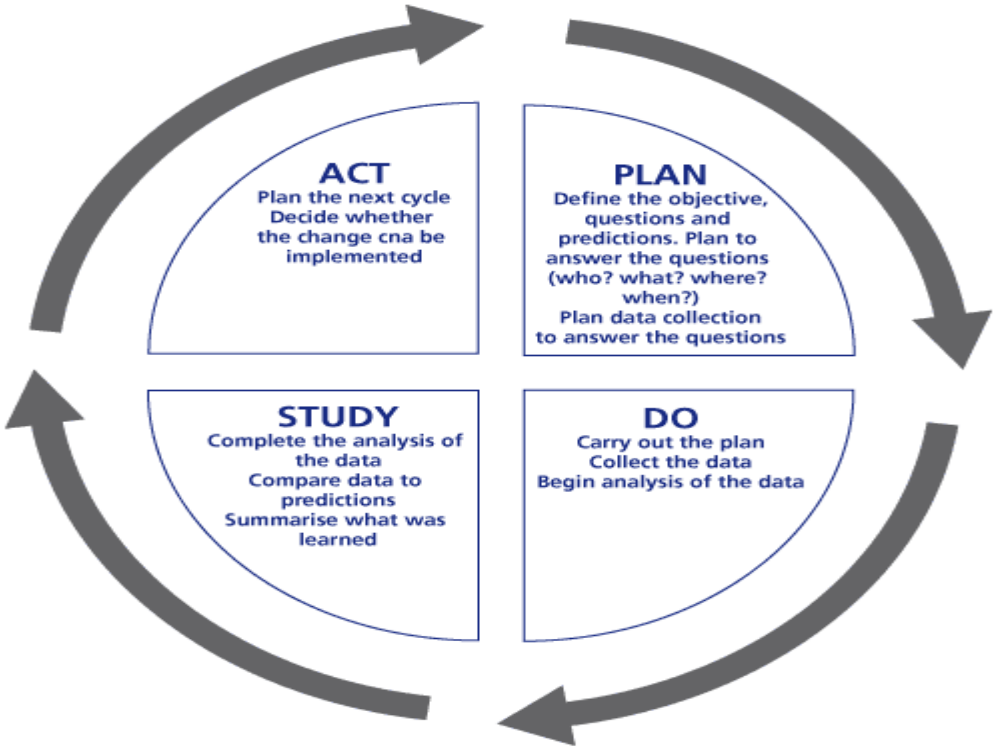

Figure 2-2: PDSA Cycle Stages

The rationale for PDSA comes from systems theory and the concept that systems are made up of interdependent interacting elements and are therefore unpredictable and non-linear: small changes can have large consequences. Short-cycle, small-scale tests, linked to reflection, are seen as helpful because they enable health care teams to learn on the basis of action and its observed effects (Berwick 1998; Iles and Sutherland 2001; Walley et al. 2006). The approach is also valuable because the changes are not imposed: front line staffs are closely involved in determining the problems and in suggesting and testing out potential solutions.

This bottom-up approach increases the likelihood that staff will 'own' the changes, a key requirement for successful organisational change (Greenhalgh et al 2004).

The model is a structured approach to a rapid cycle test of change. It follows a scientific method to quality improvement and is most often used to improve relatively simple processes that are amenable to quick transformation. Plan refers to first understanding the process, then proposing an action aimed at improvement, and finally deciding how the action will be tested and how data will be collected to determine the effect of the action taken (Langley *et al.* 2009). Implementation of the change occurs in the do phase. The study phase studies the results of the new process and compares it to the expected outcome. The final act phase analyzes the discrepancies in outcomes (Cousins, 1998). A key feature of the PDSA cycle is that it is an iterative process. Ideally, learning and improvement occurs with each successive PDSA cycle (Beringer, 2005; Speroff and O' Connor, 2004).

According to Esmail *et al*. (2005), the methodology works well with changes that needed to be tested right away (i.e. hunches, best practice, suggestions that staff have brought up). They further state that it is a methodology with minimal risk and that after a change is tested, based on the results, the change can be adopted, adapted or modified, and re-tested or abandon all together.

Langley et al. (2009) have developed 70 change concepts that have been grouped into nine general categories listed in their 1996 landmark book on improvement '*The improvement guide: a practical approach to enhancing organizational performance'*. These are: eliminate waste, improve work flow, optimize inventory, change the work environment, customer interface, manage time, focus on variation, error proofing, and focus on the product or service.

The Model for Improvement is a bottom-up approach which increases the likelihood that staff will 'own' the changes, a key requirement for successful organisational change (Greenhalgh et al 2004).

It is similar to TQM/CQI in that it is systematic and data driven, but unlike TQM/CQI it places less attention on flowcharting processes and extensive measuring. It calls for *sufficient* data to be collected to know if the change has resulted in an improvement (Meisel et al. 1998). Changes are tested on a small scale, permitting experimentation and discarding unsuccessful tests (a typical pattern might be testing a change with one practitioner and one patient in a single clinic – then moving on to three, then five and so on). It is argued that in contrast to large scale once-and-for-all implementation of grand designs (which often fail), numerous small cycles of change can successfully accumulate into large effects; for example, an intensive care unit could improve quality by working on a series of cumulative and linked PDSAs in different aspects of care at the same time e.g. respiratory care, medication use, and patient flow (Berwick 1998).

In contrast to large-scale approaches, PDSA changes are small (therefore controlling risk and disruption), take minimal time, and require little financial investment (in staff terms) with the majority of staff needing little formal training to proceed. PDSA changes are also advantageous as they are designed in context to fit that particular set of local ircumstances: they therefore meet one of the key criteria for sustainable organisational change (Dopson and Fitzgerald 2005; Grol and Wensing 2005).

2.5.4 MFI Tools and Techniques

The MFI uses a wide range of quality tools and techniques that are used by many other models for defining the problem, analyzing the problem, solving the problem and evaluating performance. Some of these are: PDSA, control charts, run charts, error proofing, process mapping, force field analysis, cause and effect diagram, five whys, and benchmarking (Langley *et al.* 2009). (See Appendix 1, for more details on quality tools).

2.5.5 Empirical Evidence of MFI in Healthcare

PDSA either as a standalone approach or as a part of the Model for Improvement (MFI) provides a method for structuring iterative development of change and has been used as a tool in quality improvement in health care in many countries. PDSA cycles are often a central component of QI initiatives; however few formal objective evaluations of their effectiveness or application have been carried out (Ting, et al., 2009). Some PDSA approaches have been demonstrated to result in significant improvements in care and patient outcomes (Pronovost, et al., 2006), while others have demonstrated no improvement at all (Benning, et al., 2011; Vos, et al., 2010; Landon, et al., 2004). The use of PDSA cycles in healthcare is, itself, a complex intervention made up of a series of interdependent steps and key principles that inform its application (Berwick, 1998; Walshe, 2009; Deming, 1991) and that this application is also affected by local context (Øvretveit, 2011). Researchers report varied application and reporting of PDSA and lack of compliance with the principles that underpin its design as a pragmatic scientific method. The varied practice compromises its effectiveness as a method for improvement and cautions against studies that view QI or PDSA as a 'black box' intervention (Taylor et al., 2013).

PDSA cycles were used in UK as one of the redesign techniques by the National Booking Team formed in 2001 to support local teams in implementing the NHS booking program (allowing patients to choose the date and time of their outpatient appointment or hospital admission) (Neath 2007). Other Modernisation Agency initiatives also used PDSA cycles, for example, the Agency's *Ideal Design of Emergency Access (IDEA)* project in the NHS involving 10 regions from 2001-2003 (Walley and Gowland 2004). The IDEA project used process mapping, capacity and demand theory and 'lean thinking' and, the improvement work was based around PDSA improvement cycles using local teams. A study of the

Modernization Agency's *Ideal Design of Emergency Access (IDEA)* project (Walley and Gowland 2004) found mixed success in using PDSA in the case study sites: some organisations stopped at the Plan-Do part of the cycle and did not progress beyond it, in part because of problems with data collection and in part because of a tendency to revert to traditional approaches of top-down change instead of using front line teams to assess the issues properly and to monitor the performance and impact of changes. Some managers were reluctant to relinquish control over PDSA activity to teams and there was sometimes conflict between the changes that teams wanted to make and the overall objectives of the organisation. There were further more generic problems in that single changes could displace problems onto another part of the system (e.g. the four hour target time in A & E achieved by the patient waiting on a medical assessment unit instead). Other studies (e.g. Bate et al. 2002) have found similar experiences of organisations only making partial use of the PDSA method. This is similar to findings that audit cycles may not be completed (Hearnshaw et al. 1998). Another study found that planning for change using PDSA methods by managers and clinicians working together in multiprofessional teams could be a useful way for managers and clinicians to identify problems and potential solutions and to gain insights into each other's perspective (Thor et al 2004a). The systematic approach to identifying quality problems enabled frontline staff to be involved and in the process of determining problems and prioritising them enabled managers to harness staff insights and motivation for change.

An Australian study found that PDSA methods could be useful in achieving small scale gains but that the methods could founder when dealing with more intractable systemic or bureaucratic problems (Newton et al. 2007) and these limitations of the method have been echoed by other authors (e.g. Young 2005). The NHS Clinical Governance Program developed a modified version of the

PDSA cycle for use when there was significant complexity and less agreement and certainty about cause and effect relationships. This version was called RAID: Review (analysis and understanding of the service) – Agreement (agreement of all staff and stakeholders with the recommended changes) – Implementation (testing the effects of the changes) – Demonstration (evaluation and monitoring) (Rogers 2006). This format suggests a move away from the rapid introduction of change through successive swift cycles and this adaptation does not appear to have been widely adopted.

Rapid cycle change approaches have been used in a range of settings and are a key component of quality improvement collaboratives. Quality improvement collaboratives were largely developed and popularized by IHI, which in 1996 launched the Breakthrough Series of collaborative programs to support local teams in quality improvement (Kilo 1998; Mittman 2004). Quality improvement collaboratives combine rapid cycle change (PDSA methods) and inter-organisational networking to share learning (Bate et al. 2002). The NHS has created a number of quality improvement collaboratives around particular patient groups or aspects of health care. Examples include the National Primary Care Collaborative implemented by the National Primary Care Development Team (Locock 2001; Knight 2004) and the National Patients Access Team (Locock 2001) and in Scotland the Scottish Primary Care Collaborative Program supported by the Health Delivery Directorate's Improvement and Support Team at the Scottish Government (Scottish Government Directorate of Health Delivery: Improvement and Support Team 2008).

The NHS Cancer Services Collaborative was the first NHS program to adopt this IHI model and received central funding from the Department of Health to employ the programme managers and facilitators (Kerr et al. 2002). Despite initial scepticism from senior clinicians and bottlenecks caused by staffing shortages in

some specialties, the nine cancer networks using these methods cut waiting times and improved patients experiences of care; sixty five percent of the projects showed at least a 50% reduction in the time to first treatment (Kerr et al. 2002). However, it was unclear whether the interventions caused the improvements and there is no data comparing the cancer networks using the collaborative method with those that did not (Kerr et al. 2002). A study of the NHS Orthopaedics Services Collaborative in 37 trusts in four NHS regions from April 2000-May 2001 (Bate et al. 2002) found that the majority of trusts did achieve their main objective of reducing the length of stay for orthopaedic patients, but only to a modest extent compared to the initial claims that the Collaborative would yield a 'breakthrough' change in service provision. There were striking variations in implementation between the trusts: seven trusts withdrew from the collaborative and there was a high turnover of project managers in its lifetime (Bate et al. 2002). The researchers noted significant implementation challenges in the study sites including:

• Confusion about the setting, need for and adoption of local targets and measures

• The lack of evidence to support the reduction in length of stay (the main focus) and limited guidance given to promote its safe adoption

• Partial adoption of the PDSA cycle in some organizations: the method was often used inappropriately and therefore did not provide intensive activity or rapid improvement

• Limited evidence of any networking between the organized days; the collaborative was therefore closer to a series of clustered time-limited projects rather than a fully operational networked learning community

• Lack of resources allocated to the process (e.g. training of project managers in process mapping skills only took place late in the program)

• Insufficient attention to developing receptive contexts locally especially in securing managerial and clinical champions to sanction the PDSA 'experiments' and to lead through active participation in them

• The lack of interest of many participants: many admitted that the Collaborative never featured highly among their competing priorities.

The researchers concluded that: *"…like most management techniques of this nature, the Breakthrough Method is not inherently a 'good thing' or a 'bad thing' but is contingent upon a whole range of factors and conditions: the classic case of 'it all depends'"* (Bate et al 2002).

In Scotland, the Scottish Government's Improvement and Support Team reports early results from the Scottish Primary Care Collaborative Program of improvements in managing demand, in providing quicker access to GPs and practice nurses and in improving the physiological markers of patients with long term conditions (Scottish Government Directorate of Health Delivery: Improvement and Support Team 2008).

Outside the UK, the collaborative model has been used successfully with volunteer quality improvement teams in the US (Kosseff and Niemeier 2001; Mills and Weeks 2004) but attempts to spread the improvements more widely through the health system were disappointing (Kosseff and Niemeier 2001). A meeting of researchers involved in evaluating collaboratives in the US, UK and Sweden (Ovretveit et al. 2002) concluded that quality collaboratives have had some success and that many teams and organisations have benefited from taking part. However, there is only limited evidence on the impact of the collaborative improvement model in terms of changes in outcomes or in clinical practice (e.g. Kerr et al. 2002; Mittman 2004; Schouten et al. 2008): *"…decisions to rely heavily on the collaborative or other methods of quality improvement should await better evidence on whether and how each method is responsible for successes. It is*

possible that certain highly motivated, capable organizations may achieve comparable improvements through other means" (Mittman 2004).

In common with other quality improvement initiatives, there are striking differences between organizations (Bate et al. 2002; Pearson et al 2005) and participation by organizations and by health professionals (in particular doctors) can be difficult to secure (Kosseff and Niemeier 2001; Gollop et al. 2004). Addressing aspects of care in collaborative may expose wider long-standing problems that are difficult to address (e.g. staffing shortages in some specialties, (Kerr et al. 2002) or differences in perspective between professionals from different health care sectors (Newton et al. 2007). Experience across different countries and health systems suggest a range of factors that influence the success of collaboratives. These include: appropriate sponsorship (success is less likely if there is conflict between the sponsor's perspective and that of participants); appropriate choice of topic (complex or less familiar topics are less likely to succeed or to attract participants); the need for active involvement of senior managers and physicians; and alignment with the organization's strategic goals (Kosseff and Niemeier 2001; Mills and Weeks 2004; Wilson et al. 2004). However, successful quality improvement is likely to need a broad range of actions and supportive contextual factors, many of which are outside the reach of collaborative members and their support team in the organisation. The support team can help by facilitating accurate recognition and diagnosis of quality problems and by generating energy to tackle them and provide the team with the knowledge and skills to address problems but that may not be enough to achieve lasting change (Mittman 2004).

2.5.6 Strengths and Weaknesses of the MFI

The PDSA cycle presents a scientific method for testing changes in complexsystems (Moen and Norman, 2006). The four stages follow the scientific

experimentalmethod of formulating a hypothesis, collectingdata to test this hypothesis, analyzing andinterpreting the results and making inferences toiterate the hypothesis (Speroff and O'Connor, 2004). The principles of PDSA cycles promotethe use of a small-scale, iterative approach to test interventions, as this enables rapid assessment andprovides flexibility to adapt the change according tofeedback to ensure fit-for-purpose solutions are developed (Greenhalgh, et al., 2004; Damschroder, et al., 2009; Powell et al., 2006). It can draw on the ideas and ingenuity of local staff and can enable low-risk testing of changes in the clinical setting. Starting with small-scale tests providesusers with freedom to act and learn; minimizing riskto patients, the organization and resources requiredand providing the opportunity to build evidence forchange and engage stakeholders as confidence in theintervention increases. Thus it can help to secure commitment to changes and to embed them in everyday routines (Young 2005).

In line with the scientific experimental method, thePDSA cycle promotes prediction of the outcome of atest of change and subsequent measurement over time(quantitative or qualitative) to assess the impact of anintervention on the process or outcomes of interest. Thus, learning is primarily achieved through interventionalexperiments designed to test a change. In recognitionof working in complex settings with inherentvariability, measurement of data over time helpsunderstand natural variation in a system, increaseawareness of other factors influencing processes oroutcomes, and understand the impact of anintervention. It can be scaled up or scaled down to address different types of quality issues (e.g. small processes in one clinic waiting room or the operation of operating rooms) and can be used relatively informally: 'huddles' with staff can produce ideas worth testing immediately and immediate feedback can be sought from a patient at the end of a consultation(Berwick 1998).

However, as in all bottom-up change initiatives, there may be conflict between the changes that local individuals or teams want to make and the organisation's strategic objectives (Savage and Scott 2004; Thor et al 2004a; Walley and Gowland 2004). Given the range of initiatives in healthcare setting, one improvement project may inadvertently conflict with another (Walley and Gowland 2004). Objectives and targets need to be handled carefully to avoid displacing the problem elsewhere (e.g. the four hour target time in A & E can just be displaced to the patient waiting on a medical assessment unit): "*The achievement of the target can be used to hide underlying chaos*" (Walley and Gowland 2004: 357).

Problems can also arise where potential changes identified in one department are thwarted because of wider processes (e.g. cross-departmental processes) that are less amenable to rapid cycle testing.

Experience in health care settings also shows that teams may be unable or unwilling to carry out the full cycle of Plan-Do-Study-Act and may therefore risk jumping to premature 'solutions' or fail to benefit from the full potential of the approach. In particular, the well documented problems with obtaining robust data in health care threaten to jeopardize the principle of accurate and timely measurement of the impact of changes and subsequent review on which the approach relies.

Although PDSA cycles are often a central component of QI initiatives, few formal objective evaluations of their effectiveness or application have been carried out.18 There is only limited evidence in the peer-reviewed literature in terms of changes in outcome or practice patterns from the rapid cycle change approach and quality improvement collaborative. It is likely that ongoing work at various sites will begin to fill these evidence gaps (Ting, et al., 2009; Pronovost, et al., 2006; Benning, et al., 2011; Vos, et al., 2010).

2.6 SIMLIATITIES AND DIFFERENCES BETWEEN THE MODELS

Research shows that there is almost no traditional experimentation associated with the models and there is absence of evidence on costs. The models show a number of differences (in terms of pace and scope of change, focus of change activities and enabling or mandating improvement). The differentiating factors are actually a matter of emphasis on the core concepts of systems thinking, process view, variation, flow and customer focus. The apparent contradictions between approaches are also due to the differing assumptions about value and its definition. The models also show strong commonalities and similarities between them (in terms of objectives, tools and implementation approach). All approaches are based on same principles by which organizations operate. They all also draw on a fairly common body of tools for improvement, with some labeled by one approach as being an essential element. This means that the distinctions between the approaches are often blurred in practice. It means also that a clear cut taxonomy is neither feasible nor useful and it is impossible to identify a single 'right' model.
Despite their different names and apparent differences in methods, many of these models share some simple underlying principles (Øvretveit, 2009):

2.6.1 Systems Thinking and Process View:

Systems thinking and process view has been an approach to viewing organizations for many years (Checkland 1981). Systems thinking can be described as exploration of *"the properties which exist once the parts of the system have been combined into a whole"* (Iles & Sutherland 2001). The systems view is fundamental to a lot of the thinking in improvement, perhaps particularly to

Deming's insights, and is inherent in many of the quality improvement approaches. This has been appreciated to be a strength in the healthcare context(Scalise 2003).

A consequence of viewing organization as systems is an increased focus on the processes which comprise such systems. Academics from many fields have recognized the importance of the process view, where process management is defined as entailing three practices: mapping processes, improving processes and adhering to systems of improved processes - an approach that is reflected in much study of both quality improvement and patient safety(Benner &Tushman 2003).It is argued that taking a process view is one of the key characteristics of organizations which are successful in improvement, along with adopting evidence-based practice, learning collaboratively and being ready and able to change (Plsek 1999). This process view is not only about changing organizations but also examining and improving the interaction between elements of the organization, including the individuals who work within them.

It is interesting that the approach which has probably had the biggest impact in healthcare to date (PDSA) does not explicitly refer to processes (Langley et al. 1996), although the approach appears to be based on the assumption that work is or can be organized into processes.While TQM was very successful at improving the quality of many processes, there were some processes that were so plagued by defects that continuous incremental quality improvement alone would not be enough to produce a quality product or service. That is, despite the best efforts of process improvement teams, some processes were so inefficient and defect-prone that they needed to be completely redesigned. This opened the way for 'business process reengineering" in the early 1990s. BPR is the radical redesign of business processes to achieve dramatic process improvements, such as cost, quality, service, and speed (Hammer and Champy, 1993). While both BPR and TQM focus on

processes, TQM is based on continuous improvement, whereas BPR is mostly based on performing radical change. The Lean approach, on the other hand, focuses on flow, so it has tools to design flow systems according to its philosophy(Carr, et al., 1992). Other improvement approaches focus more on the analysis of existing process design, rather than providing guidance on how to design a process.

2.6.2 Managing flow:

Managing flow through a process is a key concept in quality management, largely derived from the manufacturing experience. While this draws on the concepts of capacity, demand and inventory, it merits separate consideration because of its current popularity in healthcare. The Lean approach focuses on elements of processes for smooth pull-based flow. Similarly TQM leads to the design of a process with the focus on maximizing the system's goal. The importance of flow is increasingly emphasized within healthcare and that understanding variation is essential to improving flow (Brideau 2004; Haraden&Resar 2004).

2.6.3 The concept of variation:

The emphasis on variation in the improvement approaches differs. Approaches based on statistical thinking (TQM, Six Sigma) are based on the principles that: all work occurs in a system of interconnected processes, variation exists in all processes, understanding and analyzing the variation are keys to success (Antony 2004; Snee 1990). Lean also suggests reducing process variation (in the interests of making flow as smooth as possible). These principles are also in line with Deming's viewthat as variation is reduced, quality is improved(Deming 1986). Variation is argued to be inherent in healthcare due to patientand professional

variability (Haraden&Resar 2004). Patient variability is random and cannot be eliminated or reduced, but must be managed, whereas non-random variability should be eliminated. This links with the concepts of causes of variation which are the basis of SPC. It is argued that *"it is variation … that causes most of the flow problems in our hospital systems"*(Institute for Healthcare Improvement 2003).

2.6.4 The concept of customer

Another concept which underpins most of the approaches is that of identifyingthe customer, who may be internal or external to the organization, and subsequently their needs (Walshe and Smith, 2011). Whether the customer is explicitly identified, or whether their requirements are translated into a clear objective for a process, the process has to be clear before improvement can take place(Nolan 1998). In Six Sigma 'what is critical to quality'; as far as the customer is concerned; is used to define the measures used to determine the 'defects' to be reduced. Similarly, in Lean the customer's conception of value (which might be thought of as the ratio of benefits to costs) defines which bits of processes are useful (value-adding), the rest being waste (steps or components the customer would not wish to pay for). Interestingly, while Six Sigma and Lean are predicated on the principle that the system should seek to provide more quality or benefit to the customer and/or at lower cost, TQM does not automatically assume this is the way to maximize the goal of the organization (Andersson, et al., 2006)

2.7 COMBINATION OF APPROACHES

The review of the five models has shown that, in practice distinctions between the models are not always clear-cut: there are many areas of overlap, with many of the approaches employing very similar tools and techniques. In implementation, quality improvement models and their tools are used in a variety of ways. They are

rarely applied singly or sequentially; what is more common in healthcare settings is to draw on combinations or hybrids of the main approaches and their tools (Powell, et al., 2009).

According to Boaden et al (2008), there are some wider studies which consider the impact of quality improvement as a generic organizational change, rather than any single labeled approach. Ovretveit (2009) stated that, the grouping used by many researchers describes many of the quality improvement approaches such as PDSA cycles, Six Sigma and lean. This relatively narrow grouping excludes studies of interventions, such as clinical audit, guideline implementation, accreditation and inspection, and financial incentive schemes, some of which can be grouped in a subcategory of methods for implementing changes that have been found to improve quality.

The literature suggests that, there is a potential for integrating two or more of these quality improvement approaches and developing a model that incorporates set of TQM, BPR, Six Sigma, Lean and other interventions. For instance, there is the perspective that Lean and Six Sigma should be considered within TQM frame as it was explored in Klefsjö et al. (2001).The literature shows that, there has been increasing use of a combination of lean thinking and Six Sigma in the healthcare (Lean Six Sigma) in recognition of the need to streamline many healthcare processes (through lean approaches) before the more exacting tools of Six Sigma can be applied (Powell, et al., 2009). It is obvious that integration and adoption of some quality improvement approaches into one model could bring more positive results owing to the effect of synergy. Isolated and random efforts will not bring significant improvements as opposed to the set of principles, techniques and tools that are continuously influencing the process of creating a product or delivering a service in order to maintain high level of quality *(*Klefsjö et al., 2001*)*.

2.9 SUSTAINABILITY OF IMPROVEMENT

As quality improvement continues to be a major focus in healthcare, there is growing interest in developing strategies to ensure that such improvement is sustained in the long term. Organizations have experienced the fact that complex systems tend to evolve or revert back to previous iterations organically. So the task to sustain the gains is really this: how organizations can stabilize the systems that result in excellent performance so that it is resistant to these typical dynamics?

Changes that improve the quality of health care should be sustained. Falling back to old, unsatisfactory ways of working is a waste of resources and can in the worst case increase resistance to later initiatives to improve care**(**Hovlid et al., 2012).Researchers, funders, and managers of health programs and interventions have become concerned about their long-term sustainability. However, most research about sustainability has not considered the nature of the program to be sustained. Health-related interventions may differ in their likelihood of sustainability and in the factors likely to influence continuation (Scheirer, 2013).

Around one in three improvement changes within healthcare services fail after implementation (NHSI, 2008).This happens for a wide variety of reasons but it will be disheartening for those who have invested in the change to see it flounder. Sustainability should not be left to chance. It should be embed into the quality improvement project from the start.

Sustainable changes are undertaken with the involvement of stakeholders. Engaging others in developing and implementing the changes will result in them taking ownership and having an interest in keeping them going(Anderson, 2010).It is important to ensure that the project has obvious advantages for all concerned. People will put up with some disadvantages if they can also see some improvement

for themselves or those they are most concerned about. Aligning the change to the values or vision of the organization so that everyone can clearly see how it links in with their own goals will make it more meaningful to them personally.

It is important that there is a commitment to ongoing training to support the change, including sufficient resources secured for new staff (Maurer, 2010). A potential danger is that there will be an initial flurry of training, with resources and funding provided for the implementation of any improvement but, over time, other matters will take priority and resources may be diverted elsewhere.

Maurer (2010) identifies senior management and leadership support as the vital component for ensuring sustainability until the change becomes embedded in the organization and is no longer seen as “the change”. Everyone in the organization needs to know that the most senior people fully support the project, and that there is sufficient funding to cover the costs of sustaining any improvement.

Embedding the change in working practices is likely to involve changing policies, protocols or pathways of care to reflect the improvement or new way of working. These can then be used to set new standards or benchmarks to measure against. The ultimate goal of any change agent is to implement the innovation to the point where no one can undo the changes made (Moore, 2007).

Over the past few decades, an understanding of healthcare quality as a system property has emerged (Berwick, 2003; Batalden and Stoltz, 1993; IOM, 2001). Accordingly, the quality of health care primarily depends on the function of the system and to a lesser degree on the skills of individuals (Berwick, 2003;). Changing the system is therefore the most effective route to improvement; i.e., an organization needs to change its way of operating to produce improved outcomes,

and these changes must be maintained to sustain the improvements ((Berwick, 2003; Shojania and Grimshaw, 2005).

The sustainability of systemic change is poorly understood. Use of theoretical frameworks allows for an understanding of factors that contribute to sustainability (Grol, et al., 2007; Walshe, 2007).Only recently have researchers started to make headway in investigations on the impact of quality improvement interventions and collaboratives in healthcare (Schouten, et al., 2008), mostly referring to immediate improvement in the short term (Bray, et al., 2009), with no strong evidence of sustained impact in the long term (Ovretveit and Staines, 2007). Considering such complex multi-level interventions aim to change entire organizational and safety cultures and systems (Benn, et al., 2009), it is a process where changes may surface further down the line or alternatively yield successful results in the short term, only for it to fall by the wayside at a later date (Buchanan et al., 2005).

Reasons for continuation of some interventions over others are unexplored and focused research on the sustainability of patient safety and quality improvement collaborative successes are limited (Ovretveit and Staines, 2007; Ovretveit et al., 2002). In a recent systematic review of the impact of quality improvement collaboratives, Schouten et al. (2008) reported that there was 'hardly any information' on their sustainability. Arguably, this is an area that needs to be addressed now more than ever as implementation of organizational interventions to improve quality and safety is on the rise and, often by their very own definition, popular applied improvement techniques, such as continuous quality improvement, aim to sustain improvement long after the original implementers have left.

There is a large evidence base which helps to present the range of multi-factorial challenges that surround any plans to spread and sustain the gains in

quality improvement work (Jeffcott, 2014). Given the current climate, where financial constraints are pushing organizations to make the best use of their resources, having a better understanding of the factors affecting spread and sustainability of change is of strategic importance. This justifies the increasing interest in these topics.

Jeffcott (2014) produced a resource that identifies and explains 10 key factors underpinning successful spread and sustainability of quality improvement in NHS Scotland. This resource highlights ten factors which are vital to plan for at the outset of improvement work to optimize spread and sustainability of quality improvement initiatives. The factors were identified through review of both systematic and non-systematic reviews, since the year 2000 (Appendix 2 explains the 10 factors).

In 2013 the Healthcare Improvement Scotland produced a “Guide on spread and sustainability” to summaries the existing resources and key pieces of research around spread and sustainability. The aims of this guide are: first, to increase the understanding of the key issues around spread and sustainability; second, to signpost readers to existing valuable resources on these topics; third, to assist quality improvement practitioners in the process of planning for spread and sustainability of improvement and its implementation and; finally to advise supporting organizations on initiatives that could facilitate spread and sustainability of improvements at a national level. The framework proposed in this guide is divided into five different sections: 1. Innovation; 2. Spread ; 3. Decision to adopt; 4. Implementation; and 5. Sustainability (Appendix 3 explains the framework).

The former NHS Institute for Innovation and Improvement developed a very powerful suite of resources to help organizations to plan for sustainability. The NHS Institute for Innovation and Improvement's sustainability model (Maher, et al., 2010) identifies the main factors affecting sustainability of change, which are grouped under three themes: staff, process and organization (Appendix 4 explains the IHI sustainability model).

2.10 SUMMARY OF LITERATURE REVIEW

Most quality improvement initiatives used in healthcare organizations are based on models and tools first used in manufacturing. Among these models are Total Quality Management (TQM), Lean Thinking, Six Sigma, Business Process Reengineering (BPR), and the Model for Improvement. These models have been adopted in various ways by many healthcare organizations since the early 1990s.

This literature review has explored the implementation of these models and examined evidence for their effectiveness in healthcare organizations. The review revealed that there is no one right method or approach that emerges to be the most effective and that many healthcare organizations have used a combination of models and tools. The review reflects a wide range of studies that do provide insight into the experiences of implementing these quality improvement approaches in different healthcare settings, and broad lessons can be drawn about the potential for successful adoption in healthcare. The successful implementation of quality improvement programs in any healthcare organization places key responsibilities not only on front line staff planning and making changes to patient care but also on middle and senior managers. Managers need to be actively engaged in quality improvement efforts to ensure that quality improvement activities are aligned with the strategic goals of the organization.

The broader literature shows that, whatever model or approach used to quality improvement, there is a broad set of critical conditions that need to be in place for successful implementation. These conditions include: provision of the practical and human resources to enable quality improvement; the active engagement of health professionals, especially doctors; sustained managerial focus and attention; the use of multi-faceted interventions; coordinated action at all levels of the health care system; substantial investment in training and development; and the availability of robust and timely data through supported IT systems. The success or otherwise of implementation depends crucially on the interaction between the local context and the approach as it is applied.

The broader literature on organizational change, together with the studies reviewed in this chapter, will help the researcher develop a new model for healthcare quality improvement in Saudi Arabia. Based on what this literature review suggests, the researcher will carefully consider the local circumstances and provide the 'best fit' locally, followed by application in the local context in a programmed and sustained way, which may include considerable adaptation of the proposed approach to suit the local circumstances and to respond to emerging developments.

CHAPTER THREE

RESEARCH METHODOLOGY

3.0 STUDY DESIGN

The purpose of this research is to develop, apply and evaluate the applicability, effectiveness and potential benefits of a proposed quality improvement (QI) model for Saudi hospitals. This study is made up of three sequential mixed study phases adopting true experiment as the main research methodology. Research methodology refers to a procedural framework's particular style and the particular research methods used to collect data from real practical settings for solving specific problems (Remenyi, 2005). Yin (2008) detailed factors that should be taken into consideration when selecting the most suitable research methodology. These factors are the research questions, the researcher's control over behavioural events, and the contextual factors. Orlikowski and Baroudi (1991) argued that although there are many research methodologies that can be used to study a social phenomenon in its practical setting, the selection of the most appropriate one is always dependent on the nature of the research topic and questions, and also the researcher's capabilities and experiences.

The aim of phase one is to obtain in-depth insight that effectively informs the development of a best fit quality improvement model for Saudi hospitals. The methodology of phase one was a mixed-method approach using two data collection tools: questionnaires and interviews to identify the organizational characteristics impeding or underpinning quality improvement and sustainability in Saudi hospitals. In chapter 2, the existing models for quality improvement in healthcare were thoroughly investigated, exploring the evidence on their applicability,

effectiveness and potential benefits. The questionnaire aimed to uncover the current level of quality improvement implementation in Saudi hospitals. The interview aimed to understand the organizational characteristics that impede or underpin quality improvement and sustainability in Saudi hospitals. Based on this understanding, this phase was divided into three sub-phases: the questionnaire, the interview, and the development of the model.

Phase two aimed to recruit three MOH hospitals to apply the QI model in real world. It includes: selecting the hospitals, forming five QI teams in each hospital, training the QI teams, checking the availability of resources in each hospital to ensure they are adequate to carry out the experiment and test the hypotheses.The five QI teams in each hospital will work on randomly selected five quality indicators. Each team will work independently on one quality indicator.The pretest (baseline) data for each indicator will be developed in this phase.

In Phase three true experimental studies will be used adopting Pre-test Post-test control-group design. In each hospital 10 clinical indicators will be used, five for the experimental group and five for the control group. The true experimental research approach aims to evaluate the effect of the proposed model on a group of five randomly selected clinical indicators. This phase also will include the use of a mixed method study consisting of quantitative and qualitative methods. The quantitative method will consist of a user experience survey aimed to understand the usability of the model. The qualitative method will involve document review such as quality improvement teams meeting minutes and reports.

Quantitative and qualitative methods were used across the three phases of this study. The use of quantitative research seeks to quantify the data and apply some form of statistical analysis whereas qualitative research provides insight and

understanding for the problem. It is often viewed that quantitative and qualitative research is complementary rather than competitive (Creswell and Plano, 2011) and the argument of integrating qualitative and quantitative research has beenemphasized by leading scholars in health services and outcomes research (O'Cathain, et al., 2007; Wisdom, et al., 2012).

In the following sections, each of the three phases of the research will be discussed describing the study design, study area, study population, sampling techniques, data collection and analysis.

3.1 PHASE ONE METHODOLOGY: DEVELOPING THE QI MODEL

3.1.1 Study Design

The first phase of the research was designed to develop a quality improvement model for Saudi hospitals. Both quantitative and qualitative research methods were used in this phase. A questionnaire was performed to understand the current level of quality improvement implementation in Saudi hospitals, while semi-structured interviews were used to understand the organizational characteristics underpinning or impeding quality improvement implementation in Saudi hospitals. The primary data from questionnaires and interviewstogether with secondary data from extensive literature review were used to design a quality improvement model that is capable of addressing the challenges and barriers to quality improvement in Saudi hospitals. This first phase was also designed to facilitate better recruitment of participants for the experimental study in phase three.

3.1.1.1 Questionnaires:

In the present study, the degree of QI implementation was defined as the extent to which the Saudi hospitals apply the QI concepts and practices in its management system. The level of QI implementation was scored using Malcolm BaIdridge National Quality Award Criteria (MBNQAC) through a survey adapted from Quinn and Kimberly (1984). The survey incorporates the seven dimensions of the MBNQAC measured by 50 question items that address organization-wide QI efforts to improve the quality of care and services. These are: leadership, information and analysis, strategic quality planning, human resource utilization, quality management, quality results, and customer satisfaction. The following is a brief description of each.

Leadership: is measured by 10 practices: support to QI, driving QI efforts, allocating adequate resources, participation in QI activities, setting clear vision, managing change, acting on improvement suggestions, engagement of physician leaders, thorough understanding of QI, and confidence on success of QI efforts.

Information and Analysis: is measured by 7 practices: involving employees in determining what data to collect, collecting data to measure performance, improving accuracy of the data, improving timelines of data collection, improving the use of data, using data in QI, and comparing data with other top performing hospitals.

Strategic Quality Planning: is measured by 6 practices: giving employees time to participate in QI activities, setting goals for QI aligned with the hospital strategic goals, disseminating goals, involving employees in developing plans for QI, involving middle management and frontline employees in setting priorities for QI.

Human Resources Utilization: is measured by 8 practices: employees' education and training in QI, data management, and job skill and performance, employee rewarding and recognition, inter-departmental collaboration, empowerment of employees, supporting employees in take risks, and encouraging employees to make suggestions for improvement.

Quality Management: is measured by 7 practices: regular checking of equipment and supplies, coordination of QI efforts, implementing effective policies and procedures, relationship with suppliers, building quality in new services, continuous improvement, and keeping records for QI measures.

Quality Results: is measured by 5 practices: measurable improvements in healthcare, measurable improvements in clinical support departments, measurable improvements in non-clinical support services, measurable improvements in patient satisfaction results, and measurable improvements in cost reduction.

Customer Satisfaction: is measured by 7 practices: assessing the current and future patient needs and expectations, handling patients' complaints, using feedback from patient to improve services, communicating patient satisfaction to hospital staff, assessing physician satisfaction, and assessing employee satisfaction.

3.1.1.1.1 Pilot Study of the Questionnaire

Five hospitals were selected for the pilot test of the questionnaire using convenient snowball sampling techniques and the researcher's personal experience and knowledge of the Saudi hospitals. Other reasons included the ease with which the hospitals could be contacted and the data collected from them. The hospitals selected in the questionnaire development sub-phase were only used for this

development; they were not used later in evaluating the level of quality improvement implementation in the Saudi hospitals.

The purpose of the pilot test was to: check whether each question could measure the desired objective, to refine the questions and check for any misunderstanding of the questions so that respondents from different professional and educational backgrounds would not have any problem in answering the questions. The feedback was used in modifying the questionnaire to make it clearer and to avoid any confusion or ambiguity.

3.1.1.2 Semi-structured interviews:

Semi-structured interviews were used in this phase to provide insight into the factors that drive or hinder quality improvement and to understand and evaluate how context and implementation interact in Saudi hospitals. The researcher prepared an agenda of the interview in advance, including the number of questions. This acted as a guide, although an interviewer may not necessarily follow this guide rigorously. By using a semi-structured interview method, a researcher can ensure that the same topics are covered in each interview while it still allows emphasis to be shifted as appropriate (Cornford and Smithson, 2006).

Prior to the interview participants signed a consent form and interviews lasted approximately 45-60 minutes. Besides face-to-face, the interviews were carried out using modern communication technologies such as Skype, IMO, and LINE. With new technology and new approaches to data collection, new communication programs, such as Skype, could be used for qualitative research to conduct interviews with individuals as well as groups, to hold small focus groups, and much more (Sullivan, 2013; Berg, 2007; Markham. 2008). The use of the new communication technology save time and money as it has the ability to substitute physical mobility when great distance separate the researcher from the

interviewees in a wide country such as Saudi Arabia. Face-to-face interviews were tape-recorded while other interviews were recorded using paper records. Recording the interview is believed to increase the accuracy of the data and to prevent data being lost during transcription.

The information provided by participants was kept in locked cupboards under the custody of the investigator and no one else had access to the data. The recorded information was kept anonymously for transcription purposes. After transcription, the data were analysed anonymously by attaching a unique ID to each interviewee's information. Anonymity was maintained during report/paper writing, presentation and publication.

3.1.2 Study Area

This study was conducted in MOH hospitals across the Kingdom of Saudi Arabia. It covered all the 13 regions of the country including both city and town hospitals as well as tertiary, specialist and general hospitals.

3.1.3 Study Population

The population under study in the first phase is the individuals working as quality directors in MOH hospitals in Saudi Arabia. This population features members of the hospitals who have depth knowledge and experience in the research topic and can provide rich information about the factors impeding or underpinning quality improvement in Saudi hospitals. Private hospitals and government public hospitals, such as University hospitals and National Guard hospitals, will be excluded due to difficulties in accessing these hospitals.

3.1.3.1 Sampling Technique for the Questionnaire:

The questionnaires were restricted to MOH hospitals in all the provinces of Saudi Arabia. At the time of study there were 220 operating MOH hospitals across the country. Military hospitals and National Guard hospitals were excluded because of difficulties in accessing these hospitals. Random sampling technique was used to select a representative sample. The sample was limited to quality directors in the selected hospitals because they have the professional knowledge and experience in quality improvement science and could provide accurate information about the current level of QI in their hospitals. Other professionals such as leadership and clinical staff were excluded because they have their own views to quality improvement. Besides most of them lack the technical knowledge about quality and their feedback would cause great bias and error in the current research. The survey was emailed to the directors of quality departments at each of the hospitals. A cover letter was attached to explain the nature and purpose of the research, and the directors were asked to complete the survey and to return it by email.

3.1.3.2 Sample Size for the questionnaire

A random sample of 60 hospitals was selected from different provinces representing approximately 27% of the operating MOH hospitals in Saudi Arabia.

3.1.3.3 Sampling Technique for the Interviews:

Whereas quantitative studies strive for random sampling, qualitative studies often use purposeful or criterion-based sampling, that is, a sample that has the characteristics relevant to the research question (Cresswell and Plano Clark 2011).

In this phase of the research mixed purposeful sampling technique was used, namely: criterion and critical case. The sampling started with criterion sampling strategy where all cases that meet some criteria were selected. The criteria for selection included: relevance and depth of their experience in the field of research, knowledge about quality improvement methods and tools, and past experience in conducting quality improvement projects in the hospital. According to Patton (2002), criterion sampling strategy is typically applied when considering quality assurance issues where all cases that are information-rich and that might reveal a major system weakness that could be improved were selected. In addition to knowledge and experience, Bernard (2002) and Spradley (1979) note the importance of availability and willingness to participate, and the ability to communicate experiences and opinions in an articulate, expressive, and reflective manner. Several criteria for selecting interviewees for this phase were used. Criterion sampling was followed by critical case sampling. From those who met the criteria, cases that will produce critical information about the characteristics of Saudi hospitals that facilitate or hinder quality improvement were selected. This method permits logical generalization and maximum application of information to other cases because if it is true of this one case, it is likely to be true of all other cases (Patton, 2002; Bernard, 2002).

3.1.3.4 Sample Size for the Interviews:

The sampling of staff for the interviews was purposeful as the aim was to study the perspectives of quality directors. The sampling process in quantitative studies is different as the aim of them is to generalise and therefore a sample needs to represent the population; in qualitative research, on the other hand, there is no aim for generalizability (Anderson, 2010). There are no rules for sample size in qualitative research. It depends on what one wants to know, the purpose of the

study and practical factors such as the amount of useful information obtained from each participant (Morse. 2000). Often qualitative researchers refer to the redundancy criterion: that is when no new information is forthcoming from new sampled units, stop collecting data (Hardon, et al., 2001). The validity, meaningfulness and insights generated from such studies have more to do with the information richness of the cases selected, and the analytical qualities of the researcher than with the sample size (Hardon, et al., 2001; Hudelson, 1994). According to Paton (2002), when interviewing key informants a sample size of approximately five people would be sufficient. Therefore, in the current research, a sample of 12 quality experts representing different provinces was selected for qualitative in-depth interviews.

3.1.4 Model Development:

3.1.4.1 Development Process

Triangulation was used as a technique to combine primary and secondary data in developing the model and ensuring that it is robust, comprehensive and well-developed. The primary data included the results of the questionnaires and the semi-structured interviews. The secondary data involved intensive review of the literature on the key quality improvement models, their strengths and weaknesses, and evidence of their use in healthcare in order to utilize their strengths and evidence-based practices in the proposed model. Triangulation simply means using multiple data sources to help the researcher develops a comprehensive understanding of phenomena. The proposed model was developed and sent to twelve quality experts in the Saudi healthcare sector for review and feedback. The model was further improved through pilot testing in real life contexts. Feedback

from quality improvement teams during experiments, and findings of the user experience survey were also used to further improve and refine the model.

The proposed model is not a brand new approach to quality improvement as it draws on hybrids of the main approaches and their tools. Therefore, it cannot be clearly distinguished from the other key quality improvement models. It is an effort to integrate and adopt some quality improvement principles, techniques and tools from different approaches into one model that could bring more positive results to the Saudi hospitals owing to the effect of synergy.It mainly incorporates the IHI Model for Improvement, Trilogy of Juan and Lean tools and techniques besides a set of TQM principles and strategies that were found effective in the Saudi context. As explained in chapter 3, there is a potential for integrating two or more of these quality improvement approaches.

3.1.4.2 The Five Parts of the Model

As shown in Figure 3-1, the Model is composed of the following five main parts: 1) organizational foundation for Quality; 2) quality control; 3) quality planning; 4) quality improvement; 5) sustaining improvements**.**

Figure 3-1: The Proposed Quality Improvement Model

3.1.4.2.1 Part 1: Organizational Foundation for Quality

The results of this study showed that Saudi hospitals face a significant stumbling block to their quality improvement initiatives. Their workforce is not able to adapt to change, putting productivity and engagement at serious risk. This lack of preparedness has an unfortunate result: quality improvement strategies tend to fail, undermining an organization's ability to achieve the goals the change initiative is designed to produce. Adoption and implementation of quality improvement initiatives require changes in structure, system, and process as a necessary precondition to achieve improved business performance and changes in employee behavior. Preparing the organization for change is the first and most critical leadership practice before adopting any quality initiative. With careful planning and the support of top leaders, Saudi hospitals can help their workforces adapt to change. In fact, when managers and employees are unwilling to embrace change, the result can be everything from high turnover and absenteeism to decreases in employee engagement, performance, productivity, and patient satisfaction.

The findings of the questionnaires on quality improvement implementation revealed unaccepted level of healthcare quality in Saudi hospitals despite the huge expenditure on healthcare services. The thematic analysis of the interviews carried out with 12 quality directors in Saudi hospitals showed that quality improvement work in healthcare requires an understanding of not only the methodology and science of improvement but also a mastery of the concepts of change management. A significant contribution to the low level of QI implementation in Saudi hospital is the failure of most QI models to effectively integrate change management (including how to effectively resolve resistance to change). Saudi hospitals

struggle with resistance to change in culture, specifically from physicians, nurses and managers.

As shown in Figure 3-2, four critical practices are suggested for establishing the organizational foundation for quality improvement and the successful management of change in Saudi hospitals: 1) build the right culture, 2) manage human resources, 3) focus on processes and systems, and 4) provide the necessary resources and facilities. Without the incorporation of these change management concepts quality improvement cannot be achieved or sustained.

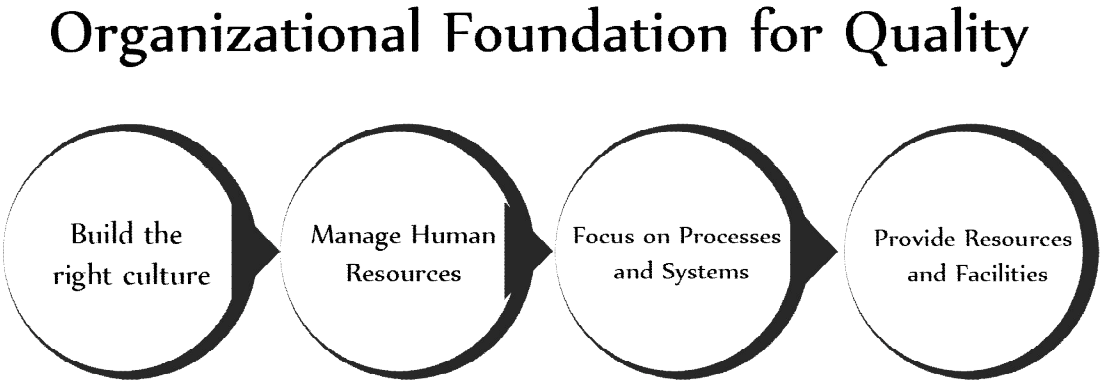

Figure 3-2: Organizational Foundation for Quality

Factor 1: Build the right culture

The first step is to start with an objective assessment of the organization's current culture, its readiness for change and commitment to improving the quality of its care and services. Cultural change can be successful only when an organization has a good understanding of the difference between the culture it currently has, and the culture it is trying to build. Clear and objective measurement is one common feature of successful cultural change.

Organizational Culture is defined as a mixture of values, sets, beliefs, communications and explanation of behavior that provides guidance to people.

Many quality initiatives fail to generate the required improvement effects due to lack of readiness of culture and other behavioral issues during quality initiatives or programs. The culture of the entire organization must reflect true motivation and commitment to perfection. The organization needs to spend significant time and energy building the right culture. Change will only come when the whole organization really wants it and strives to make it. The following best practices, derived from change management literature, are recommended to build the right culture in Saudi hospitals.

Best practices:

- ✓ Assign a change team of influential people whose power comes from a variety of sources, including job title, status, expertise, and political importance to lead the change and work as an effective agent to prepare the members in facing numerous challenges brought about by the change. Convincing people that change is necessary often takes strong leadership and visible support from key people within the organization.
- ✓ Develop a sense of the need for change, lead open, honest and convincing dialogue with leadership and employees, and ensure that at least 75% of people start talking about the need for change.
- ✓ Establish a clear perfection-related vision, goals and targets consistent with the mission and aligned with the strategic objectives of the organization. A clear vision can help everyone understand why you are asking them to do something perfectly. When people see for themselves what you are trying to achieve, then the directives they are given tend to make more sense.
- ✓ Communicate the vision and build buy-in from all levels of the organization by establishing a good dialogue with people. Address their minds and emotions; communicate frequently and powerfully; call special meetings to

communicate the vision; talk about it every chance you get "walk the talk" to keep it fresh on everyone's mind; first change yourself and demonstrate the kind of behavior that you want from others.

- ✓ Put in place the structure for change, and continually and systematically tackle resistance to change and check for barriers. Removing obstacles can empower the people to execute your vision, and it can help the change move forward. Regardless of the amount of change required, effective and sustained change should be incremental because people change gradually.
- ✓ Secure strong clinical and administrative leadership commitment and support.
- ✓ Ensure sustained and active participation in quality improvement activities by hospital board members and senior managers.
- ✓ Build strong belief among staff that they as well as patients will benefit from the changes.
- ✓ Focus on employees and process improvement and pay special attention to cost and waste reduction as well as improving patient satisfaction.
- ✓ Report regularly quality dashboards and scorecards reflecting selected performance indicators to senior management and hospital Board.
- ✓ Establish supportive organizational structures such as quality-related committees.
- ✓ Ensure safe environment that encourage staff to report errors without fearing to be blamed or penalized.
- ✓ Make the changes show in day-to-day work and seen at all levels of the organization from management to front-line staff. Ensure strong and continuous support from the o leaders including the existing and new.

Factor 2: Manage Human Resources

The hospital should place great emphasis on recruiting and retaining top-level professionals. It should ensure that the right people, with the right skills, are in the right place at the right time. This is accompanied by an effort to encourage these professionals to form working teams to promote quality.

Best practices:

- ✓ Establish an effective Human Resources department guided by effective HR Management plans.
- ✓ Place a great emphasis on: keeping staffing levels high and vacancy rates low; provide competitive salaries; and respect and empower your employees.
- ✓ Monitor the performance of healthcare providers and ensure that they must continue to meet certain performance and practice standards to retain credentials.
- ✓ Provide opportunities for continuing education and professional advancement for physicians and nurses.
- ✓ Respect, engage and empower physicians and nurses to play key role in quality improvement projects (QIPs) and to conduct QI analysis and improvement with IT support.
- ✓ Ensure involvement and participation of all employees at all level in the organization in improving the quality.
- ✓ Provide continuous training and education to employees in quality improvement strategies and problem solving skills.
- ✓ Emphasize QI in new employee orientation and regular staff meetings.

- ✓ Establish QI training and activities as part of the daily responsibilities rather than extra burden on top of other tasks.
- ✓ Carry out regular culture gap analysis and develop action plans before embarking on any change program.

Factor 3: Focus on Processes and Systems

The hospital should strive to provide high quality care based on state-of-the-art practices to each patient in a respectful, professional, and compassionate manner. This can be achieved through redesigning care delivery processes so that steps that have no value for patients are eliminated and the input of caregivers is not merely heard and respected but actually used on a daily basis. Instead of (management by objectives) which focus on meeting objectives, the model adopts Deming's approach of "management by process," whereby managerial competencies and systems govern behavior. Processes within a health care organization contain two major components: 1) what is done (what care is provided), and 2) how it is done (when, where, and by whom care is delivered). Improvement can be achieved by addressing either component; however, the greatest impact for QI is when both are addressed at the same time.

Best practices:

- ✓ Develop a quality improvement toolkit that describes a general approach to quality improvement as well as specific changes that can improve care delivery as evaluated by clinical quality measures. QI tools that have been successfully utilized by Saudi hospitals include: Process mapping, Cause and Effect diagram, Brainstorming, Affinity diagram, Pareto diagram, Prioritization matrix, Force Field Analysis, Delphitechnique, Gantt chart, Multi voting, Run chart, and Control Chart.

- ✓ Use process mapping to better understand the health care processes within its practice system. A process map provides a visual diagram of a sequence of events that result in a particular outcome. By reviewing the steps and their sequence, an organization can often evaluate, improve or redesign a current process.
- ✓ Eliminate Non-value Adding Activities:it helpsadjust the process**,** improve quality of care, lower costs, and increase staff and patient satisfaction.
- ✓ *Enable senior managers to* actually visit the work areas to become familiar with frontline workers daily tasks and challenges, energize people to develop new care models that improve the patient experience, overcome barriers to change, embrace failures as learning experiences, and celebrate successes

Factor 4: Provide Resources and Facilities

The patient is the center of all health services. Healthcare managers should know the expectations of patients and give their staff the resources, supplies, tools and support they need to practice high-quality medicine on a daily basis, and to identify and investigate quality problems.

Best practices:

- ✓ Participate in accreditation systems for hospitals such as the Saudi Center for Accreditation of Healthcare Institutions (CBAH) which is mandatory for all Saudi hospitals, the Joint Commission International (JCI), and the Canadian Accreditation Council (CAC). Accreditation is usually a voluntary program in which trained external peer reviewers evaluate a healthcare organization's compliance and compare it with pre-established performance standards.
- ✓ Provide ease of access to the other important sources for standards, best practice and quality such as: the Agency for Healthcare Research and

Quality (AHRQ), the Institute for Healthcare Improvement (IHI).

- ✓ Develop evidence-based policies and procedures, job descriptions, and business management plans.
- ✓ Invest in advanced medical technology to generate efficiencies and cost savings for the healthcare system and the economy.
- ✓ Invest in Information Technology (IT). In order for hospital personnel to make their policies and procedures work effectively, they need a modern information system producing real-time data on patient health status, test results, and other key factors. Recent reports document the benefits realized by healthcare organizations resulting from the use of IT, including cost savings from reduced medication errors and improved clinical care (Meyer J.A. et al. (2004).
- ✓ Invest in QI departments with qualified staff that abstract records, analyze data, and facilitate the QI process.
- ✓ Facilitate access to guidelines and protocols, and offer support to physicians to develop a consensus around their own evidence-based best practices.
- ✓ Use Quality Improvement staff to facilitate rather than mandatethe QI process. QI should not be perceived as being forced upon staff or as an admonishment by upper management. Rather, QI staff present data and foster an interactive, participatory process with department leaders and staff taking the lead in developing solutions.

3.1.4.2.2 Part 2: Quality Control

Quality Control (QC) refers to constant measuring, evaluating, monitoring, and comparing performance measures to ensure that services rendered to customers meet quality standards. It is a systematic, cyclic process to determine whether improvements has been achieved and sustained. The main goal of quality

control is to collect valid and reliable data reflecting actual performance. Quality Control as it pertains to this model serves three main purposes: 1) identify variation, gaps, and areas for improvement; 2) ensure that improvement is sustained overtime; 3) ensure that best practice is sustained. In healthcare, not all variations are negative. Some variations are best practices and should be sustained. This is why the model connects Quality Control pphase directly to the Sustainability phase because in positive variation the two steps of Quality Planning and Quality Improvement will not be required.

In order to implement an effective quality control program, the hospital should implement the following eight-step process (Figure 3-3): 1) establish a data warehouse; 2) develop a list of quality indicators; 3) measure actual performance; 4) summarize data and perform initial analysis; 5) compare with evidence-based standards and benchmarks; 6) perform intensive analysis; 7) prioritized for improvement; and 8) provide accurate and timely feedback.

Figure 3-3: Quality Control

Step 1: Establish a Data Warehouse (DW)

- ✓ Although the data can be collected manually and stored as hard or electronic copy, it is always recommended that the data collection, analysis and display should be automated. A data warehouse is a repository of many different databases across the entire organization. The aim of a data warehouse is to have an integrated, single source of data that can be used to drive QI initiatives and make it possible to identify the areas that will yield the greatest improvements.
- ✓ Ensure that the data is standardized and cleaned before loading into the data warehouse..Typically, a data warehouse is housed on the organization's mainframe server or increasingly, in the cloud (online storage provider).

Step 2: Develop a List of Quality Indicators:

- ✓ The leadership should select a list of performance measures to be monitored and tracked over time. The Quality Council is responsible for chartering and approving teams to determine the most appropriate measures (indicators) to be included in the list.
- ✓ Involve staff in the measure selection process. The measures should be meaningful to staff, because they may be involved in collecting the data and the data will be a reflection of the work they do. They should be able to clearly see how these measures can support their work.
- ✓ Prioritizing for QC should be based on: 1) mission, vision, strategic goals, and available resources; 2) monitoring important organization functions over time; 3) the six IOM aims; 4) feedback of patients, staff, payers, and other stakeholders; 5) high volume, high risk, high cost or problem prone processes; 6) areas targeted for further study, based on previous data and other available information; 7) performance measures or feedback related to accreditation, regulatory, or other requirements; 8) utilization, quality

control, risk management, patient and environmental safety or infection control findings.

- ✓ Before making the decision to independently develop measures, the hospital should investigate and utilize (if appropriate) measures already developed nationally or internationally. AHRQ websites provide hundreds of well-tested, current performance measures.

Step 3: Measure Actual Performance:

- ✓ Use outcome measures (see appendix -) to measure results of care which can be expressed as 'The five Ds': (i) death; (ii) disease; (iii) discomfort (iv) disability and (v) dissatisfaction. The purpose of outcome measures is to evaluate effectiveness of care and to screen for opportunities to improve care process and services.
- ✓ Use p*rocess indicators to* measure steps in processes and assess what the provider did for the patient and how well it was done.
- ✓ Use s*tructural indicators*: they are only warranted when an outcome is unacceptable and is not improved by decreasing process variation and therefore requires structure change. They include material resources (such as facilities and equipment), human resources (such as the number and qualifications of personnel), and organizational structure (such as peer review and reimbursement). It is now assumed that structure will be addressed, not by indicator measurement, but by other feedback sources or within the context of QI Team activity (Brown, 2014).
- ✓ Use *Balancing Measures:* to ensure that improvement in one part of the system does not cause problems in other parts of the system. They are only used when necessary.

- ✓ *Userate-based and sentinel event* in measuring performance. Rate-based measurement: uses data about events that are expected to occur with some frequency. These can be expressed as proportions, rates, ratios, or mean values for a sample population. To permit comparisons among providers or trends over time, proportion or rate-based indicators need both a numerator and a denominator specifying the population at risk for an event and the period of time over which the event may take place. Sentinel events measurement identify individual severe events such as unexpected death, loss of limb or function. They represent the extreme poor performance and trigger further analysis and investigation.
- ✓ Collect regular data to measure performance and assess whether the correct processes are being performed and desired results are being achieved. Measurement is essential to understand whether the organization delivers quality healthcare and to know how its health services have affected individual and population levels of physical, mental and social functioning (Institute of Medicine, 1999). Data collection is a systematic way to collect accurate and timely data in hard copy or online using data collection tools such as: data sheets, check sheets, surveys/questionnaires, interviews and focus groups. It begins with assessing what data are really needed and how they can be collected. The design of data collection methods should maximize the use of data already available, minimize duplication of efforts, maximize accuracy and coordinate data collection efforts across the organization.

Step 4: Summarize Data and Perform Initial Analysis:

- ✓ Aggregate collected data (tabulate, summarize, and trend overtime) to enhance the organization's analysis and reporting capabilities.

Summarization of data is done in ways that permit meaningful interpretation and formulation of accurate conclusions regarding the quality of patient care and services. Data aggregation may be done manually or through specialized software.

- ✓ Display the aggregated data using statistical tools and techniques (totals, percentages, averages, etc.). Charts such as run charts, control charts, and dashboards provide a visual display of the data and help convey ideas about the data that might not be readily apparent if they were displayed in a table or as text.
- ✓ Conduct initial analysis which is usually the responsibility of those persons closest to the process being measured. Initial analysis may involve: review for accuracy, validity and reliability of data; undesirable variation, triggers; determine if immediate action, continued measurement, or intensive analysis is necessary; identify cases requiring intensive analysis; and identify and separate peer review issues from process issues.
- ✓ Refer peer review issues and concerns about the performance of an individual practitioner to the appropriate peer review body to assume responsibility for the analysis and any necessary action.

Step 5: Compare with Evidence-based Standards and Benchmarks:

- ✓ Compare indicators with evidence-based standards and benchmarks within and outside the hospital.
- ✓ Set triggers for each measure. A trigger serves as a “wake-up call” or a signal that prompts the hospital to begin intensive analysis of the process or function under study. Data triggers include: sentinel event (0% acceptability); expected performance rate (e.g. clean and clean-contaminate

surgical site infection rate >5%); a trend (e.g. C-section monthly rate increase >5% over a 6-month period); a pattern (e.g. hospitalization rate difference >5% between patient care practitioners for four consecutive quarters); outliers to pre-established upper and lower control limits (e.g. time in recovery room >2 hours while the upper and control limits are 1-2 hours).

- ✓ Us other internal qualitative triggers such as: patient and staff feedback, and external triggers such as: literature, practice guidelines, best practice, national and international benchmarks, reference databases, and evidence-based standards.

Step 6:PerformIntensive Analysis:

- ✓ Perform Intensive Analysis when indicated by triggers. Intensive analysis means additional in-depth investigation or special study and ideally should be carried out collaboratively, with involvement of persons who have the knowledge, expertise, and experience with the process and outcome under review. It seeks to identify and clarify: clear opportunities to improve care and service processes; significant deficiencies in care and service processes; the scope and severity of problems; and possible causes of problems or root causes of variation.
- ✓ Use patterns and trends to identify where systems are falling short, to make corrective adjustments, and to track outcomes.
- ✓ Calculate measures at multiple points in time (at least annually) to track changes over time and therefore, the measures should be calculated at multiple points in time. The first measurement (called the baseline), will help the organization to identify problems and to establish baseline results. Successive measurements allow an evaluation of the impact of the quality

improvement efforts and make it possible to monitor and sustain incremental improvements.

- ✓ Display and analyze the data to compare the measures to the quality improvement goals. If the results meet or exceed the organizational goals, it is still important to continue measuring at regular intervals to continuously monitor quality. If the measures show room for improvement, launch a quality improvement project.
- ✓ Use the data collected in assessing physician performance. Clinician performance measurement and reporting is a strategy used to evaluate physician adherence to evidence-based care guidelines and serves as a basis for physician incentives and rewards programs. In many cases clinicians resist efforts to measure their performance using any data. Very often this is a result of a lack of trust that performance measurement will be based on reliable and valid data and that it will serve punitive purposes rather than QI purposes. It is important to demonstrate the validity of data to clinicians and work with them to develop performance monitoring strategies.

Step 7: Prioritize for Improvement

- ✓ Identify organization wide problems and opportunities for improvement through the use of all available data sources such as: monitoring priority indicators, medical record reviews, infection control surveillance, blood usage reviews, pharmacy and therapeutic reviews, morbidity and mortality reviews, utilization review findings, internal and external surveys, incident report trends, hospital committee activity reports, internal and external customer interviews and surveys and benchmarking against external data sources.
- ✓ Review the current performance against national and international benchmarks for all priority indicators. If the priority indicator already

meets or exceeds the benchmark it should not be included in the Quality Improvement Program.

- ✓ Select those quality improvement projects of most value to the healthcare system. There are many strategies that can help the hospital in the selection process (e.g., prioritization matrix, Pareto analysis, nominal group technique, strategy grids and multi-voting technique). However, we recommend the use of a standardized form with scoring as a practical approach for prioritization. This approach combines bottom-up and top-down perspectives through integrating leadership vision with professional and improvement knowledge. The proposed form and the scoring tool are adapted from the Institute for Healthcare Improvement (IHI) and Loyola University Health System to be used to score each potential project and thereby permit a reasonably objective comparison of the improvement opportunities available to the hospital.
- ✓ Form a Quality Council chaired by the hospital director and members from admin, medical staff, and head departments to prioritize and coordinate all organization wide quality improvement activities.
- ✓ Base selection of potential major quality improvement projects on how they (1) address the IOM six aims; (2) align with the institutional mission and strategic goals; (3) improve medical outcomes, health status, access and patient, family, and caregiver satisfaction; (4) make a positive change to a key process by facilitating system integration and continuity in care; and (5) effect revenue, volumes, cost, and attractiveness to payers.

Step 8: Provide Accurate and Timely Feedback

- ✓ Provide accurate and timely feedback and summary report of performance measures and quality management activities to the hospital board, quality

council and department heads on a periodic basis (quarterly and annually).

- ✓ Use various data feedback mechanisms such as scorecards and dashboards. A scorecard provides periodic "snapshots" of performance associated with an organization's strategic objectives and plans. A dashboard measures processes in real time allowing verification of important information at a glance (an example of a dashboard is the automobile dashboard that permits verification of current speed, fuel level etc., at a glance). A dashboard uses key indicators or performance measures pulled from systems and processes within varied departments to provide a "snapshot" of performance at a given point in time, e.g. monthly or quarterly and allow leaders to see how well the organization is performing overall.

3.1.4.2.3 Part 3: Quality Planning

Quality planning is the task of determining what factors are important to a project and figuring out how to meet those factors. As shown in Figure 3-4, these factors include:Forming and training the QI Teams; Setting Aims; Establishing measures for improvement; Innovating change.

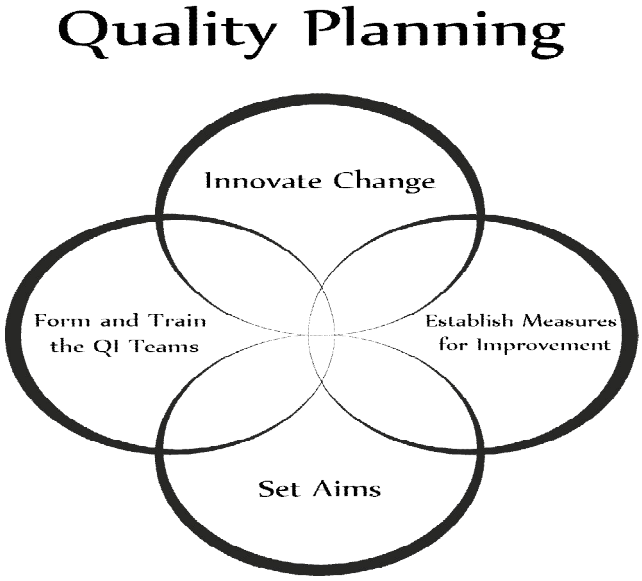

Figure 3-4: Quality Planning

Step1: Form and Train the QI Teams

- ✓ Form a team for each quality improvement project to design and/or redesign processes affecting the healthcare system performance and patient outcomes. The quality improvement team (QIT) is a group of individuals within a practice charged with carrying out improvement efforts. The purpose of teamwork is to use the knowledge, skills, experiences, and perspectives of a wide range of people especially when the task is complex, creativity is necessary, efficient use of resources is required, or the process involved is cross-functional.
- ✓ Select members for each QIT. While there is not a specific "how-to" guide for QI team selection, there are some worthy guiding principles to consider. An ideal QI team member has the following attributes: respected by a broad range of staff, excellent listener, good communicator, proven problem solver, creative, flexible, frustrated with the current situation and ready for change, and proficient in the areas and systems focused for improvement. The optimal size of a QI team is 5 - 8 individuals. However, the most important requirement is not size, but diversity of the participants.
- ✓ Set clear objectives to guide the team's activities.
- ✓ Create short-term targets with smaller target to be achievable; each "win" that you produce can further motivate the entire staff.
- ✓ Provide explicit support from the leadership, and the resources necessary to complete the project.
- ✓ Enable the team to investigate and use the data to identify and explore possible factors contributing to suboptimal performance and to be flexible enough to respond to the ongoing challenges of QI work.
- ✓ Make a QIT charter. It is the official written document that empowers the team to act. It is developed early during forming the team to serve as a

"roadmap" that guides, motivates and keeps the team focused on their purpose. It should contain three key elements: team purpose; measurable goals; and operating guidelines.

- ✓ Organize the members within a QIT to effectively accomplish the work by defining specific roles. The leader coordinates and directs the work of the team and keeps it focused on their goals and desired outcomes. The facilitator serves as a coach, consultant, and improvement adviser and provides formal or just-in-time quality training as needed to foster team progress. Team members all share responsibility for the effectiveness of the team and contribute their knowledge and insights to the QI project. Recording and timekeeping are two tasks rotated among team members and they are selected at the beginning of each team meeting based on the ground rules. Senior leaders also are required to serve as sponsors for improvement projects. Each QIT should have a senior leader appointed as the sponsor of the team's project. The QIP sponsor is usually at the senior executive level of the organization and has authority over the area where the improvement project is taking place. They play a critical role in supporting the project, empowering the team, resolving barriers, providing resources, and linking the team to the organization leadership.
- ✓ Train the QITs on teamwork, quality methods, quality improvement tools, data management, developing and testing change and explain to them the lifecycle of a QIP step by step.
- ✓ Train each QIT to develop a well-documented plan with detailed steps for collecting each data element prior to actually collecting the data or calculate the baseline. An effective data collection plan includes the following: name of the measure; purpose; population and sampling; denominator and numerator details with inclusions and exclusions; data source for the

denominator and numerator; identify individuals who collect each data element and calculate the measure; a calendar of reporting and QI Team reviews of performance data.

- ✓ Enable the team to investigate and use the data to identify and explore possible factors contributing to suboptimal performance.

Step 2: Set Aims:

- ✓ For every QI initiative set a clearly defined aim. The aim should be SMART, time-specific and measurable; it should also define the specific population of patients that will be affected. Agreeing on the aim is necessary; so is allocating the people and resources necessary to accomplish the aim. The aim statement should be consistent with the organizational goals and answer the following four questions: What to be improved? Who is affected by the improvement? How much is the improvement? Within how long the improvement will be achieved?

Step 3: Establish Measures for Improvement:

- ✓ Establish a family of measures to every QI project including outcome measures; process measures; and where applicable balancing measures. Quality improvement teams can use the same measures developed in the QC phase or develop their own family of measures. Measurement is a critical part of testing and implementing changes; measures tell the QI team whether the changes they are making actually lead to improvement.
- ✓ Train the team on sampling techniques. The team needs just enough data to know whether changes are leading to improvement. Sampling is a simple, efficient way to help a team understand how a system is performing. Sampling can save time and resources while accurately tracking performance. For example, instead of monitoring the time from

catheterization to cardiac surgery continuously, measure a random sample of 10 to 20 cardiac surgery patients per month.

- ✓ Do not relyon information systems to avoid waiting for months to receive data from the information systems department. Develop a simple data collection form, and make collecting the data part of someone's job. Often, a few simple measures will yield all the information the team needs. In addition to collecting quantitative data, QI teams should be sure to collect qualitative data, which often are easier to access and highly informative.
- ✓ Collect, aggregate, summarize and plot data for the selected measures over time using a run chart or a control chart. Run charts and control charts are two simple and effective ways to determine whether the changes the team is making are leading to improvement. Once data is plotted over time, it can help the team track a few key measures over time observing trends and other patterns.

Step 4: Innovate Change:

- ✓ Identify who the customers are, determine their needs and translate those needs into quality standards.
- ✓ Use QI tools such as process mapping, cause and effect diagram, brainstorming, and benchmarking to understands the process and develop creative approaches to deal with quality problems.
- ✓ Innovate the changes to improve the process under study and make it capable of meeting quality standards. Innovation refers to the notion of doing something different rather than doing the same thing better
- ✓ Use change concept that focus on improving the process to develop innovative ideas for improvement. To be innovative the QI team should think differently and creatively. The following change concepts that were

developed by the Associates in Process Improvement were found useful in Saudi hospitals:

- *Eliminate Waste*: look for ways of eliminating any activity or resource in the organization that does not add value to an external customer.
- *Improve Work Flow*: improve the flow of work in processes is an important way to improve the quality of the goods and services produced by those processes.
- *Optimize Inventory:*inventory of all types is a possible source of waste in organizations; understanding where inventory is in a system is the first step in finding opportunities for improvement.
- *Change the Work Environment:*changing the work environment itself can be a high-leverage opportunity for making all other process changes more effective.
- *Producer/Customer Interface:*to benefit from improvements in quality of products and services, the customer must recognize and appreciate the improvements.
- *Manage Time:*an organization can gain a competitive advantage by reducing the time to develop new products, waiting times for services, lead times for orders and deliveries, and cycle times for all functions in the organization.
- *Focus on Variation:*reducing variation improves the predictability of outcomes and helps reduce the frequency of poor results.
- *Error Proofing:*errors can be reduced by redesigning the system to make it less likely for people in the system to make errors. One way to error proof a system is to make the information necessary to perform a task available by writing it down.

- *Focus on the Product or Service:* although many organizations focus on ways to improve processes, it is also important to address improvement of products and services.

✓ Document your plan for change.

3.1.4.2.4 Part 4: Quality Improvement

The PDSA Cycle (Plan-Do-Study-Act) is a systematic series of steps for gaining valuable learning and knowledge for the continual improvement of a process or outcome (Figure 3-5).

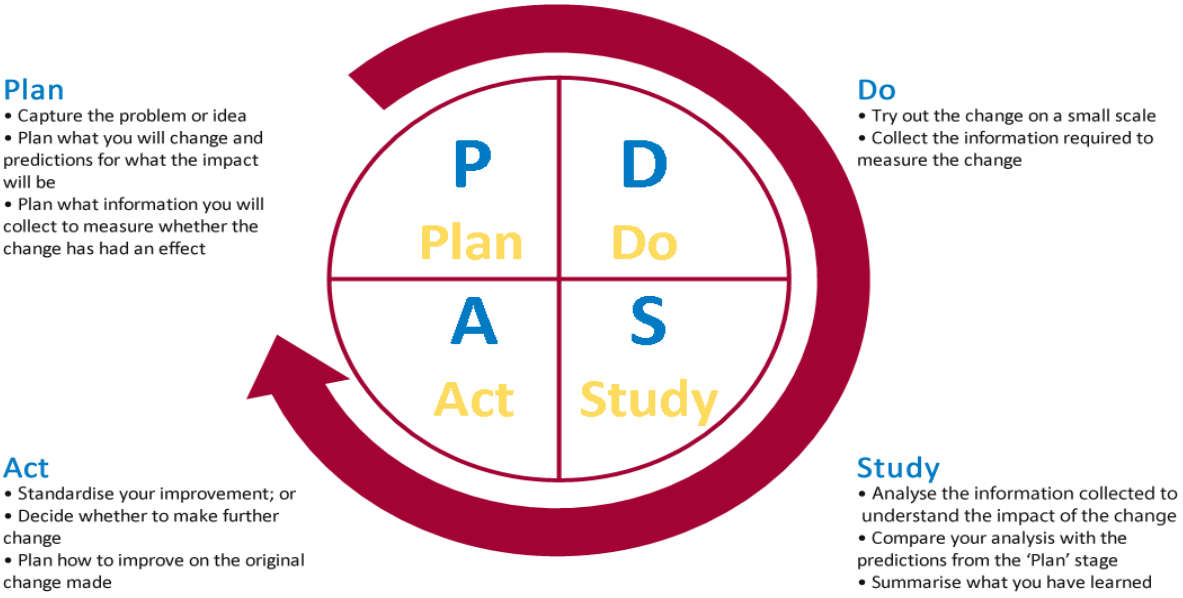

Figure 3-5: PDSA Cycle

Use the PDSA to Test Changes

✓ Apply the PDSA cycle to test the change. The PDSA consists of four stages (Plan, Do, Study, Act). Each PDSA cycle is shorthand for testing a change by developing a plan to test the change (Plan), carrying out the test (Do),

observing and learning from the consequences (Study), and determining what modifications should be made to the test or change plan (Act).

Start With Small Scale Tests

- ✓ Run the Plan-Do-Study-Act (PDSA) cycles (Figure 6) to test the change or group of changes in the real clinical environment on a small scale to see if they result in improvement.A small scale means: if the team is thinking "all patients", they should run the test on "one or two patients". However, the PDSA scale should be determined by the team based on: confidence that the change will result in improvement and the readiness of staff to accept the change. The PDSA gives the team a way to test changes on a small scale, observe and learn from what happens, refine the changes as necessary, and then repeat the cycle again before implementing anything on a broad scale.

- ✓ Conduct multiple PDSA cycles as needed and refine your change plan based on data collected and lessons learned from each cycle. Testing on a small scale has several advantages: 1) allows the team to create new knowledge by conducting small tests of change with a minimum of risk; 2)builds confidence in the impact of the changes proposed; 3) it involves less time, money and risk; 4) it is safer and less disruptive for patients and staff; 5) there is often less resistance because PDSA can be used effectively to engage staff in testing and developing the ideas for change.
- ✓ Use the PDSA worksheet to help the team documents a test of change (see appendix for the proposed PDSA Worksheet). The QI team should fill out one PDSA Worksheet for each test they conduct. The team will test several different changes, and each change will go through several PDSA cycles until the improvement aim is met. It is possible that there may be several PDSA cycles running sequentially (Figure 3-6), or even simultaneously (Figure 3-7). Sequential cycles are common when the study reveals results which suggest a

different approach is needed. Simultaneous cycles may occur when the changes are more complex, possibly involving several departments. It is important that the team identifies any interactions between simultaneous cycles, as a change in method in one cycle may alter the impact of another somewhere else. The team should keep a file (either electronic or hard copy) of all PDSA Worksheets for all changes the team tests.

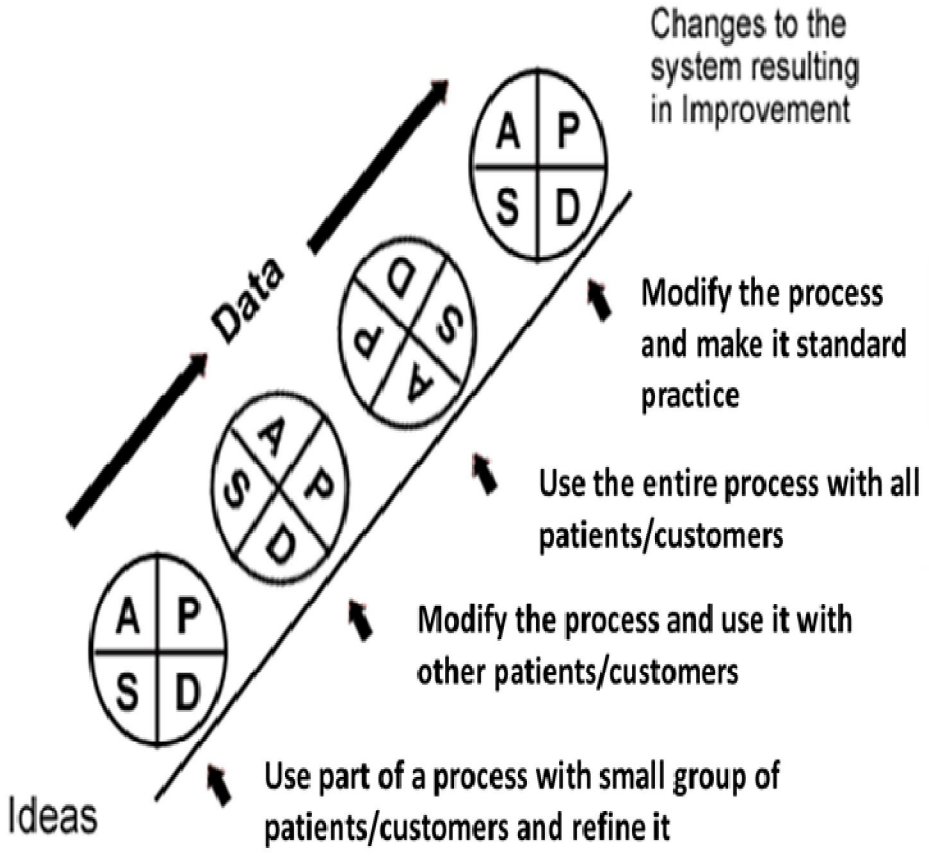

Figure 3-6: Sequential PDSA

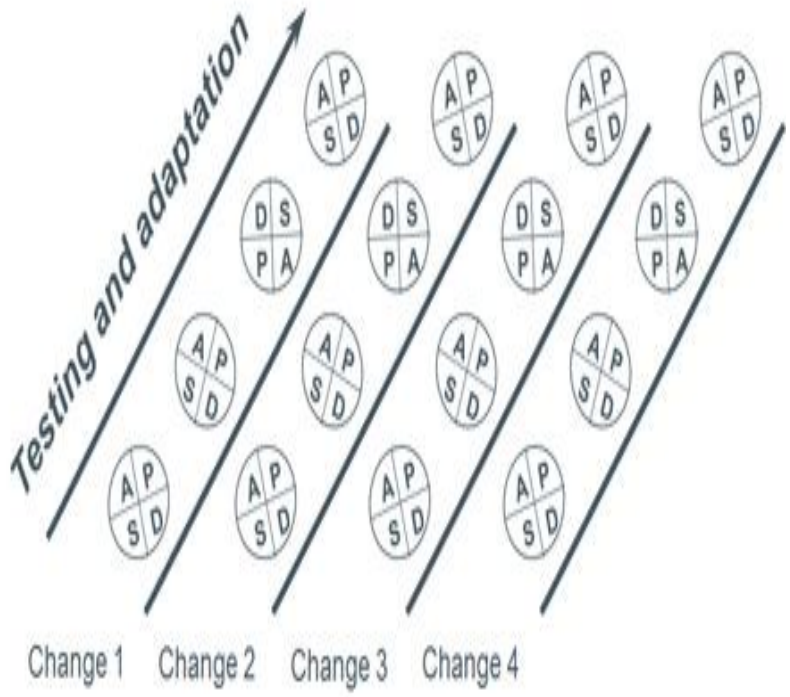

Figure 3-7: Simultaneous PDSA

Expand Tests Gradually

- ✓ Expand the tests and gradually incorporate larger and larger samples until the team is confident that the changes should be adopted more widely. Ideas with positive impact can be continued on a larger scale while ideas that do not have a positive impact are discontinued.
- ✓ Implement the change on an entire pilot population or on an entire unit. This happens after testing a change on a small scale, learning from each test, and refining the change through several PDSA cycles.

Make Change the Routine in the Organization

- ✓ Implementation is a permanent change to the way work is done and, as such, it may affect documentation, written policies, hiring, training, compensation, and aspects of the organization's infrastructure that are not heavily engaged in the testing phase.

3.1.4.2.4 Part 5: Sustain Improvement

Table 3-8 shows the proposed Sustainability Framework to sustain improvements. It is an easy-to-use tool tohelp QI teams in Saudi hospitals effectively implement and sustain change over the long term. It is both a planning and diagnostic tool that will assist the QI team to plan for sustainability, identify strengths and weaknesses in the plan, recognize and understand key barriers for sustainability, self-assess against a number of key criteria for sustaining change, predict the likelihood of sustainability for their improvement initiative and monitor progress over time.

Link the use of the framework to a specific quality improvement project rather than to assess whether a department, whole organization or health community is likely to sustain change in general.

Apply the following 7 factors to sustain change in your healthcare organization. The 7 factors are relating to process (3 factors), staff (2 factors) and organizational issues (2 factors).

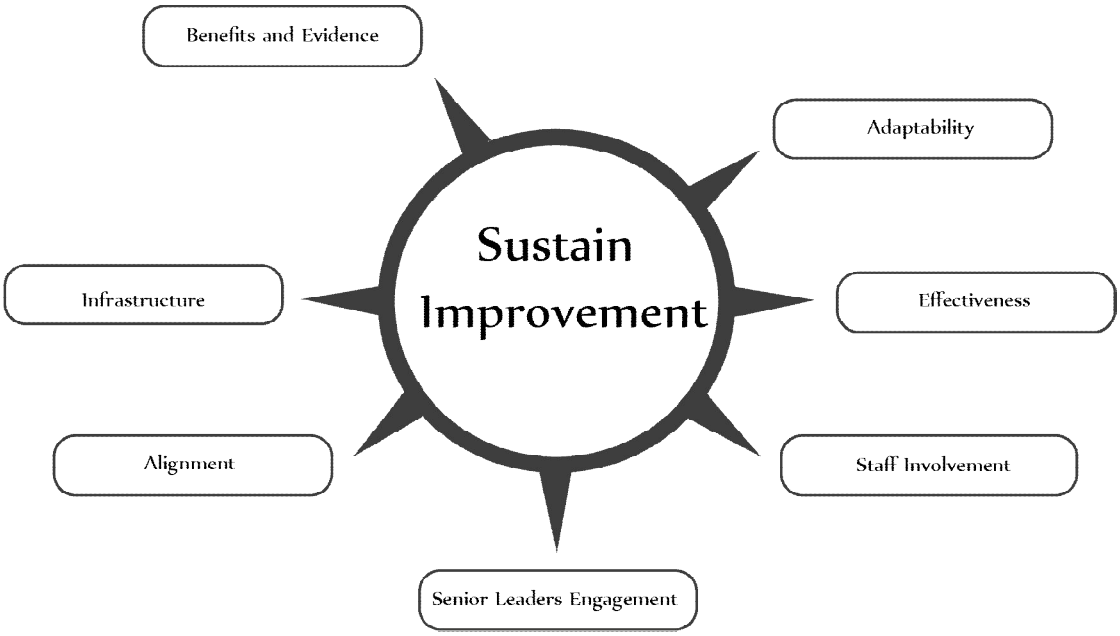

Figure 3-8: Sustainability Framework

Factor 1:Benefits and Evidence: is about ensuring that there is evidence that the change will produce benefits that are obvious to staff, patients and the organization. Evidence of benefits above and beyond those gained through the existing process will give people reason to support, accept and participate in the change. The sustainability of a change will be greatly enhanced if, in addition to improving the patient's experience, the staff can also recognize a benefit to their own role. The harder it is for people to see the benefits for patients, themselves and the organization, the harder it will be to convince them to accept the proposed or new change.

Factor 2: Adaptability: is about ensuring that the improvement can continue in the face of ongoing changes in staff, leadership, organization structures, etc. Ensuring that the improvement is flexible to the surrounding systems will help make it sustainable and help it become a platform for continuous improvement. Adaptability can be very important in determining whether a new or improved process will be sustained over the long run. Ensure that the improved process can adapt to link in with and even support other organizational changes, would not be disrupted if specific individuals or groups left the project, and its focus will continue to meet the improvement needs of the organization.

Factor 3: Effectiveness: is about ensuring that the organization has a system in place to continually and effectively monitor the progress of change. Measuring keeps the QIT informed about success and identifies further areas for improvement. In the absence of feedback, serious flaws or 'slipping back' may go unnoticed. The team should ensure that there is a system in place to provide evidence of impact (including benefits analysis), monitor progress, communicate the results, and that there is set up to continue beyond the formal life of the project.

Factor 4: Staff Involvement: is about ensuring that key staff at all levels that are affected by the change are involved from the outset and trained in any new skills needed. Staffs who feel valued are more likely to be motivated to make change work while aggressive resistance can be detrimental. Reducing scepticism by increasing belief in the change and helping staff to feel empowered in their work is essential. Negative beliefs and behavior lead to negative outcomes.

Factor 5:Senior Leaders Engagement: is about engaging senior leaders (administrative and clinical) and encouraging them to interact with staff and take responsibility for sustaining change. Any improvement initiative should have a senior sponsor and this sponsorship should continue as the initiative enters the sustaining phase. A respected leader who has invested in the improvement will be influential and help the team overcome barriers. Clinicians are powerful agents of change; without their support, sustainability will be difficult. Scepticism among clinicians and the relative scarcity of clinicians willing to take on the responsibility of leading improvement are significant risks to sustaining improvement. The QIT should involve clinical leaders from the time of design and throughout the improvement process. This is done through demonstrating the benefits of the change for patients, other staff and the organization.

Factor 6:Alignment: is about ensuring that there is synergy between the improvement and organizational goals and vision. One of the reasons often cited for unsustained change initiatives is that there is no clear vision or strategy that identifies how the change 'fits' into the organization. Therefore the culture of the organization does not support staff to be receptive to change. Every organization should have a clear stated vision for its future and goals. Clear

links with the organizational goals and vision helps ensure long-term success for the improvement.

Factor 7: Infrastructure: is about ensuring the improvement effort is supported during and beyond the formal life of the project. When a new process is implemented, the roles and responsibilities of staff as well as structure and relationships are likely to change. There are several elements to the infrastructure, including staff, facilities, equipment, job descriptions, policies, procedures and communication systems that all need to be examined (and possibly modified) to ensure that they support the new process. A change is much more likely to be sustained if it is embedded in the organization. One of the key elements to successfully implementing and sustaining change is to have an effective strategy for communicating the intent, design, testing and implementation of the change. When people feel informed they are much more likely to support the change.

3.1.4.2 Revision of the Model

The proposed QI model was sent by email to the same 12 quality experts who participated in the semi-structured interviews. As mentioned above they were selected using a mixed purposeful sampling technique. They were selected based on their knowledge and experience in the research topic and can provide critical information about the applicability and potential effectiveness of the proposed model in Saudi hospitals.

Feedback from the quality experts was received via email and through open discussion using telephone contacts as well as modern communication technology such as Skype, IMO and LINE.

3.1.4.3 Pilot Study of the Model:

A pilot study in real-life situation was carried out before the final trial to refine and improve the proposed model. The purpose of the pilot study was to ensure that the proposed QI model is sound and methods used for applying it are sound and to work out the kinks in a study protocols before launching a main experiment. Pilot study was the mock drill, which was conducted from July 2014 to December 2014.

A one group Pre-test, Post-test design was used to carry out the pilot study. There is a single clinical indicator under observation, with a careful measurement being done before applying the proposed QI model and then measuring after. Although this design has minimal internal validity but it is appropriate to serve the purpose of the pilot study which is to refine and fine-tune the model before launching the final trial. This design can be presented in Table 3-1as follows:

Table 3-1: One group Pre-test, Post-test

Pre-test	Treatment	Post-test
O	X	O

The model was applied on a small scale to evaluate its effectiveness in improving and sustaining surgical safety in the operating room in a hospital in Tabuk Region. Administrative permission was procured formally from the Director and the Quality Improvement Council to perform the pilot study.A multidisciplinary quality improvement team was formed by the hospital. The team

included seven people chaired by the head department of surgery, the quality director as a facilitator, and a representative from surgery, operating room, anesthesia, nursing, and a senior administrator.

The team received one week training on the QI Model and tools. The training was conducted in the hospital auditorium using PowerPoint presentations, worksheets, assignments and open discussion. The team received frequent formative tests and feedback until they achieved mastery in the proposed quality improvement model. At the end, the team members were given summative test with the gap of one day after the last lecture. This test consisted of a paper pencil test and a practical (skill) test on application of the model. The findings of this training course showed promising indicators that the team would be effective in implementing the proposed model Team members were not aware that the proposed model was being tested (blind trial).

The aim of the team was to decrease the probability of wrong procedure, wrong patient, wrong site, and wrong body part surgeries in the operating room from 1.2% to 0% in three months starting July 2014 and to sustain improvements for another three months ending in December 2014.

The team used three process measures, namely: compliance rate to surgical site marking policies and procedures, compliance rate to post-operative verification checklist, and compliance rate to Surgical Safety Checklist. The outcome measure is the number of surgical events (wrong patient, wrong body part, and wrong procedure).

During the pilot study, because of time constraint the project lasted for three months and sustainability was monitored for another three months. Limitation of time constraint was taken care of at the time of final study. The experience gained

in the pilot study was used to fine-tune the proposed QI model, the research approach, the research design, learning material, and the research methodology for the present investigation.

3.2 PHASE TWO METHODOLOGY: APPLICATION OF THE QI MODEL

3.2.1 Study Design

The second phase aimed to recruit three MOH hospitals to apply the QI model in real world. It includes: selecting the hospitals, forming five QI teams, training the teams, checking the availability of resources in each hospital to ensure they were adequate to carry out the experiment and test the hypotheses.The five QI teams in each hospital will work on randomly selected five quality indicators. Each team will work independently on one quality indicator.The baseline data for each indicator will be developed in this phase.

3.2.2 Hospital Selection Process

In the second phase of this study, the researcher aimed to select a sample of MOH hospitals to carry out the experiments in real life context. The researcher contacted many quality directors across the country requesting their participation in the study. Those who showed interest were briefed about the proposed model and the work expected from them. The briefing was carried out through telephone, Skype, IMO, Line and email. Seven MOH hospitals volunteered to participate in applying the model. The selection of hospitals was based on the following criteria: 1) A Ministry of Health hospital that is easily accessible to the researcher and willing to voluntarily participate in the study; 2) Provides diversity to the study to ensure

representation of both tertiary and general hospitals as well as different provinces; and finally 3) Presence of leadership commitment and support.

Three Ministry of Health hospitals in Saudi Arabia were selected to conduct the experiments, two in Tabuk Province and one in Northern Boarder Province. Table 3-2 shows the demographic of the three hospitals. Hospital 1 (300 beds) is located in Tabuk city and has the latest state of the art medical technology and provides third levels of specialized medical care. Hospital 2 (200 beds) is located in a town and provides second level care including internal medicine, surgery, pediatrics, obstetrics and gynecology as well as some subspecialty services. Hospital 3 (110 beds) is located in Arar city and provides second level of care in internal medicine and surgery. The latest hospital does not provide pediatrics or obstetrics and gynecology services.

Table 3-2: Hospitals demographics

	location	Beds	Type	Outpatient visits	Emergency department visits	Total admissions	Total surgeries	Occup-ancy rate
H.A	City	300	Tertiary	77228	176585	12440	4727	83%
H.B	City	200	General	37637	48492	1080	5678	30%
H.C	Town	110	General	57877	51936	4072	1293	58%

*based on the hospital statistics for the year 1436

3.2.3 Formation of the Quality Improvement Teams

In each hospital, five QI teams were formed by the hospital Quality Improvement Council based on recommendations of the concerned head departments. Each team

was chartered to improve one clinical indicator from those randomly selected for the experimental group**.** The teams were formed during the period from March to May, 2015. Each team composed of a team leader and 5 team members as well as a facilitator and a sponsor. The individuals were selected based on the recommendation of the Institute for Healthcare Improvement (IHI) which recommends that every team includes at least one member who has the following roles: Clinical leadership, Technical expertise, Day-to-day leadership, Project sponsorship (IHI, 2017).

The leader coordinates and directs the work of the team and keeps it focused on their goals and desired outcomes. The facilitator serves as a coach, consultant, and improvement adviser and provides formal or just-in-time quality training as needed to foster team progress. Team members all share responsibility for the effectiveness of the team and contribute their knowledge and insights to the QI project. The QIP sponsor is a senior executive who plays a critical role in supporting the project, empowering the team, resolving barriers, providing resources, and linking the team to the organization leadership.

3.2.4 Training of the Quality Improvement Teams

These groups were considered suitable for the study because the participants had considerable knowledge and experience in the processes under study and an interest in achieving measurable improvement for their clinical indicators but had limited knowledge or experience in the process of quality improvement. However, this lack of experience in conducting quality improvement projects was an advantage because it help in evaluate of the suitability of the QI method for use by hospital staff who have limited skills in the quality improvement science.

The contribution of the quality director in each hospital was central to the application of the model bearing in mind that most QIT members had little or no experience in quality improvement projects. Luckily, the quality directors in the participating hospitals happened to have participated previously in the development and revision of the proposed QI model. They provided guidance through each of the steps of the model, helping teams to resolve difficulties which arose during the application process, and taking responsibility for administrative aspects of the process such as meeting minutes, data collectionand analysis.

Equal conditions for all QI teams in the three hospitals were established. All factors of the contents of the training program and training length in time were equated. The researcher conducted workshops to train all QI teams in the three hospitals (Table 3-3). Each workshop took five full working-days with a daily period of 4 hours. All groups were taught the same material during the month of June, 2015. The training program included the steps in the proposed QI model.

All groups were taught using lectures, workshops and open discussions. The researcher trained all groups to avoid any potential factor. The purpose of this phase of training was to maximize experiment fidelity through careful training.

Table 3-3: Training Course on the QI Model

SN	Day	Time	Topic
1	Day 1	08:00 – 09:00	Introduction to quality improvement
2		09:00 – 10:00	Critical success factors
		10:00 – 10:15	Coffee break
3		10:15 – 12:00	Healthcare quality control

4	Day 2	08:00 – 09:00	Prioritizing for improvement
5		09:00 – 10:00	Forming quality improvement teams
		10:00 – 10:15	Coffee break
6		10:15 – 12:00	Teamwork and GRPI model
7	Day 3	08:00 – 09:00	Setting aims and establishing measures
8		09:00 – 10:00	Data collection planning
		10:00 – 10:15	Coffee break
9		10:15 – 12:00	Change concepts and ideas
10	Day 4	08:00 – 09:00	Quality improvement tools
11		09:00 – 10:00	Data display and analysis
		10:00 – 10:15	Coffee break
12		10:15 – 12:00	Testing changes on small scale
13	Day 5	08:00 – 09:00	Implementing changes
14		09:00 – 10:00	Sustaining improvement
		10:00 – 10:15	Coffee break
15		10:15 – 12:00	Monitoring for sustainability

3.2.5 Resources for Application of the Model:

The concepts behind the QIPs in this research recognize that both structure (*inputs*) and activities carried out (*processes*) are addressed together to ensure or improve quality of care (*outputs/outcomes*). It is important to ensure that the available resources are relatively adequate to carry out the experiment and test the hypotheses. It is difficult at this stage to create a list of the required resources (e.g., costs, materials, personnel, equipment, etc.) because this can only be known from

the work of the QI Teams. However, the researcher met with the quality director, medical director, nursing director, and support services director to ensure that the available resources are relatively adequate for the approved quality improvement projects (QIPs). These meetings also aimed to ensure that there were no significant variations among the hospitals regarding the available resources as they are all affiliated to the Ministry of Health. Hence, there was no need to make any modifications in the design of the research to fit the available resources.

The key requirements at this stage were to give the individuals involved in the quality improvement projects (QIPs) the time, authority, material and support to carry out the following roles:

- To attend a 5-day training program on the proposed model;
- To meet weekly for 30 – 60 minutes to discuss the team progress;
- To track quality indicators and collect data from different resources;
- To test changes in small scales and implement them on large scales;
- To redesign work processes, policies, procedures, guidelines …etc.
- To incorporate change in daily routine;
- To monitor performance in order to ensure sustainability;
- To report to the Quality Council and provide feedback to all staff.

3.2.6 Pretest *(*Baseline) Data:

Prior to launching the proposed QI model, the QI teams collected six-month baseline data for each of the ten clinical indicators involved in the study from July 2015 to December 2015. The baseline data included both the experimental and control groups. Successive measurements allow an evaluation of the impact of the proposed quality improvement model and make it possible to monitor and sustain incremental improvements.

3.2.7 The Improvement Process

The teams used the proposed model as a roadmap for the improvement journey. Quality improvement tools were used to determine the system and process factors contributing to the problem under study and to identify the interventions to prevent them. The QI teams used QI tools as needed to keep steady progress towards their objectives. QI tools used by teams to understand problems and innovate interventions at both the system level and process level included: brainstorming, Affinity diagram, fishbone diagram, process mapping and run chart. PDSA cycles were used as to accelerate the change. For each change, one last PDSA cycle was run at the end of the sixth month to ensure sustainability of improvement.

3.3 THIRD PHASE METHODOLOGY: EVALUATIN OF THE QI MODEL

3.3.1 Study Design

In the Third Phase true experimental study design was used. The researcher adopted Pre-test Post-test control-group design (adopted from Watenable, et al., 1984). In each hospital 10 clinical indicators were used, five for the experimental group and five for the control group. The true experimental research approach aimed to evaluate the effect of the proposed model on a group of five randomly selected clinical indicators. This phase also included the use of a mixed method study consisting of quantitative and qualitative methods. The quantitative method consisted of a user experience survey aimed to understand the usability of the model. The qualitative method involved document review such as quality improvement teams meeting minutes and reports.

This section covers the research design and methodology used in the third phase, including sampling, population, establishing rigour during and after data collection, ethical considerations and data analysis.

Experimental research approach is a systematic, objective method of discovery with empirical evidence under rigorous control. The researcher manipulates one or more variables (independent variable/s), and controls and measures any change in other variables while controlling for the influence of confounding extraneous variables.The control is achieved by holding constant all the conditions except for the phenomenon under study for both the experimental group and the control group. Research approach and research design is the blue print of the procedures that enable the researcher to test hypotheses.

The research design helps the researcher in the selection of subjects for observation, and in determination of the type of analysis to be used for interpretation of the data. The selection of the research design depends upon the purpose of the study and the conditions under which the study is conducted.

Multiple experiments were conducted in three MOH hospitals over the period of 18 months. The first six months for forming and training QI teams and to collect baseline data, the second six months for application of the proposed model to improve randomly selected clinical indicators, and the last six months for monitoring sustainability of improvement.

The aim of the multiple experiments is to evaluate the effect of the QI model on a group of randomly selectedclinical indicators.

The researcher controlled the following:

1) controlled the assignment of subjects to experimental (treatment) and controlled groups through the use of a table of random numbers. This procedure guaranteed that all subjects had the same chance of being in the experimental or control group. Because of strict random assignment of subjects, it was assumed that the two groups were equivalent in all important dimensions and that there were no systematic differences between the two groups;

2) controlled the timing of the independent variable (treatment) and which group was exposed to it. Both groups experienced the same conditions, with the exception of the experimental group, which received the influence of the independent variable (treatment) in addition to the shared conditions of the two groups;

3) controlled all other conditions under which the experiment took place. Nothing but the intervention of the independent variable was assumed to produce the observed changes in the values of the dependent variable.

The following steps were carried out:

1) Randomly assigned subjects to treatment or control groups;

2) administered the pre-test to all subjects in both groups;

3) ensured that both groups experience the same conditions except that in addition the experimental group experiences the treatment;

4) administered the post-test to all subjects in both groups;

5) assessed the amount of change on the value of the dependent variable from the pre-test to the post-test for each group separately.

This design with reference to Best and Kahn (2003) may be represented as shown in Figure 3-9 below:

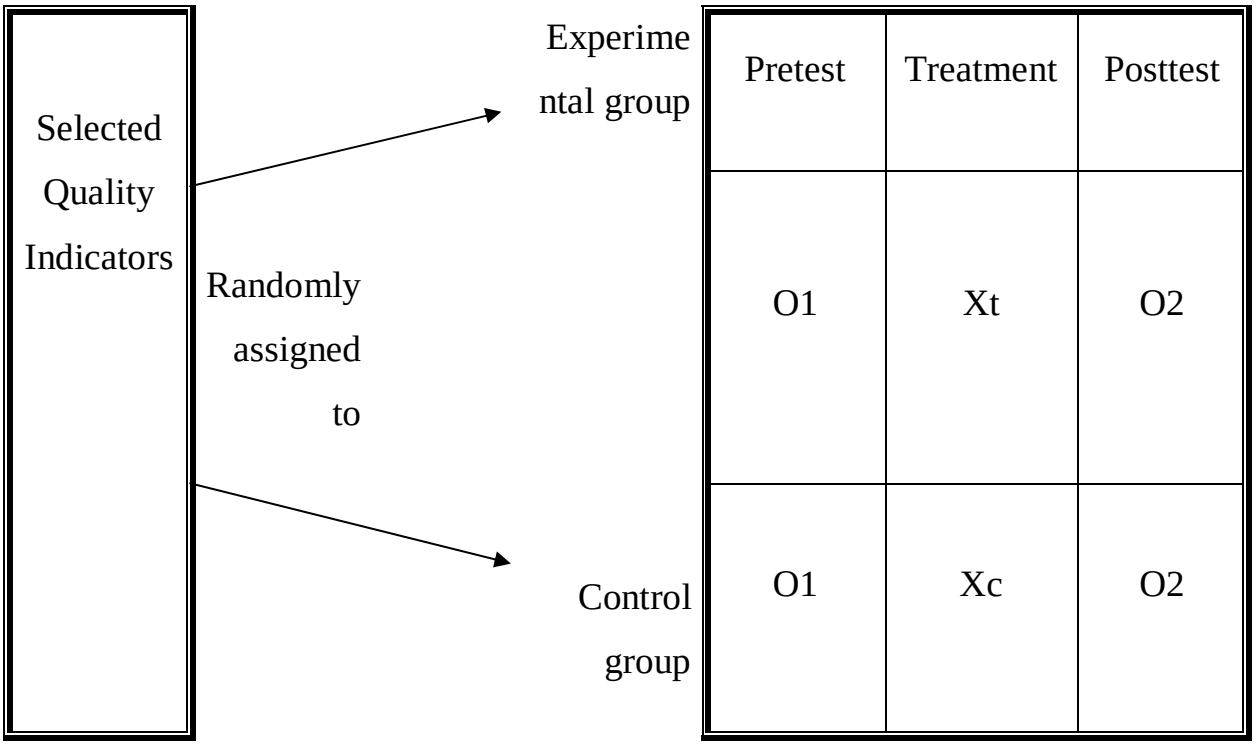

Figure 3-9: Design of Experiments

- Xt represents the treatment condition,
- Xc represents the control (non treatment) condition
- O1 represents the pretest assessment of the dependant variables
- O2 represents the posttest assessment of the dependent variables

In this design, Pre-test was administered on both the experimental and control groups before the application of the experimental treatment and post-tests at the end of the intervention period. The proposed QI model was the treatment. This diagram can be expanded as show in Table 3-4.

Table 3-4: Expanded Design of Experiments

Scientific Random Assignment of Subjects to:	1st observation (measurement) of the dependent variable O_1 = Pre-test	Exposure to the Treatment (X) (independent variable)	2nd observation (measurement) of the dependent variable O_2 = Post-test
Experimental Group	Experimental Group's average score on the dependent variable	X	Experimental Group's average score on the dependent variable
Control Group	Control Group's average score on the dependent variable	-	Control Group's average score on the dependent variable

The difference in the control group's score from the pre-test to the post-test indicates the change in the value of the dependent variable that could be expected to occur without exposure to the independent variable X.

Control group pre-test score	-	control group post-test score	=	control group difference on the dependent variable

The difference in the experimental group's score from the pre-test to the post-test indicates the change in the value of the dependent variable that could be expected to occur with exposure to the treatment variable X.

Experimental group pre-test score	-	Experimental group post-test score	=	Experimental group difference on the dependent variable

The difference between the change in the experimental group and the change in the control group is the amount of change in the value of the dependent variable that can be attributed solely to the influence of the independent variable X.

Control group difference attributable to X	-	Experimental group difference	=	difference attributable to X

There were several reasons for selecting true experimental research for data collection in this phase. Firstly, as the researcher is interested in determining cause-and-effect relationships, empirical observations from experiments provide the strongest basis for inferring causal relationships(Oskar, 2008). Secondly, in an experiment, an independent variable (the cause) is manipulated and the dependent variable (the effect) is measured; any extraneous variables are controlled (Moore and McCabe, 1993). Thirdly, experiments are objective as the views and opinions of the researcher do not affect the results of the study. This is good as it makes the data more valid, and less bias. Finally, it represents the most valid approach to the solution of quality problems, both practical and theoretical, and to the advancement of quality improvement as a science (Gay, 1992).

The Pre-test Post-test control-group design allows the researcher to control for threats to the internal and external validity of the study. Threats to internal validity compromise the researcher's ability to say whether a relationship exists between the independent and dependent variables. Threats to external validity compromise the researcher's ability to say whether this study's findings are applicable to any other groups.

3.3.2 Study Area

The experimental study was carried out in three MOH hospitals in Saudi Arabia. Two hospitals were in Tabuk Region and one was in the Northern Border. Hospital A was 300 bedded, hospitals B was 200 bedded and hospital C was 110 bedded.

3.3.3 Study Population

The aim of this phase was to evaluate the effectiveness of the proposed model on clinical outcome indicators. The entire population consists of 49 evidence-based clinical outcome indicators developed by the Saudi Ministry of Health. These indicators are uniformed in the sense that the data elements are clearly defined including the numerator and denominator as well as sources of data for each indicator. This standardization eliminates any possibility of variations in the measurement process and thus facilitates comparison between MOH hospitals. Data on these indicators are collected monthly by Clinical Audit departments in all MOH hospitals and reported periodically to the Ministry of Health.

3.3.3.1 Sampling Technique:

A sample is a portion of the population that has been selected to represent the population of interest. A sample is used in research when it is not feasible to study the whole population from which it is drawn. Sampling technique is defined as the method used in drawing samples from a population usually in such a manner that the sample will facilitate determination of some hypothesis concerning the population. The process of sampling makes it possible to accept a generalization to the intended population based on careful observation of variables, within a relatively small proportion of population. In the present investigation, the sample is drawn from the population of 49 clinical indicators developed by the Ministry of Health in Saudi Arabia. The sample was drawn using simple random sampling

technique in which each member of the population has an equal probability of being chosen. The sample is meant to be an unbiased representation of the group.

By means of a two stage randomization (Bos et al., 2008) ten clinical indicators from the population were divided into two (equivalent) groups. This was followed by randomly assigning each group of clinical indicators to the experimental group or the control group. Thus each group has randomly selected and randomly assigned clinical indicators. All clinical indicators in the two groups took a pre-test (O1) to establish the baseline data. Random selection and assignment was accomplished because each of the clinical indicators had equal chance to be selected and assigned to either the experimental group or the control group.

3.3.3.2 Sample Size

The sample size was 10 clinical indicators constituting 20.4% of the population. The relatively small sample size could be justified by the fact that QIPs require extra efforts and time from multidisciplinary teams. Moreover, it is necessary to take into consideration that applying the model is completely voluntary by the participating hospitals and therefore should be convenient and avoid creating additional burden on the hospital staff.

3.3.4 Variables of the Research

Variables are anything that can change or affect the results of a study. In an experimental method, the experiment is conducted by changing the value of one variable and measuring the changes in another variable while holding or assuming surroundings constant. The variable that is varied by the experimentalist is called an independent variable and variable that is measured is called as dependent variable. Variables that are held constant are called controlled variables and those, which are not controlled but can affect the outcome, are called extraneous

variables. In general, many variables need to be considered in any experimental study. Obviously, if the number of variables involved is more, more complex is the study. The present study is based on quality improvement process. Quality improvement is a process that includes many variables such as hospital's characteristics, improvement methodology used, QI teams' characteristics etc. In addition, these variables interact as QI teams work towards their goals and incorporate new knowledge, behaviors, and skills that add to their range of learning experiences. In the present study, the researcher identified many variables involved in the experiment. These are classified into independent variables, dependent variables, controlled variables, and extraneous variables as listed below:

3.3.4.1 Independent Variable (IV)

This is the variable that is changed to examine its effect on the dependent variables. In this study, the independent variable is the proposed model for QI.

3.3.4.2 Dependent Variables (DVs)

The dependent variable is what is affected by the independent variable. In this study the dependent variables are 10 quality indicators randomly selected from the population and randomly assigned to the experimental and control groups.

3.3.4.2.1 Experimental Group

The dependent variable is what is affected by the independent variable. The following 5 quality indicators randomly selected represent the experimental group:

1. Ventilator Associated Pneumonia (VAP)
2. Cancellation of Scheduled Elective Surgical Operations
3. Average patient waiting time in the ER till admission (except to ICU)
4. Surgical site infection (SSI) rate

5. Hospital acquired pressure ulcers

3.3.4.2.2 Control Group

The control group consists of 5 quality indicators randomly selected. These are:

1. Medication Errors
2. Central Line-Associated Blood Stream Infection (CLABSI) in Adult ICU
3. Hospital mortality rate
4. Patient falls
5. C.P.R failure rate

3.3.5 Controlled Variables (CV)

Controlled variables are factors which could affect the dependent variable but are kept constant throughout the experiment. Controlled variables are as follows:

1. QI team members.
2. Training.
3. Team charter.
4. Timeframe to achieve the goals.
5. Sponsor.
6. Facilitator.

The researcher has controlled these six variables, so that they do not have any influence on the results caused by the intervention carried during experiment. The first variable of QI members was controlled by ensuring that every team includes at least one member who has the following roles:clinical leadership, technical expertise, day-to-day leadership, and project sponsorship. The total number of members in each team was seven.

To control the second variable, namely, training, the same topics, the same training schedule, the same forms and the same work sheets were used for teaching all the groups. The third variable, team charter, was controlled by using a uniformed team charter for all groups. The fourth variable, timeframe, was controlled by giving each team the same timeframe to achieve the goals. Each team was given two months for establishing the baseline data, 6 months to complete the improvement process, and 6 months to monitor sustainability. The fifth variable, sponsor, was controlled by assigning one sponsor (the medical director) for the five teams in each hospital. The sixth variable, facilitator, was controlled by assigning one facilitator (the quality director) for the five teams in each hospital. To equate the knowledge and skills of the facilitators they received the same training on how to couch, guide and assist QI teams through the lifecycle of a QI project.

3.3.6 Controlling for Threats to Internal Validity

Internal validity refers specifically to whether an experimental treatment/condition makes a difference to the outcome or not, and whether there is sufficient evidence to substantiate the claim (Cook and Campbell, 1979; Campbell and Stanley. 1963). The degree of control exerted over potential extraneous variables determines the level of internal validity. Controlling for potentially confounding variables minimizes the potential for an alternative explanation for treatment effects and provides more confidence that effects are due to the independent variable. Eight threats to internal validity have been defined: history, maturation, testing, instrumentation, regression, selection, experimental mortality, and an interaction of threats (Slack and Draugalis, 2001; Cook and Campbell, 1979; Campbell and Stanley. 1963).

1) History: did some unanticipated event occur while the experiment was in progress and did these events affect the change in the dependent variable? No, because the history threat occurs for both groups, the difference between the two groups will not be due to the history event.

2) Maturation: were changes in the dependent variable due to normal developmental processes operating within the subject as a function of time? No, because both groups experienced the same developmental processes and changed (matured) at the same rate.

3) Statistical Regression: did subjects come from low or high performing groups? Differences between the two groups that could influence the dependent variable would be controlled for as subjects were generally equivalent at the beginning of the research.

4) Selection: were the subjects self-selected into experimental and control groups, which could affect the dependent variable? No, the subjects were randomly assigned and all had equal chance of getting the treatment or control condition.

5) Experimental Mortality: did some subjects drop out? did this affect the results? The same number of clinical indicators made it through the entire study in both the experimental and control groups, so there appeared to be no bias.

6) Testing: Did the pre-test affect the scores on the post-test? Both groups were exposed to the pre-test and so the difference between groups was not due to testing.

7) Instrumentation: Did the measurement method change during the research? The measurement method and instruments did not change.

8) Design contamination: did any of the QI teams have a reason to want to make the research succeed or fail? The researcher conducted qualitative investigation to exclude any design contamination.

3.3.7 Controlling for Threats to External Validity

External validity refers to the generalizibility of the treatment/condition outcomes across various individuals, settings, and times (Cook and Campbell, 1979; Campbell and Stanley. 1963). Cronbach (1982) stated that if the study lacks generalizability, then the so-called internally valid causal effect is useless to decision makers. In a similar vein, Briggs (2008) asserted that although statistical conclusion validity and internal validity together affirms a causal effect, construct validity and external validity are still necessary for generalizing a causal conclusion to other settings. Typically, group research employing randomization will initially possess higher external validity than will studies (e.g., case studies and single-subject experimental research) that do not use random selection/assignment (Cronbach, 1982). Campbell and Stanley (1963) have identified 4 factors that adversely affect a study's external validity.

1. Reactive or interaction effect of testing: a pretest might increase or decrease a subject's sensitivity or responsiveness to the experimental variable. Indeed, the effect of pretest to subsequent tests has been empirically substantiated (Willson & Putnam, 1982, Lana, 1959).In such situations the researcher cannot conclude that members of the population who were not pretested would perform in a similar manner to the participants in the study. Restated, to generalize the results of the study the researcher would have to specify that a particular type of pretesting also be done because the pretesting could be serving as an extra, unintentional independent variable.

2. Interaction effects of selection biases and the experimental variable: an interaction between how the subjects were selected and the treatment (e.g., the independent variable) can occur. If subjects are not randomly selected from a population, then their particular demographic/organismic characteristics may bias their performance and the study's results may not be applicable to the population or to another group that more accurately represents the characteristics of the population.Selection bias was handled by random assignment, which means participants in the different groups that are being compared are equivalent to the general population.
3. Interactive effects of experimental arrangements:it is difficult to generalize to non-experimental settings if the effect was attributable to the experimental arrangement of the research. The performance of subjects in some studies is more a product or reaction to the experimental setting (e.g., the situation where the study is conducted) than it is to the independent variable. For example, subjects who know they are participants in a study, or who are aware of being observed, etc., may react differently to the treatment than a subject who experienced the treatment but was not aware of being observed, etc. If the performance of people in an experimental group was affected (positively or negatively) by certain features of the experiment, or by the fact that it was seen by them as an experiment, findings from the experimental group may not apply to samples from the general population who will receive the intervention in a non-experimentalsetting. This is controlled through replicating the research in natural settings.

3.3.8Data Collection Methods

Different data collection methods were used in this phase to collect the empirical evidence. These methods included continuous measurement of the 10

quality indicators (5 experimental group and 5 control group), a user experience questionnaire, and analysis of documents. In the following sections, each method is explained; thereafter, the benefit of triangulating these methods is explained.

3.3.8.1 Continuous measurement of the indicators

An indicator description sheet was developed for each of the ten quality indicators including both the 5 experimental and the 5 control groups. The sheet states clearly the name of the indicator, the numerator, denominator, source of data, sampling technique, and methods of collecting and displaying data. A data collection sheet was designed for each indicator, a team member was dedicated to collect and present the data in a timely manner. The quality director assisted the QI teams in data analysis and identifying patterns and trends using Run Charts.

3.3.8.2 User Experience Questionnaire

Study questionnaires were distributed to members of the multidisciplinary QI team members in each of the three MoH hospitals. This questionnaire was a further refined version of the tool that was used in the first phase of the study, and had been modified in response to the feedback received during the previous phase, and to ensure that the tool met the requirements of this phase of the work

As the aim of this questionnaire was to understand the user experience, the data were intended to be used for descriptive and inferential purposes (Field, 2013). Based on Tshebshiev's theory, a random sample size of 30 or more participants was needed in order to carry out meaningful statistical analysis (Punch, 2013). Therefore, the second phase of the study aimed to achieve a sample of 30 respondents in each experimental study site.

3.3.8.3Document analysis

One of the qualitative tools that can aid in understanding the problem in-depth is documentation (Anderson, 2010). Documentation was used to corroborate and augment evidence from other sources and to provide some general information with regard to the studied cases. Documentation analysis was carried out using many forms, such as Quality Improvement Teams' minutes, reports and documents, implementation documents, reports, medical records, administrative records, etc. In this respect, participants were asked for any documents that were thought to be related to the adoption process of the proposed QI model in their hospitals, as long as they were not confidential (Anderson, 2010).

3.3.9 Triangulation of Methods

Maxwell (2004a; 2004b; 2012) described triangulation as the collection of empirical data by a variety of methods from a range of different individuals and settings. Yin (2008) outlined four types used to triangulate the results reported in a study: data triangulation, investigator triangulation, theory triangulation and methodological triangulation. Within this research, two approaches were used to triangulate the results: data triangulation and methodological triangulation. With regard to data triangulation, Remenyi (2005) detailed several ways to achieve this type of triangulation, such as the use of multiple data collection methods, multiple informants and cases. From one side, when qualitative data are analysed and presented in a meaningful way, it can help in examining the research issue in-depth and may obtain more powerful information than the quantitative methods (Anderson, 2010). However, the lack of objectivity may be an issue in understanding the reality (Creswell and Clark, 2007). Therefore, quantitative analysis can actually decrease a researcher's subjectivity in interpreting the reality

(Tashakkori and Teddlie, 2008). The triangulation was used in this study to enhance the researcher's understanding of the phenomena and assist the development of a robust and comprehensive quality improvement model.

3.3.10 Data Analysis

The quantitative data were entered by two different data entry operators to ensure accuracy. A similar approach was also taken in a hospital survey carried out by Jaana et al. (2012). An error list was generated to check errors. The data were then transferred into Statistical Software for Social Sciences (SPSS) for analysis. In addition to analysing each form of data separately, the analysis aimed to deepen the understanding of the findings by comparing and contrasting them, by triangulating the sources, as a way of enhancing the validity and reliability of the research (Anderson, 2010).

3.3.10.1 Qualitative analysis

Qualitative methods were used in the first and third phases. Semi-structured interviews were used in the first phase while experiments were used in the third phase. The analysis of the interview data was carried out using a thematic approach. As described previously in the literature review, there is a broad set of critical success factors or necessary conditions that need to be in place for successful implementation of quality improvement. The success or otherwise of implementation depends crucially on the interaction between the local context and the model as it is applied. It is necessary to understand the generic characteristics of Saudi hospitals that make quality improvement particularly challenging in this field, and to carefully consider local circumstances to design the model that provides the ‘best fit’ locally. This is followed by application in the local context in

a programmed and sustained way, which may include considerable adaptation of the model to suit the local circumstances.

This research adopted the following six-step guideline of Braun and Clarke (2006) for analysing the qualitative data using a thematic analysis approach:

1- *Familiarising oneself with the collected data*: the researcher needs to immerse himself in the data in different ways, such as transcribing the data, reading and re-reading the data, and noting down initial concepts.

2- *Generating initial codes*: the researcher generates as many potential codes as possible during this stage. The result should be a long list of different codes.

3- *Searching for themes*: the codes then need to be re-focused at a broader level by collating the generated and relevant codes into potential themes.

4- *Reviewing themes*: the researcher needs to refine the themes and their codes again, and examine each theme and its initial codes if they appear to form a coherent pattern. Sometimes, there is a need to develop new themes and rearrange the codes into new ones.

5- *Defining and naming themes*: once the themes have been fully reviewed, each theme must be redefined and named to reflect what aspects of the data each theme has captured. Each theme has its own story that must be fitted into the broader overall story of the results of the research.

6- *Producing the report*: once the scope for each theme is precisely described, in order to assure the validity of the analysis, the researcher starts reporting the complex story in a way that is easy for readers. The report should be also supported by sufficient evidence and quotations to enhance the reliability and validity of the themes.

3.3.10.2 Quantitative analysis

In the experimental study phase, quantitative methods were used to evaluate the effect of the proposed QI model on a group of clinical indicators. A user experience questionnaire was used to identify and understand the usability of the model from the perspective of the individuals involved in multidisciplinary QI teams in the three hospitals. Methodological triangulation was used to combine the quantitative with the qualitative methods. The analysis of the quantitative data from the questionnaire was compared and contrasted to the analysis of the qualitative data in order to give a holistic view, as well as giving a more in-depth analysis of the background to the quantitative data.

In the statistical analysis, for the quantitative data, mean and standard deviations were reported for continuous variables (e.g., age, working experience of the respondent) whereas percentages were reported for categorical variables (e.g. gender, position, level of education of the respondent, etc. (Field, 2013). The characteristics of the hospitals were also represented.

Quantitative analysis was not only used to describe the user experience from the perspectives of quality improvement team members but also to be “another eye” in understanding it (Field, 2013). Therefore, descriptive statistics, such as mean, mode, average and standard deviation, were used since the qualitative analysis “looks at X in terms of how X varies in different circumstances rather than how big is X or how many X are there” (Anderson, 2010). Therefore, the use of quantitative analysis in this study was more rigorous and focuses on inferential and differential analysis such as ANOVA, multiple regression and non-parametric mean comparison tests (Punch, 2013; Field, 2013).

On the one hand, non-parametric mean comparison tests were used to measure the significant differences between cases while, on the other, multiple regression and ANOVA were used to test the relationship between concepts that emerge from the cross-sectional qualitative analysis (Punch, 2013).

Chapter Four

RESULTS & ANALYSIS

4.1 RESULTS OF PHASE ONE STUDY

4.1.1: Results of the Pilot Study of the Questionnaire

4.1.1.1: Quality Improvement Models Used in the Pilot Study Hospitals

As shown in Table 4-1, 80% of the hospitals use FOCUS PDCA as an approach to quality improvement, while only 20% use TQM. Other models such as lean Thinking, Six sigma or Business Process Reengineering were not used in any of the five hospitals involved in the pilot study.

Table 4-1: The QI Approaches used in selected hospitals of KSA in the questionnaire development sub-phase

Hosp. No.	**Bed capacity**	**Employees**	**Quality Improvement Approach**	**QI Staff**
1	1000	5000	FOCUS-PDCA	7
2	500	2200	FOCUS-PDCA	4
3	300	1700	FOCUS-PDCA	3
4	200	1200	FOCUS-PDCA	2
5	100	800	Total Quality Management	2

4.1.1.2 The Level of QI Implementation in the Pilot Study Hospitals

As shown in Table 4-2, the average score on a 5-Likert scale is 2.57 which reflects significantly low QI implementation in the five hospitals.

Table 4-2: The QI Implementation in the pilot study hospitals of KSA in the questionnaire development sub-phase

Category	**Strongly agree (5)**	**Agree (4)**	**Neutral (3)**	**Disagree (2)**	**Strongly disagree (1)**
Leadership	2	2	1	0	0
Information and analysis	0	1	0	4	0
Strategic planning	0	1	0	2	2
Human resources utilization	0	1	0	2	2
Quality management	0	1	0	3	1
Quality results	0	1	0	3	1
Customer satisfaction	1	1	0	3	0

4.1.2 Results of the Questionnaire

4.1.2.1 Demographic Characteristics of Participants

General characteristics of the participants are shown in table 4-3. Out of 43 participants 34 (79.07%) were males, and 9 (20.93%) were females. Regarding the age 13 (30.23%) participants were found to be 40 to 49 years old, while 30 (69.77%) were above 50 years old. Those with bachelor degree were 13 (30.23%) while participants with post graduate degrees were 30 (69.77%). The majority were Physicians 29 (67.44%), while administrators were only 14 (32.56%). The work experience was more than 10 years for all the participants 43 (100.00%).

The predictor variable in this study was the QI implementation measured by 50 questions from question 1 to 50 each question has score on 5-Likert scale with the following values: strongly disagree (1), disagree (2), neither (3), agree (4), and strongly agree (5), with a total score ranging from 50 to 250. The participant agrees on a given statement when the mean is (3.5) or more. A mean below this value, indicates a negative response. Mean ± SD for QI implementation score for different variables was reported.

Table 4-3: Demographic characteristics (n=43)

Characteristics	N (%)
Gender	
Males	34 (79.07%)
Females	09 (20.93%)
Age	
40-49 years	13 (30.23%)
≥ 50 years	30 (69.77%)
Education	
Bachelor	13 (30.23%)
Master/Doctorate	30 (69.77%)
Staff position	
Physician/dentist	29 (67.44%)
Administrator	14 (32.56%)
Experience	
More than 10 years	43 (100.00%)

4.1.2.2 Impact of the Demographic Characteristicsof Participants on Quality Improvement Implementation

As shown in Table 4-4, the t-test for two independent variables revealed no significant relationship between the demographic characteristics of respondents and the level of quality improvement implementation (p-value >0.05). This means the gender, age groups, education level, staff position are not determinant factors of QI implementation in Saudi hospitals. However, as shown in table 3, we found that information and analysis was significantly associated with age group (p-value 0. 010), education level (p-value 0.010), and staff position (p-value 0.005).

Table 4-4: The relationship between the level of QI implementation and the demographic characteristics of participants

Variables	Characteristic	Mean ± SD	t-test	p-value
Information & Analysis	Male	16.79 ± 4.25	0.222	0.826
	Female	16.44 ± 4.03		
	Bachelor	19.15 ± 4.30	2.709	0.010
	Master/Doctorate	15.67 ± 3.69		
	Physician	15.51 ± 3.80	2.98	0.005
	Administrator	19.21 ± 3.87		
	40 to 49 years	19.15 ± 4.30	2.709	0.010
	50 years or more	15.67 ± 3.69		

4.1.2.3 Degree of QI implementation In Saudi Hospitals

One Sample t-test was used to compare the sample mean to a hypothesized population mean to determine whether the two means are significantly different. As shown in Table 4-5, the general level of QI implementation in Saudi hospitals was significantly low across the seven dimentions with p-value <0.05.

Table 4-5: QI Implementation Scores using Malcolm BaIdridge National Quality Award Criteria (MBNQAC)

Varibles	Sample size	Median	Mean	SD	t-test	FD	p-value
Leadership (10)	43	30	27.954	5.6986	-2.355-	42	0.023
Information & Analysis (7)	43	21	16.721	4.1595	-6.746-	42	0.000
Strategic Quality Planning (6)	43	18	15.233	4.4499	-4.078-	42	0.000
Human Resource Utilization (8)	43	24	20.698	5.4752	-3.955-	42	0.000
Quality Management (7)	43	21	19.256	5.8395	-1.959-	42	0.050
Quality Results (5)	43	15	14.163	3.7604	-1.460-	42	0.000
Customer Satisfaction (7)	43	21	14.744	4.8555	-8.449-	42	0.000

4.1.2.4 Correlation betweenthe Dimensions of QI Implementation

As shown in Table 4-6, Pearson's correlation coefficient revealed the association between the dimensions of QI implementation. Leadership has direct

positive association with all the dimensions except with Information and Analysis and Strategic Quality Planning (p-value = 0.01).Indeed, the result shows clearly the critical role of leadership as a key driver to the implementation of all QI dimensions.

There is no coorelation between Information and Analysis and the other dimensions except with Strategic Quality Planning (p-value =0.01).This means that, strategic quality planning depends largely on a good information management system.Saudi hospitals that have the greatest emphasis on data collection, analysis and use achieve a higher score in QI.

The test revealed direct positive association between Strategic Quality Planning and all the other dimension of QI implementation except Customer Satisfaction (p-value =0.01).

There is direct positive association between Human Resources and Quality Management, Quality Results and Customer Satisfaction (p-value =0.01). Indeed, this shows the importance of human resources utilization in achieving the desired quality results and ensuring customer satisfaction.

Quality Management is positively associated with Quality Results and Customer Satisfaction (p-value =0.01). This means good quality management accompanied by proper utilization of human resources is the key success factor for fruitful quality improvement efforts in Saudi hospitals.

Quality Results is positively associated with Customer Satisfaction (p-value =0.01). Indeed, all quality improvement activites aim to provide quality and safe care that meet or exceed patients' needs and expectations. Customer satisfaction is a critical indicator that the QI initiative is successful in producing good results.

Table 4-6: The relationship between Leadership and the other dimensions of QI

	LD	I&A	SQP	HRU	QM	QR	CS
Leadership (LD)		0.049	0.252	[0.544]**	[0.679]**	[0.469]**	[0.473]**
Information & Analysis (I&A)			[0.718]**	0.229	0.053	0.257	0.074
Strategic Quality Planning(SQP)				[0.558]**	[0.412]**	[0.474]**	0.254
Human Resource Utilization (HRU)					[0.896]**	[0.472]**	[0.712]**
Quality Management (QM)						[0.384]*	[0.707]**
Quality Results (QR)							[0.365]*
Customer Satisfaction (CS)							

* p-value = 0.50

** p-value = 0.01

4.1.3 Result of the Interviews

Twelve individual interviews were carried out with quality experts in different Saudi hospitals, all of whom were seniors with average age of 48 years

and more than 18 years of experience. Each interview took an average of 55 minutes. Besides face-to-face, the interviews were carried out using modern communication technologies such as Skype, IMO, and LINE.

4.1.3.1 Organizational factors underpinning QI and sustainability in hospitals in Saudi Arabia

Thematic analysis revealed that participants have identified four themes and 43 sub-themes as critical success factors for quality improvement and sustainability in Saudi hospitals, as illustrated in Table 4-7. Success factors included: Culture, Human Resources Management, Processes and Systems, and Structure.

Table 4-7: Organizational Factors underpinning QI and sustainability

Themes	Sub-Themes
Organizational Culture	1. Assess the organization's current culture 2. Secure leadership commitment to QI 3. Develop a sense of the need for change 4. Establish supportive organizational structures (e.g., Quality Council) 5. Assign a change team of powerful employees 6. Align QI with the organizational strategic objectives 7. Commit to achieving the QI goals and objectives 8. Build strong belief that QI benefits staff, patients, and the organization 9. Form and train Quality Improvement teams 10. Focus on employees and process improvement 11. Ensure safe environment that encourage staff to report errors without fear

	12. Ensure involvement and participation of all employees in QI activates 13. Establish multi-disciplinary teams to manage and coordinate patient care 14. Respect, engage and empower physicians and nurses to take lead of QI teams 15. Carry out regular culture gap analysis 16. Continually identify and remove barriers 17. Tackle resistance to change 18. Report regularly quality dashboards and scorecards to management and Board 19. Make the changes show in day-to-day work and seen at all levels 20. Celebrate QI successes
Human Resources Management	21. Develop staff skills in data management 22. Develop staff skills in data retrieval 23. Emphasize QI in new employee orientation and regular staff meetings 24. Establish QI training and activities as part of the daily responsibilities 25. Provide opportunities for continuing education and professional advancement 26. Keep vacancy rates low

Processes and systems	27. Select key performance indicators 28. Dedicate qualified staff to manage data 29. Monitor the performance of care givers 30. Compare indicators with benchmarks 31. Communicate performance data 32. Set the direction for the QI program 33. Form multidisciplinary QI teams 34. Use a systematic QI method and QI tools 35. Use Plan-Do-Study-Act (PDSA) to test change 36. Use QI professionals to facilitate change
Structure	37. Invest in advanced medical technology 38. Invest in Information Technology 39. Invest in qualified QI professionals 40. Develop and implement effective management plans 41. Develop and implement evidence-based policies, procedures, guidelines, and protocols 42. Participate in accreditation systems 43. Provide ease of access to important sources for standards and best practice

4.1.3.2Quality improvement methodologies that are widely used in healthcare improvement in Saudi MOH hospitals

The interviews with quality leaders revealed that three methodologies are the most widely used approaches for improving healthcare quality in the MOH hospitals in

Saudi Arabia (as illustrated in figure 4-1). These are FOCUS-PDCA, the IHI Model for Improvement (MFI) and Total Quality Management (TQM). The results showed that (75%) of hospitals use FOCUS-PDCA, (17%) use the IHI Model for Improvement, and only (8%) use TQM.

All participants agreed that Lean Thinking, Six Sigma and Business Process Reengineering are not used in any MOH hospital at least at the organizational level. However, it is agreed that Saudi hospitals tend to use concepts, ideas and tools from different quality improvement approaches and they seldom adhere to one particular model.

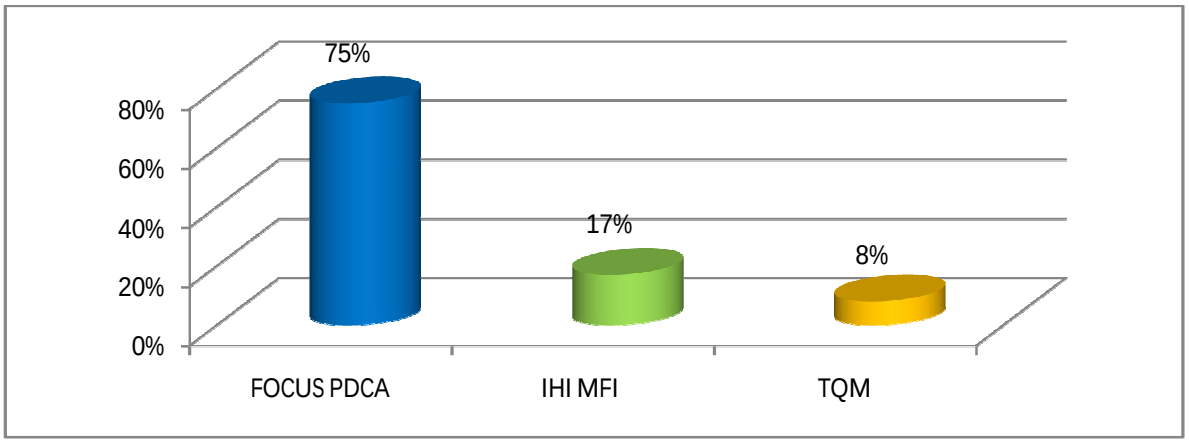

Figure 4-1: The most popular QI approaches in Saudi hospitals

4.1.3.3The most commonly used QI tools in Saudi hospitals

There are several tools and techniques used to support quality improvement in hospitals. Each improvement tool is linked to the improvement journey which provides a structured process to help individuals and teams consider the key aspects of testing and implementing change. Many of these tools and techniques were provided by the key improvement models such as TQM, Lean Thinking and Six Sigma. The interviewees named 10 QI tools as the most effective techniques in Saudi hospitals. Figure 4-2 illustrates these ten tools.

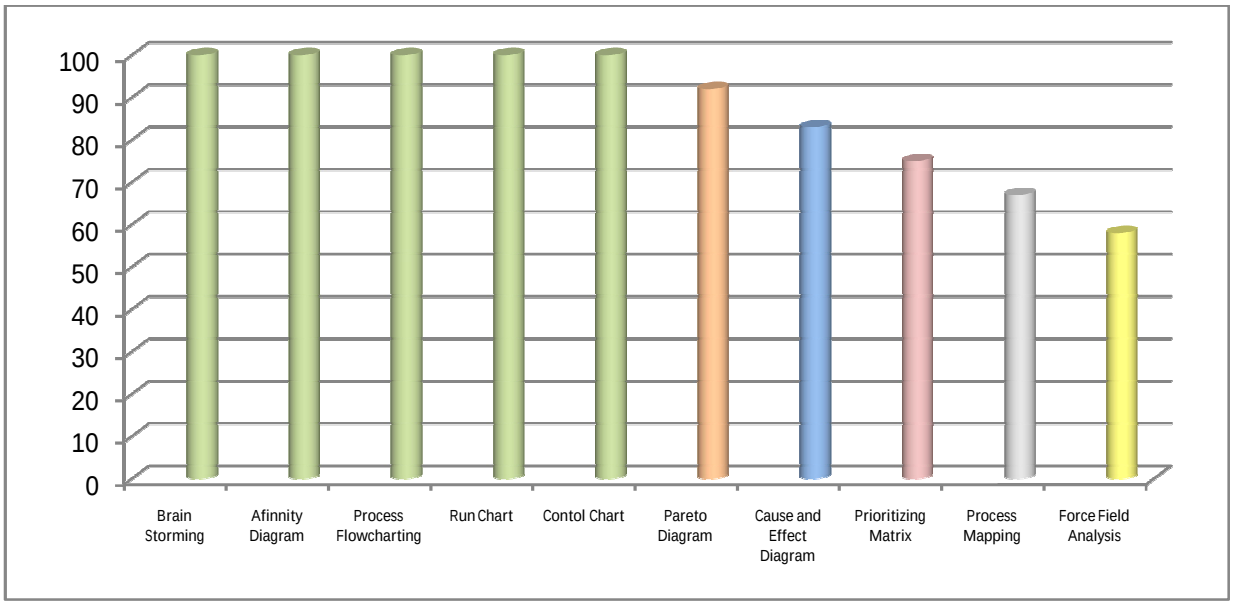

Figure 4-2: The most effective and commonly used QI tools in Saudi hospitals

4.1.4 Result of the Pilot Study of the Model

4.1.4.1 Pretest Data

As shown in table (4-8), the team collected baseline data for each indicator as a monthly average rate of the previous six months period (July, 2014 toDecember, 2014) and the targeted rate for each indicator at the end of the quality improvement project.

Table 4-8: The baseline rates, the targeted rates, and type of indicator

Process/Outcome Indicator	Baseline	Targeted	Type
Compliance to surgical site marking	0%	100%	Process
Compliance to post-operative verification checklist	45%	100%	Process
Compliance to Surgical Safety Checklist	0%	100%	Process
Surgical events (average of six months)	1.2%	0%	Outcome

4.1.4.2 Compliance to Surgical Site Marking

Figure 4-3 shows the compliance rate to surgical site marking increased gradually from 0% to 100% on the third months after five successive PDSA cycles. There was resistance from surgeons to adopt the process. However, through change concepts proposed in the model and several PDSA cycles the team managed to change the attitude of surgeons. The graph also shows that the improvement was sustained for three months after intervention

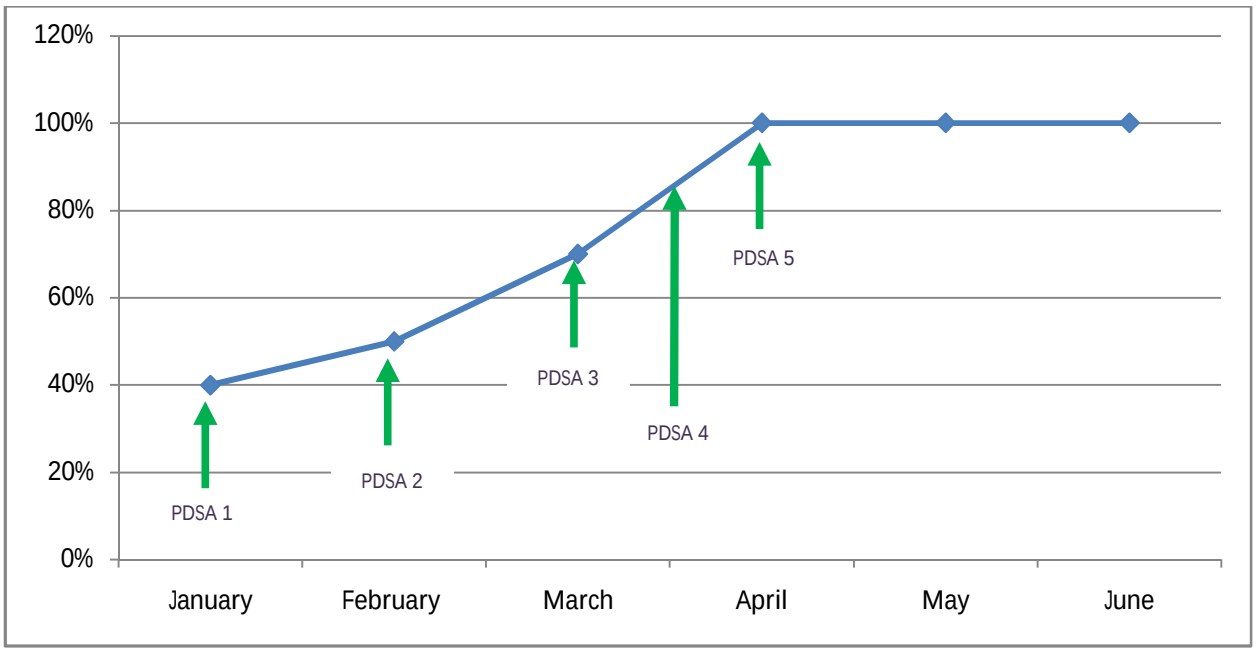

Figure 4-3: Compliance to surgical site marking

4.1.4.3 Compliance to Preoperative Verification Checklist

As shown in Figure 4-4, the team used four PDSA cycles to increase the compliance rate to the preoperative verification checklist from 35% to 100%. Unlike the marking process which was introduced for the first time and faced great resistance, the verification process went smoothly as it is an established procedure and was used for many years in the hospital.

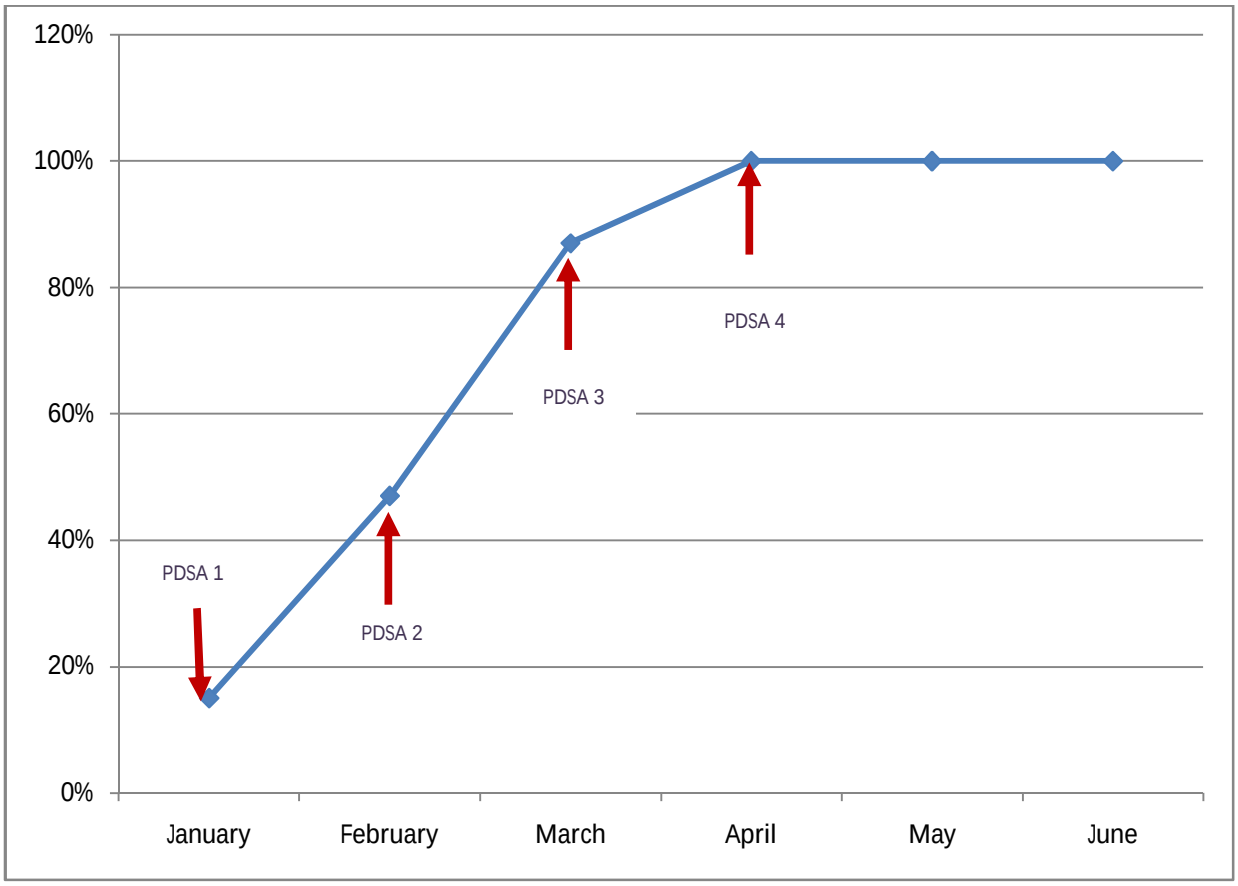

Figure 4-4: Compliance to the preoperative verification checklist

4.1.4.4 Compliance to Surgical Safety Checklist

As shown in Figure 4-5, the surgical safety checklist was introduced for the first time in the hospital. The QI team had to increase the rate from 0% to 100% in three months.

The task was a very challenging and the team was faced with unexpected extreme resistance from surgeons to adopt the change. The QI team used six PDSA cycles and it took four months instead of the planned three months to achieve the goal.

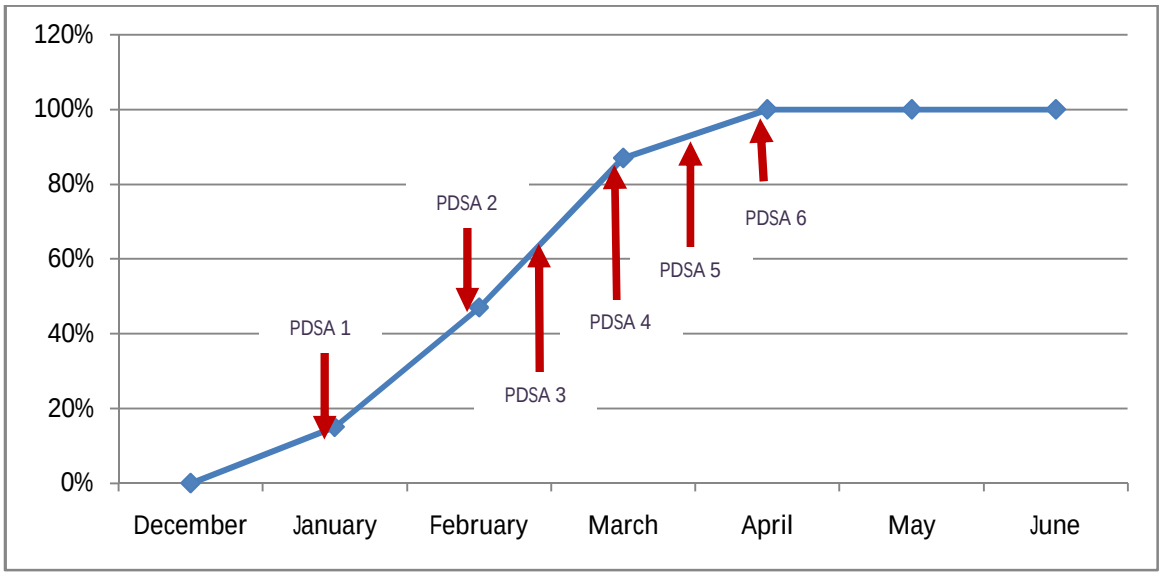

Figure 4-5: Compliance to surgical safety checklist

4.1.4.5 Number of Surgical Events

Figure 4-6 shows the number of surgical events (near misses) during the six month of the intervention. The team took four months to successfully bring the number of surgical events to zero and to sustain improvement for two months.

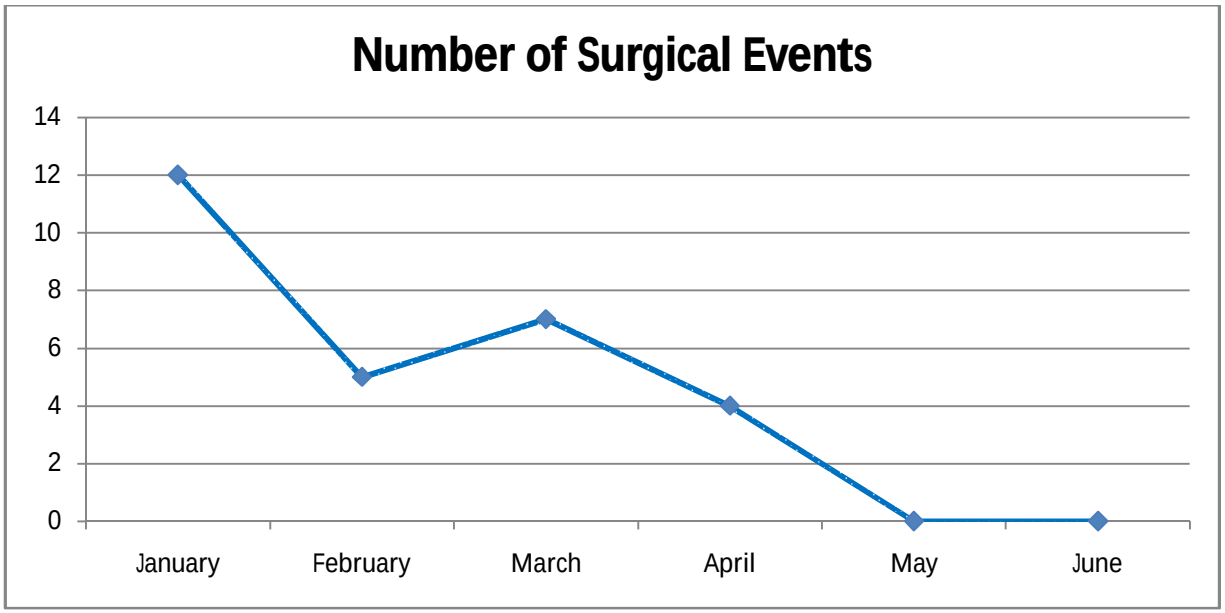

Figure 4-6: Number of surgical events for six months

4.2 RESULTS OF PHASE TWO STUDY

4.2.1 Pretest Data for Hospital A

Table 4-9 shows the Pretest (Baseline) data for hospital A. Data was calculated for each of the experimental and control groups as monthly average percentages for six months from January to June, 2015.

Table 4-9: The Pretest data (baseline) for Hospital A

SN	Clinical Indicator	Group	Percentage
1	Medication Errors per 100 prescriptions	Control	8.9%
2	Central Line-Associated Blood Stream Infection (CLABSI) in Adult ICU	Control	9.2%
3	Hospital mortality rate	Control	4%
4	Patient falls	Control	3.5%
5	Cardiopulmonary Resuscitation (CPR) failure rate	Control	87%
6	Ventilator Associated Pneumonia (VAP)	Experimental	0.8%
7	Cancellation of Scheduled Elective Surgical Operations	Experimental	43.8%
8	Percentage of patients waiting more than one hour in the ER till admission (except to ICU)	Experimental	100%
9	Surgical site infection (SSI) rate	Experimental	4%
10	Hospital acquired pressure ulcers	Experimental	5.1%

4.2.2 Pretest Data for Hospital B

Table 4-10 shows the Pretest (Baseline) data for hospital B. Data was calculated for each of the experimental and control groups as monthly average percentages for six months from January to June, 2015.

*Table 4-10: The Pretest data (baseline) for Hospital B**

SN	Clinical Indicator	Group	Percentage
1	Medication Errors per 100 prescriptions	Control	5.3%
2	Central Line-Associated Blood Stream Infection (CLABSI) in Adult ICU	Control	1.7%
3	Hospital mortality rate	Control	1.9%
4	Patient falls	Control	1%
5	Cardiopulmonary Resuscitation (CPR) failure rate	Control	88.2%
6	Ventilator Associated Pneumonia (VAP)	Experimental	0.5%
7	Cancellation of Scheduled Elective Surgical Operations	Experimental	18.2%
8	Percentage of patients waiting more than one hour in the ER till admission (except to ICU)	Experimental	78.6%
9	Surgical site infection (SSI) rate	Experimental	1.4%
10	Hospital acquired pressure ulcers	Experimental	2.9%

4.2.3 Pretest Data for Hospital C

Table 4-11 shows the Pretest (Baseline) data for hospital C. Data was calculated for each of the experimental and control groups as monthly average percentages for six months from January to June, 2015.

*Table 4-11: The Pretest data (baseline) for Hospital C**

SN	Clinical Indicator	Group	Percentage
1	Medication Errors per 100 prescriptions	Control	0.9%
2	Central Line-Associated Blood Stream Infection (CLABSI) in Adult ICU	Control	11.5%
3	Hospital mortality rate	Control	2.2%
4	Patient falls	Control	0.4%
5	Cardiopulmonary Resuscitation (CPR) failure rate	Control	82.8%
6	Ventilator Associated Pneumonia (VAP)	Experimental	0.3%
7	Cancellation of Scheduled Elective Surgical Operations	Experimental	7.2%
8	Percentage of patients waiting more than one hour in the ER till admission (except to ICU)	Experimental	90.2%
9	Surgical site infection (SSI) rate	Experimental	1.9%
10	Hospital acquired pressure ulcers	Experimental	0.9%

4.2.4 Pretest Data for the Three Hospitals

Table 4-12 shows the Pretest (Baseline) data for the three hospitals. Data was calculated for each of the experimental and control groups as monthly average percentages for six months from January to June, 2015.

Table 4-12: The pretest data (baseline) for the participating hospitals

SN	Clinical Indicator	Group	Hosp. A	Hosp. B	Hosp. C
1	Medication Errors per 100 prescriptions	Control	8.9%	5.3%	0.9%
2	Central Line-Associated Blood Stream Infection (CLABSI) in	Control	9.2%	1.7%	11.5%
3	Hospital mortality rate	Control	4%	1.9%	2.2%
4	Patient falls	Control	3.5%	1%	0.4%
5	Cardiopulmonary Resuscitation (CPR) failure rate	Control	87%	88.2%	82.8%
6	Ventilator Associated Pneumonia (VAP)	Experimental	0.8%	0.5%	0.3%
7	Cancellation of Scheduled Elective Surgical Operations	Experimental	43.8%	18.2%	7.2%
8	Percentage of patients waiting more than one hour in the ER till admission (except to ICU)	Experimental	100%	78.6%	90.2%
9	Surgical site infection (SSI) rate	Experimental	4%	1.4%	1.9%
10	Hospital acquired pressure ulcers	Experimental	5.1%	2.9%	0.9%

4.3 RESUTLS OF THE PHASE THREE

The experiment was performed in the three hospitals simultaneously during a period of 12 months from July 2015 to June 2016. During the first six months (July to December, 2015), the proposed model was applied to improve the five selected clinical indicators in the experimental group, while the second six months (January to June, 2016) were used to monitor sustainably of the improvements. To facilitate comparison during and after the intervention, all clinical indicators were measured as percentages and calculated as averages of six months period.

4.3.1 Results of Hospital A

4.3.1.1 Pretest

The t-test for two independent samples was conducted to understand the difference in pretest measures between the control group and the experimental group in Hospital A. As shown in Table 4-13, the test showed no differences in the pretest measures between the two groups (p-value = 0.821).

Table 4-13: Differences in pretest measures between the control group and the experimental group in Hospital A

Variable	Comparison Groups	Mean ± SD	t-test	p-value
Clinical Indicators	Control Group	22.52 ± 36.14	0.241	0.821
	Experimental Group	29.72 ± 43.36		

4.3.1.2 Posttest

Paired t-test for two connected samples was run to understand the difference between pretest and posttest measures for the control group and the experimental

group in Hospital One. The test revealed significant differences between the pretest and posttest in the experimental group while showed no changes in the control group (Table 4-14). This means that, the application of the proposed model has led to significant improvements in the experimental group (p-value = 0.035).

Table 4-14: Differences between pretest and posttest measures for the control group and the experimental group in Hospital A

Variable	Comparison Groups	Mean ± SD	t-test	p-value
Clinical Indicators	Control Group	22.64 ± 36.08	2.551	0.035
	Experimental Group	11.10 ± 36.08		

4.3.1.3 Sustainability

The t-test for two independent samples was conducted to uncover the difference in posttest measures in the experimental group after sixth months in Hospital A. The test revealed no difference between the posttest measurements and the measurements after six months of the intervention (see Table 4-15). This means that, the improvement attributed to the proposed model has been sustained for six months after the intervention.

Table 4-15: Differences in posttest measures in the experimental group after sixth months of intervention in Hospital A

Variable	Comparison Groups	Mean ± SD	t-test	p-value
Clinical Indicators	Experimental Group	19.92 ± 11.34	1.738	0.157
	Measures after six months	24.74 ± 15.28		

4.3.2 Results of Hospital B

4.3.2.1 Pretest

The t-test for two independent samples was conducted to understand the difference in pretest measures between the control group and the experimental group in Hospital B. As explained in Table 4-16, the test showed no differences in the pretest measures between the control group and the experimental group(p-value = 0.980).

Table 4-16: Differences in pretest measures between the control group and the experimental group in Hospital B

Variable	Comparison Groups	Mean ± SD	t-test	p-value
Clinical Indicators	Control Group	19.62 ± 38.37	.027	0.980
	Experimental Group	20.32 ± 33.37		

4.3.2.2 Posttest

Paired t-test for two connected samples was run to understand the difference between pretest and posttest measures for the control group and the experimental group in Hospital B. As shown in Table 4-17, the test revealed significant differences between the pretest and posttest measurementsin the experimental group while it did not show any changes in the control group. This means that, the application of the proposed model has led to significant improvements in the experimental group (p-value = 0.004).

Table 4-17: Differences between pretest and posttest measures for the control group and the experimental group in Hospital B

Variable	Comparison Groups	Mean ± SD	t-test	p-value
Clinical Indicators	Control Group	19.68± 38.45	15.46	0.004
	Experimental Group	7.520 ± 15.46		

4.3.2.3 Sustainability

The t-test for two independent samples was conducted to uncover the difference in posttest measures in the experimental group after sixth months in Hospital B. As shown in Table 4-18, the test revealed no difference between the posttest measurements and the measurements after six months of the intervention (p-value = 0.704). This means that, the improvement attributed to the proposed model has been sustained for six months after the intervention.

Table 4-18: Differences in posttest measures in the experimental group after sixth months of intervention in Hospital B

Variable	Comparison Groups	Mean ± SD	t-test	p-value
Clinical Indicators	Experimental Group	7.52 ± 15.46	0.408	0.704
	Measures after six months	7.54 ± 15.56		

4.3.3 Results of Hospital C

4.3.3.1 Pretest

The t-test for two independent samples was conducted to understand the difference in pretest measures between the control group and the experimental group in Hospital C. As explained in Table 4-19, the test showed no differences in the pretest measures between the control group and the experimental group (p-value = 0.985)**.**

Table 4-19: Differences in pretest measures between the control group and the experimental group in Hospital C

Variable	Comparison Groups	Mean ± SD	t-test	p-value
Clinical Indicators	Control Group	19.56 ± 35.64	.020	0.985
	Experimental Group	20.10 ± 39.28		

4.3.3.2 Posttest

Paired t-test for two connected samples was done to understand the difference between pretest and posttest measures for the control group and the experimental group in Hospital C. As explained in Table 4-20, the test revealed significant differences between the pretest and posttest measurementsin the experimental group while it did not show any changes in the control group (p-value = 0.006). This means that, the application of the proposed model has led to significant improvements in the experimental group.

Table 4-20: Differences between pretest and posttest measures for the control group and the experimental group in Hospital C

Variable	Comparison Groups	Mean ± SD	t-test	p-value
Clinical Indicators	Control Group	19.50 ± 35.55	4.57	0.006
	Experimental Group	8.24 ± 17.54		

4.3.3.3 Sustainability

The t-test for two independent samples was conducted to uncover the difference in posttest measures in the experimental group after sixth months in Hospital C. As shown in Table 4-21, the test revealed no difference between the posttest measurements and the measurements after six months of the intervention (p-value = 0.804). This means that, the improvement attributed to the proposed model has been sustained for six months after the intervention.

Table 4-21: Differences in posttest measures in the experimental group after sixth months of intervention in Hospital C

Variable	Comparison Groups	Mean ± SD	t-test	p-value
Clinical Indicators	Experimental Group	8.24 ± 17.54	0.508	0.804
	Measures after six months	8.26 ± 17.64		

4.3.4 Results of User Experience

4.3.4.1 User perception toward the proposed model

The t-test for one group was conducted to understand the user experience in the three hospitals. As explained in Table 10, the test showed that participants generally have significantly positive perceptions about the QI model. This means that members of the QI teams who used the proposed QI model are satisfied with the comprehensiveness of the model, ease to learn and use applicability in the local circumstances, fulfilling the needs of users, ability to produce sustained measurable improvements in quality, and enhancing their knowledge and experience in the quality improvement science. It also means that, they have a positive attitude towards recommending the model to other departments and hospitals. In general, as illustrated in Table 4-22, there was a significantly positive attitude toward the model among respondents (p-value = 0.000). Indeed, this evidence supports the claim that, the model fits the local circumstances in Saudi hospitals.

Table 4-22: User perception toward the proposed model

Variable	Sample size	Mean ± SD	t-test	p-value
User Experience	79	48.52 ± 3.39	11.85	0.000

4.3.4.2 Differences in user experience between hospitals

One-Way ANOVA test was conducted to determine the differences in user experience between the three hospitals. As illustrated in table 4-23, although there was a general positive attitude toward the proposed model, the ANOVA test

showed significant variation between the perceptions of respondents in the three hospitals (F-value = 6.210; p-value =0.003). This variance in responses reflects the impact of the local circumstanced in each hospital on the successful application of the model. It showed that, the success or otherwise of implementation depends crucially on the interaction between the local context and the model as it is applied.

Table 4-23: Variations in user experience between hospitals

Variable	Source of Variation	Total groups	df	Mean	F-value	p-value
User Experience Survey	Between groups	125.814	2	62.907	6.210	0.003
	Among groups	769.908	76	10.130		
	Total	895.722	78			

4.3.4.3 Smallest significant differences between hospitals

As the Analysis of Variance (ANOVA) test showed significant results, Fisher's Least Significant Difference (LSD) test was run to determine the smallest significant differences between the hospitals. The LSD enables direct comparisons between two means from two individual groups. Any difference larger than the LSD is considered a significant result. As shown in Table 4-24, the LSD showed that the respondents in Hospital B (200 beds) had a significantly higher positive experience with the proposed model than that of Hospital A (300 beds).

It also revealed that the respondents in Hospital C (100 beds) had a significantly higher positive experience with the proposed model than that of Hospital B. Again,

this variation shows the effect of the local context in the successful implementation of the model. The results also show that the model works better in smaller hospital compared to larger hospitals. This could be due to the relative ease of building a quality culture and managing change in small hospitals.

Table 4-24: The smallest significant differences between hospitals

Variable	Hospitals	**Mean difference**	**Std. error**	**p-value**
User Experience	Hospital C	2.20610	0.58757	0.000
	Hospital B	1.88306	0.61142	0.002
	Hospital B	2.20610	0.58757	0.000
	Hospital A	1.88306	0.61142	0.002

4.3.4.4 The Impact of Gender on User Experience

Two-Sample t-test for two unequal sample sizes was conducted to know the differences in user experience between males and females. The test revealed no significant impact of gender in user experience (p-value = 0.658)as illustrated in Table 4-25,.

Table 4-25: The impact of gender on user experience

Variable	Gender	Sample size	Mean ± SD	t-test	p-value
User Experience	Male	38	48.34 ± 2.91	0.444	0.658
	Female	41	48.68 ± 3.81		

4.3.4.5 The Impact of Age on User Experience

One-Way ANOVA test was conducted to determine the impact of the age in the user experience. As shown in Table 4-26, the test revealed no significant impact of age on the user experience (p-value = 0.850).

Table 4-26: Impact of Age on User Experience

Variable	Source of variation	Total groups	df	Mean	F-value	p-value
User Experience Survey	Between groups	9.424	3	3.141	0.266	0.850
	Among groups	886.298	75	11.817		
	Total	895.722	78			

4.3.4.6 The Impact of the Work Experience on the User Experience

One-Way ANOVA test was conducted to determine the impact of work experience in the user experience. As illustrated in Table 4-27, the test revealed no significant impact of the work experience on the user experience (p-value = 0.917).

Table 4-27: Impact of Work Experience on User Experience

Variable	Source of variation	Total groups	df	Mean	F-value	p-value
User Experience Survey	Between groups	2.048	2	1.024	0.087	0.917
	Among groups	893.674	76	11.759		
	Total	895.722	78			

4.3.4.7 The Impact of Education Level on User Experience

Two-Sample t-test for two unequal sample sizes was conducted to know the differences in user experience between respondents with bachelor degrees and those with postgraduate ones. As illustrated in Table 4-28, the test revealed no significant impact of the education level in the user experience (p-value = 0.594).

Table 4-28: Impact of the Education Level on the User Experience

Variable	Edu. level	Sample size	Mean ± SD	t-test	p-value
User Experience	Bachelor	55	48.65 ± 3.54	0.536	0.594
	Postgraduate	24	48.21 ± 3.05		

4.3.4.8 The Impact of Staff Position on User Experience

One-Way ANOVA test was conducted to determine the impact of the staff position on the user experience. As shown in Table 4-29, the test revealed no significant impact of the staff position on the user experience (p-value = 0.226).

Table 4-29: Impact of the Staff Position on the User Experience

Variable	Source of Variation	Total groups	Df	Mean	F-value	p-value
User Experience Survey	Between groups	50.115	3	16.705	1.482	0.226
	Among groups	845.606	75	11.275		
	Total	895.722	78			

CHAPTER FIVE

DISCUSSION, CONCLUSION AND RECOMMENATIONS

5.1 Discussion

The challenges that face the Saudi healthcare system have been the driving force behind the research presented in the thesis. Despite many years of use of various quality improvement models within the Saudi care system, healthcare services are still in need of improvement pertaining to safety, timeliness, effectiveness, and efficiency. As is evident from empirical research, healthcare systems are particularly complex. Added to this complexity, the Saudi healthcare system involves healthcare professionals who have different backgrounds, educational qualifications, languages and cultures. The system also rests on longstanding, hierarchical and bureaucratic linear structures that are increasingly contrasted against the emerging flat, participative and transformational structures supported by the quality philosophy.

Poor quality and patient safety have put increased strain on the Saudi healthcare system. Simultaneously, the level of available resources to be pumped into the system will probably not increase. However, one proposed solution to these challenges is quality management and improvement. The underlying logic is that continuous improvement will increase efficiency, quality and safety, making it possible to deliver “more with less”.

Thus, quality improvement ideas have emerged as a possible solution to these challenges, also inspiring the development of a new scientific field – improvement science – where quality management theory, practices and methods are

continuously being translated to the healthcare context. However, many reports show that quality improvement in a complex healthcare context is far from easy. On the contrary, many efforts fail, or it is not known whether the initiatives improved quality, safety or efficiency of the care processes.

Therefore, the research questions of the thesis concern what are the organizational characteristics that impede or underpin quality improvement and sustainability in Saudi hospitals? How the available evidence on the effectiveness of the existing key quality improvement models informs the development of a new QI model that works in the Saudi context? And what is the effect of the proposed quality improvement model on a group of randomly selected clinical indicators in Saudi hospitals?

The objectives of this research were to: a) develop a quality improvement model that fits best into health care in the local circumstances, b) apply the model in real life settings, and c) evaluate the effectiveness of the model in improving and sustaining randomly selected quality indicators. This research includes a three-phase sequential mixed study. In the first phase a proposed quality improvement model was developed using primary data from questionnaires and interviews and secondary data from literature review. The questionnaire aimed to uncover the current level of quality improvement implementation in Saudi hospital as measured by seven critical dimensions adapted from the literature. The interviews aimed to understand the organizational characteristics that impede or underpin quality improvement in Saudi hospitals. The second phase aimed to apply the model in real life setting through a series of experiments in three MOH hospitals using trained quality improvement teams. In the third phase pretest-posttest control group design was used to evaluate the effectiveness of the suggested model in producing sustained measurable improvement in a group of randomly selected clinical indicators in real life settings.

This chapter discusses the implications of this research in relation to the literature and its aim is to incorporate the research findings into the current body of knowledge. The results of this research are contrasted and compared with the previous work of other researchers. The chapter's structure follows that of the previous chapter in which each output is discussed alone. Finally, the whole framework is discussed in relation to the literature.

This research started by exploring the current degree of quality improvement implementation in Saudi hospitals. The degree of quality improvement implementation is defined as the extent to which Saudi hospitals apply the QI concepts and practices in their management system. These practices are: leadership, information and analysis, strategic quality planning, human resource utilization, quality management, quality results, and customer satisfaction. Analyzing the current situation at the beginning of this thesis was considered necessary to identify the gap between actual and expected performance.

The results of the questionnairesrevealed that, the mean score computed across the seven dimensions was (2.52 ± 0.50). This score is far from the score achieved by Korean hospitals (3.34 ± 0.50) which was computed for 67 hospitals with bed number more than 400 (Lee et al., 2002). It is also very low compared to the score achieved by US hospitals (3.33 ± 0.15) which was calculated for 61 hospitals with an average bed capacity of 223 (Shortell, et al., 1995). The mean scores for each of the seven dimensions ranged from 2.80 to 2.11, suggesting ample room for improvement at the level of all the seven dimensions. These scores are significantly low compared to the mean score in Korean hospitals which ranged from 3.08 to 3.88 (Lee et al., 2002).

Of the seven dimensions, 'leadership' (2.80 ± 0.57) achieved the highest score, followed by quality management' (2.75 ± 0.83) and 'human resource utilization'

(2.59 ± 0.69). The lowest score was registered for 'customer satisfaction' (2.11 ± 0.69), followed by 'information and analysis' (2.39 ± 0.59), and 'quality results' (2.47 ± 0.57). These findings show that, quality improvement implementation, as measured by the seven critical practices, is significantly poor in Saudi hospital (p-value <0.05). It also means that, the quality and safety of patient care provided by Saudi hospitals fall far short of what is optimal. Apparently, Saudi hospitals are facing serious challenges in implementing quality improvement strategies and their success has been very minimal.

Another finding of our study is that, based on the positive association with the other QI implementation dimensions, human resources utilization and quality management are found to be the key drivers to successful implementation of QI in Saudi hospitals. We also found that, QI efforts in Saudi hospitals did not lead to the desired outcomes on customer satisfaction and quality results. Saudi hospitals scored very low in 'customer satisfaction' (2.11 ± 0.69) with (p-value 0.000) and (2.47 ± 0.57) with (p-value 0.000) in quality results. This means that, Saudi hospitals failed to meet customers' expectations or achieve sustained measurable improvements in the quality and safety of patient care. Despite the substantial resources invested by many Saudi hospitals to adapt and implement QI programs, many of them did not achieve any improvement and some only a little. This could be because Saudi hospitals utilize only a partial implementation of QI approaches, and hence are unable to achieve continuous and systematic improvement.

We also found that, strategic quality planning in Saudi hospitals is significantly poor scoring (2.54 ± 0.71) with (p-value 0.000). Strategic Quality Planning is a process that organizations undertake to identify the "right" quality initiatives to best manage quality today and on into the future. Poor quality planning is probably because the main driver for the initiation of QI in Saudi hospitals is external

pressures by the Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) rather than by any internal strategic business planning requirement.

When we excluded 'customer satisfaction' and 'quality results' as outcomes of implementing the other five dimensions, we found that, the least implemented dimension of QI in Saudi hospitals was information and analysis with significantly low score at (2.39 ± 0.59) and (p-value 0.000). This explains the poor implementation of the other dimensions of QI especially strategic quality planning which is positively associated with information and analysis (p-value 0.001). Strategic quality planning is a systematic approach to defining long-term business goals, including those to improve quality and the means to achieve them. This indicates that, inadequate information and analysis serves as the key barrier to strategic quality planning in Saudi hospitals.

Although there is a positive association between information and analysis and human resources utilization, quality management and quality results, but it was not statistically significant to consider it as a determinant factor (p-value > 0.05). However, by serving as a key barrier to strategic quality planning, which is in turn positively associated with human resources utilization, quality management and quality results, it has indirect negative impact on the these dimensions. This means poor information management leads to poor strategic quality planning which in turn leads to poor human resources utilization, quality management and quality results.

The findings of this study confirm previous studies about the importance of Information Technology in improving the quality and safety of patient care. Our results agree with the key findings of the Institute of Medicine (2001) that information technology (IT) is integral to achieving substantial quality

improvement. More specifically, the report recommended the use of IT to improve access to information and support evidence-based decision making. The AHRQ (2015) suggested the integration of helath information technology (IT) to manage information and improve the quality of care, even as it makes health care more cost effective. Lai et al. (2011) found that IT has a substantial impact on all quality management dimensions and processes. They encourage intelligent investment in IT which is geared towards effective use in supporting quality improvement processes. Our results concur with those of Bates (2002) which concluded that, Information technology has the potential to substantially improve care by bringing decision support to the point of care, by providing vital links and closing "open loop" systems, and by allowing routine quality measurement to become reality.

The thematic analysis of the interviews showed the presence of a multitude of generic characteristics that make Saudi hospitals particularly challenging for quality improvement programs. Four major challenges were identified: organizational culture, utilization of human resources, processes and systems, structure and resources. These challenges have manifested themselves in the level of quality improvement implementation in the Saudi healthcare system. Despite governmental support and many years of intensive quality improvement efforts within the Saudi healthcare system, services have still been below expectations.

These four factors were found to have the strongest impact on the facilitation of QI among Saudi hospitals. They describe the organizational characteristics that facilitate or inhibit QI implementation and sustainability in Saudi hospitals. In particular, the level of preparation of the workforce for change, building the organizational structure for QI, linking QI goals to the organization’s mission and vision, training and engaging leadership and staff, and measuring and improving performance which are the most significant organizational factors impeding quality improvement implementation.

Many studies documented for the challenges to QI implementation in Saudi hospitals, such as the previous works of Albejaidi (2010) and Al Malki et al., (2011) who found that hospitals in Saudi Arabia were facing serious challenges in improving the quality of services provided to citizens despite the enormous fiscal expenditure and huge resources allocated by the Saudi government to the health sector. The present research found that nothing had changed in terms of the level of quality improvement implementation in Saudi hospitals. A recent study by Aljuaid, et al. (2016) also went in the same direction and clearly highlighted the need to improve the quality of healthcare delivery in Saudi hospitals, specifically in areas of patient safety, clinical effectiveness and patient-centeredness.

However, although the literature refers to various factors that can hinder quality improvement implementation in Saudi hospitals, most of those studies did not test their results empirically, relying more on a conceptual discussion and personal insight (Albejadi, 2010; Jannadi et al., 2008; Walston et al., 2008). Our findings are different as they are based on empirical investigation using interviews with highly qualified quality directors who have been working for many years in Saudi hospitals. Also, the results of this research provide a recent picture of quality improvement implementation which may or may not agree with many of the findings of previous studies.

Almutairi (2014) categorizes the factors affecting quality into patient factors (such as health literacy, access to care, and culture), and providers' factors (including medical care, workload, culture, and job satisfaction). This categorization is over simplification of the complexity of factors that can significantly impede quality improvement in Saudi hospitals such as leadership, human resources, processes and systems, and resources and facilities. Some of these critical factors were also ignored in the studies of Albejadi (2010), and Jannadi et al. (2008) who grouped

the main challenges in the sector in financing of healthcare system, lack of professional workforce and being more dependent on foreign workers, and the lack of a health information system. Despite the fact that, the reliance on foreign workforce in the Saudi health care system is quoted repeatedly as one of the major challenges to successful quality strategies due to a variety of factors including high staff turnover rates, costs (Albejadi, 2010; Jannadi et al. 2008; Walston et al., 2008) and language barriers (Alahmadi & Roland, 2007), our results show that this claim is not valid as a critical factor impeding quality improvement. This could be due to the recent Saudization rules and the increasing number of qualified Saudis in different specialties who joined the MoH hospitals.

This study revealed clearly that foreign workforce is not a direct determinant factor of quality improvement implementation. However, foreign workforce can indirectly affect quality improvement bearing in mind the high turnover among expatriates. Our findings are supported by those of a recent study by Aljuaid et al., 2015 who named factors hindering QI as failures of leadership and lack of culture of safety. Their findings did not show that foreign workforce is a factor affecting quality and thus go in line with our findings.

However, this research adds new findings with respect to Saudi hospital. First of all: none of the existing key quality improvement models can provide the right or best fit approach to quality improvement in Saudi hospitals. Second, the successful implementation of any quality improvement model in Saudi hospitals depends largely on the interaction between the quality improvement approach and the local context into which it is introuduced. Third, using hybrid models or combination of approaches will be more effective in improving and sustaining quality in Saudi hospitals.

Although these findings are new, as far as the Saudi context is concerned, the broader literature on organizational change supports our findings. Chassin (1998), Iles and Sutherland (2001), Ovretveit and Staines (2007), Leatherman and Sutherland (2008) maintain that there is no one 'right' quality improvement method or approach that can be applied that will be effective in all organizations. According to Locock (2013), success is contingent upon multiple factors, including the manner of implementation in each setting and specific local contextual factors. This means that, any quality improvement approach in the healthcare sector will be challenged by many factors such as the complex care processes; multiple stakeholders; an emphasis on individual proficiency rather than team-working; a history of challenging relationships between managers and health professionals; varying standards of data and infrastructure support for data collection and analysis; and a long history of successive top-down reorganizations and change programs.

The challenges identified in this research suggest a formidable array of complex generic contextual factors faced by health care organizations, none of which can be neglected as we strive to propose an approach to quality improvement that will have the greatest potential to resolve these problems in the local context.
The first determinant factor of QI implementation in Saudi hospitals is organizational culture. This study confirms the results of previous studies that considered culture as a major influencing factor in quality improvement. Organizational Culture is defined as a mixture of values, sets, beliefs, communications and explanation of behavior that provides guidance to people.

Many quality initiatives fail to generate the required improvement effects due to lack of readiness of culture and other behavioral issues during quality initiatives or programs. Our finding is supported by the studies of Jacobs et al., (2013), Kaplan et al., (2010), Scott et al., (2003), Shortell et al., (1995), Walshe and Freeman,

(2002) which suggest organizational culture as one important factor of successful practice change. Our findings also agree with the findings of Mosadeghrad (2006) who found that, the success of quality management in hospitals with organic organizational structure and medium organizational culture was higher than mechanistic and bureaucratic hospitals with weak organizational culture.

Extensive research on the relationship between organizational culture and change (Cameron, et al., 2004; Cameron, 2008; Cameron and Quinn, 2006) support what we concluded in this study that, without culture change, there is little chance for successful implementation of quality improvement in Saudi hospitals. This result is similar to research finding done by Zu, et al., (2010). Considering the fact that organizational culture is recognized as a key and vital agent for the implementation of comprehensive quality management programs (Hoffman and Klepper, 2000; Beer, 2003; Powell, 1995).

Unlike the literature that focuses on technical problems as the main reason for a system failure, this research found that the main shared hindering factor to quality improvement implementation in most Saudi hospitals is the lack of the organizational culture that reflects true motivation and commitment to perfection. The present research found that there is limited awareness among staff in Saudi hospitals about QI and its benefits. This lack of awareness resulted in lack of confidence among physician leaders and senior executives that efforts to improve quality will succeed, resistance to change, seeing QI as an extra burden rather that an integral part of everyday work and responsibility, and tendency to use quick fix approach rather than systematic multifaceted interventions to improve and sustain quality over time.

Another finding is that, quality improvement activities are not aligned with the strategic objectives of the organization and this led to ineffective communication, resistance to change and poor engagement of staff. Our findings confirm the

studies of Albejadi (2010), Jannadi et al. (2008), Walston et al. (2008), Alahmadi& Roland (2007) which maintained that the Saudi healthcare system does not provide a well-developed quality culture where quality strategies and other quality initiatives can flourish. This means that, nothing has changed in the organizational culture of Saudi hospitals. However, out study adds more details, depth and clarification about what exactly constitutes cultural elements.

The second determinant factor of QI implementation in Saudi hospitals is utilization of human resources. Improving quality of healthcare was once thought to be the sole responsibility of quality departments or quality professionals. The findings of this study support the philosophy that, quality improvement implementation must involve a focused effort on the part of every employee within the organization. QI requires that management, and eventually every member of the organization, commit to the need for continual improvement in the way work is accomplished. Quality improvement, which has been adopted by leading industrial companies, is a participative system empowering all employees to take responsibility for improving quality within the organization. Our study revealed the importance of proper utilization of the workforce through providing continuing education and professional advancement, involvement and participation of all employees in improving quality, engaging and empowering physicians and nurses to manage and coordinate patient care and to conduct QI analysis and improvement with IT support, addressing QI training and activities as part of the daily responsibilities rather than extra burden on top of other tasks, and tackling resistance to change in a very systematic manner.

Saudi hospitals should place great emphasis on recruiting and retaining top-level professionals and ensure that the right people, with the right skills, are in the right place at the right time. Our finding goes in line with the guidance of quality

gurus Deming (1986) and Juran (1986) who maintained that involvement and participation of all employees at all levels in the organization is critical to improve the quality of the current and future product or service. Ching-Chow (2006) concluded that human resource management practices have a significantly positive effect on the implementation of quality improvement. Our finding also go on line with the findings of recent studies by Talib et al., (2010); Idris, (2011); Irfan et al., (2012); Ali et al., (2012); Ramseook-Munhurrun, (2011); and Zakuan et al. (2008) who all found that utilization of human resources was positively correlated with organizational performance.

Moreover, our findings agree with older studies by (Westphal, Gulati and Shortell, 1997; Yang, 2003; Rad, 2005; Huq, 2005; Sanchez-Rodriguez et al., 2006; Vouzas, and Psychogios, 2007) which noted that management of human resources was significantly and positively correlated with organizational performance. The findings of this research also go in line with the findings of Bayraktar et al. (2008), Malek and Kanji (2000), Rosa et. al. (2007), Yazdani et al., (2011) and Alzalabani and Nair (2011) who emphasized the need of effective and efficient employee utilization as a key tool of QI implementation in services sector, and the findings of Schalk and Dijk (2005) who found that hospitals that focus on integrating quality management with human resource utilization achieve organizational excellence.

Our study agrees with the findings of Albejaidi (2010) and Almasabi (2013) that the lack of qualified heath workforce, high dependence on foreign medical professionals, and high employee turnover are some of the most critical challenges of quality improvement implementation in Saudi hospitals. However, in contrast to their studies, we did not find the lack of Saudi medical professionals a determinant

factor in QI implementation. This could be explained from the point of view that, the lack of Saudi medical professionals increases the turnover rate.

The third determinant factor of QI implementation in Saudi hospitals is processes and systems. The majority of research carried out so far does not address how Saudi hospitals engage in a quality improvement process marked by constant measuring, comparing, and redesigningprocesses and systems to improve their quality of care delivery. Hence, the findings of this study add unique contributions to the literature of quality improvement in Saudi Arabia and provide new insights which can be useful to guide quality managers in the successful implementation of quality strategies.

This research revealed that the lack of competent and effective quality structures (e.g. quality councils, committees, teams of change agents, quality improvement teams) to support effective and systematic change management process, absence of data warehouses to provide robust and timely data that is fundamental to decision-making and quality improvement activities, focus on individual performance rather than processes and systems, lack of inter-departmental collaboration and coordination to improve the quality of care and services the hospital provides, lack of the hospital's view to quality improvement as a continuing search for best ways to improve, absence of encouraging employees to keep records of quality measurements, lack of effective use of data from patients' satisfaction surveys and patient's complaints to improve services, lack of assessing physicians and employees satisfaction with hospital services and services provided by other employees and departments. Our research shows that these key organizational characteristics are impeding quality improvement in many Saudi hospitals.

Saudi hospital should strive to provide high quality care based on state-of-the-art practices to each patient in a respectful, professional, and compassionate

manner. This can be achieved through redesigning care delivery processes so that steps that have no value for patients are eliminated and the input of caregivers is not merely heard and respected but actually used on a daily basis. Instead of (management by objectives) which focus on meeting objectives, the model adopts W. Edwards Deming's approach of "management by process," whereby managerial competencies and systems govern behavior.

A fundamental part of quality improvement is a focus on process and systems thinking. A process is a series of steps that take inputs from suppliers (internal or external) and transforms them into outputs that are delivered to customers (again, either internal or external). The steps required to carry out the process are defined, and performance measures are continuously monitored in order to detect unexpected variation.

Our study revealed that, improvement in Saudi hospitals can be achieved by developing key performance indicators; dedicating qualified staff to manage data; monitoring the performance of care givers; comparing indicators with benchmarks; communicating performance data; setting the direction for the QI program; forming and training multidisciplinary QI teams to use the proposed QI model and associated QI tools; using Plan-Do-Study-Act (PDSA) to test change; and using QI professionals to facilitate change.This study identified ten process improvement tools that have proved to be successful in optimizing processes of care delivery in Saudi hospitals as evaluated by clinical quality measures. These are: Process mapping, Cause and Effect diagram, Brainstorming, Affinity diagram, Pareto diagram, Prioritization matrix, Force Field Analysis, Delphitechnique, Gantt chart, Multi voting, Run chart, and Control Chart.

This study showed that, when Saudi hospitals use these quality tools to reduce variation and bring service processes under statistical quality control, they positively impact quality improvement implementation. The literature advocates

the focus on processes and systems to improve quality and safety of patient care. Alaraki (2013) found a significant and positive relationship between process management and quality improvement in Saudi hospitals. Many recent and old studies support our findings. Ali et al., (2012) noted that process management had a significant relationship with hospital performance in Jordanian hospital. Irfan et al., (2012), reported a positive correlation process management and operational performance of public hospitals of Pakistan. Moreover, Sadikoglu and Zehir, (2010); ul Hassan et al. (2012); and Malik et al. (2010) indicated positive impact of process management on organization performance in India, Turkey and Pakistan firms. Zakuan et al. (2008) and Dilber et al. (2005) indicated a positive correlation between process management and organizational performance.

Other empirical studies that systematically investigated the relationships between process management and organization performance showed a positive correlation between the two (Prajogo and Sohal, 2004; Flynn *et al.*,1995; Kanji, 1998; Cua *et al.*, 2001; Feng *et al.*, 2006). While individual clinician competence remains important, many increasingly see the capability of organizational systems to prevent errors, coordinate care among settings and practitioners, and ensure that relevant, accurate information is available when needed as critical elements in providing high quality care (Institute of Medicine 2000).

The fourth determinant factor of QI implementation in Saudi hospitals is structure.Structure refers to the setting in which care is delivered including adequate facilities and equipment, qualification of care providers, administration structure and operations of programs. The results of this research show that one of the major factors that hinder quality improvement in Saudi hospitals is inadequate resources (e.g. staff, equipment, tools, supplies, and finance) to enable physicians, nurses, and other staff to practice high-quality medicine on a daily basis.

We found that, there is particularly shortage of qualified quality improvement staff that can assist in performance measurement, data analysis, and facilitation of the quality improvement process. Lack of resources in Saudi hospitals was documented in many studies. For instance, Almasabi (2013), Albejadi (2010) and Jannadi et al. (2008) maintain that financing of the healthcare system and the lack of qualified health workforce are obstacles to quality in Saudi hospitals.

Moreover, we found that there is low investment in Electronic Medical Records (EMR), Information Technology infrastructure, and IT training to facilitate quick access to health information and support health professionals and other staff using IT in new ways. Our study confirms the findings of Albejadi (2010) that Saudi hospitals lack an established and efficient National Health Information, and Khalifa (2014) who described the use of hospital information systems in Saudi Arabia as delayed or unsuccessful due to resistance and lack of realization of its benefits (Khalifa, 2014).

The potential of information technology to provide many benefits to the healthcare industry has been widely acknowledged and policy makers in many countries advocate the implementation of EMR systems (Blumenthal and Tavenner, 2010). This desire is based on the findings of many research studies that suggest electronic medical records promise considerable benefits to health care. For example, such potential benefits might include: reduced medication errors, reduced lengths of stay, reduced cost, improved documentation, better communication between care providers, and the availability of treatment options even to visitors (Rothschild, 2004; Poissant et al., 2005).

Furthermore, our study adds new findings which include, first: most of the Saudi hospitals are old buildings with poor architectural design that does not support patient safety practices and infection prevention and control activities. Second: the lack of evidence-based policies and procedures to support improving

the quality of care and services, and. Third: there is lack of ease of access to important sources of standards, best practice, quality, guidelines and protocols that offer support to clinicians in developing evidence-based best practices such as the AHRQ, CDC and IHI. Fourth: Saudi hospitals are not actively involved in using external training, peer networking, and conferences that provide guidance and feedback to health professionals.

This study suggests that, good care settings and supporting structures contribute to good implementation of quality improvement and consequently good outcomes. We found that, Saudi hospitals can successfully implement quality improvement when they focus on investing in advanced medical technology; investing in Information Technology; investing in qualified QI professionals, developing and implementing effective business management plans, developing and implementing evidence-based policies, procedures, guidelines, and protocols; participating in accreditation systems; and providing ease of access to important sources for standards and best practice such as the AHRQ and IHI.

Our findings agree with Donabedian's structure-process-outcome quality of care model which states that, improvements in the structure of care should lead to improvements in clinical processes that should in turn improve patient outcome (Donabedian, 2005). Our results agree with the study of Moore et al. (2015) that found that, medical centers that perform well in terms of structure also tend to perform well in terms of clinical processes, which in turn has a favorable influence on patient outcomes. Our findings are consist with those of Sharon et al., (2007) who argued that investment on structure such as new technology and infrastructure, evidence-based policies and procedures, clinical pathways and guidelines, error-reducing software, and patient flow management techniques, and structural changes such as multidisciplinary teams, quality-related committees facilitate a systematic problem-identification and problem-solving process,

resulting in new treatment protocols and practices, which in turn result in improved outcomes. The results of this study are also similar to those reached by Katsikea et al. (2011) who opine that, internal characteristics of an organization are critical to organizational failure and success.

This study provides empirical evidence of the best practices related to each of the four domains and how organizations can overcome the barriers to QI implementation. Any improvement in these four domains will lead to significant improvement in the implementation of all the dimensions of QI in Saudi hospitals. Our results are supported by what many quality improvement studies conclude about the conditions that are critical for successful organizational change. According to these studies, whatever quality improvement approach or combination of approaches is used, it is unlikely to be successful unless set of conditions are satisfied (Ferlieand Shortell 2001; Ham et al. 2003; Greenhalgh et al. 2004; Dickinson and Ham 2008).

Drawing from the insider action research experiences of the author, these challenges are certainly prevalent in everyday improvement initiatives as well. As this study revealed, human resource utilization is the key determinant of quality improvement in the Saudi healthcare system. As genuinely complex systems, Saudi hospitals require human resources management to be seen as continuously ongoing conversations among the workforce where learning plays a central role to encourage coordination, learning and sharing of information that lead to integrated and useful quality improvement efforts. In similar vein, Batalden and Davidoff (2007) suggest a view on healthcare as processes within systems, where knowledge of variation and knowledge of the customer from a multitude of perspectives are key interest domains in improvement science.

Further, how to lead, follow and make changes in iterative PDSA-cycles and to collaborate with teams to promote learning and manage conflict are other

important principles. Several tools and methods are also associated with these domains of interests.

The results of the research draw special attention to the importance of moving beyond identifying barriers and motivators for quality improvement, to embracing a more open and processual view on improvement. The researcher proposes that practices and theories from the key quality improvement models can be combined and integrated in a hybrid approach that will have the greatest applicability in health services in Saudi Arabia.

The model suggested in this study is based on integration of our findings that draw on quantitative and qualitative research including questionnaires, semi structured interviews, documentary analysis, and participants observation that we conducted in Saudi hospitals with the principles and concepts of the key models that were found to be effective in the local context of Saudi hospitals. It incorporates principles, concepts and tools from the IHI's Model for Improvement, Trilogy of Juran, Lean Thinking, Business Process Re-engineering (BPR) and Total Quality Management principles and tools.

The rational and synchronous use of several tools and techniques, borrowed from the methodologies mentioned above, is structured into a unique approach. The model thus offers a structured guide for quality improvement processes more suited to the reality of the local context and its dynamical evolution. This integration generated new hybrid practices and an infrastructure for QI that has the potential to support Saudi hospitals in their efforts to improve and sustain quality. The integration resulted in a five recursive phases: i) establishing the organizational foundation for Quality Improvement, ii) quality control, iii) quality planning, iv) quality improvement, and v) sustaining improvements. The model is conceived as a logical and technical support to the improvement and sustainability of quality.

The proposed quality improvement model was developed, based on these findings, to address the challenges that serve as barriers to quality improvement in Saudi hospitals. The practices of the proposed model were based on feedback from 12 quality directors working in Saudi hospitals and draw on a wide range of effective principles and techniques from different approaches as well as the researcher's work experience. The model is designed as a roadmap and guide for improvement teams and takes into consideration the cognitive, emotional, and other factors that are known to impede sustained improvements in healthcare services in Saudi Arabia and suggest a framework to optimize sustainability of quality improvement initiatives.

The value of the proposed methodology is to provide a structured frame to use several methodologies and tools with the scope of effectively managing change processes at any level within the organization. The practical implications of the idea are discussed below based on experimental studies conducted in three Saudi hospitals.

The application of the proposed model started with a pilot study in one of the biggest hospitals in Tabuk Region with the aim to further refine its constructs and sub-constructs. Preparation and planning for the application of the proposed QI model involved planning for how, where, when and who to apply QI in the organization. This required knowledge and skill regarding project planning, the context of the “receiving” organization, and regarding the proposed QI model methods, principles and tools. This phase involved the development of a draft project proposal on how to introduce process management at the hospital. It was based on quality improvement knowledge and experience, as well as on the facilitators’ knowledge of healthcare in general and in each hospital in particular. The project proposal was presented to the top management for approval before the project was initiated. The facilitators aimed enhance experiential learning among

members of the quality improvement teams. By proposing to include 5 clinical indicators, with five improvement projects in parallel in each hospital, they aimed at achieving a decrease in these indicators and to generate sufficient learning.

It was essential to have solid performance indicators to guide, and evaluate, quality improvement efforts. This step proved to be a major challenge in the case of the three hospitals, where some of the selected quality indicators were generally not agreed upon as high priorities among the three hospitals. Our study demonstrated how SPC can be a powerful and useful tool for indicator measurement, display, and analysis. Although some indicators could be of a general nature, e.g. “the number of patients per day who wait more than 2 hours to be seen by a doctor in the Emergency Department”, other indicators were very specific. On the other hand, during their work, QI teams developed additional structure, process and balancing indicators to focus for improvement efforts. Such indicators could mirror the impact (or lack thereof) of one or several local quality improvement projects at the organization level. At the same time, although the focus was on one clinical indicators, using a family of indicators were needed for each quality improvement project to know if the change did result in improvement while other parts of the system were not adversely affected. This justifies that, additional indicators (e.g., structure, process or balancing) used latter by any of the quality improvement team involved in this study, could only happen during the execution of the improvement process.

Since the focus of this study was on five randomly selected clinical indicators, the results of whatever additional indicators used by QI teams were not included in the study. There was a strong, and explicit, emphasis on gaining experience and on learning from the quality improvement projects “learning by doing”. The outcomes

of QI projects were highlighted at the end of the project, and participants' experiences were systematically assessed and reviewed.

The model was applied in real life settings in three MOH hospitals through a series of simultaneous experiments using Pre-test Post-test control-group design. In this study the dependant variables were 10 clinical indicators randomly selected from the population and randomly divided and assigned to the experimental and control groups. Thus each of the experimental group and control group consisted of 5 quality indicators. Five quality improvement teams were formed and trained in each hospital. The experiments were carried out during the period from January 2016 to December 2016 to evaluate the impact of the model on the five randomly selected clinical indicators representing the experimental group.

The pretest measurement showed no difference in the baseline data between the controlled group and the experimental group in the three hospitals (p-value 0.821; 0.980; 0.985 consecutively). The baseline measurement included horizontal line showing the average of each indicator over a six-month period. It demonstrated inherent random variation variability that can be described as 'common cause' in clinical processes; it is the normal level of variability in the process. This means that, any observed subsequent change in the clinical indicators under study after the application of the QI model is due to the intervention as 'special-cause variation' (Portela et al., 2015).

The major finding of our study is that there was a significant difference between the pretest and posttest measurementsin the experimental group while there were no changes in the control group. This means that, the application of the proposed model has led to significant positive improvements in the experimental group in the three hospitals (p-value 0.035, 0.004, 0.006 consecutively). This evidence

proves its applicability and impact in Saudi healthcare settings. As a complex combination that draws on the strengths of different approaches, the proposed QI model is complex and multi-facetedto suit the local context of Saudi hospitals and respond to unforeseen obstacles and unintended effects. Our claim is supported by the Department of Health (2007), Greenhalgh et al. (2004), and Plsek and Wilson (2001) who stated that, the 'single-bullet' interventions are not anticipated to deliver consistent improvements, instead, effective interventions need to be complex and multi-faceted. Our findings confirm the effectiveness of the use of a combination of approaches in one philosophy that can be used for quality improvement in healthcare.

The proposed model incorporates the Trilogy of Juran and the IHI's Model for Improvement which in itself is a hybrid model as it combines the PDSA cycle and Deming's System of Profound Knowledge which is a management philosophyand summative feedback in the learning process. Our finding is supported by many researchers that suggest that healthcare organizations should abandon the tendency to adhere to a particular quality improvement approach in order to cope with healthcare challenges and enhance their capacity to solve problems in the core processes related to the patient (Hellström et al., 2013; Glouberman and Mintzberg, 2001a; Crossan et al., 2011; Lawrence et al., 2005).

The utilization of quality improvement methods and tools is mandated by many accrediting bodies including the Saudi Central Board for Acclimation of Healthcare Institutions (CBAHI). This study found that, although there are several methods, tools and techniques used to support quality improvement in healthcare, Saudi hospitals use only three methodologies for quality improvement at the organizational level, these are: FOCUS-PDCA, the IHI Model for Improvement (MFI) and Total Quality Management (TQM). The FOCUS-PDCA is the dominant model in most Saudi hospitals followed by the IHI Model for Improvement. It

worth mentioning that, both models add a thinking part for innovating change before applying the PDCA/PDSA to test the change. On the other hand, we found that, the top ten QI tools utilized in Saudi hospitals are: Brainstorming, Affinity diagram, Run chart, Control chart, Process flowcharting, Pareto chart, Cause and Effect diagram, Prioritization matrix, Process mapping, and Force Field analysis. Many of these tools and techniques were provided by the key improvement models such as TQM, Lean Thinking and Six Sigma.

Although the majority of Saudi hospitals use FOCUS-PDCA and few use the IHI Model for Improvement as a quality improvement approach, they do not strictly follow a certain model; they rather use a variety of methods, approaches and tools to assure and improve healthcare services. However, both models use the PDSA cycle to test change. This means that, any proposed model for QI in Saudi hospital should include PDSA. Although there is no evidence of what works or does not work in the local circumstances, it is apparent that the PDSA method meets the needs of Saudi hospitals in their quality improvement journey. This theoretically supports our incorporation of the PDSA cycle in the proposed QI model.

Our results go in line with the studies of Bloch et al., (2016), Caldwell, (2005); Taner & Antony, (2007); and Gowen, et al., (2008) who suggest the use of Lean Six Sigma (LSS) as a hybrid model that combines the Lean methodology and the Six Sigma approach in quality improvement in healthcare. The findings of this study provide empirical evidence to support many recent studies by Bloch et al., (2016., Huang et al., (2016), Quartz-Topp et al. (2016), and Bernet et al. (2013), that suggest the use of hybrid models for quality improvement as they blend informative and summaritve research methods and integrate effectiveness, implementation, and associated evaluation methods to enhance knowledge and strategy development in “real-world settings”.

Subsequently, such a perspective also suggests that healthcare organizations should abandon the tendency to adhere to a particular quality improvement package in the never-ending echelon of new quality management programs (for instance 'TQM', 'Six Sigma', 'Lean', 'Lean Six Sigma', 'Value-based healthcare delivery' to mention but a few of the proposed 'one and only' salvations to cope with healthcare challenges). Instead, it is suggested that the framework proposed by Dean and Bowen (1994) – principles, practices and tools – allows an additive approach to quality improvement, where the organization may continuously add new theories and practices (if needed) to refine its capacity to solve problems in the core processes related to the patient. This approach also avoids the grand narratives and discourses always associated with the packages, instead inviting co-workers in the joint development of conversational patterns pertaining to the quality improvement initiatives that continuously evolve in the organization.

Results of this study revealed that, the change was more significant in hospital B, followed by hospital C and finally hospital A. Indeed, this variation in results among the three hospitals could be attributed to the conditions that surround and interact with the QI model in the local context of each hospital.

Our finding supports the study of Ovretveit (2004) and Walshe (2007) that quality improvement approaches are critically influenced by the contexts into which they are introduced and by the processes of implementation in those contexts.

Another major finding, there was no difference between the posttest measurements and the measurements after six months of the intervention. This means that, the improvement attributed to the proposed model has been sustained for six months after the intervention (p-value 0.157, 0.704, 0.804 consecutively). The framework for sustaining improvement provided by the model was successful in helping QI teams to sustain improvement overtime.

Sustainability was achieved better in hospital C (p-value = 0.804), followed by hospital B (p-value = 0.704), and finally hospital A (p-value = 0.157). Our findings agree with the studies of Grol et al. (2007) and Walshe (2007) that highlighted the importance of the use of theoretical frameworks to sustain improvements. The bed capacity of hospital C is 110 beds, hospital B is 200 beds, and hospital A is 300 beds. Although the sustainability framework provided by the model has proved be effective in sustaining improvements in the three hospitals, there was still variation among them.

Apparently, sustaining improvement in small hospitals is much easier than in big complex hospitals. Indeed, this could be due to the complexity of big hospitals. Again this finding supports the influential effect that local context can have on the sustainability of improvement.

Moreover, our study showed that participants in the three hospitals generally have significantly positive perceptions about the QI model (p-value = 0.000). This means that, the members of the QI teams who used the proposed QI model were satisfied with the comprehensiveness of the model, ease to learn and use, applicability in the local circumstances, fulfilling the needs of users, ability to produce sustained measurable improvements in quality, and enhancing their knowledge and experience in the quality improvement science. It also means that, they had a positive attitude towards recommending the model to other departments and hospitals. Indeed, this evidence supports the claim that, the model fits the local circumstances in Saudi hospitals.

These findings support our claim that the proposed model is applicable in the Saudi context as it provides a less complex improvement approach for complex systems using a set of preplanned steps and alternative ways to quality improvement interventions. Our finding is supported by Wallin (2009) who

maintained that in implementation science, there is no one way of doing things that suits every situation and every organization, or all of its participants. However, the significant positive perception of participants means that the QI model managed to offer different ways that attract the participants and the organizational context and increased the possibility of success. By letting practitioners come up with their local problems, encouraging them to collaboratively innovate change, this approach seems to facilitate positive sustainable project outcomes.

Further, our study showed that there was significant variation between and among the three hospitals in user experience (F-value = 6.210, p-value = 0.003). This reflects the impact of the local circumstances on the implementation of quality improvement initiatives in each hospital which is supported by Wallin (2009), Ovretveit (2004) and Walshe (2007). The respondents in Hospital C (110 beds) had a significantly higher positive experience with the proposed QI model (p-value = 0.000) than Hospital B (200) (p-value = 0.002). The respondents in Hospital B (200 beds) had a significantly higher positive experience with the proposed model (p-value = 0.000) than Hospital A (300 beds) (p-value = 0.002).

This variation could be due to the effect of the hospital size on the extent of the implementation of the model. The results show that the model worked better in smaller hospitals compared to larger hospitals. However, the review of the meeting minutes of the QI teams showed that there had been some problems which could be the real causes for this variation. These were related to getting enough time for QI efforts, a lack of support from managers, and difficulties with data collection. Moreover, the knowledge and experience of the facilitator and the methods and timing of providing training and support to QI teams were also possible causes. For instance, provision of only brief training to team members in QI tools and

principles, for subsequent use without further support, would yield a relatively shallow application of the QI model, whereas extensive

QI training and/or on-going support by the QI specialists (as QI facilitators) would enable greater depth of application. Furthermore, the implementation of the influence of first phase of the model "Establishing the Foundation for Quality Improvement" which includes a set of conditions for successful implementation such as building the right culture, utilization of human resources, focus on processes and systems, and providing resources and facilities was not assessed in this study. The reason being that rigorous assessment of these practices was not possible in this research for multiple reasons. First, they are organizational-wide factors that take very long time to build in an organization. Second, they could not be assessed empirically in the experiments. Therefore, variation among hospitals could also be due to the relative ease of building a quality culture and managing change in small hospitals rather than the concepts and principles of the proposed model.

Many studies support our claim that, whatever model is used, effective quality improvement work needs necessary conditions such as leadership, clinical involvement, process focus, and resources to facilitate the change (Pollitt 1996; Ovretveit 1997; Ferlie and Shortell 2001; Grimshaw et al. 2001; Locock 2001; Ham et al. 2003; Greenhalgh et al. 2004; Touati et al. 2006;Dickinson and Ham 2008; Ward et al. 2008).

Finally, this study showed no significant impact of gender (p-value = 0.658), age (p-value = 0.850), work experience (p-value = 0.917), education level (p-value = 0.594), or staff position (p-value = 0.226) on the user experience. This means that, gender, age, work experience, education, and staff position are not

determinant factors in the implementation of the propose model. Our results go online with the findings of other studies that revealed that healthcare quality is a system property and primarily depends on the function of the system and to a lesser degree on the skills of individuals (Berwick, 2003; Institute of Medicine, 2001; Batalden, 1993). Our results confirm these findings.

It worth mentioning here, that at the beginning of the course conducted to train the QI team members in each of the three hospitals we observed the following: 1) hospital employees are not given adequate education and training in quality management, statistical methods, project management, facilitation of change that support quality improvement and improve job skills and performance; 2) lack of engagement, empowerment and support to middle management and employees to correct problems in their area when quality standards are not being met; 3) lack of effective systems for employees to make suggestions to management on how to improve quality; 4) overloaded workforce and at the same time lack of use of incentives and rewards (e.g., financially and/or otherwise) to recognize hospital employees efforts in improving quality. These observations support our findings that human resource utilization is key determinant factor in QI implementation in Saudi hospitals. Likewise, Liang et al.(2013) maintain that, human resources management can have great influence on quality improvement implementation. They opine that reward (the carrot) and punishment (the stick) had an effective impact on the successful implementation of radical projects such as quality improvement systems.

Therefore, in this research, it is proposed that, based on the empirical evidence and the literature, using both the carrot and the stick in managing QI implementation can enable a hospital to perform better in implementing quality improvement approaches. We found the reward and punishment system used to

enforce implementation of quality improvement was perceived to have a strong impact on successful implementation.

Furthermore, out findings support the viewpoint of Almasabi (2013), that despite the fact that the Saudi government has made great efforts to improve its health sector and to ensure that it is providing the best quality healthcare services; hospitals have been unable to overcome these obstacles.

5.2 CONCLUSION

The overall aim of this thesis was to develop, apply and evaluate a proposed quality improvement model for Saudi hospitals. An experimental design was used to determine whether an improvement has occurred, and if so, whether it can be attributed to the proposed QI model under study.The significantly poor implementation of quality improvement in Saudi hospitals is well documented in the literature.

This study confirmed that nothing has changed so far. The study identified four key organizational characteristics that make Saudi hospitals particularly challenging for quality improvement implementation. These are: organization culture, human resources utilization, process and systems, and structure. The significant association between organizational characteristics and effectiveness of quality improvement implementation builds on the idea that for any QI model to be effective, it must first be consistent with the local context in which it is applied. Based on the literature on change management, it is obvious that the right QI approach for any hospital will be that approach which best reflects both the internal culture and external environment of that hospital.

Our study provides empirical evidence of the best practices related to each of the four factors impeding quality improvement and how organizations can

overcome these barriers. We developed a suggested quality improvement model for Saudi hospital that combines a variety of concepts and principles from the key quality improvement models such as the PDSA, IHI Model for Improvement, Trilogy of Juran, Lean Thinking, and Total Quality Management to lead to the greatest improvement in healthcare quality.

The proposed QI model is a combined approach rather than a single method. It requires doing a lot of different things, offering different approaches, combining top-down initiatives and motivational strategies with bottom-up, micro-level activities and encouragement. To compare to the related implementation science, there is no one way of doing things that suits every situation and every organization, or all of its participants. The rational and synchronous use of several tools and techniques, borrowed from the methodologies mentioned above, is structured into a unique approach. The model thus offers different ways in a structured guide for quality improvement processes more suited to the reality of the local context and its dynamical evolution. This integration generated new hybrid practices and an infrastructure for QI that has the potential to support Saudi hospitals in their efforts to improve and sustain quality. A series of experiments were carried out in real life settings in three Saudi hospitals and the model was found effective in producing sustained measurable improvement in randomly selected clinical indicators.

The quality improvement projects were carried out by multidisciplinary teams. Researchers emphasize the importance that projects become regular work, improvements being incorporated in the organization. This is a difficult step, going from a project to sustainability. Hence, the proposed QI model incorporates a framework for sustaining improvements overtime. The study demonstrated that quality improvement teams in each hospital developed a new understanding of their healthcare system and its interdependencies. We suggest that the management

can facilitate this kind of change by focusing on how quality improvement teams are involved in sharing and reflecting on information with regard to how the hospital system as a whole can be improved. The new understanding of the hospital system represented a change in mental models of employees that influenced how the organization changed its performance. Changes originating from a new mental model represent double-loop learning. In double-loop learning, deeper system properties are changed, and consequently improvements are more likely to be sustained.

The current research has both theoretical and practical applications for Saudi hospitals. Theoretically, the research has identified the key factors that influence quality improvement as being organizational culture, human resources utilization, processes and systems, and structure. Practically, the study has proposed a quality improvement model that contains best practices for addressing the challenges as well as a road map for producing sustained measurable improvements.

5.3 LIMITATIONS

Due to the very nature of humans, even with the best of intentions in mind, the researcher is often confronted with a variety of variables which may affect the reliability of his findings. Several limitations of this study must be mentioned. As stated in the research methodology chapter, the underpinning research ontology here is that there is no single reality. In other words, the circumstances and environmental factors in one area are not necessarily the same as in others. This was part of the rationale for using experimental research design. Therefore, this research does not claim that the results can be generalized across all hospitals in the country since its evidence was drawn from three hospitals only in certain areas of the Kingdom. Nevertheless, it argues that the results are “applicable” so long as

the environmental and organizational factors in these hospitals are similar to those in other Saudi hospitals.

On the one hand, questionnaires help to elicit knowledge from a large number of people at once. However, they do not enable researchers to understand a phenomenon in depth. Moreover, the level of QI implementation and the organizational characteristics influencing QI implementation were evaluated based on the perspective of only one or few persons responsible for QI within their hospitals and, therefore, the generalization of the results should be taken with caution. In addition, certain questions in the survey relied on the subjective judgment or perceived values of the respondent and, therefore, there is a risk that the answers do not accurately reflect the current situation. However, because the individuals chosen were considered to have expert knowledge of the situations within their organizations with respect to QI, these individuals were undoubtedly the most appropriate choice for the purpose of the survey and interviews.

On the other hand, qualitative research, based on interviews, enables a researcher to gain insights directly from those with hands-on experience. Therefore, mixing the two methods enabled this researcher to understand in detail the organizational factors influencing quality improvement implementation across the hospitals. Moreover, the mix method used in this study improved the credibility of the results. Nevertheless, it cannot be argued that this research allows the results to be generalized across all hospitals in the Saudi Kingdom for the reasons shown below. Nonetheless, the triangulation enhanced the reliability of the findings by using three sources for verification.

Another limitation of this study is that although it is most powerful as it allows for measurements over time and control for confounding variables, it is not well suited to answer questions of how and why change occurred. Furthermore, some

parts of the model, namely: ‘establishing the foundation for quality’ could not be empirically evaluated in this study as it takes long time to build in an organization and therefore needs different assessment approach.

5.4 RECOMMENDATIONS

These research findings have many implications that can help professionals and decision-makers in the Saudi health sector to increase the probability of quality improvement success and to enhance organizational culture, encouraging the implementation of higher levels of QI implementation than what exist at present in their organizations. Below is a list of recommendations.

1) In preparing for the implementation of the proposed quality improvement, it may be helpful to think separately about the first part: establishing organizational structure of quality as it deals with attitudinal or philosophical changes required in managers and staff and the technical or practical parts which deal with changes required in systems and procedures.

2) Since establishing the foundation for quality improvement is perceived to be the main driver of success, a governance board of decision makers (such as a powerful change team, quality council or Senior Responsible owner) should be set up to:

    a. Bear the responsibility and accountability for implementing the quality improvement program. Otherwise, without a real buy-in to the QI program from top management, the investment in it is a waste of time and money.

    b. Carry out regular culture gap analysis and develop action plans to close the gap before embarking on any quality improvement program.

c. Identify operational objectives, and short- and long-term expectations, demonstrate continuous commitment to achieving the organization's QI goals, identify internal experts or external consultants with experience and training in QI to help get teams started, continually check for barriers and remove obstacles, and build strong belief among staff that they as well as patients will benefit from the changes.

d. Manage the perceptions and attitudes of employees regarding the quality improvement program.

e. Set and enforce (using a carrot and stick approach) newly required change in processes, practices, policies and procedures, as it has been found that the ability to enforce change, remove barriers and systematically tackle resistance were some of the key success factors for quality improvement.

f. Develop staff skills in data management and retrieval, emphasize QI in new employee orientation and regular staff meetings, and establish quality improvement training and activities as part of the daily responsibilities of all staff.

g. Select a list of key performance indicators, dedicate qualified staff to collect and analyze data about actual performance, compare indicators with benchmarks, identify areas for improvement, use a systematic QI approach, and test changes through Plan-Do-Study-Act (PDSA).

h. Invest in advanced medical technology to generate efficiencies and cost savings, invest in Information Technology, and invest in Quality Improvement departments with qualified staff. They should develop

and implement effective business management plans (e.g. strategic plan, quality improvement plan … etc.), evidence-based policies and procedures, guidelines, and protocols to support physicians and improve patient care, participate in accreditation systems for hospitals such as the Joint Commission International (JCI), and the Saudi Center for Accreditation of Healthcare Institutions (CBAHI), and to provide ease of access to other important sources for standards, best practice and quality such as: the Agency for Healthcare Research and Quality (AHRQ), the Institute for Healthcare Improvement (IHI).

3) Constantly measure, evaluate, monitor, and compare performance measures to ensure that services rendered to customers meet quality standards. It is a systematic, cyclic process to determine whether improvements has been achieved and sustained. Establish a data warehouse, develop a list of quality indicators, measure actual performance, summarize data and perform initial analysis, compare with evidence-based standards and benchmarks, perform intensive analysis, prioritize for improvement, and provide accurate and timely feedback to leadership and staff.
4) The hospital Quality Council should regularly review a variety of key indicators, identify areas in need of improvement, forms quality improvement teams, develop charters and strategies for quality improvement, and reports to the board.
5) Change requires dedicated leaders and a culture in which all staff members are engaged and empowered and anyone can become a leader to identify and solve problems. Form and train QI teams to address prioritized improvement opportunities; set aims for the quality improvement projects; establish measures for improvement; innovate change using concepts from different

quality improvement models; document the plan for change; and use the PDSA cycle to test changes.

6) Sustain improvement by ensuring evidence that the change will produce benefits that are obvious to staff, patients and the organization; the improvement is adaptable and can continue in the face of ongoing changes in staff, leadership, and organization structures; ensuring that the organization has a system in place to continually and effectively monitor the progress of change; ensuring that key staff at all levels that are affected by the change are involved from the outset and trained in any new skills needed; engaging senior administrative and clinical leaders to interact with staff and take responsibility for sustaining change; ensuring alignment between the improvement and organizational goals and vision; and ensuring the improvement effort is supported during and beyond the formal life of the quality improvement project.
7) Clinical leaders, physicians and nurses should be informed and involved in change initiatives. The hospital should encourage physicians' input and provides support for physicians in learning how to integrate information technology in the delivery of care. In doing so, the administration tries to make implementation less onerous and more user-friendly.

5.5 FUTURE RESEARCH

This research may help practitioners to understand the organizational characteristics that might limit the ability of hospitals to implement QI. Therefore, it is suggested that future research operationalies these characteristics into a framework for measuring quality improvement implementation in Saudi hospital. Furthermore, all experiments were conducted in certain areas of the country and all are MoH affiliated hospitals. There is a need for future research that compares

government and private hospitals. One important part of QI is patient-centeredness, which is translated in healthcare as patient involvement in care decisions. There will be a need for studies exploring the patient participation in these kinds of QI efforts. This research provides empirical evidence that the proposed QI was successful in producing sustained measureable improvements in three hospitals. However, further research is needed to see if the change is fully incorporated in the daily work of these hospitals.

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Appendix 1: Invitation for Participation in the Interview

1. Research Project Title

Development, Application, and Evaluation of a Quality Improvement Model for Saudi Hospitals

2. Invitation paragraph

You are being invited to take part in an interview of a research project. Before you decide it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this information.

3. What is the project's purpose?

I am conducting this research for my PhD degree at Sudan University for Science & Technology (SUST), Khartoum, Sudan. The purpose of this interview is to explore the barriers, and facilitators of quality improvement implementation in hospitals of Saudi Arabia. Additionally, I am looking for possible solutions to overcome those barriers through developing a quality improvement model that combines the strengths of the key quality improvement approaches. This study will help hospitals in Saudi Arabia to increase the potential of their quality improvement efforts to produce the desired outcome.

4. Why have I been chosen?

On the basis of the relevance and depth of your experience in the field of research, knowledge about quality improvement methods and tools, and past experience in conducting quality improvement projects in your hospital. Being decision maker in your hospital, you are fulfilling our inclusion criteria to be

considered for interview. It would be our pleasure if you could spare time for an interview.

5. Do I have to take part?

Participation in this research is entirely voluntary and it is up to you to decide whether or not to take part. Your refusal to participate will not involve any penalty or loss of benefits to which you are otherwise entitled. If you do decide to take part in the research you need to sign a consent form (attached with this information sheet). Even after giving consent, you have the right, not to answer any question you do not want, any time during interview without giving a reason and this will not affect your rights or benefits you are entitled to. If you decide to participate in this research you will be given a copy of the information sheet and a signed consent form for your personal record to keep.

6. What will happen to me if I take part?

If you decide to take part in this research, I will arrange an interview with you. It will take approximately 30-45 minutes. Interviews may be conducted on telephone, skype, IMO as well as face- to- face according to your feasibility. However, in some of the instances, the preferred method would be through telephone, skype, or IMO. Interviews will be conducted by the lead investigator (Mohammad Shamsuddin). You will be given an opportunity to discuss and share your views/opinions regarding organizational characteristics that facilitate or impede quality improvement in your organisation. Additionally, you would be given possible solutions to overcome such barriers. There will be no right or wrong answer and all types of opinions and suggestions would be welcomed and will be given equal consideration. Based on your professional knowledge and experience you are expected to take an active role in developing, reviewing and refining a quality improvement model to best fit the local circumstances in Saudi hospitals.

7. What do I have to do?

You do not need to change your routine activities and schedule. This participation does not impose any type of restriction at all, before or after interview so you should not worry in this regard.

8. What are the possible disadvantages and risks of taking part?

There is no foreseeable risk of physical or psychological harm to participants.

9. What are the possible benefits of taking part?

Whilst there are no immediate benefits for those people participating in the research, it is hoped that this work will help the ministry of health (MOH), Saudi Arabia to improve the quality and safety of patient care through implementing the principles, concepts and strategies suggested by the proposed quality improvement model. You can indicate if you would like to receive the results from this work, if so, they will be provided to you.

10. What happens if the research study stops earlier than expected?

If the research study stops earlier than expected then in this case the reason(s) will be explained to the participants.

11. What if something goes wrong?

If you have any query/complaint you can contact me without hesitation at my given contact number. However, if you feel that I could not handle your query/complaint appropriately then you can contact my supervisors Prof. Adil Abulmaaly (elsiddig_2000@yahoo.com) or Dr. Afaf Ahmed Hassan (afafahmedhassn@homail.com).

12. Will my taking part in this project be kept confidential?

All the information that you will provide/share during interview will be password protected and hard copies kept in locked cupboards. I will use the information anonymously (participant's name or personal identity will not be used; instead a unique ID will be given for research purpose). Data will also be analyzed anonymously by using that unique ID. Similarly, this anonymity will also be maintained during report/paper writing, presentation and publication by not using personal identity/name.

13. What type of information will be sought from me and why is the collection of this information relevant for the achievement of the research project's objectives?

In interview, you will be asked questions about the barriers, and facilitators of quality improvement implementation in hospitals of Saudi Arabia. Additionally, I am looking for possible solutions to overcome those barriers. You can give your opinions and suggestion in light of your experience. There will be no right or wrong answer and all types of opinions and suggestions would be welcomed and will be given equal due respect. This information should inform the development of the proposed model and its principles and practices. The model will assist the Ministry of Health (MOH), Saudi Arabia to design policies accordingly to make QI implementation more fruitful.

14. Will I be recorded, and how will the recorded media be used?

The interview will be audio recorded in order to catch all necessary details being provided in discussion. This is important in order to avoid missing any information. The voices will be transcribed to produce a transcript and destroyed after the studies are completed. The tape will not be shared with any individual outside the research team. Prior to submission of the final report the tape will be kept in locked cupboards. I will analyze data of the interview anonymously (no

name or personal identity) and you will not be mentioned in the final report or any publication.

15. What will happen to the results of the research project?

Results of the study will be submitted to the University of Sheffield by the end of 2014. Participants will not be identified in any report or presentation or publication. Findings of the study will also be shared with the government through the MOH.

16. Who is organizing and funding the research?

This study is being conducted as a postgraduate research project. The study is not sponsored by any agency or individual.

17. Who has ethically reviewed the project?

This research has received ethical approval from Ethics Committee of King Khaled Civilian Hospital, Tabuk, Saudi Arabia.

18. Contact for further information

My contact information is given below. If you have any query or need further information you can contact me without hesitation. I am very thankful for your time and cooperation.

Best Wishes

Mohammad Shamsuddin Yousuf Alaraki, PhD student
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Appendix 2: Guideline for semi-structure interview

Interviewer:	Mohammad Shamsuddin
Interviewee:	Quality Directors
Age:	No limit
Sex:	Males & Females
AA:	Mohammad Shamsuddin
P:	Participant

Interview will be conducted according to the availability and choice of the participant in terms of place and time. However, a quite, silent and undisturbed place would be preferable. It would be easier for interviewer and interviewee to communicate with each other. A Digital recorder will be positioned with telephone in such a way that it should ensure quality of sound.

Interview will be started with a formal introduction of each other. The purpose of the study and interview will be explained briefly. Key instructions will be read and explained to participants. At the end of the interview, I will thank the participant and will acknowledge their participation. They will be assured regarding privacy and confidentiality of information that they have shared with me.

Discussion will be carried out about the organizational factors that impede or underpin quality improvement implementation in hospitals of Saudi Arabia. Additionally, there will be discussion about possible solutions to overcome those barriers. Participants will be given the opportunity to express their opinion on given aspects in any order.

Appendix 3: Key Instructions for participants

- Participants will have the right to express their opinion and experiences freely.

- There is no right or wrong answer for any point.
- Participants are free to ask explanation of any point/question if it is not clear to them.
- Participant will be asked to maintain tone of their voice loud enough to be recorded.

Appendix 4: Consent form for interview participants

Title of Research Project: Development, Application, and Evaluation of a Quality

Improvement Model for Saudi Hospitals		
Name of Lead Researcher: Mohammad Shamsuddin		**Participant Identification Number:**
S. No	**Statement**	**Please initial box**
1	I confirm that I have read and understood the information sheet explaining the above research project and I have had the opportunity to ask questions about the project.	
2	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without there being any negative consequences. In addition, should I not wish to answer any particular question or questions, I am free to decline.	
3	I understand that I will be given an opportunity to discuss and share my views/opinions regarding organizational factors that facilitate or hinder quality improvement implementation.	
4	I understand that interview will be audio recorded and transcribed, which is absolute necessity for research purpose.	
5	I understand that principal investigator will keep my responses strictly confidential. I give permission for members of the research team to have access to my anonymised responses. I understand that my name will not be identified or identifiable in the report or reports that result from the research.	
6	I agree to take part in the above research project.	

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Lead Researcher	Date	Signature

Appendix 5: Interview agenda with quality directors

1. What are the main business problems that motivate MOH hospitals in Saudi Arabia to adopt and implement quality improvement approaches?

2. What is the impact of the implementation of quality improvement approaches at the organizational level?

3. Can you specify the different challenges and barriers that impede quality improvement and sustainability of improvement in the context of Saudi hospitals?

4. Which of the existing key approaches to quality improvement in healthcare provides the 'best fit' to the specific local contextual circumstances in MOH hospitals in Saudi Arabia?

5. If there is no 'best fit' locally, how do you think quality improvement in Saudi hospitals can best be approached?

6. In your opinion, what tools, concepts, and practices from different approaches are more likely to work in the local context of Saudi Arabia?

7. What are the necessary conditions, factors or practices that must be in place for successful implementation of quality improvement in the local context of Saudi hospitals?

8. How can healthcare organizations in Saudi Arabia respond to these conditions effectively and efficiently?

9. In your opinion, what are the key responsibilities that quality improvement is expected to place on the leadership, clinicians and staff?

10. What are the characteristics, practices and principles of the quality improvement model that is capable of addressing the challenges that impede sustained quality improvement in Saudi hospitals?

Appendix 6: Quality Improvement Implementation Survey

YOUR RESPONSES TO THIS SURVEY ARE CONFIDENTIAL

Individual respondents will not be identified by name in any analysis or reports. Responses will be aggregated and reported as summary statistics only. The number printed on the survey is for purposes of questionnaire follow-up only.

INSTRUCTIONS

In this section you are asked to assess your hospital's efforts to improve the quality of care and services it provides. Please read each statement carefully. Indicate the extent to which you agree or disagree that the statement characterizes your hospital by circling the appropriate response (1 = Strongly Disagree, 5 = Strongly Agree). In answering the questions, you should think about what the hospital is **actually like now**, not how you think it might be in the future or how you might wish it to be. In circling a response, please keep in mind the following general guidelines regarding the choices of response categories.

RESPONSE CATEGORIES

You should circle **Strongly Agree** when, for example, the statement represents a completely accurate description of your hospital. You should circle **Strongly Disagree** when the description is completely inaccurate. The response **Neither Agree Nor Disagree** should be circled when, based upon your experience, you believe the statement is neither a particularly accurate nor a particularly inaccurate description of your hospital. This situation may arise because there is wide variation in the activities the statement describes. For example, you might circle neither agree nor disagree when the statement is true of some departments but not of others.

		STRONGLY DISAGREE		**NEITHER**	**AGREE**	**STRONGLY**
LEADERSHIP		1	2	3	4	5

1	The senior executives provide highly visible leadership in maintaining an environment that supports quality improvement.					
2	The CEO/Administrator is a primary driving force behind quality improvement efforts.					
3	The senior executives allocate adequate organizational resources (e.g., finances, people, time, and equipment) to improving quality.					
4	The senior executives consistently participate in activities to improve the quality of care and services.					
5	The senior executives have articulated a clear vision for improving the quality of care and services.					
6	The senior executives have demonstrated an ability to manage the changes (e.g., organizational, technological) needed to improve the quality of care and services.					
7	The senior executives act on suggestions to improve the quality of care and services.					
8	The physician leadership is personally involved in quality improvement efforts.					
9	The senior executives have a thorough understanding of how to improve the quality of care and services.					
10	The senior executives generate confidence that efforts to improve quality will succeed.					
INFORMATION AND ANALYSIS		1	2	3	4	5
11	The hospital **collects** a wide range of data about the quality of care and services.					
12	The hospital **uses** a wide range of data and information about the quality of care and services to make improvements.					
13	The hospital continually tries to improve how it uses data and information on the quality of care and services.					
14	The hospital continually tries to improve the accuracy and relevance of its data on the quality of care and services provided.					
15	The hospital continually tries to improve the timeliness of its data on the quality of care and services provided.					

16	Hospital employees are actively involved in determining what data are collected for the purpose of improving the quality of care and services.					
17	The hospital compares its data to data on the quality of care and services at other top performing hospitals.					
STRATEGIC QUALITY PLANNING		1	2	3	4	5
18	Hospital employees are given adequate time to plan for and test improvements.					
19	Each department and work group within this hospital maintains specific goals to improve quality aligned with the hospital strategic goals.					
20	The hospital's quality improvement goals are known throughout the organization.					
21	Hospital employees are involved in developing plans for improving quality.					
22	Middle managers (e.g., department heads, program directors, and first line supervisors) are playing a key role in setting priorities for quality improvement.					
23	Non-managerial employees are playing a key role in setting priorities for quality improvement.					
HUMAN RESOURCE UTILIZATION		1	2	3	4	5
24	Hospital employees are given education and training in how to identify and act on quality improvement opportunities.					
25	Hospital employees are given education and training in statistical and other quantitative methods that support quality improvement.					
26	Hospital employees are given the needed education and training to improve job skills and performance.					
27	Hospital employees are rewarded and recognized (e.g., financially and/or otherwise) for improving quality.					
28	Inter-departmental cooperation to improve the quality of services is supported and encouraged.					

29	Hospital employees have the authority to correct problems in their area when quality standards are not being met.					
30	Hospital employees are supported when they take necessary risks to improve quality.					
31	The hospital has an effective system for employees to make suggestions to management on how to improve quality.					
QUALITY MANAGEMENT		1	2	3	4	5
32	The hospital regularly checks equipment and supplies to make sure they meet quality requirements.					
33	The quality assurance staff effectively coordinate their efforts with others to improve the quality of care and services the hospital provides.					
34	The hospital has effective policies to support improving the quality of care and services.					
35	The hospital works closely with suppliers to improve the quality of their products and services.					
36	The hospital tries to design quality into new services as they are being developed.					
37	The hospital views quality assurance as a continuing search for ways to improve.					
38	The hospital encourages employees to keep records of quality measurements.					
QUALITY RESULTS		1	2	3	4	5
39	Over the past few years, the hospital has shown steady, measurable improvements in the quality of care provided to medical, surgical and obstetric patients.					
40	Over the past few years, the hospital has shown steady, measurable improvements in the quality of services provided by clinical support departments such as laboratory, pharmacy, and radiology.					
41	Over the past few years, the hospital has shown steady, measurable improvements in the quality of services provided by support areas such as accounting, billing, human resources, and marketing.					

42	Over the past few years, the hospital has shown steady, measurable improvements in patient satisfaction results.					
43	Over the past few years, the hospital has shown steady, measurable cost reduction while maintaining or improving quality.					
CUSTOMER SATISFACTION		1	2	3	4	5
44	The hospital does a good job of assessing current patient needs and expectations.					
45	The hospital does a good job of assessing future patient needs and expectations.					
46	Patients' complaints are studied to prevent the same problems from recurring.					
47	The hospital uses data from patients to improve services.					
48	Data on patient satisfaction are widely communicated to hospital staff.					
49	The hospital does a good job of assessing physician satisfaction with hospital services.					
50	The hospital does a good job of assessing employee satisfaction with services provided by other employees and departments.					

Suggestion and Recommendations:

Name:	**Position:**	**Hospital:**

THANK YOU FOR YOUR TIME AND EFFORT. PLEASE RETURN THE COMPLETED SURVEY TO:

Mohammad Shamsuddin, King Fahad Specialist Hospital, Tabuk. Telephone: 0500311650
Email: nilevision@hotmail.com

Appendix 8: User Experience Survey

This survey asks for your opinions about the application of the Proposed Model for Quality Improvement and its relation to quality improvement team performance. It will take about 10 minutes of your time to complete.

Background Information

Gender		Male		Female			
Age Group		Less than 30		30 - 39		40 - 49		50 or more
Work experience		Less than 2		2 to 5		6 to 10		More than 10
Education		Less than diploma		Diploma		Bachelor		Postgraduate
Staff position		Physician		Nurse		Technologist		Administrator

Please indicate your agreement or disagreement with the following statements about your hospital.

SN	Topic	Strongly disagree	Disagree	Neither	Agree	Strongly agree
1	The model is comprehensive and well defined					
2	The model is easy to learn and use					
3	The model fits the local context in our hospital					
4	The model helps to overcome most of the challenges that impede QI programs in our hospital					
5	The model helps to introduce measurable improvements in quality indicators					
6	The model helps to sustain improvements over time					
7	The model enhances my knowledge and experience in teamwork					
8	The model enhances my knowledge and experience in participation in quality improvement projects					
9	The model is inspiring, motivating, interesting and exciting to use					

10	I recommend the use of the model in our department					
11	I recommend the use of the model in other hospitals					

Name: …….. Signature:…….…….