Investigating the Role of Lean Six Sigma in Hospital Laboratories in India

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Abstract

This research aims to investigate the applicability and significance of Six Sigma and Lean Six Sigma methodologies within the health sector, with a particular focus on clinical laboratories. The study aims to identify and explore the relevance of these quality improvement frameworks in enhancing efficiency and patient care in healthcare settings. Additionally, the research seeks to identify the potential facilitators that could support the successful implementation of the Lean Six Sigma model in selected hospitals across Kerala, as well as the constraints that may hinder its adoption. Through a comprehensive analysis of these facilitators and constraints, the study endeavors to develop a tailored Lean Six Sigma model that aligns with the specific requirements and challenges faced by healthcare institutions in Kerala. The findings from this research paves the way for optimizing healthcare processes, minimizing errors, and improving overall quality and patient outcomes in clinical laboratory settings and other healthcare facilities in the region.

Key words: Lean, Lean Six Sigma, Potential Facilitators, Potential Constraints, Health Care, Hospital Laboratories.

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1. Introduction

In recent years, the health sector has been increasingly seeking ways to enhance efficiency, optimize processes, and improve patient outcomes. One prominent approach that has gained attention is the adoption of quality improvement methodologies, such as Six Sigma and Lean Six Sigma. These methodologies, originally developed in the manufacturing industry, have shown promise in addressing challenges within the healthcare domain, particularly in clinical laboratories. The primary objective of this study is to delve into the relevance and applicability of Six Sigma and Lean Six Sigma in the health sector, with a specific focus on clinical laboratories.

Lean Six Sigma combines the strategies of lean and six sigma. Lean is famous for its ability to handle waste and six sigma is known for process improvement. It is well known that six sigma stands for standard deviation. Therefore, to improve the efficiency and quality of the process combining these philosophies will eliminate waste and reduce variability. First lean methodology is used to eliminates the waste then through six sigma tools we can improve process variation so these two methods go hand in hand in today's time. Combination of lean and six sigma also gives good results in improving the process flow. Principles of six sigma and lean have a lot of similarities, and that's why lean and six sigma has been practiced together. Both of them, at the end of the day deliver the same kind of value to the customer and to the businesses . We know that lean and six sigma both sort of originated out of manufacturing, a lot of it from manufacturing of automotive. But today it's used in the public sector, in customer service, in healthcare and can be used everywhere. Lean thinking goes back a long way. Henry Ford kind of established it early on the first mass production system by combining standard parts conveyors and workflow. Later on, Kiichiro Toyota implemented new concepts, like they came up with things like value stream and Kanban, which become to known as Toyota production system in the 90 s. It became more extensively recognized as a solution that works. Lean in manufacturing was introduced by James Womack who works at the lean institute. When taking a lean approach, the general focus is on the qualitative tools. This is one of the reasons that most lean six sigma activity begin with lean, as qualitative tools are little more intuitive. The concept of lean and six sigma is a little easier to understand then to implement.

As healthcare is people intensive and process driven industry so this is the perfect environment for lean and six sigma. Worldwide, LSS is being implemented in various service as well as manufacturing organizations. Still, healthcare sector is not much familiar with the sustainable benefits of LSS strategy, especially in developing nation like India, Sri Lanka etc. This study provides and explores the available literature on LSS in developing nation like India. Further, this paper focuses on potential facilitators or constraints that either boost or hampers the implementation of LSS in clinical laboratories of hospitals in India taking one of the states into consideration like Kerala. This study is able to focus on grey areas to effectively improve their organization performance using LSS. The explained objectives achieved in the present study can be summarized as follows:

Through investigating existing literature, best practices, and success stories, this study illuminates how methodologies like Lean Six Sigma streamline healthcare processes, reduce errors, and improve service quality, providing valuable insights into their potential impact on healthcare delivery. The second objective is to identify facilitators for Lean Six Sigma implementation in selected hospitals across Kerala, including leadership support, stakeholder engagement, and adequate resources. This understanding enables proactive planning by healthcare administrators. Conversely, the study aims to identify constraints hindering Lean Six Sigma implementation, such as cultural resistance and resource limitations, and devising effective strategies to overcome them. Finally, the study develops a tailored Lean Six Sigma model, serving as a practical guide for hospitals, with step-by-step implementation guidelines to address unique challenges in Kerala's healthcare institutions. By achieving these objectives, this research contributes to the knowledge on healthcare quality improvement, empowering professionals to establish an efficient system and enhance patient care in clinical laboratory settings and beyond.

The rest of paper is divided into four sections. The next section takes an extensive literature review into account. Third section highlights the research methodology and design into consideration. Following section inculcates the analysis and findings and ends at conclusion and recommendations.

2. Literature Review

When it comes to improving organisational performance, employing the Six Sigma methodology has several advantages. It reduces project timelines and costs while improving organisational performance. By lowering the overall manufacturing or service process cycle time, it may improve product development cycles, process design, and product lead times. It can be used to identify and remove the issue's underlying causes, ultimately lowering process variability and preventing errors (Liberatore, 2013).

The Six Sigma methodology offers recommendations that aid employees in comprehending how to perform their duties in order to address potential issues. Also, it increases the productivity of the production line and its capacity, as well as reducing organisational waste by eliminating unnecessary parts and motions and lengthening repair cycle times (Tjahjono et al., 2010). The Six Sigma method aids an organisation in choosing the optimal project to carry out its objectives. By identifying the project selection process, Six Sigma, according to Sharma and Chetiya (2010), may ensure organizational success. According to their research, 17 characteristics were shown to positively influence the effectiveness of the Six Sigma project. These 17 factors include the potential for

- waste reduction,
- the improvement of work flows,
- the potential for reducing user complaints,
- the potential for methodological simplification,
- the potential for process reengineering,
- the potential for cycle time reduction,
- the availability of assets,
- the availability of a good measurement system,
- the availability of clearly defined deliverables,
- and the potential for innovative solutions.

By choosing the most effective project methods, these 17 elements help determine if the Six Sigma program has a high potential for success or failure. Also, it enhances communication both inside and outside the organization. By fulfilling their requirements and expectations, the elements also promote client loyalty and happiness (Stanton et al., 2014). One of the crucial techniques that consistently enhances quality performance to meet organizational goals is the Six Sigma approach. In order to increase quality performance and increase customer satisfaction, many service organizations, including hospitals, educational institutions, and other service organizations, have been using the Six Sigma approach (Fortenot et al., 1994; Antony, 2006, 2015).

2.1 Lean Six Sigma

Lean Six Sigma, as described by Womack and Jones (1994), is a systematic approach aimed at eliminating waste throughout an organization's value stream, involving all members. It is recognized for its cost-cutting potential (Achanga, 2006; Bicheno, 2004), aiming to enhance efficiency, reduce costs by eliminating non-value-adding steps and inefficiencies (Motwani, 2003), decrease cycle times (Sohal and Egglestone, 1994), and increase profits to enhance competitiveness (Claycomb et al., 1999). The key principle is to produce precisely what is needed at the right time and quantity without compromising effectiveness (Monden, 1981). Lean manufacturing extends waste elimination to all aspects of production, including supplier networks, customer relationships, product design, and factory management (Phillips, 2000).

The foundation of lean lies in value stream mapping, as explained by Womack and Jones (1994) and Worley and Doolen (2006), which analyzes process activities comprehensively. The value stream encompasses the entire product generation process, representing the "flow of value" within companies. The study primarily focuses on identifying activities that enhance product value or contribute to waste (muda) (Worley and Doolen, 2006). Waste occurs throughout the value stream, especially during product transfers between departments (Womack and Jones, 1994). Taj and Berro (2005) observe that many manufacturing organizations waste over 70% of their resources.

Lean methodologies, as argued by Bhasin and Burcher (2006), have the potential to cut waste by 40%. Among the seven common types of waste are overproduction, waiting, transportation, improper processing, excess inventory, superfluous motion, and flaws (Endsley et al., 2006; Bhasin and Burcher, 2006).

2.2 Six Sigma in Health Care

The growing concerns regarding healthcare quality and cost have led to the adoption of Six Sigma initiatives in healthcare settings. Six Sigma aims to find and eliminate defects, minimize variability, and improve processes. It provides metrics to measure current process and service quality, emphasizing "critical to quality" characteristics important to both internal and external customers, resulting in time and cost reductions and revenue enhancement (Black & Revere, 2006; Carrigan & Kujawa, 2006).

The integration of Lean and Six Sigma has given rise to Lean Six Sigma (LSS), a problem-oriented approach used in healthcare to address specific challenges and improve patient care (Beck & Gosik, 2015). LSS has shown success in various healthcare organizations worldwide, with examples from Texas Children's Hospital, Royale North Shore hospital eye clinic, and Sharp Grossmont Hospital (Kovach & Borikar, 2018; Kim et al., 2021; Gallo et al., 2020).

However, the adoption of LSS in healthcare varies, with different tools and techniques being used across institutions. There is a lack of standardized implementation paradigms in the healthcare industry, leading to confusion and challenges in applying LSS (Yadav & Desai, 2016). Furthermore, some tools and techniques developed for manufacturing may not be suitable for healthcare, making it essential to identify and apply the most relevant tools for successful LSS projects in the healthcare sector (Uluskan, 2019).

In India, the healthcare sector has become a significant driver of economic growth, and many healthcare organizations, including hospitals, have adopted Six Sigma methodologies to improve operational performance, cost-effectiveness, and process quality (Taner et al., 2007). As such, ongoing research in healthcare aims to evaluate the success of Six Sigma initiatives in private hospitals based on factors like gender, position, and work history (current study).

2.3 Lean Six Sigma in Health Care

Lean Six Sigma is a process improvement technique that enhances speed and quality while reducing waste and expenses in both service and manufacturing industries (Laureani et al., 2013). In healthcare, Lean Six Sigma has been adopted since the early 2000s to increase value-added activities and improve patient care by reducing non-value-added activities and waste (DelliFraine et al., 2010). Lean Six Sigma application in healthcare has shown to improve various aspects of healthcare quality, including nurse care, physician care, hospital environment, patient safety, hospital stay, and waiting time, ultimately leading to increased patient satisfaction and loyalty (Liberatore, 2013).

Effective workforce management plays a crucial role in enhancing employee skill development and ultimately the quality performance of healthcare organizations (Ahmed et al., 2021). Engaged and empowered employees are more likely to contribute to continuous quality improvement efforts, which positively impact patient care and overall organizational performance (Leyer et al., 2021; Fletcher, 1993). Top management commitment is essential in successfully implementing Lean Six Sigma and other quality improvement initiatives within healthcare organizations (Gowen et al., 2012). Their support provides the necessary resources and direction to achieve superior quality goals and create a quality-oriented environment (Harrington, 2007).

Continuous quality improvement is a gradual approach to process improvement that involves ongoing efforts to enhance patient care and satisfaction, as well as performance monitoring and reporting to sustain improvements (Evans and Lindsay, 2011). Six Sigma initiatives focus on radical breakthrough strategies to identify and reduce errors and variations in healthcare processes (Furterer, 2011). Lean initiatives prioritize patient requirements by reducing costs and accelerating the delivery of medical services through techniques such as process mapping, value stream mapping, and just-in-time approaches (Hagan, 2011).

Patient safety is crucial in healthcare and involves avoiding and preventing adverse outcomes or injuries in the delivery of healthcare services (Burstrom et al., 2014). A robust patient safety culture, including teamwork, communication, and a supportive work environment, plays a vital role in ensuring patient safety and quality of care (El-Jardali et al., 2014).

Value-added activities in healthcare refer to the processes that directly contribute to meeting customer demands and needs, such as reducing patient wait times and efficiently managing time while delivering services (Joosten et al., 2009). Teamwork is crucial for effective healthcare delivery, fostering collaboration between roles, employees, managers, and suppliers, ultimately resolving organizational issues and improving patient care (Sabry, 2014).

In summary, Lean Six Sigma and its various components have proven to be effective tools for enhancing the quality performance of healthcare organizations, improving patient care, and increasing overall organizational efficiency and effectiveness (Laureani et al., 2013; DelliFraine et al., 2010; Liberatore, 2013; Ahmed et al., 2021; Gowen et al., 2012; Hagan, 2011; Burstrom et al., 2014; Joosten et al., 2009; Sabry, 2014).

2.4 Relationship Between Lean Six Sigma and Health Care

Based on a review of the literature (Lee and Choi, 2006; Zu et al., 2008; Kathan, 2008; Kennedy and Daim, 2010; Shafer and Moeller, 2012; D'Andreamatteo et al., 2015), the current study has constructed a conceptual framework and hypotheses. Six hypotheses are mapped into the conceptual research framework in Figure 1. The six hypotheses are explained in the following sections, along with the connections between the research variables.

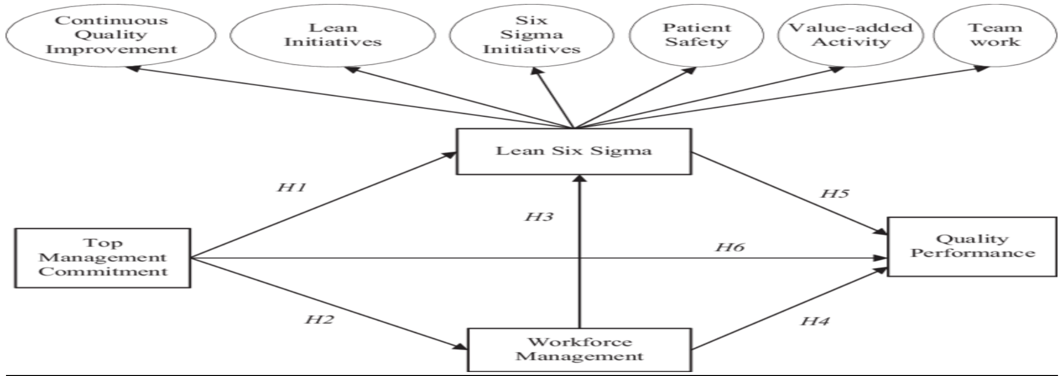


Figure 1: Conceptual Framework

2.4.1 Relationships of top management commitment with Lean Six Sigma and workforce management

Top management commitment is a crucial factor in the successful implementation of Lean Six Sigma (LSS) initiatives, as demonstrated by notable executives like Jack Welch of GE, Bob Galvin of Motorola, and Lawrence Bossidy of AlliedSignal who oversaw LSS deployment in their respective companies (Lee et al., 2014). Senior management plays a significant role in making strategic decisions necessary for LSS implementation, and their authority and power are essential in incorporating LSS black belts (advisors to project leaders) and green belts (well-trained in quality problem-solving) into the organization's human infrastructure (Lee et al., 2014). Top management commitment not only influences the success of LSS initiatives but also promotes effective healthcare workforce management, leading to increased quality performance in healthcare organizations (Shafer and Moeller, 2012).

2.4.2 Relationship between workforce management and Lean Six Sigma

Workforce management plays a crucial role in supporting the implementation of the Lean Six Sigma (LSS) strategy, leading to improved organizational performance. It encourages teamwork and employee dedication, which are essential elements for successful LSS initiatives (Guesalaga, 2014). By promoting employee participation in quality management performance and recognizing their contributions through rewards and recognition, workforce management fosters a culture of continuous improvement and commitment to the organization's high-quality goals (Dhar, 2015).

The involvement and accomplishments of employees in LSS initiatives are positively influenced by workforce management practices, thereby increasing employee interest in quality improvement and overall commitment to achieving the organization's quality performance objectives (Dhar, 2015).

2.4.3 Relationship between workforce management and quality performance

Effective workforce management plays a critical role in improving the quality performance of healthcare organizations. To achieve high-quality performance, healthcare organizations need to restructure their human resources planning to ensure fairness and equity in managing their workforce (Ehrhardt et al., 2011). Kennedy and Daim (2010) emphasize the importance of enhancing the competencies of the health workforce, including aspects like patient satisfaction, nurse and physician care, and accurate patient registration, across all levels of hospital services.

Efficient workforce management not only helps prevent early retirement of hospital specialists but also increases staff retention and satisfaction (Kennedy and Daim, 2010). However, healthcare workforce management may face specific challenges, such as duplicated services by hospital staff, lack of continuity between service providers, low pay for hospital staff, long working hours, shortage of nursing staff, insufficient doctors in emergency rooms and surgical areas, and doctors seeking higher specialty training abroad (Rechel et al., 2006). Overall, effective workforce management positively impacts the quality performance of hospitals and healthcare organizations (Ehrhardt et al., 2011).

2.4.4 Relationship between Lean Six Sigma and quality performance

The Lean Six Sigma (LSS) strategy is widely used in healthcare organizations to improve value-added activities demanded by patients. It focuses on continuously enhancing healthcare quality performance by reducing non-value-added activities, such as waste and unnecessary services (Abdallah, 2014). LSS employs Root Cause Analysis (RCA) to identify inefficiencies and errors in organizational processes, leading to the elimination of these issues and an improvement in quality performance (Khanchanapong et al., 2014).

By applying the LSS methodology, healthcare organizations can reduce waste and errors while simultaneously enhancing service quality in various areas, including nurse care, physician care, hospital environment, patient safety, hospital stay, and waiting time. This approach ensures the level of healthcare service quality and contributes to patient loyalty (Chiarini and Bracci, 2013). Overall, the implementation of the LSS methodology is expected to enhance healthcare quality in the context of this investigation.

2.4.5 Relationship between top management commitment and quality performance

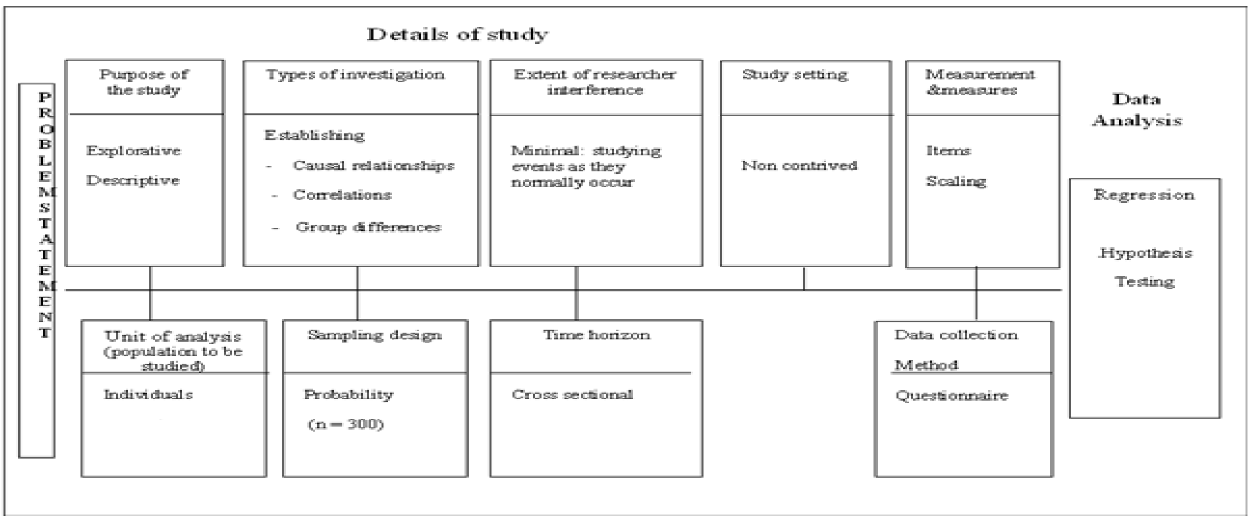
High management support plays a critical role in healthcare organizations, providing them with the necessary resources and guidance to elevate performance standards. It fosters a collaborative and learning-oriented work environment, facilitating the implementation of the quality management system and ultimately leading to higher customer satisfaction (Yeung et al., 2005; Harmancioglu et al., 2010). Senior management's strategic decision to adopt the Lean Six Sigma (LSS) approach enables the establishment of a robust quality management system in the healthcare organization, contributing to the improvement of quality performance (Zeng et al., 2015).

Top management commitment is instrumental in implementing the LSS strategy, as it helps healthcare organizations achieve superior quality goals by raising awareness and commitment among staff (Kathan, 2008). In the context of this study, senior management commitment is expected to have a positive impact on healthcare quality performance.

Many Indian hospitals have begun to use the LSS method to improve their quality performance in an effort to reduce these medical issues. However, such studies are less in number and the methodologies applied to evaluate such hospital have been mostly elementary. There is an urgent need to conduct such studies in the Indian context, especially in the light of growth in the Indian healthcare in the lasty three decades now. This work has proposed to study the influence of top management commitment on lean six sigma and workforce management which further influence quality performance.

3. Research Methodology

To accomplish the goals of this study, a research design is a step-by-step research plan. The first stage in acquiring the data required for data analysis, answering research questions, and resolving the issue that sparked the project is planning the study. The research design approach outlined by Sekaran and Bougie (2010) and depicted in Figure 3.1 is applied in this work. Each cell reflects a unique set of choices or actions that were made to guarantee the validity of the research but are not mutually exclusive. The most effective options are included in each cell, but the text focuses on the justification for and use of the chosen options.



3.1 Research Process

Source: Sekaran and Bougie, 2010

3.1 Study's Objectives

The three most popular and successful research objectives, according to Babbie (2007), are exploration, description, and explanation. Exploratory research was used to build the conceptual model for the investigation. Exploratory research is an excellent method for learning new things, formulating questions, and looking at things differently.

3.2 Study Interference and the research environment

The constructs/factors occurred organically without any intervention from the researcher because they were not adjusted.

3.3 Analysis Unit

Since it must be relevant to the population the researcher is analysing, the sample portion of the study is essential. An adequate sample unit can predict and replicate the traits of the target population. Due to the nature and scope of the study, respondents from Kerala's clinical laboratories institutions were selected as the unit of analysis for all stages of the research.

3.4 Timeframe

This study's cross-sectional analysis was done because of the population's diversity. In 2022, a pilot study was carried out.

3.5 Sampling Design

Sampling design entails choosing an acceptable subset of a target group for the goal and structure of a research investigation.

3.6 Population

The study's research population will be respondents from Clinical Laboratories of selected hospital in Kerala.

3.7 Technique for gathering data

The researcher used a standardised questionnaire (using scales) to get replies from the respondents. The questionnaire was thoughtfully created to gather accurate data about the current research problem.

3.8 Sample frame

Information was acquired from specific clinical laboratories from Kerela in the study. The study considered public colleges.

3.9 Sample Size

For the final study, a sample size of 300 was chosen using the sample size equations.

Sample size is a crucial statistical concept in empirical studies that determines the number of observations or replicates needed to assess the variability of a phenomenon. It represents the selected portion of the population for a survey or experiment. Researchers calculate the sample size by setting the margin of error, which indicates the desired precision between the sample estimate and the true population value. By using the confidence interval equation and adjusting it for the margin of error, they can find the appropriate sample size "n" required for their study. This calculation ensures the accuracy and reliability of research findings based on a sample population.

For instance, the population size is 1295, a 95% confidence level, and a 5% margin of error, a sample size of 300 is needed to determine whether the true value is within 5% of the measured or surveyed value.

$$\text{Finite population: } n' = \frac{n}{1 + \frac{z^2 \times \hat{p}(1-\hat{p})}{\varepsilon^2 N}}$$

3.10 Sampling Method

This investigation will use a multi-stage sampling strategy due to the dispersed nature of the research population. The sample selection method applied for the investigation is known as multi-stage sampling. In the first step of the process, the sample size for the study will be proportionately distributed among the clinical laboratories. The next step will include choosing several departments.

The collected data were statistically processed using the proper statistical methods to achieve the study's goals.

All the facts are listed in Table 3.1.

Table 3.1 Sampling Distribution

Optimum Sample size = 300
Number of questionnaires distributed = 350
Effective sample size = 300

Source: Authors' own

3.11 Research Instrument

A research instrument is a tool used to collect and preserve data for analysis and knowledge generation. One commonly used research instrument is a questionnaire, which gathers factual information, supports observations, or measures attitudes and opinions. Using a multipoint rating system in the questionnaire is justified as it allows for more accurate and workable item-level factor analyses compared to binary items. Multipoint scales, such as Likert and semantic differential scales, provide better psychometric properties due to their increased variation in responses.

3.12 Conceptual Design

Before developing the questionnaire, researchers assessed the expected data from the target respondents and carefully considered the overall structure, content, and data of the surveys. The questions were designed to be easily understandable and clear to the respondents, using closed-ended questions and concise statements. The language used in the questionnaire was tailored to the intended responders. The instrument was modified from various sources based on a thorough analysis of the relevant literature and expert recommendations, and it was developed to capture information on the study's variables. The questionnaire consists of two parts: one focused on the factors studied, and the other on the participants' profiles.

3.13 Data Collection Techniques

The sources used in the current research can easily be divided into primary and secondary sources depending on the data requirements.

3.14 Information sources

The study utilized data from various sources. Researchers designed a well-structured questionnaire based on existing scales from different references to collect responses from subjects. The questionnaire was modified during pre-testing to align with the study's objectives and ensure relevancy. Careful consideration was given to the order and construction of questions to encourage excellent participant responses, and any concerns about the questionnaire were addressed. Additionally, secondary sources, such as dissertations, theses, magazines, reports, and research papers, were used to supplement the study's components. Various online resources like e-libraries, forums, databases, and educational websites were accessed to gather the necessary material for the research.

4. Analysis and Interpretation

Analysis and interpretation are essential steps in the research process. They work hand in hand to provide comprehensive answers to the research questions and enhance understanding. Proper statistical analysis is necessary for meaningful interpretation, and interpretation relies on adequate analysis. In this study, statistical analysis and interpretation of data were conducted using the SPSS program, employing descriptive, inferential, and other statistical methods. Descriptive statistics were used to define the sample characteristics, while regression with structural equation modeling (SEM) was used to test important hypotheses and examine multiple relationships between independent and dependent variables. Exploratory factor analysis (EFA) determined item contributions to each factor, followed by confirmatory factor analysis (CFA) to assess item validity and reliability. Path analysis was then used to illustrate how independent variables influenced dependent variables. The questionnaire was distributed to respondents in selected hospitals' Clinical Laboratories in Kerala to gather data for the study.

4.1 Data screening and cleaning

Quality control checks were made once the data had been entered into SPSS 23 to ensure it was fit for analysis. Here, among the tests taken into account are those for "missing data," "outliers," and "unengaged" replies (Gaskin, 2016). Analysis was done on 171 replies after deleting non-functional ones. Before analysis, the data was cleaned to remove "outliers," "unengaged" responses, and missing responses in order to meet the study's objectives. For the analysis, the SPSS 25.0 program was employed.

4.2 Demographic Profiles of the Respondents

This section gives a broad summary of the respondents' demographics via frequency distribution. After the data was collected, it was arranged in tables using a frequency distribution. A frequency distribution shows the frequency of repeated items in a graphical or tabular style. It counts the occurrences of things or visually depicts their frequency. For the current work, a total of 171 were chosen as respondents.

Profile of the respondents

The respondent profile with relation to the following categories:

- Gender
- Age
- Education
- Residence
- Type of employment
- Income
- Healthcare facility category

Table 4.1 Demographic profile

Category	Type	Frequency	Percentage
Gender	Male	95	55.6%
	Female	76	44.4%
	Others	0	0.0%
Age	18-25 years	56	32.7%
	25-30 years	54	31.6%
	30-49 years	37	21.6%
	Above 49 years	24	14.0%
Education	Graduation	33	19.3%
	Post Graduation	120	70.2%
	Others	18	10.5%
Residence	Rural	54	31.6%
	Urban	117	68.4%
Occupation	Doctor	30	17.5%
	Paramedic	24	14.0%
	Administration	88	51.5%
	Nurse	14	8.2%
	Support Staff	12	7.0%
	Others	3	1.8%
Income	Up to Rs. 3 lacs	22	12.9%
	Rs. 2 to 5 lacs	86	50.3%
	More than Rs. 5 lacs	63	36.8%
Category	Public	21	12.3%
	Private	146	85.4%

Others	4	2.3%

Demographic profile

Table 4.1 and Figure 4.1 (a) to Figure 4.1 (g) shows the participants' profile. There are more males than females, the highest number of respondents is in the age group of 18-25 years, most of the respondents are postgraduates, most of them are urban residents, most of them are in the administration section,

4.3 Descriptive Statistics

In the section on descriptive statistics, the factors' "mean" and "standard deviation" are calculated. Table 4.2 and Figure 4.2 illustrate the Means and dispersion of the different components. The variable "Quality Performance" has the lowest mean, and the variable "Patient safety" has the most excellent mean. The standard deviation number for "Barriers to six sigma" is the highest, whereas the standard deviation value for "Six Sigma" is the lowest.

Table 4.2 Descriptive Statistics

Factors	Mean	Std. Deviation
REL	3.4572	1.19708
BAR	3.2295	1.21815
FCL	3.7060	1.21453
CQI	3.6160	0.92392
TMC	3.4667	1.11609
SSI	3.2203	1.09375
WM	3.4760	1.11443
TW	3.3996	1.08020
PSI	3.8090	1.15917
LI	3.3645	1.07816
VA	3.5945	1.07588
QP	3.0593	1.13450
SS	3.5006	0.57533

Note: REL-Relevance of Six-sigma; BAR-Barriers of Six Sigma; FCL-Facilitators of Six; TMC- Top Management Commitment; WM-workforce management; QP-quality performance; CQI-continuous quality improvement; LI-lean initiatives; SSI-six sigma initiatives; PSI-patient safety; VA-value-added activity; TW-team work: SS-six sigma.

4.4 Remarks on Normality, Linearity, Multicollinearity and Auto Correlation

The study's statistical analysis yielded acceptable results for normality, linearity, multicollinearity, and autocorrelation. This indicates that the data follows a roughly normal distribution, the relationship between independent and dependent variables is linear, there is no significant correlation between independent variables, and there is no autocorrelation in the data points. These positive findings ensure the validity and reliability of the statistical analysis and support the accuracy of the study's conclusions and inferences.

4.5 Testing the Conceptual Model

4.5.1 Exploratory Factor Analysis

Exploratory factor analysis was conducted to see if the items (questions of each component utilised in the study) match their distinct factors. The "factor extraction" was done using "principal component analysis" (Nunnally, 1978), and the Rotation was done using the "varimax" and "Kaiser Normalisation" techniques. The variables were chosen because they explained more than half of the overall variation in the data and had "Eigenvalues" (factor retention thresholds) larger than one.

4.5.2 KMO and Bartlett’s Test

To establish whether the data were suitable for running EFA, sampling adequacy was assessed using the "KMO" (Kaiser et al.) and "Bartlett's test of sphericity". Table 4.3 shows that "Bartlett's test of sphericity" was 5782.565 at 595 degrees of freedom, and the value for "KMO" is 0.751 (>0.5). Therefore, it can be assumed that variables were linked.

Table 4.3 KMO and Bartlett's Test

Items		Value
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.751
Bartlett's Test of Sphericity	Approx. Chi-Square	5782.565
	Df	595
	Sig.	.000

4.5.3 Communalities

The term "communality" describes how effectively a component of a factor links to another. The communality scores are related (greater than 0.4) and fall under the threshold limits.

4.5.4 Factor Extraction Matrix

Only factors with Eigen values are more significant than one was used to extract factors, and as a result, factors collectively accounted for more than 50% of the total variation (Hair et al., 1995).

4.5.5 Rotated Component Matrix

The "rotated pattern matrix" obtained from "EFA", which shows all the items loaded on their respective factors with no cross-loadings.

4.5.6 Reliability

The instrument's reliability must be evaluated so the researcher can use the scale to gather more accurate responses from respondents. "SPSS 25.0"'s "Cronbach's alpha test" was utilised to examine the reliability. All of the alpha values are more than 0.60 (Hair et al., 2010).

4.6 Structural Equation Modeling

Because it enables examining connections between numerous independent and dependent variables, "structural equation modelling" (SEM) is frequently employed in research. The first part of the two-stage structural equation modelling process is called "exploratory factor analysis", which examines the underlying structures of variables. The measurement model must then be validated by a "confirmatory factor analysis" (CFA) after an "exploratory factor analysis" (EFA). The measuring scale and the theoretical model (research model employed in this work) developed through "EFA" are examined for validity and reliability. Following correlation analysis (CFA), "path analysis" (also known as a structural model) is used to examine the connections between latent variables. Hypotheses are tested during this stage.

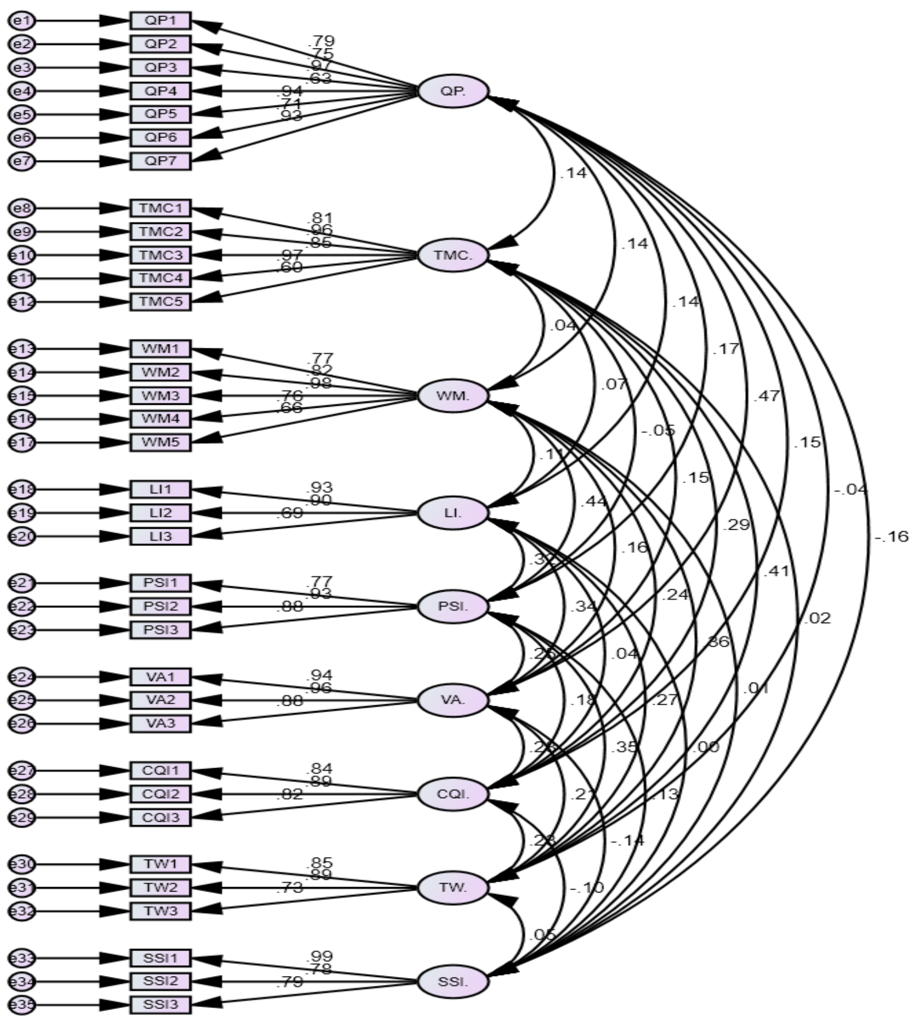
4.7 Confirmatory Factor Analysis

A confirmatory factor analysis assessed the reliability of a measurement model (Figure 2). It helps when determining the measurement model for each construct to know which observed variables (items) to keep and which to exclude.

Table 4.4 Summary of Overall Measurement Model

Fit Indices	Overall Measurement Model	
	Threshold Level	Observed Value
“CMIN/DF” (Chi-Square/Minimum Discrepancy Function by Degrees of Freedom divided)	≤ 5	3.83
“GFI” (Goodness of the fit index)	≥ .70	.881
“RMSEA” (Root mean square error	< .10	.051

of approximation)		
“NFI” (Normed Fit Index)	≥ .80	.897
“CFI” (Comparative fit index)	≥ .80	.916



Index evaluation is crucial to determining whether the proposed model fits the data obtained and, in some situations, to modify the model to suit the data better. The following indices were utilised in this study (Table 4.4).

Figure 2 Measurement Model

4.8 Validity and Reliability of the Measurement Model

The composite reliability for all the variables is found higher than the required threshold score of 0.60. The results obtained as standardised loadings are more than 0.60, demonstrate convergent validity. A value of "AVE" ("Average Variance Extracted") greater than 0.50 also demonstrates convergence validity. For all constructs along the diagonal of the matrix, the inter-construct correlation of the composite variable is less than the square root of the AVE. Therefore, statistical data supports the validity of discrimination.

4.9 Structural Model

In this study, the structural model enables the assessment of associations between independent and dependent variables. The initial structural model tested the relationships between the sub-factors. Model fit index values are shown in Table 4.5, demonstrating how well the existing structural model matches the data in figure 3. Table 4.6 provides evidence for each relationship between the independent and dependent variables.

Table 4.5 Structural Model Fit Indices

Fit Indices	**Structural Model Fit**	
	Adequate fit	
CMIN/DF (Chi-Square/Minimum Discrepancy Function by Degrees of Freedom divided)	≤ 5	3.22
GFI (Goodness of the fit index)	≥ .700	.833
RMSEA (Root mean square error of approximation)	≤ .10	0.057
NFI (Normed Fit Index)	≥ .80	.891
CFI (Comparative fit index)	≥ .80	.890

Source: Malhotra et al. (2011), Kline (2011), Byrne (2010), Holmes-Smith et al. (2004), Hu and Bentler (1999).

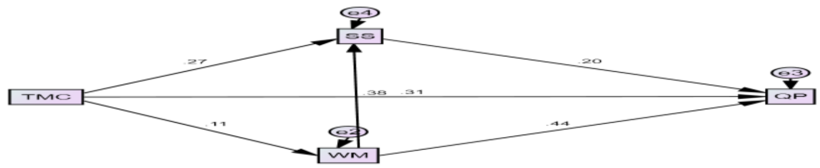


Figure 3: Structural Model

Table 4.6 Unstandard Regression Weights

Dependent Variable	Direction	Dependent Variable	Estimate	S.E.	C.R.	P
WM	<---	TMC	.113	.076	1.480	.039
SS	<---	TMC	.137	.035	3.954	***
SS	<---	WM	.198	.035	5.711	***
QP	<---	WM	.407	.057	7.166	***
QP	<---	TMC	.286	.054	5.268	***
QP	<---	SS	.358	.115	3.108	.002

Standard Regression Weights			
Dependent Variable	**Direction**	**Independent Variable**	**Estimate**
WM	<---	TMC	.113
SS	<---	TMC	.266
SS	<---	WM	.384
QP	<---	WM	.440
QP	<---	TMC	.309
QP	<---	SS	.199

4.10. Relationship Results

1. **Impact of Top management commitment on workforce management**

   Top management commitment positively and significantly influences workforce management (β= 0.11; p<0.5; R^2=0.21).

2. **Impact of Top management commitment on lean six sigma**

Top management commitment positively and significantly influences lean six sigma (β= 0.26; $p<0.5$; $R^2=0.25$).

3. **Impact of workforce management on lean six sigma**

   Workforce management positively and significantly influences workforce management (β= 0.38; $p<0.5$; $R^2=0.25$).

4. **Impact of workforce management on quality performance**

   Workforce management positively and significantly influences lean six sigma (β= 0.26; $p<0.5$; $R^2=0.46$).

5. **Impact of workforce management on quality performance**

   Workforce management positively and significantly influences workforce management (β= 0.30; $p<0.5$; $R^2=0.46$).

6. **Impact of Lean six sigma on quality performance**

   Lean six sigma positively and significantly influences lean six sigma (β= 0.26; $p<0.5$; $R^2=0.19$).

5. Findings, Discussion, Conclusion and Recommendations

5.1 Findings

The pilot study involved preliminary testing of an instrument, which included a survey with 35 participants from clinical laboratories in Kerela, India. Fifty functional solutions were selected for statistical analysis to ensure reliability. The study utilized SPSS 26.0 and exploratory factor analysis (EFA) to improve the research. Data purification processes were applied before EFA, including outlier elimination and handling missing elements. The study identified twelve factors within the dataset.

The data collection adequacy was confirmed using Bartlett's Test of Sphericity and KMO metrics. Principal Component Analysis revealed eight factors accounting for over 81% of data variation, meeting the threshold for social sciences research. The instrument's reliability was assessed using Cronbach's alpha values, which were above the threshold (greater than 0.60). The split-half test was also conducted to evaluate consistency.

Based on factor analysis and descriptive analysis, the study identified the most essential and least significant aspects of relevance, facilitation, and barriers concerning Six Sigma. The main research study involved 171 participants from various clinical laboratories in Kerela, India.

Causal research design was used, and EFA was performed on 513 functional responses. The questionnaire used in the study demonstrated a decent level of validity.

Confirmatory Factor Analysis (CFA) with AMOS 26.0 validated the factor structure identified earlier. The scale showed strong convergent and discriminant validity, with satisfactory fit indices. A path analysis was conducted to investigate the connection between factors, and all nine hypotheses were confirmed. Overall, the research successfully improved the scale and validated its use in further studies.

5.2 Discussion

The study found that top management commitment positively and significantly influences workforce management, quality performance, and lean six Sigma in clinical laboratories in Kerela, India. The dedication of top management leads to improved workforce management, and their commitment to lean six Sigma positively impacts its implementation. Effective workforce management is crucial for successful lean six Sigma deployment and also positively affects the quality of work performed. The research supports the idea that top management practices have a noticeable influence on quality performance, and incorporating lean six Sigma approaches improves overall quality performance. The study reveals a substantial connection between top management commitment and the quality performance of healthcare organizations in Kerela.

To establish a strong link between top management commitment and quality performance, healthcare organizations should focus on planning, prioritizing, resource allocation, budgeting, training, and proper evaluation and reward systems through the lean six Sigma process assessment. Implementing informal strategies such as supportive management, employee suggestion programs, periodic employee reviews, feedback solicitation, and managing employee relations can also enhance the relationship between top management commitment and quality performance.

To improve overall healthcare organization performance, practitioners and policymakers should focus on understanding healthcare problems, fostering a culture of change and patient safety, continuous monitoring and reporting of performance findings, testing change strategies, and involving patients and stakeholders. Additionally, following guidelines such as selecting strategically significant quality projects, providing training to healthcare staff on quality tools and applications, and developing design skills can improve the quality performance of clinical laboratories.

In conclusion, the study emphasizes the significance of top management commitment, workforce management, and lean six Sigma in enhancing quality performance in healthcare organizations. Implementing the recommended strategies and guidelines can lead to improved performance and patient satisfaction in clinical laboratories.

5.3 Conclusion

The study investigates the relationship between workforce management, lean six Sigma, top management commitment, and quality performance in clinical laboratories in Kerela. Over the past three decades, the overall work done in six Sigma in healthcare has significantly increased. The research highlights the positive and significant impact of top management commitment on lean six Sigma, quality performance, and workforce management. Additionally, it shows that both lean six Sigma and workforce management influence quality performance.

The study's findings suggest that healthcare firms should fully integrate six Sigma into all aspects of their operations to streamline and enhance functioning. The research makes empirical contributions to the healthcare sector's understanding of top management commitment, workforce management, and quality performance.

Furthermore, the study emphasizes the importance of private hospitals in Kerela having better staff management and top management support. To improve overall performance in public hospitals, policymakers should consider factors such as developing an understanding of healthcare issues, fostering a culture of change and patient safety, continuous performance monitoring, testing change strategies, and involving key stakeholders.

5.4 Implications

The study explores the relationship between workforce management, lean Six Sigma, top management commitment, and quality performance in healthcare laboratories in Kerela. The findings have practical implications for various stakeholders, offering insights to help healthcare laboratories achieve their objectives. Implementing Six Sigma as a strategy for operational and service excellence can benefit senior managers and policymakers in the healthcare industry. It can lead to improved operational performance, cost-effectiveness, and process quality, as well as enhanced patient satisfaction and loyalty.

The study emphasizes the importance of top management commitment in successfully implementing quality improvement initiatives in healthcare organizations. For healthcare organizations to achieve better quality goals, top management must define specific quality objectives, prioritize quality standards, and allocate resources for ongoing quality improvement.

Workforce management plays a crucial role in healthcare organizations by supporting process management, empowering employees to participate in quality-related decision-making, and providing training opportunities to enhance employee skills and performance. The commitment shown by employees is a significant factor in determining the effectiveness of workforce management.

Quality performance in clinical laboratories is highly influenced by both leadership and employee dedication. Lean Six Sigma methodology can help healthcare organizations minimize errors, improve operational efficiency, and prioritize patient satisfaction. By focusing on client needs and eliminating waste, healthcare organizations can provide more affordable and efficient services to their patients.

Implementing Six Sigma in healthcare can shift the perspective of healthcare professionals towards prioritizing patient satisfaction and delivering better care. By reducing unnecessary expenditures and streamlining operations, healthcare providers can improve patient outcomes and reduce hospital stay durations.

The study has several flaws, including the use of a cross-sectional design, limited geographical representation, potential age group bias, and small sample size, which may have impacted the generalizability of the findings. Future research directions could involve adopting experimental or longitudinal designs, analyzing healthcare infrastructure across different regions in India, including diverse population segments, and exploring mediating factors and other psychographic aspects. Expanding the scope of research to multiple geographical locations may also be beneficial.

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