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Faculty of Graduate Studies

Department of Administrative and Financial Sciences

Master Program in Quality Management in Healthcare Institutions

Improving The Adherence Rate To Safe Surgeries Checklist In Orthopedic Surgeries At Palestine Medical Complex Using Lean Six Sigma Methodology.

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Declaration

I declare that, except where explicit reference is made to the contribution of others, this thesis is substantially my work and has not been submitted for any other degree at the Arab American University or any other institution.

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Dedication

I immensely thank my beloved father, mother, and family for their unwavering support, encouragement, and sacrifice. They have always stood by me throughout my life and during this achievement. In addition, I am eternally grateful to my husband, daughter, sons, and everyone else who helped me reach this goal.

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Abstract

Patient safety (PS) during surgical procedures is a top priority in healthcare. The Safe Surgery Checklist (SSC) is widely used to reduce errors and improve surgical outcomes. However, adherence to this checklist can vary across healthcare facilities, including in Palestine.

This study aims to improve PS in orthopedic surgeries at the PMC using the LSS methodology to increase staff adherence to the SSC. The study analyzes existing surgical processes and identifies areas for improvement in surgical procedures. It also identified factors contributing to non-adherence to the checklist.

The study applied a retrospective data / cross-sectional quantitative research approach to determine the impact of LSS on PS and adherence to the SSC in improving the quality of services in operating rooms.

In this study, we distributed 131 survey questionnaires to the respondents and received 113 usable responses (86.3% response rate). (PLS-SEM) was used to assess the effect of LSS on PS and adherence to the SSC. It highlighted the effectiveness of LSS in optimizing healthcare processes and stressed the importance of a systematic approach to improving PS in surgical settings.

The rest of the analyses used (SPSS) software 27th edition, study key variables were analyzed using (ANOVA) with the Scheffé post-hoc test. Pearson's correlation coefficient was used to examine linear associations between key variables. P-value < 0.05 was considered statistically significant.

The results showed a significant improvement in adherence rates to the SSC, increasing from 62% to 86% and reaching 96%. This led to a reduction in surgical complications and improvements in PS outcomes. The study also found that improving adherence to the SSC directly affected the quality of services and PS and acted as a mediator between LSS and QI, and between LSS and improving PS. The study argued that adherence to the SSC is crucial for enhancing quality by effectively adopting the LSS. Future research should confirm these hypotheses across a more comprehensive sample, including other healthcare entities.

Last but not least, the research guided how the LSS methodology can enhance PS, improve adherence to the SSC, and enhance the quality of hospital services. Adherence to the SSC can create links between LSS and QI and between LSS and PS in healthcare sectors.

Key Words: Lean Six Sigma, Patient Safety, Quality Improvement, Safe Surgery Checklist.

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List of Definitions of Abbreviations

Abbreviations	Title
AAUP	Arab American University-Palestine
CEO	Chief Executive Officer
CNO	Chief Nursing Officer
CSF's	Critical Success Factors
DMAIC	Define Measure, Analyze, Improve and Control
ECG	Electrocardiography
HIS	Health Information System
IPO	Infection Prevention Officer
LoS	Length of Stay
LSS	Lean Six Sigma
MMU	Medication Management and Use
MoH	Ministry of Health
PCD	Problem Context Diagram
PLS-SEM	Partial Least Squares Structural Equation Modeling
PMC	Palestine Medical Complex
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses

PS	Patient Safety
PSFHI	Patient Safety Friendly Hospital Initiative Manual
PT	Patient
QC	Quality Coordinator
QI	Quality Improvement
SIPOC	Suppliers, Inputs, Process, Output, Customer.
SSC	Safe Surgical Checklist
SSI	Surgical Site Infections
UNRWA	United Nations Relief and Works Agency
VoC	Voice of Customer
VSM	Value Stream Mapping
WHO	World Health Organization

Chapter One: Introduction

1.1 Overview

In this chapter, we outline the general structure of this research. It begins with a background of the study's setting at the Palestine Medical Complex (PMC) in Ramallah, along with a brief description of the scope and services provided at this hospital. Following this, the research problem is identified, focusing on the impact of ineffective enrollment of the safety surgical checklist on patient safety. The importance and justification of this study are then provided to clarify this problem and its effect on patient safety, and the quality of care provided.

The study's primary aim, objectives, and methodology to address this problem are also presented. The objectives are designed to be operational, achievable, and detailed later to ensure proper implementation.

This chapter also includes a separate section presenting the researcher's questions that the study aims to address. Each question is directed towards the statement of each objective to provide answers related to those goals.

Lastly, the hypotheses and assumptions about the dependent and independent variables, as well as the limitations of the research study (categorized into geographic, time, and setting limitations), are provided.

1.2 Profile of the Palestine Medical Complex (PMC)

Palestine Medical Complex (PMC) is one of the largest governmental hospitals in Palestine. It provides general and specialized services and is a referral hospital for other hospitals, showcasing its expertise and trustworthiness. The scope of the services includes some specialized services, and it delivers general and specialized services in its five main wings distributed in six semi-connected buildings. The general services include emergency rooms, general surgeries, gynecology, cardiac and internal medicine, diagnostic laboratories and radiology, pediatrics, intensive care units, and human resources departments. On the other hand, PMC provides specialized services including open heart surgeries for adults and pediatrics, kidney transplantation, neurosurgeries, orthopedic joint replacement, thoracic and

vascular, and others. The percentage of referrals from other (MoH) hospitals annually is 35% on average (PMC Quality Department, 2023).

At PMC, the scale of operations is awe-inspiring, with a total of 516 patient beds and a diverse team of 1120 health workers. This team, which includes 350 doctors and surgeons, 450 nurses, 120 allied professionals, 170 administrators, 18 pharmacists, and others, is dedicated to delivering quality healthcare. (PMC Quality Departement, 2023)

With 15 operating theaters and 28 outpatient clinics, PMC caters to a significant patient volume, with approximately 120000 patients visiting annually. The ER department efficiently handles 150000 cases each year. The high occupancy rate of 99% and the average length of stay of 2.5 days underscore the hospital's commitment to providing efficient and safe patient care (PMC Quality Department, 2023).

PMC's commitment to quality care is evident in the establishment of its quality unit in 2011 and its implementation of general principles of quality in healthcare settings. The hospital was chosen by the health minister in 2012 to lead a patient safety standards initiative. This initiative, composed of five main domains containing 136 different patient safety standards categorized into three main types: critical, core, and developmental, is a testament to the hospital's dedication to patient safety. The implementation process is designed to ensure the adoption of the most essential standards followed by the next important ones (MoH Annual Report 2022).

In 2015, the PMC was assessed by WHO experts and succeeded in implementing 109 standards, passing level three, and starting to implement standards of level four, which are more likely to be developmental standards (PMC Quality Departement, 2023).

One of those critical standards was the implementation of the SSC.; the adherence rate was variable in different types of surgeries and from month to month. The PMC annual report, 2023, shows that the compliance rate should exceed 95% while the implementation rate varies from 62% to 86% over the past five years; several approaches were used to enhance the compliance rate. To maintain higher compliance rates, the Lean Six Sigma (LSS) methodology and tools are utilized in this research to improve patient safety and compliance rates by implementing the Safe Surgery Checklist. The research took place in the operations rooms department where LSS was implemented by utilizing the DMAIC methodology (Define,

Measure, Analyse, Improve, and Control) approach using a series of improvement tools to identify sources of lack of compliance and to develop improvement strategies that would lead to raising compliance in a process or system.

The research was conducted in the orthopedic operations room as a pilot case, allowing us to test our methods and strategies thoroughly. After validation, the findings can be generalized to all operating rooms, ensuring a comprehensive approach to improving patient safety and compliance rates. Table (1.1) shows the number of surgeries done at PMC in 2022:

Table (1.1): Total number of surgeries done at the PMC during 2022

Month	**Surgeries**
01\2022	1171
02\2022	677
03\2022	1065
04/2022	566
05/2022	898
06/2022	930
07/2022	934
08/2022	1447
09/2022	1207
10/2022	1215
11/2022	1271
12/2022	1255
TOTAL	**12636**

Source: MoH Annual Report 2022

1.3 Safe Surgery Checklist Background

The WHO Patient Safety Standards Initiative Assessment Manual 2009 clarifies that the Safe Surgery Checklist is not just a tool but a critical component of patient safety and quality throughout the safe surgery guidelines, experience, and requirements. Its appropriate completion is often the primary mechanism utilized to ensure patient safety. The checklist is a process for reviewing and verifying critical components in patient identification before, during, and post-incision. It is the most valuable process for preventing "Never Events" such

as wrong-person, wrong-site, wrong medication, and wrong-procedure errors. To maintain the quality of hospital care throughout a patient's surgical experience, the quality department at the PMC provides evidence-based practices bundled together to prevent intra-operative complications and reduce postoperative adverse events. It is expected to conform to the quality measures to provide high-quality care. Five of the safety measures can be accomplished before the start of any surgical procedure. The SSC. contains three main phases during the surgical procedures, and all phases occur in the operating department. The phases are pre-entering the operating room in the recovery room, pre-incision inside the operating room (known as the time-out phase), and post-incision before leaving the operating room. Including pre-incision, time-out, and post-incision processes can ensure compliance and thus help prevent complications and infections. Patient safety measures in operative service involve the wrong-patient, wrong-site surgery time-out protocol, and postoperative measures. To provide a more robust approach to patient safety in operative services, the team should view the patient through the lens of rolled throughput yield (a concept that approaches patient safety as one cumulative process) and view the time-out protocol and safety measures as one consistent process. The performance of processes and steps is interrelated among doctors, nurses, surgeons, and anesthesiologists. Through the lens of rolled throughput, a patient should pass through the cumulative steps of the total safety process free of defects or issues (WHO, 2009).

1.4 Research Problem

The widespread adoption of the WHO Safe Surgeries Checklist has not been consistent across hospitals and surgical departments, leading to suboptimal improvements in patient safety during operative procedures. The main challenge lies in effectively implementing the checklist in operating theaters, which directly impacts patient safety and adherence to critical safety standards outlined by the WHO. Understanding the underlying reasons for this implementation challenge is crucial. One potential technique is the application of LSS principles and methodologies to identify and address the root causes of this implementation gap. However, there is limited research on using LSS to enhance the adoption and effectiveness of the WHO SSC.

The SSC is available through the Avicenna Health Information System (HIS) software at PMC, all surgical teams can fill out the form for each patient. A low adherence rate to implementation increases sentinel, adverse, and near-miss events that could lead to severe patient harm, it is estimated that 16% of major surgical procedure cases have morbidity complications; the use of SSC. can prevent eighty percent of them (Keijzer et al., 2017).

In this research study, it is noted that the PMC monitoring and auditing process from managers needs further support, and the daily operations rooms (OR) capacity needs to adequately match the demand of daily operation lists. Daily shortage and variation attributed to insufficient OR team, power, communications, and logistics. The PMC managerial team needs new, practical, powerful tools to enhance implementation and adherence to SSC. This study proposes the LSS. methodology as an advanced, straightforward approach to facilitate implementation and increase loyalty and compliance.

The problem with the PMC is that the patient safety indicators show a low adherence rate to implementing the SSC, not exceeding 86%. This may increase morbidity and mortality rates among patients who underwent surgical procedures.

This research study investigates how LSS tools and techniques can overcome the barriers to successfully implementing the WHO Safe Surgeries Checklist and ultimately enhance patient safety in our hospital's operative setting. Specific areas that could be explored include:

1. Identifying the key factors hindering effective WHO checklist adoption, such as organizational, cultural, and procedural issues.
2. Analyzing the current state of surgical processes using LSS methodologies to pinpoint waste, variability, and other inefficiencies that compromise patient safety.
3. Designing and testing LSS-based interventions to streamline the checklist implementation process and improve compliance.
4. Evaluating the impact of the LSS enhanced checklist implementation on crucial patient safety metrics and patient outcomes.

Addressing this research problem could provide valuable insights to help hospital leadership leverage the WHO Safe Surgeries Checklist more effectively by applying LSS principles, ultimately enhancing patient safety in the operative setting and other operational departments.

1.5 . Research Significance and Justification

The SSC is a critical tool that has been shown to improve patient safety and reduce surgical complications when implemented properly; implementing the SSC. constitutes an essential standard that measures patient safety practices that should be effectively adopted and implemented in all healthcare settings worldwide. However, studies have found that adherence rates to the full completion of the checklist can be low, ineffective, and suboptimal in many healthcare settings (WHO, 2009).

With consistent and thorough use of the SSC, the surgical teams can benefit significantly from its benefits. Incomplete or inconsistent use of the checklist means that critical safety steps may be skipped, increasing the risk of adverse events such as wrong-site surgery, retained foreign objects, patient harm, and surgical site infections (WHO, 2009).

Many studies and research have stated several factors that affect effective adherence rates. Russ et al. (2015) noted that some of the key factors contributing to poor adherence rates include:

1- *Lack of leadership buy-in and oversight:* Without solid support and enforcement from administrative and surgical leadership, teams may not prioritize consistent checklist use.
2- *Poor team engagement and communication:* If the surgical team does not believe in the checklist's value, some members may resist adequately completing it.
3- *Workflow disruptions:* Integrating the checklist into existing surgical processes can be challenging, leading teams to try to rush through it or skip steps.
4- *Insufficient training and education:* Surgical staff may need to fully understand the purpose and importance of each step in the checklist, reducing their motivation to use it properly.
5- *Organizational culture challenges:* In some settings, a culture of hierarchy and resistance to standardized protocols can undermine consistent checklist adherence.

Addressing these barriers to successful implementation is critical to ensuring the full patient safety benefits of the safe surgery checklist are realized. Improving adherence rates should be an essential quality improvement priority for any healthcare organization performing surgical procedures (Russ et al., 2015).

In the PMC, several factors contributed to the low staff adherence rate to implementing the SSC. for all surgical procedures in the operating theatre. This low adherence rate would increase risks

associated with patient harm since the WHO indicates the SSC. to enhance safety and eliminate morbidity and mortality.

Regarding surgical site infections, like any other surgical interventions, orthopedic surgeries correlate with increased surgical site infections in the PMC; the table analysis below shows an increased surgical site infections (SSI) during the first trimesters of 2023 to reach 15%, affecting patient safety, satisfaction, and quality of service. Additionally, those infections would contribute to an incremental increase in the cost and burden of service to the patient, staff, and system. Table(1.2) noted that infections affect 119 patients (7.8 %) from 1512 patients who underwent orthopedic surgical intervention in 2022.

Table (1.2): Number of SSI Reports in Orthopedic at PMC 2022

Month	**Total number of surgeries**	**Inflamed operations**	**Percentage of SSI**
1	154	8	5%
2	41	7	17
3	112	9	8%
4	69	6	9%
5	85	9	11%
6	105	9	9%
7	202	12	6%
8	203	13	6%
9	143	13	9%
10	157	12	8%
11	110	10	9%
12	131	11	8%
TOTAL	**1512**	**119**	**Total %: 7.8**

Quality Department- PMC 2023

This research study is the first in Palestine to introduce the LSS methodology and tools to enhance the effective implementation of the SSC to manage and mitigate related critical risks, reduce patient harm, and maintain patient safety and quality.

1.6 Surgical Safety Checklist Significance and Importance

Implementing the SSC has significantly reduced surgical complications and mortality rates (Haynes et al., 2009). However, studies have also highlighted challenges and variations in its adoption, highlighting the need for further optimization and standardization (Bergs et al., 2015; Raval et al., 2017).

Applying LSS methodologies to the SSC process can address these challenges by identifying and eliminating waste, reducing process variability, and promoting a culture of continuous improvement.

Orthopedic surgery, in particular, poses unique risks and complexities due to the invasive nature of procedures and the potential for complications such as surgical site infections, wrong-site surgeries, and postoperative complications. Optimizing the SSC specifically for orthopedic settings can enhance patient safety and minimize preventable adverse events, ultimately improving patient outcomes and reducing healthcare costs associated with complications and readmissions (Raval et al., 2017).

Justification: LSS has proven to be effective in various healthcare settings, including hospitals, clinics, and surgical environments (Denton & Denton, 2019). By applying its principles to the SSC, this research aims to identify and eliminate non-value-added activities and waste in the checklist process, streamlining workflows and improving efficiency. And to standardize the checklist implementation across orthopedic surgical teams, reducing variability and promoting consistent adherence. And enhance staff training and engagement, foster a safety culture, and promote checklist compliance. Then implementing data-driven decision-making and continuous improvement strategies to sustain and optimize the checklist process over time.

By addressing these general objectives, this research contributes to the body of knowledge on patient safety in orthopedic surgery while also providing practical recommendations for healthcare organizations to improve their SSC implementation and achieve better patient outcomes (Denton et al., 2019).

Appendix (H) provided in the appendixes is a sample from the official MoH indicators software used in the PMC; it shows how to monitor and calculate the percentage of adherence by dividing the number of orthopedic surgeries implementing the SSC. by the total number of orthopedic surgeries each month. The figure's findings indicate the need for an improvement

strategy to raise the compliance rate, which varied from 62% to 86% during the past three years (PMC Annual Report, 2023).

1.7 Research Objectives

This research aims to deploy and utilize the LSS. methodology to improve compliance and adherence rates by implementing the safe surgery checklist to the safety process and introducing a robust approach to patient safety and quality. The objectives of this research are as follows:

A. To raise compliance rate among operating theatre staff regarding the importance of applying the safe surgery checklist.
B. To raise operating theatre staff awareness about the LSS. approach to improving safety and quality of care in the department.
C. To deploy the LSS. approach to improve compliance with implementing a safe surgery checklist.
D. To introduce valuable recommendations to maintain high compliance rates regarding proper checklist implementation to maintain patient safety and quality.

1.8 Research Questions

In this research study, the following questions were examined:

1) Does implementing the LSS methodology significantly raise awareness among operating theatre staff regarding the importance of SSC in orthopedic surgeries?
2) Does implementing the LSS methodology significantly impact adherence to the safe surgery checklist in orthopedic surgeries?
3) Does implementing the LSS methodology significantly impact service quality in orthopedic surgeries?
4) Does implementing the LSS methodology significantly improve patient safety in orthopedic surgeries?

1.9 Research Hypotheses

Table (1.3) presents the study hypothesis that can guide the study methodology to evaluate the effectiveness of applying Lean Six Sigma principles to improve the SSC in orthopedic surgery settings. The research hypotheses and hypothesized path are described in Table 1.3 and depicted in (Figure 1.1).

Table (1.3): Research Hypotheses

Code	Description	Hypothesized path
PLS-SEM causal effect hypotheses		
H1	Implementing the LSS methodology improves the adherence to the SSC.	LSS → SSC
H2	Implementing LSS methodology improves the service quality.	LSS → QI
H3	Patient safety is improved through the implementation of LSS.	LSS →PS
H4	Improvements in adherence to the SSC result in improved patient safety.	SSC → PS
H5	Improvements in adherence to the SSC result in improved hospital services.	SSC → QI
H6	Improvements in patient safety result in improved service quality.	PS → QI
PLS-SEM mediation effect hypotheses		
H7	The adherence to the SSC mediates the link between LSS and QI in hospital services.	LSS → SSC → QI
H8	The adherence to the SSC mediates the link between LSS and patient safety.	LSS → SSC → PS
H9	Patient safety mediates the indirect effect of the LSS methodology on quality performance.	LSS →PS → QI
H10	Patient safety mediates the indirect effect of adherence to the SSC on quality performance.	SSC →PS → QI
H11	The link between adherence to the SSC and patient safety mediates the indirect effect of the LSS methodology on quality performance.	LSS →SSC →PS → QI
Other: comparative and correlations hypotheses		

H12	There are significant differences in the mean of the study constructs (i.e., the implementation of Lean Six Sigma methodology, patient safety, adherence to the safe surgery checklist, and quality of improvement)among the participants based on their demographic factors (i.e., age, gender, social status, educational level, work experience, and job title).
H13	Significant associations exist between the study constructs (i.e., implementing Lean Six Sigma methodology, patient safety, adherence to the safe surgery checklist, and quality improvement). **In this study, the following hypotheses were tested: see Figure 1.**

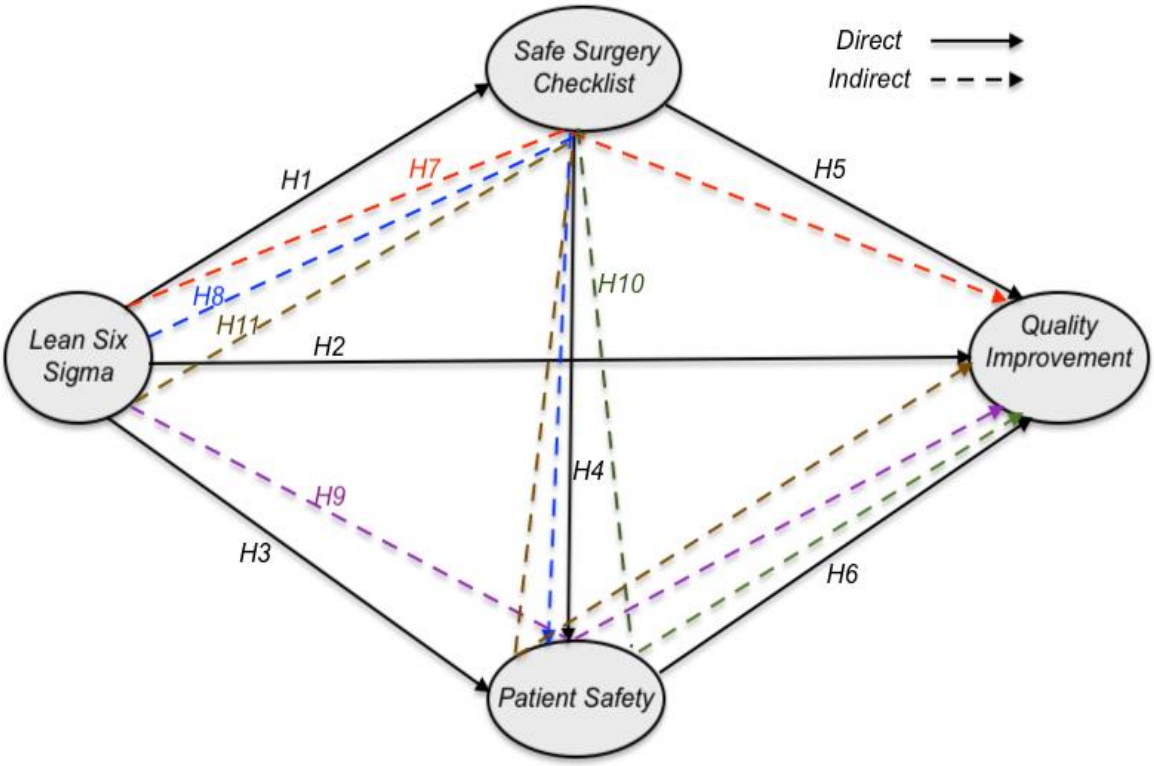


Figure (1.1): Research Framework with Hypotheses.

Figure (1.1) explains the research questions and hypotheses that guide the study design, data collection, and analysis processes to evaluate the effectiveness of applying LSS principles to improve the safe surgery checklist in orthopedic surgery settings.

1.10 Thesis Structure

After the first chapter, this thesis is divided into other six main chapters:

Chapter Two: Literature Review

This chapter presents the literature review and most recent studies that discuss the importance of LSS. to enhance service quality, mainly in healthcare settings, and the importance of a safe surgery checklist to maintain patient safety and improve healthcare service quality. More new international and local empirical studies are needed to effectively utilize LSS methodologies to enhance the quality of healthcare services.

Chapter Three: Research Methodology

This section outlines the methodology used to achieve the study's main objectives by employing the LSS methodology and tools to enhance the implementation of the SSC. It describes the research design, data collection methods, data analysis, and tools used in each phase of the LSS methodology. Additionally, it addresses the validity and reliability of the research instrument. Furthermore, the section explains the tools and diagrams developed and utilized to assess the current situation in the PMC, along with specific findings from these LSS. tools.

This chapter explains the define and measure phases, detailing the work, tools, and diagrams used to understand the research requirements and achieve the research's aims and objectives. Additionally, the chapter discusses the tools used to analyze the current situation in the PMC, along with specific information about the results of those LSS. tools.

This chapter focuses on the improvement and control phases of the DMAIC approach. It explains the tools and diagrams used to identify the root causes of deficiencies and provide effective solutions.

Chapter Four: **Results and Discussion**

This chapter discusses and compares the research results with findings from other studies in the literature review. It describes the data analysis and presents the findings related to the research hypotheses. This chapter comprises six main subsections and shows the research results using the PLS-SEM findings.

Chapter Five: **Conclusion and Recommendations /Future Work**

In this chapter, we present and discuss the research conclusions. We then provide direct and summarized recommendations to enhance staff compliance with the effective implementation of the SSC. for the PMC leadership. Additionally, we discuss the study's limitations and propose areas for future work.

1.11 Chapter Summary

This introductory chapter presents an overview of the LSS methodology to be implemented in the operating theatre rooms at the PMC. It provides a background about the PMC and then presents the problem of the SSC.'s need for more effective implementation. The chapter provides evidence-based data and justifies the study's importance in finding solutions to overcome the lack of implementation.

A separate section presents the research's main aim and objectives, as well as the research questions and hypothesis.

Chapter Two: Literature Review

2.1 Overview

This chapter discusses the previous literature regarding the application of LSS methodology to improve the quality of healthcare services, especially patient safety, mainly adherence to the SSC, and its importance in the operating theater. Finally, the most relevant previous empirical studies are briefly reviewed.

Globally, the WHO reports indicate that all healthcare systems work to ensure all domains of quality and reduce the cost of service delivery, which is the main challenge for those systems. Health systems suffer from additional challenges as demographic shifts towards aging populations, workforce shortages, technological advances, and the applications of artificial intelligence in service delivery, while healthcare costs are still rising and unaffordable to many communities.

Internationally, the burden of lack of quality practices leads to medical errors; a recent study published in 2022 estimated the global burden of deaths due to medical errors. The key findings from this study include an estimated 23 million patients who experience medical errors each year. Of these, approximately 5.2 million patients die due to these errors. This means that medical errors account for around 9.6% of total global deaths annually. The countries with the highest rates of deaths due to medical errors were low- and middle-income countries, with an estimated 13.5% of deaths attributed to medical errors. In high-income countries, an estimated 7.9% of deaths were due to medical errors (Panagiotis et al., 2022).

An additional study by Teeling, et al. (2023) shows that inequalities in access to healthcare persist in many countries, stemming from disparities related to income, geography, ethnicity, and gender. This leads to unequal health output experiences. At the same time, healthcare costs keep rising globally, making it challenging for some people and localities to afford needed clinical care. Lack of affordability can cause treatment delays or inadequate care, further perpetuating poor health outcomes. The combination of healthcare access gaps and cost barriers creates a pressing issue - segments of the population need help to readily obtain quality, affordable care. This results in preventable health disparities and suboptimal outcomes. Several

tools must be used to enhance healthcare outcomes; LSS. is one of those valuable tools (Teeling et al., 2023).

To overcome these challenges, all managers of healthcare entities use several tools and practices to enhance quality, increase patient satisfaction, reduce harm, and reduce cost. LSS is one of the tools that was used to achieve these goals (WHO.2018 https://apps.who.int/iris/handle).

Many articles explore the importance of implementing LSS in healthcare settings. This chapter provides the most recent publications regarding the significance of LSS applications to healthcare delivery services that will be reflected in service quality, staff performance, and outcomes. This chapter will represent a literature review regarding deploying LSS methodology in the Palestinian healthcare sector, mainly the operating theater at the Palestine medical complex.

2.2 Introduction to Lean

Lean is a philosophy, principles, and practices that originated from the Toyota Production System (TPS) in the mid-20th century. The core idea of lean is to maximize value and minimize waste by continuously improving processes and eliminating non-value-added activities. Lean principles have been widely adopted across manufacturing, healthcare, and service industries to enhance efficiency, quality, and customer satisfaction.(Malmbrandt et al., 2013).

When speaking about Lean, Teeling, et al. (2023) clarify that Lean combines a management system, methodology, and philosophy that can support employees and enable them to deliver enhanced patient care services. Although initially deployed for use in the automobile industry and utilized in engineering, designing, and production operations, Lean's inherent benefits led to its adoption across pharmaceutical, electronic, and healthcare industries. Applications of Lean in healthcare have resulted in notable improvements in process flow, impacting factors such as patient wait times, freeing up clinician time for care, reducing errors, and improving patient outcomes. Essentially, Lean implementation in healthcare focuses on shortening the time between when a patient enters and leaves a care facility by eliminating Non-Value Added (NVA) time and activities for patients and staff. Despite fundamental differences

across healthcare contexts, Lean has been used globally to improve healthcare processes. Antony et al., (2007) note Lean's versatility for process enhancement even in varied healthcare settings (Teeling et al., 2023).

Healthcare staff use the Lean philosophy as an improvement methodology. It was developed to improve productivity in automobile manufacturing and engineering operations and then picked up by the healthcare sector to improve quality and productivity outcomes and reduce costs by eliminating wasted time (Batsheva et al., 2022).

Ahmed et al. (2022) in their study stated that the Lean approach is interested in efficiency to deliver quality services to beneficiaries; it is people-focused, seeking to empower employees at all levels of a company to make continuous improvements by learning to identify "waste" Overall, the processes, to provide quality at the source (quality assurance) as well as to minimize the need for more expensive quality control techniques. Lean utilizes the Shewart improvement cycle Plan, Do, Check, Act (PDCA) across all levels of the business. Additionally, Lean promotes ongoing small changes driven by frontline workers to eliminate waste and streamline workflows. Moreover, Lean should be embedded in the organizational culture to facilitate employee-led, continual enhancement by reducing non-value-added activities across all processes.

Ahmad et al. (2022) added that the Lean approach promotes continuous improvement cycles that drive business growth, profitability, lower costs, and improved customer satisfaction through increased efficiency. Lean centers on enhancing efficiency to deliver high-quality services to customers. It stresses speed of service while eliminating wasteful complexity and expenses. By focusing on streamlining key business activities, removing non-value-added steps, and empowering employees to identify and eliminate waste, Lean enables organizations to operate with greater agility and reduced costs. This results in delivering top-notch services at maximum speed - fulfilling customer needs while growing profits. In this way, Lean's emphasis on continually enhancing workflow and eliminating inefficiencies leads to competitive advantage and financial strength (Ahmed et al., 2022).

Lean principles have been applied to various healthcare operations to improve efficiency, reduce waste, and enhance patient care. Studies have shown that lean techniques, such as value stream mapping and process redesign, can significantly improve patient flow and reduce wait

times in emergency departments, outpatient clinics, and inpatient units (Ng et al., 2010; Dickson et al., 2009).

Lean principles have been utilized to optimize operating room scheduling, reduce setup times, and minimize delays and cancellations, resulting in increased efficiency and better resource utilization (Cima et al., 2011; Fairbanks, 2007).

Lean tools like just-in-time inventory management, kanban systems, and visual controls have been implemented to streamline supply chain processes, reduce inventory levels, and minimize waste in healthcare organizations (Jarrett, 2006; Mustafa &Gillingham, 2008).

Lean techniques, such as workflow analysis and process redesign, have improved laboratory processes, reduced turnaround times, and enhanced quality and accuracy (Raab et al., 2006; Serrano et al., 2010).

Lean principles have been used to optimize clinic layouts, improve patient scheduling, and enhance communication and coordination among healthcare providers, improving patient satisfaction and reducing wait times (Niemeijer et al., 2011; Guthrie, 2006).

Challenges and Barriers to Lean Implementation Despite the potential benefits, implementing lean in healthcare organizations can face several challenges and barriers. These include organizational culture and resistance to change, lack of leadership support and commitment, inadequate staff training and involvement, and difficulties sustaining lean initiatives over time (Radnor et al., 2012; Balle & Regnier, 2007).

Benefits and Outcomes of Lean in Healthcare Numerous studies have highlighted the positive outcomes of lean implementation in healthcare settings. These benefits include improved process efficiency and productivity, reduced waste and costs, enhanced patient safety and quality of care, and increased staff satisfaction and engagement (Mazzocato et al., 2010; Jimmerson et al., 2005; Bushell &Shelest, 2002).

Future Directions and Recommendations While the literature demonstrates the potential of lean principles in healthcare operations, further research is needed to address gaps and explore strategies for successful and sustainable lean implementation. Additionally, integrating lean with other quality improvement methodologies, such as Six Sigma, may provide a more

comprehensive approach to continuous improvement in healthcare (Radnor & Osborne, 2013; Stamatis, 2011).

2.3 Introduction to Six Sigma

Six Sigma is a unique approach that originated at Motorola in the 1980s as a quality improvement methodology to improve quality by identifying and removing the causes of defects and minimizing variability in manufacturing and business processes, mainly in Japan, to recover after World War II. They follow different cores, methodologists, and tools.

Motorola's successful implementation of Six Sigma led to dramatic quality improvements and significant cost savings, which brought widespread recognition to the methodology. In the 1990s, many Macro companies like General Electric GE, Allied Signal, and Sony also adopted and popularized Six Sigma, further spreading its use across different industries (Ahmad et al., 2022).

When we want to clarify the main aim of Six Sigma, Ahmed et al. (2022) stated that Six Sigma aims to identify and eliminate deviation from sustainable managerial processes. Its power lies in its strong focus on the "Voice of the Customer" (VoC) and the development and application of data-driven tools to identify and present the current state of processes. This facilitates the detection and removal of variability. The most common Six Sigma approach for improvement is the DMAIC (Define, Measure, Analyze, Improve, Control) framework, which often utilizes advanced statistical tools during the analysis phase. Ahmad et al. (2007) add that Six Sigma best addresses specific problems through focused projects that follow the DMAIC structure. Six Sigma provides a data-oriented methodology to reduce variability and defects by integrating the customer perspective, statistical analysis, and process control. Six Sigma is grounded in quantitative methods, employing data-driven control systems to integrate quality, processes, costs, people, and responsibility (Ahmed et al., 2022).

Thomerson et al. (2010) add more data about the history of the Six Sigma approach developed by Motorola in 1980 to optimize productivity using statistical analytics for process capability improvement. They defined Six Sigma as a data-driven process improvement methodology that aims to reduce variation and defects in organizational processes. They

mentioned that Six Sigma was first developed in the manufacturing sector. Then, it was introduced to the healthcare industry in the 1990s as hospitals sought new ways to improve quality, patient safety, and efficiency (Thomerson et al., 2010).

Eid et al. (2015) mentioned that Six Sigma in Healthcare Operations has been applied to various areas of healthcare operations to improve quality, reduce errors, and streamline processes. Six Sigma projects have been undertaken to optimize patient flow in emergency departments, outpatient clinics, and hospital units, reducing wait times, improving resource utilization, and enhancing patient satisfaction (Eid et al., 2015; Mandahawi et al., 2010).

Six Sigma methodologies have also been employed to improve operating room efficiency, reduce delays and cancellations, and enhance surgical instrument tracking and inventory management (Cima et al., 2011; Fairbanks, 2007; Berte, 2006).

Six Sigma initiatives have focused on improving laboratory processes, reducing turnaround times, minimizing test result errors, and ensuring accurate and timely diagnoses (Raab et al., 2006; Nevalainen et al., 2000).

Moreover, Six Sigma techniques have been utilized to optimize inventory levels, streamline supply chain processes, and reduce waste and costs associated with medical supplies and equipment. (Mustafa &Gillingham, 2008; Jarrett, 2006). Six Sigma has been applied to various clinical processes, such as medication administration, infection control, and disease management, to improve patient safety, reduce adverse events, and enhance treatment outcomes (Kaplan et al., 2014; Chassin, 2008).

Challenges and Barriers to Six Sigma Implementation Despite its potential benefits, implementing Six Sigma in healthcare organizations can face several challenges and barriers. These include resistance to change, lack of leadership support, inadequate training and resources, data availability and quality issues, and difficulties sustaining long-term improvement efforts (Chassin, 2008; Antony et al., 2007).

Benefits and Outcomes of Six Sigma in Healthcare Numerous studies have reported positive outcomes from Six Sigma implementations in healthcare settings, such as improved quality and patient safety, reduced costs and waste, increased efficiency and productivity, and enhanced customer (patient) satisfaction (Eid et al., 2015; Mandahawi et al., 2010; Kaplan et al., 2014; Chassin, 2008).

While Six Sigma has demonstrated effectiveness in healthcare operations, further research is needed to address challenges and explore successful and sustainable implementation strategies. Integrating Six Sigma with other quality improvement methodologies, such as Lean, may provide a more comprehensive approach to continuous improvement in healthcare. Combining those methodologies makes it more feasible to have effective and efficient healthcare services (Radnor & Osborne, 2013; Stamatis, 2011).

2.4 Lean and Six Sigma

Lean Six Sigma (LSS.) is a mix of Lean and Six Sigma methodologies and an integrated and refined approach built upon Lean and Six Sigma foundations. The selection of tools in LSS depends on a given business's specific context and objectives. In this sense, the practical application of various LSS tools and techniques represents the outworking of the underlying LSS methodologies. However, LSS synergizes these methodologies into a cohesive system that can be tailored based on business needs. It is not a rigid toolkit but a strategic framework for process improvement that draws flexibly from LSS principles and methods. The strength and power of LSS lie in its ability to synthesize the best of Lean and Six Sigma into a customized program for maximizing value and minimizing waste (Ahmed et al., 2022).

Laureani and Antony (2017) added that integrating LSS methodologies in healthcare settings has gained significant attention in recent years as a unified approach to improve quality, efficiency, and patient outcomes. Lean focuses on eliminating waste and improving flow, while Six Sigma emphasizes data-driven problem-solving and reducing variation. These complementary approaches provide a robust framework for healthcare organizations to address complex challenges. LSS has been applied in healthcare, including emergency department operations, surgical services, medication management, and hospital-acquired infection control.

By leveraging the strengths of both Lean and Six Sigma, healthcare organizations can streamline processes, eliminate inefficiencies, and enhance the reliability and safety of patient care. The successful implementation of LSS healthcare settings requires strong leadership, a commitment to continuous improvement, and the engagement of frontline staff. Practical training and developing a quality-focused culture are also critical factors in ensuring the sustainability of LSS initiatives.

Overall, integrating Lean and Six Sigma in healthcare settings has demonstrated the potential to drive significant improvements in quality, cost, and patient outcomes. It is a valuable strategy for healthcare organizations seeking to enhance performance and deliver better care (Laureani & Antony, 2017).

2.5 Impact of Lean Six Sigma on Quality of Healthcare

The quality of healthcare services has become a worldwide priority, especially for value-based services. However, those services still need more contributions to reduce the increasing number of adverse events in healthcare settings. According to the Journal of Patient Safety in the United States, there are more than 210 thousand preventable deaths each year (Ahmed et al., 2022). A global effort on quality of care is imperative to improve those services. There is an international consensus that there is a need for a comprehensive improvement model to enhance this sector. LSS is the recent approach of choice among many organizations that aim to improve their services by raising the quality of care to meet their patient's expectations. LSS has been used to reduce waiting time, reduce healthcare-acquired infections, enhance surgical approaches, and reduce medication errors and expenditures. Moreover, applying LSS can reduce costs for individuals and entities and form a precise quality improvement environment for the entity (Ahmed et al., 2022).

Furthermore, Alharthi et al. (2020) explored the role of LSS in improving the safety and quality of orthopedic surgeries in a tertiary care hospital in Saudi Arabia. The authors reported a substantial decrease in surgical site infections, readmission rates, and length of stay, attributing these improvements to implementing standardized processes and continuous monitoring using control charts and other Lean Six Sigma tools (Alharthi et al., 2020).

Although there was a similarity with Alharthi et al. (2020) study in the main aim to enhance the quality of the healthcare service, there were still different tools where applied, in this research we applied the SSC to decrease mortality, morbidity, and infections.

Timmons et al. (2014) stated that LSS is a data-driven and customer-focused methodology that aims to improve processes and reduce waste and variability. When applied in healthcare settings, LSS has been shown to positively impact the quality of care. Their study examined the effect of LSS on various healthcare outcomes. The review found that LSS interventions

improved all quality dimensions, such as patient safety, by reducing medical errors and adverse events. Patient experience, with shorter wait times and improved patient satisfaction. Clinical effectiveness, with better adherence to clinical guidelines and protocols. Efficiency, with reduced costs and improved resource utilization. The study also noted that successful LSS implementations in healthcare require strong leadership, practical training, and a culture supportive of continuous improvement (Timmons et al., 2014).

2.6 Impact of Lean Six Sigma on Patient Safety

A literature review shows that LSS undoubtedly benefits patient safety and the quality of care. Patient safety became the primary domain for improving healthcare quality, and many practices were introduced to enhance patient safety.

To improve the outcomes of healthcare services, Trakulsunti et al. (2023) clarified that LSS is a managerial tool that was used and still to reduce harm and improve safety in the healthcare process; there is evidence to suggest that Six Sigma can contribute to enhancing patient safety. The application of LSS in the healthcare field promises to improve the quality and safety of healthcare, enhancing the efficiency of medical staff. “Efficiency is the use of resources for the results achieved. Typical resources include medications, time, human effort, technology, costs, and materials”. (Trakulsunti, et al., 2023). LSS has been applied in surgical settings to reduce the incidence of surgical site infections (S.S.Is). By analyzing data and identifying key factors contributing to surgical site infections (SSIs), hospitals have implemented LSS projects to improve hand hygiene, sterilization techniques, and post-operative care. These initiatives resulted in a reduction in SSIs, enhancing patient safety in the surgical setting. All reviewed studies about applying LSS in a surgical department show a successful reduction in surgical complications and improved patient safety indicators, such as infection rates and postoperative mortality (Trakulsunti et al., 2023).

In Italy, Montella, et al. (2017) conducted a related study with the main aim of the study was that The Application of LSS methodology can Reduce the Risk of Healthcare-Associated Infections (HCAIs) in Surgery Departments and improve the quality of healthcare services provided. The team's goal was to improve the outcomes of the process by reducing the number of patients affected by sentinel bacterial infections and, consequently, the number of inpatient

days at risk of HCAIs. Using LSS tools and analysis, the Key Finding was that Pseudomonas Aeruginosa was the most severe bacteria in the analyzed patients, with a positive correlation between the number of positive patients and the number of procedures, the number of procedures the cause with the greatest effect on the Continuous Total Quality in addition to the increase of day of admission. Four main types of causes were registered:

• Type of materials used, clinical equipment, medications used, and artificial intelligent tools.
• Surgical criteria, regarding pre-, intra-, and postoperative protocols
• Service staff, practical procedures, and education information related to health personnel
• Managerial aspects: strategies and standard procedures regulating service processes. LSS methodology was applied with data on more than twenty thousand patients who underwent a wide range of surgical procedures between January 2011 and December 2014 (Montella et al., 2017).

Six Sigma is usually connected with lean, using the (DMAIC) framework to improve change, it focuses on the customer and user's voices and expectations of the service, aiming to improve safety, quality, efficiency, performance, and satisfaction (Charles R. et al., 2012). Strong evidence exists for the direct correlation between the SSC and improved patient safety outcomes. Studies suggest implementing and adhering to such checklists can substantially reduce surgical complications and mortality rates across healthcare environments. (Haynes et al., 2009).

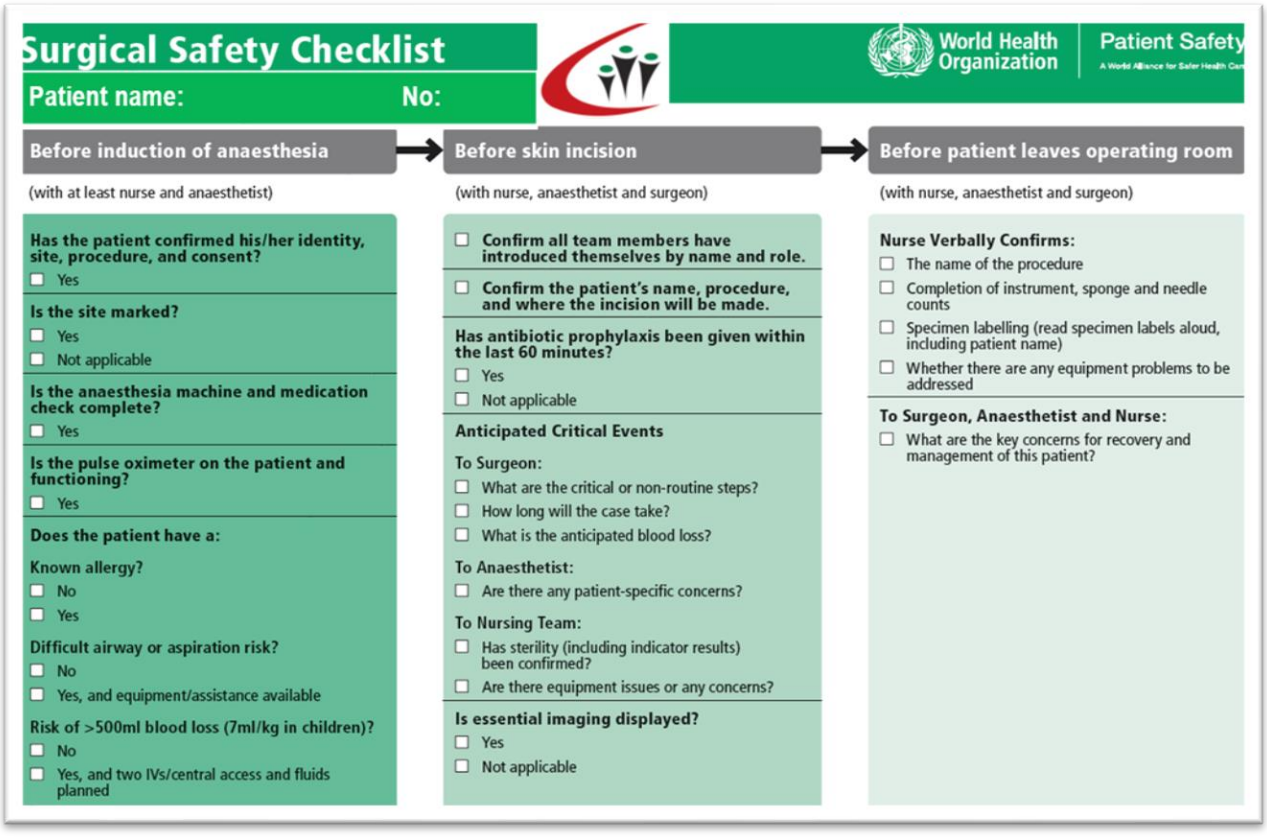
2.7 Safe Surgery Checklist

2.7.1 What is the Safe Surgeries Checklist (SSC)

The Safe Surgeries Checklist (SSC) was developed by the WHO in 2007 to support the initiative “Safe Surgeries Safe Lives” to reduce surgical mortalities worldwide. It focuses on strengthening communication among surgical staff before, during, and after operations. It depends on some applicable and critical safety-control actions to eliminate the avoidable events and risks associated with surgical patients (WHO, 2009).

Literature indicates that applying the checklist decreases mortality, morbidity, and infections. In Palestine, the MoH has adopted the SSC at all governmental hospitals since 2012 to reduce patient harm. Some hospitals show high compliance rates, while others have lower rates. In this study, we would like to assess the role of LSS in enhancing the adherence rate, highlight the barriers to the implementation of the WHO SSC at PMC, and suggest measures that can be taken to improve the adherence rate.

Figure (2.1) shows the form of the checklist, as shown in the figure, the checklist contains three primary stages to be followed: Before Induction of Anesthesia, Before Skin Incision, and Before the Patient Leaves the Operating Room. The three stages contain 21 items related to patient safety to act as risk preparedness and mitigation actions, this includes and is not limited to patient identification, surgical site marking, lab and radiology tests, preparation of blood units, staff and equipment readiness, and other items.



Surgical Safety Checklist

World Health Organization | Patient Safety

Patient name: No:

Before induction of anaesthesia (with at least nurse and anaesthetist)

Has the patient confirmed his/her identity, site, procedure, and consent?
- ☐ Yes

Is the site marked?
- ☐ Yes
- ☐ Not applicable

Is the anaesthesia machine and medication check complete?
- ☐ Yes

Is the pulse oximeter on the patient and functioning?
- ☐ Yes

Does the patient have a:

Known allergy?
- ☐ No
- ☐ Yes

Difficult airway or aspiration risk?
- ☐ No
- ☐ Yes, and equipment/assistance available

Risk of >500ml blood loss (7ml/kg in children)?
- ☐ No
- ☐ Yes, and two IVs/central access and fluids planned

Before skin incision (with nurse, anaesthetist and surgeon)
- ☐ **Confirm all team members have introduced themselves by name and role.**
- ☐ **Confirm the patient's name, procedure, and where the incision will be made.**

Has antibiotic prophylaxis been given within the last 60 minutes?
- ☐ Yes
- ☐ Not applicable

Anticipated Critical Events

To Surgeon:
- ☐ What are the critical or non-routine steps?
- ☐ How long will the case take?
- ☐ What is the anticipated blood loss?

To Anaesthetist:
- ☐ Are there any patient-specific concerns?

To Nursing Team:
- ☐ Has sterility (including indicator results) been confirmed?
- ☐ Are there equipment issues or any concerns?

Is essential imaging displayed?
- ☐ Yes
- ☐ Not applicable

Before patient leaves operating room (with nurse, anaesthetist and surgeon)

Nurse Verbally Confirms:
- ☐ The name of the procedure
- ☐ Completion of instrument, sponge and needle counts
- ☐ Specimen labelling (read specimen labels aloud, including patient name)
- ☐ Whether there are any equipment problems to be addressed

To Surgeon, Anaesthetist and Nurse:
- ☐ What are the key concerns for recovery and management of this patient?

Figure (2.1): WHO Safe Surgery Checklist Form (WHO, 2009).

2.7.2 Role of Safe Surgery Checklist

The WHO introduced the SSC for implementation in 2009, aiming to reduce mortality and complications among surgical patients significantly. This checklist comprises 21 items that healthcare professionals must review at three distinct time points:

1. Sign In: Before anesthesia induction.
2. Time Out: Before skin incision.
3. Sign Out: After the procedure, before patients leave the room.

The WHO checklist is unique in its claim to universality. The initial study conducted by the WHO to implement the SSC was in high, middle, and low-income settings, including an African hospital. More than fifteen thousand patient records were reviewed and analyzed; the study concluded that the checklist program could improve surgical patient safety across diverse clinical and economic environments, making healthcare professionals worldwide part of this significant initiative.

The WHO study also suggested that implementing the checklist was inexpensive. Only two items—pulse oximetry and antibiotic prophylaxis—would require significant resources, but these were reportedly available, albeit inconsistently utilized, at all study sites, including low-income hospitals. This cost-effectiveness reassures healthcare professionals about the feasibility of implementing the checklist.

Another critical aspect of the WHO checklist is its blend of technical checks like antibiotic confirmation and "non-technical" items focused on teamwork, communication, and situational awareness, such as team introductions and procedure confirmations. Aveling et al., (2020), and Röhsig et al. (2020) stated that Adverse events (AE) related to healthcare are expected, with around 40% occurring in operating rooms (ORs). However, approximately 50% of these critical incidents are deemed preventable. The WHO introduced the WHO SSC in 2008 to reduce this irrevocable harm. This tool aims to improve compliance with safety procedures performed before surgery to minimize the risk of adverse events during the operation and post-surgical complications afterward. Specifically, the WHO SSC involves carrying out defined steps across three phases: 1) before anesthesia induction (Sign In), 2) before surgical incision (Time Out),

and 3) before the patient leaves the OR (Sign Out). Standardizing this pre-operative checklist aims to catch potential errors and reduce preventable adverse outcomes for surgical patients. Over the past decade, numerous studies have validated the effectiveness of the WHO SSC in reducing morbidity, mortality, perioperative complications, and length of hospital stay. This evidence has prompted many institutions globally to adopt this tool rapidly.

However, challenges in implementing the WHO SSC, considered a complex social intervention, have also been highlighted and discussed across studies. Some have even questioned the utility of the checklist. Difficulties with WHO SSC implementation are often tied to institutional contexts where it was introduced without adequate supporting strategies.

Factors like top-down rollout, insufficient team training, and mandated adoption due to regulatory requirements have all been linked to failed implementation with no gains in patient outcomes. Investigations have revealed that professionals frequently misuse the WHO SSC or complete it at the end of surgery rather than before. Moreover, despite the existence of manuals and materials to assist implementation, the process is not standardized. Formal training of surgical teams is generally lacking (Röhsig et al., 2020).

In the previous study by Röhsig et al. (2020), a quality improvement strategy was described to enhance compliance with the WHO SSC at Hospital Moinhos de Vento (HMV) in Porto Alegre, Brazil. The strategy's key components included forming a multidisciplinary team, process mapping and gap analysis, checklist adaptation to the local context, staff training and education, and continuous monitoring. The implementation steps were as follows:

1. Baseline assessment of compliance (found to be 78.6%) 2. Identification of barriers through staff surveys and interviews 3. Checklist modification based on local needs and feedback 4. Implementing targeted interventions: * Educational sessions for surgical teams * Visual aids in operating rooms * Integration of the checklist into electronic health records 5: regular audits and performance feedback 6. Continuous improvement cycle based on ongoing results The strategy outcomes were remarkable, with the compliance rate increasing from 78.6% to 95.0% over 12 months, improved team communication and safety culture, and reduced surgical complications.

Another study conducted in India in 2018 by Jain et al, highlighted the difficulties in adopting the WHO SSC and recommended actions and measures to overcome them. The main

barriers identified by the study were hierarchy, overload, delay in starting the operation, low adherence and application in emergencies, simulating the anxiety and worry in awake patients, routine ineffective Tick-box exercise, and Sign-out time, the most common barrier.

The study recommends that to overcome those barriers, several strategies should be followed, such as conducting local campaigns, training continuously, piloting and starting small before expanding, local adjustment and adaptation, a straightforward format for all team members, and regular audits. The study also recommends that the WHO SSC is a promising tool to reduce surgical complications worldwide in terms of efficiency, effectiveness, and safety. Teamwork by the surgeons, anesthetists, and paramedical staff is crucial to overcome the sociocultural and organizational hurdles to ensure successful implementation of the WHO surgical checklist (Jain et al., 2018).

In the United Kingdom, Keijzeret al (2017) indicated the importance of accepting and applying the SSC in their study aimed to determine staff compliance with completing the checklist for pediatric emergency plastic surgery patients at the emergency department. The study expanded over four months on 150 patients and highlighted the importance of raising awareness about the WHO surgical safety checklist to optimize perioperative safety. It identified ongoing issues of concern that should be monitored through future audits while confirming that the checklist process is being carried out to a high standard overall, with 91% compliance in most cases. Further auditing is recommended to ensure continuous improvement with multi-center audits at the regional and national levels, which may provide additional insights into the use of the WHO checklist, help identify common systemic issues, and reveal variations in deployment and practice across different healthcare settings.

The study recommended that surgical checklists such as the WHO SSC and the Surgical Patient Safety System checklist represent valuable and promising interventions for reducing patient harm, morbidity, and mortality related to surgical procedures (Keijzeretal, 2017).

Previously, Treadwell et al. (2014) showed that the WHO SSC had been successfully implemented across diverse settings, including all surgical procedures, academic and community hospitals, and high-economic, industrialized, and low-economic developing nations. The study stated that SSC are associated with enhanced detection of potential safety hazards, decreased surgical complications, and improved communication between operating room staff. However,

other concurrent safety initiatives independent of the checklists may explain some of these improvements. Critical elements for effective checklist implementation comprise obtaining leadership support, training staff on utilizing the checklist, customizing the checklist based on staff feedback, and avoiding duplicating information already routinely documented (Treadwell et al., 2014).

Moreover, Aveling et al. (2013) study aimed to identify and compare the influence of WHO SSC adaptation and adherence in operating rooms in three different hospitals (two hospitals in the United Kingdomandanotherhospital in Africa); the study concluded and recommended that successful implementation of a surgical checklist is likely optimized in any setting when utilized as a part of a multifaceted program targeting cultural and organizational change to strengthen patient safety. It should not be assumed that simply introducing a checklist will automatically improve communication and clinical processes. Instead, the checklist should be embedded within more comprehensive efforts to transform culture, enhance teamwork, and prioritize organizational safety. Viewing it as one tool within a broader patient safety movement can help maximize its impact. Surgical teams require training, ongoing coaching, and leadership support to adopt new behaviors fundamental to safety fully. The checklist enables standardized practices but requires enabling culture and systems to realize their full benefits (Aveling et al., 2013).

A systematic review by Gillespie et al. (2018) examined the effectiveness of the SSC in reducing surgical complications and mortality. The study analyzed data from 11 studies involving over 44,000 patients and found that proper implementation of the checklist was associated with a significant reduction in surgical complications (relative risk reduction of 36%) and mortality (relative risk reduction of 57%). However, the authors noted considerable variability in checklist compliance rates across different healthcare settings, highlighting the need for improved measurement and monitoring.

Another study by Russ et al. (2015) developed and validated an observational tool for measuring the use of the WHO SSC. The study involved observing 109 surgical procedures across three hospitals and measuring checklist adherence using a standardized observational tool. The findings revealed substantial variability in checklist compliance, with an overall adherence rate of 67%. The authors emphasized the importance of reliable measurement tools to identify areas for improvement and assess the impact of interventions.

2.7.3 Application of LSS in the Operations Room

A new research study conducted in the United Arab Emirates UAE (2023) by Shreeranga Bhat et al., says that all healthcare systems work to ensure effective, efficient, equitable, accessible, safe, and high-quality services. For this reason, all managers of healthcare entities use several tools and practices to maintain quality and satisfaction and reduce harm and cost. Inherently, errors occur due to humanity's nature, which is for sure responsible for adverse events; currently, the auditing and elimination of incident events represents a higher priority for the healthcare sectors and managers in parallel with reducing the incidence of those events is a quality indicator of the services provided. Surgical site infections and complications are among the most investigated incidents and issues in all healthcare settings. The most common practical approaches for reducing the risk of adverse events are the surveillance approach, guidelines, policies, procedures, and continuous training of healthcare providers and personnel. For more effective tools, the strategic managers in many hospitals have committed to implementing a management tool enterprise; the LS findings also show that health services improvement activities depend on patients (internal customers). Most health entities prefer reducing value stream delay time and errors by external experts and consultants (experts with master black-built certificates). Additionally, it should be mentioned that the LSS projects were successfully implemented due to solid commitment from top management leadership, transparent, effective communication, and multi-functional staff. Staff resistance to change is the main noted barrier during the research study analysis. Moreover, LSS is executed with standard tools and techniques within the DMAIC approach (Shreeranga et al., 2023).

While reviewing the literature, a strong correlation is noted between improving the quality of healthcare services and the deployment of LSS. Another critical study by Noronha et al., (2023) finds that the processing time of treatment is reduced in addition to the implementation of sustainable corrective actions. Applying the LSS strategies supports the endodontic unit in enhancing treatment and processing time from an average of 116 min to 84 min (Noronha et al., 2023).

Ankit Singh et al. (2022) stated that patient flows in healthcare have to be standardized, which means the progressive movement through process care from initial engagement, admission, surgical interventions, and treatment to discharge requires process standardization

and maintaining a high level of quality and satisfaction through solid management steps due to the complexity of service and staff involved in the operating theaters (O.R.). Many steps are required for surgical procedures, from patient preparation (as consultations, scheduling, diagnostic procedures, patient education, and consent) to operating room procedures (patient identification, prophylactic administration, site marking, time out, anesthesia, and recovery). Staff can rely on LSS principles to improve those steps, eliminate delay, eliminate unwanted variations, and improve outcomes and efficiency of care. Targeted areas can be identified to apply the LSS during surgical procedures; the WHO identified three main areas to be monitored effectively: before induction of anesthesia, before patient incision, and before the patient leaves the operation room.

A structured, evidence-based checklist with operating and quid manuals is developed to prevent harm and improve patient outcomes. Due to the complexity of the service and the environment, tasks in the operating rooms should be coordinated efficiently (Ankit Singh et al., 2022).

In the era of healthcare, many articles are reviewed to enrich the understanding of the importance of LSS. All related articles indicate a positive correlation between enhancing patient safety and deploying LSS methodologies. There is evidence-based data about implementing the safe surgery checklist to decrease patient harm and maintain safety, deploying LSS, to improve compliance, and SSC will maintain security (Ankit Singh et al., 2022).

In their study, Tzadok B. et al. demonstrated the strengths of the LSS in improving severe stroke treatment rates and reducing value stream leading time for process-led time. On the other hand, the study did not significantly use the LSS tools to improve quality performance in a rural hospital. The intervention LSS tools allowed the waiting time for the CT scan to decrease from 52 to 26 minutes, and the treatment time was reduced from 94 to 75 minutes (Tzadok et al., 2022).

Regarding medication management and use (MMU), Trakulsunti et al.(2021) in their study clarify the purpose of how the use of LSS and its tools will eliminate MMU errors in the admissions pharmacy of a university hospital in Thailand. The study shows a decrease in the number of MMU errors by 67% and improved patient safety and communication skills in the pharmacy team (Trakulsunti et al., 2021).

Moreover, in a study published by Trakulsunti et al. (2020), the aim was to propose an LSS process map to guide healthcare staff in the implementation of LSS tools for reducing medication errors. The finding resulted in a process map that includes three steps: cultural readiness for LSS deployment in reducing MMU errors; preparation, initialization, and implementation of LSS; and finally, control and sustainability (Trakulsunti et al., 2020).

Regarding the importance of LSS to patient safety, Charles et al. (2012) conducted a significant study in the United States with the primary aim was examining how process enhancement tools reduce the impact of clinical errors to enhance three hospital outcomes: in-patient safety, operational effectiveness, and competitiveness. The results revealed that continuous quality improvement activities and LSS tools were significant in "eliminating hospital errors, reducing surgical site infections, and improving hospital effectiveness. The findings highlighted the crucial role of LSS in enhancing patient safety outcomes by minimizing medical errors and improving overall hospital performance (Charles et al., 2012).

Many studies correlate between LSS methodology and the effectiveness of operating theater rooms; many studies connect LSS methodology and the point of operating theater rooms and how to improve the rate of health care compliance rate, an example by Cima et al. (2011) with the aimed to initiate an assessment of surgical patient flow, LSS DMAIC approach and tools were selected as the process quality improvement methodology. They started by developing a value stream map of patient flow that detailed the event location, personnel, information technology requirements, alternative pathways, key performance elements at each step, and bottlenecks. The study that used the LSS methodology stated that three specialties improved regarding process design, start time, and enhanced patient flow through the department. The study's conclusion is increased effectiveness, safety, efficiency, and accost reduction with financial performance across the entire operating department (Cima et al., 2011).

2.8. Palestinian Healthcare system

2.8.1 National Indicators

A report by the Palestinian Ministry of Health (2023) highlighted that the Palestinian population is 14.3 million: 5,4 living in Palestine (3,2 in the West Bank and 2,2 in the Gaza Strip)—also,1.7 million live in the 1948 territories and 7.2 in the Diaspora. The Palestinian population is young; more than 1/3 of the Palestinians are 15 years old or less, representing 38% of the population (103.3 males per 100 females). The fertility rate was 3.8 births. The percentage of people above 65 years was 3.5%. The life expectancy rate was 74.3 years, while the crude birth rate was 28 births/1,000 population. Crude Death Rate was 3.0 per 1,000 population (Palestinian Ministry of Health, 2023).

2.8.2 System indicators

The five leading suppliers of health services in Palestine are the MoH, the Military Services, the United Nations Relief and Works Agency (UNRWA), Non-Governmental Organizations (NGOs), and the private sector. All those sectors work together to provide healthcare services to all citizens at all levels: primary, secondary, and tertiary healthcare (Palestinian Ministry of Health, 2023).

There are 770 primary healthcare centers in Palestine, and the population per center is 6,600. The total number of hospitals in Palestine was 93, with 6,900 beds. The number of patient beds per 10,000 was 1.3 beds, while the number of hospitals per 100,000 population was 1.7 hospitals. The average Occupancy Rate of beds was 88%, while the average LOS of patients in MoH hospitals was only 2.5 days. In Palestine, there are 56500 healthcare workers (from which 16000 doctors and 25000 nurses are employed), 20000 of whom are MoH employees.

Additionally, Table (2.1) shows more than three hundred thousand surgical procedures each year, as shown below in Table (2.1) (MoH, 2023).

Table (2.1): The number of operations by provider in Palestine (MoH 2023).

Provider	West Bank	Gaza Strip	Total
Ministry of Health	74,538	88,105	162,643
NGOs	60,310	34,938	95,248
Private	38,652	2,174	40,826
UNRWA	1,658	/	1,658
PMMS	/	3,214	3,214
Total	175,158	128,431	303,589

2.8.3 Top 10 Causes of Death in Palestine

The top ten causes of death in Palestine are mentioned in the following Table (2.2). However, the number of ordinary diseases varied according to geographical area and residency in the West Bank and Gaza Strip; Table (2.2) shows those differences (MoH, 2023).

Table (2.2): Major 10 Causes of Death by District, Palestine 2022. (MoH, 2023)

West Bank		
#	Cause of Death	%
1	Ischemic heart diseases	25.3%
2	Malignant Neoplasm	13.8%
3	Diabetes Mellitus	12.8%
4	Cerebrovascular disease	10.5%
5	COVID-19	8.3%
6	Injuries	5.6%
7	Diseases in the perinatal period	5.5%
8	Hypertensive heart disease	5.2%
9	Congenital Malformations	4.8%
10	Disease of the nervous system	2.8%

Gaza Strip		
#	Cause of Death	%
1	Ischemic heart diseases	17.8%
2	Malignant Neoplasm	15.1%
3	Cerebrovascular disease	11.6%
4	COVID-19	6.8%
5	Unknown causes	5.8%
6	Disease of respiratory system	4.3%
7	Congenital Malformations	3.9%
8	Hypertensive heart disease	3.8%
9	Diseases in the perinatal period	3.3%
10	Diabetes Mellitus	3.2%

2.9 Palestine Medical Complex (PMC)

2.9.1 Background

PMC is the largest MoH hospital in Palestine; it contains 516 beds for patients and 1120 healthcare workers. It delivers general and specialized services with 15 operating theaters performing 15000 operations annually. The PMC is a referral hospital with 35% of its clients from outside of Ramallah Governorate; the PMC outpatient clinics receive about 120000 patients per year, while the ER department deals with 150000 annually. The occupancy rate is about 99%, with an average length of stay 2.5 days (PMC Quality Departement, 2023).

2.9.2 The Application of LSS Enhances the Implementation of the SSC.

The PMC leadership has committed to implementing the SSC since 2012. Implementation compliance varies over time; the compliance rate should exceed 95%, while the implementation rate has ranged from 62% to 86% over the past five years (PMC et al., 2023).

In this research, the role of the LSS methodology was assessed in terms of compliance rate to enhance patient safety and compliance with the implementation of the safe surgeries checklist by healthcare workers, reducing patient harm in operating rooms. The project took place in the operative service where LSS is to be implemented by utilizing its DMAIC approach and a series of LSS tools to identify sources of noncompliance and to develop improvement strategies that would lead to enhanced compliance in operating rooms.

2.10 Barriers to Prober Implementation of SSC that Form the Conceptual Framework

According to the literature, many barriers affect the proper implementation of the S.C.C. Studies eleven challenges in implementation: poor communication among staff, weak leadership, an overload of items checking and the time of singe-out, long time for checklist completion, and lack of roles and responsibilities. Other barriers also identified are the hierarchy of the operating theatre, delay in starting, low adherence in emergencies, some patients' anxiety, and tick-box consideration by staff (Jain et al., 2018). All those barriers are summarized in Figure (2.2)

Figure (2.2): Barriers affect the implementation of the S.C.C (Jain et al., 2018).

2.11 Strategies to Overcome Lack of Implementation

Jain et al. (2018) indicate some strategies that an organization has to follow to enhance implementation as developing local adjustments and adaptation, conducting awareness activities and campaigns, assigning a regional champion, training before, during, and after the performance, starting small in one room, enhancing teamwork, audits, and measures. The WHO SSC is an essential tool to limit the surgical-site complications of any procedure worldwide. The applying team (surgeons, anesthetists, nurses, and paramedics) must work together to overcome the barriers to successfully implementing the WHO surgery checklist; this concludes that:

- Adverse events and surgical complications contribute to a large number of mortalities and morbidities.

- SSC reduces adverse events and maintains safety, quality, and cost.
- SSC is a must at all healthcare entities.
- Low adherence rate of PMC staff.
- LSS methodology can help enhance the adherence rate to maintain safety.
- This proposal is the first in Palestine.
- The implementation of the project is to be expanded to other OR rooms (Jain et al., 2018).

2.12 More Empirical Studies

Implementing LSS methodologies in healthcare has been emphasized in recent literature. Samanta et al. conducted a study in 2023 where they evaluated 154 articles using specific structural dimensions to categorize the literature into various groups. They performed content analysis to synthesize the information, demonstrating how healthcare organizations use LSS methodology to improve cost, quality, and productivity. The paper reviews case studies that describe the implementation of LSS in healthcare organizations and identifies future research directions. The findings revealed a growing number of articles discussing the application of LSS in healthcare over the past five years. However, there are still unexplored themes, such as applying LSS in non-clinical areas like pharmacy, internal logistics, maintenance, and medical records. Additionally, only 20% of articles mentioned post-intervention data for up to three years, raising questions about the sustainability of the improvements (Samanta et al., 2023).

Another research study by Doyle et al. (2022) investigated the operational experiences of providing surgical services. The study focused on improving efficiency in an Operating Theatre environment and thoroughly examined the clinical flow process for surgical patients in the preoperative setting. This case study was set in the Queen Elizabeth Hospital Birmingham, one of the largest teaching hospitals in Europe. The study identified issues such as late starts, delayed patient turnaround, and unplanned overruns, emphasizing improvement. The study highlights common challenges in managing scheduled work in a busy environment through stakeholder interviews and structured patient flow observations. The research recommends the introduction of a link practitioner to work between the surgical wards and the Theatre suite, as well as introducing turnaround teams in the Theatre suite to address these challenges. These

recommendations aim to overcome operational difficulties in the surgical services setting and are suggested for future integration and research (Doyle et al., 2022).

A study by Sohhal et al. (2022) identified critical success factors (CSFs) for LSS projects in healthcare. The study analyzed 62 completed projects conducted by Green Belts with the guidance of Black Belts. The research team, comprising practitioners and academics, used a grounded theory approach to identify numerous success factors, narrowed to eight through brainstorming sessions and workshops. The success of these projects was evaluated based on whether they achieved their stated objectives and key performance indicators. The study found significant correlations between all eight identified CSFs and project success. This research contributes to the literature on management control, operations management, and healthcare by providing a robust evaluation method and identifying specific success factors that can benefit managers of continuous improvement projects (Sohhal et al., 2022).

In the study by Tlapa et al. (2022) 4018 studies were reviewed, of which 39 met the inclusion criteria and were selected. The study found that healthcare services have increasingly utilized dual interventions integrating lean and Six Sigma with simulation modeling. The study focused on evidence-based practice, complied with the PRISMA guidelines, aimed to evaluate the effects of these dual interventions on healthcare services, and provided insights into which paradigms and tools produce the best results. The study reported predominantly positive results in 73 outcomes, mainly related to patient flow, such as length of stay, waiting time, and turnaround time. However, there was little evidence of the impact on patient health and satisfaction, staff well-being, resource use, and savings. Furthermore, the study found that 74% of the interventions utilized discrete event simulation as the central simulation paradigm, with 66% utilizing lean and 28% utilizing LSS. The findings confirmed that dual interventions mainly focus on utilization and access to healthcare services, particularly on patient flow problems or problems concerning the allocation of resources, but need more evidence of implementation.

The study recommended further research and practical applications, including Industry 4.0 technologies. It highlighted the need for more evidence on patient and staff health, well-being, and satisfaction. The study suggested increasing patient and staff participation in the evaluation process and expanding interventions to reduce infection rates or errors in medication. The interventions benefitted from a problem-solving, data-driven, and team-oriented approach, allowing hospital decision-makers to evaluate improvement proposals. However, the study

recommended increased use of these paradigms and more Industry 4.0 technologies to capture data and behavioral representations in various settings and contexts due to the need for reported patient and staff satisfaction outcomes.

In a recent study conducted in Canada as a project completed at St. Boniface Hospital to reduce overtime in operating rooms by Slagerman S., published in (2021) LSS was used to assess the entire system and identify multiple areas for improvement. One of the significant findings was that case duration estimates had the most potential for reducing overtime. Wait times and availability of care are important issues within Manitoba's healthcare system, and a new method for improvement is needed to address these areas. The research aims to prove the efficacy of using LSS in healthcare to generate improvements and promote the usage of continuous improvement methodologies in the healthcare environment. This resulted in creating and testing predictive models against the current method of surgeon estimates. All models demonstrated improvement over the surgeon estimates, including a 45-63% increase in on-time cases, a 49-59% reduction in overtime errors, and a 71-89% improvement in the overtime-to-undertime error ratio. It is recommended that a predictive modeling approach be used in the future. The LSS project successfully identified other areas needing improvement, ranked by potential impact, and provided process analysis and mapping that can be used in future projects. It also identified other causes of errors in scheduling. Additionally, had LSS not been used, the project would have focused on a less impactful area—first-case on-time starts. Through the data-driven process of LSS, the impact of bias was removed, and it was found that first-case on-time starts were not as influential to overtime as assumed. The research concluded that LSS can be effectively applied in complex hospital environments. It is recommended that hospitals consider implementing experienced teams to lead and train hospital employees in LSS or other continuous improvement methods (Slagerman, 2021).

Regarding the (WHO) SSC, Farag et al. (2020) discussed in their conceptual paper the adoption of the WHO SSC has been widespread to enhance patient safety during surgical procedures. However, compliance rates still need to be improved in many healthcare settings. This paper suggests a Six Sigma-based framework for increasing compliance with the WHO SSC.

The DMAIC methodology of Six Sigma was utilized to identify the root causes of non-compliance, implement targeted interventions, and improve checklist adherence. The framework includes process mapping, cause-and-effect analysis, and statistical process control to systematically address compliance barriers and monitor progress. The outcomes of this conceptual paper demonstrate that the proposed Six Sigma framework offers a structured approach to enhancing compliance with the WHO SSC. Key components comprise defining compliance goals, measuring baseline adherence rates, analyzing the root causes of non-compliance, implementing process improvements, and establishing control measures to maintain progress. The authors illustrate using Six Sigma tools and techniques throughout the DMAIC cycle, emphasizing their potential effectiveness in improving checklist compliance and patient safety (Farag et al., 2020).

In their study by Stomberg et al. (2020) they highlighted the widespread adoption of SSC to enhance patient safety despite suboptimal compliance rates. The study aimed to use LSS methodology principles to improve adherence to the SSC in a large academic medical center in the United States. A multidisciplinary team conducted a thorough surgical workflow analysis, identified improvement areas, and implemented targeted interventions based on Lean principles. The key measure was the compliance rate with the SSC before and after the interventions. Before the Lean interventions, the average compliance rate was 67%. After implementing process changes guided by Lean principles, such as standardizing workflows and improving communication, the compliance rate significantly increased to 91% ($p < 0.001$). Staff feedback indicated improved team dynamics, better communication, and a more efficient surgical process. The study demonstrated the effectiveness of applying Lean methodology principles to enhance compliance with the surgical safety checklist. The authors recommend:

1. Conducting a thorough process mapping and analysis to identify areas for improvement in the surgical workflow.
2. Involving a multidisciplinary team, including surgeons, nurses, and other operating room staff, in the Lean implementation process.
3. Focusing on standardizing procedures, eliminating non-value-added steps, and improving communication and teamwork.

4. Providing adequate training and resources to support the sustained implementation of Lean interventions.
5. Continuously monitor compliance rates and make adjustments as necessary.
6. Exploring the application of Lean principles to other aspects of patient safety and quality improvement in the operating room setting (Stomberg et al., 2020).

An additional study conducted in India by Lakshmi et al. (2019) showed that the SSC recommended by the (WHO) to improve patient safety has been implemented with notable results. However, their impact in low- and middle-income countries has yet to be studied. The study aimed to assess the effects of implementing the WHO SSC in a tertiary care hospital in India. They used a pre-post intervention study design to compare outcomes before and after checklist implementation. The primary outcomes were compliance rates with the checklist and surgical site infection rates, while secondary outcomes included other postoperative complications, mortality rates, and staff perceptions of teamwork and communication.

The study results showed that 1,247 surgical procedures were included (623 pre-intervention, 624 post-intervention). Compliance with the WHO checklist increased from 0% pre-intervention to 92.3% post-intervention ($p < 0.001$). Surgical site infection rates significantly decreased from 8.2% to 5.1% ($p = 0.03$) after checklist implementation, and staff surveys indicated improved perceptions of teamwork, communication, and safety culture following the intervention (Lakshmi et al., 2019).

Gil-Moreno and Luvianca (2017) explain in their study that quality improvement tools are widely used in the healthcare industry to enhance efficiency, patient safety, and cost reduction. The study delves into the effects of an LSS process improvement initiative on the overall process efficiency and patient safety in a large hospital provider's Labor and Delivery (L+D) units. The research focuses on utilizing modeling and simulation methodology to investigate the influence of a localized process improvement intervention on the overall output of the L+D unit by examining patient flow, system capacity, and unit performance. The simulation models capacity profiles and patient flow to determine patient throughput and waiting times. Baseline data was collected from information systems logs from two Sentara Healthcare facilities. Ultimately, the simulation analysis offers evidence to guide decision-making regarding the implementation of process improvement

across different scenarios; the results demonstrate a significant reduction in the registration process and the "Time to Arrive to the Physician" (Gil-Moreno et al., 2017).

Cima et al. (2009) highlighted that operating rooms can be complex environments where communication breakdowns, inefficient processes, and lack of standardization can jeopardize patient safety. The goal was to use LS.S principles to enhance safety and efficiency in operating rooms at a large academic medical center. A diverse team conducted a thorough analysis of operating room workflows, pinpointed areas for improvement, and introduced LSS interventions such as process mapping, standardization, and waste elimination. The main focus was on staff perceptions of safety culture, teamwork, communication, and operational metrics like on-time surgery starts and turnover times. Following the implementation of Lean interventions, staff surveys indicated significant enhancements in safety culture, teamwork, and communication in the operating rooms. Moreover, the percentage of on-time surgery starts rose from 62% to 78%, and the average turnover time between cases decreased by 25%. Qualitative feedback from staff emphasized improved standardization, better coordination, and reduced waste as significant advantages of the Lean implementation (Cima et al., 2009).

2.13 Related Local Studies

Only some studies use LSS methodologies in the context of Palestinian healthcare services. One of the more recent studies is by Abu Sharikh et al. (2019). This study demonstrated that integrating LSS can be a powerful tool for improving strategy and saving time. The study's main objective was to assess the impact of LSS practices on the quality of physiotherapy services at UNRWA healthcare centers using a descriptive-analytical approach. Data was gathered through a questionnaire distributed to 49 physiotherapists working at UNRWA healthcare centers between July 2016 and August 2017, following a stratified random sampling method. The results indicated a significant relationship between LSS dimensions and the quality of healthcare services in physiotherapy units at UNRWA healthcare centers. Additionally, LSS was adopted in 81% of the healthcare centers, and patient satisfaction regarding the quality of healthcare services in physiotherapy units was 89%. The study highlighted the effectiveness of LSS dimensions on the quality of healthcare services in physiotherapy units at UNRWA healthcare centers. The study also

recommended employee training and rewards for the successful implementation of LSS based on a needs assessment. Although employees were found to practice LSS, there needed to be more clarity regarding its concept as an approach. The average of all LSS dimensions' means was 4.05, with a mean percentage of applications at 81.04%. Moreover, LSS dimensions were found to be applied in UNWRA healthcare centers in the Gaza Strip. These high mean percentages indicated that LSS dimensions were practiced in the physiotherapy units, but the methodology had yet to be ultimately adopted. Therefore, the study recommended the adoption of LSS as a practice and approach in the physiotherapy units in UNRWA healthcare centers in Palestine.

Additionally, it was highly recommended that training and rewards be provided for physiotherapists to implement LSS based on a needs assessment successfully (Abu Sharikh et al., 2019).

A study conducted by Hussein (2018) in Palestine sought to assess the degree of implementing Six Sigma in private hospitals in Northern Palestine. The survey involved 300 self-administered questionnaires on Six Sigma implementation, and data from 282 usable questionnaires were collected and analyzed. The results indicated a moderate degree of Six Sigma implementation in private hospitals in northern Palestine. The study also emphasized the significant influence of management and financial support on Six Sigma implementation. The analysis revealed that specific related factors significantly impact Six Sigma implementation, while factors such as knowledge, experience, and training also play essential roles. The study's practical implications suggest that decision-makers and quality managers consider Six Sigma implementation by prioritizing the most influential factors rather than allocating resources to address all aspects. The study recommends that managers activate and enhance Six Sigma knowledge and support through knowledge management functions and training (Hussein, 2018).

2.14 Chapter Summary

This chapter provides evidence-based data regarding the benefits of deploying the LSS methodology to enhance the quality and safety of care, focusing mainly on deploying the WHO-SSC to reduce adverse events and mortalities. The chapter starts with an introduction about the history and the origin of LSS, how Six Sigma began, and how it was combined with Lean to act as a unified tool for maintaining service quality and enhancing customer satisfaction. Evidence-based data shows that adverse events and surgical complications contribute to a large number of mortalities and morbidities. SSC reduces adverse events and maintains safety, quality, and cost. SSC is a must at all healthcare entities. LSS methodology can help enhance the adherence rate to maintain safety.

Moreover, this chapter covers the most recent related studies and briefly overviews the indicators of Palestinian healthcare. It also provides background about the PMC and its services, mainly in the operating theater, where thousands of operations occur yearly.

Finally, this chapter illustrates the main barriers and challenges affecting the proper implementation of the SSC and provides a conceptual framework for overcoming those barriers.

Chapter Three: Methodology

3.1. Overview

This chapter explores the diverse methodological approaches employed in LSS as a robust framework for process improvement and quality management. The chapter covers several critical methodological components, including Research Strategy, which examines and discusses the application of cross-sectional studies in LSS and will explore how LSS utilizes historical data and past experiences to inform current improvement efforts and predict future outcomes. In addition, detailed observational techniques were provided in LSS to gather first-hand information about processes and workflows. Moreover, it covers the crucial role of training in LSS methodology, including approaches to educating team members on LSS principles, tools, and techniques. It examines how questionnaires are designed and implemented in LSS methodology to gather quantitative data from teams.

LSS is a crucial methodology that combines Lean and Six Sigma principles to improve processes, eliminate waste, and enhance quality. This research leverages LSS tools and techniques to address the challenges of practical implementation and compliance with the SSC in healthcare organizations.

Lean principles focus on identifying and eliminating non-value-added activities, known as waste, from processes. Lean defines the eight types of waste: defects, overproduction, waiting, non-utilized talent, transportation, inventory, motion, and excess processing (Antony et al., 2018). By reducing or eliminating these wastes, Lean aims to streamline processes, improve efficiency, and enhance customer value.

On the other hand, Six Sigma is a data-driven approach that emphasizes reducing process variations and defects. It utilizes statistical tools and techniques, such as the Define, Measure, Analyze, Improve, and Control (DMAIC) methodology, to identify root causes of problems, implement solutions, and ensure sustained process improvement. (Pyzdek& Keller, 2014)

Combining these two methodologies, LSS provides a comprehensive framework for process optimization and quality improvement. It enables organizations to identify and eliminate waste,

reduce variations, and enhance process capabilities, ultimately improving outcomes and customer satisfaction (Henshaw et al., 2016).

In this study, LSS was applied to the implementation process of the SSC. The DMAIC methodology guides the systematic approach to defining the problem, measuring current performance, analyzing the root causes, implementing improvements, and controlling sustained compliance with the checklist.

LSS has been highlighted as a potential program that can help healthcare providers in hospitals achieve quality improvements while minimizing costs. Implementing LSS was designed to increase quality by reducing variation, defects, and costs while eliminating waste in the process (Antony et al., 2018). In improving SSC in hospitals, implementing LSS proves beneficial by enhancing the efficiency of processes, reducing errors, and ensuring better quality outcomes for patients undergoing surgery (Improta et al., 2015).

By implementing LSS methodologies, hospitals can continuously work towards improving the safety and efficacy of surgical procedures. The successful implementation may require management commitment(Filiz&Mehavatsoğlu,2020)—input from frontline staff, utilizing various quality tools, and previous training in LSS methodologies. Therefore, employing LSS tools in the context of hospital surgery checklists can help address patients' demand for improved quality of care while meeting cost-related challenges faced by healthcare providers. By following the DMAIC methodology along with Lean tools, hospitals can identify issues, map processes, analyze causes, and implement improvements to enhance the safety and effectiveness of SSC (Henshaw et al., 2016).

3.2 The Research Strategy

To assess the role of LSS on adherence rate, several approaches were used in this methodology depending on LSS recommendations: staff awareness, Retrospective search, observations, training, and questionnaire. The methodology strategy outlined, here are some details on how LSS principles and tools can be applied to improve adherence to the SSCin healthcare operations in the PMC:

3.2.1 Cross-Sectional Study

Study Design: The study employed a cross-sectional design, which involves collecting data at a single point in time from operation units and various departments within thePMC. This design is suitable for assessing the prevalence of SSC compliance and its association with implementing LSS interventions across orthopedic surgeries and settings within the complex.

3.2.2 Retrospective Search

Several steps were included to collect and analyze data on SSC compliance rates as patient safety metrics from hospital records and databases. In parallel to the use of statistical tools like control charts to understand the baseline performance and identify areas with high variation or defects. Then perform a root cause analysis (Fishbone Diagrams) to identify potential causes of non-compliance or adverse events related to SSC.

3.2.3 Observations

The researcher conducts direct observations on surgical procedures and the uses of the SSC to identify potential waste, inefficiencies, or deviations from the standard process. This helps to identify any communication or teamwork issues that may impact the effective use of the checklist.

3.3 Training

The researcher assesses the importance of the training provided to surgical teams on the. Then the researcher develops and implements standardized training programs using LSS principles to ensure consistent understanding and applying the checklist.

3.4 Study Questionnaires

In this study, we applied a cross-sectional quantitative research approach to determine the effect of LSS on patient safety and adhere to a safe surgery checklist to improve the quality of PMC services in operating rooms for orthopedic patients. We used a self-administered survey questionnaire to collect data from respondents. This was mainly developed based on four research variables: implementing LSS methodology, patient safety, adherence to the safe surgery checklist, and quality improvement. A five-point Likert scale (1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = strongly agree) was used to measure the responses to each item of each research variable. Table (3.1) illustrates the research instruments of the study. Furthermore, the questionnaire includes work-related sociodemographic information (i.e., age, gender, social status, level of education, PMC experience, and job title).

3.4.1 Questionnaire Assessment

We assessed the validity of the questionnaire through content validity. Four faculty members from the health sciences department at Arab American University (AAUP) reviewed the questionnaire. Their feedback was used to craft the questions understandably. In this study, the Cronbach'salpha (CBα) of the study constructs (LSS, patient safety, safe surgery checklist, and quality improvement) was (0.92,0.89, 0.90, and 0.92, respectively). All four constructs exceeded the threshold value for CBα of 0.70 (Hair et al., 2017) and presented acceptable reliability. Table (3.1) shows the details and scoring of each item.

Table (3.1): Details of Constructs.

Variable	Role	Code	Items	Source
Lean Six Sigma LSS	IV	LSS1	Application of LSS practices to create a well-organized work environment in the hospital	Ahmed et al. (2024). Gowenet al. (2012)
		LSS2	Root cause analysis, fishbone diagrams, or value stream maps can be used to identify the causes of quality problems in healthcare processes.	
		LSS3	Continuous training programs on process improvement tools for the hospital staff	
		LSS4	Using LSS tools led to reduced healthcare costs.	
		LSS5	Using LSS improvement methods for continuously developing the hospital's projects	
Patient Safety	MV	PS1	Patient safety is a top priority of the hospital	WHO Patient Safety Initiative 3rd edition (2020) El-Jardali et al. (2014)
		PS2	Patients are involved in the treatment plan and decision-making regarding treatment.	
		PS3	The patient's family members participate in the treatment plan and decision-making regarding treatment.	
		PS4	Treating patients occurs within clinical practices based on evidence during therapeutic and surgical interventions.	
		PS5	An enhanced work environment for patients: design, environmental risk management, people with special needs	
		PS6	The hospital management offers several programs to ensure continuous education/training for the staff.	
Safe Surgery Checklist SSC	MV	SSC1	The level of general commitment to implement the SSC is satisfactory.	WHO guidelines for safe surgery (2009)
		SSC2	The SSC process is led during each surgical operation	
		SSC3	The SSC items are simple and easy to understand and apply	
		SSC4	The hospital management provides ongoing support and training to staff regarding the SSC commitment	
		SSC5	The hospital management provides mechanisms and feedback regarding compliance with the SSC	
Quality Improvement	DV	QI1	The overall performance of the hospital has improved	Ahmed et al. (2024) Gowenet al. (2012)
		QI2	Medical errors in inpatient services have been reduced	
		QI3	Medical complications in inpatient services have been reduced	
		QI4	Adverse events and incidents in patients have been reduced	
		QI5	Patient waiting times have been minimized	
		QI6	Patients' complaints have declined	
IV: independent variable, MV: mediating variable, DV: dependent variable				

3.5 Research Focus-Connecting Operating Department at PMC

The research focuses on implementing LSS methodologies in the operating department at PMC to improve patient safety by enhancing adherence to the LSS for orthopedic surgeries. The SSC is a crucial tool developed by the WHO in 2009 to enhance patient safety and prevent adverse events during surgical procedures. However, many hospitals need help consistently implementing SSC in their operating rooms.

The research involves qualitative methods, such as retrospective data collection, observation focus groups, process mapping, and statistical analysis of relevant data from the hospital's records and databases.

3.6 DMAIC Approach Objective and Tools

The DMAIC approach is a core methodology in LSS that can be applied to improve the implementation of the SSC in orthopedic surgery operating rooms.

3.6.1 Define Phase

A related study has been identified that defines the importance of the DMAIC phase in the adherence rate of surgical malpractice in terms of "The Safe Surgery Checklist has been shown to improve surgical outcomes, but its implementation remains inconsistent across different healthcare settings." (Haugen et al., 2015) The following steps should be followed when applying this phrase:

- ✓ Clearly define the problem or opportunity for improvement related to the Safe Surgery Checklist implementation.
- ✓ Establish project goals, scope, and team members.
- ✓ Use tools like Project Charter, problem Context Diagram (PCD), as well as Suppliers, Inputs, Processes, Outputs, and Customers (SIPOC) to define the project boundaries and stakeholders.

3.6.2 Measure Phase

In this phase, Russ et al. (2015) suggest measuring compliance with the SSC to evaluate its effectiveness and identify areas for improvement (Russ et al., 2015). The following steps should be taken when applying this recommendation:

- ✓ Collect baseline data on SSC compliance rates.
- ✓ Utilize data collection techniques such as direct observation, process mapping, and data mining from PMC records.
- ✓ Apply statistical tools like control charts and capability analysis to measure the current process performance.

3.6.3 Analyze Phase

We identified inefficiencies and root causes of variations and waste during the analysis phase. This was documented in a study that emphasized identifying and addressing the root causes of non-compliance with the SSC to improve its implementation and effectiveness (Haugen et al., 2015). In this phase, the following tools were applied:

- ✓ Analyze the collected data to identify root causes of non-compliance, process variations, and potential areas for improvement.
- ✓ Use tools like cause-and-effect diagrams and hypothesis testing to identify potential root causes.
- ✓ Apply statistical techniques like regression analysis and analysis of variance (ANOVA) to demographic data to determine significant factors affecting checklist compliance.

3.6.4 Improve Phase

The improvement phase aims to identify and address potential solutions to problems, as discussed in the study by Antony et al. (2018), This research study develops and implements solutions to address the identified root causes and improve the SSC implementation process.

3.6.5 Control Phase

Continuous evaluation and monitoring are necessary to uphold and perpetuate the improvement phase of implementing the SSC, which poses the most significant challenge in all healthcare organizations. This recommendation is highlighted in the study by Weiser et al. (2010), to implement the control phase, the next steps should be followed:

- ✓ Implement control measures to sustain and monitor SSC compliance and process performance improvements.
- ✓ Use statistical process control (SPC) techniques like control charts and control plans to monitor and control the process.

- ✓ Develop standardized work instructions, training programs, and continuous improvement plans to maintain the gains achieved.
- ✓ Conduct regular audits and feedback loops to ensure ongoing compliance and identify opportunities for further improvement.

By following the DMAIC approach and leveraging various LSS tools and techniques, healthcare organizations can systematically improve the implementation and compliance with the SSC, leading to enhanced patient safety and better-quality outcomes.

The research involved a collaborative effort with the PMC hospital's surgical teams, including surgeons, nurses, anesthesiologists, and other relevant stakeholders.

3.7 Research Setting

In 2024, the total number of patient beds at PMC reached 516, and there were 1120 healthcare workers from various professions, including 350 doctors and surgeons, 450 nurses, 120 allied professionals, 170 administrators, 18 pharmacists, and others. The complex provides general and specialized services in five main wings, which include 15 operating theaters. The outpatient clinics at PMC receive approximately 120000 patients annually, while the E.R. Department handles 150000 cases annually. The occupancy rate is about 99%, with an average length of stay of 2.5 days. Approximately 15,000 operations are performed at PMC each year.

The research study focuses on the orthopedic operations room in the operating theatre. Starting in December 2023, an ad hoc committee or core team was established to work on improvements. The core team consists of four frontline employees with high qualifications. The research study applied to orthopedic surgeries, and any improvements identified were recommended for all 15 operating rooms at PMC. The committee members were selected from six primary categories:

- ✓ The leadership members.
- ✓ Head quality department.

- ✓ Orthopedic Surgeons.
- ✓ Orthopedic nurses.
- ✓ Anesthesiologists and technicians.
- ✓ All heads of the nurse, all of whom acted as LSS. Advocacy team.

3.8 Population Of The Study

All 131 healthcare surgical staff from the operating theatre room who participated in and monitored all orthopedic surgery were the targeted population of the study (managers, quality coordinators, surgeons, anesthesiologists, and nurses).

3.9 Data Collection

In this research, several methods were used to collect quantitative data needed to complete the study, including a questionnaire about the role of LSS in the adherence rate of the SSC. Quantitative data were obtained from a team of safe surgery checklist implementations, and questions were directed to anesthesiologists, surgeons, nurses, managers, technicians, and quality officers.

The objectives of the questionnaires were to understand the current process of using the SSC during orthopedic operation surgeries in all its three phases (paranesthesia, time out, post-surgery). Another objective was to identify pain points, challenges, and potential areas of waste or non-value-added activities during the checklist implementation process by using techniques like process mapping to represent the current state and identify opportunities for improvement visually.

The questionnaire was composed of several sections each section contained several items for the participant to measure their agreement, those sections were demographic data of participants, four latent variables about the role of LSS in enhancing the adherence rate to the SSC with six items, followed by five items related to SSC implementation, then six items regarding patient safety and finally five items related to quality improvement. The participants

had to follow the five Lickert Scale to fulfill the questionnaire which ranged from strongly disagree to strongly agree.

Were conducted with all persons responsible for implementing and monitoring the SSC from different sections, including the clinical manager, nursing manager, orthopedic surgeons, anesthesiologists, anesthesia technicians, and quality.

In this study, we distributed 131 survey questionnaires to the respondents through the hospitals' administration and received 113 valid responses (86.3% response rate). Of those 113 respondents, 10 (8.8%) were orthopedic surgeons, 11 (9.7%) were orthopedic residents, 49 (43.4%) were nurses, 16 (14.2%) were anesthesiologists, 17 (15.0%) were anesthesia technologists, and 10 (8.8%) were managers. Furthermore, Table 3.2 illustrates the response rates by job title. Table (3.2) shows the response rate from each category.

Table (3.2): Respondents' response rate by their jobs (N = 113).

Job title		**Team**	**Response n (%)**
1	Orthopedic surgeon	13	10 (76.9)
2	Orthopedic resident	14	11 (78.6)
3	Nurse	55	49 (89.1)
4	Anesthesiologist	17	16 (94.1)
5	Anesthesia technologist	19	17 (89.5)
6	Manager	13	10 (76.9)
Total cohort		**131**	**113 (86.3)**

3.10 Records From Health Information System (HIS) Avicenna

PMC has an electronic health information system called Avicenna, where the data of all patients is recorded electronically in a unique file for each patient with a specific file number.

SSC is one of the forms that patients who perform a surgical procedure should fill out. This checklist should be managed by a team of orthopedic surgeons, anesthesiologists, and O.R. nurses. Unfortunately, data collected from Avicenna during the past five years reported a low

adherence rate, which varied from month to month between 62% and 86%, as shown in Figure (1) in Chapter One.

3.11 Data Analysis

Partial Least Squares Structural Equation Modeling (PLS-SEM) was used to determine the effect of LSS on patient safety and adherence to the SSC in improving the quality of PMC services in orthopedic surgeries. PLS-SEM is a multivariate statistical analytical tool that simultaneously evaluates all the structural paths among the variables in a conceptual model (Hair et al., 2017; Hair et al., 2020). Smart PLS 4.1.3 software was employed to analyze the measurement and hypothesized structural equation models, where the constructs' reliability, internal consistency, and validity were established. The rest of the analyses used the Statistical Package for Social Sciences (SPSS) software 27 edition. Categorical variables were expressed as frequencies and percentages. Continuous variables were described as means and standard deviations. Agreement scores regarding the study key variables by participants' general characteristics were analyzed using an independent t-test and analysis of variance (ANOVA) with the Scheffé post-hoc test. Pearson's correlation coefficient was used to examine linear associations between key variables. P-value < 0.05 was considered statistically significant. The significance level was set at 5% for all calculations.

3.12 Ethical Considerations

The study obtained ethical approval from relevant Palestinian institutional review boards (IRB) or ethics committees. Appropriate measures were taken to ensure patient and hospital data confidentiality and privacy. Informed consent was obtained from participating hospitals and individuals, as required. The ethical approval forms are added to the list of appendixes (D&E)at the end of this thesis.

3.13 Significance

This cross-sectional study will provide valuable insights into the effectiveness of LSS interventions in improving SSC compliance in the PMC. The findings can inform best practices and strategies for implementing LSS principles to enhance patient safety during surgical procedures in the Palestinian healthcare system. Additionally, the study may identify unique challenges and cultural factors that must be considered when implementing LSS interventions in the Palestinian context.

3.14 Define Phases of Lean Six Sigma

To improve the safety and quality of surgical procedures, the SSC's adherence rate should be improved. This research applies the DMAIC approach to maintaining the SSC's effective implementation. The Define phase of the DMAIC methodology provides a structured framework for identifying and defining the problem or opportunity for improvement related to implementing the safe surgery checklist.

Implementing SSC is a critical step in ensuring patient safety and reducing the risk of preventable errors during surgical procedures. This is particularly important in orthopedic surgery, where complex and invasive procedures are performed, and strict adherence to standardized safety protocols is crucial.

The Define phase is the foundation for the entire DMAIC methodology, establishing the scope, goals, and stakeholders involved in the improvement initiative. By clearly defining the problem or opportunity, the team can better understand the current state, identify potential root causes, and align on the desired future (Alharthi et al., 2021). This phase also involves gathering relevant data and information, mapping the process, and establishing project boundaries and constraints.

In orthopedic surgery, the Define phase involves identifying areas where the SSC implementation could be improved, such as inconsistent use, lack of compliance, or gaps in the

checklist. It may also involve defining the project's scope, whether it is focused on a specific orthopedic procedure or the entire department (Ronen et al., 2019).

By thoroughly defining the problem context diagram and establishing a clear project charter and SIPOC, the team can ensure that the subsequent phases of the DMAIC approach are focused and aligned with the overall goals of improving patient safety and surgical outcomes through the effective implementation of SSC.

In this phase we use three specific tools related to the define phase as shown in Figure (3.1), those three tools are:

- ✓ The Problem Context Diagram (PCD)
- ✓ The Project Charter
- ✓ The Suppliers, Inputs, Process, Outputs, and Customer (SIPOC) diagram

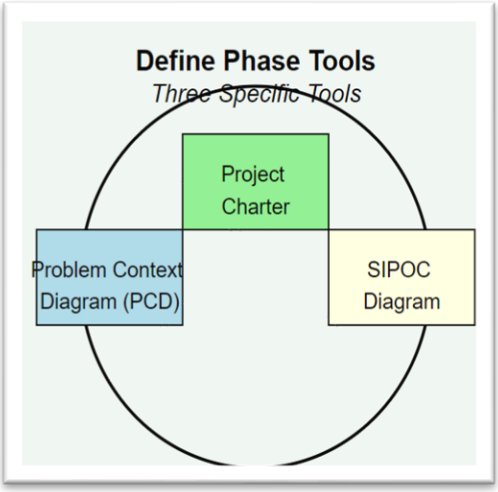


Figure (3.1): Define Phase Tools

3.14.1. Problem Definition

The SSC is available through the HIS software at PMC, and all surgical teams can fill out the form for each patient. A low adherence rate to implementation will increase sentinel, adverse, and near-miss events that could lead to severe patient harm .It is estimated that 16% of major surgical procedure cases have morbidity complications; the use of SSC can prevent eighty percent of them. (Keijzer et al., 2017)

This research notes that managers' PMC monitoring and auditing process needs further support, and daily OR capacity must adequately match daily operation list demand. Daily shortages and variations are attributed to overload, hierarchy, poor communications, and other factors.

The PMC managerial team needs new, practical, powerful tools to enhance implementation and adherence to SSC. This project proposes the LSS Methodology as an advanced, straightforward approach to facilitating implementation and increasing loyalty and compliance.

The problem with the PMC is that the patient safety indicators show a low adherence rate to implementing the SSC, which was at most 86%. This may increase morbidity and mortality rates among patients who underwent surgical procedures.

This is the first study in Palestine to use the LSS methodology to assess and improve the adherence rate of the SSC.

3.14.2. The Problem Context Diagram (PCD)

In the Define phase of the DMAIC approach for implementing an SSC, a Problem Context Diagram (PCD) was established by researcher contact observation of the current process to visualize the problem statement, its scope, and the various factors or elements contributing to the problem. Figure (3.2) illustrates the diagram that provides a holistic overview of the suppliers and customs that affect the adherence rate to the SSC as shown below:

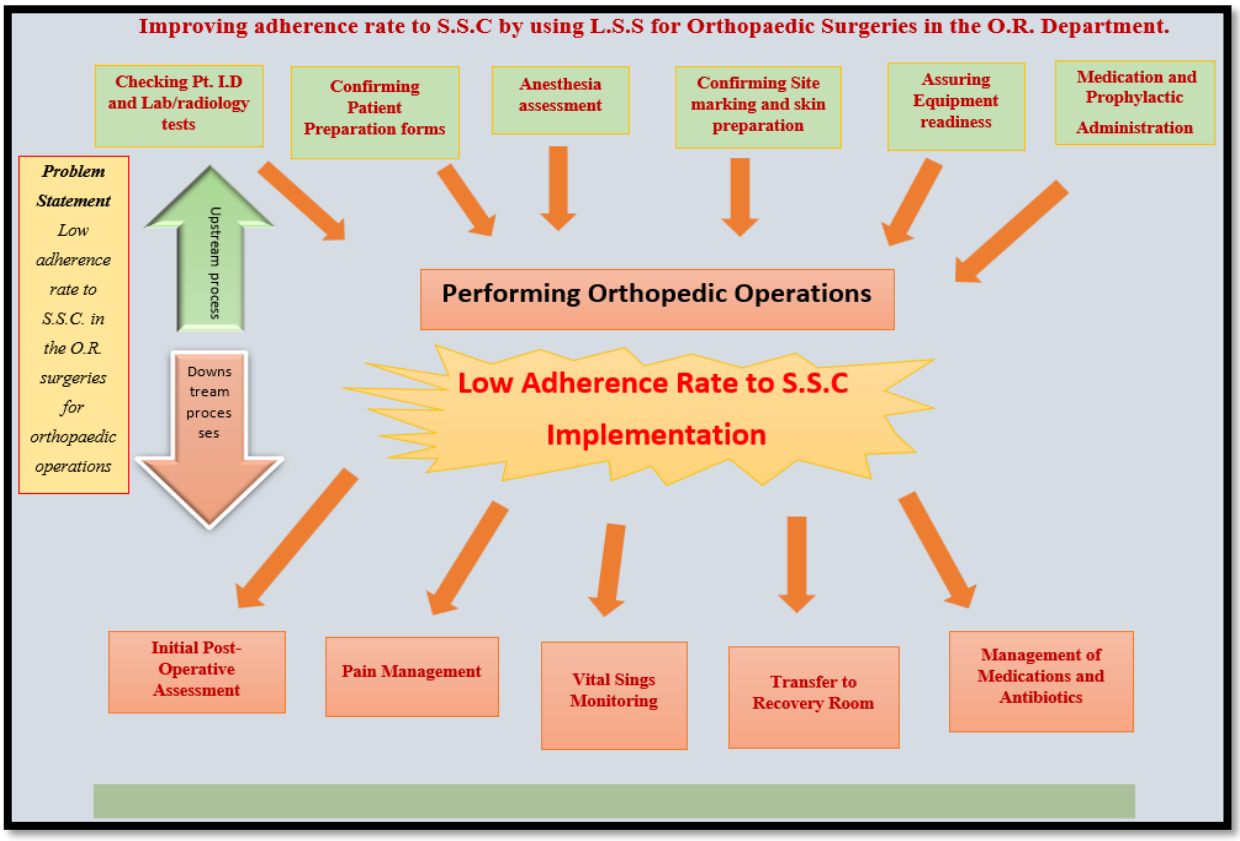


Figure (3.2): Problem Context Diagram

By using the PCD tool, which was established by the contact observation of the researcher, the ad-hoc committee team was able to determine the upstream steps that contribute to the process of enhancing the rate of an SSC implementation; these steps are as follows:

"Checking Patient ID and Lab/Radiology Tests" process is a critical component in the Problem Context Diagram, especially about the SSC to ensure the correct patient is receiving the intended procedure and to verify that all necessary pre-operative tests are available and reviewed which verifying patient's name, date of birth, and medical record number, patient's ID bracelet. Additionally, it is vital to confirm that all required blood tests are completed. Results are available to ensure all necessary imaging studies (X-rays, MRIs, CT scans) are available for the correct patient and body part.

"Confirming Patient Preparation Forms" is a crucial step in the pre-operative process for orthopedic surgeries. It ensures that all necessary pre-operative preparations have been completed by verifying that the patient is ready for surgery and confirming that all required documentation is in order, including the Consent Forms (informed consent for the surgery is signed and dated, consent for anesthesia, and blood transfusion). Additionally, confirm completion of pre-op fasting requirements, removal of jewelry, dentures, and contact lenses, and proper skin preparation; this aligned with the medication reconciliation and allergy alert forms.

"Anesthesia Assessment is also a critical step in this process where Checking for completion of all anesthesia steps according to the anesthesia plan is confirmed by the responsible anesthesiologists, Confirming that the patient is fit to operation, all lab tests, radiology test, ECG are reviewed, all required blood units are available, all anesthesia equipment is maintained and ready.

"Confirming site marking and skin preparation" is also a critical step of the upstream factors. It ensures that the surgical site has been marked correctly and that this marking matches the consent and surgical plan. In addition to Checking for proper skin preparation, hair is removed correctly from the incision area.

"Assuring equipment readiness" is a crucial step that concerns the readiness of all equipment and instruments; anesthesia equipment and other instruments should be checked for availability, sterility, and functionality effectively. Artificial joints, plates, screws, and drills are

the most instruments that were used and should be checked effectively because the use of the wrong implant size or type or unavailability of necessary equipment leads to improvisation or delays.

"Medication and Prophylactic Administration" is also critical before, during, and after the operation. All Medication is checked to prevent errors (e.g., wrong dosage, allergic reactions) or overmedication risks due to lack of communication about administered drugs. Confirming that antibiotic prophylaxis is administered in the correct timing

While the downstream factors are more closely tied to the following factors:

"Initial Post-Operative Assessment" is a critical post-operative step that includes assessing the wound closure, sponge account, patient physical posture, and procedure timing to mitigate delays, cancellations, and increased complication risks.

"Pain Management" is used as an indicator of patient orientation level after anesthesia. Patient pain levels should be monitored and documented. It is the process of providing medical care that alleviates or reduces pain. Mild to moderate pain can usually be treated with analgesic medications like aspirin. For chronic or severe pain, opiates and other narcotics may be used with steroids or nonsteroidal anti-inflammatory drugs when the pain is related to inflammation or with antidepressants.

"Vital Sings Monitoring" is a crucial postoperative process to maintain patient safety after a surgical procedure and detect any postoperative complications that may arise. One of the essential aspects of postoperative care is monitoring the patient's vital signs, a set of physiological measurements that indicate the body's overall health status. These include heart rate, blood pressure, respiratory rate, and body temperature. Post-operative patients are at high risk of developing complications like bleeding, infection, and respiratory distress. For instance, an increase in heart rate and respiratory rate could indicate the onset of sepsis, a life-threatening disease. Similarly, a drop in blood pressure could signify internal bleeding or hypovolemia. Early detection of such complications can help prevent further deterioration and improve patient outcomes.

Vital sign monitoring is also essential in assessing the effectiveness of pain management. Pain is a common post-operative symptom that can cause discomfort and distress to the patient.

The pain can be managed using medications, but these medications can have side effects that affect the vital signs. For example, opioids can cause respiratory depression, leading to a drop in respiratory rate. Monitoring the patient's vital signs can help determine the appropriate pain medication and dose to avoid adverse effects.

Additionally, vital sign monitoring is critical in determining when a patient can be discharged. The patient's vital signs must be stable for a certain period before discharge, indicating that they are safe to return home. Vital sign monitoring also helps the healthcare team to determine the patient's readiness for physical activity and rehabilitation. Monitoring the critical signs helps detect and treat post-operative complications, assess the effectiveness of pain management, and determine the patient's readiness for discharge. Early detection of complications can lead to prompt intervention, improve patient outcomes, and prevent life-threatening situations. Therefore, healthcare professionals must prioritize vital sign monitoring in post-operative care to ensure patient safety and promote a speedy recovery.

"Transfer to Recovery Room" is also a crucial step that requires specific actions to be addressed to maintain the safety of the transferring process. At the end of a surgical procedure, the surgical team performs several tasks in post-operative care, such as wound dressing, specimen handling, and operating room cleaning. After a surgical procedure, the patient is transferred to the recovery room for post-operative care. This step is crucial as it allows continuous monitoring of the patient's vital signs and anesthetic and surgical complications. Post-operative issues such as pain and nausea/vomiting are managed in a controlled environment. An element of disorientation is not uncommon, and recovery staff should be on hand to reassure the patient as the anesthetic's effects wear off and they regain full consciousness. This step is vital in ensuring the patient's safety and promoting a smooth recovery process.

"Management of Medications and Antibiotics" is one of the most critical postoperative procedures that should be monitored. It follows the standard protocol and includes prophylactic antibiotics administered for 24 hours and low-molecular-weight heparin. Postoperative management also provides for the administration of maintenance fluids and the replacement of ongoing losses. Close monitoring of electrolytes should occur in this step, and intravenous fluids should be discontinued as soon as the patient can tolerate oral fluids. It is part of a multimodal

management strategy for pain, nausea, and blood loss devised jointly by both orthopedic surgeons and anesthesiologists.

3.14.3. The Project Charter

The Define phase of the DMAIC methodology is a critical first step in any process improvement initiative, laying the foundation for the successful execution of the project.

Developing a comprehensive project charter is essential in improving the safe surgery checklist in orthopedic operations. It ensures alignment among stakeholders, clarifies project goals, and establishes a roadmap for the subsequent phases. This charter is a document and a tool that keeps everyone informed and involved in the process. (Dempsey et al., 2021)

The project charter is a formal document that outlines the improvement project's scope, objectives, and boundaries. It defines the problem statement, the expected benefits, and the resources required to undertake the initiative. By clearly articulating these elements, the project charter provides a shared understanding among team members, sponsors, and stakeholders. This shared understanding fosters collaboration and commitment, making everyone feel united in their goal.

In the case of improving the safe surgery checklist for orthopedic operations, the project charter may address issues such as inconsistent compliance, gaps in the checklist design, or ineffective integration into the surgical workflow. It should also outline the project's objectives, such as reducing surgical errors, improving patient outcomes, or enhancing staff engagement with the checklist process. (Ronen et al., 2019)

Furthermore, the project charter should identify the key stakeholders involved, including surgical teams, hospital leadership, quality improvement professionals, and patient representatives. This ensures that diverse perspectives and concerns are considered throughout the project's lifecycle (Improta et al., 2015).

By establishing a well-defined project charter in the Define phase, the team can effectively navigate the subsequent phases of the DMAIC approach, ensuring that the improvement efforts remain focused, aligned with organizational goals, and driven by data-driven decision-making.

The project charter has been developed and approved by the project add-hoc committee team, as shown in Table (4.1); it shows the following elements:

Project problem: The project problem is the need to properly implement an SSC in the operating theaters, which could harm the patient and affect the quality of service.

Project purpose: The compliance rate should exceed 95%, while the implementation rate has varied from 62 % to 86 % over the past five years. These objectives are not just numbers but the focus of our work and the goals we strive to achieve. They keep us on track and remind us of our ultimate aim.

Project scope: All operating rooms where orthopedic surgeries are performed and all relevant staff in the PMC.

The business case: The PMC started implementing the patient safety standards in 2012, and the SSC is one of those standards. The lack of proper implementation of an SSC in the operating theaters could harm the patient and affect the quality of service. The compliance of implementation varies from department to department, and from month to month, the compliance rate should exceed 95% to reduce medical errors, adverse events, and operational complications. In comparison, the implementation rate varies from 62 to 86 % over the past five years. This project requires up to 6 months from the start of writing the charter. Table (3.3) presents the project charter:

Table (3.3): The project charter for improving the SSC for orthopedic operations.

<table>
<tr><td>Project Sponsor</td><td colspan="3">Palestine Medical Complex Chief Executive Officer Dr. Ahmad Betawi</td></tr>
<tr><td>Team Leader</td><td colspan="3">Quality coordinator Mr. Ayman Abu Mohsen</td></tr>
<tr><td>Project Title</td><td colspan="3">Applying the LSS methodology to improve compliance with the implementation of a safe surgery checklist</td></tr>
<tr><td>Date</td><td colspan="3">6/12/2023</td></tr>
<tr><td>Issue</td><td colspan="3">Dec 2023</td></tr>
<tr><td colspan="4">Problem Definition and Purpose
What problem or outcome do you dislike? What is the project trying to accomplish? Which process gives this output? What measure will show any improvement? What is the present performance? What is the goal performance? What is the timing for reaching this goal?</td></tr>
<tr><td colspan="4">The project problem is the need to properly implement an SSC in the operating theatres, which could harm the patient and affect the quality of the service provided. The quality coordinator monitors the project using walk-around observations, reviewing the patient file, form, checklists, and interviews with physicians, nurses, and patients.
This project aims to deliver safe and effective orthopedic surgeries to patients, with a consistent adherence rate to a safe surgery checklist that reaches at least 95% commitment.</td></tr>
<tr><td colspan="4">Business Case (Issues to be addressed/process to be improved)
How does this problem impact our customers, the business, employees, and the environment?
Why is this a priority? What are the key deliverables to be expected? What other indirect benefits may arise from this work?</td></tr>
<tr><td colspan="4">The PMC implemented patient safety standards in 2012, including SSC. Implementation compliance varies from department to department and month to month. The compliance rate should exceed 95%, while the implementation rate ranges from 62% to 86% over the past five years.</td></tr>
<tr><td colspan="2">Key Players
Who are the Sponsor/ Team Leader/Team Members/ Other Key People who need to be involved?</td><td colspan="2">Scope
Which area/department within the organization, products/market segments/customers, will be covered? What is out of scope?</td></tr>
<tr><td>Sponsor</td><td>PMC CEO</td><td colspan="2" rowspan="2">In scope: O.R. department -Kuwaiti Wing</td></tr>
<tr><td>Team Leader</td><td>Quality Coordinator</td></tr>
<tr><td>Team Members</td><td>Ad-hoc committee,</td><td colspan="2" rowspan="2">Out of scope: Other departments</td></tr>
<tr><td>Other Key People</td><td>Surgical Nurses, Physicians, anesthesia tech</td></tr>
<tr><td colspan="2">Enablers/Risk Mitigation
What needs to be in place to ensure the project progresses?</td><td colspan="2">Barriers/Risks
(<u>Not</u> the opposite of enablers)
What are the potential barriers to the work?</td></tr>
<tr><td colspan="2">Leadership commitment with internal circular.
Spirit of teamwork.</td><td colspan="2">Lack of awareness.
Employee resistance to change
Lack of Communication.</td></tr>
</table>

Policies and procedures. Tools and logistics (educational materials, warning signs, clippers, swabs, meeting room, snacks). Training Hall (PMC hall) Access to HIS & Internetwork.	Lack of budget. Vacations & Travelling.
Support Estimates Estimate the people, equipment, expertise, and capital required for the project.	
An ad-hoc committee will direct the project's execution. They will need a Project budget, educational materials, forms, signs, a laptop, and other logistics; the initial project is about 3000 NIS.	

3.14.4. SIPOC Tool

The SIPOC diagram is a visual representation that identifies the Suppliers, Inputs, Processes, Outputs, and Customers associated with the process under consideration. This tool helps define the process's boundaries, the stakeholders involved, and the inputs and outputs that must be monitored and optimized. (Alharthi et al., 2021)

In the Define phase of the DMAIC methodology, a critical tool that can aid in establishing a comprehensive understanding of the process being improved is the Suppliers, Inputs, Process, Outputs, and Customer (SIPOC) diagram. When embarking on an initiative to enhance the safe surgery checklist in orthopedic operations, the SIPOC diagram provides a structured framework for mapping out the critical elements involved in the process. (Dempsey et al., 2021)

The SIPOC diagram can help improve the safe surgery checklist by identifying suppliers that provide essential resources for the surgical process, such as equipment manufacturers, sterilization services, and regulatory bodies. It can also highlight the required inputs, including surgical instruments, patient information, and the checklist. (Improta et al., 2015)

Additionally, the SIPOC diagram allows the team to clearly outline the core process being analyzed: implementing and utilizing the safe surgery checklist in orthopedic operations. This process may involve several steps, such as pre-operative briefings, time-outs, and post-operative debriefings. (Ronen et al., 2019)

Furthermore, the diagram can help identify the desired outputs of the process, such as completed surgeries, improved patient outcomes, and compliance records. It also ensures that

the customers or stakeholders benefit from successfully implementing the safe surgery checklist, including patients, surgeons, hospital management, and regulatory bodies, are recognized and considered (Dempsey et al., 2021). The diagram is attached in Figure (3.3):

Key Business Process Name: Improving adherence rate to S.S.C to Perform Safe Orthopaedic Surgeries.

Suppliers	Input	Process	Output	Customers
Hospital administration, Medical supply companies.	Surgical Staff, Surgical equipment, Medical supplies, Avicenna software for tests, current adherence data, Patient information, and staff training materials.	**Process Purpose:** to deliver safe and effective orthopedic surgeries to patients with an improving adherence rate to S.S.C **Process Owner:** Chief of Orthopaedic Surgery.	Completed orthopedic surgeries with a high safety checklist adherence rate and Reduced surgical errors.	Orthopedic surgery patients, recovery room staff, surgeons, nursing and technician staff, the Hospital quality control department, and the Healthcare management body.

Process Steps (High Level)	Review the current adherence →	Identify barriers to checklist use →	Develop improvement strategies by L. S. S →	Implement staff training →	Monitor checklist usage →	Collect and analyze data Provide feedback	**Results Measures** 1-Number of successful orthopedic surgeries. 2-Average lead time for orthopedic surgeries. 3- Percentage of commitment with S.S.C	**Customer Needs** 1. Patients expect safe surgeries with ZERO errors and on-time surgery. 2. Surgeons want efficient processes that don't delay procedures. 3. Nursing staff need clear, easy-to-follow checklists. 4. Hospital administration wants to improve S.S.C metrics and regulatory compliance.
Process Measures	Percentage of surgeries using the complete checklist	Time taken to complete the checklist	Number of staff trained on checklist use					
Present Data	The current adherence rate is estimated between (62%-86%).	Average time to complete the checklist (15 minutes).	Percentage of staff trained (87%).					
Goal Performance	Increase adherence rate to 95% within 6 months.	Reduce average checklist completion time to 9 minutes.	Achieve 100% staff training completion.				**Results Concerns** 1. A 5% failure rate of orthopedic surgeries might not directly correlate with checklist adherence. 2. Potential initial slowdown in surgical preparation times. 3. A 5% staff Resistance to compliance S.S.C rate.	**Date** JUN 31, 2024
Sources of Variation & Waste	Lack of accountability for checklist completion.	Time pressure during surgical preparation.	Inconsistent training across shifts.					**Version** 1.0
Impact on Performance	Increased adherence leads to fewer surgical errors	A streamlined checklist reduces preparation time	Comprehensive staff training improves overall surgical safety culture					

Figure (3.3): SIPOC Diagram

3.14.5 Define phase Tollgates (summary)

In the Define phase of the DMAIC methodology for improving the safe surgery checklist, there are typically several tollgates that were review points that need to be met before proceeding to the next phase. These tollgates help ensure that the Define phase is completed thoroughly and that the project has a solid foundation. The five tollgates are as follows:

3.14.5.1 Problem Statement And Project Scope Tollgate

- ✓ Review and approve the clearly defined problem statement related to the safe surgery checklist process.
- ✓ Validation of the project scope, including the surgical procedures, operating rooms, and departments covered.

3.14.5.2 Process Mapping Tollgate

- ✓ Review and approve the high-level process by applying the SIPOC of the current safe surgery checklist process.
- ✓ Confirmation that potential areas of waste, variation, or potential failures have been identified.

3.14.5.3 Project Charter Tollgate

- ✓ Review and approve the project charter, including the problem statement, project scope, goals, team members, and other vital details.
- ✓ Verify that relevant stakeholders and leadership have endorsed and approved the project charter.

3.14.5.4. Baseline Metrics Tollgate

- ✓ Review and validation of the established baseline metrics or performance measures related to the safe surgery checklist process.
- ✓ Confirmation that the baseline metrics are appropriate, measurable, and aligned with the project goals.

These tollgates typically involve review and approval from the project team, relevant stakeholders, and potentially a steering committee or oversight group. Meeting these tollgates ensures that the Define phase has been completed thoroughly, all necessary inputs have been gathered, and the project has a solid foundation before proceeding to the Measure phase of the DMAIC methodology**.**

3.14.5.5. Define Phase Summary

In the define phase, the problem has been identified with the current SSC process and its impact on patient safety. Gather input from key stakeholders (managers, surgeons, nurses, anesthesiologists, and quality officers) and map the existing checklist workflow to identify potential areas of waste or failure. Establish baseline metrics to measure the effectiveness of the checklist process before implementing improvements.

3.15 Measure Phase

The measure phase in the DMAIC approach is crucial for establishing a baseline understanding of the SSC process in operation rooms, especially for orthopedic surgeries. This phase involves collecting data and measuring key performance indicators (KPIs) related to checklist adherence using LSS tools, surgical outcomes, and patient safety. By accurately measuring the existing process, healthcare organizations can identify areas for improvement and set targets for future progress.

So, in the Measure Phase, several tools and techniques can be employed to quantify the current state of the safe surgery checklist process. By accurately measuring the current state of the safe surgery checklist process using these tools, healthcare organizations can establish a baseline for improvement, identify critical areas for intervention, and set realistic targets for enhancing patient safety and surgical outcomes. The following tools were applied to understand the as-is situation of the process:

- ✓ **Flowcharts** to visualize the current checklist process, identify potential bottlenecks, and pinpoint areas for measurement.
- ✓ **Eight wastes**.
- ✓ **Analysis of the questionnaire.**
- ✓ **Statistical process control (SPC)**: Utilizing control charts and other SPC techniques to monitor and analyze the variability in checklist adherence and surgical outcomes. This is illustrated in Figure (3.4):

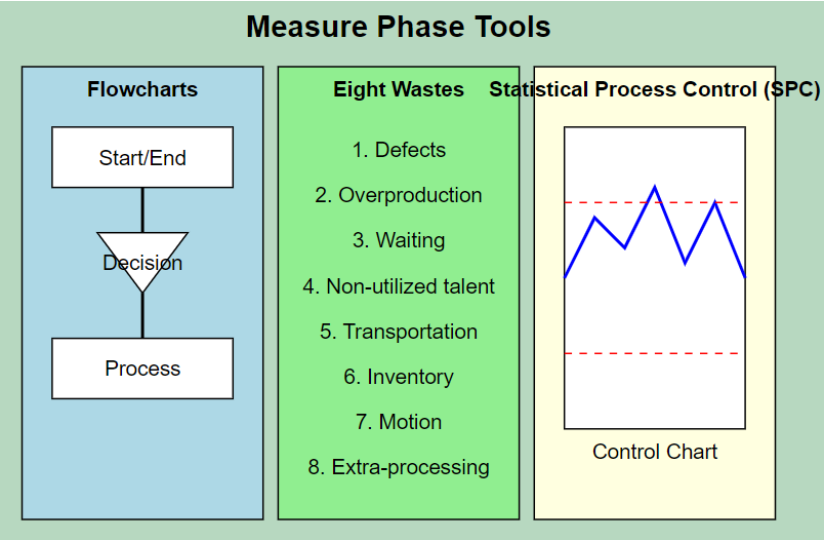


Figure (3.4): Measure Phase Tools

3.15.1 Flow Chart

One of the essential tools is a visual representation of the sequence of steps involved in a process, making it easier to understand, analyze, and identify areas for improvement. The patient flow is illustrated in Figure (3.5).

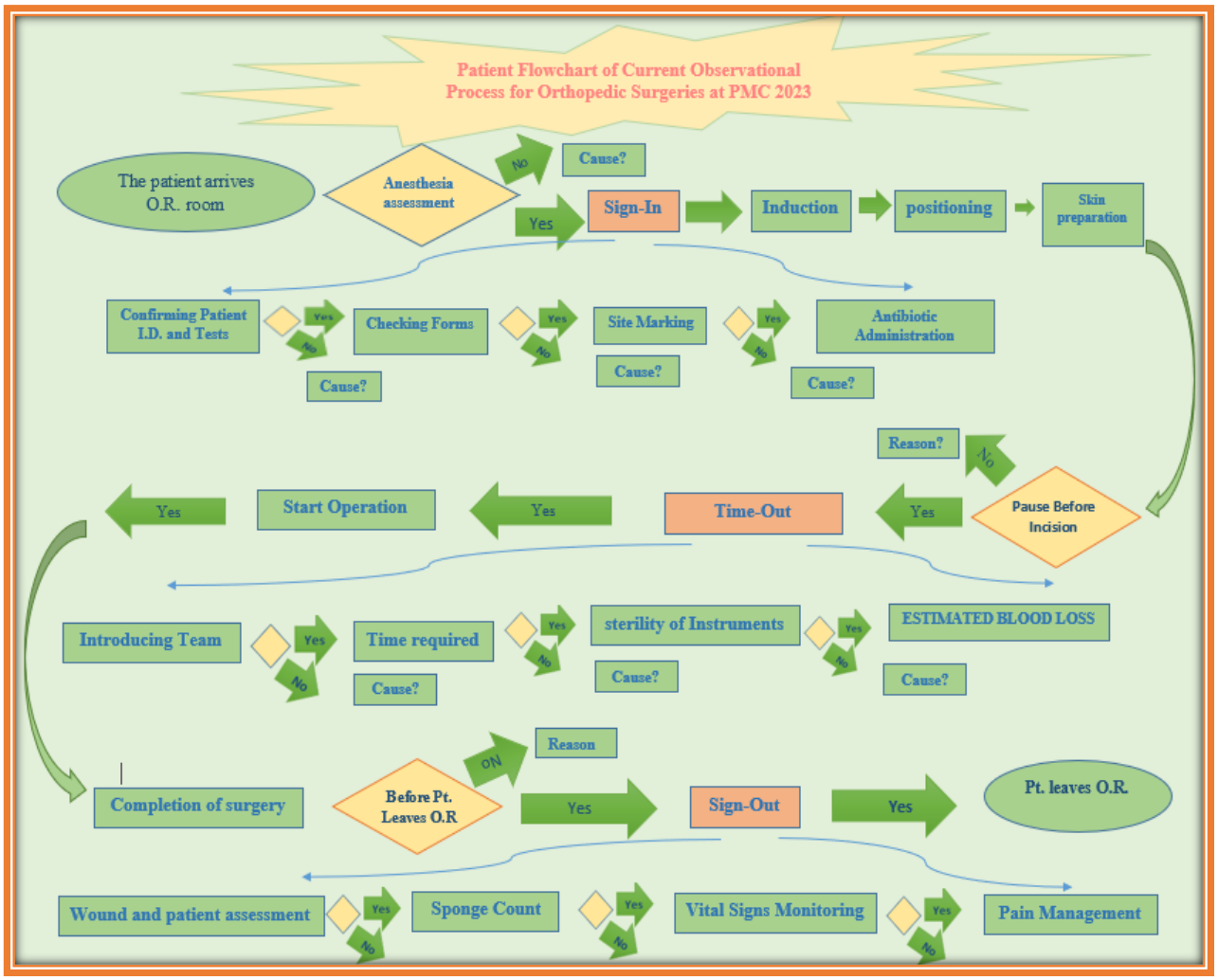


Figure (3.5): The flow charts of the current observational process and tracing of orthopedic surgery patients for a SSC in the operating theatre department.

From the flow chart above, it is noticed that:

- ✓ The process has many steps to be performed.
- ✓ The process has three approval stages.
- ✓ Non-value-adding steps exist in the process.
- ✓ Non-value-adding steps cause waste in time, and defects were identified

Flow charts can be utilized in this study to illustrate the detailed process steps, which helps understand the process steps and eliminate the non-value-adding steps. Flow charts are useful for visually representing a process's steps and decision points. In the context of tracing

orthopedic surgery patients for safe surgery checklists in the operating theatre department, the key steps included in the flow chart are:

1- *Patient Identification and Verification step:* In this step, the recovery room staff confirms the patient's identity (name, date of birth, medical record number) and verifies the surgical site and procedure by cross-checking patient information with the surgical consent form and medical records. The staff also confirms the administration of prophylactic antibiotics and other necessary medications.

Major obstacles observed are that sometimes the anesthesiologist did not assess the patient the previous day, and they found him not fit for the operation. Other barriers related to non-fasting or consent forms need to be signed. Other obstacles pertain to financial issues, such as copayments. These obstacles are symbols of non-added values where time waste was noticed and can be eliminated by defining the cause through root cause analysis and corrective issues to remove non-efficient time.

2- *Pre-operative Checks (sign-in) step:* This step is the patient's induction, where the staff reviews the patient's medical history, allergies, and current medications. The staff also confirms the availability of the required surgical instruments, implants, and equipment. The staff ensures that necessary pre-operative tests and imaging studies are completed and reviewed. Moreover, the staff verified the correct site and procedure with the surgical team. The main issue observed was that the surgical site was not marked on the surgical sites. Other problems related to improper documentation on patient records. These defects are other signs of non-added values where time waste was noticed and can be eliminated by defining the root cause analysis and corrective issues to remove non-efficient time.

3- *Safe Surgery Checklist: Surgical Timeout step:* In this phase, the process is stopped for briefing and introducing surgical team members. Additionally, the staff Confirms the patient's identity, surgical site, and procedure. Then, the staff verifies relevant medical records and implant information availability. Also, the staff discusses anticipated critical events, potential complications, and contingency plans to address any last-minute concerns or issues raised by the surgical team. The main problem in this phase is the need for more commitment and effectiveness in the participating (time-out) phase due to work overload.

4- *Intra-operative before the patient leaves the operating room (sign-out) step:* The operation staff monitors the patient's vital signs and surgical progress and discusses any concerns before leaving the theater. The staff documents any deviations from the planned procedure or unexpected events and ensures proper handling and labeling of specimens. The main challenge observed was staff fatigue and stress due to long working hours, mainly in primary operations such as joint replacement. That leads to Inefficiencies in implementing the process of complying with the SSC in orthopedic surgeries.

This study represents and analyzes all steps of the Flowchart, identifying potential bottlenecks, redundancies, or non-value-added activities that contribute to inefficiencies or non-compliance with the SSC.

3.15.2 Eight Wastes

The SSC introduced by the WHO in 2008, is a critical tool designed to enhance patient safety and prevent adverse events during surgical procedures. However, despite its proven effectiveness, many healthcare organizations need help with low compliance rates, leading to potential risks and compromised patient outcomes (Gillespie & Marshall, 2015). One approach that has gained traction in addressing this challenge is the application of LSS principles, which aim to eliminate non-value-added activities and optimize processes.

LSS is a robust methodology that combines Lean principles and focuses on reducing waste and improving efficiency. Six Sigma is a data-driven approach to reducing process variation and defects (Antony et al., 2018). Central to the Lean philosophy is eliminating the eight wastes, often called "muda" in Japanese (Laureani& Antony, 2017). These eight wastes are categorized into eight categories: defect, overproduction, waiting, non-utilized talents, transportation, inventory, motion, and Excess processing. Abbreviated into one word, it is called (DOWN TIME) by identifying and eliminating these non-value-added activities, healthcare organizations can streamline processes, reduce inefficiencies, and improve compliance with critical protocols like the SSC. (Siddiqui et al., 2019).

Table (3.4): Eight wastes in the process and tracing of orthopedic surgery patients for SSC in the operating theatre**.**

Workflow			DOWNTIME							
Step	**Activities**	**Executed by**	**Defect**	**Over-production**	**Waiting**	**Non-utilized Talents**	**Transport**	**Inventory**	**Motion**	**Excessive Processing**
1	Sign In Process (Before Anesthesia)	Nurse & anesthesiologist	Improper surgical site markings, incomplete patient information	Performing unnecessary tasks or collecting excessive information can lead to waste.	Waiting for consent forms to be signed or financial clearance.		Patients are not being assessed adequately before arriving at the operating room, leading to delays or cancellations.	Excess or insufficient inventory of equipment can cause disruptions leading to postponed procedures		Inefficient or duplicated documentation processes, causing delays and errors.
2	Time out. (Before Skin Incision)	Surgeon				Lack of commitment or engagement during the "time-out" phase, leading to potential errors				
3	Sing Out (before the patient leaving	Nurse & Anesthesia							Inefficient movement or searching for necessary items can waste time and effort	

The eight wastes that exist in the three phases of the process of SSC (Sign in, Time out, Sign Out) and tracing orthopedic surgery patients for safe surgery checklist in the operating theatre department are summarized in Table (3.4) as follows:

1. **Transportation:** Unnecessary movement of patients, staff, or equipment can lead to delays and inefficiencies. Patients must be assessed or prepared adequately before arriving at the operating room, leading to delays or cancellations.
2. **Inventory:** Excess or insufficient inventory of supplies or equipment can cause delays or disruptions, such as the unavailability of required surgical instruments, leading to postponed procedures.
3. **Motion:** In the Sing-Out phase, Inefficient movement or searching for necessary items can waste time and effort. Staff searches for medical records, consent forms, or surgical site markings.

4. **Waiting:** In the Sign-In phase, Waiting for consent forms to be signed or financial clearances delay the surgical process.
5. **Overproduction:** Performing unnecessary tasks or collecting excessive information can lead to waste. Redundant documentation or unnecessary pre-operative tests add complexity and potential errors.
6. **Over-processing:** Performing more work than necessary or following inefficient processes can lead to waste. Inefficient or duplicated documentation processes, causing delays and potential errors.
7. **Defects:** Errors, omissions, or deviations from standard procedures, such as improper surgical site markings, incomplete patient information, or deviations from the planned procedure, can lead to rework or potential harm.
8. **Underutilized human potential:** Failure to involve or empower staff can lead to missed opportunities for improvement in the Sing-In phase and lack of commitment or engagement during the "time-out" phase, leading to potential errors or oversights.

We apply LSS principles to address this waste in upcoming modules. Value stream mapping: Identify and eliminate non-value-added activities in the SSC process. Root cause analysis in the next chapter: Use tools like fishbone diagrams to identify the root causes of inefficiencies or non-compliance with SSC.

3.15.3 Control Chart

Control charts are powerful visualization tools used in the Measure phase of the DMAIC methodology, which displays process data points plotted against control limits and is calculated based on the process's natural variation. By analyzing the pattern of data points on the control chart, one can determine whether the process is in a state of statistical control or if special causes of variation require investigation and corrective action. The application of LSS methodologies has gained significant traction in the healthcare industry, as it offers a structured approach to improving patient safety, quality of care, and operational efficiency. (Montgomery, 2009)

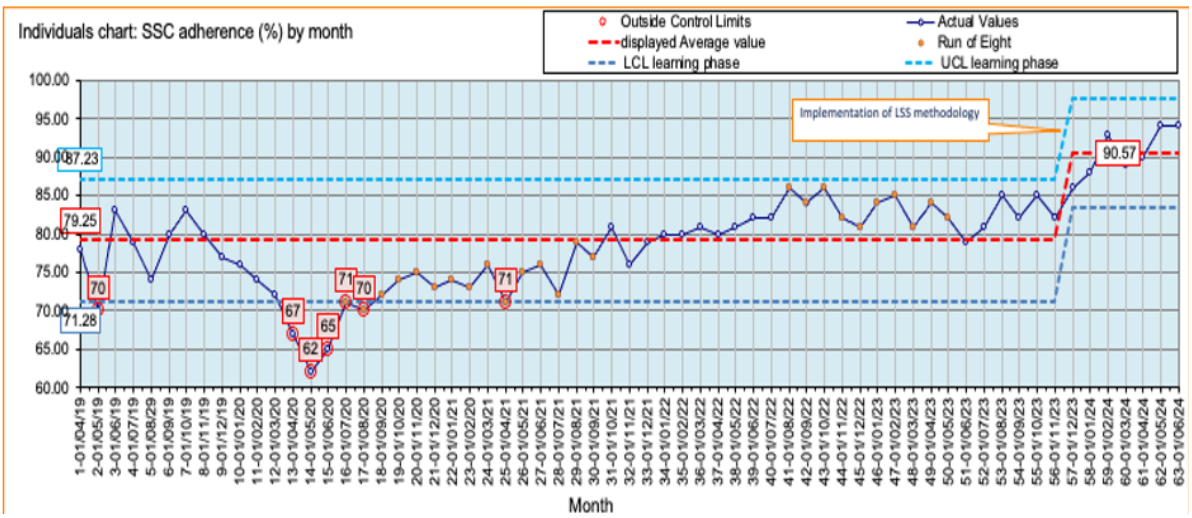


Figure (3.6) The control chart showed that the implementation rate of an SSC has varied from 62 % to 86 % over the past five years.

Figure (3.6) illustrates a low adherence rate with about 30 data points measuring commitment to SCC before implementing the LSS Methodology. The data started improving significantly in December 2023. Before deploying LSS, the data varied from 70% to 86%. After the intervention of deploying LSS, the data points show significant improvement, reaching 95% compliance in March 2024.

The Variation before LSS Implementation: The process exhibited considerable variation before the LSS implementation, with several points falling outside the control limits. This suggests the presence of special causes of variation, indicating a lack of process stability and potential opportunities for improvement.

Lower Adherence Period: There was a period where the adherence percentage dropped significantly, with several data points falling below the lower control limit, indicating a concerning decrease in SSC adherence during that time frame. The lack of proper implementation of an SSC in the operating theaters could harm the patient and affect the quality of service.

Improved Stability after LSS: After implementing the LSS methodology, the process appears to have stabilized, with data points clustering more tightly around the average value

and remaining within the control limits. This suggests that the LSS interventions successfully reduced variability and improved the consistency of SSC adherence.

3.16 Analyze the Phase

The Analyze phase of the DMAIC methodology is essential for understanding the root causes of a problem and identifying potential areas for improvement. In enhancing compliance with the SSC, this phase thoroughly examines the factors contributing to non-compliance and the barriers preventing consistent adherence to the checklist.

One of the primary goals of the analysis phase is to identify the sources of variation that lead to deviations from the desired process or outcome (Antony et al., 2016). By analyzing the data collected during the Measure phase, healthcare organizations can uncover valuable insights into the reasons behind non-compliance with the SSC.

The Important Tool in the analysis phase was the Control Chart, this tool is illustrated in the next part.

3.16.1 Cause and Effect Diagram

This tool helps identify potential causes of a problem by categorizing them into major categories such as people, processes, equipment, and environment. (Sokovicet al., 2010). To understand and identify possible root causes of wastes in the safe surgery checklist process, the cause and effect analysis was conducted to analyze and detect factors that are causes of surgical delays and inefficiencies in the safe surgery checklist process, categorized into four main areas: environment, people, process, and materials.

By analyzing the root causes, targeted improvements can be developed to address the identified wastes and inefficiencies; moreover, it illustrates the reasons for a problem being faced. Figure(3.7) describes the main factors that contribute to improper implementation of the SSC:

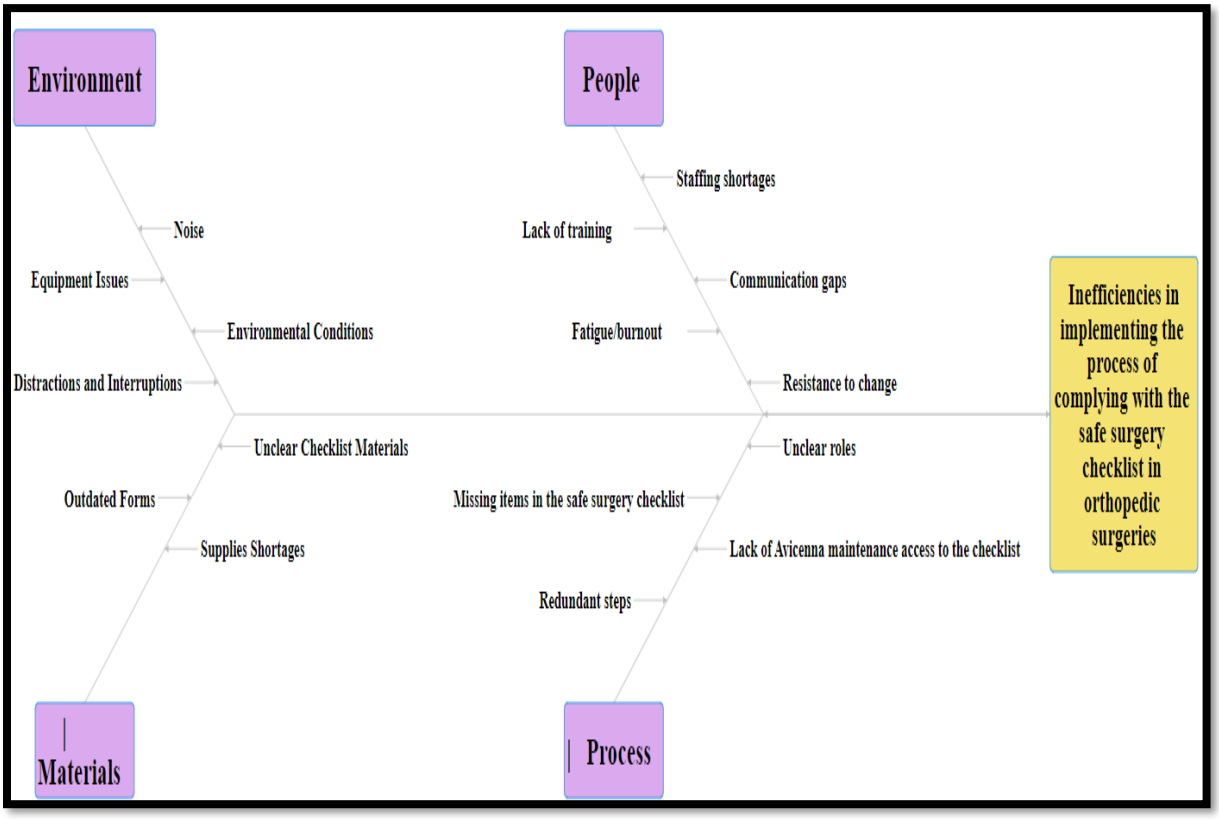


Figure (3.7): The Cause and Effect Diagram

The cause and effect analysis found that the leading cause for Inefficiency in implementing the process of complying with the SSC in orthopedic surgeries, as shown in Figure (3.7). These causes and effects were deducted from:

1: The Interviews: Several interviews with the key participants were conducted in this study. Qualitative data were obtained from the safe surgery checklist forms, which compromise 19 items that must be checked at three phases at the time of surgery (sing in, time out, and sing out) and were directed to the managers, anesthesiologists, surgeons, and nurses in PMC for orthopedic surgeries.

2: Observations: These were deduced from directly observing surgical procedures and using the Safe Surgery Checklist to identify potential waste, inefficiencies, or deviations from the standard process. Identify any communication or teamwork issues that may impact the effective use of the checklist. Each of these causes has sub-causes, which are the reasons for inefficient processes. The leading causes with their root causes were summarized in Figure (3.7) as follows:

1- People:

People are a factor that plays a leading role in the process; it has sub-causes as follows:

A. shortage of staffing:

Inadequate staffing levels with employees and technicians play a significant factor in the failed implementation process of an SSC. As deduced from the interviews and observations, inadequate staffing levels create insufficient performance in the process. The lack of staff affected two steps, forming a bottleneck. The estimation step of the remaining personnel may be overworked and stretched thin, leading to increased stress, fatigue, and a higher risk of errors or oversights, i.e., error traps.

Moreover, more dedicated personnel must ensure adherence to SSC, as staff members may prioritize other tasks perceived as more urgent. These two steps need to be implemented at the right time, and the staff in the PMC needs to increase.

B. Lack of Training:

The employees, " doctors, nurses, and technicians" are facing a lack of training, which causes staff members not to receive comprehensive training on the purpose, components, and proper implementation of SSC; they indicate that they suffer a lack of the necessary understanding and knowledge to comply with it effectively combined with lack of knowledge about the rationale behind the checklist with its importance in preventing surgical errors which can lead to a lack of commitment and adherence.

Implementing standardized training for different staff members, engaging all team members in the training process, and using interactive and hands-on methods can reinforce the checklist's importance and promote its consistent application across the surgical team.

C. Communications Gaps

Communication gaps can be a significant root cause contributing to inefficient processes and non-compliance with the SSC as deduced from Observations; these were deduced from directly observing surgical procedures and using the SSC to identify potential causes. A lack of transparent and standardized communication protocols leads to three crucial steps that form a

bottleneck in the information being missed and misinterpreted, increasing the risk of errors and oversights related to the SSC.

Secondly, the Breakdowns in team communication need more open dialogue, and essential information may not be shared, leading to skipped or misunderstood steps. So effective communication among all members of the surgical team, including surgeons, nurses, anesthesiologists, and support staff, is essential for ensuring Safe Surgery. Finally, documented communication challenges during observation were handoffs between shifts and teams. There is a risk of information being lost or miscommunicated if proper handoff protocols are not followed. This can lead to a lack of continuity and understanding of the SSC status, potentially compromising patient safety. Implementing clear communication protocols, fostering a culture of open communication and teamwork, minimizing distractions and interruptions, and ensuring effective handoff procedures can help improve compliance with the SSC. Regular team briefings, training in effective communication techniques, and encouraging a non-hierarchical environment where all team members feel empowered to speak up can contribute to better communication and adherence to the checklist.

D. Fatigue and Burnout

Fatigue and burnout were significant root causes contributing to inefficient processes and non-compliance with the SSC in orthopedic surgery; there were critical root causes that were observed during the process:

- ✓ **Physical and Mental Exhaustion**

Orthopedic surgeries are physically demanding and mentally taxing, often involving long hours, 2-8 hours in the operating room, and intensive procedures such as Total Hip Jiont and Total Knee Jiont replacement.

Fatigue is due to the physical strain of standing for extended periods, performing intricate surgical maneuvers, and maintaining concentration throughout lengthy operations.

Mental exhaustion arises from the high cognitive load required in orthopedic surgeries, decision-making under pressure, and the need for precise execution.

✓ **Impaired Cognitive Function**

As deduced from training and discussions, fatigue and burnout lead to impaired cognitive function, including decreased attention span, difficulty concentrating, and slower reaction times.

These cognitive impairments can increase the risk of overlooking crucial steps in the SSC failing to recognize potential errors or complications during the surgical procedure.

✓ **Diminished Attention To Detail**

When surgeons, nurses, and other surgical team members are fatigued or experiencing burnout, their vigilance and attention to detail can be compromised. This can result in missing essential cues, overlooking critical information, and failing to follow the SSC meticulously, potentially leading to errors or omissions.

✓ **Increased Risk Of Errors And Adverse Events**

Numerous studies have linked fatigue and burnout among healthcare professionals to an increased risk of medical errors, adverse events, and compromised patient safety.

In orthopedic surgery, fatigue and burnout can increase the likelihood of surgical complications, wrong-site surgeries, or other preventable errors that could have been avoided by strict adherence to SSC.

✓ **Decreased Compliance And Motivation**

When facing fatigue and burnout in surgical team members, they become less motivated to follow established protocols and procedures, such as the SSC, especially if they perceive it as an additional burden or administrative task. This can lead to a gradual erosion of compliance and adherence to safety protocols, risking patient safety.

Treating fatigue and burnout among orthopedic surgical teams is critical for ensuring efficient processes and consistent compliance with the SSC.

Strategies such as implementing reasonable work schedules, providing adequate rest periods, promoting a healthy work-life balance, and fostering a supportive work environment

can help mitigate the effects of fatigue and burnout. Additionally, emphasizing the importance of the SSC's importence in preventing errors and promoting patient safety can encourage compliance even in situations of high physical and mental demand.

E. Resistance To Change

Resistance to change is a significant factor and root cause contributing to non-compliance with the SSC in orthopedic surgery. This creates an increase in resistance to change, which can manifest itself in the implementation and enhanced rate of the SSC:

- ✓ **Established Routines And Habits**

Orthopedic surgeons and surgical teams have well-established routines and habits that they have followed for many years. Introducing a new methodology, DMAIC, to the adherence rate of the SSC can disrupt these ingrained habits and routines, leading to resistance and reluctance to change established practices.

- ✓ **Perception Of Added Burden**

Some surgical team members perceive the SSC as an additional administrative burden or an unnecessary step that slows the surgical workflow. This perception leads to resistance, as they may view the checklist as an impediment to their efficiency and productivity.

- ✓ **Skepticism About The Benefits**

The surgical team was not entirely convinced of the tangible benefits and importance of the SSC in reducing errors and improving patient safety before training and lectures; they were resistant to adopting it. The DMAIC methodology training arises from an understanding of the evidence supporting the effectiveness of the checklist.

- ✓ **Fear Of Exposing Knowledge Gaps Or Weaknesses**

The SSC revealed knowledge gaps and areas where certain team members need additional training or support, as discussed during lecture sessions and training discussions—the fear of exposing these weaknesses or appearing incompetent leads to resistance to adopting the checklist fully.

It is essential to overcome resistance to change and ensure adequate training and implementation of the DMAIC approach to the adherence rate of the SSC. Strategies to overcome the obstacle of resistance to change include:

- ✓ Involve surgical teams in the implementation process and address their concerns and feedback.
- ✓ Providing clear and compelling evidence of the benefits and importance of the checklist in reducing errors and improving patient outcomes.
- ✓ Fostering a culture of continuous improvement and open communication, where exposing knowledge gaps is seen as an opportunity for growth rather than a weakness.
- ✓ Offering comprehensive and ongoing training, emphasizing the rationale behind the DMAIC approach of LSS and its role in promoting patient safety, eliminating non-added value processes, and saving time. On the other hand, PMC hospitals can increase the likelihood of successful training and implementation of the SSC, ultimately improving compliance and patient safety in orthopedic surgery.

2– Process

Inefficient processes and non-compliance with the SSC in orthopedic surgery were noted. Several significant factors related to the process were examined during observation, tracer, and interviews. These include unclear roles, missing items, redundant steps, and the need for access to the checklist. Here are the details of how these factors can contribute to the issue**:**

Unclear roles: As discussed earlier, when roles and responsibilities within the surgical team are not clearly defined or understood, the operational teams also agreed on this during training and discussion, leading to confusion and miscommunication about who is responsible for specific tasks or steps within the checklist. This lack of clarity results in crucial steps being overlooked or incorrectly someone else's responsibility, leading to gaps in the checklist implementation.

Missing Items In The SSC: Some non-comprehensive items in the workplace were due to a lack of standardization, inadequate development, and failure to update the checklist to reflect changes in best practices or procedures. The quality department modified these and involved representatives from all relevant disciplines (surgeons, nurses, anesthesiologists, technicians,

etc.) in the review and revision process to ensure that the checklist accurately reflects each team member's roles, responsibilities, and workflows to suit the work in the PMC.

Redundant Steps: Sometimes, the SSC contains redundant or unnecessary steps (non-added value), leading to inefficiencies, confusion, and potential non-compliance. These arise from a lack of streamlining or optimization of the checklist, or they may be remnants of outdated practices that must be revised. The sign-in phase in the recovery room was modified at PMC so that anesthesia follows the patient in the orthopedic department before moving to the recovery room, reducing time wastage.

Lack Of Avicenna Maintenance Access To The Checklist: The SSC is readily available and accessible to all members of the surgical team in the PMC, but there was much pressure on the Avicenna system, which made them unable to complete it in the required time and only when the system improved. This needs immediate maintenance because it confuses the work and wastes time.

3-Materials: Several significant factors related to the materials and resources used with the checklist must be examined. These factors include unclear checklists, outdated forms, and supply shortages, contributing to the issue.

Unclear Checklist Materials: The physical materials associated with the SSC need to be better designed, more precise, and more apparent in their presentation and organization, which leads to confusion and inconsistent implementation among surgical team members. On the other hand, an unclear checklist material results in the omission of crucial steps and incorrect execution of the required tasks, ultimately compromising patient safety and the effectiveness of the checklist.

The ad-hoc committee at PMC, comprising a multidisciplinary team with extensive experience in surgical practices, conducted a comprehensive review and redesign of the SSC materials. This team, which included representatives from managers, various surgical specialties, nurses, anesthesia, and quality coordinator officers or assistants, ensured that the checklist materials were user-friendly and tailored to the specific needs of orthopedic surgery.

Outdated Forms: Outdated forms became a significant barrier to compliance with the SSC due to needing to align with the latest best practices and regulatory requirements, leading to

incomplete information being captured during the surgical process. In the operations room at PMC, comprehensive training and regular refresher sessions about the role of LSS methodology were provided to ensure all surgical team members were familiar with the updated SSC materials, understood how to use them effectively, and were equipped to address potential challenges or material shortages effectively.

Supplies Shortages: The successful implementation of the SSC relies on the availability of necessary supplies and materials. The shortages and lack of access to these materials lead to disruption of the surgical workflow and non-compliance with the checklist. As team members, your commitment to following the checklist is crucial. We need to develop an efficient materials management system to ensure the availability of necessary supplies and resources for properly implementing the SSC. Furthermore, we collaborate with supply chain professionals and vendors to proactively anticipate and address potential material shortages.

Inventory management strategies, such as just-in-time ordering or safety stock levels, should also be implemented in the long run to minimize the risk of material disruptions.

4- Environment: There were specific details about the significant factors in the operating environment that were considered as a root cause for inefficient processes and non-compliance with the SSC in orthopedic surgery:

Noise: Sources of noise include:

- ✓ Equipment alarms and monitoring devices.
- ✓ Conversations among staff or visitors.
- ✓ Noisy ventilation or air handling systems.

During the interviews with team members, the team members discussed the high noise levels from equipment alarms, which impaired communication and affected concentration among the surgical team. Excessive noise leads to misunderstandings, missed critical information, and increased stress levels, affecting the team's ability to follow the checklist accurately.

Equipment Issues: The source of Equipment issues includes Malfunctioning and poorly maintained equipment that disrupted the surgical workflow and caused deviations from established protocols, including the Safe Surgery Checklist. When interviewed by the operations team, they said that the Avicenna device and system get stuck a lot and need maintenance due to being donated.

Environmental Conditions: Potential ecological issues include:

- ✓ Inadequate temperature control or ventilation.
- ✓ Improper lighting levels or glare.
- ✓ Poor air quality and circulation.

During the conversation and meeting with the doctors, the most hindering factor in complying with the SSC was that there was no stable air conditioning inside the rooms, the humidity was high, and most of the operations had a high temperature. Since orthopedic operations take a long time, the doctors might be exposed to sweat, which also increases the level of infection and inflammation of the wound site. They became more anxious. They needed to improve compliance by filling out the SSC.

Distractions And Interruptions: Sources of distractions and interruptions may include:

- ✓ Non-essential personnel entering the operating room.
- ✓ Ringing phones.
- ✓ Noise.

By following and observing some orthopedic surgeries, the frequent distractions and interruptions were becoming a significant barrier to compliance with the SSC. They disrupted the team's concentration and led to missed steps or errors in following the Checklist.

It is imperative to analyze the operating environment thoroughly, identifying specific areas of concern and their potential impact on compliance with the SSC. This analysis should involve input from various stakeholders, including surgeons, nurses, anesthesiologists, facility managers, and quality coordinators. By understanding the significant environmental factors, the

PMC can develop targeted interventions and implement strategies to mitigate their impact, improving patient safety and the quality of care in orthopedic surgery.

3.16.2 Analyze Phase Tollgates

- ✓ **Potential Root Cause:** The leading causes of inefficiency in implementing the process of complying with the safe surgery checklist in orthopedic surgeries were identified by conducting interviews with operations team employees.
- ✓ **Narrow Root Cause:** The sub-causes for each leading cause were identified by creating the cause and effect diagram.

3.17. Improve and Control Phases of DMAIC

3.17.1 Overview

This section presents the research findings reached in the previous chapter. A set of tools, such as the flow chart, compromises a tracer for patient flow, which helps understand the process steps and detect unnecessary non-value-adding steps.

Then, the eight wastes tool was used to determine and recognize the waste in each step, as illustrated in Chapter Four Table (4.2). Additionally, as a result of cause analysis, it shows factors that contribute to the lack of adherence rate to SSC. The study indicated the bottleneck in the need for more commitment to effective implementation that leads to patient harm. The Improve and Control phases of the DMAIC methodology are critical in implementing sustainable solutions to address identified problems or opportunities for improvement. In enhancing patient safety and quality by effectively implementing the SSC for orthopedic surgeries in operation rooms, the LSS methodology offers a structured framework for driving meaningful improvements and ensuring long-term sustainability.

LSS aims to eliminate waste, reduce variability, and continuously improve processes by combining lean principles and statistical tools. In healthcare, these methodologies have proven

invaluable in improving patient outcomes, reducing errors, and enhancing operational efficiency (Chassin& Loeb, 2013).

Two main tools are used in this phase; the Control Charts, and the Out-of-Control Action Plan (OCAP)

3.17.2 Improve Phase

The improvement phase aims to identify potential solutions to the problem discussed in the research, implement the improvement, measure the new performance, and document the new process. Based on the research outcomes, identify the waste, variations, and inefficiencies facing implementing the SSC for orthopedic surgeries at the PMC. It is recommended that the PMC implement the following improvement techniques: solutions.

3.17.2.1 The Solution To Inefficient Compliance With Safe Surgery Checklist Implementation

One significant challenge in implementing the SSC is ensuring consistent and efficient compliance by healthcare professionals. Inefficient compliance can lead to lapses in patient safety, increased risks, and compromised quality of care. To address this issue, the improvement phase of the DMAIC methodology can be leveraged to develop and implement targeted solutions.

1. Standardize The Checklist Process

- ✓ Develop a standardized Safe Surgery Checklist approach, including clear policy, roles, responsibilities, and step-by-step procedures.
- ✓ Involve all stakeholders (surgeons, nurses, anesthesiologists, etc.) in the process design to ensure buy-in and practicality.
- ✓ Provide comprehensive training and education programs about LSS to ensure consistent understanding and application of the checklist

2. Continuous Monitoring and Feedback

✓ This phase showed that the effective adoption of the LSS methodology improved patient safety and adherence to the surgical safety checklist after establishing a robust system for monitoring compliance with the SSC, using statistical process control (SPC) tools like control charts. The improving hospital service quality. Additionally, this phase showed improved adherence to the SSC in the improving phase as illustrated in Figure (3.8).

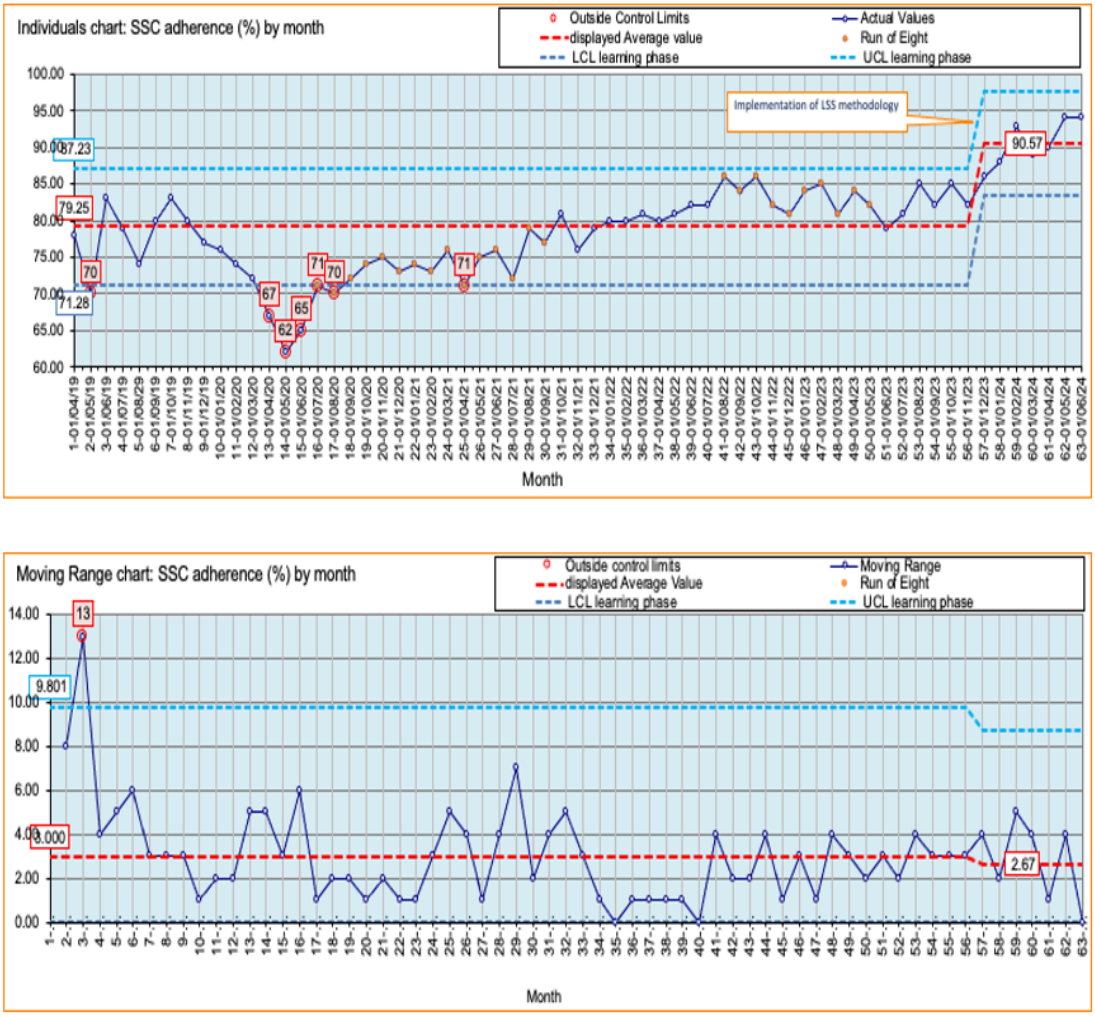


Figure (3.8): Control chart and C_{pk}

✓ The above figure illustrates the adherence percentage to the surgical safety checklist for orthopedic surgeries in PMC (April 2019 to June 2024). Because the aim of implementing the SSC is to reach a 100% commitment, the lower specification limit (LSL) is 70, the upper specification limit (USL) is 90, the cp is 1.25, and the C_{pk} is 1.16.

- ✓ Provide regular feedback to healthcare professionals on their performance, highlighting areas for improvement and celebrating successes.
- ✓ Encourage continuous improvement by involving staff in identifying and implementing solutions to address non-compliance.

3. Leadership Commitment and Accountability

- ✓ Ensure strong PMC leadership commitment and support for the SSC initiative, fostering a patient safety culture.
- ✓ PMC leadership should maintain clear channels for effective communications among and between staff levels and team members in the operations room.
- ✓ The environmental safety and shortages should take more attention from the PMC leaders
- ✓ More effort is needed from the PMC leaders to fulfill the shortage in materials, workforce, and other needs to ensure more effective implementation and commitment to SSC
- ✓ Enhance accountability measures by MoH, including periodic audits and performance evaluations related to checklist compliance that Evolved in the Patient Safety Friendly Hospital Initiative Manual (PSFHI).
- ✓ Recognize and reward individuals or teams who consistently demonstrate high compliance and commitment to patient safety.

3.18 The Control Phase

This phase is a crucial stage and final step in the DMAIC methodology of LSS, ensuring the sustainability and ongoing effectiveness of the improvements implemented during the previous phases. In enhancing patient safety by improving compliance with the Safe Surgery Checklist for orthopedic surgeries, the Control phase plays a vital role in maintaining the gains achieved and fostering a culture of continuous improvement.

During this phase, healthcare organizations can leverage the principles and tools of LSS to establish robust monitoring and control mechanisms, facilitate standardization, and promote accountability and ownership among healthcare professionals. Effective control measures sustain the improvements and enable organizations to promptly identify and address any deviations or potential lapses in compliance with the SSC (Alharthi et al., 2020).

This research demonstrated the successful application of LSS methodologies, including the Control phase, in improving the quality and safety of orthopedic surgeries in a PMC. It highlighted the importance of the Control phase in sustaining the improvements achieved by implementing standardized processes, continuous monitoring, and adherence to the SSC. This success should instill confidence in the effectiveness of LSS methodologies in healthcare settings.

3.18.1 The Control Phase Key Activities

- ✓ Establishing a comprehensive monitoring system: Implementing statistical process control (SPC) tools, such as control charts, to monitor compliance with the SSC and detect any deviations or particular cause variations.
- ✓ Conducting regular audits and assessments: Periodic audits and assessments can help evaluate the ongoing effectiveness of the SSC implementation and identify areas for further improvement.
- ✓ Providing continuous training and education: Ongoing training and education programs for healthcare professionals can reinforce the importance of the SSC by using LSS tools and ensure consistent understanding and application.
- ✓ Fostering a culture of continuous improvement: Encouraging healthcare professionals to identify opportunities for further improvement actively and implementing corrective actions when necessary.
- ✓ Ensuring leadership commitment and accountability: Strong PMC leadership commitment and clearly defined accountability measures are crucial for sustaining the improvements and promoting a culture of patient safety.

3.18.2 Out-of-Control Action Plan (OCAP)

An out-of-control action plan should be created to follow up on all controls in the research setting; any deviation from the intended plan objectives should be controlled. These actions address vital areas that could lead to poor adherence to the SSC, focusing on completion rates, team communication, and accurate patient information, which are crucial for patient safety in orthopedic surgeries. Table (5.1) identifies the OCAP that should be followed to control deviations and return to plan the effective process:

Table (3.5) The Out-of-Control Action Plan (OCAP)

No	Deficiencies Description	Process Step	Responsibility	Specification limits Requirements	Response Plan/Action to be taken	Resources
1.	Low checklist completion rate	Checklist implementation during surgery	Surgical team leader	100% checklist completion for all orthopedic surgeries	Implement electronic checklist with mandatory fields; Conduct daily audits; Provide immediate feedback to teams	Electronic health record system; Quality improvement team
2.	Lack of team communication during the checklist process	Time-out before incision	All surgical team members	All team members actively participate in time-out	Implement structured communication protocol (e.g., SBAR); Conduct team communication training	Communication training resources; Simulation lab
3.	Incomplete or inaccurate patient information	Pre-operative patient verification	Pre-op nurse, Anesthesiologist	All patient information must be verified and accurate before entering the OR.	Double-verification system: Implement barcode scanning for patient identification	Patient identification system; Staff training resources

3.19 Chapter Three Summary

This chapter explores the LSS methodology employed in conducting the research. By integrating LSS's structured approach with diverse data collection techniques, healthcare institutions like PMC can gain valuable insights into their current SSC processes, identify areas ripe for improvement, and implement evidence-based solutions to boost patient safety and surgical outcomes.

The chapter firstly outlines the researcher's strategic approach, detailing the research environment, data-gathering methods, and analytical techniques. It also addresses ethical considerations and underscores the pivotal role of LSS in elevating the quality of healthcare services.

Then the chapter addresses the LSS methodology followed to conduct the research. By combining the structured LSS methodology with various data collection methods, healthcare organizations such as PMC can gain insights into the current state of the SSC process, identify opportunities for improvement, and implement data-driven solutions to enhance patient safety and surgical outcomes.

The measure phase in the DMAIC approach was applied to understand and analyze the current process performance. In addition, areas in which improvements are needed were identified. The as-is situation of the process was understood by applying the measure phase tools: flow chart, eight wastes, and Control chart. Each tool illustrated significant results. It showed that the process is unstable, with several variations. In this phase, the process bottlenecks were identified.

The problem and process inefficiencies and the root causes for the variation and waste were identified in the analysis phase; the improvement opportunities were also defined. By creating the cause-effect diagram, the leading causes that caused the problem in the process were analyzed; there were four leading causes: people, process, materials, and environment. Each main cause included root causes that led to Inefficiencies in implementing the process of complying with SSC in orthopedic surgeries; in this chapter, the root causes were illustrated and

discussed in detail. Based on the root cause analysis, the improvement opportunities were defined and were to be implemented in the improvement phase.

DMAIC methodology focuses on their application to enhance patient safety through improved adherence to SSC for orthopedic surgeries at the PMC. In the Improve phase, the chapter outlines strategies to address inefficient compliance with the SSC. It recommends standardizing the checklist process, implementing continuous monitoring and feedback systems, and strengthening leadership commitment and accountability. The effectiveness of these improvements is demonstrated through statistical process control tools, which show enhanced adherence to the SSC.

The Control phase builds upon these improvements, emphasizing the importance of sustaining gains and fostering a culture of continuous improvement. This phase involves establishing a comprehensive monitoring system using statistical process control tools, conducting regular audits and assessments, providing ongoing training and education on LSS and SSC, nurturing a culture of continuous improvement, and ensuring sustained leadership commitment and accountability.

The research results are significant. They show that the effective adoption of the LSS methodology improved patient safety and increased adherence to the SSC. Notably, the research reveals that adherence to the SSC is a mediator between LSS implementation, quality improvement, and patient safety enhancement.

Then the chapter underscores the crucial role of SSC adherence in achieving quality improvement through LSS. It provides valuable guidelines for healthcare organizations seeking to enhance patient safety and service quality using the LSS methodology. By demonstrating the successful application of LSS methodologies in improving the quality and safety of orthopedic surgeries at PMC, the chapter offers compelling evidence of the effectiveness of these approaches in healthcare settings.

Finally, this chapter comprehensively overviews how LSS can significantly improve surgical safety processes. It offers theoretical insights and practical strategies for healthcare organizations aiming to enhance their patient safety measures.

Chapter Four: Results

4.1 Overview

This chapter describes the conducted data analysis and displays the findings regarding the research hypotheses. This chapter comprises six main subsections: The 1st presents descriptive results about respondents' sociodemographic characteristics. The 2nd section provides descriptive results about the study constructs. PLS-SEM findings are illustrated in the 3rd section. The fourth section conducts comparative tests to examine the mean difference of the latent constructs according to sociodemographic predictors. Correlation analysis among the latent constructs is presented in section five. Lastly, a concise summary of the findings is provided in section six. Moreover, This chapter will discuss the results presented in the previous chapter and compare them with similar studies from the literature review.

4.2 Respondents Socio-demographic

Table (4.1) shows the general characteristics of the sample. The findings revealed that nearly two-thirds (65.5%) of the respondents were males, about three-quarters (74.3%) were married, and most (57.5%) had a bachelor's degree. Nearly one-quarter (24.8%) were 29 years or younger. The majority of them (43.4%) were nurses. Only 22.1% had 1 - 5 years of work experience in the PMC, as shown in Table (4.1).

Table (4.1) Socio-demographic characteristics of the sample (N = 113)

Characteristic		**n (%)**
Gender	Male	74 (65.5)
	Female	39 (34.5)
Social status	Single	29 (25.7)
	Married	84 (74.3)
Level of education	Diploma	18 (15.9)
	Bachelor	65 (57.5)
	Master	19 (16.8)
	Doctorate/Specialist	11 (9.7)
Age (years)	< 30	28 (24.8)
	30 – 34	42 (37.2)
	≥ 35	43 (38.1)

PMC experience (years)	1 – 5	25 (22.1)
	6 – 10	30 (26.5)
	11 – 15	26 (23.0)
	≥ 16	32 (28.3)
Job title: Orthopedic surgeon		10 (8.8)
	Orthopedic resident	11 (9.7)
	Nurse	49 (43.4)
	Anesthesiologist	16 (14.2)
	Anesthesia technician	17 (15.0)
	Management	10 (8.8)

4.3 Respondents' Agreement Regarding The Study's Latent Constructs

Table (4.2) and Figures (4.1) summarize respondents' level of agreement with each item of the study variables (i.e., the implementation of LSS methodology, patient safety, adherence to the SSC, and quality of improvement). Most of the participants (91.2%) believed that "using LSS tools led to reduced healthcare costs" (LSS4).

The majority (86.7%) believed that "patient safety is a top priority of the hospital" and "patients are involved in the treatment plan and decision-making regarding treatment" (PS1 and PS2). Nearly two-thirds (67.3%) agreed or strongly agreed that "an enhanced work environment for patients: design, environmental risk management, people with special needs" (PS5). The majority (80.5%) agreed or strongly agreed that "the surgical safe list items are simple and easy to understand and apply"(SSC3). Only 56.6% agreed or strongly agreed that "the level of general commitment to implementing the SSC is satisfactory" (SSC1). Only 62.8% believed that "the safe surgical checklist process is led during each surgical operation" (SSC2). Less than two-thirds (64.6%) agreed or strongly agreed that "the hospital management provides mechanisms and feedback regarding compliance with the SSC" (SSC5). More than three-quarters (78.8%) believed that "the overall performance of the hospital has improved" (QI1). However, about one-third (31.9%) agreed or strongly agreed that "patient waiting times have been minimized" (QI5), and only 56.6% believed that "patients' complaints have declined" (QI6). The overall agreement level about the study variables is presented in Table 4.3. The highest mean score was for the implementation of the LSS methodology (the mean was 81.9 ± 12.80 out of 100), followed by enhancing the patient safety variable (the mean was 78.47 ± 12.23) and the lowest was for the quality service improvement variable (the mean was

69.50 ± 16.73). Respondents' level of agreement with the questionnaire statement is shown in Table (4.2).

Table (4.2): Respondents' level of agreement with the latent constructs (N =113).

Item		n (%)[a]	Mean ± SD
Lean Six Sigma			
LSS1	Application of LLS practices to create a well-organized work environment in the hospital	98 (86.7)	4.04 ± 0.77
LSS2	Use root cause analysis, fishbone diagrams, or value stream maps to identify the causes of quality problems in healthcare processes	95 (84.1)	4.00 ± 0.82
LSS3	Continuous training programs on process improvement tools for the hospital staff	101 (89.4)	4.14 ± 0.67
LSS4	Using LSS tools led to reduced healthcare costs	103 (91.2)	4.16 ± 0.65
LSS5	Using LSS improvement methods for continuously developing the hospital's projects	98 (86.7)	4.13 ± 0.76
Patient safety			
PS1	Patient safety is a top priority of the hospital	98 (86.7)	4.11 ± 0.74
PS2	Patients are involved in the treatment plan and decision-making regarding treatment	98 (86.7)	3.96 ± 0.61
PS3	The patient's family members take part in the treatment plan and decision-making regarding treatment	79 (69.9)	3.79 ± 0.81
PS4	The process of treating patients takes place within a set of clinical practices that are based on evidence during therapeutic and surgical interventions	85 (75.2)	3.89 ± 0.81
PS5	An enhanced work environment for patients: design, environmental risk management, people with special needs	76 (67.3)	3.74 ± 0.84
PS6	The hospital management offers several programs to ensure continuous education/training for the staff	99 (87.6)	4.02 ± 0.79
Safe surgery checklist			
SSC1	The level of general commitment to implementing the safe surgical checklist is satisfactory	64 (56.6)	3.42 ± 1.16
SSC2	The safe surgical checklist process is led during each surgical operation	71 (62.8)	3.45 ± 1.05
SSC3	The surgical safe list items are simple and easy to understand and apply	91 (80.5)	3.81 ± 0.85
SSC4	The hospital management provides ongoing support and training to staff regarding the safe surgical checklist commitment	82 (72.6)	3.81 ± 1.02
SSC5	The hospital management provides mechanisms and feedback regarding compliance with the safe surgical checklist	73 (64.6)	3.71 ± 1.08
Quality improvement			
QI1	The overall performance of the hospital has improved	89 (78.8)	3.88 ± 0.88
QI2	Medical errors in inpatient services have been reduced	76 (67.3)	3.69 ± 0.91

QI3	Medical complications in inpatient services have been reduced	68 (60.2)	3.61 ± 0.99
QI4	Adverse events and incidents in patients have been reduced	69 (61.1)	3.03 ± 1.06
QI5	Patient waiting times have been minimized	36 (31.9)	3.03 ± 1.22
QI6	Patients' complaints have declined	64 (56.6)	3.42 ± 1.16

[a] Frequencies and percentages are based on the total number of 113 respondents who agreed or strongly agreed with each statement.

Table (4.3): The overall score for the study latent constructs (N = 113).

Variable	Mean ± SD		Scores range	Theoretical range
	Out of 25/30	%		
Lean Six Sigma	20.47 ± 3.20	81.9 ± 12.80	9 - 25	5 - 25
Patient safety	23.54 ± 3.67	78.47 ± 12.23	8 - 30	6 - 30
Safe surgery checklist	18.21 ± 4.36	72.84 ± 17.44	5 - 25	5 - 25
Quality improvement	20.85 ± 5.04	69.50 ± 16.73	6 - 30	6 - 30

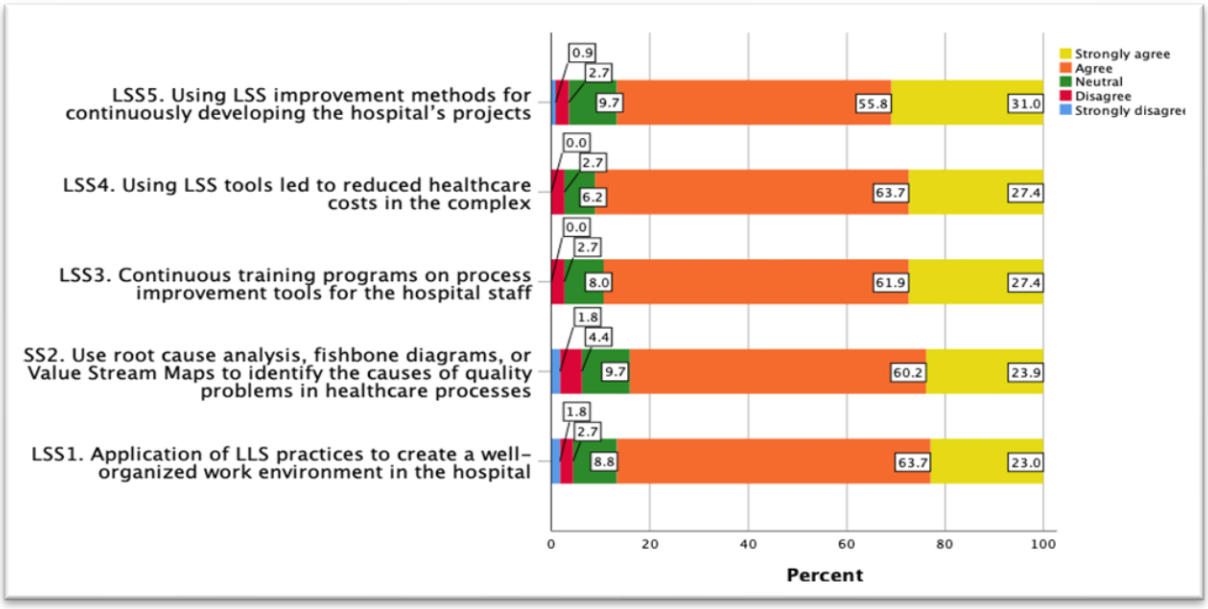


Figure (4.1): Participants agree regarding implementing LSS (N = 113).

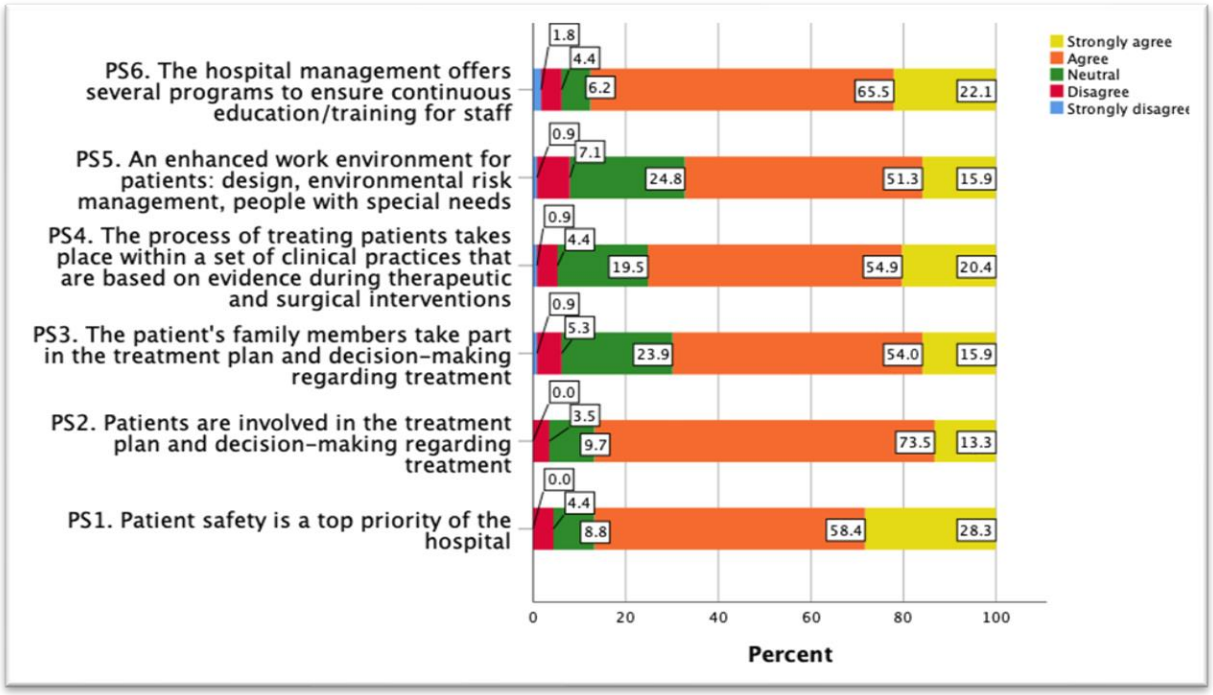


Figure (4.2): Participants agree regarding patient safety (N = 113).

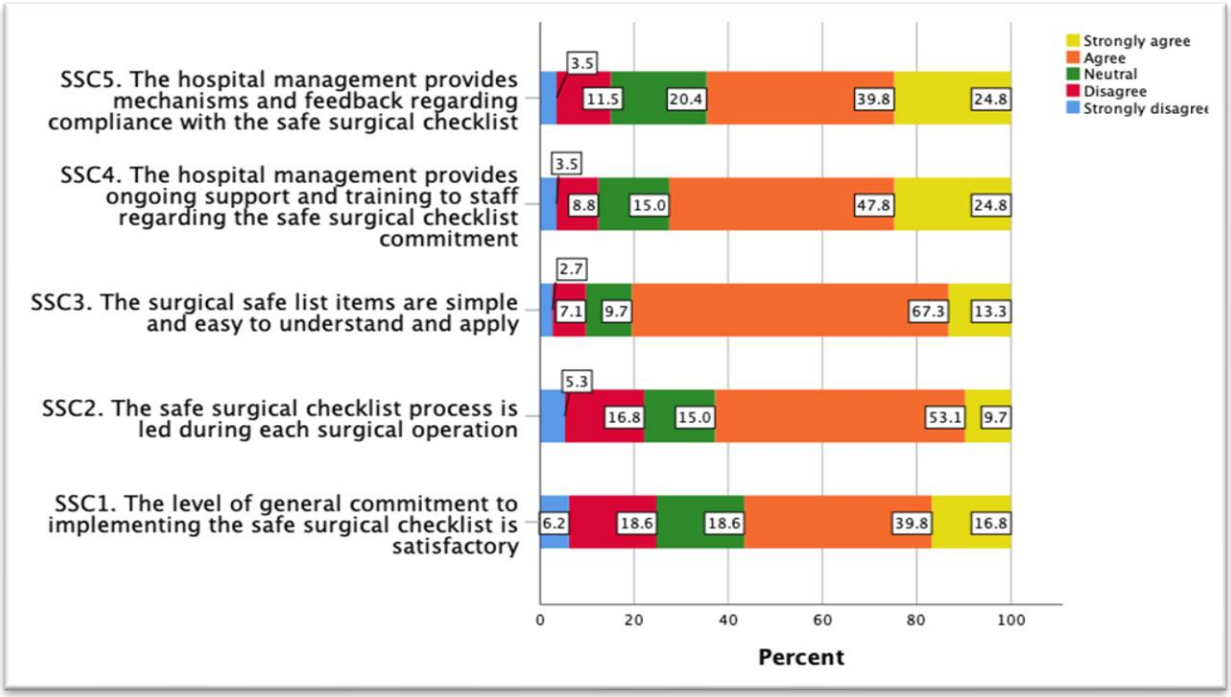


Figure (4.3): Participants agreement regarding the adherence to the safe surgery checklist (N =113)

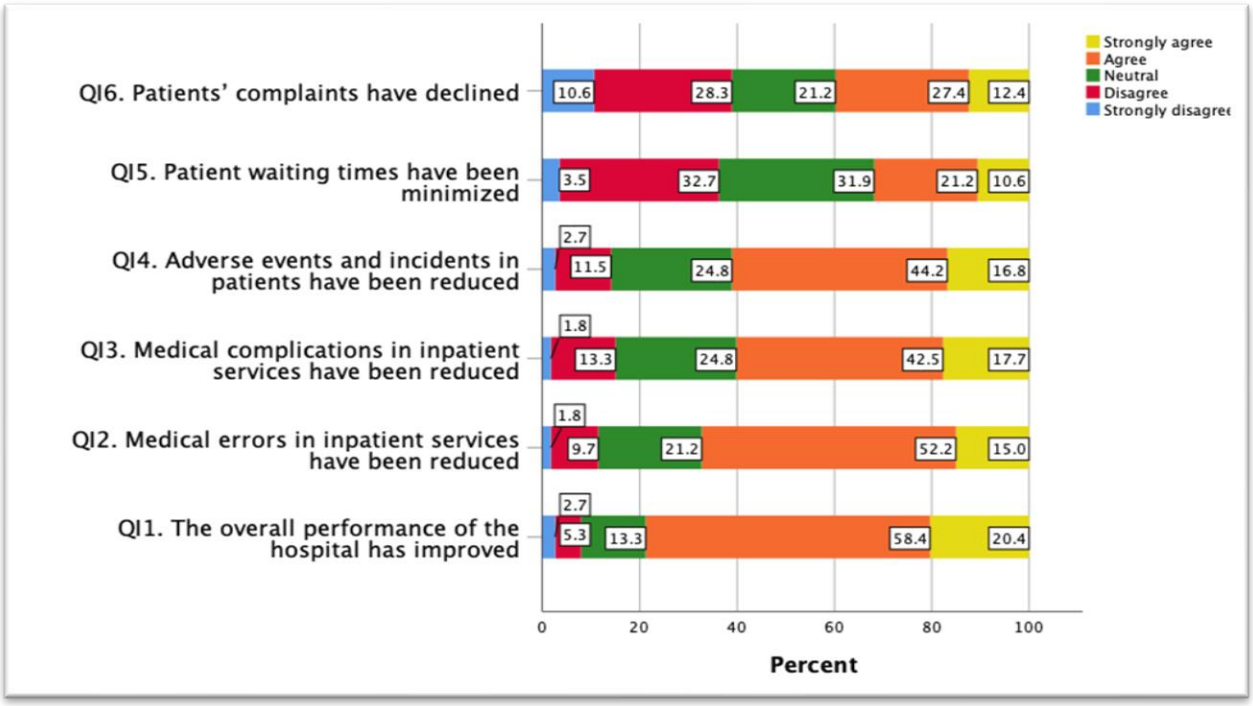


Figure (4.4): Participants' agreement regarding the quality of service improvement (N = 113).

4.4 Partial Least Squares Structural Equation Modeling (PLS-SEM)

In this section, Partial Least Squares Structural Equation Modeling (PLS-SEM) was used to determine the effect of LSS on patient safety and adherence to the SSC in improving the quality of PMC services in orthopedic surgeries. This approach was recently employed by Ahmed et al., 2024 to investigate the influence of LSS on patient safety towards the quality improvement of Malaysian hospitals. Similarly, Ahmed et al., 2018 also followed a similar approach to investigate the effects of LSS and workforce management on the quality performance of Malaysian hospitals, where the direct and indirect relationships between top management commitment and the quality performance of the healthcare organizations in Malaysia were examined.

4.4.1 Assessment of the Measurement Model

The measurement model was evaluated before the hypothesized structural model was analyzed. Various reliability, internal consistency, and validity tests were used to check the measurement quality of the research constructs (Hair et al., 2017; Hair et al., 2020). Internal consistency and reliability of the construct were checked by performing the most commonly used tests of instrument reliability, namely Cronbach's alpha (CBα), composite reliability (CR), and rho_A. The construct and convergent validity were evaluated based on outer loadings and average variance extracted (AVE) values to test the instrument's validity.

Furthermore, three tests were used to ensure discriminant validity: the Fornell-Larcker criterion, Cross Loadings, and a Heterotrait-Monotrait Ratio (HTMT). Lastly, we checked the possibility of collinearity issues of the constructs by a variance inflation factor (VIF) (see Tables 4.4 – 4.6). The calculated values of CBα, CR, and rho_A for all four constructs exceed the threshold value of 0.70, indicating that all research variables had good reliability and internal consistency.

It was observed that both outer loadings and AVE values were above the threshold values of 0.7 and 0.5, respectively, which met the construct and convergent validity requirements. Our discriminant validity findings indicated that the constructs' values had more significant loadings than other constructs within their respective underlying constructs.

The values from the Fornell-Larcker criterion test also showed that the construct's square root of the AVE is higher than its correlation with other constructs in the study.

Furthermore, the Heterotrait-Monotrait Ratio test values are less than the cut-off value 0.85. Therefore, the discriminant validity of the measurement model was acceptable. The VIF values of all four constructs are less than the cut-off value of 3.3. Thus, no collinearity issue was found.

Table (4.4): Construct the measurement model's validity, reliability, and collinearity (N = 113).

Variable	Item	Reliability and internal consistency			Construct and convergent validity		Collinearity
		CB*α*	CR	rho_A	Outer Loading	AVE	VIF
Lean Six Sigma	LSS1	0.923	0.942	0.928	0.886	0.765	3.243
	LSS2				0.922		3.275
	LSS3				0.897		2.919
	LSS4				0.875		2.246
	LSS5				0.788		1.987
Patient Safety	PS1	0.888	0.913	0.898	0.783	0.637	1.819
	PS2				0.804		2.524
	PS3				0.804		3.081
	PS4				0.814		2.781
	PS5				0.822		2.076
	PS6				0.761		1.890
Safe Surgery Checklist	SSC1	0.899	0.925	0.900	0.841	0.713	3.045
	SSC2				0.860		3.083
	SSC3				0.822		2.112
	SSC4				0.844		3.091
	SSC5				0.855		2.633
Quality Improvement	QI1	0.915	0.934	0.934	0.808	0.706	2.419
	QI2				0.899		3.265
	QI3				0.909		3.147
	QI4				0.948		3.017
	QI5				0.736		2.905
	QI6				0.712		2.510

Table (4.5): Cross loadings of the constructs (N = 113).

Variable	Item	Lean Six Sigma	Patient Safety	Safe Surgery Checklist	Quality Improvement
Lean Six Sigma	LSS1	0.886	0.477	0.318	0.477
	LSS2	0.922	0.459	0.282	0.435
	LSS3	0.897	0.393	0.209	0.327
	LSS4	0.875	0.338	0.281	0.412
	LSS5	0.788	0.380	0.402	0.438
Patient Safety	PS1	0.434	0.783	0.452	0.474
	PS2	0.359	0.804	0.282	0.383
	PS3	0.325	0.804	0.266	0.338
	PS4	0.378	0.814	0.323	0.384
	PS5	0.377	0.822	0.547	0.552
	PS6	0.370	0.761	0.419	0.496
Safe Surgery Checklist	SSC1	0.337	0.448	0.841	0.613
	SSC2	0.347	0.445	0.860	0.614
	SSC3	0.457	0.527	0.822	0.568
	SSC4	0.438	0.485	0.844	0.593
	SSC5	0.458	0.477	0.855	0.626

Quality Improvement	QI1	0.438	0.525	0.655	0.808
	QI2	0.286	0.443	0.627	0.899
	QI3	0.329	0.431	0.650	0.909
	QI4	0.395	0.513	0.694	0.948
	QI5	0.049	0.184	0.424	0.736
	QI6	0.122	0.333	0.462	0.712
Shaded values: the outer loadings.					

Table (4.6): Discriminant validity results (N = 113).

Fornell-Larcker criterion of the variables.				
Variable	Lean Six Sigma	Patient Safety	Safe Surgery Checklist	Quality Improvement
Lean Six Sigma	0.875	_	_	_
Patient Safety	0.473	0.798	_	_
Safe Surgery Checklist	0.348	0.501	0.844	_
Quality Improvement	0.485	0.566	0.714	0.840
Results of Heterotrait-Monotrait Ratio (HTMT).				
Variable	Lean Six Sigma	Patient Safety	Safe Surgery Checklist	Quality Improvement
Lean Six Sigma	_	_	_	_
Patient Safety	0.511	_	_	_
Safe Surgery Checklist	0.349	0.509	_	_
Quality Improvement	0.522	0.611	0.772	_
Shaded values: the square roots of the AVE of the constructs.				

4.4.2 Structural Model and Hypothesis Testing

In this section, the research hypotheses were tested using the PLS-SEM method. The PLS-SEM is a predictive approach that enables estimating complex models with many constructs, indicators, and structural paths. Furthermore, bootstrapping with the 5000 replications approach was used to determine the significance of path coefficients (e.g., Henseler et al. 2018). The PLS-SEM tests' results are illustrated in Tables 4.7 and 4.8.

Furthermore, Figure 4.5 graphically depicts the path coefficients (βs) and statistical significance (p-values) of the individual predictors as well as the coefficient of determination (R^2) values of all four latent constructs of the model. The PLS-SEM analysis revealed that LSS has a strong positive and significant impact on adherence to the SSC in orthopedic surgeries (β = 0.485, and p-value < 0.001). LSS also directly affects patient safety (β = 0.260,

and p-value = 0.015). Adherence to the safe surgery checklist also has a strong positive and significant impact on patient safety (β =0.440, and p-value < 0.001). Adherence to the SSC significantly correlates with quality improvement (β =0.645, p-value < 0.001). Further, the results show that patient safety positively relates to quality service at the 10% significance level (β = 0.154, and p-value = 0.097).On the other hand, the LSS. direct impact on quality improvement was insignificant (β =-0.038, and p-value = 0.625). Thus, we conclude that hypotheses 1, 3,4, and 5 (H1, H3, H4, and H5) are supported at the 5% significance level (see Table 4.7).

Table 4.8 illustrates that LSS methodology mediates hospitals' quality improvement via adherence to the SSC (β = 0.313, and p-value <0.001). The LSS also indirectly influences patient safety through the mediating effect of adherence to the SSC (β = 0.213, and p-value <0.001). However, the indirect impact of LSS and adherence to the SSC on quality improvement via patient safety were insignificant (p-values = 0.156 and 0.138, respectively).

Finally, the indirect influence of LSS on quality improvement via the mediating effect of adherence to the SSC on patient safety was also insignificant (p-value = 0.163). Therefore, we conclude that hypotheses 7 and 8 (H7 and H8) are supported at the 5% significance level.

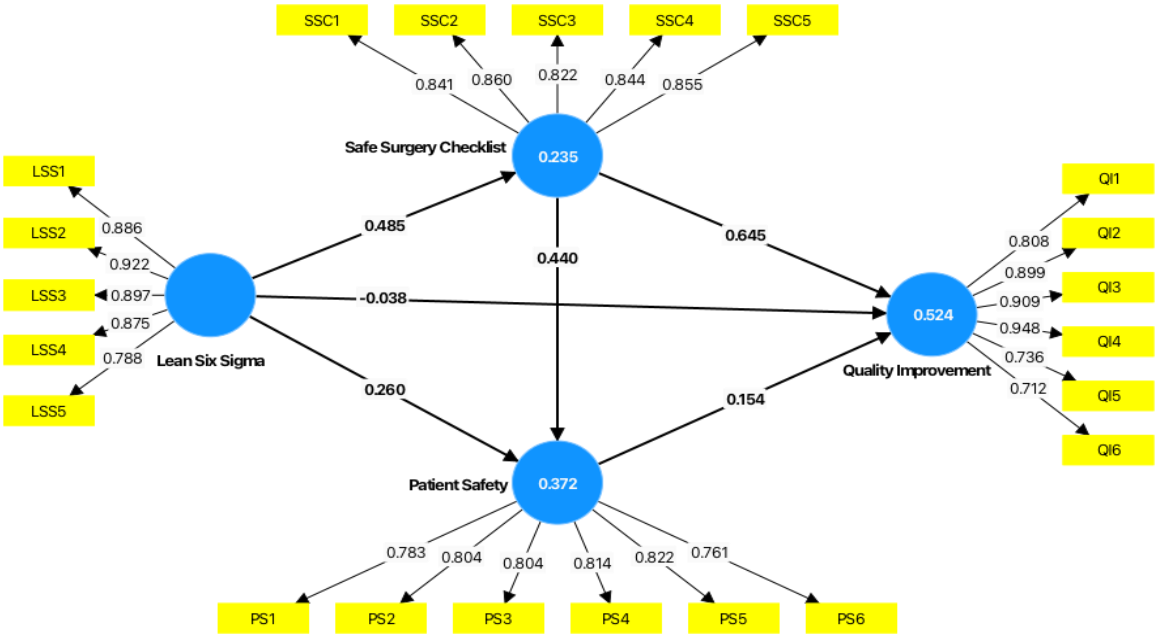


Figure (4.5): Output of PLS-SEM (N = 113).

Lastly, the PLS-SEM findings also indicate that the path coefficients are compatible with the study's data, see Table 4.9. The bootstrapping values of the predictive relevance using Stone–Geisser's Q^2 for the three endogenous constructs(adherence to SSC, patient safety, and quality improvement) were greater than 0, indicating that the predictive relevance was established.

The results also reveal that LSS explained 23.5% of the adherence to the SSC, and LSS's methodology explained 37.2% of the total variation in patient safety. Moreover, quality improvement is explained by LSS, and adherence to the SSC is at 52.4%

Table (4.7): Output of PLS-SEM: Results of path coefficients (N = 113).

Hypothesized paths		**β**	**SD**	**t-stats**	**p-value**	**Remarks**
H1	Lean Six Sigma (LSS) → Safe Surgery Checklist (SSC)	0.485	0.065	7.454	< 0.001	Supported
H2	Lean Six Sigma (LSS) → Quality Improvement (QI)	-0.038	0.079	0.485	0.625	Not supported
H3	Lean Six Sigma (LSS) → Patient Safety (PS)	0.260	0.107	2.435	0.015	Supported
H4	Safe Surgery Checklist (SSC) →Patient Safety (PS)	0.440	0.076	5.816	< 0.001	Supported
H5	Safe Surgery Checklist (SSC) → Quality Improvement (QI)	0.645	0.098	6.565	< 0.001	Supported
H6	Patient Safety (PS) → Quality Improvement (QI)	0.154	0.093	1.660	0.097	Not supported

Table (4.8): Output of PLS-SEM: Results of mediating effect (N = 113).

Specific indirect effects		**β**	**SD**	**t-stats**	**p-value**	**Remarks**
H7	Lean Six Sigma → Safe Surgery Checklist → Quality Improvement	0.313	0.061	5.107	< 0.001	Supported
H8	Lean Six Sigma → Safe Surgery Checklist → Patient Safety	0.213	0.045	4.716	< 0.001	Supported
H9	Lean Six Sigma → Patient Safety → Quality Improvement	0.040	0.028	1.418	0.156	Not supported
H10	Safe Surgery Checklist → Patient Safety → Quality Improvement	0.068	0.046	1.482	0.138	Not supported
H11	Lean Six Sigma → Safe Surgery Checklist → Patient Safety → Quality Improvement	0.033	0.024	1.396	0.163	Not supported

Table (4.9): Output of PLS-SEM: Coefficient of determination ($\mathbf{R^2}$)and predictive relevance).

Predictor	R^2	Adjusted R^2	Predictive Relevance (Q^2)
Safe Surgery Checklist	0.235	0.228	0.227
Patient Safety	0.372	0.360	0.207
Quality Improvement	0.524	0.511	0.107

4.5. Comparative Analysis of the Latent Constructs based on Sociodemographic Characteristics

In this section, we presented our findings about the differences in the mean agreement scores of the study latent constructs (i.e., implementation of LSS, patient safety, adherence to the SSC, and quality improvement) according to sociodemographic characteristics.

4.5.1. Implementation of LSS and sociodemographic characteristics

The differences in the mean agreement scores regarding the implementation of LSS methodology according to sociodemographic characteristics are shown in Table 6.10. The only significant differences in agreement scores were found according to the job title. It was observed that anesthesiologists and managers had significantly higher agreement scores than orthopedic residents and anesthesia technologists. Furthermore, managers had considerably higher scores than nurses; this is illustrated in Table (4.10).

Table (4.10): Relationship between the implementation of LSS and sociodemographic characteristics (N = 113).

Characteristic		Mean ± SD	p-value (T or F)	Scheffé Test
Gender	Male	20.23 ± 3.41	0.276	
	Female	20.92 ± 2.76		
Social status	Single	19.55 ± 3.49	0.074	
	Married	20.79 ± 3.06		
Level of education	Diploma	20.72 ± 2.27	0.673	
	Bachelor	20.17 ± 3.67		
	Master	20.79 ± 2.25		
	Doctorate/Specialist	21.27 ± 3.20		

Age	< 30	19.50 ± 3.49	0.179	
	30 – 34	20.71 ± 3.45		
	≥ 35	20.47 ± 2.66		
PMC experience	1 – 5	19.44 ± 3.64	0.204	
	6 – 10	21.10 ± 3.30		
	11 – 15	21.00 ± 2.91		
	≥ 16	20.25 ± 2.87		
Job title	Orthopedic surgeon[a]	20.40 ± 3.09	0.011*	b, e < d, f
	Orthopedic resident[b]	19.18 ± 4.75		c < f
	Nurse[c]	20.41 ± 3.04		
	Anesthesiologist[d]	22.00 ± 1.96		
	Anesthesia technician[e]	18.82 ± 2.86		
	Management[f]	22.60 ± 2.55		
* The difference is significant (p-value<0.05).				

4.5.2. Patient Safety and Sociodemographic Characteristics

Table (4.11) illustrates the differences in the mean agreement scores regarding patient safety according to sociodemographic characteristics. It was observed that participants with bachelor's and master's degrees had significantly lower scores than specialists. Younger participants (age < 30 years) had lower scores. In addition, participants with 1-5 years of working history had lower scores than those with experience of 11 years or more.

Furthermore, managers had considerably higher scores than orthopedic surgeons, residents, nurses, and anesthesia technologists. Anesthesiologists also had higher scores than orthopedic residents.

Table (4.11): Relationship between enhancing patient safety and sociodemographic characteristics. (N = 113).

Characteristic		Mean ± SD	p-value (T or F)	Scheffé Test
Gender	Male	23.36 ± 4.10	0.506	
	Female	23.79 ± 2.71		
Social status	Single	22.52 ± 3.94	0.091	
	Married	23.86 ± 3.54		
Level of education	Diploma[a]	23.28 ± 3.41	0.011*	b, c < d
	Bachelor[b]	22.86 ± 3.49		
	Master[c]	22.79 ± 3.82		
	Doctorate/Specialist[d]	25.73 ± 3.52		
Age	< 30[a]	21.96 ± 3.89	0.034*	a < b, c
	30 – 34[b]	24.11 ± 3.59		
	≥ 35[c]	23.93 ± 3.39		
PMC experience	1 – 5[a]	22.04 ± 4.02	0.037*	a < c, d
	6 – 10[b]	23.03 ± 3.27		
	11 – 15[c]	24.77 ± 3.08		
	≥ 16[d]	24.09 ± 3.87		
Job title	Orthopedic surgeon[a]	23.00 ± 3.92	< 0.001*	a, b, c, e < f
	Orthopedic resident[b]	21.09 ± 4.97		b < d
	Nurse[c]	22.96 ± 3.25		
	Anesthesiologist[d]	25.00 ± 2.76		
	Anesthesia technician[e]	23.06 ± 3.05		
	Management[f]	27.80 ± 3.67		
***** The difference is significant (p-value<0.05).				

4.5.3. Adherence to the Safe Surgery Checklist and Sociodemographic Characteristics

The differences in the mean agreement scores regarding the adherence to the SSC according to sociodemographic characteristics are summarized in Table (4.12). we noticed that married participants had considerably higher scores than singles. Younger participants (age < 30 years) had lower scores than others. Participants with 1-5 years of working history had lower scores than those with experience of 11 years or more. Managers scored higher than orthopedic surgeons, residents, nurses, and anesthesia technologists. In addition, anesthesiologists and nurses also had higher scores than anesthesia technologists.

Table (4.12) Relationship between adherence to the SSC and sociodemographic characteristics (N = 113).

Characteristic		Mean ± SD	p-value (t or F)	Scheffé Test
Gender	Male	18.11 ± 4.52	0.728	
	Female	18.41 ± 4.10		
Social status	Single	15.86 ± 4.67	0.001*	
	Married	19.02 ± 3.96		
Level of education	Diploma	18.56 ± 4.97	0.336	
	Bachelor	17.92 ± 4.50		
	Master	17.63 ± 3.48		
	Doctorate/Specialist	20.36 ± 3.59		
Age	< 30[a]	16.04 ± 4.33	0.008*	a < b, c
	30 – 34[b]	18.83 ± 4.20		
	≥ 35[c]	19.02 ± 4.15		
PMC experience	1 – 5[a]	16.00 ± 4.19	0.015*	a < c, d
	6 – 10[b]	18.00 ± 4.52		
	11 – 15[c]	19.62 ± 3.75		
	≥ 16[d]	19.00 ± 4.29		
Job title	Orthopedic surgeon[a]	17.60 ± 3.47	< 0.001*	a, b, c, e < f
	Orthopedic resident[b]	17.27 ± 4.54		e < c, d
	Nurse[c]	18.92 ± 4.14		
	Anesthesiologist[d]	18.63 ± 3.63		
	Anesthesia technician[e]	14.47 ± 4.69		
	Management[f]	22.10 ± 1.29		
***** The difference is significant (p-value<0.05).				

4.5.4. Quality Improvement and Sociodemographic Characteristics

Table (4.13) summarizes the differences in the mean agreement scores regarding the quality service improvement according to sociodemographic characteristics. It was noticed that married participants had considerably higher scores than singles. Younger participants (age < 30 years) had lower scores than others. Furthermore, managers had higher scores than others. Moreover, nurses also had higher scores than anesthesia technologists.

Table 4.13. Relationship between quality improvement and sociodemographic characteristics (N = 113).

Characteristic		**Mean ± SD**	**p-value (t or F)**	**Scheffé Test**
Gender	Male	20.86 ± 5.28	0.965	
	Female	20.82 ± 4.63		
Social status	Single	17.97 ± 4.65	< 0.001*	
	Married	21.84 ± 4.81		
Level of education	Diploma	21.94 ± 5.76	0.310	
	Bachelor	20.08 ± 5.20		
	Master	21.79 ± 4.50		
	Doctorate/Specialist	22.00 ± 3.09		
Age	< 30[a]	18.53 ± 4.58	0.017*	a < b, c
	30 – 34[b]	21.36 ± 4.71		
	≥ 35[c]	21.86 ± 5.28		
PMC experience	1 – 5[a]	19.08 ± 4.86	0.066	
	6 – 10[b]	20.03 ± 4.74		
	11 – 15[c]	22.19 ± 4.53		
	≥ 16[d]	21.91 ± 5.47		
Job title	Orthopedic surgeon[a]	20.07 ± 2.75	0.006*	a, b, c, d, e < f
	Orthopedic resident[b]	20.00 ± 5.29		e < c
	Nurse[c]	21.37 ± 5.42		
	Anesthesiologist[d]	19.81 ± 2.88		
	Anesthesia technician[e]	18.12 ± 5.41		
	Management[f]	25.7 ± 3.27		
***** The difference is significant (p-value<0.05).				

4.5.5 Correlations among the Study's Latent Variables

Table 4.14 presents the bivariate correlations between the mean agreement scores of the study variables (implementation of LSS, patient safety, adherence to the SSC, and quality improvement). It was observed that all the bivariate associations were significant as seen below:

Table (4.14): Correlation matrix for the study variables, Pearson's correlation coefficient (p-value) (N = 113).

Variables	Lean Six Sigma	Patient safety	Safe surgery checklist	Quality improvement
Lean Six Sigma	__	__	__	__
Patient safety	0.466* (< 0.001)			
Safe surgery checklist	0.474* (< 0.001)	0.545* (< 0.001)		
Quality improvement	0.307* (0.001)	0.456*(< 0.001)	0.694* (< 0.001)	
*Association is significant at a 5% level of significance.				

4.6. Summary of Chapter Four

In this study, we developed a reflective research PLS-SEM model with the eleventh hypothesis to determine the effect of LSS on patient safety and adherence to the safe surgery checklist in improving the quality of hospital services in orthopedic surgeries in the PMC. Our findings reveal that LSS significantly influences patient safety and adherence to the safe surgery checklist. The adherence to SSC also significantly influenced patient safety and service quality improvement. Adherence to SSC partially mediates the links between LSS and service quality improvement and between LSS and patient safety. The present research findings provide a guideline for the practitioners of healthcare organizations to adopt the LSS methodology to ensure excellent patient safety and better adherence to SSC towards the continuous quality improvement of healthcare services.

The analysis regarding respondents' agreement with the study variables revealed that the highest agreement mean score was for the implementation of the LSS methodology (the mean was 81.9 ± 12.80 out of 100), followed by patient safety (the mean was 78.47 ± 12.23) and the lowest was for the quality service improvement (the mean was 69.50 ± 16.73). Furthermore, most participants (91.2%) believed that "using LSS tools led to reduced healthcare costs," Reinforcing the optimistic view of the financial benefits of this methodology. The majority (86.7%) felt that "patient safety is a top priority of the hospital" and "patients are involved in the treatment plan and decision-making regarding treatment." The majority (80.5%) agreed or strongly agreed that"the surgical safe list items are simple and easy to understand and apply." However, only 56.6% agreed or strongly agreed that "the level of general commitment to implementing SSC is satisfactory"(SSC1). Only 62.8% believed that the "SSC process is led during each surgical operation." Less than two-thirds (64.6%) agreed or strongly agreed that "the hospital management provides mechanisms and feedback regarding compliance with SSC." More than three-quarters (78.8%) believed that "the hospital's overall performance has improved." However, about one-third (31.9%) agreed or strongly agreed that "patient waiting times have been minimized," and only 56.6% believed that "patients' complaints have declined."

Generally, managers had the highest agreement scores for the study variables, whereas anesthesia technologists had the lowest. Participants with bachelor's and master's degrees had

significantly lower scores regarding patient safety than specialists. Younger participants (age < 30 years) had lower agreement scores than others regarding patient safety, adherence to an SSC, and quality improvement. Married participants had higher agreement scores than singles regarding adherence to the SSC and service quality improvement. Participants with 1-5 years of working history had lower scores than those with experience of 11 years or more regarding patient safety and adherence to the SSC.

Finally, all the bivariate linear associations between the study variables were significant.

Chapter Five: Discussion

5.1 Overview

This chapter provides Adetialed discussion of the rsults of the study, followed by a conclusion, recommendations, and requirements for future studies regarding the best practices that could be implemented regarding study dimensions to enhance patient safety and the quality of the service supplied regarding the adherence rate to SSC.

In the discussion of this research study, we examined the effect of employing the LSS methodology on patient safety and adherence to SSC in improving the quality of hospital services in orthopedic surgeries at the PMC. We applied cross-sectional quantitative research using a self-administered survey questionnaire based on the previous literature.

Of the 113 respondents, 10 (8.8%) were orthopedic surgeons, 11 (9.7%) were orthopedic residents, 49 (43.4%) were nurses, 16 (14.2%) were anesthesiologists, 17 (15.0%) were anesthesia technologists, and 10 (8.8%) were managers. To the best of our knowledge, this is the first study in this area of research in Palestinian healthcare institutions that deployed the LSS methodology to enhance patient safety by improving the adherence rate in implementing the SSC.

A reflective PLS-SEM research model with eleventh hypotheses (six direct and five indirect hypotheses) was developed, where patient safety and adherence to the surgical safety checklist served as the model mediators. A similar approach was recently used to investigate the influence of LSS on patient safety towards the quality improvement of Malaysian hospitals (Ahmed et al., 2024). The latter mediator variable was patient safety, yielding four potential hypotheses. In addition, Ahmed et al., 2018 also followed a similar approach to investigate the effects of LSS and workforce management on the quality performance of Malaysian hospitals, where the direct and indirect relationships between top management commitment and the quality performance of the healthcare organizations in Malaysia were examined.

Our primary research findings of the PLS-SEM research model indicated that implementation of LSS methodology had a strong positive and significant effect on adherence to SSC ($\beta = 0.485$, and p-value < 0.001) as well as on patient safety($\beta = 0.260$, and p-value = 0.015).

Adherence to SSC also had a strong positive significant relationship with patient safety ($\beta = 0.440$, and p-value < 0.001) as well as with the quality improvement of hospital services ($\beta = 0.645$, and p-value < 0.001). Additionally, the LSS methods indirectly influenced the quality improvement of the hospital services through the mediating effect of adherence to SSC ($\beta = 0.313$, and p-value < 0.001). Furthermore, adherence to the SSC partially mediated the link between LSS and patient safety ($\beta = 0.213$, and p-value < 0.001). Although patient safety had a significant positive relationship with the quality improvement of hospital services ($\beta = 0.154$, and p-value $= 0.097$) at a 10% significance level, the mediating role of patient safety between the LSS and quality improvement was insignificant.

The results also revealed that LSS explained 23.5% of adherence to SSC. LSS explained 37.2% of the total variation in patient safety. Moreover, LSS explained that quality improvement and adherence to SSC were at 52.4%.

Lastly, the control charts (Figures 5.1, 5.2, and 5.3) depict how the percentage of adherence to SSC for orthopedic surgeries at the PMC had changed over time (April – 2019 to June – 2024). The charts supported our research findings. Clearly, a visual inspection of these charts shows an increasing or upward trend in the percentage of adherence to the SSC during the last six months (i.e., the adoption of the LSS methodology period).

Generally, our findings were consistent with those obtained in the previous studies in this area of research. For instance, Ahmed et al., (2018) and Ahmed et al., (2024) showed that effective adoption of LSS significantly influenced patient safety and quality improvement. Furthermore, Niñerola et al., (2021) and Iswanto, (2021) highlighted that effective employment of LSS methodology lowers errors, enhancing patient safety.

Additionally, Walter et al. (2023) and Mohamed et al. (2021) showed that process standardization improves service quality in the healthcare sector, raising patient safety and satisfaction.

Moreover, Noronha et al. (2023) indicated that adopting the LSS methodology in the healthcare sector improves services like patient safety, security, doctor and nursing care, and shorter waiting times in clinics and hospitals.

The relationship between LSS and quality improvement in healthcare is complex and multifaceted. This study sheds light on the indirect nature of LSS's influence on quality enhancement, particularly through the lens of the SSC implementation at PMC. Quality improvement in healthcare requires a comprehensive approach, incorporating various tools, activities, and cultural shifts. While LSS provides a robust framework for process optimization, its impact on quality is often realized through specific interventions. In this research, we focused on the SSC as one such intervention within a broader patient safety initiative.

Our findings reveal a novel perspective: LSS methodologies indirectly affect quality improvement in hospital services through the mediating factor of SSC adherence. This mediation model offers several insights:

1. Causal Pathway: The implementation of LSS principles appears to enhance adherence to the SSC, which subsequently leads to improved quality and patient safety outcomes.

2. Operational Mechanism: SSC adherence serves as a practical manifestation of LSS principles, translating theoretical concepts into actionable safety measures.

3. Indirect Influence: Rather than directly impacting quality improvement, LSS methodologies work through intermediary tools like the SSC to effect change.

4. Mediation Dynamics: The relationship between LSS and quality improvement may be partially or fully mediated by SSC adherence, highlighting the checklist's crucial role.

This mediation model provides a more nuanced understanding of how LSS methodology influences healthcare outcomes. It emphasizes that the success of LSS in improving quality is closely tied to the effective implementation and adherence to specific tools like the SSC.

Furthermore, our research underscores the significance of SSC adherence in the healthcare sector. Not only does it mediate the LSS-quality improvement relationship, but it also plays a vital role in achieving superior service quality through the successful adoption of LSS principles.

In conclusion, this study offers new insights into the intricate relationships between LSS, quality improvement, and patient safety in healthcare settings. It highlights the importance of considering indirect effects and specific interventions when evaluating the impact of broad methodologies like LSS on healthcare quality.

5.2 Conclusions

In conclusion, applying LSS at the PMC using the DMAIC approach was a robust problem-solving methodology to improve the process. This research aimed to demonstrate that the effective adoption of the LSS methodology can significantly improve patient safety and adherence to the SSC, thereby enhancing hospital service quality. Notably, the study also shows that improving adherence to the SSC directly impacts the quality of services and patient safety and acts as a mediator between the LSS and quality improvement in hospitals and between the LSS and improving patient safety. These findings underscore the crucial role of adherence to the SSC in achieving quality improvement through the effective adoption of the LSS methodology.

The present research findings provided fundamental guidelines on how the LSS methodology can be adopted to enhance patient safety, improve adherence to the SSC, and improve the quality of hospital services. Adherence to the SSC can mediate in creating links between LSS and quality improvement and between LSS and patient safety in healthcare sectors.

Essential LSS tools in healthcare help visualize the entire patient journey, identifying waste and opportunities for improvement. DMAIC provides a structured approach to problem-solving and continuous improvement. It monitors and controls processes to ensure consistency and quality and identifies the underlying causes of problems or defects. The research uses the following tools of the DMAIC approach: Problem Context Diagram (PCD), project charter, SIPOC, flowchart, Eight Wastes, control chart, and Cause and Effect Diagram (Fish diagram).

In the Define phase, the process problem was first defined by applying the CIPOC to understand the high level of process steps, process measures, goal performance, sources of variation and wastes, and impact on performance. The target was to increase the adherence rate to the SSC, ranging from 62% % to 86% to 95%. The project charter has been developed; hence, the problem, scope, and objectives were determined.

Measure phases were applied to understand and analyze the current process performance. In addition, areas for improvement were identified by applying tools such as the flowchart, Eigth wastes, and Control Chart. Each tool illustrated significant results.

In the analysis phase, a cause-and-effect analysis was conducted; hence, the root cause of the low adherence rate is applying the SSC at the PMC. The root causes were summarised as the following: People, Processes, Environmental, and Materials. Based on the root causes analysis, a set of potential solutions should be applied to improve the process.

All these tools are essential for the future. These LSS tools are crucial for healthcare because they provide systematic approaches to improving efficiency, reducing errors, and enhancing patient outcomes. As healthcare faces increasing pressures to deliver high-quality care while managing costs, these tools offer methods to optimize processes, reduce waste, and improve patient safety. They also promote a culture of continuous improvement, which is essential for healthcare organizations to adapt to evolving challenges and technologies.

5.3 Theoretical And Practical Implications:

5.3.1 Theoretical Implications:

1. Expanding the understanding of LSS application in healthcare settings.
2. Establishing the mediating role of checklist adherence in the relationship between LSS and quality/safety outcomes.
3. Contributing to the body of knowledge on process improvement methodologies in complex healthcare environments.
4. Offering a framework for integrating quality improvement initiatives with patient safety protocols.

5.3.2 Practical Implications:

1. Providing healthcare administrators with a roadmap for implementing LSS to improve surgical safety and overall quality.
2. Highlighting the importance of checklist adherence as a critical lever for improving patient safety and service quality.

3. Offering specific strategies for enhancing checklist compliance through LSS methodologies.
4. Demonstrating the potential for LSS to create sustainable improvements in healthcare processes and outcomes.
5. Providing evidence-based support for investing in LSS training and implementation in healthcare organizations.
6. Emphasizing the need for a systemic quality improvement approach beyond individual interventions.

This research bridges the gap between theoretical LSS concepts and practical application in healthcare, offering both a conceptual framework and actionable insights for improving patient safety and service quality through enhanced adherence to SSC. It underscores the potential of LSS as a robust methodology for addressing complex challenges in healthcare delivery. It sets the stage for future research and implementation efforts in this critical area.

5.4 Research Limitations

There are several limitations to this study:

First, the major limitation was the lack of knowledge about implementing the LSS methodology. Hence, the researcher followed an extensive educational and training program six months before data collection to develop the study participants' knowledge regarding successfully adopting the LSS methodology.

Second, due to the vast number of surgical procedures conducted daily at the PMC, this study was limited to only the orthopedic operations rooms, where all interventions will occur. Therefore, all orthopedic patients in this room and orthopedic staff (doctors, surgeons, anesthesiologists, and related management teams) were included. So this research focussed solely on the PMC services in orthopedic surgeries; thus, the results might not apply to other health sectors and services.

Third, the lack of similar studies in local Palestinian and adjacent Arab countries restricted comparison and discussion. For these reasons, future research must confirm the hypotheses across a more comprehensive sample, including other healthcare sectors and services. A

dditionally, this research study is part of the thesis proposal for the master's degree program, and its time is limited to the spring and summer of 2024.

5.5 Recommendations and Future Research

This research study significantly improves patient safety in orthopedic surgeries. The research findings are expected to provide guidelines to enhance the quality performance of the PMC and other healthcare organizations in Palestine, thereby instilling confidence in the reader about the positive impact of this research.

A comprehensive approach is necessary to effectively utilize LSS to improve patient safety through enhanced adherence to SSC for orthopedic surgeries. The journey begins with process mapping, where a detailed map of the current surgical process is created, meticulously identifying all steps involving the SSC. This visual representation provides a clear understanding of the workflow and highlights potential areas for improvement.

Following the mapping phase, data collection and analysis become crucial. Gathering baseline data on checklist adherence rates allows for a quantitative assessment of the current situation. This data is then analyzed using tools like Pareto charts and value stream mapping to uncover the root causes of non-compliance. These insights form the foundation for targeted improvements.

Staff training plays a pivotal role in this improvement process. Comprehensive training sessions are conducted to educate all relevant personnel on the importance of the checklist and proper usage techniques. These sessions emphasize the checklist's critical role in ensuring patient safety and fostering a culture of compliance and understanding.

Visual management techniques are implemented in the operating room to reinforce the importance of the checklist. Visual cues and reminders are strategically placed to prompt checklist usage at critical points during the surgical process. These serve as constant reminders to staff, helping to integrate the checklist seamlessly into their workflow.

Through cross-functional process optimization, the scope of improvement extends beyond the operating room. LSS principles are applied across the perioperative process, identifying and eliminating broader systemic issues affecting checklist adherence. This holistic approach ensures that improvements are sustainable and far-reaching.

Our efforts to improve checklist adherence are not limited to our healthcare system. To gain a global perspective, we have established an international database. This database allows us to compare checklist adherence rates and share best practices across healthcare systems worldwide. By participating in this global benchmarking initiative, we are contributing to a more significant, collaborative effort and learning from diverse experiences, which promotes the adoption of proven strategies worldwide.

Our commitment to quality extends to implementing error-proofing techniques known as poka-yoke. These fail-safe measures are designed to make skipping or incorrectly completing checklist items difficult. By building quality into the process, we reduce the likelihood of human error and ensure consistent adherence to the checklist. This reassures our team that we have robust systems to support them in their work.

A system for real-time monitoring of checklist adherence is developed, allowing for immediate corrective action when deviations occur. This real-time feedback loop enables swift responses to non-compliance, maintaining high patient safety standards throughout each surgical procedure.

Finally, a culture of continuous improvement is established. The checklist process is regularly reviewed and updated based on staff feedback and ongoing data analysis. This ensures that the checklist remains relevant, effective, and aligned with the evolving needs of the surgical team and patients.

By implementing these recommendations, healthcare organizations can leverage LSS methodologies to significantly enhance adherence to SSC in orthopedic surgeries, ultimately improving patient safety outcomes.

For further research, it is recommended that future research build upon the comprehensive approach outlined in this research and expand and deepen our understanding of LSS application in healthcare settings, particularly in improving adherence to SSC. A key area for exploration is the long-term sustainability of the improvements achieved through this methodology. Longitudinal studies could track the ongoing effectiveness of the implemented changes, providing insights into maintaining high levels of checklist adherence over time.

Additionally, researchers should investigate the transferability of these findings to other medical specialties beyond orthopedic surgeries. This could involve adapting the process mapping and improvement strategies to different surgical contexts, potentially uncovering unique challenges and opportunities in each field.

Another promising avenue for future research is the integration of advanced technologies into the LSS framework. Studies could explore how artificial intelligence, machine learning, or augmented reality enhance checklist adherence's real-time monitoring and error-proofing aspects. This technological integration could lead to more sophisticated and responsive systems for patient safety.

Furthermore, an in-depth analysis of the human factors involved in checklist adherence is needed. Future studies could delve into the psychological and cultural aspects that influence staff compliance, incorporating insights from behavioral science to develop more effective training and motivation strategies.

Lastly, given the global benchmarking initiative mentioned in the study, future research could focus on comparative analyses across different healthcare systems and cultures. This could provide valuable insights into how LSS methodologies can be adapted to diverse healthcare environments, potentially leading to a more nuanced and globally applicable approach to improving patient safety through enhanced checklist adherence.

These future directions would build upon this study's solid foundation and contribute to the broader goal of continuously improving healthcare quality and patient safety worldwide.

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Appendices

Appendix A: Study Questionnaire in English:

Dear Participant:

In the context of preparing a master's thesis entitled **"Improving the Adherence Rate to Safe Surgeries Checklist in Orthopedic Surgeries at Palestine Medical Complex Using Lean Six Sigma Methodology.**

," The researcher Ghadi Muhammad Amarneh, in the Master's program in Quality Management at the College of Graduate Studies at the Arab American University, as part of her thesis, is conducting field research to improve the rate of adherence to the surgical checklist in orthopedic surgeries at the Palestine Medical Complex / Palestinian Ministry of Health through the use of the attached research questionnaire.

The administrative and surgical staff are qualified to handle this questionnaire. They are interested in applying the surgical checklist to enhance patient safety during surgical interventional procedures in operating rooms for orthopedic patients.

Therefore, you are kindly requested to be careful in answering the following questions, which relate to the level of awareness and commitment to applying it according to specialization and nature of work. Given the importance of your opinion in enriching the study, we hope for your cooperation in answering the questions in the questionnaire accurately and objectively, as all data will be used for scientific research purposes only, noting that the estimated time to complete this questionnaire is about ten minutes.

For further inquiries and clarifications: Ghadi Muhammad Amarneh, Master's student, Quality Management Program in Health Institutions

Ramallah - Palestine 0562401291E-mail: ghadi1988@hotmail.com

Part 1: Sociodemographic Characteristics

Please answer the following questions by putting an (X) in the appropriate place:

1- **Age:** ( ) 20-24 ( ) 25-29 ( ) 30-34 ( ) 35 or more

2- **Gender:**( )Male ( ) Female

3- **Marital status:**( )Single ( ) Married ( ) Widowed ( ) Divorced

4- **Level of education:**( ) Diploma ( ) Bachelor ( ) Master ( ) Doctorate/Specialist

5- **Job title:** ( ) Orthopedic surgeon( ) Resident physician( ) Nurse ( ) Anesthesiologist ( ) Anesthesia technician ( ) Management ( ) Other: Specify .....

6- **PMC experience (years):**( ) 1-5 ( ) 6-10 ( ) 11-15 ( ) 16 or more

Part 2: Lean Six Sigma, Patient Safety, Adherence to the Safe Surgery Checklist, and Quality Improvement

Below is a set of questions related to assessing the commitment of health workers and surgical staff, specifically to implementing the surgical checklist concerned with enhancing patient safety during surgical interventional procedures in operating rooms for orthopedic patients. Please put (X) inside the box that expresses your degree of agreement with each of the following statements based on your experience in your work.

Section 1: Implementation of Lean Six Sigma (L.S.S)methodology

Paragraph	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. Application of LLS practices to create a well-organized work environment in the hospital					
2. Use root cause analysis, fishbone diagrams, or Value Stream Maps to identify the causes of quality problems in healthcare processes					
3. Continuous training programs on process improvement tools for the hospital staff					
4. Using LSS tools led to reduced healthcare costs in the complex					
5. Using LSS improvement methods for continuously developing the hospital's projects					

Section 2: Patient Safety

Paragraph	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. Patient safety is a top priority of the hospital					
2. Patients are involved in the treatment plan and decision-making regarding treatment					
3. The patient's family members take part in the treatment plan and decision-making regarding treatment					
4. The process of treating patients takes place within a set of clinical practices that are based on evidence during therapeutic and surgical interventions					
5. An enhanced work environment for patients: design, environmental risk management, people with special needs					
6. The hospital management offers several programs to ensure continuous education/training for staff					

Section 3:Adherence to the Safe Surgery Checklist					
Paragraph	**Strongly Disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**
1. The level of general commitment to implementing the safe surgical checklist is satisfactory					
2. The safe surgical checklist process is led during each surgical operation					
3. The surgical safe list items are simple and easy to understand and apply					
4. The hospital management ongoing support and training to staff regarding the safe surgical checklist commitment					
5. The hospital management provides mechanisms and feedback regarding compliance with the safe surgical checklist					
Section 4:Quality Improvement					
Paragraph	**Strongly Disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**
1. The overall performance of the hospital has improved					
2. Medical errors in inpatient services have been reduced					
3. Medical complications in inpatient services have been reduced					
4. Adverse events and incidents in patients have been reduced					
5. Patient waiting times have been minimized					
6. Patients' complaints have declined					

Appendix B: Study Questionnaire in Arabic:

عزيزي / عزيزتي المشارك / ة :

في إطار اعداد رسالة بحث ماجستير بعنوان "**تحسين معدل الإلتزام بالقائمة الجراحية التفقدية في عمليات جراحة العظام في مجمع فلسطين الطبي باستخدام منهجية لين ستة سيجما**" ،تقوم الباحثة عدي محمدعمارنة في برنامج ماجستير إدارة الجودة في كلية الدراسات العليا الجامعة العربية الامريكية كجزء من أطروحتها بإجراء بحث ميداني لتحسين معدل الالتزام بالقائمة الجراحية التفقدية في عمليات جراحة العظام / مجمع فلسطين الطبي / وزارة الصحة الفلسطينية/ من خلال إستخدام إستبانة البحث المرفقة.

إن الأشخاص المؤهلون للتعامل مع هذه الإستبانة في هذه المرحلة هم الطاقم الصحيوالجراحي المهتم بتطبيق القائمة الجراحية التفقدية المعنية بتعزيز سلامة المريض أثناء الإجراءات الجراحية في غرف العمليات لمرضى جراحة العظام،وعليه يرجى منكم توخي الدقة في الإجابة على الأسئلة التاليةنظرا لأهمية رأيكم في إثراء الدراسة نأمل تعاونكم بالإجابة على الإستبيان بدقة وموضوعية، حيث سيتم إستخدام كافة البيانات لأغراض البحث العلمي فقط علما أن الوقت المقدر لإكمال هذا الإستبيان حوالي عشرة دقائق.

لمزيد من الاستفسارات والإيضاحات :عدي محمد عمارنة / طالبة ماجستير / برنامج إدارة جودة في المؤسسات الصحية / رام الله – فلسطين

اولا: البيانات الديموغرافية :

يرجى الإجابة عن الاسئلة التالية بوضع إشارة (X) في المكان المناسب:

1- **العمر:**( ) من 20- 24 ( ) من 25 – 29 ( ) من 30-34 ( ) من 35 فاعلى.

2- **الجنس:** ( ) ذكر( ) انثى.

3- **الحالة الإجتماعية :** ( ) متزوج ( ) اعزب ( ) ارمل ( ) مطلق.

4- **التحصيل الاكاديمي :**( ) دبلوم ( ) بكالوريوس ( ) ماجستير ( ) دكتوراه /اخصائي

5- **المهنة :** ( ) جراحة عظام ( ) طبيب مقيم ( ) ممرض ( ) طبيب تخدير ( ) فني تخدير( ) الادارة

غير ذلك: حدد.....

6- **سنوات الخدمة في المجمع:** ( ) من1-5 سنوات ( ) من 6-10 ( ) من 11-15 ( ) 16 فاعلى

ثانيا : معايير الإلتزام بالقائمة الجراحية واستخدام منهجية اللين ستة سجما: في مايلي مجموعة من الاسئلة تتعلق بتقييمالتزام العاملين الصحيين والطاقم الجراحي بتطبيق القائمة الجراحية التفقدية المعنية بتعزيز سلامة المريض باستخدام منهجية اللين ستة سجما اثناء الإجراءات التداخلية الجراحية في غرف العمليات لمرضى جراحة العظام، يرجى وضع (X) داخل المربع الذي يعبر عن درجة موافقتك على كل من العبارات التالية من واقع خبرتك في عملك:

القسم الاول: استخدام أدوات اللين ستة سجما في الرعاية الصحية:					
الفقرة	لا اوافق بشدة	لا اوافق	محايد	اوافق	اوافق بشدة
1- تطبيق أدوات اللين ستة سيجما لخلق بيئة عمل جيدة التنظيم في المجمع.					
2- استخدام أدوات اللين ستة سيجما مثل التحليل الجذري "عظمة السمكة" وخريطة تدفق القيمةمن أجل تحديد العوائق امام تحسين الجودة في المجمع.					
3- التدريب المستمر على منهجيات اللين ستة سجما للتحكم في التحسين المستمر لجودة الخدمات في المجمع.					
4- استخدام أدوات اللين ستة سجما لتقليل تكاليف الرعاية الصحية في المجمع.					
5- استخدام أدوات اللين ستة سجما بهدف التطوير المستمرلمشاريع الرعاية الصحية المستقبلية في المجمع.					
القسم الثاني: تعزيز سلامة المريض:					
الفقرة	لا اوافق بشدة	لا اوافق	محايد	اوافق	وافق بشدة
1- تعتبر سلامة المرضى اولوية قصوى لدى إدارة المجمع.					
2- يتم اشراك المرضى في الخطة العلاجية والاجراءات التداخلية والموافقة المبنية على المعرفة والشكاوي والاقتراحات وغيرها.					
3- يتم اشراك ذوي المرضى في الخطة العلاجية والاجراءات التداخلية والموافقة المبنية على المعرفة والشكاوي والاقتراحات وغيرها.					
4- تتم عملية علاج المرضى ضمن مجموعة من الممارسات السريرية التي تستند الى الدلائل والبراهين أثناء التداخلات العلاجية والجراحية.					
5- يتم مراعاة وجود بيئة عمل آمنة للمرضى (التصميم، ادارة المخاطر البيئية، ذوي الاحتياجات الخاصة.....).					
6- تتخذ إدارة المجمع عدة برامج لضمان التعليم/التدريب المستمرلكافة العاملين لضمان سلامة المرضى.					

القسم الثالث: الالتزام بالقائمة الجراحية التفقدية:					
الفقرة	لا اوافق بشدة	لا اوافق	محايد	اوافق	اوافق بشدة
1- مستوى الإلتزام العام بتطبيق القائمة الجراحية التفقدية الآمنة مُرضٍ.					
2- تقاد عملية القائمة الجراحية التفقدية الآمنة أثناء كل عملية جراحية.					
3- بنود القائمة الجراحية الآمنة بسيطة وسهلة الفهم والتطبيق.					
4- توفر إدارة المجمع الدعم والتدريب المستمر لمقدمي الرعاية الصحية فيما يتعلق بالالتزام بالقائمة الجراحية التفقدية.					
5- توفر إدارة المجمع آليات المراقبة والتغذية الراجعة المستمرة حول الالتزام بالقائمة الجراحية التفقدية الآمنة.					
القسم الرابع: التحسين المستمر للجودة في الرعاية الصحية.					
الفقرة	لا اوافق بشدة	لا اوافق	محايد	اوافق	اوافق بشدة
1- الأداء العام للطاقم الطبي في المجمع في تحسن مستمر.					
2- الأخطاء الطبية في المجمع في تناقص.					
3- المضاعفات الجراحية في المجمع في تناقص.					
4- الحوادث العرضية في المجمع في تناقص.					
5- وقت الإنتظار للمرضى في المجمع في تناقص.					
6- عدد حالات الشكاوي المقدمة من المرضى في تناقص.					

Appendix C: Details of Questionnaire Constructs

Table 3.1: Details of Constructs.

Variable	Role	Code	Items	Source
Lean Six Sigma	IV	LSS1	Application of L.L.S practices to create a well-organized work environment in the hospital	Ahmed et al. (2024). Gowenet al. (2012)
		LSS2	Root cause analysis, fishbone diagrams, or value stream maps can be used to identify the causes of quality problems in healthcare processes.	
		LSS3	Continuous training programs on process improvement tools for the hospital staff	
		LSS4	Using LSS tools led to reduced healthcare costs.	
		LSS5	Using LSS improvement methods for continuously developing the hospital's projects	
Patient Safety	MV	PS1	Patient safety is a top priority of the hospital	WHO Patient Safety Initiative 3rd edition (2020) El-Jardali et al. (2014)
		PS2	Patients are involved in the treatment plan and decision-making regarding treatment.	
		PS3	The patient's family members participate in the treatment plan and decision-making regarding treatment.	
		PS4	Treating patients occurs within clinical practices based on evidence during therapeutic and surgical interventions.	
		PS5	An enhanced work environment for patients: design, environmental risk management, people with special needs	
		PS6	The hospital management offers several programs to ensure continuous education/training for the staff.	
Safe Surgery Checklist	MV	SSC1	The level of general commitment to implementing the safe surgical checklist is satisfactory.	WHO guidelines for safe surgery (2009)
		SSC2	The safe surgical checklist process is led during each surgical operation	
		SSC3	The surgical safe list items are simple and easy to understand and apply	
		SSC4	The hospital management provides ongoing support and training to staff regarding the safe surgical checklist commitment	
		SSC5	The hospital management provides mechanisms and feedback regarding compliance with the safe surgical checklist	
Quality Improvement	DV	QI1	The overall performance of the hospital has improved	Ahmed et al. (2024) Gowenet al. (2012)
		QI2	Medical errors in inpatient services have been reduced	
		QI3	Medical complications in inpatient services have been reduced	
		QI4	Adverse events and incidents in patients have been reduced	
		QI5	Patient waiting times have been minimized	
		QI6	Patients' complaints have declined	

IV: independent variable, MV: mediating variable, DV: dependent variable

Appendix D: IRB Approval Form

Arab American University

Institutional Review Board - Ramallah

الجامعة العربية الأمريكية

مجلس اخلاقيات البحث العلمي – رام الله

IRB Approval Letter

Study Title: "Improving the Adherence Rate to Safe Surgeries Checklist in Orthopedic Surgeries at Palestine Medical Complex Using Lean Six Sigma Methodology".

Submitted by: Ghdi Mohammed Ahmad Amarni

Date received: 3rd April 2024

Date reviewed: 14th May 2024

Date approved: 16th May 2024

Your Study titled **"Improving the Adherence Rate to Safe Surgeries Checklist in Orthopedic Surgeries at Palestine Medical Complex Using Lean Six Sigma Methodology"** with the code number **"R-2024/A/79/N"** was reviewed by the Arab American University Institutional Review Board - Ramallah and it was approved on the 16th of May 2024.

Sajed Ghawadra, PhD
IRB-R Chairman
Arab American University of Palestine

الجامعة العربية الأمريكية - فلسطين
مجلس اخلاقيات البحث العلمي - رام الله
IRB-R
ARAB AMERICAN UNIVERSITY-PALESTINE
INSTITUTIONAL REVIEW BOARD - RAMALLAH

General Conditions:

1. Valid for 6 months from the date of approval.
2. It is important to inform the IRB-R with any modification of the approved study protocol.
3. The Bord appreciates a copy of the research when accomplished.

Appendix E: MoH & PMC Approval

State of Palestine
Ministry of Health
Education in Health and Scientific Research Unit

دولة فلسطين
وزارة الصحة
وحدة التعليم الصحي
والبحث العلمي

Ref.: ....
Date:..................

الرقم:
التاريخ:

عطوفة الوكيل المساعد لمجمع فلسطين الطبي المحترم،،،

تحية واحترام،،

الموضوع: تسهيل مهمة بحث

يرجى تسهيل مهمة الطالب: غدي محمد عمارنه – برنامج ماجستير ادارة الجودة/ الجامعة العربية الامريكية، وباشراف د. اشرف الدميري في عمل بحث بعنوان:

" تحسين معدل الالتزام بالقائمة الجراحية التفقدية في عمليات جراحة العظام في مجمع فلسطين الطبي باستخدام منهجية لين ستة سيجما "

من خلال السماح للطالب بجمع معلومات عن طريق توزيع استبانة، وذلك في:

– مجمع فلسطين الطبي

على ان يتم الالتزام بأساليب وأخلاقيات البحث العلمي، وعدم التعرض للمعلومات التعريفية المشاركين .

على ان يتم تزويد الوزارة بنسخة PDF من نتائج البحث، التعهد بعدم النشر لحين الحصول على موافقة الوزارة على نتائج البحث.

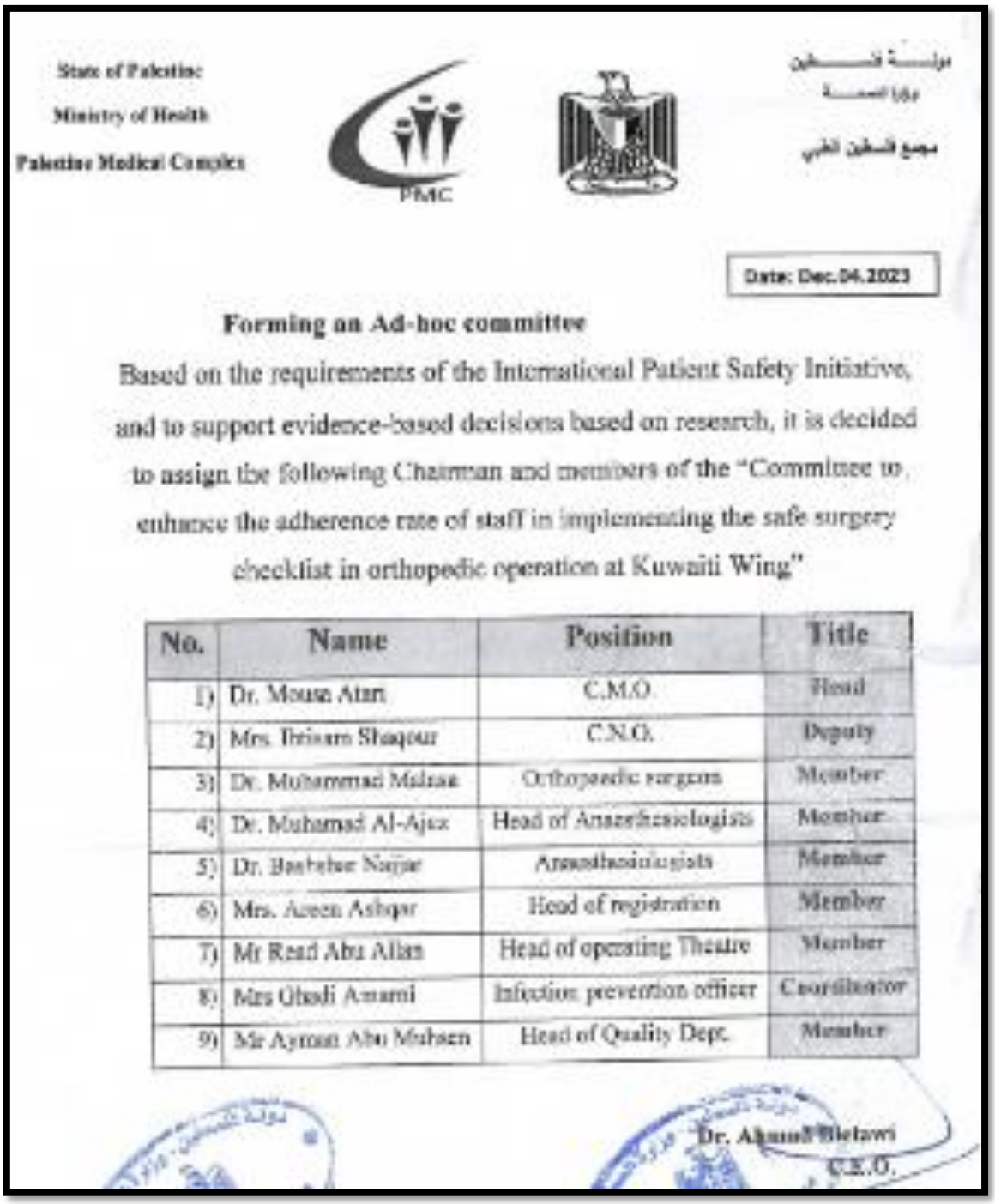
مع الاحترام،،

د. عبد الله القواسمي

رئيس وحدة التعليم الصحي والبحث العلمي

نسخة: عميد الدراسات العليا المحترم/ الجامعة العربية الامريكية

Appendix F: SSC Ad-hoc Committee



State of Palestine
Ministry of Health
Palestine Medical Complex

PMC

دولة فلسطين
وزارة الصحة
مجمع فلسطين الطبي

Date: Dec.04.2023

Forming an Ad-hoc committee

Based on the requirements of the International Patient Safety Initiative, and to support evidence-based decisions based on research, it is decided to assign the following Chairman and members of the "Committee to enhance the adherence rate of staff in implementing the safe surgery checklist in orthopedic operation at Kuwaiti Wing"

No.	Name	Position	Title
1)	Dr. Mouin Atari	C.M.O.	Head
2)	Mrs. Ibtisam Shaqour	C.N.O.	Deputy
3)	Dr. Muhammad Malkas	Orthopaedic surgeon	Member
4)	Dr. Muhamad Al-Ajez	Head of Anaesthesiologists	Member
5)	Dr. Basbebar Najjar	Anaesthesiologists	Member
6)	Mrs. Aseen Ashqar	Head of registration	Member
7)	Mr Read Abu Allan	Head of operating Theatre	Member
8)	Mrs Ghadi Amami	Infection prevention officer	Coordinator
9)	Mr Ayman Abu Mohsen	Head of Quality Dept.	Member

Dr. Ahmad Bielawi
C.E.O.

Appendix G: Targeted Audience of Training


Lean Six
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Emergency W
Specialized su
Kidney Unit Bu

State of Palestine
Ministry of Health
Palestine Medical Complex

دولة فلسطين
وزارة الصحـــــة
مجمع فلسطين الطبي

الرقم	الاسم	الوظيفة	الايميل	هاتف	التواقيع	ملاحظات
11	سعيد [illegible] كريم	عرضة قانونية		0569364788		
12	رانيا [illegible] زعرب	HN ICU		0599726647		
13	[illegible]	HN Gynecology		0569571745		
14	[illegible]	HN CCU ER		0595822110		
15	[illegible]	H.N		0597467260		
16	[illegible]	[illegible]		0566511566		
17	[illegible]	H.N		0568814002		
18	[illegible]	TH-W		0599934790		
19	[illegible]	PW		0566233140		
20	[illegible]	[illegible]		0597939517		
21	[illegible]	Q.E		0562401292		
22	[illegible]	[illegible]		0599115343		
23	ميار [illegible]	Endoscop		0598561843		
24	[illegible]	PICU				

02 / 2957942 فاكس 02 / 2982922 هاتف

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Palestine Medical Complex

دولـة فلسطين
وزارة الصحـــــة
مجمع فلسطين الطبي

Ref: QPSF025

التاريخ: 02/06/2024

قائمة حضور اجتماع رؤساء الاقسام وتدريب اللين ستة سجما / قسم الجودة وسلامة المريض

مكان الاجتماع : قاعة الاجتماعات– / جناح الجراحات التخصصية / مجمع فلسطين الطبي

الرقم	الاسم	الوظيفة	الايميل	هاتف	التوقيع	ملاحظات
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5	[illegible]	رئيس تمريض العظام	ayman_dhib@yahoo.com	0599/721613 0569/300681	[illegible]	
6	[illegible]	رئيس [illegible]		0599813870	[illegible]	
7	[illegible]	[illegible] رئيس قسم [illegible]		0597939926	[illegible]	
8	[illegible]	رئيس قسم العناية [illegible]		0598756074	[illegible]	
9	[illegible]			056[illegible]	[illegible]	
10	[illegible]	[illegible]		0599[illegible]	[illegible]	

State of Palestine
Ministry of Health
Palestine Medical Complex

دولـة فلسطين
وزارة الصحـــــة
مجمع فلسطين الطبي

Ref: QPSF025

التاريخ: 04/06/2024

قائمة حضور اجتماع رؤساء الاقسام وتدريب اللين ستة سجما / قسم الجودة وسلامة المريض

كان الاجتماع : قسم العظام / مكتب الاطباء / جناح الطوارئ / مجمع فلسطين الطبي

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4	صالح [illegible]	طبيب مقيم [illegible]	dr.saleh.[illegible]@gmail.com	0597307243	[illegible]	
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6	[illegible]	[illegible]			[illegible]	
7						
8						
9						
10						

State of Palestine
Ministry of Health
Palestine Medical Complex

دولة فلسطين
وزارة الصحـــــة
مجمع فلسطين الطبي

Ref.: QPSF025

التاريخ/19/05/2024

قائمة حضور تدريب اللين ستة سجما / قسم الجودة وسلامة المريض

مكان الاجتماع : قاعة الاجتماعات- / العمليات / جناح ابناء رام الله / مجمع فلسطين الطبي

الفئة المستهدفة: اطباء اختصاصيي التخدير والانعاش

الرقم	الاسم	الوظيفة	الايميل	هاتف	التوقيع	ملاحظات
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4	فاطمة جمال مناصرة	مقيمة تخدير	fatima.manasrah6@gmail.com	0595716348		
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6	لشكار أحمد المغار	أخصائي تخدير	Thedoctor@hotmail.com	0595889647		
7	محمد خالد كنعان	مقيم تخدير	ms7amma1993@gmail.com	0599201108		
8	د. محمد احمد العالم	اخصائي تخدير	dr.ajez.as@gmail.com	0599695986		
9						

Appendix (H): An Indicator of Staff Adherence Rate to SSC at the PMC:

Year	Month	Hospital	No of Surgeries That SSC implemented	Total No of Surgeries	% of SSC impementation
2020	1	PMC	71	93	76%
2020	2	PMC	73	99	74%
2020	3	PMC	71	98	72%
2020	4	PMC	47	70	67%
2020	5	PMC	49	79	62%
2020	6	PMC	51	79	65%
2020	7	PMC	60	85	71%
2020	8	PMC	65	93	70%
2020	9	PMC	71	99	72%
2020	10	PMC	69	93	74%
2020	11	PMC	73	97	75%
2020	12	PMC	61	83	73%
2021	1	PMC	63	85	74%
2021	2	PMC	64	88	73%
2021	3	PMC	62	82	76%
2021	4	PMC	61	86	71%
2021	5	PMC	70	93	75%
2021	6	PMC	72	95	76%
2021	7	PMC	79	109	72%
2021	8	PMC	77	98	79%
2021	9	PMC	73	95	77%
2021	10	PMC	79	98	81%
2021	11	PMC	90	119	76%
2021	12	PMC	99	125	79%
2022	1	PMC	65	81	80%
2022	2	PMC	69	86	80%
2022	3	PMC	80	99	81%
2022	4	PMC	82	103	80%
2022	5	PMC	89	110	81%
2022	6	PMC	93	113	82%
2022	7	PMC	99	121	82%
2022	8	PMC	80	93	86%
2022	9	PMC	85	101	84%
2022	10	PMC	85	99	86%
2022	11	PMC	93	113	82%
2022	12	PMC	75	93	81%
2023	1	PMC	79	94	84%
2023	2	PMC	84	99	85%
2023	3	PMC	77	95	81%
2023	4	PMC	76	91	84%
2023	5	PMC	86	105	82%
2023	6	PMC	89	113	79%
2023	7	PMC	83	103	81%
2023	8	PMC	77	91	85%
2023	9	PMC	84	102	82%
2023	10	PMC	78	92	85%
2023	11	PMC	75	91	82%

إستخدام منهجية ألحيود السداسي(اللين ستة سجما) لتحسين معدل إلتزام ألموظفين بتطبيق القائمة ألتفقدية للجراحة ألآمنة في غرف العمليات لمرضى جراحات ألعظام في مجمع فلسطين ألطبي.

غدي محمد أحمد عمارنة

أسماء لجنة ألإشراف:

د. أشرف ألميمي

د.يحيى صلاحات

د. سامي الصدر

ملخص:

يعد ضمان سلامة ألمرضى أثناء العمليات ألجراحية أولوية حاسمة في مجال ألرعاية ألصحية، لقد تم إعتماد ألقائمة ألمرجعية للجراحة ألآمنة، ألتي وضعتها منظمة ألصحة ألعالمية، على نطاق واسع كبروتوكول موحد للحد من ألأخطاء ألتي يمكن ألوقاية منها لتحسين نتائج الإجراءات ألجراحية. ومع ذلك، فإن ألإلتزام بهذه ألقائمة ألمرجعية يمكن أن يختلف بين مرافق ألرعاية الصحية بما في ذلك مرافق ألرعاية الصحية في فلسطين.

هدفت هذه ألدراسة إلى تعزيز سلأمة ألمرضى في جراحأت ألعظام في مجمع فلسطين ألطبي من خلال أستخدام منهجية ألحيود ألسداسي(أللين ستة سجما) لتحسين معدل إلتزام ألموظفين بألقائمة ألتفقدية ألمراجعة للجرأحة ألأمنة .

في هذه ألدراسة، قمنا بتوزيع 131 إستبيأنأً على ألمشاركين من خلال إدارة ألمستشفى وتلقينا 113 أجابة قابلة للأستخدام (معدل ألإستجابة 86.3%). في هذه ألدراسة، قمنا بتطبيق نهج ألبحث ألكمي / ألبيانات

بأثر رجعي لتحديد تأثير أللين ستة سيجما على سلامة ألمرضى و ألإلتزأم بألقائمة ألجراحية ألآمنة في تحسين جودة الخدمات داخل مجمع فلسطين ألطبي في غرف ألعمليات لمرضى جراحات ألعظام.

تم استخدام نمذجة ألمعادلات ألهيكلية بألمربعات ألصغرى ألجزئية (PLS-SEM) وبرنامج ألحزمة ألاحصائية للعلوم ألاجتماعية (SPSS) ألاصدار ألسابع وألعشرون. تم تحليل درجات ألإتفاق فيما يتعلق بألمتغيرات ألرئيسية للدراسة حسب ألخصائص ألعامة للمشاركين بإستخدام اختبار **t** مستقل وتحليل ألتباين (ANOVA) مع إختبار Scheffé أللاحق. تم إستخدام معامل إرتباط بيرسون لفحص ألارتباطات ألخطية بين ألمتغيرات ألرئيسية. اعتبرت ألقيمة $P < 0.05$ ذات دلالة احصائية.

وأظهرت ألنتائج تحسناً ملحوظاً في معدلات ألإلتزام بقائمة ألجراحة ألآمنة، حيث إرتفعت من 62% إلى 86% لتصل إلى 96%. وأدى ذلك إلى إنخفاض ألمضاعفات ألجراحية وتحسين نتائج سلامة ألمرضى. ووجدت ألدراسة ايضاً أن تحسين ألإلتزام بقائمة ألتحقق من ألسلامة ألجراحية لا يؤثر بشكل مباشر على جودة ألخدمات وسلامة ألمرضى فحسب، بل يعمل ايضاً كوسيط بين منهجية ألحيود ألسداسي(أللين ستة سجما) وتحسين ألجودة في ألمستشفيات وبينت منهجية ألحيود ألسداسي(أللين ستة سجما) وتحسين سلامة ألمرضى. وقالت ألدراسة ان ألإلتزام بقائمة ألتحقق من ألسلامة ألجراحية أمر بالغ ألأهمية لتحقيق تحسين ألجودة من خلال إعتماد منهجية منهجية ألحيود ألسداسي(أللين ستة سجما) بشكل فعال.

ومع ذلك، هناك بعض ألتحديات فيما يتعلق بألحاجة ألى مزيد من ألمعرفة حول تنفيذ هذه ألمنهجية. إتبعت ألباحثة برنامجًا تعليميًا وتدريبيًا مكثفًا قبل ستة أشهر من جمع ألبيانات لتطوير معارف ألمشاركين في ألدراسة فيما يتعلق بتبني منهجية ألحيود ألسداسي(أللين ستة سجما) بنجاح. ركز هذا ألبحث فقط على خدمات

جراحة ألعظام في مجمع فلسطين ألطبي، ولا توجد دراسات مماثلة في ألوطن ألفلسطيني ألمحلي وألدول ألعربية ألمجاورة قيد ألمقارنة وألمناقشة.

وأخيرًا وليس آخرًا، وجّه ألبحث كيف يمكن لمنهجية ألحيود ألسداسي(أللين ستة سجما) تعزيز سلامة ألمرضى، وتحسين ألإلتزام بألقائمة ألجراحية ألتفقدية وتحسين جودة خدمات ألمستشفى. يمكن أن يؤدي ألإلتزام بألقائمة ألجراحية ألتفقدية إلى انشاء روابط بين منهجية ألحيود ألسداسي(أللين ستة سجما) وتحسين ألجودة، وبين منهجية ألحيود ألسداسي(أللين ستة سجما) وسلامة ألمرضى في قطاعات ألرعاية ألصحية.

ألكلمات ألمفتاحية: منهجية ألحيود ألسداسي (لين ستة سيغما)، تحسين ألجودة، سلامة المرضى، قائمة ألجراحة الآمنة.