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ADMINISTRATIVE INFORMATION

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 May 2025 and was last updated on 22 May 2025.

INTRODUCTION

Review question / Objective • How does Lean Six Sigma impact healthcare quality in Saudi Arabia? • What are the challenges facing the implementation of Lean Six Sigma in healthcare facilities in Saudi Arabia?

Rationale Despite the widespread global success of Lean Six Sigma (LSS) in enhancing patient safety, reducing inefficiencies, and lowering healthcare costs, its implementation in Saudi Arabia remains inconsistent. Studies show that while some hospitals in the country have adopted LSS to improve pharmacy automation and reduce diagnostic turnaround times, many healthcare institutions still lack structured LSS programs, mainly due to limited expertise, workforce resistance, and inadequate infrastructure. Moreover, existing research lacks a comprehensive evaluation of LSS's effectiveness in Saudi healthcare settings, leaving a critical gap in understanding its benefits and barriers. Thus, this study aims to systematically review existing

literature to evaluate the impact of Lean Six Sigma on healthcare quality in Saudi Arabia. By identifying key challenges in its implementation, this research will provide valuable insights for healthcare policymakers, hospital administrators, and quality improvement professionals. The findings will contribute to the growing evidence supporting LSS as a tool for optimizing Saudi healthcare operations and enhancing patient care.

Condition being studied Lean Six Sigma impact on healthcare quality.

METHODS

Search strategy Key terms used were: "Lean Six Sigma," OR "DMAIC framework," OR "process improvement," AND "Lean methodology," AND "patient safety," OR "healthcare quality," AND "Saudi Arabia," OR "Kingdom of Saudi Arabia." The search terms were refined using the Boolean operators (AND, OR, and NOT) to facilitate the search process consistently throughout the included databases. The search was enhanced

repeatedly to locate relevant papers and remove irrelevant ones. The final analysis included only research directly related to LSS in Saudi healthcare, which was evaluated using predefined criteria.

Participant or population Saudi healthcare system.

Intervention Lean Six Sigma as a quality improvement method of the Saudi health care system.

Comparator None.

Study designs to be included Various study designs were eligible for inclusion, encompassing quasi-experimental studies, prospective and retrospective quality improvement projects (pre-post design), case study reports, and qualitative studies.

Eligibility criteria This review included studies specifically discussing the application of LSS in healthcare settings within Saudi Arabia, focusing on research evaluating the impact of LSS on key healthcare quality metrics (e.g., patient safety, operational efficiency, cost reduction, and workflow optimization). Only articles published in English were considered, and all selected studies must be peer-reviewed journal articles to guarantee credibility and methodological rigor. Various study designs were eligible for inclusion, encompassing quasi-experimental studies, prospective and retrospective quality improvement projects (pre-post design), case study reports, and qualitative studies. Furthermore, the review was limited to studies published between January 2010 and December 2023 to capture recent advancements and developments in LSS implementation in Saudi healthcare.

Information sources This systematic evaluation of Saudi Arabian healthcare quality and LSS obtained data by comprehensively searching the published literature for relevant studies for the study questions. PubMed, ScienceDirect, Google Scholar, and the Saudi Digital Library were the central databases searched stepwise for relevant research studies.

Main outcome(s) Lean Six Sigma's impact on healthcare quality in Saudi Arabia (e.g., operational efficiency, patient safety, medication management, and resource optimization).

Additional outcome(s) Challenges facing the implementation of Lean Six Sigma in healthcare

facilities in Saudi Arabia (sustainability, resistance to change, and management support).

Quality assessment / Risk of bias analysis The research's methodological rigor and relevance of the studies included in this systematic review were evaluated using the Quality Assessment of Diverse Research (QuADS) tool (Harrison et al., 2021). This comprehensive tool was chosen to analyze various study designs, including qualitative and quantitative research approaches. Each study was graded according to its research design, data collection, and outcome measure robustness. These criteria clarified how to evaluate study findings for reliability and validity. The QuADS tool comprises 13 quality assessment criteria with a four-point Likert scale from zero to three, where (0) characterizes that the criterion is completely not mentioned, and (3) signifies that the respective criterion is explicitly mentioned. The total score of each study was calculated and ranged between 0 and 39. The cut-off value of the acceptable quality level of each study was 70.0% (≥ 27.5).

Strategy of data synthesis A thematic analysis was conducted to synthesize qualitative findings by coding the results of each included study, organizing these codes into descriptive themes, and developing higher-level analytical themes that captured broader patterns across the literature. Based on the approach outlined by Thomas and Harden, this process enabled a systematic identification of recurring concepts and relationships, providing a structured and nuanced understanding of the research topic. By iteratively refining and integrating themes, we constructed a comprehensive narrative highlighting key impacts of LSS on healthcare quality and challenges facing its implementation.

Subgroup analysis No subgroup analyses were done in our systematic review.

Sensitivity analysis In this systematic review utilizing thematic analysis, a sensitivity analysis was conducted to enhance the rigor and transparency of the qualitative synthesis. This involved critically appraising each included study for methodological quality before extracting themes and systematically re-examining our thematic findings by varying key parameters. Specifically, we assessed whether the exclusion of studies deemed lower in quality, the use of different qualitative methodologies, or the inclusion of studies that contributed a disproportionately large number of themes would alter our overall synthesis results. Through this process, we found that specific themes were sensitive to the inclusion

or exclusion of specific studies, particularly those generating a larger number of themes, and that omitting studies based on critical appraisal could result in missing important themes not otherwise identified. This iterative sensitivity analysis enabled us to determine the robustness of our main conclusions. It ensured that our thematic synthesis was not unduly influenced by individual studies or methodological choices, ultimately increasing confidence in the reliability of our findings.

Country(ies) involved Saudi Arabia.

Other relevant information

Inclusion and exclusion criteria:

This review included studies specifically discussing the application of LSS in healthcare settings within Saudi Arabia, focusing on research evaluating the impact of LSS on key healthcare quality metrics (e.g., patient safety, operational efficiency, cost reduction, and workflow optimization). Only articles published in English were considered, and all selected studies must be peer-reviewed journal articles to guarantee credibility and methodological rigor. Various study designs were eligible for inclusion, encompassing quasi-experimental studies, prospective and retrospective quality improvement projects (pre-post design), case study reports, and qualitative studies. Furthermore, the review was limited to studies published between January 2010 and December 2023 to capture recent advancements and developments in LSS implementation in Saudi healthcare.

Studies were excluded if they focused solely on Lean or Six Sigma methodologies without an integrated LSS approach, were unrelated to the healthcare sector, or were not conducted in Saudi Arabia. Additionally, research lacking sufficient data or measurable outcomes to assess the effectiveness of LSS interventions was omitted. Non-peer-reviewed sources, such as opinion pieces, editorials, or general reviews without empirical data, were also excluded to ensure the inclusion of rigorous and relevant evidence.

Data extraction:

The researchers independently extracted key information from the full-text articles and then compared their findings to identify and correct any discrepancies. The data were synthesized qualitatively and interpreted in response to the research question, aiming to assess the impact of LSS on healthcare quality in Saudi Arabia. This systematic approach ensured that essential details from each study were captured consistently and comprehensively. Extracted data included study characteristics, specifics of the LSS interventions,

healthcare settings, outcomes, and challenges related to implementation. The review specifically evaluated how LSS initiatives have influenced quality in Saudi hospitals. Authorship, publication year, and study design were also collected to provide context regarding each study's methodology and timeline. This extraction process maintained these contextual factors, enabling a nuanced analysis of LSS effectiveness across various research designs.

In addition, the intervention information covered each study's LSS tools and methodologies. Quality improvement tools like DMAIC and FOCUS-PDSA are popular. Reports included root cause analysis, value stream mapping, and Pareto analysis. This information is required to understand how LSS was used and adapted to Saudi Arabia's healthcare challenges. In each study, the healthcare settings and demographic data were collected. Tertiary care hospitals, specialist units, outpatient clinics, and government healthcare facilities were used. This diversity allowed LSS techniques to adapt to Saudi healthcare circumstances. Clinical staff and patients received medication management, infection control, diagnostic efficiency, and resource optimization interventions. The extraction process produced a complete dataset for assessing LSS's impact on Saudi healthcare quality while highlighting the main encountered limitations. Documenting research features, intervention details, healthcare settings, findings, and implementation challenges helped the review synthesize and draw conclusions.

The extracted intervention information also detailed each study's specific LSS tools and methodologies. Standard quality improvement frameworks like DMAIC and FOCUS-PDSA, as well as tools like root cause analysis, value stream mapping, and Pareto analysis, are needed. Collecting this information was essential for understanding how LSS strategies were applied and tailored to address the unique challenges of Saudi Arabia's healthcare system. For each study, data on the healthcare setting and relevant demographic information were also gathered, encompassing a range of environments including tertiary care hospitals, specialized units, outpatient clinics, and government healthcare facilities. This variety demonstrated the adaptability of LSS techniques to different contexts within Saudi healthcare. Interventions targeted areas (e.g, medication management, infection control, diagnostic efficiency, and resource optimization) and benefit clinical staff and patients. The comprehensive extraction process resulted in a robust dataset for evaluating the impact of LSS on

healthcare quality in Saudi Arabia and highlighted key limitations encountered. Systematically documenting study characteristics, intervention specifics, settings, outcomes, and implementation challenges enabled the review to synthesize findings and draw informed conclusions.

Keywords Lean Six Sigma, Healthcare Quality Improvement, Patient Safety, Saudi Arabia, DMAIC Methodology, Systematic Review.

Dissemination plans We planned to publish the systematic review study in a peer-reviewed journal.

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