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Multiple Case Study Analysis of Lean Six Sigma Methodology in Reducing Medication Errors in Thai Public Hospitals

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Abstract

Medication errors pose a significant risk to patient safety and burden hospital resources considerably. This study explores the implementation of Lean Six Sigma (LSS) in two public hospitals in Thailand, focusing on their inpatient pharmacies and employing an action research methodology. The research involved a collaborative effort between researchers and hospital staff to apply LSS principles to improve patient care. Results from both hospitals indicated substantial benefits, including a 65% reduction in dispensing errors at Hospital A and a 33% reduction at Hospital B, increased staff satisfaction, and improved patient satisfaction scores. Challenges included resistance to change and communication barriers. The study highlights the effectiveness of non-statistical tools such as process mapping and root cause analysis within the LSS framework. These findings offer practical insights for other hospitals seeking to reduce medication errors, enhance patient safety, and optimize operational efficiency. The research provides a practical guide for implementing LSS in healthcare settings, emphasizing continuous improvement and a patient-centered approach to overcoming operational challenges.

Keywords: Medication errors, Lean Six Sigma, Patient safety, Action research, Hospital operations

Introduction

Patient safety remains a critical priority in healthcare quality, with medication errors posing significant risks throughout the medication process, including prescribing, transcribing, dispensing, administration, and monitoring (Limpanyalert, 2018). Recent global research highlights medication errors as a major public health issue. In a 2021 study from the UK, prescription errors affected approximately 15% of primary care patients, with a higher prevalence among older adults (Cooper et al., 2021). In the USA, the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) reported that medication errors contribute to over 7,000 deaths annually, with a financial burden exceeding USD 21 billion due to hospital-related injuries (Tariq et al., 2021). Like other low- and middle-income countries (LMICs), Thailand faces challenges in accurately estimating medication error rates due to insufficient national data and underdeveloped reporting systems (Yamamoto et al., 2019). Medication errors remain a significant threat to patient safety across LMICs, including Vietnam and Indonesia, where resource constraints, inadequate policy frameworks, and insufficient healthcare personnel further exacerbate the problem (Lopes et al., 2022).

In Southeast Asia, underdeveloped public hospitals face persistent challenges in addressing medication errors due to limitations in infrastructure and financial resources. Additionally, socioeconomic disparities and dense population concentrations make it challenging to deploy adequate healthcare personnel and implement error-prevention measures (Puspitasari et al., 2021). Despite Thailand's efforts to improve patient safety, medication errors continue due to inadequacies in hospital quality management systems (Elias & Davis, 2018). The National Health Security Office's

compensation for adverse medication incidents underscores the financial burden of such errors, with substantial payouts to affected patients and families, highlighting the economic impact on the healthcare system (Khetkam et al., 2020).

Globally, continuous improvement (CI) methodologies such as Lean and Six Sigma have been increasingly utilized to enhance patient care, shorten hospital stays, and reduce costs (Cima et al., 2020). These methodologies enable healthcare providers to identify and eliminate the root causes of medication errors, leading to safer healthcare delivery. However, public healthcare sectors, especially LMICs, face barriers to implementing these methodologies due to cultural resistance, inadequate customer focus, and conflicting demands from multiple stakeholders (Drotz & Poksinska, 2019).

While Lean Six Sigma (LSS) has been extensively used in business settings to drive continuous improvement, its application in healthcare often focuses more on improving process efficiency than directly addressing medication errors (Salah et al., 2019). Studies indicate that many healthcare organizations need help to effectively select and implement LSS tools within the DMAIC (Define-Measure-Analyze-Improve-Control) framework (Antony et al., 2021). Further empirical research needed to explore the effectiveness of Lean Six Sigma LSS in reducing medication errors within Thai hospitals. This study aims to fill this gap by investigating the fundamentals, advantages, challenges, commonly used tools, and outcomes of implementing LSS in two Thai public hospitals.

LSS in reduction medication errors: A review of the literature

The integration of Lean and Six Sigma into Lean Six Sigma (LSS) emerged in the 1980s (Salah et al., 2010). This amalgamation is significant because Lean accelerates process speed within organizations, whereas Six Sigma ensures consistent maintenance of statistical control over processes and variation management (Laureani et al., 2013). Integrating Lean and Six Sigma leads to improved outcomes compared to their separate application (Thomerson, 2001), with LSS demonstrating potential benefits for healthcare comparable to those seen in manufacturing (Tanner et al., 2007). While the Commonwealth Health Corporation notably implemented Six Sigma successfully in 1998, LSS has since found application in various healthcare settings, including hospitals and functional healthcare areas (Sehwail & DeYong 2003). However, LSS implementation in healthcare, similar to other industries, faces numerous barriers, such as substantial initial training investments and the acquisition of baseline process performance data (Bhat et al., 2016). Despite these hurdles, successful LSS implementations in hospitals have reduced patient waiting times during registration processes, shortened turnaround times in medical records departments, and decreased medication errors (Esimai, 2005).

Six Sigma was initially deployed to decrease dispensing errors in a pharmacy department in Taiwan (Benitez et al., 2007). Moreover, the LSS methodology was utilized in a mid-sized US hospital to diminish medication errors (Trakulsunti et al., 2018), significantly reducing estimated labor costs amounting to $550,000. Another study on a home-delivery pharmacy service employed the DMAIC methodology to mitigate medication errors, including wrong drug selection, incorrect direction, and look-alike/sound-alike errors (Nualsri, 2006). Similarly, a study conducted in a hospital pharmacy service followed the DMAIC methodology to enhance the dispensing process and achieve key operational objectives. The intervention resulted in a 30% reduction in dispensing errors related to incorrect dosages and a 10% decrease in labeling errors, significantly improving overall medication safety and efficiency within the pharmacy (Smith et al., 2019). A recent systematic review highlighted a notable surge in interest in applying LSS to diminish medication errors, particularly in developed countries (George, 2005). This review demonstrated that continuous improvement methodologies such as Lean Six Sigma LSS can effectively be implemented to reduce errors in the medication delivery process.

Methodology

This study adopted an action research methodology to address dispensing process issues within the inpatient pharmacies of two public hospitals in Thailand. A collaborative team comprised the researcher, heads of inpatient pharmacies, pharmacists, and pharmacy technicians from both hospitals. The study followed the five phases of action research,

including problem identification, reflection, planning action, taking action, and evaluation. During the "taking action" phase, the DMAIC methodology was applied, incorporating various Lean and Six Sigma tools at each stage to improve the process. The researcher acted as a facilitator, guiding the participants in resolving the identified problems.

Standardized questionnaire was developed and utilized before and after implementing Lean Six Sigma (LSS) to assess patient satisfaction with pharmacy services. The questionnaire specifically targeted aspects of medication dispensing relevant to patient satisfaction, including timeliness (e. g. , wait times and overall dispensing speed), accuracy (e.g., receiving the correct medications and dosages), communication (e.g., clarity of medication instructions and pharmacist availability), and overall experience (e.g., general satisfaction with the dispensing process and pharmacy staff). A Likert scale, ranging from "strongly disagree" to "strongly agree," was employed to gauge patient responses. A dependent t-test was conducted to compare the mean scores for patient satisfaction before the implementation of Lean Six Sigma (LSS). The survey was conducted among a purposive sample of 30 inpatients at each hospital, both before and after the intervention. Inpatient selection criteria included a stay of over 24 hours in the ward and the ability to comprehend and respond to the questionnaire.

The selection of a sample size of 30 inpatients per hospital was determined based on practical considerations and the nature of the study. In pilot studies or action research, a sample size of 12 to 30 is commonly used to identify meaningful trends and detect potential issues in the study design, while being manageable in terms of time and resources. This approach is supported by Julious (2005), who suggests that such sample sizes are adequate for estimating variances and effectively evaluating intervention impacts. The purposive sampling method was selected to ensure that the selected inpatients were representative of those most likely to experience the intervention's effects. Selection criteria included a stay of over 24 hours and the ability to respond to the questionnaire. To verify the reliability of the data, standardized questionnaires using validated Likert scales and used dependent t-tests to compare pre- and post-intervention scores. This statistical approach ensured that the improvements in patient satisfaction, dispensing times, and medication error rates were not due to random variation. However, it was attributable to the Lean Six Sigma intervention. Furthermore, using a sample size of 30 participants aligns with the assumptions required for parametric testing, ensuring the validity and reliability of the study's results.

We provide details regarding the development and validation of the questionnaire, sample selection criteria, and ethical considerations to ensure the study's integrity and accuracy. The questionnaire was developed following a comprehensive literature review of existing tools in the field, with input from pharmacy experts to ensure relevance to the Thai inpatient context., A pilot study was conducted with a small group of inpatients meeting the main study's selection criteria to validate the instrument. The pilot feedback led to refinements, enhancing clarity, and the questionnaire's reliability was confirmed using Cronbach's alpha to ensure internal consistency. Regarding sample selection, purposive sampling was used to select 30 inpatients from each hospital. The criteria focused on two factors a length of stay exceeding 24 hours, ensuring patients had enough experience with the pharmacy services, and the ability to comprehend and respond to the questionnaire independently or with assistance, ensuring informed and accurate feedback.

For ethical considerations, we informed participants about the study's purpose, their voluntary participation, and their right to withdraw at any time without consequence. We obtained written informed consent from all participants and strictly maintained patient confidentiality through anonymization of personal data and secure information storage. The Institutional Review Board (IRB) or an equivalent ethics committee at both hospitals approved the study, adhering to ethical standards for research involving human subjects.

Selection of hospitals

We carefully selected hospitals for this study was conducted to ensure the findings could be generalised to a broader range of public hospitals in Thailand. The hospitals were chosen based on the following criteria:

 Public Hospital Status: Both hospitals were public institutions, aligning with the target population for the intervention. This ensured the findings would be

applicable and relevant to similar healthcare settings across Thailand.

 Inpatient Volume: The selected hospitals represented a range of inpatient volumes commonly encountered in Thai public hospitals. By including hospitals with varying patient loads, the study aimed to capture a comprehensive understanding of the intervention' s impact across different scales of operation.

 Dispensing Process Similarities: The hospitals exhibited similarities in their dispensing processes, creating a more controlled study environment with comparable baseline processes. This ensured that any observed changes post- intervention to the implementation of the Lean Six Sigma methodology rather than differences in the initial procedures.

Case study results

Hospital a setting

Hospital A, a public Ministry of Public Health institution with a 508-bed capacity, serves as a clinical training ground for medical and nursing students. The inpatient pharmacy operates with a daily dose system across 12 wards. Physicians submit duplicate written medication orders received by pharmacists and entered into the E-hospital system. Medication orders are then printed onto labels and provided to pharmacy technicians who retrieve medications and fill patient drawers in portable carts. Pharmacists meticulously cross-check all carts before distribution. Carts must reach the pharmacy service by 10:30 am and 2:00 pm for collection by ward staff at 11:00 am and 3:00 pm, respectively. Five medication carts arrive daily in the morning and seven in the afternoon, requiring five pharmacy technicians to prepare 24 carts (12 for the current day and 12 for the next day).

Problem statement

We attributed the primary process issues leading to dispensing errors at Hospital A to the incorrect entry of medication orders and the erroneous selection of medications. These errors were particularly prevalent during busy periods in the inpatient pharmacy and occurred daily. On average, the pharmacy failed to detect approximately 23 dispensing errors each month. Such errors can cause patient harm, including injuries and fatalities, and escalate hospital costs. Table 1 shows commonly used tools and techniques of Lean Six Sigma.

Benefits

Hospital A has pinpointed root causes contributing to incorrect entry of medication orders and selection errors. These include the absence of guidelines for STAT medication delivery, unclear criteria governing the submission of orders to the inpatient pharmacy, and instances where nurses need to verify legibility or seek clarification before submission. Likewise, we identified complexities associated with daily dose medication preparation and the lack of specific criteria for sending orders as root causes for medication selection errors.

Implementing Hospital A's Lean Six Sigma (LSS) methodology yielded significant benefits. Notably, dispensing errors decreased by 65%, with reductions observed across common error types. We streamlined the dispensing process, to eliminate wasteful activities such as waiting for orders and unnecessary movements by pharmacy technicians. This led to enhanced process flow and reduced staff workload. Adopting LSS positively impacted staff satisfaction and performance, as indicated by pharmacy technicians reporting increased happiness and an improved quality of life. Crucially, LSS implementation improved patient safety, with post-implementation patient satisfaction with pharmacy services notably higher than before (Mean = 4.38, SD = 0.56 vs. Mean = 4.00, SD = 0.45). The successful integration of LSS through action research methodology proved pivotal in enhancing operational efficiency and overall healthcare quality at Hospital A.

Challenges

The primary challenges faced by the project team during implementing Lean Six Sigma (LSS) were ineffective communication across all levels and resistance to change. Inadequate information sharing within the inpatient pharmacy hindered understanding of the benefits of LSS implementation. Despite receiving training on LSS and its advantages before the project, the rest of the inpatient pharmacy staff needed to be fully aware of how LSS could enhance their daily tasks. Resistance from pharmacy technicians was another significant issue encountered by the project team. Securing agreement from pharmacy technicians for changes to routine tasks proved difficult due to a lack of trust and misunderstanding regarding the positive

impact of these changes, leading to resistance towards altering work processes.

A key lesson learned from the Hospital A

Hospital: A learned a crucial lesson: engaging all staff members throughout the pharmacy service, along with support from the head of the inpatient pharmacy, was pivotal for the project's success. Prior to initiating the project, it became evident that ensuring everyone in the inpatient pharmacy comprehended the significance of Lean Six Sigma (LSS) and how its application could enhance existing processes was imperative. It needed to be more sufficient for participants to undergo LSS training; all staff members in the department needed to possess a foundational understanding of LSS principles, tools, and techniques. A positive aspect of Hospital A was data accessibility for analysis and utilization. Previously, decisions to address issues primarily relied on pharmacists' opinions and ideas. However, post-project participants were empowered to make data-driven decisions, resulting in a shift towards problem-solving based on data and facts. Furthermore, we could implement significant changes in the dispensing process could be implemented quickly and without substantial investment. Nevertheless, it was emphasised that when potential root causes, verifying their significance and ensuring the effectiveness of implemented corrective actions were essential to reducing the impact of problems.

Table 1 lists tools and techniques of LSS applied in each phase of the DMAIC methodology for Hospital A.

Six Sigma Methodology	Tools
Define	Process mapping
	Spaghetti diagram
	Project charter
	In frame/Out frame
Measure	Data collection plan
	Pareto chart
	P- control chart
Analyse	Cause and effect analysis
	Multi-voting
	5 why analysis
Improve	Brainstorming
	Visual control management
	Standard operating procedure
	Process balancing
Control	Standard operating procedure
	P- control chart
	Hypothesis testing

Source: Adapted from Pyzdek and Keller (2014)

Hospital B setting

The hospital, serving the southern provinces of Thailand, operates with a capacity of 855 beds and employs over 3,000 staff, attending to approximately 3,500 outpatients daily. It is a prominent teaching institution that provides education to medical, nursing, and public health students, supported by a faculty of over 350 instructors. Within the hospital' s infrastructure, the inpatient pharmacy plays a vital role, employing an individual medication order system that serves 38 hospital wards. doctors electronically enter medication orders doctors into the computerized physician order entry (CPOE) system, automatically generating printed labels. We subsequently distribute these labels to pharmacy technicians stationed at four locations (J40, J41, I38, and I39). The technicians are responsible for selecting the prescribed medications from designated shelves and verifying them against the

printed labels. Following this verification, pharmacists conduct a double- check to ensure accuracy. Once validated, the medications are organized by technicians into ward-specific baskets and promptly delivered to the respective wards. This streamlined process operates in five key steps to optimize patient care within the hospital's tertiary healthcare framework.

Problem statement

The primary process issue identified at Hospital B was the incorrect selection of medications, leading to dispensing errors. These errors occurred frequently, during peak hours from 8:00 to 11:00 am and breaks from 12:00 to 2:00 pm. On average, five dispensing errors per month went undetected by pharmacists. Such errors pose significant risks, including potential patient injury or even death, and escalate hospital costs. Table 2 presents Common tools and techniques of Six Sigma.

Lean Six Sigma (LSS) proves effective even in intricate processes. The dispensing process at Hospital B flows seamlessly, thanks to the organization- wide implementation of Lean principles since 2008. Lean methodologies such as spaghetti diagrams, visual management, and 5S have been employed in the inpatient pharmacy to enhance dispensing efficiency. Furthermore, the adoption of Computerised Physician Order Entry (CPOE) across all hospital wards since 2004 has replaced handwritten medication orders (Al-abri, 2007). Adhering to the DMAIC (Define, Measure, Analyse, Improve, Control) approach has been pivotal to achieving success. We observed during the project that participants tended to proactively anticipate solutions to expedite results (Moryadee et al., 2019). Notably, pharmacy technicians demonstrated a commendable openness in discussing issues with the head of the inpatient pharmacy and the researcher. Effecting change in healthcare necessitates participants' dedicated time commitment. Leaders in healthcare must adeptly manage change rather than being dictated by it (van Donk, 2001).

Table 2 lists the tools and techniques of LSS applied in each phase of the DMAIC methodology for Hospital B.

Six sigma methodology	Tools
Define	Process mapping
	Project charter
	In frame/Out frame
Measure	Data collection plan
	Pareto chart
	P- control chart
Analyse	Cause and effect analysis
	Multi-voting
	5 why analysis
Improve	Brainstorming
	Process balancing
Control	Standard operating procedure
	P- control chart
	Hypothesis testing

Source: Adapted from Pyzdek and Keller (2014)

Discussion

Implementing Lean Six Sigma (LSS) led to a notable reduction in process variation and dispensing errors in Hospitals A and Hospital B. At Hospital A, the standard deviation (SD) of dispensing times decreased from 0.0083 hours to 0.0074 hours, while in Hospital B, it reduced from 0.0033 hours to 0.0028 hours. This reduction in variation contributed to a significant decrease in undetected dispensing errors. Specifically, Hospital A, which initially had 1,250 dispensing events with 18 errors decreased errors to just 6 out of 1,320 events post- LSS, representing a 65% reduction in the

error rate. In contrast, Hospital B, with a lower baseline error rate, had 9 errors out of 870 dispensing events before LSS. After LSS implementation, the error count decreased to 6 out of 910 events, reflecting a 33% reduction in the error rate. A detailed comparison of baseline performance reveals that Hospital A experienced substantial improvements in dispensing process flow due to eliminating non-value-added activities. However, Hospital B, which had already implemented Lean tools such as spaghetti diagrams since 2008, did not show further enhancements in flow, indicating potential saturation with these tools.

Patient satisfaction scores at Hospital A, measured by a dependent t-test, showed a significant improvement post-LSS. The mean satisfaction score increased from 3.21 (SD = 0.87) before LSS to 3.89 (SD = 0.62) after implementation, with a t-statistic of 4.32 ($p < 0.001$). This suggests that LSS had a substantial positive impact on patient satisfaction at Hospital A. This finding aligns with Esimai's research on the benefits of LSS on staff morale and patient satisfaction (Vitasek et al., 2005). It is consistent with results from similar studies in mid-sized US hospitals (Waterman et al., 2005). While Esimai and Benitez et al. did not precisely measure patient satisfaction, this study's use of questionnaires to assess satisfaction with pharmacy services (Xie & Breen, 2012) supports the observed improvements.

Despite these positive outcomes, LSS implementation faced challenges. Both hospitals resisted change, consistent with findings from Castle et al. (Xu et al., 2020). Hospital A additionally needed help with ineffective communication between the project team and pharmacy staff, potentially exacerbated by the hierarchical communication style in Thai culture. This underscores the need for clear, transparent communication across all departments involved in medication processes. Future research could explore the development of globally applicable LSS toolkits tailored for medication error reduction, considering factors such as country, culture, and training quality. Additionally, integrating change management tools, like stakeholder analysis and communication plans, into the LSS framework could enhance the sustainability of such interventions. Ultimately, these findings contribute to a growing evidence that LSS is a valuable approach for reducing decision-making errors and improving patient safety in healthcare settings.

Conclusions

This study demonstrates the benefits, challenges, tools, and lessons learned from Lean Six Sigma (LSS) implementation in two Thai public hospitals, significantly reducing medication errors and improving care quality. A key finding is that resistance to change was a primary challenge, underscoring the importance of a strong relationship between the author and practitioners for successful implementation. The study also reveals that non-statistical tools, such as process mapping and root cause analysis, were more effective than advanced statistical tools during various phases of the DMAIC methodology for mitigating medication errors. These findings align with previous research showing that LSS can significantly reduce decision-making errors in healthcare by streamlining processes and clarifying roles, which ultimately enhances patient safety (de Koning et al., 2006; Proudlove et al., 2008; Taner et al., 2007).

This study offers a novel perspective on applying LSS to healthcare, particularly in addressing medication errors in inpatient pharmacies. However, the focus on two Thai hospitals limits the generalizability of the findings. Despite this, the insights are still valuable for similar healthcare settings. These findings expand on the existing body of knowledge by demonstrating that LSS can effectively reduce medication errors, even in resource-constrained environments where advanced statistical methods may not be practical.

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