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Lean Six Sigma to reduce Medication Errors in hospitals

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Abstract

Medication errors are one of the primary causes of patient mortality and morbidity and a costly problem in hospitals. Although healthcare organizations have endeavored to reduce medication errors by using several tools and techniques, this issue still remains. It is important for healthcare sectors to employ an appropriate process excellence methodology to reduce the number of medication errors which will save costs and quality of care. Lean and Six Sigma are two of the most powerful process improvement methodologies widely adopted by many international companies today. The authors argue that these methodologies are equally applicable in reducing errors within the medication process. Both Lean and Six Sigma use appropriate tools from their toolboxes to improve medication process. This paper will present the benefits, challenges, and tools and techniques of Lean and Six Sigma in reducing medication errors. The paper is valuable for healthcare practitioners and professionals as a guideline to achieve the optimal benefit of Lean and Six Sigma implementation to reduce medication errors. Moreover, the paper also provides a greater awareness for senior managers and medical directors in hospitals about the role of Lean Six Sigma and its associated tools and techniques in tackling medication errors.

Keywords
Lean Six Sigma, Medication Errors, Healthcare,

1. Introduction
Medication error is one of the primary causes leading to patient morbidity and mortality [1]. Medication error is any error that occurs at any stage in the medication process, stemming from prescribing, transcribing, dispensing or administration. A report published by the Institute of Medicine (IOM), *To Err Is Human: Building a Safer Health System*, has raised attention regarding the problem of preventable adverse drug events resulting from medication errors in the healthcare industry [2]. The report estimated that medication errors cause one out of every 131 outpatient deaths, one out of 854 inpatient deaths and result in a total of 7000 deaths every year. This report has been widely cited in many published studies as a key message for raising awareness regarding patient safety. However, after 15 years of the IOM report, the Institute for Healthcare Improvement (IHI) stated that patient safety has continually been compromised due to the healthcare system, despite there being some improvements according to two reports from the UK and the USA namely '*Continuous Improvement of Patient Safety: The Case for Change in the NHS' and ' Free from Harm: Accelerating Patient Safety Improvement Fifteen Years'* [3]. These reports point out that there is a long way to go to ensure an adequate level of safety for all patients. The World Health Organization (2016) further stated that medication errors have become a global issue and have been reported in different parts of the world [4]. Medication errors cause at least one death every day and injure approximately 1.3 million people every year in the USA. Medication errors lead to patient injury and death and further contribute to a detrimental economic outcome. Globally, the cost associated with medication errors is US$ 42 billion each year, which represents almost 1% of the global expenditure on health [5]. Unless a new approach is implemented by healthcare sectors to prevent medication errors, patients will continue to die or be injured as a result of such errors [6]. It is very important for healthcare sectors to employ an appropriate process excellence methodlogy to reduce the number of medication errors. Lean and Six Sigma are two of the most powerful business strategies for the continuous improvement in hospitals and are appropriate to solve specific problems. The next sections analyze existing knowledge regarding the following: Lean, Six Sigma, and Lean and Six Sigma in reducing medication errors.

2. Literature Review
Lean is a philosophy that focuses on the elimination of waste and non-value added activities from the process, improvement of speed and reduction of operational costs. Applying lean in the healthcare sector, particularly in

hospitals, has shown an improvement in quality of care, patient safety, staff and patient satisfaction [7]. Currently, the implementation of lean is favoured by healthcare managers worldwide because it combines cost reduction with an outstanding standard of health service to the patient, it is easy to understand and is straightforward to use by healthcare staffs [8]. Evidence has shown that just over 57 percent of the employment of lean in healthcare occurs in the USA, followed by the UK which accounts for 29 percent, about five percent in Australia and another nine percent internationally [9]. Six Sigma is a business management strategy and data-driven methodology, which aims to reduce variation within a process which can result in defects or errors. It was first applied in the manufacturing industry, and has widely commanded attention subsequently in healthcare delivery. Many leading healthcare organizations have successfully implemented Six Sigma, and this has resulted in important outcomes such as reduced Emergency Room (ER) cycle time, increased timely completion of medical records, increased bed availability and a reduction in medication errors [10].

A medication error is a result of failure in the treatment process which contributes to or has the potential to cause patient harm [11]. The errors usually result from the failure of the system itself rather than the individual performance of staff [12]. Going back to the early 2000s, a study by Chan (2004) first implemented Six Sigma to reduce dispensing errors in a pharmacy department in Taiwan [13]. Furthermore, Lean was implemented to reduce missing dose incidents in a university hospital inpatient pharmacy [14]. A study by Esimai (2005) combined Lean and Six Sigma methodology in a mid-sized hospital to reduce medication errors[15]. This study has yielded a dramatic reduction in estimated labour costs of $550,000. Similarly, a study conducted by Hintzen et al., (2009) showed that the hospital can save the inpatient pharmacy $82,650 annually by reducing the number of errors and missing doses[14]. There has been evidence that LSS tools have been applied in order to eliminate medication errors. Nevertheless, the current literature has shown the limitations of Lean and Six Sigma application in reducing errors in the medication process, when compared with other healthcare settings such as the emergency department, surgery/operating room and intensive care unit. The purpose of the paper is to present the benefits, challenges, and tools and techniques of Lean and Six Sigma in reducing medication errors which will be explained in the next section.

3. Key findings

3.1 Benefits of Lean

The key benefits of Lean is the reduction in medication errors, improvement of workflow, reduction of waste and improvement of medication room layout. Such benefits can contribute to cost savings and improve patient safety and staff and physician satisfaction. For example, the implementation of lean in the sterile product area (SPA) and inventory area at the university hospital inpatient pharmacy can save $289,256 annually due to the reduction of waste, improvement in workflow and decreased staff requirements [14]. After implementation of lean process improvement, the number of production errors such as incorrect labelling in the SPA decreased 83% and average number of missing i.v. doses reduced from 53 to 13.8 each day [14]. Moreover, the employment of lean can also improve medication administration safety by reducing the rate of serious medication events in the hospital [16].

Table 1: The benefits of lean

Application area	Benefits	References
Inpatient Pharmacy -sterile products area (SPA)	Work flow improvement Waste reduction Decreased staff requirements Reduction in missing doses, expired products and production errors Annual cost saving Quality and patient safety improvement	[14]
Inpatient Pharmacy -inventory area	Decreased number of outdated drugs Reduction in medication inventory	[14]
Inpatient Units	Medication administration errors reduction Medication room layout improvement	[18]
Community Hospital	Medication administration safety improvement Staff and physician satisfaction improvement	[16]
Pharmacy division	Reduction in missing medication	[22]

3.2 Challenges of Lean

The main challenges of Lean implementation in the reduction of medication errors include resistance to change, incorrect lean tools' selection and lack of top management support. Resistance can appear all level in the hospitals including top management, middle management and healthcare practitioners. The main primary reasons are a lack of clarity regarding the change, fear of learning something new [17] and doing something different from the normal routine. The selection of lean tools is another challenge faced by healthcare practitioners. Healthcare practitioners may use a wrong tool to solve the problems due to lack of understanding about Lean concepts. This can lead to the failure of lean employment in the medication process. Lack of top management support is another challenge that occurs in many hospitals. A strong leadership at the top management level in the hospitals can create a true lean transformation. Without their support, this can lead to issues such as limited access to resources and a lengthy of decision making process [17].

3.3 Lean tools and techniques in the context of medication errors

Table 2 shows lean tools classified according to their purpose including improving medication flow, identifying causes, eliminating non-value added activities and waste and identifying customer needs. The employment of these lean tools can contribute to the reduction of medication errors. The popular lean tools which are aimed at reducing errors in the medication process include process mapping, value stream mapping, standardized operating procedure, visual process control and poka-yoke. The project team can use process mapping to depict the process steps of the medication process, while value stream mapping represents all important flow of information and materials throughout the complete medication process. Process mapping tools can help healthcare practitioners to understand the current problems in the medication process such as poor flow, rework loops and delays. Standard operating procedure is a step by step set of instructions helping healthcare practitioners to perform the work correctly such as standardizing pharmacy order entry process [16], standardizing nursing work [18]. Moreover, it can be used to facilitate new staff members training during orientation [16]. Visual process control is used to create a transparent environment by using several displays and visual markers [19, 20]. For example, in order to reduce distract or interrupt a nurse in the medication room, no talking zone was hanged in the middle of the room [18]. In the medication inventory area, a color-coded bin system was implemented to differentiate the different zone in such area [14]. Poka-Yoke or mistake proofing, is making it impossible for an error to occur by the use of any devices or methods [19] and stopping an error before passing to another phase of the work. Some examples of mistake proofing devices which have been used to avoid medication errors include using an automatic dispensing machine [13], barcoding [21] and an online medication ordering system [22].

Table2: Lean tools used to reduce medication errors.

Improve medication flow	Identify causes	Eliminate non-value added activities and waste	Identify what customer needs
Value stream mapping	Cause and effect analysis	5S	Voice of customer (VOC)
Spaghetti diagram	5 why root cause analysis	Visual process control	
Process mapping		Poka-yoke	
Process observation		Two-Bin replenishment system	
		Work cell optimization	
		Computing minimum safe batch sizes	
		Kanban	
		Standard operating procedure	

3.4 Benefits of Six Sigma

The key benefit of Six Sigma methodology is the reduction of the number of errors in different phases of the medication process which mostly occurs in the pharmacy department in the hospital, as summarized in Table 3. For example, the project team in the pharmacy department followed DMAIC methodology to improve the dispensing process and achieve operational goals; as a result, dispensing errors were reduced by over 30% [13]. Another study showed that the percentage of order entry errors consistently improved by 90% to achieve less than 0.04 errors per bed every month for four months after employment of Six Sigma [23]. The application of Six Sigma in a home-delivery service resulted in an improvement in the data collection process and a decline in dispensing accuracy rate and a number of several types of medication errors including wrong dose selection (33%); wrong direction (49%);

sound-alike / look-alike (SALA) errors (69%) and patient name errors (46%) [24]. Moreover, the implementation of Six Sigma not only reduces medication errors, but can also improve staff working performance, patient safety and satisfaction and hospital's profitability in the long term. For instance, the reduction in the number of human errors during the process of their working can improve staff frontline performance after the adoption of Six Sigma methodology [13]. Additionally, in order to achieve the benefits, the healthcare practitioners should be supported by their top management. It is necessary for healthcare organizations to invest in training staff before the implementation of the Six Sigma project. However, training alone would not guarantee the successful project. Also, coaching and mentoring by champions and experts are needed.

Table3: The benefits of Six Sigma

Medication phase	Benefits	References
Transcription	Order entry errors' reduction Improve patient satisfaction	[23]
Dispensing	Dispensing errors' reduction Improvement of staff frontline productivity Increase in patient safety	[13]
Prescription Dispending	Prescription and dispensing errors' reduction	[24]
Prescription	Prescription errors' reduction Increase in hospital's profitability	[22]

3.5 Challenges of Six Sigma

The major challenges of Six Sigma are lack of top management support and availability of data. A study by Castle et al. (2005) identified that a team implementing a Six Sigma project to reduce medication errors in a home-delivery pharmacy service encountered many impediments in the early phase [24]. Firstly, it was difficult to gain agreement to make changes in the process and senior management buy-in to agree to this transformation. People in the organization are afraid of the unknown [25]. Secondly, there were variations among pharmacies in the data collection process which can contribute to contradictory medication error reporting and, finally, there was a lack of advanced data collection tools. Healthcare organization should consider barriers of Six Sigma before implementation in order to gain the maximum benefits from Six Sigma methodology.

3.6 Six Sigma tools and techniques in the context of medication errors

Table 4 shows Six Sigma tools and techniques are used against the DMAIC roadmap by four studies. The define phase aims to identify the scope and goals of the projects [26] and problems associated with the process. Voice of customer and process mapping have been used to determine what customers need and identify problems associated with medication processes [13, 24]. The customers could be pharmacists, nurses or patients. The next phase is the measure phase which aims to collect data from the process in order to measure the baseline performance of the process. Data collection and analysis and baseline measurement are used to ascertain the baseline performance, showing the current state of the problem. For example, at an outpatient clinic, pharmacists and nurses were trained to use data collection sheets to record the errors when they find medication errors in a process in order to collect current data regarding medication errors [13]. Subsequently, the root causes of the problems that contribute to the occurrence of the medication errors will be identified in the analyse phase. The common tools used in this phase include brainstorming, cause and effect diagrams and process mapping [13, 22, 24]. Gemba is another tool that can be used to validate potential causes by observing the process [26]. Moreover, root cause analysis can be used to identify the root causes of the problems that lies in the linkage between process steps or within process steps. The next phase is the improve phase which aims to identify and implement solutions, for examples, creating a procedure to enhance sound-alike / look-alike (SALA) alert, providing an ongoing education and training for the pharmacist for each of the selected root causes in order to improve the process performance [24,26]. The common tool used in this phase is poka-yoke such as computerized physician order management (CPOM), an automatic dispensing machine for drug prescription to indicate a dosage error. Finally, in order to control the sustainability of process performance, control chart and run chart will be used to sustain the reduction of medication errors over a period of time and to identify when additional analysis might be required.

Table 4: Six Sigma tools used in various phases of DMAIC methodology.

Study title	Define	Measure	Analyse	Improve	Control
Hospital reduces medication errors using DMAIC and QFD [23]	Not mentioned	Process mapping	Brainstorming	QFD Pugh election matrix VOC	Control chart
Use of six sigma to improve pharmacist dispensing errors at an outpatient clinic [13]	VOC	Baseline measurement Data collection and analysis	Process mapping	Poka-yoke	Control chart Run chart
Using Six Sigma to reduce medication errors in a Home - Delivery Pharmacy Service [24]	Process mapping	Data collection and analysis	Brainstorming Process control plan	Poka-yoke Linear regression analysis	Control chart
Eliminating US hospital medical errors [22]	Not mentioned	Baseline measurement	Cause and effect analysis	Poka -yoke	Not mentioned

4. Discussion and Implications

The powerful finding of Lean and Six Sigma is a significant outcome regarding the reduction of medication errors that can cause patient's health problem or harm. However, Lean focuses on the elimination of waste and activities from the medication process, improvement of workflow and medication room layout. Six Sigma, on the other hand, focuses on the reduction of variation within a process which can result in defects or errors. The chief challenge of both Lean and Six Sigma implementation is a lack of top management support and commitment. To be successful, it is important for top management in hospitals to understand the concept and benefits of Lean and Six Sigma and provide support and resources to the Lean Six Sigma project team. The most common lean tools include process mapping, value stream mapping, standardized operating procedure, visual process control and poka-yoke. It is interesting to highlight that process mapping is the most popular lean tool to reduce medication errors because it visually represents the process steps and helps to identify the existing problems in the medication process and opportunities for improvement. Standardized operating procedure, visual process control and poka-yoke have been used to eliminate non value added activities and waste within the medication process. Moreover, several Six Sigma tools have been used against DMAIC methodology. There is still a lacking of use of a number of tools in the define phase, however, other common tools can be used in this phase such as Critical to Quality (CTQ), Project Charter and SIPOC (Supplier- Input- Process- Output- Customer). Another dominant tool used in the improve phase is poka-yoke or mistake proofing whereby devices or systems and software programming are implemented to prevent the errors. Control charts have been applied in the control phase to maintain the improvement of the process over a period of time. This paper is valuable for healthcare sectors seeking to reduce errors in the medication process or other processes that need to improve. Furthermore, it would be of interest to hospitals, with the dual aims of improving patient safety and reducing operational costs. The key findings from this paper can be used as a guideline for healthcare practitioners and professionals before implementation of a Lean Six Sigma project to reduce medication errors by considering their benefits and challenges. Also, the different tools and techniques of Lean and Six Sigma can be followed in tackling medication errors.

5. Conclusions

Lean and Six Sigma are two most powerful process improvement methodologies that can be applied by the healthcare sector to reduce medication errors. Lean and Six Sigma, including the tools, benefits and challenges of application in the context of medication errors, has not been reported before in the literature and therefore this paper could bridge this gap. In addition to improving the medication process, Lean tools can be employed to enhance the workplace environment which could reduce excessive workloads for staff, incorrect dosage calculation and miscommunication, while Six Sigma tools can be developed to reduce mean errors and even variation in error rate in the process. This paper provides a greater awareness for senior managers and medical directors in hospitals about the role of Lean Six Sigma and its associated tools and techniques in tackling medication errors.

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