Reducing medication errors using LSS methodology: A systematic literature review and key findings

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The paper aims to systematically review the literature of Lean, Six Sigma, Lean Six Sigma (LSS) intervention and its tools and techniques to reduce medication errors in hospitals. Subject specific journals according to the top journal ranking lists in the Business School and Healthcare sector are used for assessment. Eight databases including Medline, PubMed, EBSCOhost, Web of Knowledge, Scopus, Embase, CINAHL and PsycINFO were used to collect relevant articles from year 1996-2016. A total of 24 studies were identified from the search which have met the criteria for the systematic literature review. There is a noticeable increase of interest in the application of process excellence methodologies such as Lean, Six Sigma and Lean Six Sigma to reduce medication errors especially in the developed countries. Many themes have emerged in this paper including: tools and techniques of Lean and Six Sigma in the context of medication errors, Lean and Six Sigma methodology, types of medication errors, LSS project selection, benefits, challenges and success factors. The results of this study are expected to benefit healthcare practitioners in implementing the LSS methodology to reduce medication errors.

Keywords: Lean; Six Sigma; Lean Six Sigma; Medication errors; Healthcare; Systematic Literature Review

1. Introduction

Medication error is one the primary causes leading to the patient morbidity and mortality (Christopher et al., 2014). According to the National Coordinating Council for Medication Error Reporting and Prevention (2017), medication error is a ‘preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer’. Medication errors can occur at every
stage of the medication delivery, stemming from prescribing, transcribing, dispensing and administration. The severity of medication errors range from trivial to life-threatening (Walsh et al., 2013). Medication errors have become a global issue and have been reported in different part of the world (World Health Organization, 2016). Medication errors cause at least one death every day and injure approximately 1.3 million people every year in the USA (U.S. Food and Drug Administration, 2016). A study in the UK found that a prescription error may affect 12% of all primary care patients and, 38% in those aged 75 years and above (World Health Organization, 2016). Another study in Mexico revealed that 58% of prescriptions contained an error, mostly due to dosage regimen and inappropriate drug selection (Zavaleta-bustos et al., 2008). In Australia, the error rates of administration ranged from 15% to 20%, when the administration is based on a ward stock system (Runciman et al., 2003). In Canada, 4% of inpatients have experience of dispensing or administration errors (Covenant Health, 2015). However, in Thailand, the rate of medication errors in Thai hospitals has not been estimated due to a lack of national data (Chumchit et al., 2015). Evidence shows that medication errors contribute to patient injury and death and further contributes to a detrimental economic outcome. In the UK, medication errors cost the National Health Service (NHS) up-to £770 million for adverse drug reaction and inpatient harm in the hospitals (Torjesen, 2014). Unless a new approach is implemented to prevent medication errors, patients will continue to die or be injured as a result of such errors (Crane & Crane, 2006). Therefore, it is extremely important for the healthcare sectors to employ an appropriate process excellence methodology to reduce medication errors for improving patient safety and thereby a reduction in the financial costs.

The healthcare managers have been unsuccessful in utilizing effective tools and processes to reduce medication errors (Hussain et al., 2015). Buttigieg et al. (2016) claimed that quality in healthcare worldwide has been improved by continuous improvement (CI). It is widely implemented in every type and size of organization, from manufacturing to the public sector,
to manage the achievement of quality (Brown et al., 2008). The most popular business strategies for employment of continuous improvement in the manufacturing and service sectors are Lean and Six Sigma (Albiliwi et al., 2015). Lean focuses on the elimination of waste and non-value added activities from the process, improvement of speed and reduction of operational costs. Six Sigma, on the other hand, aims to reduce variation within a process which can result in defects or errors. Lean or Six Sigma is appropriate to solve specific problems (Laureani & Antony, 2017a). However, the integration of Lean and Six Sigma can contribute to better outcomes than the separate implementation of each methodology (Bhat et al., 2014). Lean Six Sigma (LSS) uses appropriate tools from both philosophy through the implementation of DMAIC methodology (Albiliwi et al., 2015; Laureani & Antony, 2017b). Multiple researchers have implemented Lean, Six Sigma and LSS in several areas of the healthcare sector (e.g. Bhat et al., 2014; Gijo & Antony, 2014; Gijo et al., 2013). However, a systematic literature review of Lean, Six Sigma and LSS to reduce medication errors has not yet been reported in the current literature.

Therefore, the aim of this study is to systematically review the literature of Lean, Six Sigma, LSS intervention and its tools and techniques to answer the following research questions:

- What tools and techniques of Lean and Six Sigma have been used to reduce medication errors?
- What are the benefits, challenges and success factors of LSS that have led to a reduction in medication errors?
- What is the current status in the use of process excellence methodologies to reduce medication errors in the global context?
2. Methodology

In this study, a systematic review was conducted to find the relevant articles by following four main steps: (1) ascertain the inclusion and exclusion criteria; (2) identify the sources of information used to collect the articles and search strategy; (3) describe the study selection process; and (4) specify the data extraction process. These four steps have also been found in previous systematic literature review studies such as Balaid et al. (2016), Burns et al. (2016) and Teo et al. (2016). The following steps have been used in the systematic literature review methodology.

2.1 Eligibility criteria

The eligibility criteria are identified to ensure that the included articles are relevant to the study (Balaid et al., 2016). In this review, inclusion criteria included the academic articles in peer reviewed journals published in English between January 1996 and December 2016. Articles were included when they clearly discussed the implementation of Lean, Six Sigma, LSS and its tools and techniques to reduce medication errors or improve medication management. In contrast, exclusion criteria included grey literature such as books, magazines, conference papers, white papers, editorials etc. Studies published in all languages other than English, published before January 1996 were also excluded. The review excluded studies that discussed other methodologies, e.g., continuous improvement such as total quality management (TQM), Kaizen, technology to reduce medication errors, improve medication management and reconciliation.

2.2 Information sources and search strategy

The articles were initially retrieved through subject specific journals and key academic databases. Subject specific journals were identified based on the top journal ranking lists in the Business School and Healthcare sectors. Primary databases used included Medline, PubMed, EBSCOhost, Web of Knowledge, Scopus, Embase, CINAHL and PsycINFO. These eight
academic databases were selected because they provided relevant journal articles covering several fields of study such as Biomedicine, Health, Pharmacological, Social Science, and Natural Science. The search strategy began with the identification of keywords, search strings and applying search intervention in the selected databases. The following search strings: “Lean” AND “Medication Error” “Six Sigma AND Medication Error” “Lean Six Sigma AND Medication Errors” “Tool and Technique AND Medication Error” “Quality Tool AND Medication Error” and “Quality Technique AND Medication Error” are not adequate. Therefore, we included articles that met the exclusion criteria.

Full text article reviewed for eligibility
n = 42

Articles included in the study
n = 24
Lean (n =5)
Six Sigma (n=5)
Lean Six Sigma (4)
Tools and techniques (10)

Reasons for exclusion
Excluded based on title and abstract
Duplicate articles
Met the exclusion criteria
- Not peer reviewed
- Published before January 1996
- Published in languages other than English

Figure 1. Study selection process.
Medication Error” were applied to search all of the relevant articles from the selected journals and aforementioned databases.

2.3 Study selection process

Figure 1 presents the selection process of the study. In each step, the number of included and excluded studies are documented with explanations for exclusion (Tranfield et al., 2003). A total of 5,369 articles were initially retrieved from searching the databases and an additional two articles from the subject specific journals. The reviewers independently screen the titles and abstracts by applying the inclusion and exclusion criteria (Ozawa & Sripad, 2013). Duplicate studies and articles subject to the exclusion criteria were discarded at this stage. The remaining 42 full-text articles were carefully reviewed based on the inclusion and exclusion criteria. Eighteen articles had to be excluded because they discussed methodologies other than Lean, Six Sigma, LSS and its tools and techniques. Finally, 24 final articles were selected for the inclusion in the study for further analysis.

2.4 Data extraction

The data from the included articles were extracted and stored on the data extraction form to reduce human error and bias (Tranfield et al., 2003). The authors independently reviewed each article and carefully placed the data into MS excel spreadsheets (Balaid et al., 2016). The extracted data included year of publication, journal and article title, objective, type of study, authors’ country, tools and techniques used, key findings, benefits, challenges, and success factors. These items were linked to research questions and the overall aim of the research (Balaid et al., 2016). Finally, the included studies are represented in a form of table providing a summary and visual presentation of the studies (Denyer & Tranfield, 2009).

3. Key findings

3.1 Publication trend

The study shows the publication trend of Lean, Six Sigma, LSS and its tools and techniques
implementation in the healthcare sector to reduce medication errors and improve medication management. As shown in Figure 2, a study by McNally et al. (1997) used failure mode and effect analysis (FMEA) to eliminate possible medication errors in a ward stock drug distribution system in an Australian hospital. It is interesting to note that, in 2004, Six Sigma was first applied to reduce dispensing error in a pharmacy department in Taiwan (Chan, 2004). The following year LSS was implemented to reduce medication order entry errors in a mid-sized hospital (Esimai, 2005) while Lean was first implemented to reduce missing dose incidents in 2009 in a university hospital inpatient pharmacy (Hintzen et al., 2009). In 2015, four papers were published about the reduction in medication errors. A study by Critchley (2015) used Lean methodology to improve medication administration safety in a community hospital in Canada, while Rodriguez-Gonzalez et al. (2015) used FMEA to improve medication administration process in a hospital setting in Spain. Hussain et al. (2015) recommended the implementation of the Toyota Production System (TPS), combined with human performance improvement (HPI), to eliminate medication errors in the hospitals. However, Luton et al. (2015) used Lean and Six Sigma methodology to reduce the occurrence of errors in the preparation, dispensing, and administration of human milk and formula. Although, few studies were published between 2003 and 2016, the trend shows an increase between the selected periods.

3.2 Country distribution

The country of the selected studies was classified according to the origin of the first author of the articles. Figure 3 shows that the USA has the highest number of publications, which accounts for 60% compared with other countries. Spain is second in term of number of publications with three articles which employed FMEA to reduce medication errors in the medication process. The other countries - England, Iran, Taiwan, Italy, Canada and Australia - have published one article each on the search topic.
The study demonstrates that the USA is the leading country reporting Lean, Six Sigma and LSS implementation to eliminate medication errors in hospitals. In Asia, a study conducted in Taiwan by Chan (2004) shows improvement in pharmacist dispensing errors at an outpatient clinic through the implementation of Six Sigma. In other Asian countries such as Thailand, Malaysia and Indonesia, there is a lack of data on medication errors, resources and government support (Salmasi et al., 2015) which may lead to the limited research on medication errors in
the Asian countries. The review also found that a study by Critchley (2015) from Canada was the only published research using lean methodology to improve medication administration safety in a community hospital; Whereas other countries mostly focused on FMEA adoption to reduce possible medication errors in the medication process.

### 3.3 Methodology category

Figure 4 presents the distribution of types of articles reporting implementation of Lean, Six Sigma, LSS and its tools and techniques used to reduce medication errors in the healthcare sector. The findings of the analysis demonstrated that over three-quarters of the papers were based on case studies because LSS methodology can be applied in a particular organization to evaluate the benefits of LSS implementation. The remainder were conceptual, theoretical or technical studies.

![Figure 4. Selected study distribution based on type of methodologies.](image)

![Figure 5. Selected studies distribution based on number of authors.](image)

### 3.4 Number of authors

The distribution of number of authors is shown in Figure 5. In total, 24 articles were selected for review and as can be seen, the majority of the selected studies were written by three to seven authors, followed by two authors whereas a few articles were written by single and more
than seven authors. The highest number of co-authors was nine, for the publication by Aboumatar et al. (2010), applying LSS solutions to reduce the possibility of chemotherapy preparation errors.

3.5 Tools and techniques of Lean Six Sigma in the context of medication errors

From the reviewed articles, 22 lean tools which were aimed at reducing errors in the medication process were identified. These included process mapping, brainstorming, Voice of the Customer (VOC), standardized operating procedures, poka-yoke, cause and effect diagram, Value Stream Mapping (VSM), just in time (JIT), process observation and analysis, time and motion study, work cell optimization, visual process controls, workplace inspection, 5 why root cause analysis, A3 problem solving report, one-piece flow, Kanban, spaghetti diagram, bird’s eye view maps, 5S practice, standardized weekly audit and two bin replenishment. Figure 6 shows the top five lean tools which are widely used to reduce medication errors. It is interesting to highlight that process mapping is the most popular lean tool to reduce such errors because it visually represents the process steps and helps to identify the potential errors in the medication delivery process.

![Figure 6. Top five lean tools used to reduce medication errors.](image-url)
In addition, 22 Six Sigma tools and techniques were extracted from the review. These tools and techniques are widely used in the Six Sigma implementation and included process mapping, problem definition, data collection and analysis, pareto diagram, simple linear regression, brainstorming, Quality Function Deployment (QFD), VOC, Pugh selection analysis, control chart, cause and effect analysis, FMEA, review historical chart, baseline measurement, poka-yoke, run chart, t-test, chi square, process control plan, standardized operation procedures, SIPOC (Supplier-Input-Process-Output-Customer) analysis and QFD matrix. Table 1 shows Lean and Six Sigma tools and techniques are used against the DMAIC roadmap by five studies. It should be noted that Lean tools which are used in DMAIC methodology include process mapping, brainstorming and poka-yoke.

**Table 1 Lean Six Sigma tools used in various phases of DMAIC methodology.**

<table>
<thead>
<tr>
<th>Study title</th>
<th>Define</th>
<th>Measure</th>
<th>Analysis</th>
<th>Improve</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>lean Six Sigma reduces medication errors (Esimai, 2005).</td>
<td>Problem definition</td>
<td>Data collection</td>
<td>Brainstorming</td>
<td>Brainstorming</td>
<td>Simple linear regression analysis</td>
</tr>
<tr>
<td></td>
<td>Project charter</td>
<td>and analysis</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Process mapping</td>
<td>Pareto diagram</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital reduces medication errors using DMAIC and QFD (Bentiz et al., 2007).</td>
<td>Not mentioned</td>
<td>Process mapping</td>
<td>Brainstorming</td>
<td>QFD</td>
<td>Control chart</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Pugh Selection Matrix</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>VOC</td>
<td></td>
</tr>
<tr>
<td>Use of six sigma to improve pharmacist dispensing errors at an outpatient clinic (Chan, 2004).</td>
<td>Review historical data</td>
<td>Baseline measurement</td>
<td>Process mapping</td>
<td>Poka-yoke</td>
<td>Control chart</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Data collection and analysis</td>
<td></td>
<td></td>
<td>Run chart</td>
</tr>
</tbody>
</table>
-----------------------------------------------------------------------------
Using Six Sigma to reduce medication errors in a Home Delivery Pharmacy Service (Castle et al., 2005).

<table>
<thead>
<tr>
<th>Process mapping</th>
<th>Data collection and analysis</th>
<th>Brainstorming</th>
<th>Poka-yoke Linear regression analysis</th>
<th>Control chart</th>
</tr>
</thead>
</table>

Applying Lean Six Sigma to improve medication management (Nayar, et al., 2016)

Moreover, the tools and techniques of LSS are used across the medication process including prescribing, transcribing, dispensing and administration, as shown in Table 2. FMEA is a Six Sigma tool used in every stage of medication process, because it could identify the potential of medication errors in every phase of the medication process. Other tools and techniques such as process mapping and data collection and analysis are used in prescribing and dispensing phase. However, in transcribing phase, FMEA is a single tool used to reduce errors because of the limitation of the literature.

3.6 Lean Six Sigma project selection

The selection of the right project is a critical activity within any continuous improvement initiative (Sharma & Chetiya, 2010). If organizations do not select the right project at the early phase of the initiative, the LSS initiative could be a waste of resources, potentially leading to frustration for many within an organization. Antony (2004) provided eight key guidelines for the selection of LSS projects; (1) projects should be linked to a business strategy plan and organization goals; (2) projects should represent a major improvement in both financial improvement and process performance improvement; (3) projects should be doable in less than six months; (4) project goals must be clearly identified and measureable; (5) project selection criteria should be created; (6) the projects should be supported and approved by senior
management; (7) project deliverables should be defined in terms of their impact on one or more critical characteristics in the products or services; (8) projects must be selected based on realistic and good metrics. However, in this review, none of the selected studies discuss how to select LSS projects and what criteria should be used to select the project. Only five studies mentioned project team members without explaining the criteria to select such members (Bentiz et al., 2007; Castle et al., 2005; Chan, 2004; Esimai, 2005; Luton et al., 2015) and their responsibilities and project’s goals (Benitez et al., 2007; Castle et al., 2005; Luton et al., 2015).

Table 2 Lean Six Sigma tools and techniques used in medication process.

<table>
<thead>
<tr>
<th>Prescribing</th>
<th>Transcribing</th>
<th>Dispensing</th>
<th>Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process mapping</td>
<td>FMEA</td>
<td>Process mapping</td>
<td>Value Stream Mapping</td>
</tr>
<tr>
<td>Cause and effect analysis</td>
<td>Data collection and analysis</td>
<td>Data collection and analysis</td>
<td>Just in time Process observation and analysis</td>
</tr>
<tr>
<td>Poka-yoke</td>
<td>Linear regression analysis</td>
<td>Control chart</td>
<td>Time and motion study</td>
</tr>
<tr>
<td>FMEA</td>
<td>Process control plan</td>
<td>Brainstorming</td>
<td>Work cell optimization</td>
</tr>
<tr>
<td>Data collection and analysis</td>
<td>Review historical data</td>
<td>Review historical data</td>
<td>Visual process control</td>
</tr>
<tr>
<td>Linear regression analysis</td>
<td>VOC</td>
<td>Baseline measurement</td>
<td>Workplace inspection t-test</td>
</tr>
<tr>
<td>Control chart</td>
<td>Poka-yoke</td>
<td>Poka-yoke</td>
<td>Chi-square</td>
</tr>
<tr>
<td>Process control plan</td>
<td>Run chart</td>
<td>Run chart</td>
<td>Linear and logistic regression analysis</td>
</tr>
<tr>
<td>Brainstorming</td>
<td>FMEA</td>
<td>FMEA</td>
<td>FMEA</td>
</tr>
</tbody>
</table>

5 why root cause analysis
A3 problem solving report
Project team charter
SIPOC
Spaghetti diagram
Bird's eye view maps
Standard operating procedures
Cause and effect analysis
Run chart
5 S
3.7 Lean and Six Sigma methodologies

Six Sigma has the ability to reduce variability from processes from two major methodologies: DMAIC and Design for Six Sigma (DFSS) (Aboelmaged, 2011). DMAIC consists of five phases of continuous improvement cycle: Define the scope and identify the problem associated with the process; Measure the baseline performance showing the current state of the problem; Analyse the root causes of the problem; Improve the current state by deriving the root causes of the problem; and Control the sustainability of process performance (Wang & Chen, 2010). It is important to note that Six Sigma methodology is used to tackle problems in existing processes and the stringent assumption we always make is that the design is robust. In contrast, DFSS methodology employs the following five phases: define; measure; analyse; design; optimise and, verify (DMADOV) to replace existing systems with new processes (Albiliwi et al., 2017).

The authors observed from the analysis of current literature that only five selected studies have implemented DMAIC methodology to reduce medication errors in different categories. Benitez et al. (2007) and Esimai (2005) followed the DMAIC methodology to improve the order medication entry process. Benitez et al. (2007) revealed that, during the improve phase, DFSS is implemented to design one standard medication order process which can be used in whole hospital units except an emergency unit (EU). As a result of DFSS initiatives, the chronological sheet from all patient charts is replaced by the existing patient care activity record (PCAR). After the process change, the percentage of order entry accuracy improved by 90% to less than 0.04 per bed every month for four month. Chan (2004) implemented DMAIC methodology to reduce dispensing errors in a pharmacy department which can reduce 230 errors per million in dispensing errors. A study by Castle et al. (2005) used DMAIC methodology to reduce several types of medication errors including wrong drug selection, wrong direction and sound-alike/look-alike (SALA) errors in a home-delivery
pharmacy service. A case study conducted by Nayar et al. (2013) used the DMAIC process step to improve medication management of dual care veteran patients.

Lean methodology includes five key principles: define value; define value stream; create flow; establish pull based on customer requirement; and seek perfection (Carlborg et al., 2013). This study found that of the selected studies most use only lean tools to reduce medication errors. However, the study conducted by Critchley (2015) implemented Lean methodology to improve medication administration safety in a community hospital in the community hospital in Canada.

3.8 Types of medication errors

Types of medication errors can be classified based on different factors such as the medication process and the underlying cause. Medication errors can occur at every stage of the medication process stemming from prescription, transcribing, dispensing and administration of the drug by the nurse. Prescription error encompasses faults in the dose selection, omitted transcription and poor handwriting (Velo & Minuz, 2009). Medication ordering errors occur when the incorrect drug is ordered by physicians (Stefanacci & Riddle, 2016). Dispensing errors are linked to the pharmacy where such errors involve the dispensing of an incorrect medication or dosage form to the patient (Roy et al., 2005), misinterpretation of the order, name confusion, poor labeling and poor packaging and design (Fisher et al., 2001; Revere & Black, 2003). Administration errors include omission error, wrong time errors, improper dose errors, wrong dosage (Stefanacci & Riddle, 2016) improper route of administration and wrong patient (Revere & Black, 2003).

The review of literature indicated that administration error is the most dominant type of medication error, as shown in Figure 7. This demonstrates that errors occurring in the administration phase need to be greatly reduced, followed by reduction in dispensing, preparation and prescription errors. The study also found that administration errors are the area
where Lean thinking and FMEA have most been used to reduce errors, while Six Sigma is commonly used to reduce dispensing errors in the pharmacy department.

![Pareto chart demonstrating types of medication errors.](image)

**Figure 7. Pareto chart demonstrating types of medication errors.**

### 3.9 Benefits

#### 3.9.1 Lean and Six Sigma

Figure 8 presents the benefits of Lean, Six Sigma and LSS in the context of medication errors from a thorough review of various case studies and other pertinent literature. The key benefit of such interventions through process excellence methodologies is the reduction of errors in the medication process such as missing medication (Hintzen et al., 2009), expired medication errors (Hussain et al., 2015) and order entry errors by the pharmacy (Benitez et al., 2007; Esimai, 2005), mostly occurring in the pharmacy department in the hospital. In terms of financial benefits, the implementation of LSS has reduced the estimated labour cost of $550,000 in a mid-sized hospital (Esimai, 2005) and can save the hospital inpatient pharmacy $82,650 annually by reducing the number of errors and missing doses (Hintzen et al., 2009). Moreover, the implementation of Six Sigma can also improve staff working performance. For instance, Chan (2004) mentioned that 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.

3.9.2 FMEA

FMEA has its own benefits such as reduction of medication errors in the prescribing, preparation, validation, dispensing and administration process (Arenas Villafranca et al., 2014; Lago et al., 2012; Rodriguez-Gonzalez et al., 2015; Sheridan-Leos & Schulmeister, 2006). Another benefit of FMEA is the improvement of safety in the medication preparation process (Aboumatar et al., 2010), prescription process (Kunac & Reith, 2005) administration process (Riehle et al., 2008; Rodriguez-Gonzalez et al., 2015) and drug delivery process (Lago et al., 2012).
3.10 Challenges

The challenges of LSS identified from a thorough review of the literature include: 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. 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 unknown and do not understand the need for change when important change occurs (Banuelas Coronado & Antony, 2002). 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. Four researchers further report the challenge of FMEA implementation to reduce errors in the medication process. The major challenge of FMEA adoption is that it is a costly and time consuming processes. Also, it can be challenging for those who are inexperienced (Sheridan-Leos & Schulmeister, 2006). Although, FMEA can be considered as of great value, there is little evidence to support that it can be used for quantitative prioritization of the failures of the process because it lacks both reliability and validity (Velez-Diaz-Pallares et al., 2013).

3.11 Critical Success Factors

Critical success factors are important to the successful implementation of any quality improvement initiatives (Desai et al., 2012). It can help people to understand what factors are important for making LSS successful and what factors are not important to the success (Antony & Banuelas, 2002). In the review, seven success factors were extracted from LSS implementation to reduce medication errors including understanding of LSS tools and
techniques and its philosophy, top management support, training, staff engagement, leadership capability, appropriate team formation or implementation infrastructure and cultural change.

According to the literature, understanding LSS tools and techniques and its philosophy plays a big role in LSS implementation. Before implementation of an LSS project, appropriate management support helps the team towards specific needs and goals by understanding Lean tools and philosophy (Hintzen et al., 2009) and Six Sigma philosophy (Chan, 2004). A clear vision from the top management (Luton et al., 2015) and appropriate management support for dedicated offline resources from senior administration are critical factors leading to the success of LSS projects (Ching et al., 2013; Hintzen et al., 2009). Top management of the organization must drive LSS initiatives (Banalas Coronado & Antony, 2002). The LSS initiative will be difficult without the top management support and commitment (Pande et al., 2000). Training is another significant factor leading to successful projects. As reported by Castle et al. (2005), the entire team received training as green or black belts while the executive staff or project sponsor trained as Lean Six Sigma yellow belts (Hintzen et al., 2009). The belt system assists the execution of LSS project throughout the organization (Antony&Banuelas, 2002). Critchley (2015) states that the level of staff engagement in identifying opportunities to improve and implement solutions to those opportunities using Lean tools is a key factor leading to the success of the project. Moreover, leadership involvement is required to lead to patient safety improvement (Critchley, 2015). Leadership has the ability to motivate people in the organization and encourage them to collaborate in order to achieve the business goals (Pamfilie et al., 2012). Identifying appropriate team members is another factor leading to the success of the project. For example, a team member is selected based on the basis of the alignment of their daily responsibility with the project’s objective in order to maximize resources (Castle et al., 2005). Embedding LSS into the healthcare culture also results in the success of the project (Luton et al., 2015).
It is important to highlight that in the literature, the implantation of FMEA in the context of medication errors has shown its own success factors which include staff engagement, multidisciplinary team, well-communicated plan, use of an FMEA facilitator, leadership sponsor and sufficient resources.

4. Discussion and Implications

The systematic review identified 24 research papers from eight databases and subject specific journals. The low sample size of selected studies was also found in other systematic literature review articles such as Andersen et al. (2014), Moraros et al. (2016), Mason et al. (2015), Deblois & Lepanto (2016), Burns et al. (2016), Materla et al. (2017) and Vest & Gamm (2009). As Albiliwi et al. (2015) mention, when conducting a literature review there is no agreed minimum number of papers to be reviewed. Additionally, of the 24 studies included in this review, five applied Lean, five used Six Sigma, four used LSS and 10 used LSS tools and techniques. It can be considered that 40% of the selected studies included FMEA implementation, because it is one of the Six Sigma tools used in the improve phase of the methodology. The literature also indicates that the implementation of Lean, Six Sigma, LSS and FMEA increased between 2015 and 2016 which accords with the study of Mason et al. (2015). The USA is the leading country that reports the highest number of Lean, Six Sigma, LSS and FMEA publications. Albiliwi et al. (2015) report that the USA published the largest number of LSS articles in the manufacturing sector. However, in Europe, a few papers have been published on Lean, Six Sigma, LSS and FMEA to reduce medication errors. In Asia, Thailand is far behind the USA because of a lack of knowledge to select the tools, lack of project selection criteria and lack of resources (Nonthaleerak & Hendry, 2008).

Tools and techniques, benefits, challenges, success factors of Lean, Six Sigma, LSS and FMEA are explored in the literature. The literature shows that Lean and Six Sigma tools implemented across DMAIC methodology mostly use non-statistical tools especially in the
improve phase. FMEA is the only six sigma tool used to identify the potential errors in every phase of the medication process. However, other tools such as process mapping and cause and effect analysis could be used in the four phases of the medication process to understand the current medication process flow and cause of errors. The literature also shows that administration errors are the most dominant type targeted by healthcare practitioners to reduce. This demonstrates that there is a high rate of possible errors in the medication administration process (Najar et al., 2016). The review of literature reveals that Lean, Six Sigma and LSS implementation can reduce errors in the medication delivery process. However, the implementation of FMEA has shown its own benefit which is the reduction of potential errors in the medication process. Additionally, from the analysis of literature, important factors which are responsible for medication errors’ reduction are identified including manpower such as minimizing distraction and workload of the staff members; machinery such as using automatic dispensing machine and computerized physician order management (CPOM); environment such as an improved medication room layout and method, such as using LSS methodology. Moreover, the finding of this review indicates that lack of top management support and the data collection process are the most challenging factors in the implementation of Lean and Six Sigma to reduce medication errors, whereas time constraints and cost are the barriers of FMEA adoption. The success factors which are the same for Lean and Six Sigma include understanding the toolkit and training. This finding, similar to that of Pepper & Spedding (2010), indicates that training staff is a keystone to gaining significant results. However, Albiliwi et al. (2015) claim that Six Sigma training is costly for many organizations. Researchers argue that it is necessary for organizations to invest in training staff before the implementation of the LSS project. However, training alone would not guarantee the successful project. Also, coaching and mentoring by champions and experts are needed, but this has not been mentioned in the current literature. Additionally, the findings of LSS critical success
factors in reducing medication errors are very similar to critical success factors in healthcare sectors in several aspects including support and commitment of top management, appropriate training and education, staff commitment to process improvement and understanding of LSS methodology and its associated tools and techniques. In healthcare, many researchers mention that project selection and prioritization is critical to the success of the project (Antony et al., 2007; Desai et al., 2012; Manville et al., 2012; Bhat et al., 2016), however, this factor has not appeared to be critical in the context of medication errors. Selection of the right project can help the management and staff to realise the true benefits and strengths of LSS (Bhat et al., 2016).

The key research gaps in the current literature are identified. The extant literature does not provide a roadmap to guide practitioners to follow for the implementation of Lean, Six Sigma or LSS to reduce medication errors. The current literature highlights that very few studies use pure Lean, Six Sigma and LSS to reduce medication errors. Previous studies have shown a lack of understanding in how to use LSS tools and techniques. There are a few papers published on the fundamental challenges in the use of LSS methodology to tackle medication errors. Moreover, several limitations of this study have been identified. The number of included studies is very limited because medication error is a very specific area for review when compared with other sectors such as manufacturing and healthcare.

The key findings of the review can be used as a guideline for healthcare practitioners before implementation of an LSS project to reduce medication errors by considering their benefits, challenges and success factors. Also, this study is valuable for healthcare sectors seeking to reduce errors in the medication process.

5. Conclusions and agenda for future research

The key finding of the systematic literature review reveals that there is a noticeable increase of interest in the Lean, Six Sigma and LSS application to reduce medication errors especially in
the developed countries. Continuous improvement methodologies such as Lean, Six Sigma and LSS can be implemented to reduce errors in the medication delivery process. Furthermore, the integration of Lean and Six Sigma may lead to better results, because practitioners can use tools from both philosophies. Lean tools can be employed to improve the workplace environment which could reduce staff stress and dose miscalculation while six sigma tools can be utilised to reduce errors in the medication process. Also, practitioners can draw upon FMEA to reduce the potential of medication errors and improve the safety of medication processes. Additionally, healthcare practitioners should consider the challenge of Lean, Six Sigma or LSS before beginning the LSS project. Project team members should understand the purpose of the Lean and Six Sigma philosophy and its tools and techniques as well as undergoing the training. However, lack of management support and insufficient data collection processes can lead to the failure of the project.

The review reveals that the current literature does not provide a Lean, Six Sigma or LSS road map for practitioners to follow in order to reduce medication errors in their hospitals. Therefore, this could be a fruitful area for the future research. Moreover, another important topic for consideration is that the previous literature does not discuss how to select LSS projects and what criteria to use to select such projects. Furthermore, there is a need to understand how the LSS toolkit can be implemented against each phase of DMAIC methodology.

References


in Saudi Arabian organization: findings from a survey. 


