
A systematic review of empirical studies pertaining to Lean, Six Sigma and Lean Six Sigma quality improvement methodologies in paediatrics

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Abstract: Lean, Six Sigma and Lean Six Sigma (LSS) are the quality improvement (QI) methodologies that have proved their merits in healthcare organisations since the 1990s. The aim of this paper is to present a systematic review of literature on the implementation of these QI methodologies in paediatrics by using a three-phase systematic review process (SRP), i.e., planning, conducting and reporting. The literature search was carried out in Web of Science, Scopus, and PubMed for articles published until April 2019. The broad range of outcomes from SRP was collated into six common themes: time optimisation, motion reduction, error mitigation, dosage optimisation, efficiency enhancement, and revenue generation. It is suggested that researchers and practitioners in paediatrics need to understand these QI methodologies deeply and deploy these in a profound way to realise their true potential. This is the first systematic review to synthesise the implementation results of QI methodologies in paediatrics.

Keywords: Lean; Six Sigma; Lean Six Sigma; LSS; paediatrics; systematic literature review and empirical research.

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1 Introduction

Lean, Six Sigma and Lean Six Sigma (LSS) are the business improvement methodologies for achieving the fastest rate of improvement in customer satisfaction, cost, quality and process speed in both the manufacturing and service sectors. There is significant growth in the last 20 years for the utilisation of these process improvement methodologies in the health sector. As per the frequency of publications; Lean, Six Sigma and LSS are the most adopted quality improvement (QI) methodologies for improving quality in hospitals (Glasgow et al., 2010). Many other authors reinforced that Lean, Six Sigma and LSS are the most widely accepted QI methods in the health sector (Kollberg et al., 2006; De Mast et al., 2006; Lifvergren et al., 2010; Seidi and Newhouse, 2012; Chiarini and Bracci, 2013).

Empirical research builds and verifies the theory simultaneously (De-Margerie and Jiang, 2011). The articles in empirical research in the field of operations management show a positive trend in recent years (Vamsi Krishna Jasti and Kodali, 2014). The term 'Empirical' is defined as "systematic process of deriving and analyzing data by direct and indirect observations" (Roth, 2007).

A systematic review of literature in regard to utility and efficacy of Lean and Six Sigma in other branches of medical science like radiology (Amaratunga and Dobranowski, 2016), surgery (Mason et al., 2015) and acute care (Deblois and Lepanto, 2016) has already been published. Manufacturing and service organisations use LSS projects for process improvement on a continuous basis that is empirical in nature (Gupta et al., 2019). The aim of this paper is to systematically review and analyse the published articles in the area of paediatrics dealing with empirical studies on Lean, Six Sigma and LSS methodologies, which is the first of its kind. This paper also tries to provide future directions in the presented field to the professionals and academicians.

The paper is organised in the following way: Section 1 introduces the paper, Section 2 provides the conceptual basis important to comprehend the work, and Section 3 reports the article and database selection methodology. The detailed study characteristics are discussed in Section 4. Section 5 narrates the summary of the paper and finally, the scope for future work and conclusion are discussed in Section 6.

2 Conceptual basis

Lean and Six Sigma are the process improvement methodologies initially developed and practiced in the manufacturing sector. Lean management or Lean production at first came into picture from the book entitled *The Machine That Changed the World* published in 1990 by The Institute of Technology, Massachusetts (USA). The five fundamental components which briefly describe lean are: specify the value, identify the value stream, make the value-creating step flow, let customers pull value from the enterprise and seek perfection (Womack and Jones, 1997). The main objective of lean is to eliminate waste from a system (Liker, 2004). Maximisation of operational efficiency, speed and quality with optimum cost is achievable through lean (Holweg, 2007). The main focus of lean is to eliminate the waste (which may include energy, time and material) and ultimately increasing efficiency. Cases of using lean in healthcare were first observed in the UK (2000) and in the USA (2001). However, in the year 2009 it was apparent that the US leads the publications on implementation of Lean in hospitals with 57% followed by the UK with 29% (Brandao de Souza, 2009). The results obtained by the implementation of Lean in hospitals are a capacity increase, cost reduction, reduction in waiting time and time of stay, etc. The major tools employed in order to achieve the above results were value stream mapping (VSM), Kaizen and work standardisation (Mazzocato et al., 2012). Several other kinds of literature reported the implementation of lean in hospital (Alsmadi et al., 2012; Cardoen et al., 2015; Hassanain et al., 2017; Costa et al., 2017; Improta et al., 2018; Cerfolio et al., 2019).

The word ‘Six Sigma’ was first coined by Engineer Bill Smith while working in the Motorola Company in 1980. After the success of Motorola, other industries like General Electric, Honeywell etc. embraced ‘Six Sigma’ as the central business strategy (Hammer, 2002). Since the last 15 years, Six Sigma got its widespread acknowledgment after the publication of the book *Six Sigma: The Breakthrough Management Strategy Revolutionizing the World’s Top Corporations* (Harry and Schroeder, 2005). A lot of case study manuals published in order to propose the step by step approach to implement Six Sigma in the health sector (Frings and Grant, 2005; Woodard, 2005; Gowen et al., 2008; Allen et al., 2010).

It is clear from the literature that there is a conceptual difference between these two QI approaches. Lean methodology appraises only that which adds value to the product/service and remaining all are nothing but a waste. Six Sigma uses a five-step approach to alleviate quality issues. However, the main focus of both methodologies is to satisfy customer needs, reducing the cost and improving the process (Arthur, 2011). Hence, the integration of Lean and Six Sigma termed as LSS is the gist of current QI initiatives in the healthcare sector.

3 Research methods

The present study followed a three-phase systematic review process (SRP) as proposed by Tranfield et al. (2003). The three phases are: planning the review, conducting the review and reporting and dissemination. The first two phases were then presented in the form of preferred reporting items for systematic review and meta-analysis (PRISMA) diagram as proposed by Liberati et al. (2009). A detailed analysis of the selected papers is then presented. According to Soni and Kodali (2011) “Empirical articles are used to describe the ‘field-based’ experiences involving data collection procedures by direct observations or from naturally occurring processes rather than laboratory or simulation studies.”

3.1 Planning the review

Two points are to be pondered upon before starting SRP. Firstly, to know what keywords should be used that justifies the research question; secondly, what keywords justify our publication area. These two points steer towards the SRP protocol as illustrated in Table 1.

All the studies published in lean, Six Sigma and LSS pertaining to paediatric have been considered for this review. In other words, no time constraints were given to the year of publication. Three databases: Web of Science, Scopus, and PubMed were searched on 23rd April 2019 to get the related articles. The topic of this paper is pertinent to the publications from the above databases to justify their selection.

Table 1 SRP research protocol

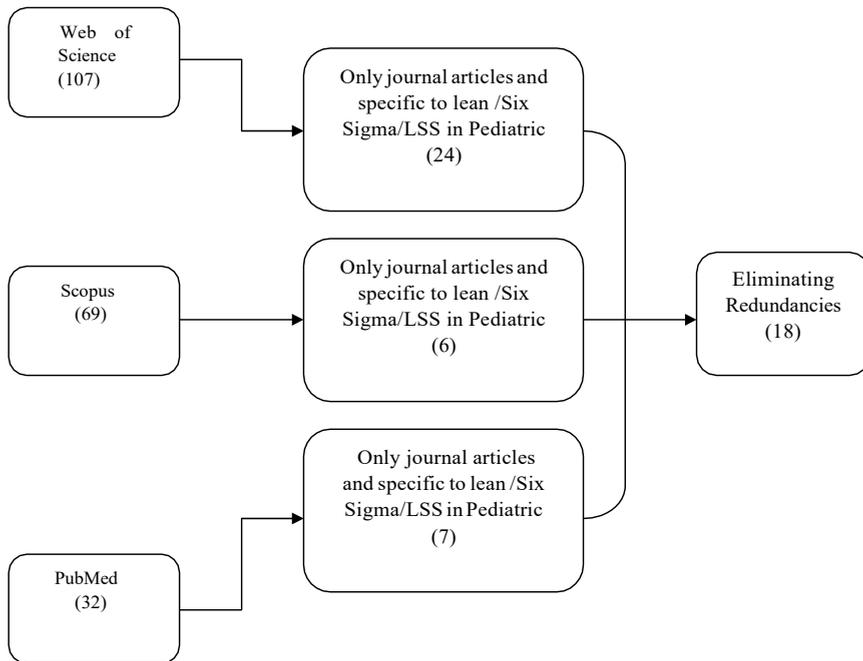
<i>Component</i>	<i>SRP protocol</i>
Groups	<ol style="list-style-type: none"> 1 Paediatric 2 Empirical research 3 Continuous improvement
key words	<ol style="list-style-type: none"> 1 Lean, Six Sigma , lean Six Sigma 2 Paediatric, childcare, hospital 3 empiric, action research, case study,
Boolean operator	‘AND’ for between groups ‘OR’ for within groups
Database	Web of Science, Scopus and PubMed
Inclusion criteria	<ol style="list-style-type: none"> 1 Involves hospital based or outpatient based pediatric department 2 Lean, Six Sigma and LSS methodologies implemented 3 Adequately describes an empirical study
Language	English
Document type	Journal articles
Year of publication	No filter

The combination of words used for article search in the databases were: ‘lean’ or ‘Six Sigma’ or ‘lean Six Sigma’ and ‘paediatric’ or ‘childcare’ or ‘hospital’ and ‘empiric’ or ‘action research’ or ‘case study’. The word ‘empirical’ means the researches which are based on real-world observations (Flynn et al., 1990). The analysis is limited to only journal articles in the English language. Conference proceedings, editorials, book chapters and letters were not entertained for the review. Another filter, i.e., publications do not behold the aspects of lean, Six Sigma and LSS were excluded.

3.2 Conducting the review

The SRP research protocol as stated in Table 1 was followed to conduct the initial search that resulted in a total of 208 articles in 43 different journals within the purview of exploration. The schematic tree diagram of filtered articles from three different articles was shown in Figure 1. After deleting the duplicate articles between databases and completing all filtering criteria mentioned in the SRP protocol, finally 18 articles were picked for review. The PRISMA diagram, the most followed diagram to represent a systematic review of the literature is shown in Figure 2 (Liberati et al., 2009).

Figure 1 A schematic tree diagram of filtered articles



3.3 Reporting and dissemination

Figure 3 exhibits that implementation of Lean, Six Sigma and LSS in paediatrics is growing with time. During the year 2010–2012, no study was reported that implemented any of these QI methodologies. But during the last three years, the data shows that ‘LSS’ is the principal QI methodology implemented in paediatrics. The detailed dissemination is reported in the next section where each article is explored in detail.

4 Study characteristics

Out of 18 studies that included qualitative analyses; four used Six Sigma, two lean and 12 LSS as QI methodologies in paediatrics. All included studies were grouped into six common themes: time optimisation (five studies), motion reduction (one study) error mitigation (five studies), dose optimisation (two studies), improvement in throughput efficiency by multiple improvement actions (four studies) and revenue generation (one study). Nearly 84% of the included studies were published in the last six years out of which 80% implemented LSS as the QI methodology (Figure 3).

Figure 2 PRISMA flow diagram of included studies (see online version for colours)

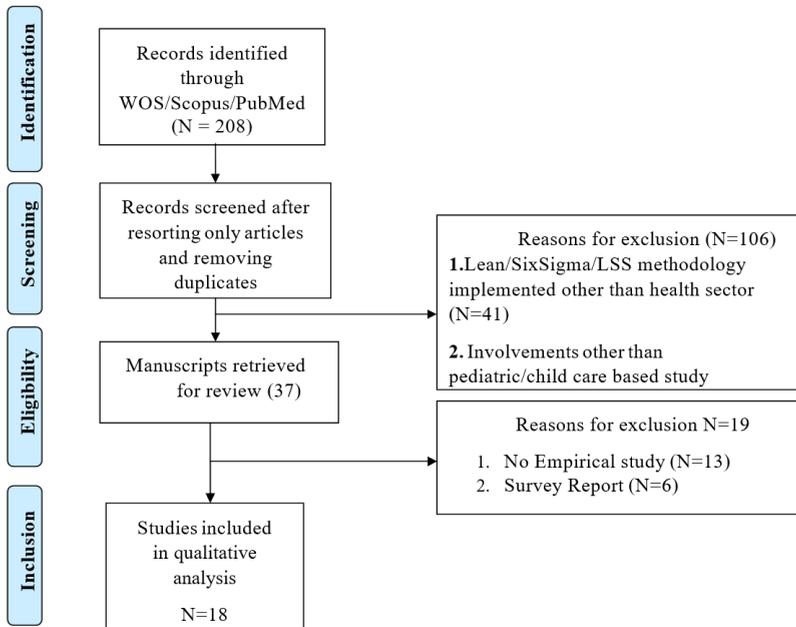
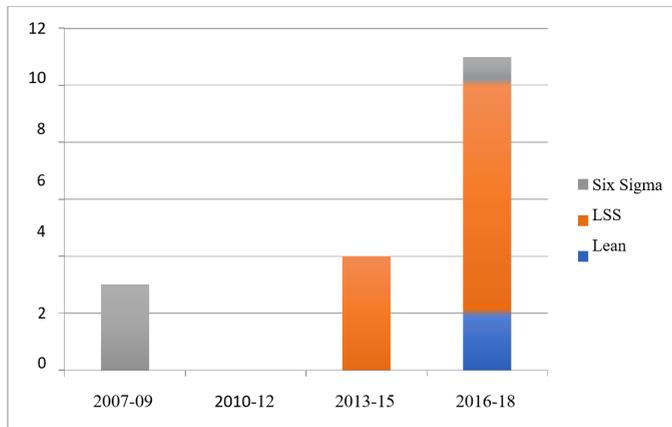


Figure 3 Year wise grouping of studies (see online version for colours)



4.1 Descriptive synthesis of studies

In the above mentioned studies some studies had a single outcome, where as some others had multiple outcomes. This wide array of results was summarised in the form of six common themes as described below. The themes were explicitly categorised based on the end results proclaimed by the respective authors.

Theme 1 Time optimisation

Time is the most valuable asset in the world and optimising time is essential in any organisational setup. In the case of the health sector different categories of time functions to be dealt with are:

- 1 appointment wait times
- 2 in-department wait times
- 3 cycle times.

Appointment wait time is the time elapsed between the day when a request for examination was sent and the day when actual examination takes place. In-department wait time is the time period during which the patient waits until the procedure begins upon arrival in a department. Cycle time is the total time spent on performing an examination. Five studies addressed the case of optimising time, out of which two studies were based on reducing the overall time from patient arrival to discharge (Jayasinha, 2016; Beck et al., 2016). In-department waiting time, i.e., the time a patient waits upon arriving another department for further procedures was reduced (Tagge et al., 2017). Fratino et al. (2009) reported the intervention of Six Sigma to reduce the time between the admission of a patient into the hospital and getting a particular treatment like hydration and chemotherapy. Lean implementation results in 30 minutes reduction in both bed request time of patients and the total duration of stay at the emergency department (ED) (Migita et al., 2018).

Theme 2 Motion reduction

The distance walked by doctors, nurses or any other support staff within hospital premises is the measure of motion. The motion of personnel and material inside the hospital is inevitable but there exist certain motions that are absolutely unnecessary. Such motions are referred to as non-value-added (NVA) motions. These NVA motions need to be addressed in order to take the countermeasures. Roberts et al. (2017) reveal that the yearly distance walked by assistant technicians (ATs) at Sheikh Zayed Institute for Pediatric Surgical Innovation, Washington, DC was reduced significantly after LSS intervention.

Theme 3 Error mitigation

Error in the health sector has a risk on the life of the patient. Especially, when patients are children who cannot express their pain/feeling through words then it's difficult to judge the upshots and take necessary actions. Hence, to avoid the slightest of error in paediatrics is the most essential CI intervention. Five studies that measured this outcome

include: surgical complication error (Barach and Kleinman, 2018), communication error (Czulada et al., 2016), milk feeding error (Luton et al., 2015), infection errors leading to ventilator-associated pneumonia (VAP) (McBeth et al., 2018) and breast milk administration error (Douglas et al., 2007).

Theme 4 Dose optimisation

There exists certain type of doses during which the patients were exposed to excess medical radiations. These radiations are very much harmful to the patients. Though these doses are an essential part of the patient treatment, the excess exposure results in major side effects which very much is harmful to the patient. The frequency of a computed tomography (CT) scan was reduced in two hospitals after the implementation of LSS methodology (Greenwood et al., 2015; Tekes et al., 2016).

Theme 5 Improvement of throughput efficiency by multiple improvement actions

Whenever a single QI project results in a number of beneficiary outcomes then throughput efficiency is taken into account. Four studies reported multiple action plans for improving the throughput efficiency of a hospital. Penn State Hershey Children's Hospital (PSHCH), located in central Pennsylvania, achieved several benefits like reduced discharge order entry time, decreased lost referrals resulting revenue generation and an increase in overall satisfaction and trust in doctor (Beck and Gosik, 2015). Several action plans taken in order to increase throughput efficiency after VSM outlined for the given hospital. VSM for the current state appears to be 42 days between fax referral of patient and registration but benchmarking standard restricts to 14 days only (Lee et al., 2014). The per-patient handoff communication error from operating room (OR) to paediatric intensive care unit (PICU) reduced significantly and patient waiting time along with other NVA activities also decreased in Mayo Clinic Children's Centre, a tertiary academic paediatric medical centre (Gleich et al., 2016). Mistry et al., (2008) reported four improvements at Duke Children's Hospital, Durham, NC out of which two were time minimisation and the other two increased in a number of patients in lab tests.

Theme 6 Revenue generation

Revenue of a hospital can be generated in many ways like increasing the patient volume, getting more insurance claims and obtaining more output by utilising fewer resources, etc. LSS intervention helps in generating revenue by reducing the insurance claim denials in Texas Children's Hospital (Kovach and Borikar, 2018).

4.2 Synthesis of results

The descriptive synthesis of results is performed and the findings were assessed by various parameters: type of QI interventions, source, aim, tangible outcomes, year and authors (Table 2).

Table 2 Descriptive synthesis of results

<i>Aim of study</i>	<i>Authors</i>	<i>Publication year</i>	<i>Centre</i>	<i>Outcomes</i>	<i>Method</i>
Motion reduction	Roberts et al.	2017	Sheikh Zayed Institute for Pediatric Surgical Innovation, Washington, DC	The distance walked per day by the ATs in the base line was reduced from 26.4 km to 19.2 km	LSS
Error mitigation	Barach and Kleinman	2018	Hospitals in USA	Surgical complication rates were lowered to more than one-third and death rates were lowered to almost one-half (from 1.5 to 0.8%)	LSS
	Czulada et al.	2016	pediatric intensive care unit (PICU) North Carolina Children's Hospital	Improved quality care and reduced error witnessed by improvement in the mean percentage of families communication from 13% to 65%	LSS
	Luton et al.	2015	Texas Children's Hospital	For both human and formula milk, the feeding errors reduced by 83%	LSS
	McBeth et al.	2018	Davis, Children's Hospital, Sacramento, California.	Ventilator Associated Pneumonia cases reduced significantly from 7.86 to 1.16 per 1,000 ventilator days within two years and sustained a rate of near 0 for 5 years	Six Sigma
	Douglas et al.	2007	Tertiary Care Centre at Children's Hospital Illinois	The sigma level for the breast milk administration process was improved from 5.2 to 6, i.e., from 104 potential errors to 3.4 potential errors in a million opportunities	Six Sigma
Dose optimisation	Greenwood et al.	2015	St Louis Children's Hospital and Mallinckrodt Institute of Radiology Washington.	CT use in children reduced by roughly 50%	LSS
	Teke et al.	2016	Quaternary Care Academic Children's Center	Number of orders for Head CTs of children with hydrocephalus was reduced by 75%	LSS

Table 2 Descriptive synthesis of results (continued)

<i>Aim of study</i>	<i>Authors</i>	<i>Publication year</i>	<i>Centre</i>	<i>Outcomes</i>	<i>Method</i>
Improvement of throughput efficiency	Beck and Gosik	2015	Penn State Hershey Children's Hospital (PSHCH), located in central Pennsylvania	1 200 minutes reduction in discharge order entry in medians. Lost referrals reduced from 20 to 0 which results in revenue generation, estimated between \$275,000 and \$412,000 dollars without additional resources. 50 percentile growth of 'trust in doctor', 3 percentile increase in 'Overall satisfaction and 22 percentile rise in 'would recommend this hospital to others'.	LSS
	Lee et al.	2014	Johns Hopkins Hospital Maryland	VSM for the current state appears to be 42 days between fax referral of patient and registration but benchmarking standard restricts to 14 days only	LSS
	Gleich et al.	2016	Mayo Clinic Children's Center	Per patient handoff communication error from Operating Room (OR) to Paediatric Intensive Care Unit (PICU) reduced significantly from 1.9 to 0.3. Patient waiting time and other non value added activities were decreased by 58 minutes(from90 to 32 minutes)	LSS
	Mistry et al.	2008	Duke Children's Hospital, Durham, NC	2 Decrease in the postoperative handoff turnaround time from 15.3 min to 9.6 min The time to obtaining critical laboratory studies was reduced by 10.6 minutes (13 min to 2.4 min) Completion of chest radiographs increased by 34% Cardio-respiratory monitoring increased from 86% to 99%	Six Sigma
Revenue generation	Kovach et al.	2018	Texas Children's Hospital	The number of insurance claim denials for Emergency Center patients reduced to 70 or fewer and thereby increased revenue generation	LSS

5 Discussion

In paediatrics, various NVA activities that result in increased waiting time, patient discontent, etc. can be mitigated by lean methodology as it adds value to products and services. Various lean tools employed in paediatrics include VSM 5S, Kaizen, process flow diagram, just in time, checklist, etc. Six Sigma uses a five-step approach to alleviate quality issues. The five steps: define, measure, analyse, improve and control (DMAIC) constitutes many tools like Pareto analysis, failure mode effects analyses, statistical process control, Ishikawa Diagram, etc. which were effectively used in mitigating paediatric quality issues. The integration of Lean and Six Sigma termed as LSS is the gist of current QI initiatives.

The prospects of Lean, Six Sigma and LSS methodologies as QI initiatives within paediatrics are the focus of this study. The outcome has been accessed based on 6 common themes which provide the understanding of these methodologies through the entire paediatrics context. The findings indicate that the maximum interventions are for time optimisation and error reduction. All the studies reported in this paper are of the US context; still, these methodologies can be practiced universally. One of the objectives of this study is to highlight the applicability and impact of the QI methodologies through careful evaluation of the published articles. Hence, the practitioners and researchers of paediatrics across the globe may implement these CI methodologies in order to get similar benefits.

6 Conclusions and future scopes

The usefulness of Lean, Six Sigma and LSS in healthcare settings has been reported through systematic literature reviews (Vest and Gamm, 2009; Villa, 2010; Anamaria et al., 2018). But, the aggregate benefits within the boundary of paediatrics remain unrevealed. The findings of the systematic literature review reveal the beneficiary outcomes of these interventions within paediatrics. Adoption of Lean in the Malaysian healthcare industry resulted in reduced waste and defects, fast delivery with minimal cost, reduced cycle time, accelerated process, etc. (Habidin et al., 2014). But, when considering the improvements among the studies it is undeniably difficult to differentiate the level of benefits between the QI interventions. Even focused clinical improvements were secured from all the included studies but the statistical significance of them was not fairly demonstrated.

Future works should consider regional, economic and cultural factors in order to compare the level of improvements due to QI interventions. Practitioners and academicians, especially in developing countries, should try to foster the use of these QI interventions in all healthcare settings. Studies have to be carried out by performing multiple interventions in a similar scenario in order to validate their cost-effectiveness and sustainability. The means to sustain these practices need to be focused on. One of the most promising areas for future research is to investigate the factors of success and failure of these interventions. The present study will serve as a supplement for researchers and practitioners in paediatrics to comprehend and contrive the QI methodologies in a better way.

Lean, Six Sigma and LSS methodologies require substantial staff training for data collection and statistical analyses. Multilevel trained personnel (green belt, black belt,

and master black belt) were assigned respective tasks for smooth flow of LSS projects in industrial settings but the same is unnoticeable from the studies. One of the limitations of this review is the incapability of recommending the methodologies for improving specified outcomes in paediatrics.

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