

Systematic Review of Literature on Lean and Six Sigma in Healthcare and Directions for Future Research

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Abstract

Healthcare organizations have increasingly turned to Lean and Six Sigma (LSS) as management systems to achieve quality and efficiency in patient care. This study aims to classify this body of literature and to discover factors that enable and prevent successful LSS implementations. Peer-reviewed literature in journals that were published through 2018 in English language were sought through a search of multiple databases. The inclusion criterion was broad in that all areas of healthcare and interpretations of LSS were considered. The literature search yielded 368 publications. One third of the studies present a U.S. affiliation and only 19% has been conducted in developing countries. The case study is the most popular study type but only represents around 52% of the body of literature. Lean and the ED are preferred approach and setting, respectively. Factors that enable and prevent successful implementation were grouped by Managerial, Preparation, People, and Project relationships. There is a need for future literature to provide a longitudinal balanced view on the benefits and challenges of implementations, and for studies to follow experimental designs for statistical validity. This is the most inclusive review about LSS in healthcare as it includes different study types, healthcare settings and LSS tools together.

Keywords

Literature review; Lean, Six Sigma, Healthcare, Hospital.

1. Introduction

Lean and Six Sigma (LSS) entered the healthcare literature nearly two decades ago as a novel approach to performance improvement in healthcare (Christianson, et al. 2005; D'Andreamatteo, et al. 2015). Having been proven in manufacturing as a means to increase productivity while controlling costs, the healthcare industry sought to adopt the same principles into performance improvement. The realized benefits of LSS in healthcare, however, have mostly been elusive (Holden, 2011; Makary & Daniel, 2016; Vest & Gamm, 2009). There may be several reasons for this as procedurally the leap from industry to healthcare is a big one, yet the core idea of eliminating waste in Lean and of reducing variability in Six Sigma transcends the domain of application.

Lean, as a management system, may be defined as creating value to customers by reducing waste and using less resources (Womack & Jones, 2003). Lean focuses on improving the complete process rather than optimizing a specific function within one (Al-Balushi et al. 2014; Savage, et al. 2016), and hence is intended to be a mindset and long-term process improvement system within an organization. In contrast, Six Sigma is both a short- and long-term process improvement methodology (Harry & Schroeder, 2000). The focus of Six Sigma is on reducing system variability using the Define, Measure, Analyze, Implement, and Control (DMAIC) process, and seeks to tie investments to clear profit returns (George, 2002). Combining these approaches into Lean Six Sigma (LSS) draws on the strength of each and leads to a robust process improvement approach.

The rate of publication of literature on LSS in healthcare has been growing at an ever increasing rate over the past two decades, and the first objective of this review is to classify this accumulated body of literature by the 5 W's of who, what, when, where, why, and how. The second is to systematically review this broad base of literature to identify those factors that enable and prevent successful LSS implementations in healthcare. A summary of this literature review is given in Table 1.

Table 1. Summary of Literature Review.

Identification
Database: Medline, Emerald Insight, Taylor and Francis, Science Direct, Wiley, Elsevier, BioMed Central, Wolter Kluwer, BMJ, Springer-Link, Inderscience, Oxford Academic, Sage, EBSCO
Terms: Lean <i>OR</i> Toyota Production System <i>OR</i> Six Sigma <i>AND</i> Healthcare <i>OR</i> Hospital
Inclusion: English Language; Terms in Title, Abstract, or Keywords
Exclusion: Conference Papers, Books, Reports, Editorial Letters, etc.
Classification of Literature
Year: Year of Publication
Geography: Location of Study or Author Affiliation
Study Type: Case Study (Descriptive/Experimental), Theoretical/Conceptual, Ethnographical/Phenomenal, Survey, Longitudinal/Cross-Sectional, Empirical/Observational, Review, Other
Process Improvement Approach: Lean, Six Sigma, or Lean/Six-Sigma
Healthcare Setting: Emergency Department, Surgery, Support Area, Clinic, Operating Room, Laboratory, Intensive Care Unit, Oncology, Other
Primary Objective of LSS Activity: Time/Efficiency, Quality/Defects, Financial/Cost Savings, Patient Satisfaction, Staff Satisfaction, Patient Safety, Staff Safety, Other
Authors' Background: Engineering, Business, Medical, Other
Identification of Factors
Enabling Factors: Identification of factors that enable successful LSS projects in healthcare
Preventative Factors: Identification of factors that prevent successful LSS projects in healthcare

2. Methodology

The search strategy used in this review was aimed at building a comprehensive and non-restrictive set of publications on LSS in healthcare. Towards this end, the databases of Table 1 were searched according to the inclusion/exclusion criterion shown. Additionally, a few seminal papers and journal articles from previous literature reviews were included as candidates, regardless of whether or not they met the criterion. Using this search strategy and removing duplications yielded 368 publications on LSS in healthcare through December of 2018.

The discovered articles were stored on a shared drive and independently analyzed according by at least two of the authors of this article, with the intent to reduce errors and mitigate reviewer bias in the systematic review. In addition, all articles meeting the search criterion were given equal weight in the analysis, removing any bias due to reputation in the analysis. The reviews were combined and assessed by the authors, whereupon discrepancies were resolved through group discussion and consensus.

The research question of this study is: How is the body of knowledge about LSS classified and characterized in terms of: Number of publications per year, geography, study type, process improvement approach, healthcare setting, primary objective of LSS activity, authors' affiliation, publisher, journal, enabling and preventing factors for successful LSS implementations?

3. Results

3.1. Classification of Literature

The base of literature was classified according to the dimensions given in Table 1 using descriptive statistics. The classification demonstrates interesting trends in the field, both in academics and practice.

Category 1: Year of Publication

The first publication date back to the year 1998 and overall rate of literature growth has been increasing ever since. Figure 1 shows the number of publications per year. The peak years were 2012 that had 41 articles and 2018 that had 42 articles until December. A regression of publications on time supports the assertion that articles have been experiencing exponential growth over the past two decades.

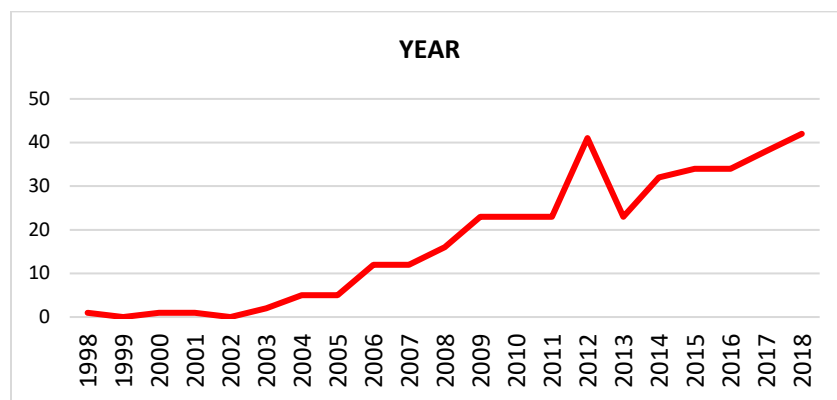


Figure 1. Number of publications per year.

Category 2: Geographical Location

A breakdown by specific countries in which the LSS project was conducted or reported is given in Figure 2, for which the United States has over one-third of all publications. Interestingly, this country has the most expensive health expenditure, yet there are no identifiable benefits associated to healthcare outcomes. This implies most healthcare organizations in the United States are characterized by having a lot of waste within their processes regardless their improvement efforts.

Figure 2 further displays the percentage of those publications that were case studies. The final grouping of "others" includes Portugal (5 articles), Finland (5), Jordan (5), Spain (4), Norway (4), Germany (3), Egypt (3), and Colombia (3), and a few others that were less frequent.

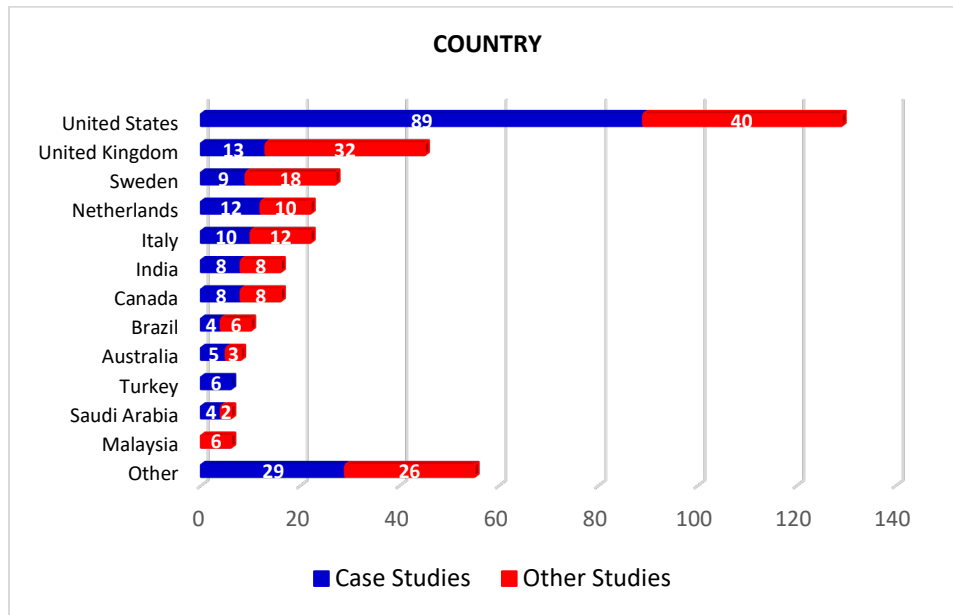


Figure 2. Frequency of Publications by Country.

It is interesting to note that a classification of countries outside the United States as developing or developed countries by OCED, as shown in Figure 3, shows that less than one fifth of the literature comes from developing countries.

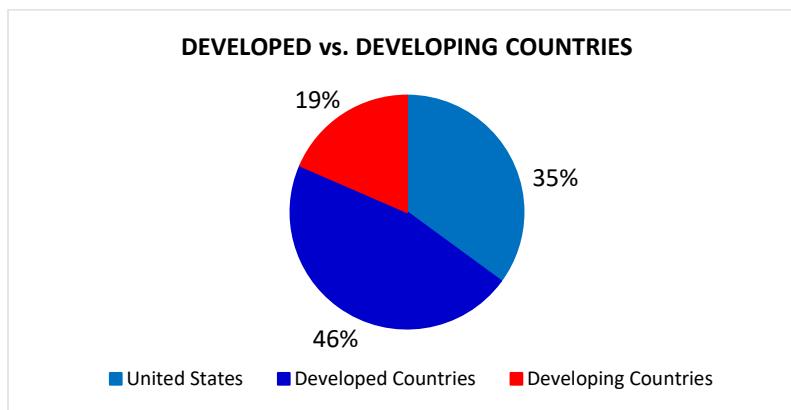


Figure 3. Percentages in Developed versus Developing Countries.

Category 3: Study Type

The literature was classified according to the type of study or research activity that was reported, using the scheme offered by (Leedy & Ormrod, 2005). Findings are presented in Figure 4, noting that over half of the literature was reporting a case study on which an actual LSS project was conducted.

Restricting attention to only case studies, a follow-up question becomes how the project was conducted and subsequently reported. 93% of the studies presented results in a descriptive format, which articles typically claimed that LSS positive implemented result without baseline comparisons.

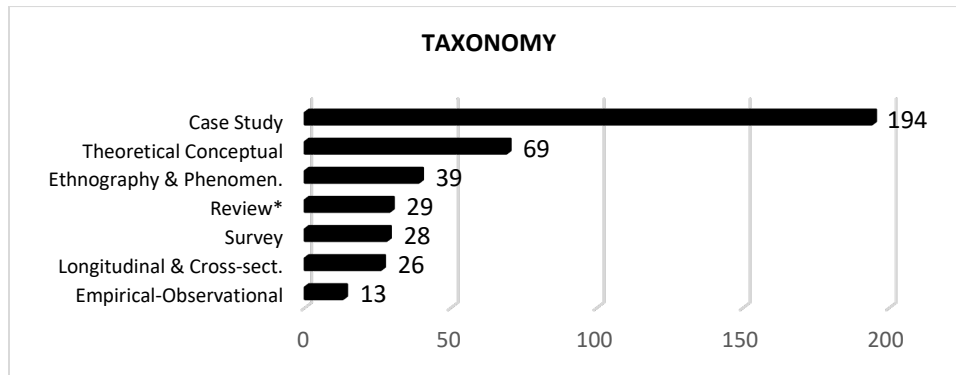


Figure 4. Frequency of Study Types in the Literature.

Category 4: Process Improvement Approach

The management system of Lean, Six Sigma, or Lean Six Sigma that was reported by the articles is presented in Figure 5, noting that the majority of literature focused on Lean rather than Six Sigma or Lean Six Sigma.

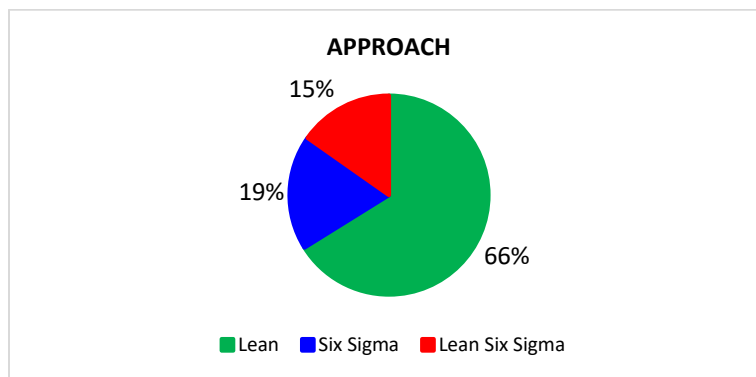


Figure 5. Percentages of Process Improvement Approaches.

Category 5: Healthcare Setting

There is a wide array of healthcare settings in which LSS may be implemented, including inpatient and outpatient care facilities. A breakdown by different setting is given in Figure 6, noting that some specialties, such as radiology, pharmacy, pathology, psychiatry, orthopedic, pediatrics, and telemetry units, are not shown due to low frequency. It is interesting to note that the two leading areas of LSS implementation are in the often most variable setting, Emergency Departments, and the most controlled setting, Surgery.

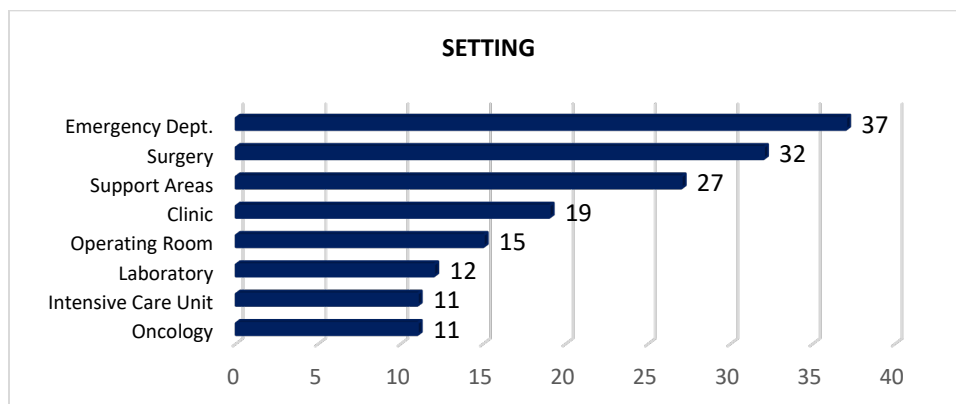


Figure 6. Frequency of Healthcare Settings.

Category 6: Objective of LSS

A grouping of the objectives of using LSS in healthcare is given in Figure 7. It is not surprising that Time and Efficiency improvements were the most common objective as these metrics are commonly associated with process improvement efforts.

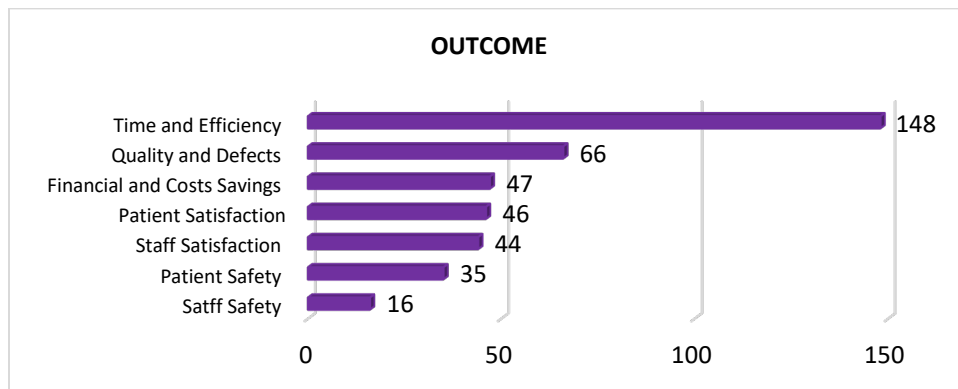


Figure 7. Frequency of LSS Objectives.

Category 8: Affiliations

The affiliation of the authors of LSS articles is given in Figure 8, which affiliations are broadly grouped as medical and health, engineering, or business and management. The diversity of affiliations is not surprising as LSS grew out of engineering environments, it is commonly taught in management, and it is directly applied by medical professionals.

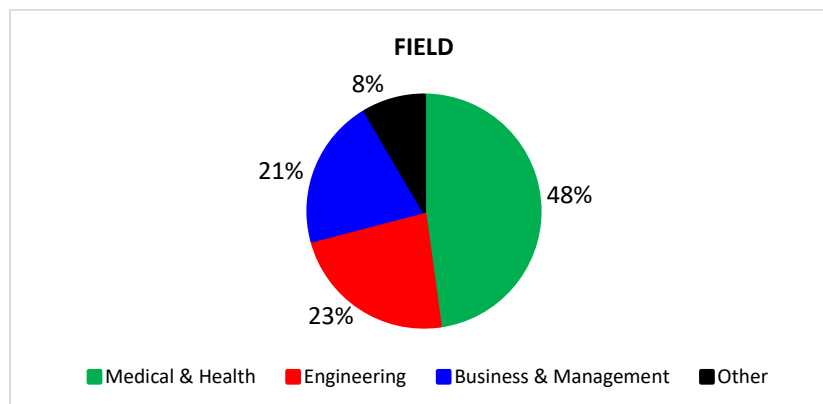


Figure 8. Percentage of Literature by Type of School.

Category 9: Publishers and Journals

One last part of this descriptive review are the publishers and journals that have published the most research works related to LSS, which are presented in Figures 9-10. There are other publishers and journals that have published relevant studies in this matter; however, they are not listed due to a low frequency, less than seven and six, for publishers and journals, respectively.

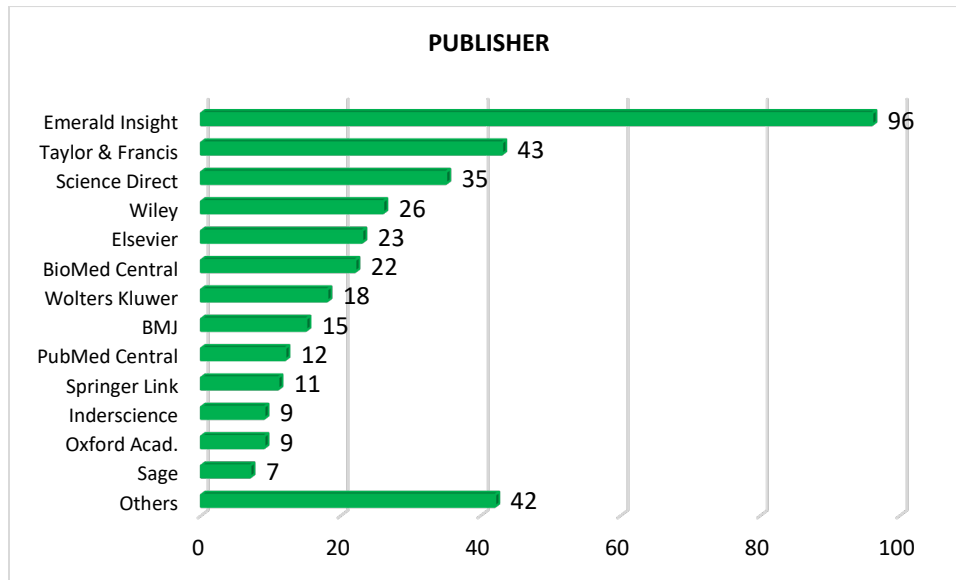


Figure 9. Frequency of Publishers of Literature.

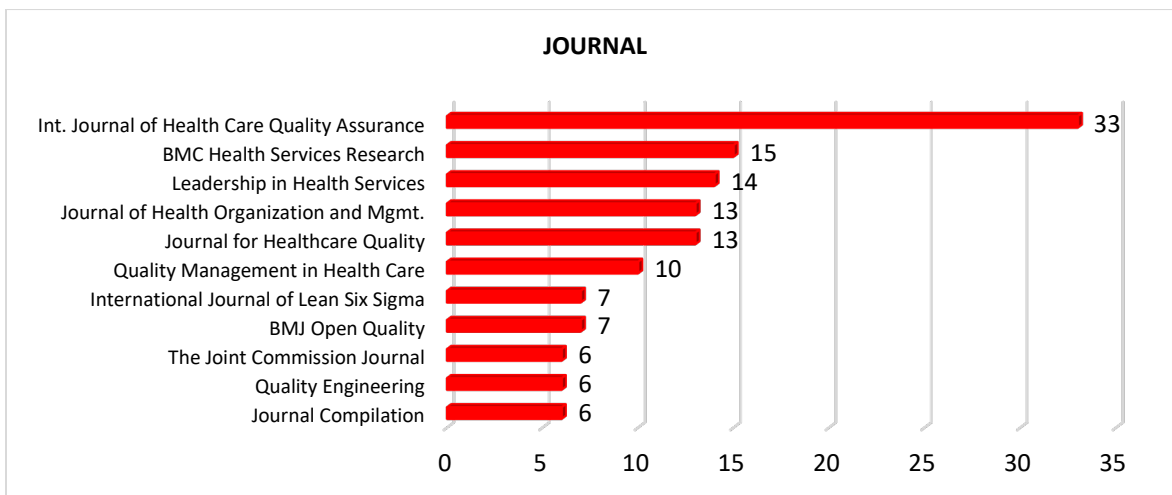


Figure 10. Frequency of Journals Publishing the Literature.

3.2. Factors Enabling Successful LSS Projects

A systematic review of the literature suggests that there are several factors that enable successful LSS implementations in a healthcare setting. A summary of these is given in Table 2, which were broadly grouped by Management, Preparation, People, and Projects.

The two most often cited factors of a successful LSS project falls under the grouping of Management. As in any LSS project in any setting, leadership is fundamental in sustaining the effort, as is managerial support in creating a shared vision with a daily presence (Aij et al., 2013). The second of Preparation includes the need for expert guidance, often by an external consultant or a Master Black Belt (Hintzen et al., 2009). In addition, a project needs to carefully assemble and train teams, defining process owners and sponsors, with employees that are engaged and emerge as informal leaders (Chassin, 2008; Mazur et al., 2012; Simon & Canacari, 2012). The remaining two groupings are of People and Projects. A successful implementation requires significant participation of clinical personnel that have effective communication and cross-departmental cooperation (Adams et al., 2004; Al-Balushi et al., 2014; Antony et al., 2007; Arbune et al., 2015; Burström et al., 2014; Laureani et al., 2013). The project itself should have a tight

definition and selection, and keep a focus on what is relevant to the patient in order to avoid wasting resources (Adams et al., 2004; Andersen & Røvik, 2015; Snyder & McDermott, 2009). Throughout the project, consideration should be given to data collection and monitoring metrics to gauge success (Al-Balushi et al., 2014; Andersen et al., 2014; Arbune et al., 2015; Chassin, 2008; Kim et al., 2009).

Table 2. Factors Enabling Successful LSS Implementations in Healthcare

Group	Factors	Selected References
Management	Leadership	Adams, et. (2004); Aij, et at. (2013); Al-Balushi et al. (2014); Antony, et al. (2007); Bhat, et al. (2014); Bhat & Jnanesh, (2014); Furman & Caplan (2007); Kim, et al. (2009); Laureani, et al. (2013); Nelson-Peterson & Leppa (2007); Snyder & McDermott (2009); Steed (2012).
	Support	Aij et al. (2013); Andersen, et al. (2014); Antony et al. (2007); Arbune, et al. (2015); Bhat et al., (2014); Christianson et al. (2005); Deblois & Lepanto (2016); Fairbanks (2007); Hintzen, et al. (2009); ; Holden (2011); Laureani et al. (2013); Poksinska (2010); Snyder & McDermott (2009); Wijma, et al. (2009).
Preparation	Expert guidance	Chiarini (2012; Gijo & Antony (2014); Hintzen et al. (2009); Kim et al. (2009); Simon & Canacari (2012); van Lent, Sanders, & van Harten (2012); Wijma et al. (2009).
	Team assembly	Christianson et al. (2005); Hintzen et al. (2009); Mazur, et al. (2012); Simon & Canacari (2012).
	Training	Al-Balushi et al. (2014); Andersen et al. (2014); Antony et al. (2007); Bhat et al. (2014); Bhat & Jnanesh (2014); Bhat & Jnanesh (2013); Poksinska (2010).
People	Engagement	Aij et al. (2013); Aij, et al. (2015); Andersen & Røvik, (2015); Andersen et al. (2014); Bhat et al. (2014); Bhat & Jnanesh (2014); Burström, et al. (2014); Christianson et al. (2005); Deblois & Lepanto (2016); Holden (2011); Kim et al. (2009); Mazur et al. (2012); Poksinska (2010).
	Motivation	Antony et al. (2007); Bhat & Jnanesh (2014); Christianson et al. (2005); Snyder & McDermott (2009).
	Communication	Adams et al. (2004); Al-Balushi et al. (2014); Antony et al. (2007); Arbune et al. (2015); Burström et al. (2014); Laureani et al. (2013).
Projects	Project selection	Antony et al. (2007); Arbune et al. (2015); Christianson et al. (2005); Kim et al. (2009).
	Customer focus	Adams et al. (2004); Andersen & Røvik (2015); Snyder & McDermott (2009).
	Data	Al-Balushi et al. (2014); Andersen et al. (2014); Arbune et al. (2015); Chassin (2008); Kim et al. (2009).

In general, successful LSS projects require an organization to be prepared for change (Holden, 2011), exhibiting characteristics of a continuous learning environment (Aij et al., 2013). One way to start change based on LSS is to introduce small projects, anchor changes, and promote small wins as a way to increase change momentum (Arbune et al., 2015). When change momentum is slowly built within a healthcare organization, it has been shown that healthcare professionals may be willing to reduce their autonomy for the greater good of the hospital (Leggat, et al. 2015).

3.3. Factors Preventing Successful LSS Projects

Contrary to identifying those factors that enable success in the LSS project, different authors have identified challenges and barriers that prevent LSS initiatives from being successful (Taner, et al. 2007), a summary of which is given in Table 3. There are much fewer papers that report these challenges and barriers, however, perhaps due to the bias of authors and journals to only published positive results. The preventative factors are narrated according to the groupings of Management, Preparation, People, and Projects as in Table 2.

Table 3. Factors Preventing Successful LSS Implementations in Healthcare

Group	Challenges
Management	1- Lean and Six Sigma not part of the operations strategy 2- Lack of commitment 3- Fuzzy goals
Preparation	1- Lack of healthcare consultants and educators 2- Unclear responsibilities 3- Lack of training
People	1- Weak ownership 2- Resistance to culture change, particularly by physicians 3- Hierarchical structure and silos
Projects	1- Identify processes 2- Lack of focus 3- Difficulty to obtain data

The strongest preventative factor is resistance to culture change, primarily by clinicians and physicians (Taner et al., 2007). Implementations that attempt to use wholesale tools in the LSS initiative that are not tailored to the particular problem or user group often bring resistance (Gupta, et al. 2016). Other barriers include weak ownership, unclear goals, unclear roles and responsibilities, and a lack of managerial commitment (Gupta et al., 2016). Finally, interventions that do not effectively measure and report the effects of LSS implementation to stakeholders lack sustainability (Gupta et al., 2016).

4. Discussion

The body literature on LSS in healthcare has matured over the past many years, covering a broad array of research activities and exemplifying several factors that enable and prevent success. Some observations from this collective review, however, suggest that there is room for improvement, specifically in statistical design, breadth of application, reporting of patient centered outcomes, and bias in the literature.

First, many authors have claimed that many research papers on LSS in healthcare have a crucial weakness in their statistical research design (Brackett, et al. 2013; Deblois & Lepanto, 2016). As in any scientific study, a weak design gives rise to inappropriate analyses, threatens validity, and lacks power (Gupta et al., 2016). Moreover, it is difficult for LSS methodology to gain acceptance as scientifically validated practice for process improvement in healthcare without sound designs (Gupta et al., 2016). A second observation is that many articles consider only a narrow application of LSS in a healthcare setting, without considering the effects on the organization as a whole (Mazzocato, et al. 2010), making it difficult to claim that LSS is beneficial as a whole (Andersen & Røvik, 2015). A third observation is a lack of hard evidence related to LSS improving patient related outcomes in healthcare (DelliFraine, et al. 2010). There is empirical evidence that this is so, but only limited knowledge of how and why (DelliFraine et al., 2010). The final observation is that while there are many case studies describing positive implementations of LSS, there are few that detail failed implementations. In fact, there is not a single publication that firmly criticizes the use of LSS in a healthcare setting (DelliFraine et al., 2010). Not having such papers in the body of literature misses a key learning opportunity into practical challenges and roadblocks (Glasgow, et al. 2010).

Although these gaps in the literature may be applicable to other improvement programs in healthcare, this research does not attempt to generalize the findings to those programs. Future research should be conducted in order address that.

5. Conclusion

This study presents a comprehensive literature review of the nearly two decades of research on the use of LSS in healthcare. In total, 368 research articles published through December 2018 were amassed using a broad inclusion criterion. The articles were classified according to the 5w's, and systematically reviewed for factors the enable or prohibit LSS implementation.

Learning from the published literature and closing the gap in future publications is the first step to fully realizing the benefits of LSS in healthcare (Hasle, et al. 2016). While there is a plethora of reported evidence of LSS being successful in narrow instances, there is not nearly as much evidence of what not to do or what might go wrong. To have full learning, both the positives at an organization and societal levels, and the negatives in specific instances need to be explored and reported upon. In the next two decades, we suggest that the LSS literature embrace this full learning spectrum, and that reported projects follow a strong statistical design to increase scientific validity.

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