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# Pharmaceutical Supply Chain Transformation through Application of the Lean Principle: A Literature Review

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**Abstract:**

***Purpose:*** The aim of this paper is to review relevant previous literature in order to identify gaps in the existing research relating to the lean application within the Pharmaceutical Supply Chain.

***Design/methodology/approach:*** A systematic literature review is undertaken to analyze and classify the previous literature into four categories, namely; the supply chain area, research approach, research objective, and lean supply chain elements.

***Findings:*** The results indicated that most attention was focused on manufacturing, while upstream suppliers, downstream activities and the entire supply chain process have received comparatively scant consideration. Similarly, the issues of information technology management, supplier management, customer relations, and logistics management, in addition to practitioner involvement represent inadequately developed topics. Future research should, therefore, address these omissions, while also including the integration of quality compliance and digital innovation in as far as they relate to pharma 4.0.

***Practical implications:*** This article serves as a guide to acquiring adequate knowledge of lean application in the Pharmaceutical Supply Chain in order to support practitioners and researchers in their future work.

***Originality/value:*** This study represents one of the limited number of reviews of the relevant literature on the subject which is potentially helpful in developing a roadmap of lean principle application to the Pharmaceutical Supply Chain.

***Keywords:*** lean principle, pharmaceutical, supply chain, literature review, lean supply chain.

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## 1. Introduction

The Pharmaceutical Supply Chain (PSC) is more complicated and challenging than that utilized in other industries, while being strictly regulated due to its direct impact on human health and safety (Mehralian, Moosivand, Emadi & Asgharian, 2017). Drug quality must be effectively assured at the appropriate point, quality and time across the entire chain from supply to consumption (WHO, 2010). Therefore, the PSC is not only required to provide high-quality, safe products, but also to ensure excellent service (Mouaky, Berrado & Benabbou, 2016) and regulatory compliance (Sieckmann, Ngoc, Helm & Kohl, 2018).

For many years, pharmaceutical companies were in the enviable position of enjoying excellent profit margins due to the percentage expenditure on goods being relatively low vis-a-vis their total cost structure (Garza-Reyes, Betsis, Kumar & Radwan Al-Shboul, 2018). Accordingly, the production lead time required 120 to 180 days, a significantly longer period than that of the consumer-packaged goods industry at only 3-7 days (OPPI & PricewaterhouseCoopers, 2011). This condition induced the industry to implement the simple strategy of buffering long lead times by maintaining extremely large inventories in order to avoid drug shortages (Shah, 2004). In this sense, the industry generally maintained finished product inventories for between 60 and 90 days, considerably longer than the consumer goods industry's holding period of 10 to 40 days (OPPI & PricewaterhouseCoopers, 2011). Based on McKinsey & Company benchmark, the PSC costs resulted mainly from maintaining inventories and obsolete products which accounted for 50% of their output (Alicke, Ebel, Schrader & Shah, 2014). Since industry is subject to increasing competition Elbermawy, Al Manhawy and Ibrahim (2014) argued that the PSC must adapt its conventional practices in order to carry out the process. However, these do not constitute easily achievable objectives due to the high level of interdependency, uncertainty, and unpredictability inherent in PSC processes (Papalexi, Bamford & Dehe, 2016).

Alicke and Lösch (2016) argued that the lean principle represents one of the most effective systems for eliminating waste within the supply chain since up to half the cost of PSC was hidden and unmanaged. In this regard, Papalexi et al. (2016) recommended that the pharmaceutical industry adopt the lean principle in its supply chain practices because its application to the PSC could be seen as a potential solution for improving the efficiency of existing processes (Mouaky et al., 2016). The literature revealed that many organizations have benefited from the application of lean supply chains to improve responsiveness at lower cost (Jasti & Kodali, 2015). Even though the lean principle is not restricted to a specific industrial sector (Ugochukwu, Engstrom & Langstrand, 2012), this study established the fact that the academic literature focusing on lean initiatives within the PSC remains limited. Previous contributions were found to be more focused on the non-pharmaceutical industry sector.

For instance, Tortorella, Giglio, Fettermmann and Tlapa (2018) reviewed the literature in order to establish the extent to which lean supply chain practices had been adopted within automotive and metallurgical sector manufacturing companies in Brazil. Meanwhile, Ciccullo, Pero, Caridi, Gosling and Purvis (2018) reviewed the literature relating to the integration of environmental and social sustainability pillars within the lean and agile supply chain management paradigms of industry in general. Shah and Ganji (2017) conducted a literature review of lean production and supply chain innovation intended to improve the performance of baked foods suppliers. Jasti and Kurra (2017) examined the reliability and validity of the existing lean supply chain framework within several industry sectors, including those of automotive and machine production. Another example was provided by Marodin, Tortorella, Frank and Godinho Filho (2017) who investigated the impact of lean shop floor practice and lean supply chains on quality and inventory turnover. The research respondents were largely drawn from the automotive and metal industry sectors.

Despite the contribution of the previous literature to the development of lean supply chain concepts, this study argues the need to address certain shortfalls, due to the unfeasibility of generalizing the findings and conclusions contained there to other industries (Jasti & Kurra, 2017). The present study supports the view of Ugochukwu et al. (2012) that this previously neglected subject requires further exploration. Their opinion inspired an in-depth review of the previous literature on the lean principle to identify the extent of its adoption within the PSC.

Against this background, two research objectives were identified. The first was to discuss the evidence, patterns, contradictions and inconsistencies present in the previous literature. The second was to identify any gaps and highlight underdeveloped areas as an opportunity for future research. In order to achieve these objectives, the study focuses on analysis and classification of the supply chain, its elements, lean supply chain objectives and the research methodology applied. The findings will, consequently, support researchers and practitioners in pharmaceutical organizations to understand the extent and implications of research for lean principle implementation within supply chain activities. This study also contributes to the increasing literature on the subject by providing insights and suggestions for future areas of investigation.

## 2. Literature Review

### 2.1. Lean Supply Chain

Lean philosophy constitutes a systematic method whose objective is greater production in a shorter period of time, while requiring less human effort, space, and equipment. This will increase customer value by eliminating waste within the process (Womack & Jones, 1996; Machado, Scavarda & Vaccaro, 2014). Historically, the automotive manufacturer Toyota incorporated lean thinking into its Toyota Production System (TPS) applied throughout the manufacturing process in order to improve operational excellence (Joosten, Bongers & Janssen, 2009). Meanwhile, the lean supply chain constitutes an adaptation of lean manufacturing principles as applied to supply chain activities that create value for customers by eliminating waste (Anand & Kodali, 2008). Recent competition is no longer between companies, but within the supply chain (Alkunsol, Sharabati, Al Salhi & El-Tamimi, 2018). Hence, extending lean practice to the entire supply chain is important since a company's inability to vie with competitors depends exclusively on its internal organization (Jasti & Kurra, 2017). In this regard, the company needs to integrate the downstream and upstream activities with a focus on total value stream competitiveness to deliver greater customer benefit (Manzouri, Ab Rahman, Saibani & Zain, 2013). According to Ugochukwu et al. (2012), any company operating a lean supply chain in its processes demonstrates a streamlined flow and effective communication across the entire supply chain. The numerous basic principles in traditional and lean supply chain practices are summarized in Table 1.

A comprehensive literature review has been adopted by researchers to analyse the evolution of the lean principle within the supply chain context. Ugochukwu et al. (2012) reviewed the literature to identify the trends and issues in the field. An article by Martínez-Jurado and Moyano-Fuentez (2014) evaluated the links between lean management, supply chain management and sustainability identified in the literature. Jasti and Kodali (2015) performed an extensive analysis of literature published between 1988 and 2013 to identify the elements constituting the lean supply chain framework. Another literature review was completed by Ciccullo et al. (2018) who studied 73 academic papers which addressed the integration of lean, agile and sustainable supply chain management paradigm. A recent work contributed by Sinha and Matharu (2019) reviewed 447 research articles drawn from 51 academic journals. They indicated that the interest in the lean principle has gained momentum over the past few years due to global competition and increasing operational costs.

| Basic Principle | Traditional Supply Chain | Lean Supply Chain |
|---|---|---|
| Relationship patterns | Sporadic, transaction-focused | Collaborative, mutually beneficial |
| Contract terms | Short-term | Long-term |
| Number of suppliers | Multiple source supply | Single or dual supply |
| Supplier selection criteria | Price | Performance |
| Pricing practice | Competitive bids | Target costing |
| Technical support | Non-existent focus/limited program | Supplier development program |
| Communication and information sharing | Infrequent | Frequent and open |
| Problem-solving | Limited feedback, low level of shared risk | Frequent feedback, a high level of shared risk |
| Quality | Inspection-intensive | Designed-in, strict process and evaluation systems |

Table 1. Traditional Supply Chain vs. Lean Supply Chain (Martínez-Jurado & Moyano-Fuentez, 2014; Manzouri et al., 2013)

However, lean integration across the supply chain network requires further significant development in order to be successfully adapted (Tortorella et al., 2018). Numerous organizations have struggled to implement lean supply chains due to a lack of knowledge, ignoring the potential synergies between the supply chain stage and focusing exclusively on the narrow scope (Jasti & Kodali, 2015). Marodin et al. (2017) stated that very little empirical research had integrated both upstream and downstream activities since most focused on the individual dimension. Hence, Tortorella et al. (2018) highlighted the need to investigate integrated lean practice application in the supply chain as a means of achieving competitive advantage.

### 2.2. Lean Supply Chain in the Pharmaceutical Industry

The prodigious contemporary challenges for the pharmaceutical industry are those of reducing operating costs and timelines to improve overall efficiency producing a significant rise in profits (Gebauer, Kickuth & Friedli 2009). Keeling, Lösch and Schrader (2010) reported a huge opportunity for the PSC to improve its processes. Zubedi and Khan (2014) stated that lean application changes the mindset, operating system and management system of industry to provide improved products more rapidly and cost effectively. Hence, it is essential that industry understands the methods of adapting lean practice in order to boost operational excellence and profitability (Gebauer et al., 2009).

In contrast to the rapid and successful implementation of the lean principle in other industrial operations (Sieckmann et al., 2018), Alkhalidi and Abdallah (2018) claimed that lean initiatives have yet to be widely adopted by the pharmaceutical sector. This is attributable to industry's greater focus on quality that is strictly controlled by regulatory compliance (Wan Ibrahim, Rahman & Abu Bakar, 2017). It is mandatory for the PSC parties to comply with relevant legislation and regulations to ensure that drug quality is maintained by safe and effective handling across the entire chain (WHO, 2010). However, lean practices and regulatory compliance were in stark contrast to each other; the lean principle focusing on waste elimination, value creation and simplify procedure, while regulatory compliance concentrates on quality and safety (Jaiganesh & Sudhahar, 2013). Regulatory compliance could be regarded as a challenge, a source of conflict and a barrier to implementation of lean practice in the field (Sieckmann et al., 2018). The compliance protocol requiring numerous written procedures, inspections and testing was time-consuming and caused delays in the production process (Khlat, Harb & Kassem, 2014). As a consequence, applying a Just in Time system within this sector is challenging, since when maintaining service levels, a sizable buffer stock often compensates for a long lead time (Papalexi et al., 2016).

Against this background, Pavlović and Božanić (2010) argued that lean principle and regulatory compliance demonstrates certain overlaps in their scope to provide value creation through standardized work, relationships and communication, simple flow and improvement. The evidence supporting synergy was contributed by Houborg (2010) who investigated lean implementation in a Danish pharmaceutical company. He claimed that the integration of these best practices had successfully reduced lead times in the overall supply chain by 50-75%, while doubling production with the same resources. This assertion was also confirmed by Bevilacqua, Ciarapica, De Sanctis, Mazzuto and Paciarotti (2015) who applied the lean tool to standardizing working practice under Good Manufacturing Practice (GMP) procedures. This resulted in batch change and changeover time reduction of 50%, while increasing overall equipment effectiveness by 25%.

Alicke and Lösch (2016) believed applying lean principles to the PSC could become a significant competitive differentiator, while not requiring major capital investments. Redesigning the operation is required to ensure regulatory compliance while simultaneously supporting continuous improvement (Pavlović & Božanić, 2010). Given that the PSC has unique and complex characteristics (Mehralian et al., 2017), when it adopts lean principles it needs to avoid merely adopting generalizations from other industries (Anand & Kodali, 2010). However, the adoption of lean initiatives within the PSC requires further exploration since it is still in its early stages (Singh, Kumar & Kumar, 2016).

Compared to other pharmaceutical industry-related sectors such as those mentioned in the previous literature there is limited discussion of lean supply chain initiatives. Therefore, in order to close this gap, further investigation of PSC transformation through lean principle application is recommended to maintain its relevance to the current situation. The findings will help to facilitate the future work of practitioners and researchers, while also making a significant contribution to the existing body of knowledge.

## 3. Research Methodology

### 3.1. Literature Selection

This article constitutes a review of the previous literature on lean application within the pharmaceutical industry and follows several steps as suggested by Fattah, Rehn, Reierth and Wisborg (2013) (see Figure 1). Four scientific databases were consulted, namely; ProQuest, Science Direct, Research Gate, and Google Scholar, while recommendations from peers were also collated. In establishing the search criteria, the study specified keywords for the identifying of relevant literature. The lean-related keywords to be applied during the search contained the phrase: 'lean supply chain' in conjunction with other terms such as 'supply chain' and 'pharmaceutical'.

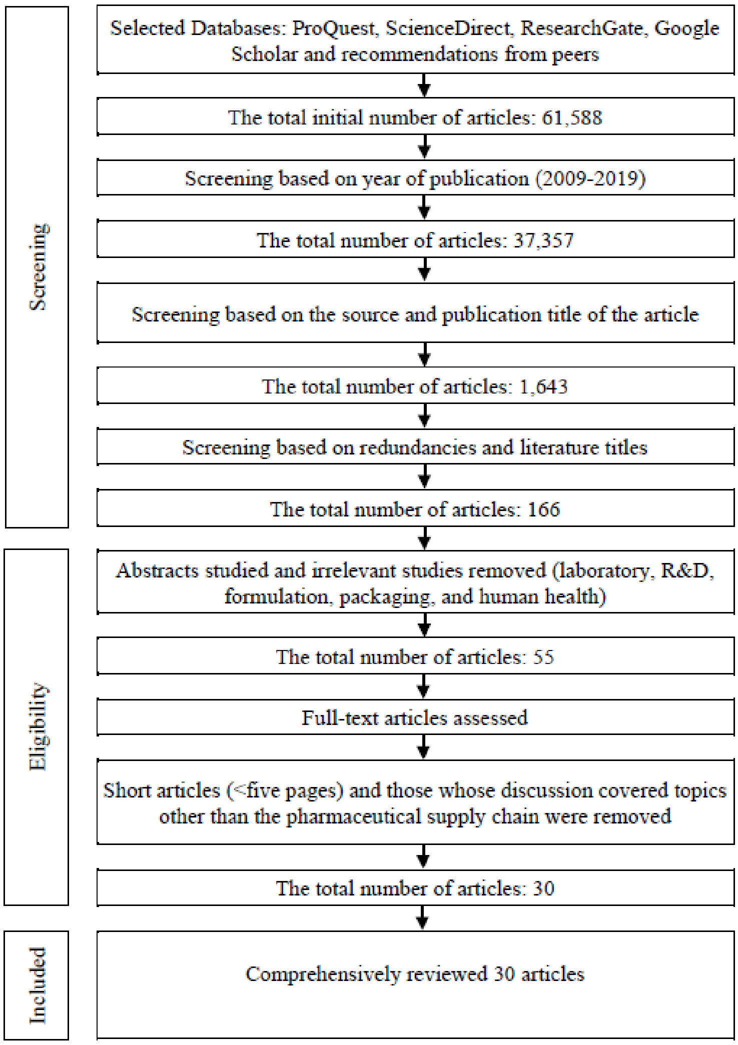


Figure 1. Literature Selection

This study employed data base-supplied filters used to assess the articles against three criteria, namely; the year of publication, title, and source. Since it aimed to appraise recent developments in this area, only those articles published during the period 2009-2019 were selected. An additional criterion, the relevance of titles and abstracts, was applied to reduce the number of articles to one that was manageable with any redundancies being omitted. The selection process yielded thirty articles which were subjected to an appropriately comprehensive review.

### 3.2. Literature Classification

Thirty articles were assessed against the four criteria (see Table 2) of 'supply chain area,' 'lean supply chain objective', 'lean supply chain element,' and 'research approach'. The supply chain area was sub-divided into three broad sections; lean supply, lean distribution, and the lean supply chain as the integration of end-to-end supply chain activities (Anand & Kodali, 2008). The identified PSC actors included; suppliers, manufacturers, distributors, healthcare service providers, customers, prescribers, and pharmacists (Mouaky et al., 2016).

| Dimension | Remark | Reference(s) |
|---|---|---|
| Supply chain areas | The three aspects of lean implementation in the supply chain area comprise:<br>• Lean supply (upstream activities), including supply and production.<br>• Lean distribution (downstream activities), including warehousing, transportation, retailing and customer service.<br>• Lean supply chains representing the integration of end-to-end supply chains.<br>PSC members comprise suppliers, manufacturers, distributors, healthcare service providers, customers, prescribers, and pharmacists. | Anand & Kodali (2008);<br>Mouaky et al. (2016) |
| Lean supply chain objective | The objective of lean implementation is the achieving of operational excellence (reduced costs, shortened lead times, and improved quality) through the eradication of waste. | Womack & Jones (1996) |
| Lean supply chain element | The tools and techniques required to move the company from traditional practice to a lean supply chain, including top management commitment, information technology (IT) management, supplier management, elimination of waste, JIT production, customer relationship management, logistics management, and continuous improvement. | Jasti & Kodali (2015) |
| Research approach | A roadmap and the tools employed to achieve the research objectives, including; surveys, case studies, literature reviews and action research. | Costa & Godinho Filho (2016) |

Table 2. Literature Classification

Meanwhile, the objective of a lean supply chain is to create customer value by reducing costs, shortening lead times, and improving quality through the elimination of waste within the process (Womack & Jones, 1996). Since cost, time and quality represent the criteria adopted to measure the degree of leanness (Costa & Godinho Filho, 2016), consequently, these criteria were also applied to categorize the articles. Lean supply chain elements such as tools and techniques that essential to achieve lean objectives (Jasti & Kodali, 2015) also gained a focus of this study. Consequently, the articles were grouped based on these elements. The articles were also classified according to their respective research approaches; e.g., case study, survey, literature review, and action research (Costa & Godinho Filho, 2016). Assessment and analysis were conducted to determine previous knowledge gained, identify the research gap, and provide recommendations regarding future investigations.

## 4. Findings

### 4.1. Supply Chain Area

As can be seen in Figure 2, the topic of Lean Supply discussed in 63.3% of articles dominates the field. In contrast, analyses of lean distribution have failed to attract equal attention, being the focus of a mere 33.3% of publications. This finding supports the opinion of Martínez-Jurado and Moyano-Fuentes (2014) who mentioned that the number of studies of lean application in the downstream area is relatively low compared to that relating to the upstream variety. Meanwhile, only 3.3% of articles discussed the lean supply chain's integrative character, thereby indicating that the topic lacked exposure. Further support for this view was provided by Anand and Kodali (2008), who had argued earlier that the integrated supply chain was underdeveloped.

Figure 3 shows the distribution of articles across the PSC members. Discussion centering extensively on manufacturers featured in 63.3% of articles, while that of manufacturing-related lean practice under the cGMP was the most widely featured (Houborg, 2010; Chowdary & George, 2012; Pavlović & Božanić, 2010; Jaiganesh & Sudhahar, 2013; Khlat et al., 2014). The second topic of significant concern in manufacturing is that of lean practice combined with six sigma to become lean sigma (Ismail, Ghani, Ab Rahman, Deros & Haron, 2014; Elbermawy et al., 2014; Alkunsol et al., 2018).

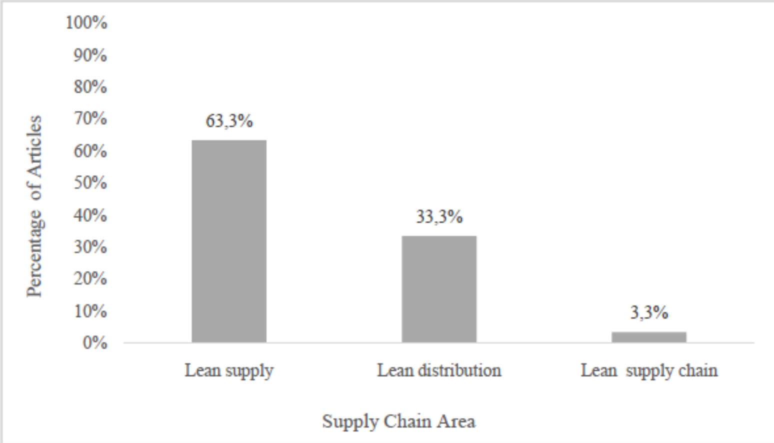


Figure 2. Article Distribution based on Supply Chain Area

Meanwhile, 26.7% of articles were found to focus on the lean principle as a strategic approach for healthcare service providers. Even though lean supply chain application in the healthcare industry is relatively new (Khorasani, Maghazei & Cross, 2015), as mentioned by Curatolo, Lamouri, Huet and Rieutord (2013) the existing evidence confirms that the lean principle has been adapted effectively to this sector. Interestingly, the healthcare sector has focused on inventory management, while progressing from push delivery to strategic information system-based logistical models. For instance, Guimarães, Carvalho and Maia (2013) explained vendor-managed inventory (VMI) implementation, while Papalexi et al. (2016) explored the implementation of the Kanban system as a means of improving operations. Meanwhile, the use of prescribing technology such as no carbon required (NCR) and digital scanning in medication distribution system in hospital has been addressed by Ker, Wang, Hajli, Song and Ker (2014).

Distribution is an essential activity within integrated PSC since it protects drugs against counterfeiting, illegal importation, theft and the manufacture of substandard medicines (WHO, 2010). Mouaky et al. (2016) and Papalexi et al. (2016) highlighted the issue of inefficient distribution which negatively impacts the pharmaceutical sector. However, only 6.7% of articles addressed lean implementation by distributors. Even though delivery of the product from the manufacturer to the patient is crucial within PSC, the issue of pharmaceutical transportation has only been addressed by Alicke and Lösch (2016). Folinas and Ngosa (2013) focused on lead time improvement in the operations of a pharmaceutical warehousing and distribution company through the application of value stream mapping tools.

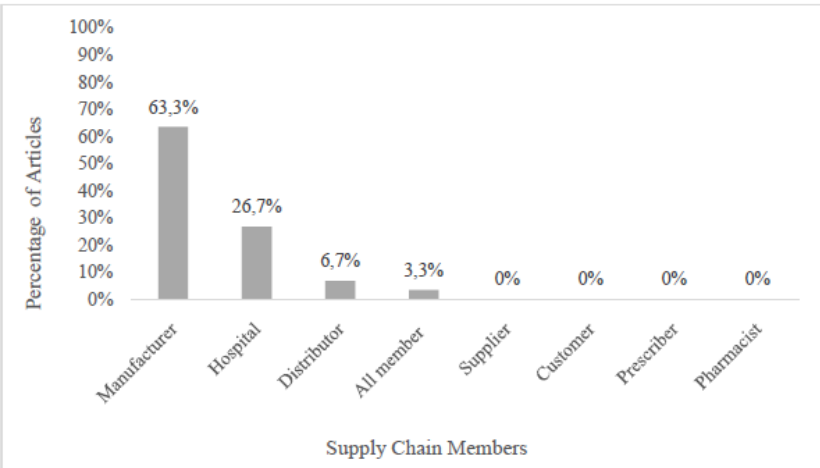


Figure 3. Article Distribution based on Supply Chain Member

However, this study found only 3.3% of articles by Mouaky et al. (2016) that focused on all supply chain members through implementation of the Kanban system as a means of managing multi-echelon PSC inventories. Accordingly, this study indicated that all previous authors appeared to ignore the discussion of lean principle in the suppliers, customers, prescribers, and pharmacists.

### 4.2. Lean Supply Chain Objectives

The lean supply chain objectives consisted of three aspects: producing a higher quality product at the lowest possible cost with the shortest lead time through the total elimination of waste (Ugochukwu et al., 2012). The focus of the lean principle was invariably on the customer and value stream (Womack & Jones, 1996). Meanwhile, the PSC aims to deliver a safe and effective product based on quality compliance (Jaiganesh & Sudhahar, 2013). This study revealed that the majority of the articles (56.7%) within this category focused on the combination of cost, lead time, and quality (see Figure 4). 20% of articles emphasized cost and time, 10% highlighted cost and quality, 6.7% accentuated time and quality, and 3.3% focused on cost and the factor of time. There is no research focus on quality only.

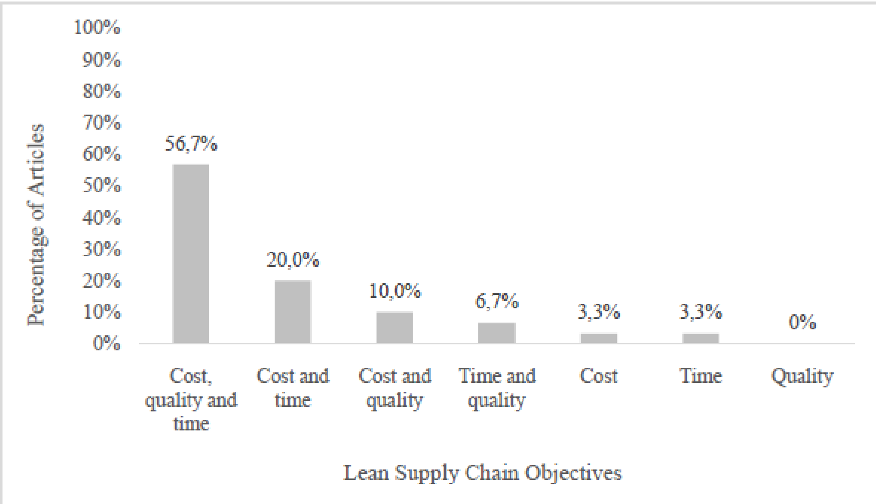


Figure 4. Article Distribution based on Lean Supply Chain Objectives

Significant advantages resulted for the pharmaceutical industry through its implementation of the lean principle (Nenni, Giustiniano & Pirolo, 2014; Srinivasan & Shah, 2018). This was confirmed by the current study which highlights several authors' assertion that the lean principle has produced various improvements (see Table 3). Keeling et al. (2010) argued that industry is underperforming in its management of working capital. Hence, inventory reduction was prioritized for improvement within PSC since it is a substantial waste which needs high investment but achieves a low return (Singh et al., 2016). The tremendous opportunities exist to improve PSC inventory management by integrating its including; planning, production, distribution and purchasing (Keeling et al., 2010). As far as cost-benefit is concerned, the study found it to be primarily generated by reductions in inventory that lead to less storage space as highlighted Papalexi et al. (2016). This evidence showed positive progress of the PSC that has started to concern on its working capital performance to provide higher company's profitability.

Lead time reduction has resulted mainly from shorter processing times. Long process time remains a major issue for the PSC (Shah, 2004). The focus on improvements in lead time enables it to accelerate response times and the delivery of goods to market, thereby enhancing the quality of service to the customer (Ismail et al., 2014). Karam, Liviu, Cristina and Radu (2018) provided evidence that the shorter process lead time has promoted higher production output. Meanwhile, the objective of enhancing quality is achieved by improving the quality of products or services for the customer. This focus was closely aligned with the recommendation of Singh et al. (2016) that the PSC should address quality issues which remain challenging.

| Objective | Improvement | Reference |
|---|---|---|
| Cost | Reduced inventory level | Houborg (2010); Chowdary & George (2012); Guimarães et al. (2013); Elbermawy et al. (2014); Nenni et al. (2014); Bevilacqua et al. (2015); Khorasani et al. (2015); Costa and Godinho Filho (2016); Mouaky et al. (2016); Papalexi et al. (2016) |
| | Improved production efficiency | Houborg (2010); Karam et al. (2018); Sieckmann et al. (2018) |
| | Reduced storage area | Chowdary & George (2012); Nenni et al. (2014); Papalexi et al. (2016) |
| | Reduced workforce number and overtime | Chowdary & George (2012); Costa & Godinho Filho (2016) |
| | Reduced transaction cost | Guimarães et al. (2013); Ker et al. (2014) |
| | Improved productivity | Ismail et al. (2014); Zubedi & Khan (2014); Alicke and Lösch (2016); Costa & Godinho Filho (2016); Mouaky et al. (2016); Srinivasan & Shah (2018) |
| Time | Reduced lead time processing | Houborg (2010); Folinas & Ngosa (2013); Elbermawy et al. (2014); Ismail et al. (2014); Ker et al. (2014); Khlat et al. (2014); Nenni et al. (2014); Bevilacqua et al. (2015); Khorasani et al. (2015); Alicke & Lösch (2016); Costa & Godinho Filho (2016); Papalexi et al. (2016); Wan Ibrahim et al. (2017); Karam et al. (2018); Srinivasan & Shah (2018) |
| | Reduced customer query cycle time | Curatolo et al. (2013); Folinas & Ngosa (2013) |
| | Reduced lead time quality approval | Houborg (2010) |
| | Reduced set up time | Nenni et al. (2014) |
| | Reduced lead time change over | Houborg (2010); Bevilacqua et al. (2015) |
| Quality | Improved quality of product or service | Joosten et al. (2009); Pavlović & Božanić (2010); Chowdary & George (2012); Guimarães et al. (2013); Khlat et al. (2014); Machado et al. (2014); Alicke and Lösch (2016); Papalexi et al. (2016); Karam et al. (2018); Sieckmann et al. (2018) |
| | Reduced customer complaints | Folinas & Ngosa (2013); Khorasani et al. (2015); Alkhalidi & Abdallah (2018) |
| | Reduced waste, defects and errors | Gebauer et al. (2009); Houborg (2010); Ker et al. (2014); Costa & Godinho Filho (2016); Alkhalidi & Abdallah (2018); Alkunsol et al. (2018) |

Table 3. Improvements Resulting from Lean Supply Chain Implementation

### 4.3. Lean Supply Chain Elements

Thirty research articles were categorized on the basis of the lean supply chain element proposed by Jasti and Kodali (2015) with the following attributes: E1= Information technology management, E2=Supplier management, E3=Elimination of waste, E4=JIT production, E5=Customer relationship management, E6=Logistics management, E7=Top management commitment, E8=Continuous improvement (see Table 4).

| No | Element of Lean Supply Chain | Sub Element |
|---|---|---|
| 1 | Information technology management (E1) | • Use of EDI for inter-departmental communication<br>• Centralized documentation database<br>• Enterprise resource planning system<br>• Information technology employed in the customer base<br>• Effective and transparent information flow across the supply chain<br>• Use of bar coding and scanners within logistical systems<br>• Use of bar coding and scanner in logistics systems<br>• Electronic commerce<br>• Modelling analysis and simulation tools<br>• Computer-aided, decision-making support systems |

| No | Element of Lean Supply Chain | Sub Element |
|---|---|---|
| 2 | Supplier management (E2) | • Strategic supplier development<br>• Supplier evaluation and certification<br>• Long-term supplier partnership<br>• Long-term supplier partnerships<br>• Supplier involvement in design<br>• Supplier feedback<br>• Supplier proximity<br>• Single source and reliable suppliers or limited suppliers<br>• Single source and reliable suppliers or few suppliers<br>• Cost-based negotiations with suppliers<br>• Cost-based negotiation with suppliers<br>• Manage suppliers through commodity teams<br>• Joint decisions regarding cost savings |
| 3 | Elimination of waste (E3) | • Standard products and processes<br>• Standard containers<br>• Focused factory production<br>• Design for manufacturing<br>• Flexible manufacturing cells or U-shape manufacturing cells<br>• Visual control<br>• Single minute exchange of die<br>• Andon<br>• 5S<br>• Point-of-use tool system<br>• Elimination of the seven forms of waste throughout the supply chain<br>• Eliminate the seven wastes throughout supply chain |
| 4 | JIT production (E4) | • JIT deliveries throughout supply chain<br>• Single piece flow<br>• Pull production<br>• Kanban<br>• Production levelling and scheduling<br>• Synchronized operational flow<br>• Plant layout<br>• Point-of-use storage system<br>• Pacemaker<br>• Small lot size |
| 5 | Customer relationship management (E5) | • Specification of value from the customer's viewpoint<br>• Post-sales service to customer<br>• Customer involvement in design<br>• Continuous evaluation of customer feedback<br>• Customer enrichment<br>• Concurrent engineering<br>• Group Technology<br>• Delivery performance improvement<br>• Takt time<br>• Quality function deployment<br>• Failure mode and effect analysis |
| 6 | Logistics management (E6) | • Time window delivery requirements or tight time windows<br>• Effective logistics network design<br>• Consultants as logistics managers<br>• Consignment inventory or vendor-managed inventory<br>• Advanced material requirement planning and scheduling structure<br>• Use of third-party logistics for transportation system<br>• Milk run or circuit delivery<br>• Mastering of the demand forecasting process<br>• Postponement<br>• A, B, C material handling<br>• Elimination of buffer stocks |

| No | Element of Lean Supply Chain | Sub Element |
|---|---|---|
| 7 | Top management commitment (E7) | • Create vision and objectives for lean supply chain<br>• Employee training and education in LSCM<br>• Organization structure and associated relationships<br>• Cross-enterprise collaborative relationships and trust<br>• Joint planning of processes and products with suppliers<br>• Resources allocation<br>• Development of a learning culture-specific organization<br>• Holistic strategy for integrating systems or organizational policy deployment<br>• Employee empowerment<br>• Stable and long-term employment<br>• Leadership development |
| 8 | Continuous improvement (E8) | • Multi-skilled workforce<br>• Built-in quality systems<br>• Value stream mapping through supply chain<br>• New product development<br>• Statistical process control<br>• Quality improvement teams or quality circles<br>• Cross-functional teams within the organization<br>• Use of flat hierarchy<br>• Value engineering |

Table 4. Elements of the Lean Supply Chain (Jasti & Kodali, 2015)

The contents of Table 5 illustrate the type of elements mentioned in previous research culminating in published work predominantly focused on top management commitment (76.7%), continuous improvement (73.3%), elimination of waste (60%), and Just-in-Time production (50%). The relatively less acknowledged elements comprised; Information Technology (IT) management (30%), supplier management (23.3%), customer relationship management (16.7%), and logistics management (6.7%). There were differences in terms of the number and type of elements because previous authors had focused on a specific lean objective. For instance, Sieckmann et al. (2018) who studied lean production in pharmaceutical SMEs concentrated on top management commitment without analyzing technology and information sharing. Similarly, Sieckmann et al. (2018) and Houborg (2010) who had studied improvement culture agreed that leadership and knowledge were essential since a lack of training and expertise would precipitate lean deployment failure (Sieckmann et al., 2018). However, Houborg (2010) did not emphasize customer relationships during deployment of the improvement initiatives, as recommended by Garza-Reyes et al. (2018). In contrast to Sieckmann et al. (2018), Nenni et al. (2014) focused on the role of IT management and innovation in creating continuous production flow to improve manufacturing, while disregarding top management commitment.

Mouaky et al. (2016) emphasized the role of technology-based coordination and communication in improving inventory strategy, but did not mention supplier-customer relationships or logistics management as highlighted by Alicke and Lösch (2016). Meanwhile, as with Mouaky et al. (2016), Papalexi et al. (2016) paid attention to the importance of technology-based communication between different supply chain stages. Even though continuous improvement is included as the element considered by numerous authors to be of paramount importance in successful lean implementation, it was not regarded as a crucial factor by Papalexi et al. (2016), Muoaky et al. (2016), and Ker et al. (2014). Papalexi et al. (2016) placed greater importance on communication between different supply chain stages, in addition to the availability of knowledgeable and reliable suppliers being critical to successful lean deployment. Ker et al. (2014) focused on the application of digital technology to promote improvement in multi-hospital health systems. A contrasting opinion was presented by Al Hasan and Al-Zu'bi (2014) who argued that human aspects such as employee involvement, rather than continuous improvement and waste elimination, significantly influence radical product innovation.

| No | Year | Author | Element of Lean Supply Chain | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | E1 | E2 | E3 | E4 | E5 | E6 | E7 | E8 |
| 1 | 2009 | Gebauer et al. | | | | x | | | x | x |
| 2 | 2009 | Joosten et al. | | | x | | | | x | |
| 3 | 2010 | Houborg | | x | | | | | x | x |
| 4 | 2010 | Pavlović and Božanić | | | x | x | | | x | x |
| 5 | 2012 | Chowdary and George | x | x | x | x | | | x | x |
| 6 | 2013 | Curatolo et al. | | | x | | | | x | x |
| 7 | 2013 | Folinas and Ngosa | x | x | | x | | | x | x |
| 8 | 2013 | Guimarães et al. | x | x | | x | | x | x | |
| 9 | 2013 | Jaiganesh and Sudhahar | | | | | | | x | x |
| 10 | 2014 | Al Hasan and Al-Zu'bi | | | | | | | x | x |
| 11 | 2014 | Elbermawy et al. | x | | x | | | | | x |
| 12 | 2014 | Ismail et al. | | | x | | | | x | |
| 13 | 2014 | Ker et al. | x | | | | | | | |
| 14 | 2014 | Khlat et al. | | | x | x | | | | x |
| 15 | 2014 | Machado et al. | | | x | x | x | | x | x |
| 16 | 2014 | Nenni et al. | x | | | x | | | | |
| 17 | 2014 | Zubedi and Khan | | | x | x | | | x | x |
| 18 | 2015 | Bevilacqua et al. | | | x | x | | | | x |
| 19 | 2015 | Khorasani et al. | x | | | | | | x | x |
| 20 | 2016 | Alicke and Lösch | x | x | x | | x | x | x | x |
| 21 | 2016 | Costa and Godinho Filho | | | x | x | | | | x |
| 22 | 2016 | Mouaky et al. | x | | | x | | | x | |
| 23 | 2016 | Papalexi et al. | | x | | x | x | | x | |
| 24 | 2017 | Wan Ibrahim et al. | | | x | | | | x | x |
| 25 | 2018 | Alkhalidi and Abdallah | | | | x | | | x | x |
| 26 | 2018 | Alkunsol et al. | | | x | | | | x | x |
| 27 | 2018 | Garza-Reyes et al. | | | x | x | x | | x | |
| 28 | 2018 | Karam et al. | | | x | | | | x | x |
| 29 | 2018 | Sieckmann et al. | | x | x | | x | | x | x |
| 30 | 2018 | Srinivasan and Shah | | | x | | | | | x |
| | | | 9 | 7 | 18 | 15 | 5 | 2 | 23 | 22 |

Table 5. Article Distribution based on Lean Supply Chain Elements

Figure 5 contains an article distribution list based on each lean supply chain element. In general, this study indicated the presence of more than one element applied in the previous analysis. The majority of authors, 43.3% in total, addressed three elements in their research, while 20% mentioned two elements, and 13.3% made reference to four elements and five elements. Only 3.3% of articles discussed one element and six elements, while another 3.3 % article explored seven elements. At present, no author has addressed all eight elements in a single article.

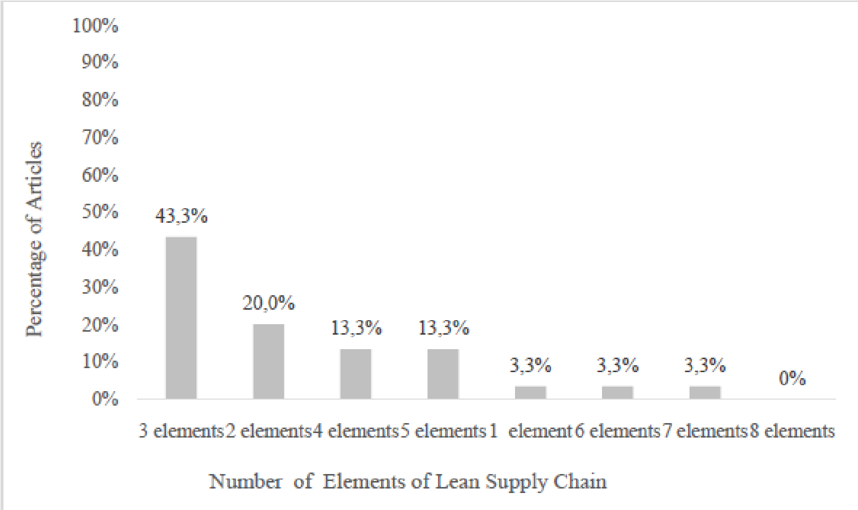


Figure 5. Article distribution based on the number of elements

### 4.4. Research Approach

This category addresses the investigative approaches employed by previous studies. This research found that 40% of articles employed a case study design, with primary data being gathered by means of direct observations (Costa & Godinho Filho, 2016). The second most common approach adopted in the research undertaken for 30% of the articles was that of administering a survey which involved eliciting and collating information from individuals or communities (Costa & Godinho Filho, 2016). 26.7% of articles incorporated a literature review in order to identify and organize relevant explored and unexplored concepts (Curatolo et al., 2013). The least utilized approach was action research whose objective was to promote an understanding of the actions of a group during the changes and improvements to a process (Coughlan & Coghlan, 2002). It featured in only 3.3% of the articles. Figure 6 presents the distribution of articles based on their respective research methodologies.

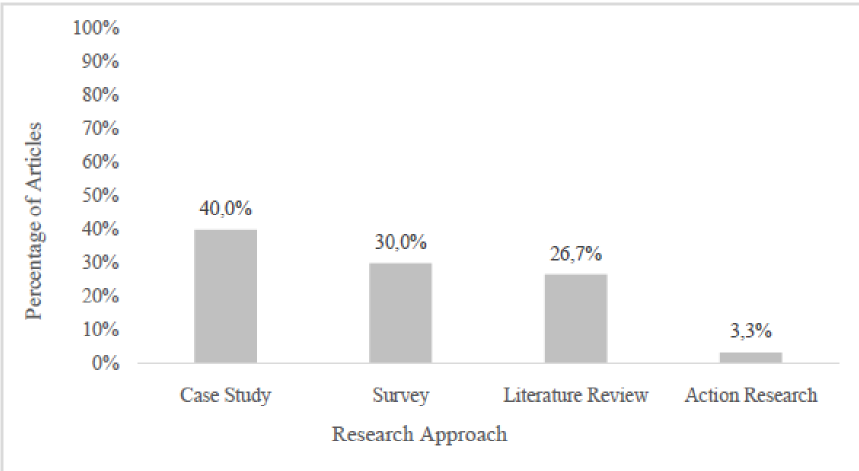


Figure 6. Article Distribution based on Research Approach

## 5. Discussion

With regard to the aforementioned categories, this study identified four major deficiencies. The first indicated that, while the research focus was on upstream manufacturing, the relationship of the lean principle to the supplier, the downstream PSC and the integrated PSC has not been extensively explored. Guimarães et al. (2013) claimed that the lean principle offers multiple benefits to the buyer. However, in the interests of promoting lean practice sustainability, they suggested that the advantages of implementation from the perspective of the supplier require more comprehensive exploration in any future research.

The limited attention paid to distribution in downstream PSC potentially exacerbates the quality issues and leads to higher inventory levels (Singh et al., 2016). The lack of discussion regarding downstream PSC resulted from the inherent tension of striking a balance between the manufacturing and distribution cycles. Lean manufacturing requires relatively stable conditions with levelled production (Heijunka), whereas downstream PSC experiences high variability in market demand (Martínez-Jurado & Moyano-Fuentes, 2014). Moreover, in a heavily regulated industry, downstream PSC activity is even more complicated in the case of ethical products. This involves the physician deciding, through the issuing of prescriptions to patients, who can legally obtain drugs and secondly, the insurance companies which reimburse any payment involved (Scherer, 2000). Papalexi et al. (2016) recommended the application of the lean principle to upstream and downstream PSC activity as a means of achieving integration and, by extension, greater effectiveness since an imbalanced focus impedes lean PSC sustainability.

The second gap relates to lean objectives from the perspective of quality. The pharmaceutical industry enforces extremely strict standards where the existence of a regulatory authority is crucial to controlling the quality and safety of drugs (Shah, 2004). According to the WHO (2010), every party actively engaged in the distribution of pharmaceutical products must comply with current regulations, including; current Good Manufacturing Practice (cGMP), Good Storage Practice (GSP) and Good Distribution Practice (GDP). In addition, identification of risk throughout the PSC is essential to managing uncertainty and preventing destructive effects in terms of the quality and safety of the health system that could endanger a patient's life (Abolghasemi, Khodakarami & Tehranifard, 2015). However, this study found that in the previous literature the quality aspect concentrated narrowly on scrap, customer complaints, service quality, and lean cGMP practice. None has discussed quality risk management relating to GSP and GDP as mandatory within PSC.

The third gap related to the lean supply chain element, namely; supplier management, customer relationship management, logistics management and IT management, has attracted little attention in previous studies. Supplier partnerships and long-term strategic alliances constitute the main success factors in lean principle implementation (Khorasani et al., 2015). The lean principle applied through Just-in-Time management requires supplier management to oversee supply reliability in order to prevent the risk of drug shortages (Papalexi et al., 2016). Supplier involvement had a positive effect in achieving the desired level of quality (Garza-Reyes et al., 2018). Guimarães et al. (2013) argued that vendor-managed inventory implementation entails strong partnerships, information integration and collaboration with the supplier. However, this study found that establishing a long-term relationship with the key supplier was marked by a lack of discussion within the PSC.

The customer represents the focus of lean principles (Machado et al., 2014). Consequently, the relationship with the customer constitutes a key success factor in lean implementation (Sieckmann et al., 2018). Since patient-related demand within healthcare is highly unpredictable due to the diversity of patient characteristics (Postacchini, Ciarapica, Bevilacqua, Mazzuto & Paciarotti, 2016), patient participation in the innovative program will deliver the greatest benefit (Papalexi et al., 2016). For example, comprehensive data on customer consumption will enable the PSC to improve the accuracy of forecasts (Khorasani et al., 2015). However, a lack of consensus with regard to how the PSC should manage the customer relations was evident in the previous literature.

Alicke, Dubeauclard and Schmeink (2017) indicated that numerous opportunities remain for optimizing waste reduction within the pharmaceutical logistic network capable of producing savings of 15%-30% in relation to distribution costs. Accordingly, the PSC should consider the design of reverse logistic optimization to collect, ensure the security of and track the return of drugs through medical channels to the manufacturer for disposal (Singh et al., 2016). In addition, Alicke and Lösch (2016) stated that transportation is crucial to the PSC in ensuring that quality standards are well-maintained when products reach their consumers. However, this study found that logistics management has not been adequately discussed in previous studies.

The exploitation of pharma 4.0 will help companies to create value which supports sustainable commercial growth (Ding, 2018). The lean principle and digital transformation can be applied in tandem to deliver innovation (Sanders, Elangeswaran & Wulfsberg, 2016). The Internet of Think (IoT) enables the disrupting and revolutionizing of the lean principle rendering it relevant to current business trends (Sinha & Matharu, 2019). Integrated IT management is crucial since it enables the PSC to ensure product availability, provide a more rapid customer service and enhance both inventory control and product visibility (Guimarães et al., 2013). Technology-based information sharing provides accurate data that enables the company to reduce delays in decision making (Ding, 2013) and facilitates a rigorous monitoring system, while also promoting improved PSC connectivity (Mouaky et al., 2016). The existence of advanced technologies has promoted a subsequent significant evolution of integration, collaboration and coordination across the entire supply chain through web-based information sharing (Simatupang & Sridharan, 2002). However, the present study found that the majority of previous studies did not refer to this recent interesting topic which could help the PSC in developing digital transformation.

The fourth gap is the absence of an action research approach. From the analysis of the review, few published studies have employed action research to address the research question. This finding reflects that of Näslund, Kale and Paulraj (2010) who reported a limited number of action research-based supply chain management articles being published in the leading journals. The shortcomings of action research as a form of empirical operational management are regarded as rooted in non-specific, unclear and inconsistent activities compared to other research approaches such as case studies and surveys (Coughlan & Coghlan, 2002). Moreover, the validity of the research findings can be compromised due to practitioner involvement in the activity itself which can potentially result in a failure to create a robust conceptual framework (Näslund et al., 2010). Nevertheless, action research has the advantage of elucidating the actual perspective of insiders who have the necessary access and capability to intervene in and influence the project (Coughlan & Coghlan, 2002). Moreover, the approach generates actionable knowledge since the theory is directly applicable to practice in the real world (Näslund et al., 2010).

Several authors have, accordingly, acknowledged benefits beyond cost, speed and quality, such as improved employee satisfaction, balanced workload, improved motivation and enhanced morale. Moreover, enhanced flexibility, visibility, information integration, and partnerships as well as innovation also constituted concrete results of lean principle implementation. However, critics of the lean principle exist. For instance, Al Hasan and Al-Zu'bi (2014) argued that it constitutes a barrier to innovation because low task and low skill jobs were tightly controlled by the emphasis on speed and standardized processes. The JIT method addresses only the single source with long term partnerships which meet the company's requirements leading to high dependency and lower bargaining power (Garza-Reyes et al., 2018). Furthermore, Kaizen culture also encourages companies to limit employees' access to information and allow them less authority for decision making (Khlat et al., 2014). In contrary, Houborg (2010) claimed that the lean principle successfully creates an improvement culture that nurtures innovation. In the meantime, Taherimashhadi and Ribas (2018) asserted that lean culture allows the employee to have an equal opportunity to promote higher-level positions and generate a sense of ownership of the organization.

The combination of lean principle with Six Sigma best practice has been discussed in previous articles. In order to gain a greater competitive edge in an increasingly changing market, the PSC requires deeper knowledge of how to drive innovation (Keeling et al., 2010). Meanwhile, agility enables the PSC to increase its quality, thereby enhancing patient satisfaction (Mehralian et al., 2017). In line with Costa and Goldinho Filho (2016), this study recommended the adoption of the lean principle not only with regard to Six Sigma best practice, but also supply chain innovation and agile strategy. Furthermore, the contradictions, conflicts, barriers, motivational factors, opportunities and benefits of the lean supply chain in combination with recommended best practice and strategy have yet to be explored.

While strict quality regulations need to be respected, lean practice remains a crucial method of improving PSC performance within the current challenging competitive environment. The lean supply chain emphasizes integration of supplier and customer processes to streamline and optimize the overall flow of value (Anand & Kodali, 2008). Following the same principle, this study presents a lean supply chain that integrates upstream and downstream activities into a coherent whole in order to improve PSC performances. Meanwhile, the PSC is also responsible for preventing shortages of drugs and increasing their accessibility, rather than maintaining a narrow focus on increasing profit (Ding, 2018). Hence, this study concerned with establishing a lean supply chain not only for commercial purposes but also as a form of social responsibility. By delivering greater responsiveness, product availability to the market which is critical for life-threatening medical situations will be ensured (Mehralian et al., 2017). However, this study indicated that the previous literature had neglected the important topic discussed above. Therefore, this article could be considered as the first study in supporting future research into developing lean principle models and accelerating their implementation within the PSC.

## 6. Conclusion

There are many challenges for the pharmaceutical industry in the current era of globalization. The PSC is required to reduce unnecessary costs while improving the quality of products and services delivered to patients. The lean principle has been acknowledged as the optimum method through which the PSC might address the current challenge by eliminating waste. Numerous organizations have struggled to adopt lean supply chain practices due to their exclusive focus on individual aspects and the restricted perspective of their application. Hence, for greater PSC effectiveness and sustainability, the lean method should be applied in the field supply chain as an integrated process. The critical success factor of lean supply chain implementation is that of understanding its elements in order to overcome barriers to implementation. The PSC must ensure that elements are in place while the appropriate approach in prioritizing and managing these will lead to successful lean implementation. This article highlights the fact that regulatory compliant lean supply chain integration which guarantees quality and digital transformation will ensure impactful PSC innovation and optimum performance.

This article emphasizes the importance of lean principle application to the entire PSC, thereby enabling industry to remove waste across the value chain effectively and deliver higher responsiveness. This article accommodated synergies from both upstream and downstream activities important to enhancing understanding of the lean application within entire supply chain. Nevertheless, certain limitations exist. Firstly, the study excluded geographical context-related impacts on the lean supply chain. Previous literature on the subject revealed that lean adoption can produce different results depending on the diverse socio-economic and socio-cultural background of society. Secondly, the study excluded discussion of both the environmental benefits and the quality of life within the work system resulting from lean principle adoption. Therefore, it is suggested the authors should accommodate this limitation on future studies. The research gaps highlighted in this article enable the practitioners and researchers to identify the necessary work to be undertaken in the future on lean application in the PSC. This article also contributes to an expansion in the limited body of knowledge regarding the integrated adoption of lean principles within the PSC.

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