Impact of Lean Tools in the Supply Chain: Pharmaceutical Industry Perspective

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***Abstract*—The aim of this paper is to identify the impact of the application of lean tools in the pharmaceutical supply chain (PSC) through a literature review. Supply chain inefficiencies before and during the COVID 19 pandemic, most applied tools, and lean improvements found in the PSC are identified. Databases such as Scopus and Proquest were used to collect the peer-reviewed articles to be studied. Results show the most frequent inefficiencies in the supply chain are found in operating costs, scrap rates, delivery times, and drug shortages. The improvements identified can be summarized in three factors: cost reduction, time reduction, and improvement in the management of activities. The most studied tools are Kaizen, Kanban, Total Quality Management (TQM), and Value Stream Mapping (VSM). Literature reveals that lean tools have a significant impact on quality improvement of information, products and/or services, as well as on the reduction or elimination of activities that do not generate value; in addition, there is little evidence of reduction of unnecessary movements of workers. The value of this paper addresses the impact of the pandemic on PSC, describing the versatility that each of the tools had in their role to reduce lean wastes. The versatility allows to identify which tool may be available according to the need of the practitioner.**

***Index Terms*—Lean, pharmaceutical industry, supply chain, waste**

I. Introduction

Currently, lean tools have been conceptualized as those that allow the elimination of waste or activities that do not generate value in the processes to improve the use of resources and performance of activities [1]. In terms of business sectors, lean tools have been systematically applied in industries such as automotive, construction, hospitality, food, electrical, textile, and health, among others.

The first sector where the lean concept was introduced was the automotive industry. The benefits of these tools have been evidenced in the improvement of production time, inventory turnover rate, reduction of complaints, and others, for which tools such as 5S, TPM, standardization, TQM, and Kanban, among others, were used [2]. Even though the application of lean tools has been shown to have positive results in manufacturing companies, there has to pointed out that they have not been deeply applied in the pharmaceutical sector [3]. One of the reasons for this, the authors indicated, is that pharmaceutical companies take greater importance on good manufacturing quality practices than on improving the performance of production processes.

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Furthermore, improvements should also be sought in the PSC as it plays a vital role in the distribution of essential life-saving products or services [4]. Delays in delivery times, high operating costs and waste levels are some of the hardships the PSC faces [5]. On the other hand, the 2020 crisis caused drug shortages, as well as uncertainty of supply chains, logistics and transportation, which caused financial losses to drug producing factories [4].

Similarly, Leksic *et al*. [6] mention that, in order to identify which lean tool to use and which one is best suited to the PSC under evaluation, the wastes Taichii Ohno identified should be taken into consideration. The wastes that are covered in this article are the following: defects, which are activities that do not generate value and affect the quality of products, information and/or services; overproduction, defined as excess production that consumes unnecessary time, money, effort, and inventory; extra-processing, which is a process or additional activity for processing unnecessary materials that do not add value to the product or service; waiting, which is the unnecessary idle time of resources and/or workers that the delay and/or availability of resources and information causes; transportation, which refers to equipment, goods, tools, documents or materials transported unnecessarily; inventory, related to the lack of control and accumulation of raw materials, products in process, and finished products; motion, which is the unnecessary movements of workers at workstation and/or plant; and non-utilized talent, which is considered as the underestimation of workers' skills, talents and knowledge to improve the process [7].

In view of the aforementioned, the objective of this paper is to identify the impact of the application of lean tools in the PSC but including the novel topic of the pandemic impact on this industry. For this purpose, it is essential to specify which inefficiencies are evidenced in the PSC, identify which lean tools are applied to the PSC, and describe the effects of different lean tools on the PSC. The lean tools that are discussed in this article are described as follows:

Value Stream Mapping (VSM): Vasconcelos Ferreira Lobo *et al*. [8] define that this lean tool helps diagram material and information flows to identify waste and activities that do not generate value in the analyzed process. It also allows companies to obtain the desired results by systematically capturing and analyzing data.

5S: Piñero *et al*. [9] indicate that the 5S methodology consists of the following elements: Seiri (selection), Seiton (systematization), Seiso (cleanliness), Seiketsu (standardization), and Shitsuke (self-discipline). It aims to minimize the time and resources that are used in manufacturing and other processes through the elimination of all forms of waste.

Kanban: A system of visual production control signals that

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allows the replenishment process to remain active in production lines. There are several signals to indicate replenishment, such as cards or boards, and visual or electronic signals [10].

Kaizen: A management philosophy with which improvements are obtained in the work method and which allows the reduction of waste, thus improving the performance in processes. It is also characterized by the creative participation of employees through work groups [11].

TPM: Carrillo-Landazábal *et al*. [12] argue that this methodology creates an operating system that increases the efficiency of all involved equipment to ensure its proper operation during their use, so preventing time losses due to stoppages caused by equipment failures.

TQM: As Adzrie *et al*. [13] point out, this is a management system based on the principle that each member of staff must be committed to maintaining a high standard of work in all aspects of the business activity.

Just in time (JIT): According to García-Alcaraz *et al*. [14], it is a technique that supports the processes of raw material supply, transformation, and distribution as a final product. It allows to eliminate unnecessary costs related to supply, reduce machine downtime, and ensure the adequate flow in the production process.

Single Minute Exchange of Die (SMED): According to Lozano *et al*. [15], the SMED methodology focuses on reducing waste in the production system and standardizing machine changeover times whenever any planned modification is made to the machine.

Process standardization: A predefined set of rules and conditions or requirements for performing activities or processes in a regular and optimal way. The standard defines the smooth work to be performed, as well as the correct description of the activities [16].

II. Methodology

A systematic literature review was conducted to analyze the different findings and indicators obtained from peer-reviewed scientific articles regarding the application of lean tools in PSC. To obtain these articles, databases such as Scopus and Proquest were used as they are recognized sources of peer-reviewed scientific research.

As presented in Fig. 1, the initial search used the keywords “lean” and “supply chain” in articles that were published from 2010 to 2021 and were peer-reviewed, which resulted in obtaining a total of 19,747 articles. Then a first filter was applied divided into two parts, the first one considered the keywords “supply chain,” “pharma*” and “lean” to identify the tools that are applied in the PSC and its inefficiencies, for which a total of 38 articles were obtained; the second search considered the keywords “supply chain,” “pharma*” and “covid” to identify the inefficiencies in the PSC during the pandemic, and a total of 171 articles was obtained. From these 209 articles, forty-five (45) articles were selected after reading the abstract and were considered relevant to the present research.

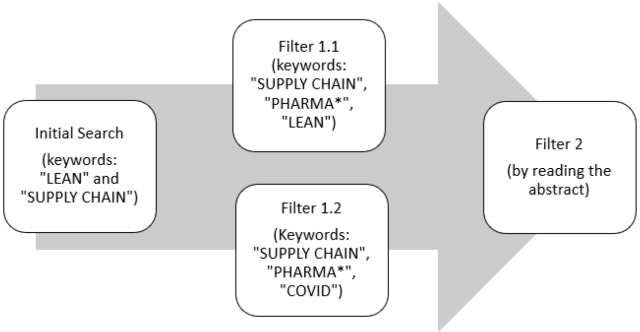

Fig. 1. Diagram of methodology.

III. Results and Discussion

Scientific articles that focus on the pharmaceutical supply chain (PSC) were chosen according to two dimensions: (i) inefficiencies pre- and during pandemic; and (ii) impact of lean tools on the PSC.

A. Pre-pandemic and in-Pandemic Inefficiencies of PSC

Covid-19 pre-pandemic inefficiencies are related to storage, inventory, costs, and waste, among others. As per storage, Dixit *et al*. [17] evidence the lack of adequate storage systems. Regarding inventory, the maintenance of an elevated level of stock represents an investment with low return as keeping inventories and obsolete products in the warehouse generates high costs and tends to be a substantial source of waste [18]. In addition to this, there are high costs for drug development, which are three to four times higher than in other manufacturing companies, as there are greater failure rates and longer clinical trial times, and the complexity of the drug industry is also higher [19]. As for waste in the supply chain, increased regulations have placed limits on waste generation, so this is one of the factors to focus on [20]. Dixit *et al*. [17] mention that this is an area that has not been given much attention and that waste management is a topic of considerable concern to researchers. Companies face problems of high scrap rates, so there is a need to optimize PSC to achieve waste elimination [21]. Moreover, there is evidence of an inappropriate distribution system and low responsiveness of supply chains [17], which, coupled with weak communication among PSC stakeholders, affects the efficient delivery of products [21].

Inefficiencies that arose during the pandemic led to changes in the supply chain dynamics. Socal *et al*. [22] demonstrate that Covid-19 led to drug shortages due to sudden and unexpected increases in the demand, which exceeded the production capacity of manufacturers. Similarly, the demand patterns for these products have undergone major changes, and have materialized, in some cases, in increases in the quantity demanded, while, in others, in abrupt decreases in the quantities patients required [23]. According to Ayati *et al*. [24], most of these products were supplied by China and India, which are the world’s largest distributors of pharmaceutical ingredients; this caused a decrease in production and contributed to drug shortages and to the increase of product prices. Regarding a research Faiva *et al*. [25] conducted in Nigeria, drug shortages were mainly due to border closures, quarantines, reduced manufacturing, poor access to resources by population, and security instability, among others. Due to the pandemic, there was evidence of distribution weakness in the pharmaceutical industry [23]. Remko [26] found that supply chain executives reported various forms of supply chain disruptions, extended lead times, and logistical bottlenecks during periods; however, the author believed that the reopening of plants would result in an acceleration of transportation capacity.

According to the foregoing, the most frequent inefficiencies in the PSC are high operating costs, high scrap rates, inefficiencies in delivery times, and shortages of raw materials and finished products; however, the inefficiencies shown in the different papers were explained in a general way without detailing their causes and consequences. In contrast to the literature review Fernando *et al*. [27] conducted, which evinces a higher frequency of topics related to strategy development concepts, inventory management and PSC performance problems, this could be explained through the sample that was selected for the study, since different databases were used to compile the articles. Although Singh *et al*. [28] present an extensive review, there is evidence of discrepancies with the publications made more than 5 years ago, since they state that the challenges in PSC are related to drug formulation, planning capacity and inventory management, lack of investment in research and development, and quality, among others.

B. Lean Tools in PSC

Throughout the supply chain, various lean tools can be applied to solve the numerous problems the pharmaceutical industry faced. Fig. 2 shows the percentage of articles that support each tool and mentions its contribution to PSC:

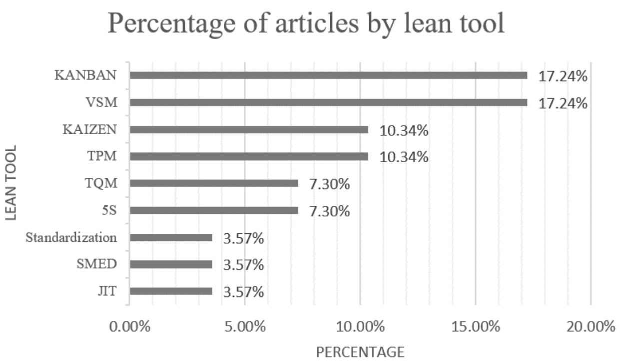

Fig. 2. Percentage by lean tools.

VSM - As can be seen, one of the methodologies with the highest frequency in the articles is VSM with 17.24%. According to Khorasani *et al*. [29], this methodology allows pharmaceutical industries to identify non-value adding steps in a process and is used to represent the current status and design a more efficient future status. VSM, together with the spaghetti diagram, may represent the flow of elements and activities in the chain of a pharmaceutical company that manages to find opportunities to accelerate the chain processes from suppliers to final customers [26]. The research of Abideen *et al*. [30] confirmed that VSM decreases production lead time and total chain process time by 51% and 44%, respectively.

Kanban - Another tool with the same value of 17.24% presence in the sample of items is Kanban. According to the case study on Kanban implementation in the PSC that Papalexi *et al*. [5] conducted, it was verified a reduction in 56.8% of products to be stored at the end of the process and, therefore, a saving of 71.8% in storage costs were obtained. In addition, they showed that, through this methodology, pharmaceutical industries gather faster and more accurate information, thus always knowing the quantity and types of products that are available in the inventory. As a result, customer service becomes much faster and more efficient. The usefulness of Kanban in avoiding and preventing the accumulation of unwanted inventories both in the production area and in the warehouses is highlighted [30]. The same position of Bevilacqua *et al*. [31] in their case study was the same, as they indicated that the amount of materials managed with Kanban falls to a minimum level and, therefore, inventory cost savings are achieved. Finally, correct implementation of Kanban allows pharmaceutical industries to manage larger volumes and different product lines more efficiently. In the same way, it allows to reduce the batch size, and the production frequency will be then significantly increased [31].

Kaizen - it has a 10.34% frequency rate. Srinivasan *et al*. [20] state through their success case that the use of Kaizen in PSC reduces the overall operating times by 22% and the inventory turnover cycle of raw and packing materials from 22 to 20 days. With respect to final product distribution, Bin Wan Ibrahim *et al*. [19] show that lead time was reduced by 46.3% using Kaizen. Other authors in their article describe that the Kaizen implementation managed to decrease the total inventory value by 30%, increase the efficiency of production area by 50%, reduce the time the quality area takes to approve products by 90% and decrease costs as a revenue percentage by 6%. Finally, regarding the production and distribution chain, this tool reduces the chain delivery time by 50%-75%, and drastically increases the productivity of each of its areas [32].

TPM and 5S - Among the tools that were already mentioned, TPM is also present with a percentage of 10.34%. The presence of 5S and TQM in the articles is 6.9% each. In a case study, TPM and 5S proved the improvement of pharmaceutical plant performance when using both methodologies as they identified the root causes of problems such as extensive search times due to material disorganization, ergonomics, information transparency, and extensive lead times [20]. Likewise, TPM encompasses fields such as preventive maintenance, evaluation, use of technologies, and cleanliness [3]. Similarly, Bevilacqua *et al*. [31] indicated that TPM helps to integrate different groups of the chain, coordinators and operators and thus generates a cooperation of various levels in the organization all with a common goal.

TQM - Regarding the benefits of TQM in PSC, the article of Sharma *et al*. [33] focuses on analyzing the relationship of supply chain management (SCM) performance to TQM, and states that the use of this lean tool enables the delivery of high-quality products, as well as product availability. Other benefits include improved supplier relationship management, information transparency, quality, and inventory management. Based on a case study, it is made evident that the joint work of TQM and SCM improves operational performance at a pharmaceutical company plant. Given this finding, authors agree that very little research has been published on the interrelationship between TQM and SCM despite its impact on productivity and efficiency of PSC operations. Therefore, it is of utmost importance to consider the association between TQM and SCM and the operational performance of a pharmaceutical company, as it is not only going to favor drug production but also ensures the delivery of quality products to consumers [33].

JIT, SMED and Process Standardization - Another group of lean tools that have been seen in the sample of articles are JIT, SMED and process standardization, which have with a presence of 3.57% each. The case study regarding a pharmaceutical company that Alkhalidi *et al*. [3] conducted evidenced that JIT methodology improved the final delivery service level index and cycle time efficiency. Furthermore, its successful implementation in the production and planning area of the PSC was also corroborated. Regarding the SMED implementation, favorable results in a pharmaceutical company subject matter of the study, such as a 61.5% decrease in the average line changeover time of its products (time elapsed between production of last product of batch X and first product to be produced in batch Y), were verified [31]. Likewise, the standardization of processes in the pharmaceutical chain increases the flexibility of response to the final consumer and increases the speed of delivery of its products [16].

C. Improvements Identified According to PSC Areas and Lean tOols

Improvements identified are classified in Table I according to the PSC areas and lean tool used.

TABLE I: IMPROVEMENTS IDENTIFIED ACCORDING TO PSC AREAS AND LEAN TOOLS

PSC area	**Improvement achieved**	**Lean tool used**
Production	Improvement of various production lines for different products	5s, SMED
	Improved production area efficiency	5s, Kaizen, TPM, TQM
	Improved production frequency	Kanban
	Reduced production costs	Kaizen
	Reduction of distance traveled in the production area	Kanban
	Reduction of the production batch	Kanban
	Reduction of production time	Kanban
Storage	Improved handling of larger volumes of inventory	Kanban
	Improved inventory management	TQM
	Improved performance in the storage process.	VSM, 5s, Kanban, Kaizen
	Improved information management in the storage area.	Kanban
	Improved warehouse inventory distribution.	Kanban
	Reduction of storage costs.	Kanban, Kaizen
	Reduction of final product to be stored.	Kanban
	Reduction of the inventory and raw material turnover cycle	Kaizen
Supply and procurement	Improved supplier relationship management.	TQM
	Reduction of supply costs.	Kaizen
Logistics	Improved service level.	TQM, JIT, Standardization
	Reduced final product delivery time.	VSM, Kaizen, TQM
Quality	Improvements in quality management.	TQM
	Reduction of rejected lots.	TQM
	Reduction of customer complaints.	TQM
	Reduced product quality approval time.	Kaizen
PSC in general	Improves the chain's value-added indicator.	VSM
	Improved decision making.	VSM, Kaizen
	Allows synchronization of different areas of the chain.	Kaizen, TPM
	Reduction of waste in the supply chain.	VSM, 5s, Kanban, Kaizen, TQM
	Reduction of processes that do not generate value to the chain.	VSM, 5s, Kanban, Kaizen
	Reduction of the total process time of the chain.	VSM, Kaizen

Table I shows that tools such as 5S, Kanban, Kaizen, TPM, TQM and SMED are applied in the production area. Regarding the storage area, articles that use VSM, 5S, Kanban, Kaizen and TQM have been collected. Regarding the supply and procurement area, it can be observed that only tools such as Kaizen and TQM are applied. As for the logistics area, it was found that tools such as VSM, Kaizen, TQM, JIT and Standardization are used. Finally, in the quality area, tools such as Kaizen and TQM are applied.

From the improvements obtained by each lean tool, it has been identified that most of the improvements in the pharmaceutical supply chain are thanks to the Kaizen, Kanban, TQM and VSM tools, the first two having the highest frequency of impact in different areas of the pharmaceutical sector chain; however, Kanban and VSM are the tools with the highest frequency in the articles presented in Fig. 2. It is made evident that the tools have been applied mostly to seek improvements related to reduction of waste, reduction of delivery time of finished product, performance in the storage process, efficiency of production area, and reduction of processes that do not generate value to the chain.

According to the most frequent improvements regarding the lean tools to achieve waste reduction, it has been shown that there is the greatest variety of tools. It is worth noting that the Kaizen tool is applied to each of the five most frequent improvements, which suggests that its application in the pharmaceutical sector is a key tool to achieve a positive impact on the supply chain. On the other hand, although TPM and Standardization are presented as tools to achieve the most frequent improvements, they have not shown as much participation in the different areas of the supply chain as the other tools.

Finally, we can conclude that the improvements in the PSC, thanks to lean tools, can be summarized in three factors: cost reduction, time reduction and improvement in the management of activities in the pharmaceutical sector chain. Moreover, Alkunsol *et al*. [34] agree that one of the most outstanding improvements of the lean methodology is also found in the quality management of products, even though it is not one of the most frequently used improvements. On the other hand, most of improvements reached were not related to a specific inefficiency but in a general way without much detail on the case, indicator or value that supports it, which makes it difficult to determine the main reason for the problem in the PSC.

D. Wastes and Lean Methodology

As Leksic *et al*. [6] mention, the lean philosophy is a constant search for improvement through the elimination of waste from the process. In order to implement lean tools in the PSC, they point out that it is necessary to identify in which activities of the process the losses or wastes are generated, since, if this factor is not known, it is possible for the chosen tool to be the wrong one, not to generate the expected results, and to rather cause the loss of time and resources. Likewise, the following steps are suggested to implement the lean methodology in companies: (i) identify and classify wastes, including root causes; (ii) identify solutions to mitigate root causes; (iii) implement and assess solutions. The impact of each tool will be classified according to the problems it solves [35].

A matrix of identified improvements and lean wastes was prepared through the following steps:

1) Matrix was built considering two axes: identified improvements vs 7+1 lean wastes.
2) Different questions were asked according to the 7+1 wastes to be used as ranking criteria, Muiambo *et al*. (2021) being taken as reference.
3) The following criteria were used to relate improvement to lean waste.

Taking as a reference the article by Muiambo *et al*. (2021), Table II was elaborated, defining questions as criteria to determine which lean waste is targeted.

TABLE II: CRITERIA ACCORDING TO WASTE

	Waste	Criteria
W1	Waiting	Reduced idle time spent on resources or people? Reduced unnecessary waiting due to delay or unavailability of resources, information or others?
W2	Defects	Improved the quality of information, products and/or services? Reduced and/or eliminated activities that do not generate value to the process?
W3	Inventory	Improved management of raw materials, work-in-process and/or finished goods?
W4	Motion	Reduced unnecessary movement of workers?
W5	Transportation	Reduced unnecessary movements of equipment, goods, tools, documents and/or materials?
W6	Overproduction	Reduced excess production that does not add value to the product or service?
W7	Extra-processing	Reduced unnecessary processing that does not add value to the product or service?
W8	Non-utilized talent	Was the talent, skills and knowledge of the workers capitalized?

Table III was then constructed, using the criterias in Table II, to determine which lean wastes were targeted by each identified improvement.

Table IV summarizes the number of times the waste has been associated with an improvement in the above table.

The largest percentage of improvements found in lean tools impacts the change of "defects", which directly affects the quality of products, information, and processes, among others. However, literature does not show much evidence on the reduction of unnecessary movements of workers compared to other changes.

TABLE III: MATRIX OF IDENTIFIED IMPROVEMENTS AND LEAN WASTES

Improvements identified	Wastes
Improvement of various production lines for different products	W1, W2
Improved production area efficiency	W2, W7
Improved production frequency	W1
Reduction of raw material consumption	W3
Reduced production costs	W6, W7
Reduction of distance traveled in the production area	W4
Production batch reduction	W7
Reduction of production time	W1, W7
Improved handling of higher inventory volumes	W3, W5
Improved inventory management	W3
Improved storage process performance	W3, W5
Improved management of information in the storage area	W2
Improved warehouse inventory distribution	W3
Reduced storage costs	W3
Reduction of finished product to be stored	W3
Reduction of the inventory and raw material turnover cycle	W3
Improved supplier relationship management	W1, W2, W8
Reduction of supply costs	W5
Improved service level	W1
Reduction in delivery time of finished product	W1
Improvements in quality management	W2
Reduction of rejected lots	W2
Reduction of customer complaints	W2
Reduced product quality approval time	W1, W2
Improves the chain's value-added indicator	W2, W8
Improves decision making	W8
Allows synchronization of different areas of the chain	W2, W8
Reduction of energy consumption	W7
Reduction of waste in the supply chain	W2, W7
Reduction of plant operating expenses	W2, W5, W6, W7
Reduction of processes that do not generate value to the supply chain.	W2, W5, W6, W7
Reduction of the total process time of the chain	W1

TABLE IV: PERCENTAGE PER WASTES

	Wastes							
	W1	W2	W3	W4	W5	W6	W7	W8
Total	8	13	8	1	5	4	7	4
Total (%)	16	26	16	2	10	8	14	8

For a better analysis of these tools and their impact on wastes, the following table was prepared by cross-referencing the information in Table I and Table III.

TABLE V: TOOLS VS. WASTES

Lean Tools	Wastes								Total
	W1	W2	W3	W4	W5	W6	W7	W8	
VSM	X	X	X		X	X	X	X	**7**
5S		X	X		X	X	X		**5**
Kanban	X	X	X	X	X	X	X		**7**
Kaizen	X	X	X		X	X	X	X	**7**
TPM	X	X					X	X	**4**
TQM	X	X	X				X	X	**5**
JIT	X								**1**
SMED	X	X							**2**
Standardization	X								**1**
Total	**8**	**7**	**5**	**1**	**4**	**4**	**6**	**4**	

Table V shows that the most versatile tools found are VSM, Kanban and Kaizen, which attack 7 out of the 8 wastes in the PSC and provide greater possibilities for improvement in the chain; while the JIT, SMED and Standardization tools only focus on reducing idle time of resources or personnel and on improving the quality of information, goods, and services by eliminating processes that do not generate value.

It is clear that the most attacked waste is waiting, which implies that most of the tools studied aim at reducing the idle time found in resources or people and at reducing unnecessary waiting due to delay or lack of availability of resources, information or other similar.

IV. CONCLUSIONS

This article investigated the impact of the application of lean tools that favors PSC. A literature review was conducted on their inefficiencies and the application of lean tools in PSC. The results of the research showed that inefficiencies appeared most frequently in operating costs, high scrap rates, delivery times, and drug shortages. These PSC improvements are summarized in three factors: cost reduction, time, and management of activities. This study also shows that the most analyzed tools in PSC are Kaizen, Kanban, TQM, and VSM.

It is evident that lean tools focus on certain types of improvements and mitigate various inefficiencies throughout the PSC, so that pharmaceutical companies, through a diagnosis of inefficiencies and expected results, implement the most appropriate methodology according to the change to be mitigated or the improvement to be achieved. Lean tools impact mostly on the improvement of quality of information, products and/or services, as well as on the reduction or removal of activities that do not generate value. However, there is no evidence regarding the reduction of unnecessary movements of workers. Finally, the research can serve as a theoretical basis for improvements in PSC when lean tools are applied.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHOR CONTRIBUTIONS

Sebastian Aguirre-Manrique and Valeria Wong-Lam researched, analyzed the data and wrote the paper, Rafael Chávez-Ugaz supervised the investigation; all authors had approved the final version.

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