Acta Pharm. Sci. Vol 63:(4), 2025
Original article
DOI: 10.23893/1307-2080.APS6351

Determining the barriers affecting lean process management with the fuzzy DEMATEL method: A study in the Turkish pharmaceutical industry

Yeter USLU[1], Erman GEDIKLI[1*], Emre YILMAZ[1], Gozde YESILAYDIN[2], Yasemin HANCIOGLU BASKOY[3]

1 Istanbul Medipol University, School of Health Sciences, Department of Health Management, Istanbul, Türkiye
2 Eskisehir Osmangazi University, School of Health Sciences, Department of Health Management, Eskisehir, Türkiye
3 Ordu University, Unye Vocational School, Department of Accounting and Taxation, Ordu, Türkiye

ABSTRACT

This study was aimed determine the most critical barriers affecting lean process management applications in the Turkish pharmaceutical industry. Organizational, managerial, financial, technical, regulatory, industry-specific, knowledge and capability barriers determined from literature. According to the analysis results, the three most critical barriers in the implementation of lean process management were determined as organizational, financial and managerial barriers respectively. The organizational barriers were the most affected category in the system, while financial barriers were the most affected category. In this context, it was emphasized that factors such as resistance to change, lack of employee participation and empowerment, cultural incompatibilities and inadequacy of reward strategies, which are among the organizational barriers, play a direct and decisive role in the success of lean applications. Inadequate financial resources and high investment costs not only make implementation difficult but also trigger other obstacles. In terms of management, lack of leadership, poor communication, and lack of trust prevent the healthy functioning of transformation processes. It is critical to establish an

* Corresponding author: Erman GEDIKLI
E-mail: egedikli@medipol.edu.tr
ORCIDs:
Yeter USLU: 0000-0002-8529-6466
Erman GEDIKLI: 0000-0002-5508-194X
Emre YILMAZ: 0000-0003-4502-9846
Gozde YESILAYDIN: 0000-0002-2901-6474
Yasemin HANCIOGLU BASKOY: 0000-0002-6337-1314
(Received: 17 Jun 2025, Accepted: 3 Jul 2025)

in-house lean culture, increase leadership and middle management support, align financial planning with lean transformation goals, and expand training programs that will ensure effective employee participation in the process.

Keywords: pharmaceutical industry, lean process management, fuzzy logic, DEMATEL

INTRODUCTION

Lean is a manufacturing philosophy that incorporates a set of tools and techniques into business processes to optimize time, human resources, assets, and productivity while increasing the quality level of products and services delivered to customers. The role of the lean management approach is very important for any organization. The principles of lean construction focus on creating sustainable change by emphasizing the efficient, waste-free, and safe flow, storage and transportation of materials to minimize costs, energy and resource consumption and provide value to customers and end users. Success of businesses with lean management can be achieved by internalizing the management style in question, continuously improving it and applying it[1].

Determining all the existing processes of the enterprises down to the smallest detail, defining and documenting them, creating a performance indicator by determining the process responsible and owners, improving and controlling the processes by monitoring the performance can be defined as process management. One of the issues that businesses need to focus on most in recent years is ensuring consumer satisfaction by using available resources efficiently, effectively and economically. As the level of competition increases day by day and the cost is at the target point in businesses, different techniques, components, and elements have come to the fore. In this case, lean process management can provide a significant competitive advantage for businesses[2].

Nowadays, businesses need to make various improvements within their structures and make these improvements permanent to keep up with rapidly developing technology, changing world conditions and the fiercely competitive environment, to respond to customer demands at a sufficient speed and to stay in the top ranks. In the quest to achieve this and make it permanent, the concepts of *"Lean Production, Lean Thinking, Lean Philosophy, Lean Management"* emerge[3].

Lean thinking is a systematic way of thinking, a philosophy. It can be defined as management aimed at improving the operational aspects of the business by eliminating waste and increasing value in product and service offerings.

Lean thinking focuses on value creation, elimination of waste, low cost, high profitability and increasing market share[4]. Lean thinking style is about structural problem solving and continuous improvement[2]. Lean thinking aims to reduce waste related to transportation, inventory, activity-related movement, waiting, overproduction, excessive processing, and errors among operational and supply chain processes in order to achieve high quality, low costs and short delivery times[5,6]. Because lean thinking requires high levels of employee involvement and changes in attitudes and behaviours, strategic employee alignment plays an important role in the pursuit of lean. It is especially important to have open, honest communication and delegation of authority to ensure employee compliance[7].

The lean approach is a customer-oriented approach that can change the organization and management style of businesses and enable the provision of quality goods and services by providing improvements in processes such as work completion time, stocks, faulty products reaching the customer, and time to bring the product to market. The manufacturing principles that make up the lean production system were developed by Eiji Toyoda and Taiichi Ohno at the Toyota Motor Plant in the 1940s and 50s. These techniques were first expressed as a whole with the concept of "lean production" by John Krafcik, a Harvard University researcher. The reason why Krafcik uses the concept of lean production is that the new system demands less for everything compared to mass production[8].

In the lean production philosophy, it is aimed to eliminate waste in the process in production activities aimed at increasing the unit output amount in the production system. In this approach of Toyota, it is essential to increase the value offered to the customer by using resources efficiently. This customer-centered approach also includes the principles of uninterrupted continuous production and continuous improvement of processes. Lean production is a production system that carries out the cheapest and error-free production in the shortest time, with the least possible resources, in a way that can fully meet customer demand, with minimal waste and by using production factors flexibly[9].

There is a lack of a universal and generalizable definition for the process in research[8]. The process is the steps taken to achieve the targeted output by using various inputs in a way that creates added value. For businesses to achieve efficient and effective processes, they must have some basic features. These basic features are briefly; identifiability, repeatability, consistency, measurability, controllability and creating added value. Each process is moved

and directed towards the customer and, together with others, contributes to his satisfaction. Process management is a series of activities carried out to monitor and improve processes regularly and continuously. Process-based management organization is task-oriented and determined by the totality of competencies and activities[10].

Process management is considered a methodology that addresses the operation and continuous improvement of processes to create value for customers while reducing waste. Process-based management is inherently oriented towards cross-functional effectiveness rather than functional efficiency[11].

Lean is a common way of expressing lean production and is a way of looking after, managing and leading an organization in a resource-efficient, flexible, and fast way[11]. He explains that the goal with lean is to focus on quality, customers and their needs, not short-term financial results. Process management is used in many industries such as manufacturing, utilities and banking. In many cases, it has proven to be a way to achieve lower costs, better customer satisfaction and higher quality[12].

The beginning of lean process management is the creation of lean behavior. Lean behavior is defined as behavior that adds or creates value. It is the minimization of waste associated with arbitrary or contradictory thoughts and actions that lead to defensive behavior, ineffective relationships, poor cooperation, and negative attitudes. For lean to be implemented, the five best-implemented components must be present. The five best applied ingredients are environmental change, leadership, culture, employee empowerment and communication. Management must have lean behaviors that will enable employees to implement the five components[13].

The lean process management system integrates with the principles that, in a sense, hold them together. These principles are intended to be created as a people development system in lean process management and provide a framework that will focus on increasing the problem-solving ability among employees[13,14].

Key Performance Indicator (KPI) – KPI is linked to the organizational goal for each level, such as company, department, division, and individual levels. In lean process management, it is very important to determine KPI through Mission, Core Value, Vision, Purpose, Strategy, Strategy Initiative, and Personal Goal for the human development system. This will align the company's overall workforce to pursue one common goal. Each level has its own contribution towards the goal. The results are compared to the goal or

target used to measure the success of the KPI. The accumulation of success from each department will reflect the overall success of the company goal.

Respect for People – Respect for People, which basically focuses on simple behaviors that every employee in the organization should create in their minds. It is an important factor in developing a lean culture throughout the organization.

Skills and Knowledge – Skills and Knowledge for employees will support them in applying the lean concept effectively and efficiently using lean tools and techniques. Skills and knowledge in lean process management are basic requirements for employees to equip themselves. Without this, they cannot perform well in solving problems of identifying and eliminating waste.

Another important element included in this human development system framework is the teamwork of top, middle and lower management. The total commitment of all these three levels will increase problem-solving ability in lean process management among employees[13]. Lean Process Management has been shown to assist organizations in developing production and administrative management solutions, making the organization leaner and at the same time 'more convenient', improving production, quality, marketing etc. It has been proven to be helpful in achieving World Class standards in aspects[14].

Factors influencing pharmaceutical lean process management are diverse. Research has shown that management's role in implementing lean positively affects organizational performance[15]. In addition, the implementation of Lean Six Sigma has been found to have a significant impact on the performance of pharmaceutical manufacturing organizations[16]. In addition, the adoption of lean principles in the pharmaceutical supply chain was recommended as a potential way to improve process efficiency[17]. Furthermore, supporting middle management and leadership have been highlighted as critical success factors for implementing lean in the pharmaceutical industry[18]. Critical success factors for successful lean implementation in public hospitals were also identified, including strategic leadership, organizational attitude, and basic operational process stability[19].

The pharmaceutical industry faces several barriers when implementing lean process management. These barriers include resistance to change, lack of lean culture, pressure from top management, lack of leadership commitment and engagement, financial barriers, lack of employee engagement and commitment to change, and lack of understanding of the lean concept[20-22]. Additionally, the size of the organization can also influence the barriers to lean implementation,

with smaller companies desiring to improve their operational and financial efficiency[23]. Furthermore, the pharmaceutical industry's capability to support lean initiatives and the applicability of lean initiatives in the European pharmaceutical sector are still topics of debate in the academic literature, indicating potential challenges in implementing lean in this industry[24].

The implementation of lean process management in pharmaceutical companies is faced with several barriers. These barriers include the special characteristics of the pharmaceutical sector, such as highly perishable products, complicated processing, and unpredictable demand[24]. But also, the barriers are not unique to this sector. Studies in other industries have identified obstacles such as lack of senior leadership focus, complacency, and lack of middle management support[22-25]. These findings suggest that the challenges in implementing lean are not specific to the pharmaceutical industry but are common across various sectors.

In conclusion, the barriers to lean process management in the pharmaceutical industry are diverse and encompass organizational, financial, technical, and regulatory aspects. So, industry is multifaceted and include resistance to change, lack of leadership commitment, financial barriers, and organizational size, and etc. These barriers are not unique to the pharmaceutical industry and are also observed in other sectors. Overcoming these barriers requires a comprehensive understanding of the specific challenges faced by pharmaceutical companies and the development of tailored strategies to address them. These detailed barriers listed in Table 1.

Table 1. Detailed categorized barriers lean process management in the industry

No.	Code	Barriers	References
1.	**OB**	**Organizational Barriers:**	
		Resistance to change and complacency Lack of employee engagement, empowerment, and commitment Cultural differences and lack of perseverance Lack of lean culture Operational resistance and cross-functional conflicts Incompatibility between lean manufacturing and the company's reward strategies	20-22, 26-29
2.	**MB**	**Managerial Barriers:**	
		Lack of senior leadership focus and commitment Lack of middle management support Lack of communication and cooperation between management and employees Pressure from top management Organizational culture and management attitude Lack of mutual trust between managers and employees	15, 22, 25, 27
3.	**FB**	**Financial Barriers:**	
		High investment costs (need for high investments and costs) Lack of financial resources	20-22, 25, 27, 30
4.	**TB**	**Technical Barriers:**	
		Size of organization Lack of standardization, stability, and integration of production processes Lack of benefit capturing and limited view of techniques Issues connected to machinery, plant configuration, and quality of materials used	23, 26
5.	**RIB**	**Regulatory and Industry-Specific Barriers:**	
		Highly regulated and technical nature of the pharmaceutical industry Lack of standardization, compliance, and quality integration requirements Highly perishable products, complicated processing, and unpredictable demand Slow response to market and absence of a strategic logistics system Lack of logistic support and poor cooperation from suppliers Disruptions in supplier commitments	15, 17, 24, 31
6.	**KCB**	**Knowledge and Capability Barriers:**	
		Low technical know-how and lack of understanding of the lean concept Lack of lean training and introduction methods Lack of employee skills, expertise, and qualified consultants/coaches Difficulties using lean tools Lack of qualification for managers and employees in lean implementation	20-22, 25, 26, 28

METHODOLOGY

Participant characteristics

As a result of the literature review, obstacles in lean process management were identified and categorized. The evaluation of the barriers obtained was carried out with 9 different participants with at least 15 years of professional experience in the sector. The evaluations of the participants were obtained with DEMATEL (The Decision-Making Trial and Evaluation Laboratory) linguistic forms.

Fuzzy DEMATEL

The steps of the fuzzy DEMATEL method are as follows;

Step 1: Generate of the matrix of the fuzzy direct relations

First, an n × n matrix is generated to identify the model of relationships between the n criteria. The influence of the elements of the rows on the elements of the columns of this matrix is expressed as a fuzzy value. In other words, equivalent fuzzy numbers corresponding to the appropriate linguistic terms are defined. In the case of multiple assessments, the mean of all the assessments shall be taken as the direct correlation coefficient. Thus, the fuzzy direct-relation matrix is generated.

$$z = \begin{bmatrix} 0 & \cdots & \tilde{z}_{n1} \\ \vdots & \ddots & \vdots \\ \tilde{z}_{1n} & \cdots & 0 \end{bmatrix}$$

Fuzzy linguistic scale consisting of triangular fuzzy numbers is used in the model as below[32-34].

Table 2. The Fuzzy linguistic scale

Code	Linguistic term	l	m	u
0	No influence	0	0	0.25
1	Very low influence	0	0.25	0.50
2	Low influence	0.25	0.50	0.75
3	High influence	0.50	0.75	1.00
4	Very high influence	0.75	1.00	1.00

Step 2: Normalize fuzzy direct relation matrix

The following formula can be used to obtain the normalized fuzzy direct relation matrix:

$$\tilde{x}_{ij} = \frac{\tilde{z}_{ij}}{r} = \left(\frac{l_{ij}}{r}, \frac{m_{ij}}{r}, \frac{u_{ij}}{r}\right)$$

$$r = \max_{i,j}\left\{\max_{i}\sum_{j=1}^{n} u_{ij}, \max_{j}\sum_{i=1}^{n} u_{ij}\right\} \qquad i, j \in \{1,2,3,\ldots,n\}$$

Step 3: Calculate the fuzzy total-relation matrix

In step 3, the fuzzy total-relation matrix can be calculated by the following formula:

$$\tilde{T} = \lim_{k\to+\infty}(\tilde{x}^1 \oplus \tilde{x}^2 \oplus \ldots \oplus \tilde{x}^k)$$

After each element is expressed as $\tilde{t}_{ij} = (l''_{ij}, m''_{ij}, u''_{ij})$, it can be calculated as follows:

$$[l''_{ij}] = x_l \times (I - x_l)^{-1}$$

$$[m''_{ij}] = x_m \times (I - x_m)^{-1}$$

$$[u''_{ij}] = x_u \times (I - x_u)^{-1}$$

In other words, the normalized fuzzy direct relation matrix is first inverted, then subtracted from matrix I (identity matrix), and finally the normalized fuzzy direct relation matrix is multiplied by the resulting matrix.

Step 4: Defuzzify the data into crisp values

Converting fuzzy data into crisp score (CFCS) procedure proposed by Opricovic and Tzeng (2003) has been used to obtain a crisp value of total-relation matrix[35]. The steps of CFCS method are as follows:

$$l_{ij}^{n} = \frac{\left(l_{ij}^{t} - \min l_{ij}^{t}\right)}{\Delta_{min}^{max}}$$

$$m_{ij}^{n} = \frac{(m_{ij}^{t} - min\ l_{ij}^{t})}{\Delta_{min}^{max}}$$

$$u_{ij}^{n} = \frac{(u_{ij}^{t} - min\ l_{ij}^{t})}{\Delta_{min}^{max}}$$

So that

$$\Delta_{min}^{max} = \max u_{ij}^{t} - \min l_{ij}^{t}$$

Calculating the upper and lower bounds of normalized values:

$$l_{ij}^{s} = {m_{ij}^{n}}/{(1 + m_{ij}^{n} - l_{ij}^{n})}$$

$$u_{ij}^{s} = {u_{ij}^{n}}/{(1 + u_{ij}^{n} - l_{ij}^{n})}$$

The output of the CFCS algorithm is crisp values.

Calculating total normalized crisp values:

$$x_{ij} = \frac{[l_{ij}^{s}(1 - l_{ij}^{s}) + u_{ij}^{s} \times u_{ij}^{s}]}{[1 - l_{ij}^{s} + u_{ij}^{s}]}$$

Compute the final crisp values:

$$z_{ij} = min\ l_{ij}^{t} + x_{ij} \cdot \Delta_{min}^{max}$$

Step 5: Determineinfluencing and affected factors

Next, calculate each row and column sum of T (in step 4). The sum of the rows (D) and columns (R) can be calculated as follows:

$$D = \sum_{j=1}^{n} T_{ij}$$

$$R = \sum_{i=1}^{n} T_{ij}$$

Where D+R represents the degree of importance of factor *i* in the overall system and D-R represents the net impact that factor *i* contributes to the system.

Step 6: Calculate the Threshold value and Obtaining the Cause-and-Effect Diagram

The threshold value must be obtained to calculate the Defuzzified Total Relation Matrix, which determines a relatively low degree of effect. To calculate the threshold value for relations, it is sufficient to calculate the average values of the matrix T. Values equal to or above this threshold value in the defuzzified total relation matrix show the relationships between the criteria. To easily

understand the relations between the criteria and their positions relative to each other, cause and effect diagram can be created that D+R is placed on horizontal axis and D-R on the vertical axis.

Step 7: Interpret the results.

RESULTS and DISCUSSION

The opinions of the experts regarding the influence of one factor on the others were converted into triangular fuzzy numbers. The answers were averaged as mentioned in Step 1 and then the fuzzy direct relation matrix was obtained as shown in Table 3.

Table 3. The Fuzzy direct relation matrix

	OB			MB			FB			TB			RIB			KCB		
OB	0.000	0.000	0.250	0.556	0.806	0.972	0.500	0.750	0.917	0.222	0.472	0.722	0.361	0.611	0.861	0.361	0.611	0.861
MB	0.611	0.861	0.944	0.000	0.000	0.250	0.556	0.806	0.972	0.139	0.389	0.639	0.306	0.556	0.778	0.306	0.556	0.778
FB	0.556	0.806	0.944	0.556	0.806	0.972	0.000	0.000	0.250	0.333	0.583	0.833	0.250	0.500	0.750	0.306	0.556	0.806
TB	0.278	0.528	0.778	0.278	0.528	0.778	0.278	0.528	0.778	0.000	0.000	0.250	0.222	0.472	0.722	0.222	0.472	0.722
RIB	0.361	0.611	0.861	0.278	0.528	0.778	0.361	0.611	0.833	0.389	0.639	0.889	0.000	0.000	0.250	0.306	0.556	0.806
KCB	0.389	0.639	0.889	0.417	0.667	0.889	0.250	0.500	0.722	0.250	0.500	0.750	0.472	0.722	0.944	0.000	0.000	0.250

After calculating the fuzzy direct relation matrix, according to equations in Step 2, this matrix can be normalized. Thus, normalized fuzzy direct relation matrix is calculated as seen in Table 4.

Table 4. The normalized Fuzzy direct relation matrix

	OB			MB			FB			TB			RIB			KCB		
OB	0.000	0.000	0.054	0.253	0.234	0.208	0.228	0.218	0.196	0.101	0.137	0.155	0.165	0.177	0.185	0.165	0.177	0.185
MB	0.279	0.250	0.202	0.000	0.000	0.054	0.253	0.234	0.208	0.063	0.113	0.137	0.139	0.161	0.167	0.139	0.161	0.167
FB	0.253	0.234	0.202	0.253	0.234	0.208	0.000	0.000	0.054	0.152	0.169	0.179	0.114	0.145	0.161	0.139	0.161	0.173
TB	0.127	0.153	0.167	0.127	0.153	0.167	0.127	0.153	0.167	0.000	0.000	0.054	0.101	0.137	0.155	0.101	0.137	0.155
RIB	0.165	0.177	0.185	0.127	0.153	0.167	0.165	0.177	0.179	0.177	0.186	0.190	0.000	0.000	0.054	0.139	0.161	0.173
KCB	0.177	0.186	0.190	0.190	0.194	0.190	0.114	0.145	0.155	0.114	0.145	0.161	0.215	0.210	0.202	0.000	0.000	0.054

The fuzzy total relation matrix was created using the data in the normalized fuzzy direct relation matrix using the formulas in step 3. The fuzzy total relation matrix is given by Table 5.

Table 5. The Fuzzy total-relation matrix

	OB			MB			FB			TB			RIB			KCB		
OB	0.911	1.380	2.946	1.075	1.532	3.067	1.013	1.477	2.968	0.649	1.179	2.701	0.814	1.314	2.857	0.785	1.282	2.813
MB	1.116	1.560	2.957	0.860	1.323	2.815	1.017	1.468	2.864	0.610	1.145	2.582	0.783	1.284	2.732	0.755	1.253	2.691
FB	1.109	1.567	3.055	1.072	1.530	3.047	0.824	1.296	2.825	0.681	1.200	2.702	0.773	1.288	2.819	0.763	1.268	2.786
TB	0.711	1.234	2.725	0.686	1.205	2.714	0.656	1.169	2.634	0.369	0.847	2.325	0.537	1.051	2.534	0.517	1.025	2.495
RIB	0.897	1.401	2.959	0.839	1.351	2.932	0.828	1.327	2.856	0.622	1.121	2.641	0.564	1.058	2.646	0.661	1.166	2.711
KCB	0.951	1.444	2.984	0.925	1.414	2.971	0.834	1.340	2.857	0.599	1.118	2.634	0.779	1.264	2.795	0.571	1.058	2.623

Afterwards, triangular fuzzy numbers were defuzzify using the formulas in step 4 and the fuzzy total relation matrix was defuzzified with the CFCS algorithm. From the defuzzified total relation matrix, the summed-up values for all rows (represented by D) and all columns (represented by R) have been calculated the formulas in step 5. Subsequently, based on these data (D+R) and (D-R) are calculated as represented in Table 6, where D-R denotes the net effects that a factor has on the system and D+R denotes the significance of a factor overall.

Table 6. Ranking of lean process management barriers

	R	C	R+C	R-C	Rank
OB	9.398	9.766	19.164	-0.367	1
MB	8.901	9.575	8.901	8.901	3
FB	9.070	9.280	9.070	9.070	2
TB	7.507	7.904	7.507	7.507	6
RIB	8.419	8.541	8.419	8.419	5
KCB	8.608	6.838	8.608	8.608	4

Among the lean process management barriers, the three most important barriers are seen to be OB, FB and MB, respectively. The least important barrier is TB. In addition, when the R-C values are examined, it is seen that the OB barrier is affected the most; the barrier with the highest power to affect the other barriers is FB (Table 6).

Figure 1 is presented so that the importance and effect of lean process management barriers can be seen and examined more clearly.

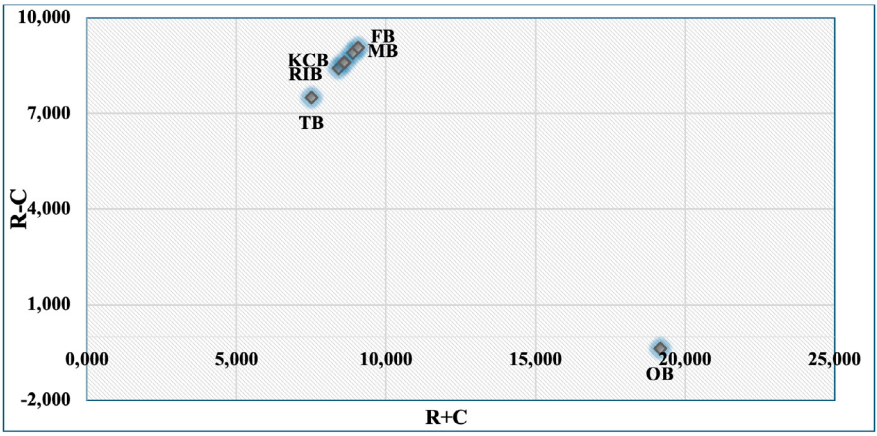

Figure 1. Cause and effect diagram of lean process management barriers

For R-C, the barriers below the zero line are the criteria affected by the other barriers. The FB barrier, which is above the zero line, affects the other barriers dominantly. On the R+C axis, the importance of the lean process management barrier increases as it moves away from zero. In this context, it can be easily seen with the help of the figure that the first three most important barriers are OB, FB and MB (Figure 1).

The threshold value was determined by taking the average of the defuzzified total relation matrix. The threshold value obtained was calculated as 1.442. On Table 7, it is seen that the values above the threshold value are indicated in bold. Also, according to Table 7, TB barrier is affected by all other barriers and at the same time affects all barriers.

Table 7. The defuzzified total relation matrix and threshold value

	OB	MB	FB	TB	RIB	KCB
OB	1.592	1.728	1.670	1.392	1.523	1.492
MB	1.736	1.530	1.651	1.346	1.481	1.158
FB	1.753	1.723	1.509	1.409	1.495	1.181
TB	1.438	1.415	1.376	1.080	1.269	0.930
RIB	1.604	1.561	1.533	1.342	1.295	1.085
KCB	1.642	1.618	1.542	1.336	1.478	0.993

*Threshold value: 1.442

Within the scope of the study, the most effective and important obstacles affecting lean process management in the pharmaceutical industry were found to be organizational, financial and managerial obstacles, respectively. So, the most effective and important obstacles to lean process management in the pharmaceutical industry are organizational obstacles, including resistance to change, employee participation, lack of empowerment and commitment, cultural differences, operational conflicts and lack of reward strategies. In literature, in line with the study findings, a study state that the lack of employee participation in the design and implementation of lean processes seriously limits the effectiveness of such initiatives[36]. Similarly, another study authors stated that the lack of effective reward strategies that can motivate employees to adopt change further increases the difficulties experienced in the process[37]. Additionally, authors found that without appropriate recognition or incentives for the adoption of lean behaviors, employees are driven away from the drive to initiate or participate in process improvements[38]. A number of studies have indicated that a strong culture of commitment to traditional practices in pharmaceutical companies can hinder the acceptance of lean management processes and weaken their sustainability[39]. Furthermore, the lack of employee awareness and participation in lean principles is directly related to operational performance in the pharmaceutical sector[40]. Operational conflicts resulting from disagreements between departments focused on different priorities and goals pose another challenge for lean management[41].

The second priority barrier is financial barriers, including high investment costs and lack of financial resources. Similarly, in another study lack of resources, along with financial constraints, are important barriers to the integration of lean management methods into operational practices[42]. Also, organizations face significant financial challenges that may hinder their capacity to effectively adopt and sustain lean practices[43]. On the other hand, effective lean management practices provide significant efficiency gains but can only be implemented if the financial resources required for implementation are available[44]. Also, lean practices will positively improve the efficiency levels of businesses and that their successful implementation is usually hindered by financial constraints[45]. Another studies, also, emphasize that the transition to lean processes requires financial investment, which requires more capital and resource allocation[46]. Financial resources play a critical role in the successful implementation of lean processes in the pharmaceutical industry and require careful financial planning and management[47].

The third effective and important barrier is the managerial barriers, which have subheadings such as lack of senior leadership and lack of middle management support, lack of communication and cooperation between management and employees, management pressure, and lack of mutual trust between managers and employees. When looking at the literature, some studies argue that lack of employee commitment and insufficient support from management can further exacerbate this resistance and lead to ineffective lean practices[15,48]. In addition, environments where communication is blocked and information flow is lacking also restrict and complicate the process of aligning the business with lean principles[49]. The importance of continuous communication to ensure that all stakeholders are on the same page in an effective lean transformation process[50]. In a study, the impact of leadership styles on corporate innovation in pharmaceutical companies and figured out democratic and participatory leadership styles significantly affect performance results in terms of readiness for lean management practices[51]. Similarly, another study highlighted that need for leadership and middle management support to ensure the successful implementation of lean tools in healthcare sectors[18].

As a result of the analysis, it was revealed that organizational, financial and managerial barriers were the most critical barriers in the effective implementation of lean practices. It was determined that organizational barriers, which stand out with subheadings such as resistance to change, lack of employee participation and empowerment, cultural incompatibilities and inadequacy of reward strategies, were the category most affected by other barriers. This situation shows that to successfully implement lean process management, lean culture should be established in enterprises, employee-centred policies should be developed and change management should be addressed strategically. Financial barriers were determined as the strongest influencing factor over all other barriers, such as high investment costs and insufficient resources. Therefore, in terms of the sustainability of lean transformation, the creation of special budgeting strategies and resource planning is of great importance. The third most effective managerial barriers include factors such as lack of leadership, insufficient support from middle management, communication gaps between management and employees and lack of mutual trust. In this context, it is necessary to increase managerial competencies, ensure strategic alignment and develop a participatory management approach in the lean transformation process.

In line with the findings, several strategic recommendations are presented. First, structural change management programs that will encourage continuous

improvement of culture and open communication in businesses should be developed. Lean investments should be prioritized in financial resource planning processes, and the necessary budgets for the transformation should be provided from internal or external sources. At the leadership level, a leadership approach compatible with the lean philosophy should be adopted, leaders should actively participate in processes, and trust-based relationships should be established with employees. In addition, training and competency development programs focused on lean management should be implemented for employees, thus increasing the ability of employees to use lean tools effectively. Structures that support horizontal collaboration between processes should be created, resistance between departments should be reduced, and a holistic improvement approach should be adopted. Finally, in areas subject to high levels of regulation, such as the pharmaceutical sector, legal regulations and sectoral policies should be updated to support the adoption of lean management.

STATEMENT OF ETHICS

This study was approved by the Istanbul Medipol University Ethics Committee for Non-Interventional Clinical Research (Decision Number: 598, Date: 22.05.2025).

CONFLICT OF INTEREST STATEMENT

The authors have no conflict of interest to declare.

AUTHOR CONTRIBUTIONS

The authors contributed equally to the article.

FUNDING SOURCES

Not applicable.

ACKNOWLEDGMENTS

Not applicable.

REFERENCES

1. Ruiz-de-Arbulo-Lopez P, Fortuny-SantosJ, Cuatrecasas-Arbós L. Lean manufacturing: costing the value stream. Ind Manag Data Syst, 2013;113(5):647-668. Doi: 10.1108/02635571311324124

2. Navarro P. Applying quality concepts to achieve environmental sustainability in the freight transport sector—reviewing process management and lean. Int J Qual Serv Sci, 2021;13(4):545-562. Doi: 10.1108/IJQSS-02-2020-0029

3. Hurriyet H, Nakandala D. Lean thinking and the innovation process. In: Al-Hakim L, Wu X, Koronios A, Shou Y, editors. Handbook of research on driving competitive advantage through sustainable, lean and disruptive innovation [Internet]. IGI Global;2016. p. 39-58. Available from: https://doi.org/10.4018/978-1-5225-0135-0.ch002

4. Ostbo P, Wetherill M, Cattermole R. Leading beyond lean: the seven drivers of productivity. Palgrave Macmillan; 2016.

5. Shah R, Ward PT. Defining and developing measures of lean production. J Oper Manag, 2007;25(4):785-805. Doi: 10.1016/j.jom.2007.01.019

6. Womack JP, Jones DT. How to root out waste and pursue perfection. Harvard Business Review; 1996 [May 15, 2025]. Available from: https://hbr.org/1996/09/how-to-root-out-waste-and-pursue-perfection

7. Knapić V, Rusjan B, Božič K. Importance of first-line employees in lean implementation in SMEs: a systematic literature review. Int J Lean Six Sigma, 2023;14(2):277-308. Doi: 10.1108/IJLSS-08-2021-0141

8. Holweg M. The genealogy of lean production. J Oper Manag, 2005;25(2):420-437. Doi: 10.1016/j.jom.2006.04.001

9. Palmberg K. Exploring process management: are there any widespread models and definitions? TQM J, 2009;21(2):203-216. Doi: 10.1108/17542730910938182

10. De Toni A, Tonchia S. Lean organization, management by process and performance management. Int J Oper Prod Manag, 1996;16(2):221-236. Doi: 10.1108/01443579610109947

11. Assen M. Lean, process improvement and customer-focused performance. The moderating effect of perceived organisational context. Total Qual Manag Bus Excell, 2018;32(1-2):57-75. Doi: 10.1080/14783363.2018.1530591

12. Paim R, Caulliraux HM, Cardoso R. Process management tasks: a conceptual and practical view. Bus Process Manag J, 2008;14(5):694-723. Doi: 10.1108/14637150810903066

13. Puvanasvaran P, Megat MHMA, Tang SH, Muhamad MR, Hamouda AMS. Lean behavior in implementing lean process management. J Appl Sci Res, 2009;5(8):930-943. Doi: hdl.handle.net/10576/10426

14. Puvanasvaran P, Megat H, Hong TS, Razali MM, Magid SHA. Lean process management implementation through enhanced problem solving capabilities. J Ind Eng Manag, 2010;3(3):447-493. Doi: https://doi.org/10.3926/jiem..v3n3.p447-493

15. Januszek S, Macuvele J, Friedli T, Netland TH. The role of management in lean implementation: evidence from the pharmaceutical industry. Int J Oper Prod Manag, 2022;43(3):401-427. Doi: 10.1108/ijopm-02-2022-0129

16. Alkunsol WH, Sharabati AA, AlSalhi NA, El-Tamimi HS. Lean six sigma effect on Jordanian pharmaceutical industry's performance. Int J Lean Six Sigma, 2019;10(1):23-43. Doi: 10.1108/ijlss-01-2017-0003

17. Argiyantari B, Simatupang TM, Basri MH. Pharmaceutical supply chain transformation through application of the Lean principle: a literature review. J Ind Eng Manag, 2020;13(3):475-494. Doi: 10.3926/jiem.3100

18. Trakulsunti Y, Trakoonsanti L. The use of Lean tools to reduce inpatient waiting time in a Thai public hospital: an action research study. Leadersh Health Serv (Bradf Engl), 2021;34(2):84-97. Doi: 10.1108/lhs-10-2020-0080

19. Naidoo L, Fields Z. Critical success factors for the successful initiation of lean in public hospitals in kwazulu-natal: a factor analysis and structural equation modelling study. Hum Resour Health, 2019;17(1):69. Doi: 10.1186/s12960-019-0405-1

20. Al-Qayoudhi SAS. A conceptual review of the adoption of lean philosophy tools in manufacturing companies. Int J Res Entrep Bus Stud, 2022;3(1):1-12. Doi: 10.47259/ijrebs.311

21. Frankowska M. Implementation barriers of lean manufacturing in the production sector. Eur J Serv Manag, 2018;28(1):125-133. Doi: 10.18276/ejsm.2018.28/1-16

22. Pereira CM, Anholon R, Batocchio A. Obstacles and difficulties implementing the lean philosophy in Brazilian enterprises. Braz J Oper Prod Manag, 2017;14(2):218-227. Doi: 10.14488/bjopm.2017.v14.n2.a10

23. Bitsanis IA, Ponis ST. The determinants of digital transformation in lean production systems: a survey. Eur J Bus Manag Res, 2022;7(6):227-234. Doi: 10.24018/ejbmr.2022.7.6.1732

24. Garza-Reyes JA, Betsis IE, Kumar V, Al-Shboul MAR. Lean readiness—the case of the European pharmaceutical manufacturing industry. Int J Product Perform Manag, 2018;67(1):20-44. Doi: 10.1108/ijppm-04-2016-0083

25. Berlec T, Kleindienst M, Rabitsch C, Ramsauer C. Methodology to facilitate successful lean implementation. Stroj Vestn/J Mech Eng, 2017;63(7-8):457-465. Doi: 10.5545/sv-jme.2017.4302

26. Bhasin S. Prominent obstacles to lean. Int J Product Perform Manag, 2012;61(4):403-425. Doi: 10.1108/17410401211212661

27. Valente CP, Mourão CAMA, Saggin AB, Neto JPB, Costa JM. Achieving excellence in lean implementation at construction companies—a case study from Brazil. In: Tommelein ID, Daniel E, editors. Proceedings of the 28th Annual Conference of the International Group for Lean Construction (IGLC); 2020, Jul 6-12. Berkeley, CA, USA. International Group for Lean Construction; 2020. Available from: https://iglc.net/Papers/Details/1773

28. Abu F, Gholami H, Saman MZM, Zakuan N, Štreimikienė D, Kyriakopoulos GL. An SEM approach for the barrier analysis in lean implementation in manufacturing industries. Sustainability, 2021;13(4):1978. Doi: 10.3390/su13041978

29. McDermott O, Antony J, Sony M, Daly J. Barriers and enablers for continuous improvement methodologies within the Irish pharmaceutical industry. Processes, 2021;10(1):73. Doi: 10.3390/pr10010073

30. Pedersen ERG, Huniche M. Determinants of lean success and failure in the Danish public sector. Int J Public Sect Manag, 2011;24(5):403-420. Doi: 10.1108/09513551111147141

31. Tezel A, Koskela L, Aziz Z. Lean thinking in the highways construction sector: motivation, implementation and barriers. Prod Plan Control, 2017;29(3):247-269. Doi: 10.1080/09537287.2017.1412522

32. Yadegaridehkordi E, Nilashi M, Nizam Bin Md Nasir MH, Safie Bin Mohd Satar N, Momtazi S. Evaluating COVID-19 infection prevention measures in Malaysia: a fuzzy DEMATEL approach. Digit Health, 2023;9:20552076231211670. Doi: 10.1177/20552076231211670

33. Singh M, Rathi R, Jaiswal A, Manishbhai SD, Gupta SS, Dewangan A. Empirical analysis of Lean Six Sigma implementation barriers in healthcare sector using fuzzy DEMATEL approach: an Indian perspective. TQM J, 2023;35(8):2367-2386. Doi: 10.1108/TQM-05-2022-0152

34. Hossain MK, Thakur V. Benchmarking health-care supply chain by implementing Industry 4.0: a fuzzy-AHP-DEMATEL approach. Benchmarking, 2021;28(2):556-581. Doi: 10.1108/BIJ-05-2020-0268

35. Opricovic S, Tzeng G. Defuzzification within a multicriteria decision model. Int J Uncertain Fuzz Knowl-Based Syst, 2003;11(5):635-652. Doi: 10.1142/S0218488503002387

36. Srinivasan G, Shah N. Kaizen and lean implementation in pharmaceutical industries: a review. Asian J Pharm Clin Res, 2018;11(7):57-63. Doi: 10.22159/ajpcr.2018.v11i7.24722

37. Hamzeh F, González VA, Alarcón LF, Khalife S. Lean construction 4.0: exploring the challenges of development in the AEC industry. Annu Conf Int Group Lean Constr, 2021;207-216. Doi: 10.24928/2021/0181

38. Lestari DA, Subroto A. Performance efficiency of quality control laboratory through implementation of lean operation. J Manaj Dan Kewirausahaan, 2022;24(1):64-72. Doi: 10.9744/jmk.24.1.64-72

39. Jayathilake H, Galahitiyawe N, Herath H. Impact of lean management implementation practices on operational performance: an empirical study of the pharmaceutical industry in Sri Lanka. Eur Mod Stud J, 2023;7(1):169-184. Doi: 10.59573/emsj.7(1).2023.15

40. Kumar N, Saini S. Some recent stories of operational excellence in SMES. Int J Res Appl Sci Eng Technol, 2023;11(12):1538-1551. Doi: 10.22214/ijraset.2023.57666

41. Ghapar F, Manan DIA, Chew LL, Othman AK, Sundram VPK. Unveiling the hidden risks: exploring vulnerabilities in the pharmaceutical supply chain. Eur Proc Soc Behav Sci, 2024;882-892. Doi: 10.15405/epsbs.2024.05.72

42. Muñoz-Villamizar A, Santos J, Grau P, Viles E. Trends and gaps for integrating lean and green management in the agri-food sector. Br Food J, 2019;121(5):1140-1153. Doi: 10.1108/bfj-06-2018-0359

43. Bilal AI, Bititci US, Fenta TG. Challenges and the way forward in demand-forecasting practices within the ethiopian public pharmaceutical supply chain. Pharmacy, 2024;12(3):86. Doi: 10.3390/pharmacy12030086

44. Siddiqui MUH, Majeed F. Applying Lean management principles for enhanced outpatient waiting times. Biomed J Sci Tech Res, 2023;52(4): 43957-43966. Doi: 10.26717/bjstr.2023.52.008290

45. Ahmed E, Saleh WA, Khashman Y. Lean implementation in Jordanian pharmaceutical industry: the case of Hikma company. Eur J Bus Manag, 2021;13(10):74-76. Doi: 10.7176/ejbm/13-10-08

46. Maware C, Parsley DM. The challenges of Lean transformation and implementation in the manufacturing sector. Sustainability, 2022;14(10):6287. Doi: 10.3390/su14106287

47. Prasad KV, Vasugi V. Readiness factors for sustainable lean transformation of construction organizations. Sustainability, 2023;15(8):6433. Doi: 10.3390/su15086433

48. Teich ST, Faddoul FF. Lean management—the journey from Toyota to healthcare. Rambam Maimonides Med J, 2013;4(2):e0007. Doi: 10.5041/rmmj.10107

49. Argiyantari B, Simatupang TM, Basri MH. Transportation performance improvement through lean thinking implementation. Int J Lean Six Sigma, 2022;13(3):622-647. Doi:10.1108/ijlss-06-2020-0075

50. Azevedo KJ, Gray C, Gale R, Urech TH, Ramirez JC, Wong EP, et al. Facilitators and barriers to the Lean enterprise transformation program at the veteran's health administration. Health Care Manag Rev, 2020;46(4):308-318. Doi: 10.1097/hmr.0000000000000270

51. Zadeh MR, Hackney R, Zeng J. Augmenting learning processes of absorptive capacity for innovation: insights for effective leadership within global pharmaceutical companies. Eur Manag Rev, 2021;19(2):263-284. Doi: https://doi.org/10.1111/emre.12477