Identifying Factors Affecting the Pharmaceutical Supply Chain Management in Iran

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Abstract

Background: This study has been conducted with the aim to identify factors affecting the management of pharmaceutical supply chain in Iran. Materials and Methods: This study was of a combined (quantity–quality) type. The assessment tool was a Likert scale-based five-option questionnaire. Content validity assessment was obtained at 0.89 according to the CVR, and construct validity was at 0.971 using factor analysis. KMO statistics was very high and indicative of a correlation of scale items. In terms of reliability of assessment in researcher-made tools, the selected items were analysed, and the results obtained showed that the applied scales enjoyed significant reliability. The sample for the survey was 100 experts in the pharmaceutical system of the country’s Food and Drug Administration, pharmaceutical companies, technical officer of pharmacies and the ministry of health and medical education. They were selected by purposive stratified non-random sampling and snowball methods. The data was analysed by exploratory factor analysis using SPSS and LISREL. Results: The results of the current study indicated a pattern with significant and direct relationship between independent and dependent variables of medicine supply chain management. The most important indicators of medicine supply chain management in order of priority were distribution management with impact factor, IT management, pharmaceutical structure, pharmaceutical structure programming, coordination, enterprise resource planning, logistics management, knowledge management, financial management, globalization, customer relationship management, and medical insurance system. Conclusions: According to the patterning indexes, it can be mentioned that the representative model has had a good fit, and a desirable compliance between a structural model with experimental data and expert opinion has been provided.


Keywords: Apical abscess; Oregano; Traditional Persian Medicine
Introduction

Today, competitiveness is considered as one of the most important factors in the development of industry and the pharmaceutical industry is no exception [1]. The importance of competition in this section is so much that governments try to balance it with economic growth. In addition to the competitiveness, high medicine price could be one of the factors that always threatens medical services, and challenges of low-income patients. High cost of medicine production and its continuous increase are being seen as a global concern. So, it has necessitated the need for a pharmaceutical chain management system [2].

The pharmaceutical industry has been defined as a system of processes, operations, and organizations involved in discovery, development, and production of drugs and medicines. Medicine chain management refers to a path through which pharmaceutical products of good quality are distributed among consumers in the right place and time [3]. Considering the characteristics of supply, storage and distribution of medicines are important because, firstly, the vast majority of people receiving healthcare services are residents of towns and villages and are deprived of medical services due to distance as well as additional charges. So, they are unable to refer to urban centres for getting services. Secondly, owing to efficient procurement, supply and distribution of regular services and drugs, the access to medicines by the poor has become possible. So, unreasonable referrals of a large part of the population to specialized centres is not needed any more [4].

In the past, pharmaceutical companies ignored the concept of supply chain management of medication, but now a number of factors lead pharmaceutical companies to change traditional ways of business. One of the factors is supply chain that is becoming a competitive advantage [5]. From the perspective of the World Health Organization (WHO), the importance of a drug is due to three main reasons: 1. Medicines constitute a considerable portion of the relationship between a patient and healthcare officials. Therefore, availability or rather lack of adequate access to them would have negative consequences on community health. 2. Management of medicine in the state sector, especially in developing countries, is a determinant of success and its improvement can help maintain the capital of countries and increase people’s accessibility to medicines. 3. Medical services and issues related to it are not only dependent on the performance of health workers, but even political, economic, financial and cultural factors have a significant impact on it.

Thus, medication management is a purposeful and conscious effort for the majority of the public to access basic medicines in order to meet public health requirements [6]. There are important challenges in the pharmaceutical chain supply, including lack of coordination between members of a drug supply chain and inventory management. Other challenges include lack of demand information at various levels of the chain, human resource dependency in the field of drug supply chain, order management, shortage avoidance, supplying medicines before their expiry dates, and warehouse management. Many medicines and vaccines must be carried and preserved under controlled temperature. Given the importance of medicine and its link with community health, it is necessary to track shipment visibility of the medicines [7-9].

The provision of an efficient master plan which is able to integrate the procurement, production and distribution plans is a critical need in the way of achieving the competitive advantage in today’s marketplace [10]. Drug supply chain safety has become a priority for public health which implies a collective process [11].

Olfat et al. (2012) pointed out that to evaluate the performance of a supply chain, having a comprehensive model in addition to reliable data is helpful. It also helps in improving the entire chain. In the article, a model related to network and multi-level nature of supply chain was used in order to evaluate the performance of all the chains in a mathematical model using financial, knowledge, participatory, and responsive indexes of supply chain. In the first section, the indexes were considered in three strategic, procedural, and operational levels. Then, they were confirmed by factor analysis.
In the second section, network data envelopment analysis model was used. The results obtained showed a strategic level with a weight of 0.98 being the most important functional level and procedural and operational levels have weights of 0.97 and 0.87, respectively. In addition, four out of 28 chains of the study have performance value of 1, and the lowest value of observed performance was 0.43 [12]. Susarla et al. (2012) have represented a mixed integer model of programming for integrated supply chain planning of multinational pharmaceuticals industry. The model tried to design a programme of integrated provision, manufacturing and supply with regard to maintenance, taxes, and raw material lifespan so that the total benefit of supply chain could be maximized. In addition, he mentioned that classical models, including the classical mathematical logic, cannot be precise by themselves. In fact, when lack of precision is due to the structure of the model, the model will not be real [13]. Holm et al. (2015) stated that according to the WHO, one-third of the population in developing countries have no access to essential medicines. In addition, many governments and healthcare units do not have a stable narcotic drug supply chain process. Unreliable drug use monitoring, contradictory medication, lack of integration, poor drug quality, and concern about the use of drugs among hospital workers for personal use are the leading causes of drug supply chain problems. Stock development and supply chain management is a simple system that is used in order to keep the drug on the pharmaceutical shelves and hospitals and prevent use of low-consumed medicines [14] whose expiry date is over. National Institute on Drug Abuse (NIDA) (2013) responded to the question that what system could be more appropriate globally to facilitate effective performance of narcotic drugs’ supply chain. To hold such a system, there are some challenges such as complexity of production, market size, access problems, and strategies applied. Many scholars believe that supply chain re-design should have two parallel systems rather than just focusing on providing services. Standards and obligations in creating and maintaining this system should be set in order to preserve this system, and national and international legal routes for all organizations involved in supply chain management must be specified. In addition to communicating with other supply chains (to supply parts and equipment), standards of the WHO, capacity building and accountability, mobilization for public-private support, studying the processes of pharmaceutical manufacture, complex provision (containing a basket of different drugs), suitable pricing, forecasting a recovery in demand, integrated information management system, flexible financial accountability, establishing innovative mechanisms, appropriate leadership, planned procedure, coordination with the private sector and new and flexible structures are also needed [15]. Ehrhardt et al. (2012) has stated that major pharmaceutical companies, particularly suppliers of drugs, grapple with low orders and need a proper strategy, a revision in production, and supply chain operations. In many companies, the old ways of the past several decades are still in use. However, the need to establish trade relations with suppliers is necessary. This includes a strong relationship, but the least is trying for mutual improvement, real desire to increase productivity, modest taxes, and removal of legal restrictions [16]. Finally, supply of medicines has been considered as one of the top priorities of healthcare reforms in Iran. In order to fulfil it, drug list (BP) has been developed and updated according to a hospitalized patient’s needs. Specialized facilities, medical and hospital credit ceiling, and the list of essential and vital medicines have been segregated. Although the medicine supply chain is a continuous process, and not all the problems can be solved at once, the proprieties and urgencies must take a special attention. In Iran, despite the high importance of the supply chain management of medicine and its wide use in the world, few studies are available in this regard. Besides, in consideration of bullwhip effect, that is, tempting medicine supplies and as was aforesaid, one has to give more attention to studies conducted with regard to programming medicine supply chain in order to maximize benefit and minimize to-
tal cost of the chain. It seems that to prepare the ground for development for supply chain management and its entry into world trade, revising policies and strategies are needed. In addition, they must be studied and solved with a broad vision and foresight. Therefore, the present study investigated and analysed this category and with satisfactory selection of suppliers. This is an effective step to present a model of supply chain management of medicine for Iran.

**Materials and Methods**

**Study Design**

The present study was a combined (qualitative-quantitative) one and applied research that has been used is given below, and in proportion:

A) A library and documentary method was used to achieve a theoretical framework, clarify transparency factors, and gain knowledge of history and literature.

B) Qualitative approach was used to identify factors affecting supply chain management of drugs using opinion of experts, and executives of the drug industry at the Food and Drug Administration (FDA), pharmaceutical companies, technical responsible pharmacist and the ministry of health and medical education officials via a semi-structured interview. The initial conceptual model has been developed, designed, and validated by maxqda software.

C) Filling questionnaires and presenting mathematical model of the factors affecting management of medicine supply chain were done using exploratory factor analysis by SPSS software and confirmatory factor analysis using LISREL.

**Participants**

The statistical population is a generalized area of the results and findings. Therefore, the population of the present study in stage B included all experts and executives of the pharmaceutical system in the FDA. The sample was selected using non-random purposive sampling and snowball method. Moreover, time interview continued until achieving data saturation. In this level, to analyse documents, Scott method was used. Scott method is to analyse content, and documentary method is referred to all methods through which the objective of the study is achieved by studying, analysing, and investigating documents and texts. It is the way in which the following steps are carried out: Determining authenticity, and credibility, as well as making data representative, and meaningful. Content analysis examines texts, and tries to extract data from text using analysis so that at first specific issues are confirmed in the text, and then, the content is examined as a whole. Afterwards, the primary conceptual model, after being designed, was given to 10 experts of the Food and Drug Administration. Finally, after having a consensus, that is at least 80 percent, the primary conceptual model was introduced. Inclusion criteria were working in the Food and Drug Administration as well as with specialized education, knowledge management, and related machinery along with interest in participating in interviews. In level C, the population included all experts in the pharmaceutical field. Given the number of people in-charge of the pharmaceutical field, the study sample included 100 individuals working in the pharmaceutical segment of the health ministry, the Food and Drug Administration, as well as educational pharmacies, private pharmacies, and pharmacy-related organizations such as Red Cross.

**Data Collection**

Structural equation modelling is a technique for data analysis that is designed to evaluate the relationship between two variables:

A) Obvious variables: Variables that are directly measured and are observed variables,

B) Latent or hidden variables, or variables that are raised as a theoretical construct.

Structural equation model compared to other data analysis techniques will allow the researcher to test the complex theoretical models in an analysis. Structural equation modelling enables the researchers to make a casual analysis of latent and observed variables simultaneously. Researchers use goodness of fit indexes to evaluate fitness. The assessment tool in this study was the Likert scale-based five-item questionnaire. Using a theoretical area, model of research
and results of measurement tools, the experts agreed on 83 items and 12 areas. The resultant content validity ratio (CVR) was 0.89, which is an acceptable value. Factor analysis was used to assess the validity of the technique, and Kaiser Mayer Olkin (KMO) statistics was equal to 0.971. This indicated a good correlation of scale items to create a factor analysis. Finally, it was determined that the factors affecting management of medicine supply chain, respectively, included pharmaceutical structure programming, including 12 questions (questions 1–12), structure of the pharmaceutical system, including eight questions (questions 13–20), structure of pharmaceutical insurance, including seven questions (questions 21–27), ERP, including seven questions (questions 28–34), coordination, including six questions (questions 35–40), IT management, including 10 questions (questions 41–50), logistics management, including 5 questions (questions 51–55), financial management, including six questions (questions 56–62), customer relationship management, including eight questions (questions 63–70), globalization, including three questions (questions 71–73), knowledge management, including five questions (questions 74–78), and distribution management, including five questions (questions 79–83).

Regarding reliability assessment of the researcher-made questionnaire, selected items were analysed, and the results showed that the applied scales have an acceptable reliability.

**Ethical Issue**

It is worth mentioning that the participants were asked to provide beforehand a well-informed oral consent for participation in the study plan. Also, the researchers never lost track of observing the ethical principles in any of the study stages and also it is noteworthy that all of the study stages were conducted by acquiring a permit from Islamic Azad University, Science and Research Branch, Tehran.

**Statistical Analysis**

The statistical techniques done on evaluation tools included factor analysis to evaluate validity, goodness of fit index for fitness of theoretical model and LISREL software for structural equation modelling and presenting the final model.

**Results**

In this section, findings of the study have been represented. factors affecting the management of medicine supply chain from the viewpoint of important patterns of supply chain management (Table-1). In the sample, most of the participants were males (68 percent), aged between 31 and 40 years (42 percent), with education of PhD senior (53 percent), and field of study of pharmacy (66 percent), in managerial positions (42 percent) and working in the FDA (32 percent), respectively. Table-2 has provided the distribution of central tendency and dispersion factors identified in the drug supply chain management. Results of Table-2 show that all paths of the model based on a significant scale items are significant and the values fluctuated between 31.30 and 57.45. In addition, in the studies, working on structural equation modelling, and examining normal distribution of variables is carried out with index stretch and skew analysis. Using a range of -7 to +7 has been proposed as acceptable for stretch and a range of -2 to +2 for skewedness of normal distribution. Skewedness of all the items is between -0.74 and 94, and stretch is between -0.49 and +0.46. In Table-3 of model fitting indexes, verifying pattern of drug supply chain management has been presented. The results of Table-3 indicate that the index of significance level in the model equals to 0.000 that is less than 0.05, so it shows that the model does not have a good fit. CFI and NFI comparative indicators have been developed to assess the acceptability of the model on the basis of comparison with the independent model that the values of more than 0.9 have been evaluated as acceptable. In the model, the mentioned index shows that the model enjoys a good fit. Parsimonious comparative fit index (PNFI) shows whether the economy of model has been cared for or not, and it is interpreted as an acceptable value when it is more than 0.5. In addition, in the model, the index men-
Table 1: The Identified Factors Affecting Management of Medicine Supply Chain

<table>
<thead>
<tr>
<th>Patterns</th>
<th>IT</th>
<th>The pharmaceutical and insurance structure</th>
<th>Knowledge management</th>
<th>Planning</th>
<th>Manpower</th>
<th>Globalization</th>
<th>Distribution management</th>
<th>Customer relationship</th>
<th>Coordination</th>
<th>Financial</th>
<th>Logistics</th>
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<tbody>
<tr>
<td>Stevens [17]</td>
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<td>Porter [18]</td>
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<td>Christopher [19]</td>
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<tr>
<td>Bowersox et al. and Stank et al. [20, 21]</td>
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<td>Lee [22]</td>
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<td>Morash et al. [23]</td>
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<td>Rosenzweig et al. [24]</td>
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<td>ACM [25]</td>
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<td>EPC [26]</td>
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<tr>
<td>Mehralian et al. [27, 28]</td>
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Table 2: Distribution of Central Tendency and Dispersion Factors Identified in Drug Supply Chain Management

<table>
<thead>
<tr>
<th>Variable</th>
<th>The impact factor</th>
<th>Parameter estimation</th>
<th>Significant level</th>
<th>The t-value</th>
<th>Skewness</th>
<th>Strain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical insurance system [29]</td>
<td>0.466</td>
<td>0.927</td>
<td>0.000</td>
<td>54.25</td>
<td>-0.63</td>
<td>0.44</td>
</tr>
<tr>
<td>Pharmaceutical structure [30]</td>
<td>0.784</td>
<td>1.000</td>
<td>0.000</td>
<td>52.43</td>
<td>-0.74</td>
<td>0.28</td>
</tr>
<tr>
<td>Pharmaceutical structure programming [31]</td>
<td>0.724</td>
<td>0.917</td>
<td>0.000</td>
<td>49.74</td>
<td>0.86</td>
<td>0.31</td>
</tr>
<tr>
<td>Erp [32]</td>
<td>0.645</td>
<td>0.960</td>
<td>0.000</td>
<td>46.59</td>
<td>-0.47</td>
<td>-0.49</td>
</tr>
<tr>
<td>Customer relationship management [33]</td>
<td>0.483</td>
<td>0.974</td>
<td>0.000</td>
<td>53.37</td>
<td>-0.69</td>
<td>-0.16</td>
</tr>
<tr>
<td>Logistics management [34]</td>
<td>0.628</td>
<td>0.978</td>
<td>0.000</td>
<td>47.14</td>
<td>0.73</td>
<td>0.12</td>
</tr>
<tr>
<td>Cooperation [31]</td>
<td>0.674</td>
<td>0.937</td>
<td>0.000</td>
<td>31.30</td>
<td>-0.71</td>
<td>-0.72</td>
</tr>
<tr>
<td>Distribution management [35]</td>
<td>0.892</td>
<td>0.953</td>
<td>0.000</td>
<td>46.66</td>
<td>0.94</td>
<td>0.41</td>
</tr>
<tr>
<td>IT management [36]</td>
<td>0.832</td>
<td>0.981</td>
<td>0.000</td>
<td>57.45</td>
<td>-0.36</td>
<td>0.28</td>
</tr>
<tr>
<td>Financial management [37]</td>
<td>0.562</td>
<td>0.982</td>
<td>0.000</td>
<td>43.51</td>
<td>0.75</td>
<td>0.39</td>
</tr>
<tr>
<td>Knowledge management [38]</td>
<td>0.597</td>
<td>0.653</td>
<td>0.000</td>
<td>53.85</td>
<td>0.84</td>
<td>0.46</td>
</tr>
<tr>
<td>Globalization [39]</td>
<td>0.539</td>
<td>0.706</td>
<td>0.000</td>
<td>56.29</td>
<td>0.39</td>
<td>-0.28</td>
</tr>
</tbody>
</table>
Table 3. Model Fit Indices Verifying Pattern of Drug Supply Chain Management

<table>
<thead>
<tr>
<th>Fit indexes</th>
<th>Criterion</th>
<th>Obtained Values</th>
<th>Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chi</td>
<td>The less the better</td>
<td>14253.842</td>
<td></td>
</tr>
<tr>
<td>Significance</td>
<td>More than 0.05</td>
<td>0.000</td>
<td>Not suitable</td>
</tr>
<tr>
<td>Chi relative</td>
<td>Between 2–5</td>
<td>3.098</td>
<td>Right</td>
</tr>
<tr>
<td>RMSEA</td>
<td>Less than 0.08, and preferably less than 0.05</td>
<td>0.032</td>
<td>Right</td>
</tr>
<tr>
<td>CFI</td>
<td>More than 0.9</td>
<td>0.935</td>
<td>Right</td>
</tr>
<tr>
<td>NFI</td>
<td>More than 0.9</td>
<td>0.961</td>
<td>Right</td>
</tr>
<tr>
<td>PCFI</td>
<td>More than 0.6</td>
<td>0.749</td>
<td>Right</td>
</tr>
</tbody>
</table>

RMSEA: Root Mean Square Error of Approximation; CFI: Comparative Fit Index, NFI: Normed Fit Index; PCFI: Parsimonious Comparative Fit Index

Figure 1. The output of structural equation from LISERL software
Medical insurance system (I), Pharmaceutical structure (S), Pharmaceutical structure programming (P), Erp (B), Customer relationship management (R), Logistics management (L), Cooperation (C), Distribution management (U), IT management (T), Financial management (F), Knowledge management (K), Globalization (G).
tioned shows that the model has a good fit. Root mean square error of approximation (RMSEA) shows whether the developed model is acceptable or not. Values of this index vary from zero to one, and the lower its value, the more acceptable the developed model is. In the model, according to the above table, the value of RMSEA equalled 0.032 showing good fit of the model. In total, the represented indexes show that the model verifying the pattern of medicine supply chain management has been confirmed in Iran, and the mentioned scales are good representatives of it. Figure-1 shows the output of structural equation from LISERL software.

Discussion

To test the model’s goodness of fit in theoretical research, with an emphasis on six indicators, fit of the developed model, on one hand, and experimental data on the other can be the focus areas. Therefore, a desirable accommodation between a structural model with experimental data and expert opinion has been provided. An emphasis on structural equation, a suitable model designed for the relationship between independent and dependent variables, and the desirable fit are indicative of structural equation modelling. In conclusion, it is proposed that the model suggested by the researcher has full fitness, because comparative indexes of CFI and NFI as well as parsimonious comparative fit index (PNFI) are at acceptable levels. In addition, the value of RMSEA equals 0.032, indicating good fit of the model. The results of the present study are aligned with the studies of Kalantari et al. (2016) [10], Susarla et al. (2012) [13], Blackstone et al. (2013) [15], Bedouch et al. (2009) [11] and Ehrhardt (2012) et al. [16]. The most important indicators of the medicine supply chain management in order of priority were: Distribution management with impact factor, IT management, pharmaceutical structure, pharmaceutical structure programming, coordination, enterprise resource planning, logistics management, knowledge management, fiscal management, globalization, customer relationship management, and medical insurance system. According to what has been stated, supply management is one of the most important factors affecting management of medicine supply chain. Although the focus of supply chains with regard to timely distribution has been on old and traditional ways of distribution, the smart management of supply chain in pharmaceutical companies has been very important. Moreover, some challenges are compliance with regulations, emerging markets, sequential coding of items and products, product variety, and learning how to use data. They are helping control costs and create value. Making a change according to the demand is a vital and important issue. The second factor affecting the management of drug supply chain is information technology. Integration of supply chain activities with technologies that are used to perform these activities is one of the competitive requirements in most industries, including the big industry of pharmacy. In addition, cases such as complexity of the business world, economic development, intense competition, new technologies, and rapidly changing customer needs prompt organizations to use some benefits like rapid flow of information, decision-making, coordination with business partners and comprehensive coordination. Therefore, adopting policies and charting instructions is required for preparation and implementation of supply chain technologies and e-commerce. The third factor affecting the management of drug supply chain is structure of the pharmaceutical system. Structure of the pharmaceutical system is evaluated based on the formalization, centralization, complexity, and type of ownership. It also includes decision making about price, amount and type of produced and imported drugs, as well as the amount of foreign exchange allocated to this sector, monetary or non-monetary support, type of production, distribution and sales as well as the number and economic aspects of manufacturers, importers, distributors, and pharmacies. In short, they include almost all basic variables of the drug system. The process dominating decision making is an official process, and like all other similar cases, it has complexities and features specified to intra-organizational relations. In addition, distribution companies are controlled and supervised by sanitation
organization, but the distribution structure is more flexible than the production process.

**Conclusion**

In general, the centralized decision-making process has actually developed a particular structure in the organization’s decision making during the years, so that the main decision maker of the pharmaceutical system is both organization-supervising manufacturing companies and representatives of producers. Therefore, the tasks that sometimes must be done by both organizations and in the competitive process are done by one organization. At the end, it is recommended that according to the competitive atmosphere nowadays, an effective supply chain programme, which integrates supply and distribution programmes in a unified framework, must be taken into account.

**Acknowledgments**

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**Conflict of Interest**

There was no conflict of interest.

**References**


