BARRIER ANALYSIS FOR THE IMPLEMENTATION OF PHARMA 4.0 TECHNIQUES IN LOGISTICS AND TRANSPORTATION OF PHARMACEUTICAL PRODUCTS- AN ISM APPROACH

SHIKHA KUMARI [1]

[1] Symbiosis Institute of operations Management, Nashik, Symbiosis International (Deemed University), Pune, India

ABSTRACT

Pharma 4.0 will connect everything through one of its important element, digitalization which will bring transparency in the system through data integrity and makes fully automated environment for pharmaceutical organizations. This study aims to analyse the barriers for the implementation of pharma 4.0 technique in logistics and transportation of pharmaceutical products. Transportation and logistics of pharmaceutical products is the crucial part. The main challenges in transportation of pharmaceutical products is transfer of consistent and accurate information, which makes the real-time traceability of the present condition of products really difficult. ISM and MICMAC analysis is used to find the variables and relation between them to derive a model that will help in designing the strategies to analyse the barriers for implementation of pharma 4.0.

Keywords

Pharma 4.0, Digitization, Industry 4.0, Logistics, Pharmaceutical products, Barriers, ISM technique and MICMAC analysis

Article Received: 10 August 2020, Revised: 25 October 2020, Accepted: 18 November 2020

Introduction

Implementation of Industry 4.0 in pharmaceuticals industry brings the concept of pharma 4.0.
Pharma 4.0 gives better opportunity in regard of product safety and security of the value chain through digitization, data analytics technology, IOT, artificial intelligence, and continuous manufacturing (Kumar, Talasila, Gowrav, & Gangadharappa, 2020).

The word logistics implies, from an expansive perspective, the activity of overseeing and directing the flows of materials, but from the time it has been introduced the process has changed, earlier the processes used to be manual and all the data used to be on paper, but now as per the changing technologies due to the need of the hour the process of logistics has evolved a lot (Gen, Cheng, & Lin, 2008). The companies are getting more inclined towards the application of advanced and new emerging technologies to gain competitive advantage and monitoring the varying customer expectations, but there are several factors that can cause problem in implementation of smart technologies i.e. Industry 4.0. In pharmaceutical industry, one of the most crucial aspect for shipping of pharmaceutical products is to monitor the temperature and moderating the risk factors (Galindo, 2016). The main challenges in transportation of pharmaceutical products is transfer of consistent and accurate information, which makes the real-time traceability of the present condition of products really difficult. The real-time tracing of the products and lack of accurate information can be reduced through addition of technology such as electronic tracking devices, Internet of Things (IOT) to mitigate the risk factors (Pachayappan, Rajesh, & Saravanan, 2016).

This analysis employs Interpretive Structural Modelling (ISM) approach for finding the relation between the variables to derive a model that will help in designing the strategy to find the barriers for implementation of pharma 4.0 for transportation of pharmaceutical products.

The further paper includes; in subsequent segment a literature review is carried out for the variables related to the analysed factors. The extent of influence between the variables are found through a survey and then Interpretive Structural Modelling and MICMAC analysis is performed for finding the result. As per the approach conclusion are drawn for the model and final section deals with the future scope of the research.

LITERATURE REVIEW

The impact of Industry 4.0 has been researched and still being researched by many researchers and organizations, which is the reason that there are many articles related to this concept. Though, the main focus is given on the latest industry scenarios and the required industrial innovations but this is not fully agreed upon all the time, and also its possible outcomes in industry and manufacturing, which are still not distinctly stated (Periera & Romero, 2017). This new industrial model comprises few of the technological advancements, such as CPS, IOT, Robotics, Big Data, Cloud Manufacturing and Augmented Reality, that is supposed to have an effect on both products and processes, which will help improving the efficiency and productivity of the firms (Schmidt, et al., 2015).

Pharma 4.0 is an integration of smart technologies, people, data and strategy for Pharma companies based on Industry 4.0, which was first proposed by the Germans (Kumar, Talasila, Gowrav, & Gangadharappa, 2020).However the concern is how far is this concept compulsory and functional. The implementation and virtualization of distinguished system may possibly be appropriate until future technologies agree for wide range and uncomplicated virtualization. Currently, the issue in pharma and healthcare industry is that the digitization and virtualization is implemented as and when required, anywhere and in anyway. (Needham & Glasby, 2015). To administer the system effectively and economically, shipment and storage of the materials are crucial aspects in order to manage the efficient flow of material (Gen, Cheng, & Lin, 2008).

(World Health Organization, 2010) mentions certain practices for distribution of pharmaceutical products defined under different sections are mentioned as-

As mentioned in Vehicles and equipment in section 10.14- Goods storing conditions unique in relation to, or restricting, the normal ecological conditions (temperature and humidity conditions), are essential while transporting them, the condition must be checked, observed and recorded.

As mentioned in Vehicles and equipment in section 10.3-Where plausible, thought ought to be given to including innovation, for example, GPS, real-time tracking devices and electrical sensors, which will help to improve the safety of pharmaceutical products during transportation.

As mentioned in Transportation and pharmaceutical products in transit section13- The environment or terms for storing the pharmaceutical products should be taken care with appropriate parameters while transporting the products. If any individual or element liable observes any variation while transporting the products, this ought to be reported to the distributor or beneficiary.

As per Dispatch and receipt for pharmaceutical products in section12.8 - means of transportation, as well as the vehicles being used, must be chosen with forethought, and local circumstances needs to be take into consideration, together with the climatic variations experienced. Shipping of products which requires controlled temperatures ought to be as per the appropriate storage and transport conditions.

As per dispatch and receipt for pharmaceutical products in section12.9- The routes for delivery should be planned and scheduled properly and the routes should be real-time taking into the risks related to security into consideration while planning the delivery schedule.

The pharma 4.0 i.e. the application of industry 4.0 techniques in pharmaceuticals will reduce the complexity in the processes to a great extent which needs to be critically examined at every step. As (Jain & Sharma, 2020) has mentioned, pharma industry is one of those industry where accuracy and precision should be given utmost importance , because in case of any oversight the consequence might be unsafe to its end user, henceforth it should always be confirmed that received raw materials, processing, and the outgoing medicines and equipment’s are carefully assessed ahead of being shipped from the warehouse, in such situation IOT can really be helpful in solving the issues to a great extent

The main barriers for the application of industry 4.0 techniques are the higher investments for upgrading the technology and the uncertain business case. Also the required skillset to meet the requirements of the new technologies and digitization (Pwc, 2014). As per (Galindo, 2016) Inadequate qualification with respect to the advancement in the technology is also one of the key challenges, because the change in technology will require to have qualified employees throughout the functional units. Also, the firms will have to go through major transition as the company will shift towards digitization and new technologies which will require high investments and due to which firms may face financial resources shortage.

Data collection, storage and processing is also one of the key challenges. As per (Ilin, Simić, & Saulić, 2019) Industry 4.0 provides large number of opportunities to bring transformation in logistics by data-driven knowledge and the requirement of several methods for storage of data and its processing is also on high demand due to the huge amount of irrelevant data which is because of the lack of guidelines for management of data. As a result, all the departments of an organization which incurs extra costs to clean the redundant data. Also as per (Ilin, Simić, & Saulić, 2019) Security is also one of the key challenges as logistics requires huge operational data and loss of such confidential data due to illegal access will lead to high costs.

Technological integration is another key challenges as it is difficult to integrate the equipment's with older specifications with new upcoming technologies, switching to digitization from industrialisation era is not easy for any organization (Quelch, 2019). The lack of standard guidelines and measures because of the various complications, these issues needs to be handled by industrial associations, trade unions and employer's associations together and not the company single-handedly (Galindo, 2016).Inflexible IT infrastructure, specially operating the old devices with devise built with new technologies is also a challenge in implementation of digitization as the technical infrastructure of every pharma companies are not so flexible (Quelch, 2019).

The lack of proper planning by management i.e. the unavailability of the required resources and undefined goals and leaders with lack of appropriate skills and relevant experience also act as an obstacle (Ilin, Simić, & Saulić, 2019). The machines and systems for all the function within an organization should work together, the heterogeneity among systems will act as an obstacle for digitization, if the system doesn't work in homogeneity it will make the decision-making process complex (Mohamed, 2018). The human and machine interaction is also a critical factor, the systems need to be reliable and stable for any kind of decision-making as the machines are capable of taking technical decisions but the decision will not always be ethically correct and this may be a matter of concern (Horváth & Szabó, 2019).

In case of logistics operation data needs to be exchanged between supplier, distributor and third party service provider, if the data and processes are not integrated properly between the stakeholders then it may create problem during digitization of the system (Ilin, Simić, & Saulić, 2019). During the real- time tracking of products, any inaccuracy in the timing or transfer of data during the shipment of pharmaceutical products may rise a safety concern for the products and so safety is also a concern for the digitization (Pachayappan, Rajesh, & Saravanan, 2016). The weak network connection may also be a concern for some of the pharma companies as the digitization fully depends on internet connection and transfer of large amount of data requires large bandwidth (Mohamed, 2018).

Organizational resistance may also act as a barrier as the employees will likely to have the fear of losing the job because of not having the expertise as per the requirement of the new technologies (Horváth & Szabó, 2019). Strict legal policies for the usage of external data is also one of the major obstacles, as digitization of system requires huge amount of sharing of data and due to the indistinct situation the companies may face problem while implementing industry 4.0 techniques (Pwc, 2014).Complex coordination between organizational units may also act as a barrier if the communication protocols are not defined, if everyone's doesn't have a common thinking at different hierarchy levels and there is lack of cooperation between the employees (Horváth & Szabó, 2019).

However, there could be a number of challenges which influences the implementation of Pharma 4.0 in transportation of pharmaceutical products but the literature review in this study highlights the key challenges. The study aims to analyse the main variables for the barriers in implementation of industry 4.0 in logistics of pharmaceutical products and relationship between all those variables with each other.

METHODOLOGY

The further process after the identification of variables was to create a questionnaire to find out the contextual relationship between the variables.

The questionnaire was sent to the industry experts with relevant experience in pharma companies. The responses received from the industry experts were then thoroughly analysed through Interpretive Structural Modelling (ISM).

Table 1 shows the 16 variables that are considered for development of ISM analysis where the variables are indicated in sequence from A to P.

Table 1: Summary of Variables Identified

Variables	Indication	Reference
Data Security & ownership	A	(Ilin, Simić, & Saulić, 2019)
Financial resources Shortage	B	(Galindo, 2016)
Technological Integration	C	(Quelch, 2019)
Standardization problems of systems	D	(Galindo, 2016)
Heterogeneity of devices & Networks	E	(Jain & Sharma, 2020)
Skilled Workforce	F	(Galindo, 2016)
Inflexible IT infrastructure	G	(Quelch, 2019)
Human-Machine Interactions	H	(Horváth & Szabó, 2019)
Safety Issues	I	(Pachayappan, Rajesh, & Saravanan, 2016)
Unstable Network connection	J	(Mohamed, 2018)
Inappropriate horizontal integration	K	(Ilin, Simić, & Saulić, 2019)
Ethical decision-making by smart devices	L	(Horváth & Szabó, 2019)
Lack of management planning	M	(Ilin, Simić, & Saulić, 2019)
Strict legal policies	N	(Pwc, 2014)
Organizational Resistance	O	(Horváth & Szabó, 2019)
Complexity in coordination across organization	P	(Horváth & Szabó, 2019)

After identifying the variables, the relationship between the 16 variables are created by analysing the survey. Then Structural Self-Interaction Matrix (SSIM) was created from the 16 variables as shown below in Table 2.

The four letters used to indicate the relationship between the variables in the SSIM represents-

- V: "ith" row variable will reach to "jth" column variable.
- A: "jth" column variable will reach to "ith" row variable.
- X: "ith" row and "jth" column variable will influence each other.
- O: "ith" row and "jth" column variable will not influence either of them.

Table 2: Structural-Self Interaction Matrix (SSIM)

	P	**O**	**N**	**M**	**L**	**K**	**J**	**I**	**H**	**G**	**F**	**E**	**D**	**C**	**B**	**A**
A	V	V	O	A	X	O	O	V	A	O	O	A	A	A	O	X
B	V	V	V	X	O	O	O	X	O	O	A	O	A	A	X	
C	V	V	O	O	O	A	O	X	O	O	A	A	V	X		
D	V	V	O	O	O	O	O	O	V	A	O	A	X			
E	V	V	O	O	O	O	O	V	V	X	O	X				
F	V	V	V	O	O	A	V	X	V	O	X					
G	V	V	A	V	V	O	V	V	V	X						
H	O	V	O	O	O	O	A	A	X							
I	V	V	O	A	X	O	X	X								
J	V	V	O	O	O	O	X									
K	V	X	O	V	O	X										
L	V	V	O	O	X											
M	V	V	V	X												

N	V	O	X													
O	A	X														
P	X															

The next step was, obtaining an initial reachability matrix. The four codes in SSIM (i.e. V, A, X, O) are replaced by 0s and 1s to get the initial reachability matrix. The codes in the SSIM matrix are replaced by 0s and 1s in the following way-

a) If the (i, j) cell is V, then the (i, j) cell becomes 1 and (j, i) cell becomes 0.

b) If the (i, j) cell is A, then the (i, j) cell becomes 0 and (j, i) cell becomes 1.

c) If the (i, j) cell is X, then the (i, j) cell becomes 1 and (j, i) cell also becomes 1.

d) If the (i, j) cell is V, then the (i, j) cell becomes 0 and (j, i) cell also becomes 0.

Where "i" represents row and "j" represents column. The Initial Reachability Matrix is illustrated in Table 3.

Table 3: Initial Reachability Matrix

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
A	1	0	0	0	0	0	0	0	1	0	0	1	0	0	1	1
B	0	1	0	0	0	0	0	0	1	0	0	0	1	1	1	1
C	1	1	1	1	0	0	0	0	1	0	0	0	0	0	1	1
D	1	1	0	1	0	0	0	1	0	0	0	0	0	0	1	1
E	1	0	1	1	1	0	1	1	1	0	0	0	0	0	1	1
F	0	1	1	0	0	1	0	1	1	1	0	0	0	1	1	1
G	0	0	0	1	1	0	1	1	1	1	0	1	1	0	1	1
H	1	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0
I	0	1	1	0	0	1	0	1	1	1	0	1	0	0	1	1
J	0	0	0	0	0	0	0	1	1	1	0	0	0	0	1	1
K	0	0	1	0	0	1	0	0	0	0	1	0	1	0	1	1
L	1	0	0	0	0	0	0	0	1	0	0	1	0	0	1	1
M	1	1	0	0	0	0	0	0	1	0	0	0	1	1	1	1
N	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	1
O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
P	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1

Then the transitivity is checked for the initial reachability matrix, the rule for checking transitivity is defined as- suppose the variable "D" is linked with variable "E" and variable "E" is linked with variable "G", then variable "D" is also linked with variable "G" as stated by (Guo, Li, & Stevens, 2012).

The final reachability matrix is achieved through Matlab coding after checking the transitivity rules as mentioned above, shown in Table 4.

Table 4: Final Reachability Matrix

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Drive Power
A	1	**1**	**1**	0	0	**1**	0	**1**	1	**1**	0	1	0	0	1	1	10
B	**1**	1	**1**	0	0	**1**	**1**	**1**	1	**1**	0	**1**	1	1	1	1	13
C	1	1	1	1	**1**	**1**	**1**	**1**	1	**1**	0	**1**	**1**	**1**	1	1	15
D	1	1	**1**	1	**1**	**1**	**1**	1	**1**	**1**	0	**1**	**1**	**1**	1	1	15
E	1	**1**	1	1	1	**1**	1	1	1	**1**	0	**1**	**1**	**1**	1	1	15
F	**1**	1	1	**1**	**1**	1	**1**	1	1	1	0	**1**	**1**	1	1	1	15
G	**1**	**1**	**1**	1	1	**1**	1	1	1	1	0	1	1	**1**	1	1	15
H	1	**1**	**1**	**1**	**1**	**1**	**1**	1	**1**	**1**	0	**1**	**1**	**1**	1	**1**	15

I	**1**	1	1	**1**	**1**	1	**1**	1	1	1	0	**1**	**1**	**1**	1	1	15
J	**1**	**1**	**1**	**1**	**1**	**1**	**1**	1	1	1	0	**1**	**1**	**1**	1	1	15
K	**1**	**1**	1	**1**	**1**	1	**1**	**1**	**1**	**1**	1	**1**	1	**1**	1	1	16
L	1	**1**	**1**	**1**	**1**	**1**	**1**	**1**	1	**1**	0	1	**1**	**1**	1	1	15
M	1	1	**1**	**1**	**1**	**1**	**1**	**1**	1	**1**	0	**1**	1	1	1	1	15
N	**1**	**1**	**1**	**1**	**1**	**1**	1	**1**	**1**	**1**	0	**1**	**1**	1	**1**	1	15
O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1
P	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	2
Dependence Power	14	14	14	12	12	14	13	14	14	14	1	14	13	13	16	15	

Final reachability matrix in Table 4 comprises of drive power which is obtained by the sum of all the 1s in the corresponding rows, indicates the influence of the variables on one another and dependence power which is the sum of all the 1s in the corresponding columns, indicates the extent of dependency of the variables on one another.

The Level Partition of the variable is done on the basis of drive power - The variables with lowest driving power will be considered at Level 1 and the variable with highest driving power will be at last level. In this case the variable "O" is at Level 1 with lowest driving power =1and the variable "K" is at Level 5 (last level) with highest driving power = 16, as shown in Table 5.

Table 5: Level Partition Matrix

Level	**Variables**	**Driving Power**
Level 1	O	1
Level 2	P	2
Level 3	A B C F H I J L	10 13 15 15 15 15 15 15
Level 4	D E G M N	15 15 15 15 15
Level 5	K	16

Apart from the above mentioned ISM approach, which explains in what way the various elements are linked with each other (Attri, Dev, & Sharma, 2013). The study also uses MICMAC technique as, the ISM technique is undertook to build a distinct hierarchical model whereas the MICMAC technique helps to find the impact as well as dependency with the inclusive design constituents, and to take into account the dependence and effect diagram which represents allocation of various components (Lee, Chao, & Lin, 2010).

Below shown Figure 1, shows the Dependence and Effect Diagram obtained using MICMAC analysis in which the vertical axis corresponds to the drive power of the variables and the horizontal axis corresponds to the dependence power of identified variables.

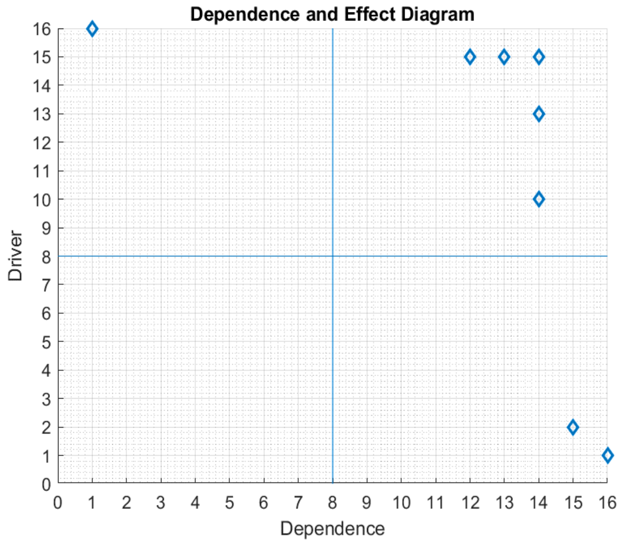


Figure 1: Dependence and Effect Diagram

The Plot is divided into four quadrants and each quadrant represents a set of variables as-

Linkage Variables are the variables whose drive and dependence power are higher than all other variables, in this analysis the linkage variables are- A, B, C, D, F, G. They are the effective connection among all the variables in the system.

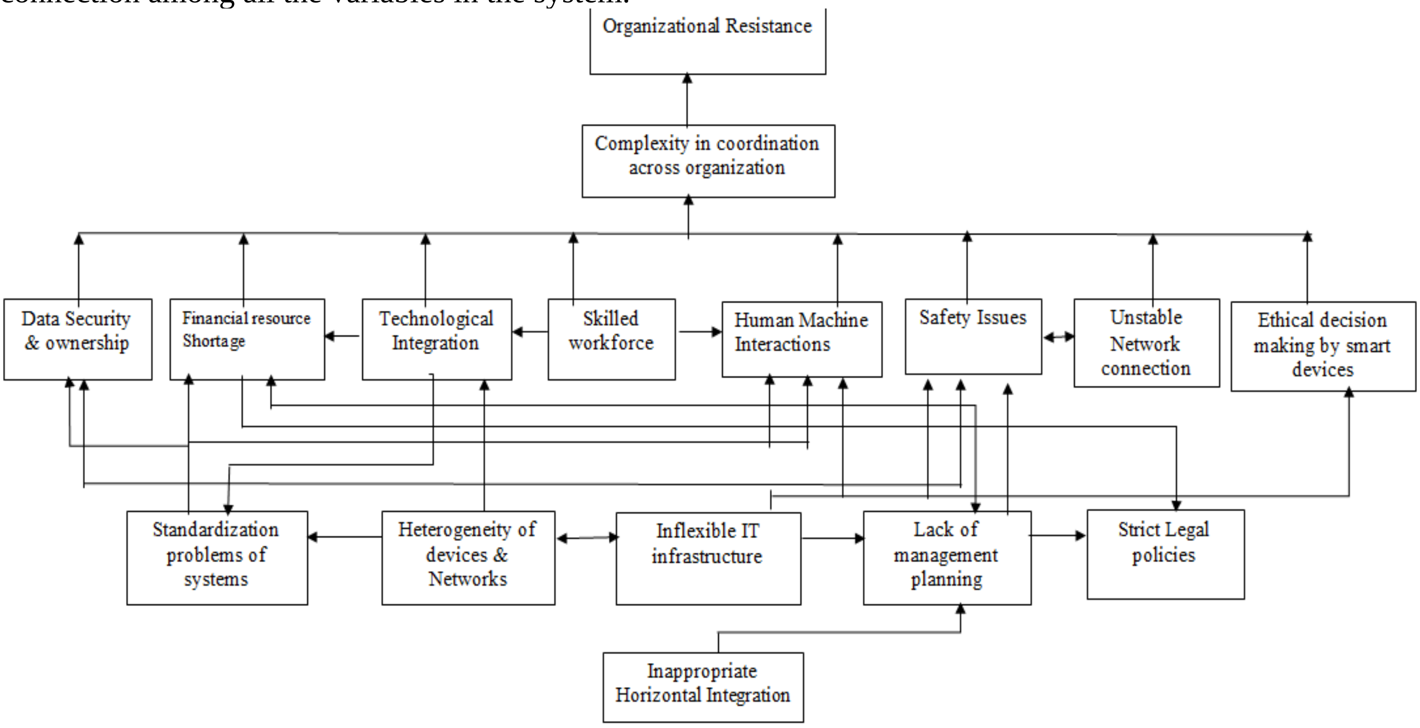
Driving variables are the variables whose drive power is high but dependence power is low, in this analysis the driving variable is- K. These variables influence the decision most.

Dependence variables are the variables whose drive power is low but dependence power is high, in this analysis the dependence variables are- O, P. These variables are the one which are influenced by other variables the most.

Autonomous Variables are the variables whose drive and dependence power both are low and these variables are generally excluded from the result of the analysis as they are highly self-governing.

RESULTS

The ISM structure as per the analysis for barriers in implementation of pharma 4.0 techniques is shown in Figure 2 which shows the interrelation among the variables which plays specific role.



CONCLUSIONS

The 16 variables analysed for this study were used to obtain the ISM model, from which the relationship between the variables and the degree of influence on each others were obtained. The conclusion drawn from the ISM and MICMAC analysis are-

Data Security & ownership, Financial resources Shortage, Technological Integration, Standardization problems of system, Skilled Workforce and Inflexible IT infrastructure are linkage variables as per the analysis, so if any changes if made will not only affect these variables but will also affect other variables.

Inappropriate horizontal integration is the driving variable as per the analysis, so this variable affects the system the most. The implementation of pharma 4.0 in the logistics of pharmaceutical products will very much depend on the horizontal integration of data and processes among stakeholders.

Complexity in coordination across organization and Organizational resistance are the dependence variable as per the analysis, so these variables will be influenced the most due to any changes in the other variables. Any of the variables identified as the barrier will ultimately affect the customer satisfaction.

Heterogeneity of devices & Networks, Human-Machine Interactions, Safety Issues, Unstable network connection, Ethical decision-making by smart devices, Lack of management planning and Strict Legal policies are autonomous variables and these variables are self-governing and these variables change in their own direction.

SCOPE FOR FURTHER RESEARCH

This study consists of technique to find the relation between the different variables to derive a model that will help in designing the strategy to find the barriers for implementation of pharma 4.0 for transportation of pharmaceutical products. However, there could be many more variables other than that is mentioned in this study. The further study can be done to analyse the various attribute that affects these variables that could help to reduce the barriers in the implication of pharma 4.0 technique.

REFERENCES

[1] Attri, R., Dev, N., & Sharma, V. (2013). Interpretive Structural Modelling (ISM) approach: An Overview. Research Journal of Management Sciences, 3-8.

[2] Galindo, L. D. (2016). The Challenges of Logistics 4.0 for the Supply Chain Management and the Information Technology. Master of Science in Mechanical Engineering, 1-85.

[3] Gen, M., Cheng, R., & Lin, L. (2008). Logistics Network Model. Network Models and Optimization, 135-229.

[4] Guo, Z., Li, Y., & Stevens, K. (2012). Analyzing Students' Technology Use Motivations: An Interpretive Structural Modeling Approach. Communications of the Association for Information Systems, 201-223.

[5] Horváth, D., & Szabó, R. (2019). Driving forces and barriers of Industry 4.0: Do multinational and small and medium-sized comapnies have equal oppurtunities? Technological Forecasting & Social Change, 119-132.

[6] Ilin, V., Simić, D., & Saulić, N. (2019). LOGISTICS INDUSTRY 4.0: CHALLENGES AND OPPORTUNITIES. 4th Logistics International Conference (pp. 293-301). Belgrade: logic.

[7] Jain, A., & Sharma, D. K. (2020). Chapter-3 Transforming pharma logistics with the Internet of Things. (V. E. Balas, V. K. Solanki, & R. Kumar, Eds.) An Industrial Approach for Pharmaceutical Industry Growth, 55-85.

[8] Kumar, S., Talasila, D., Gowrav, M., & Gangadharappa, H. (2020). Adaptations of Pharma 4.0 from Industry 4.0. Drug Invention Today, 405-415.

[9] Lee, Y.-C., Chao, Y. H., & Lin, S.-B. (2010). Structural Approach to design user interface. Computers in industry, 613-623.

[10] Mohamed, M. (2018). Challenges and benefits of Industry 4.0: An overview. International Journal of Supply and Operations Management, 256-265.

[11] Needham, C., & Glasby, J. (2015). Personalisation - Love it or hate it? Journal of Integrated Care 23(5), 268-276.

[12] Pachayappan, M., Rajesh, N., & Saravanan, G. (2016). Smart logistics for pharmaceutical industry based on Internet of Things (IOT). International Journal of Computer Science and Information Security (IJCSIS), 31-36.

[13] Periera, A. C., & Romero, F. (2017). A review of the meanings and the implications of the industry 4.0 concept. Manufacturing Engineering Society International Conference (pp. 1206-1214). Vigo: Elsevier B. V.

[14] Pwc. (2014). Industry 4.0- oppurtunities and challenges of the Industrial Internet.

London: PricewaterhouseCoopers Aktiengesellschaft Wirtschaftsprofungsgesellschaft.

[15] Quelch, R. (2019). Overcoming the challenges of today's global pharma supply chain. sydney: Contract Pharma.

[16] Schmidt, R., Mohring, M., Harting, R. C., Reichstein, C., Neumaier, P., & Jozinovic, P. (2015). Industry 4.0- Potentials for Creating Smart Products: Empirical Research Results. International Conference on Business Information Systems, Lecture Notes in Business Information Processing (LNBIP) (pp. 10.1007/978-3-319-19027-3_2). Poznań: researchgate.net.

[17] World Health Organization. (2010). WHO good distribution practices for pharmaceutical products. Geneva: who.int.