Journal of the Research Society of Pakistan
Volume No. 57, Issue No. 1 (January – June, 2020)

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Integration of Quality Management and Supply Chain Management in Pharmaceutical Distribution Sector of Pakistan

Abstract

Quality management principles and practices helps supply chain management to deliver quality products in timely manner with a competitive cost to customers. However, this integration and its relationship with performance of pharmaceuticals supply chains of healthcare sector is rarely discussed. In current study, a conceptual framework for supply chain quality management in pharmaceuticals supply chain of healthcare sector is developed on basis of published literature and focus group discussion with practitioners and empirically established its relationship with supply chain performance and business results of pharmaceutical distributors of Pakistan. Mediating effect of supply chain performance between link of supply chain quality management (SCQM) and business results is also measured. The study collected data from 246 employees working at pharmaceutical distribution set ups running either directly by manufacturers or third parties, across all provinces of Pakistan. Structural equational modelling by using Amos 24 is employed to measure the relationships. Results of study will help practitioners working at pharmaceutical distributors to understand importance of SCQM in gaining business results.

Keywords: *Management issues in healthcare sector, supply chain quality management, pharmaceutical supply chain management.*

Introduction:

Researchers showing intense focus on collaboration and integration of different partners involved in supply chain of different industries and sectors. The healthcare sector is under extreme pressure for quality improvement, as well as cost reduction. Supply chains of healthcare sector are susceptible to product recalls indicating that quality management practices are not applied in management of supply chains (Zhang et al., 2011).

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Integration of quality management and supply chain management renders critical success factors to supply quality products and services to customers, in timely manner with competitive cost (Vnichchinchai & Igel, 2011). Supply chain quality management (SCQM) concept is considered as integration of quality management & supply chain management. Though, there is growing interest in SCQM but research on this topic lacks appreciation as important dimension of SCM, also it is fragmented in published literature (Veries & Huijsman, 2011). Therefore, a deep understanding of SCQM is needed for improvement in healthcare sector performance (Shah et al., 2008).

One of the major issues in behavioural studies conducted on the field of supply chain management is focus on relationship between healthcare organisations i-e; hospitals, pharmaceutical manufacturing organisations and retailers (Narayana et al, 2012). Regardless of an emergent appreciation, literature within management of quality in healthcare sector supply chain is considerably limited. Significance of SCQM as growing research area is inspiring researchers to develop frameworks, constructs and models for quality management applicable at the operations management field (Foster, 2008).

The purpose of the study is to propose a research framework for pharmaceutical supply chain quality management based upon identification of critical factors published in literature, and to establish link of SCQM with supply chain performances (SCP) and business results (BR). The research emphasises on interface of pharmaceutical distributors. The study addresses following questions:

- What are the critical success factors of SCQM emerged from published literature?
- How these critical factors are contextualised according to healthcare sector?
- How SCQM can be linked to pharmaceutical supply chain performances in an interface with pharmaceutical distributors?
- Is there any mediating effect of supply chain performances in relationship between SCQM and business results?

The focus of this study is healthcare sector of Pakistan. The high correlation between the expenditures on health and productivity in developing countries like Pakistan is enough to emphasize the importance of this sector.

Literature review:

Supply chain management in healthcare sector:

In most of the advanced countries, healthcare is considered as an expensive sector (Lanseng & Andreassen, 2007). Healthcare sector's pharmaceutical supply chain management is facing with issues that either result into excessive build-up of inventories or stock out condition. Excessive inventories result into expiry problems within retail and hospital pharmacies. These issues arise due to absence of relationships between different partners involved in supply chains (McCutcheon

& Stuart, 2000), insufficient purchasing information, inadequate purchasing procedures and inefficient deliveries of materials, strong regularity pressure, inaccurate sales forecast & long lead times (Shah, 2004), limited knowledge of physicians about operation management and supply chain management philosophies and techniques, difficulty in forecasting of patient mix & medicine requirements (Scheller & Smeltzer, 2006), obsolete supply chain strategies and poor control of inventories (Kumar et al., 2008), simultaneously managing the demands of patients and costs (Hook, 2009).

The pharmaceutical supply chain of healthcare sector comprises of supplier or raw material manufacturers, manufacturers of finished goods, distributors, retailers and hospitals (Scheller & Smeltzer, 2006).

Total Quality Management vs. Supply Chain Management:

Total quality management (TQM) has been emerged from concept of quality management. TQM practices play vital role in developing supply chain management through reduction of waste, shipping damages, cycle stock, process variations, delivery cycle time and improves association between suppliers and customers (Lin et al., 2005). TQM is considered as a basis for SCM implementation and supply chain performance improvement (Vnichchinchai & Igel, 2011). Effective quality management in supply chain network is essential to uphold continuous high quality products delivery to customers (Zu & Kaynak, 2012). There is overlap between practices of quality management and supply chain management (Robinson & Malhotra, 2005). Both philosophies have similar eventual goals and integrations (Vanichchinchai & Igel, 2009).

Supply Chain Quality Management:

Supply Chain Quality Management is "the formal integration and coordination of processes of all organizations in a supply channel in-order to measure, analyze and continuously improve processes, products and services to create value and satisfy customers" (Robinson & Malhotra, 2005). Opportunities can be created to advance upstream and downstream relations for performance improvement through SCQM implementation (Foster, 2008). SCQM builds competencies in supply chain by quality management practices adaptation (Kuei et al., 2008).

Table 1: SCQM critical factors/ variables

Sr.No.	SCQM variables	References
1.	Leadership	Foster (2008), Kaynak & Hartley (2008), Kuei et al. (2008), Lin et al. (2005), Quang et al., (2016), Robinson & Malhotra (2005), Sarrico & Rosa (2016), Zeng et al. (2013)
2.	Human resource practices	Foster (2008), Kaynak & Hartley (2008), Lin et al. (2005), Quang et al., (2016), Sroufe & Curkovic (2008)
Sr.No.	**SCQM variables**	**References**
3.	Quality practices	Foster (2008), Kaynak & Hartley (2008), Lin et al. (2005), Quang et al., (2016), Robinson & Malhotra (2005), Sroufe & Curkovic (2008), Zeng et al. (2013)
4.	Supplier relations (strategic supplier	Foster (2008), Kaynak & Hartley (2008), Kuei & Madu (2001), Kuei et al. (2008), Lin et al. (2005), Quang et al.,

	partnership)	(2016), Sroufe & Curkovic (2008), Zeng et al. (2013)
5.	Customer focus	Foster (2008), Kaynak & Hartley (2008), Kuei & Madu (2001), Kuei et al. (2008), Lin et al. (2005), Quang et al., (2016), Sroufe & Curkovic (2008), Zeng et al. (2013)
6.	Safety	Das et al. (2008), Foster (2008)
7.	Process integration and management	Kaynak & Hartley (2008), Kuei et al. (2008), Lin et al. (2005), Quang et al., (2016), Robinson & Malhotra (2005), Zeng et al. (2013)

Theoretical framework:

On the basis of extensive literature search seven factors/dimensions of SCQM have been identified (see table 1), as leadership (LS), human resource practices (HRP), quality practices (QP), supplier relations (SR), customer focus (CF), process integration & management (PIM) and safety (SF).

Leadership: Top management effects supply chain quality management through leadership role in better supplier management, strategic planning, integration, collaboration, employee training, communication and improving supply chain linkages to enhance quality and performance (Fish, 2011; Kaynak & Hurtley, 2008).

Customer focus: It helps organizations to identify market opportunities by realizing requirements of customers (Lakhal et al., 2006). Quality, costs, flexibility and delivery are major demands of customers, so organizations that put focus on these demands can experience improvement in productivity of internal process as consequence of their efforts (Lakhal et al., 2006; Vanichchinchai & Igel, 2009).

Supplier relationship: It involves selection of few suppliers who can supply quality products and development of long term relationships with suppliers (Li et al., 2005). Supplier relationship management ensures that standards of quality products are successfully meet. Successful supplier management reduces inventory levels, process variations, safety stock level and waste generation (Flynn et al., 1995).

Human resource practices: Training of employees regarding use of quality tools and techniques, provision of good working environment for employees and employee's empowerment to suggest innovations are human resource practices (Park et al., 2003).

Quality practices: Quality based culture in supply chains helps to improve not only customer satisfaction but also operational and financial performances along all nodes of supply chain (Kaynak & Hartley, 2008). Quality practices implementation involve use of tools and techniques to improve quality of products and services, reduce supply chain cycle times and defective / rework units and positively influence customer response times (Flynn et al., 1995).

Process integration & management is set of continuous activities with purpose to interlink business processes seamlessly, increases output and reduce process variations by elimination of unnecessary processes within or across organizations (Chen et al, 2009; Flynn et al., 1995).

Safety: Workplace safety perception plays an important role in supply chains by motivating workforce and leads to quality outcomes like reliability and reduced scrap & rework (Das et al., 2008).

Researchers suggest that synergistic relationships between QM and SCM improve not only supply chain performance (Vanichchinchai & Igel, 2011) but also business results of organisations. (Lin et al., 2005). Effective SCM impacts performance of healthcare sector by increasing operational efficiencies and reducing waste generation (Scheller & Smeltzer, 2006), better inventory management and reducing significant portion of costs related to supply chains, (Chadha & Gagandeep, 2013), quality, efficiency & order fulfilment flexibility (Lega et al., 2013) thus results into more satisfied customers.

In this study, warehousing cost containment, shorter lead times and planning cycle time, flexible capacity to respond emergencies, responsiveness to customer queries and complaints, meeting customer demands with inventory and rate of expiry of medicines are contextualised supply chain performance indicators applicable in pharmaceutical distributors. Net profit, business sales growth and market share are used as business results indicators.

Methodology:

Mixed methods sequential research strategy was adapted. Focus group (qualitative) was used as preliminary method for refinement of measurement scale developed from published literature. Then survey method was used to collect quantifiable data from large population.

For focus group discussion, seven representatives from distribution sector of pharmaceutical supply chain were included. A questionnaire comprising of 64 items was used for further refinement in context of pharmaceutical SCQM and generate data that helped to shape research questionnaires for the distributor interface of pharmaceutical supply chain. Researcher acted as moderator for focus group discussion. Few Items form questionnaire were dropped to make it contextualize for pharmaceutical supply chain. The emerged scale after focus group discussion consisted of 38 items. On recommendation of focus group participants language of survey questionnaire was simplified to make it understandable by respondents. At the end of focus group moderator presented all identified issues to the participants for clarification and confirmation. Changes in questionnaire proposed by focus group participants were done in real time and showed to participants to ensure member checking.

Sampling:

There is no reliable sampling frame available for pharmaceutical distributors registered in Pakistan. This study is the first known SCQM research related to pharmaceutical supply chain in developing country like Pakistan. Due to lack of a reliable sampling frame, non-probability purposive sampling used to collect data. Purposive sampling is also considered as suitable sampling technique in situations where main object of study is to get opinions of respondents with specific experience and expertise without considering the proportion of population. Majority of pharmaceutical distributors are running at ten big cities of Pakistan. Sampling was carried out at Bahawalpur, Faisalabad, Hyderabad, Islamabad,

Karachi, Lahore, Multan, Peshawar, Quetta and Rawalpindi. Respondent organizations were selected on basis of sales volume and market reputation as smaller organizations often do not share the complexity issues and may not have developed Quality Management Systems.

Data collection:

Research instrument for this study is self-administered survey questionnaire designed to collect quantifiable data from distributors. The item generation was guided thorough literature review, academic experts review and focus group discussion with respective practitioners of pharmaceutical supply chain.

Questionnaire comprised only of closed end questions. All variables of interest were estimated through respondent's perceptual evaluation on five point Likert scale: The response categories for each item were 1very low and 5 very high. The self-administered questionnaires were sent along with covering letter for participants of study and a preaddressed postage-paid return envelope. Covering letter was used to elaborate purpose of study, significance of study, confidentiality, respondent designation for filling of questionnaires, research contribution and word of thanks.

The target respondents were CEO, Qualified Person and Operations Manager. No of questions were kept in ideal number to avoid respondent fatigue. 246 responses were received out of 500 distributed questionnaires in time period of 16 weeks indicating 49.20% response rate. Researchers suggest that minimum number of cases for structural equation modelling should be at least five times of items to be analysed (Hair et al, 1998) so sample size is well above minimum limit of 5:1 to variables in questionnaire.

Results:

Constructs were labelled, outliers screened out and normality of data checked. No missing value found in data set. Kim (2013) recommended use of z-score values when sample size is below 300. Data points outside z-score value of ± 2.5 were identified as outliers and deleted. After deletion of responses, usable responses left in data set were 199 responses. All values in data were lying between standard range of $\pm$ 2 (Trochim & Donnelly, 2006) for both skewness and kurtosis proving normal univariate distribution of data. Q-Q plots and histograms with normality plots were also drawn to confirm normal distribution of data points.

Reliability and Construct Validity:

In this research we have used Cronbach's Alpha and inter-item correlations to check internal consistency or reliability of measurement items. All items of six constructs of SCQM except SR construct, and all the items of supply chain performance and business results constructs have shown more than 0.7 values for Cronbach's alpha and 0.3 score of inter-item correlation indicating good reliability (Hair et al., 1998). SR had lowest Cronbach's alpha with 0.656. Cronbach's alpha values between 0.6 to 0.7 are also acceptable, especially in the cases where factor having only few items (Hair, et al., 2006). SR had only three items so value of 0.656 can be considered as acceptable.

Confirmatory Factor Analysis:

Confirmatory factor analysis (CFA) with Maximum Likelihood Estimation (MLE) method was carried out by using AMOS version 24 to ensure uni-dimensionality of scale, reliability and construct assessment (Anderson & Gerbing, 1982). It is most commonly used method of estimation and preferably used when sample size is at least 200 and at least three items of every construct (Hair et al., 1998). In this study both conditions of method are fulfilled. All the individual measurement models were tested for convergent validity with CFA in order to remove weak loading coefficients below 0.5 (Hair et al., 2009) and determine uni-diementionality of scale items. All items of seven constructs of SCQM and Business Results had loading coefficients exceeding 0.5 value so no item had to be deleted except item SCP7 (*Rate of expiry of medicines is reduced)* belonging to Supply chain performance construct was removed due to weak loading coefficients i-e 0.41.

All the models had average variance extracted (AVE) value more than standard limit of 0.50 and composite reliability (CR) above 0.7 (Shook et al., 2004), suggesting good convergent validity as shown in table 2. Different measures of model fit have been used by researchers to evaluate hypothesized models. Hu & Bentler (1999) suggested combination of relative fit indices such as CFI or IFI (value more than 0.95) with SRMR (value less than 0.08) or RMSEA (value less than 0.06) to minimize Type I and II errors. They preferred CFI with SRMR on TLI/RMSEA when sample size is less than or equal to 250. Normed chi-square (x^2/df) with standard value of less than 5 (Wheaton et al., 1977) is preferred over chi square index.

To assess the overall goodness of fit of each construct, four type of fit indices were employed:

1) Normed Chi-square (x^2/df ratio)
2) P- value
3) Comparative fit index (CFI)
4) Standardized Root Mean Squared Residual (SRMR).

All the constructs passed the standard limits of model fitness. Human resource practices (HRP) construct had x^2/df = 5.269 and p-value = 0.005 but values of CFI and SRMR were good enough to prove model fitness. AGFI was also included for HRP to evaluate model fitness. AGFI value of 0.87 above standard limit of 0.80 (Kline, 2005) confirmed model fitness.

Table 2: Results of Convergent Validity

Construct	items	Standardized Loading coefficients	CR	AVE	x^2/df	p-value	CFI	SRMR
LS	LS1	0.85	0.85	0.57	0.325	0.722	1.00	0.0090
α = 0.805	LS2	0.73						
	LS3	0.67						
	LS4	0.75						
HRP	HRP1	0.87	0.82	0.54	5.269	0.005	0.96	0.0382
α = 0.788	HRP2	0.61						
	HRP3	0.72						
	HRP4	0.71						
QP	QP1	0.84	0.88	0.58	0.792	0.555	1.0	0.0167
α = 0.858	QP2	0.78						
	QP3	0.77						
	QP4	0.71						
	QP5	0.71						
SR	SR1	0.80	0.78	0.65	3.653	0.026	0.94	0.0520
α = 0.656	SR2	0.81						
	SR3	0.80						
CF	CF1	0.83	0.84	0.58	0.804	0.448	1.0	0.0151
α = 0.794	CF2	0.81						
	CF3	0.70						
	CF4	0.71						
SF	SF1	0.79	0.81	0.68	0.819	0.441	1.00	0.0214
α = 0.735	SF2	0.84						
	SF3	0.85						
PIM	PIM1	0.79	0.86	0.58	2.029	0.071	0.99	0.0293
α = 0.834	PIM2	0.81						
	PIM3	0.71						
	PIM4	0.75						
	PIM5	0.73						
BR	BR1	0.85	0.83	0.70	3.019	0.049	0.97	0.0394
α = 0.734	BR2	0.83						
	BR3	0.83						
SCP	SCP1	0.82	0.92	0.51	2.769	0.003	0.95	0.0459
α = 0.808	SCP2	0.67						
	SCP3	0.65						
	SCP4	0.68						
	SCP5	0.76						
	SCP6	0.69						

Discriminant validity of first order constructs was checked by comparing square root of AVE of each factor with correlations between pair of latent variables (Andesrson & Gerbing, 1998). All constructs passed the discriminant validity assessment as square root of AVE of each construct was significantly higher than inter construct correlation (Hair et al., 2014).

Measurement Model validity:

In this study, second order CFA was conducted for SCQM to confirm that seven constructs i-e, leadership, human resource practices, quality practices, supplier relations: (strategic supplier partnership), customer focus, safety, and process integration and management were sub-constructs of boarder construct of SCQM. Loading coefficients between second order construct and its sub constructs were

also above cut off value of 0.5. The overall fit of second order model was in accordance with standards with x^2/df= 1.235, p value= 0.241, CFI= 1.00, AGFI= 0.96 and SRMR= 0.0221. Second order model of SCQM passed the standard of both convergent and discriminant validity with AVE= 0.59, CR= 0.95, also correlations of SCQM, SCP and BR were less than 0.85 (Kline, 2005). Based on the overall results of reliability and validity it can be concluded that measure models were reliable and valid and fit for further analysis.

Testing structural model fitness and relationships:

Path analysis of hypothesized structural model was assessed with same MLE method and set of fit indices (x^2/df, p-value, CFI & SRMR) along with AGFI used to analyses measurement model. Multiple fit indexes x^2/df = 1.705, p-value = 0.000, CFI =0.95, AGFI = 0.87 and SRMR = 0.0490, showed goodness of fit for hypothesized structural model.

For path analysis, the t- values (CR) of path SCQM → SCP and SCQM → BR were above the critical value of t-value>1.96 for p<0.05 and >2.33 for p<0.01 (Kline, 1998) whereas, SCP → BR less than 1.96. SCQM showed strong positive relationship with SCP with path estimate value of 0.887 and t- value 7.543 with p value = 0.001. The path estimate value of 0.741, t- values of 4.188 and p-value = 0.001 for relationship between SCQM and BR revealed significant relationship between both concepts. The relationship between SCP and BR indicated non-significant indirect effect of SCQM on BR through SCP with path estimate value of 0.171, t-value 1.219 and p value of 0.223. To determine the significance of mediation effect of SCP between SCQM and BR relationship, bootstrapping with 2000 number of samples & 95% bias-corrected confidence level was also performed. Non-significant indirect relationship with p-value>0.05 of SCQM with BR indicated no mediating role of SCP in relationship of SCQM and BR.

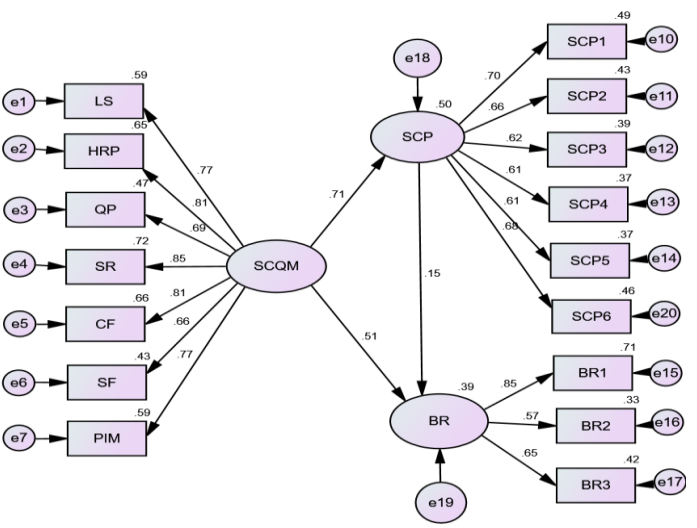

Fig 1: Structural model

Conclusion:

Excessive build-up of inventories and stock out situations are two complex situations often faced by healthcare supply chains due to issues of out-dated supply chain strategies, forecasting difficulties, budget reductions while coping increase demand of medicines, poor inventory control, inadequate and inefficient purchase procedures. Adoption of SCQM philosophy in distribution set ups can help to effectively combat these issues.

Seven critical success factors of SCQM identified from published literature are contextualised according to context of pharmaceutical distributors. A theoretical framework developed to investigate links between SCQM with supply chain performance and business results is empirically tested and validated. Direct impact of SCQM on both supply chain performance and business results is established. No mediating role of SCP in relationship between SCQM and BR observed. Distributors have focus on both satisfaction of customers (retail pharmacies and hospitals) through improvement in supply chain performance and getting profits. Rate of expiry of medicines couldn't be considered as significant indicator of supply chain performances as distributors only serve the role of post office between manufacturers and retailers for supply and return of expired medicines. Medicine expiry can be important indicator for both manufacturers and retailers.

Relevance/contribution:

This research provides practitioners with an insight about different critical factors necessary for successful implementation of pharmaceutical supply chain quality management in pharmaceutical distributors, in order to satisfy customers and gain financial benefits. The study contributes to the knowledge in SCQM within healthcare sector by providing a critical review of literature related to quality management and supply chain management integration and their combined effect on performance of organisations. Empirical studies can be conducted in retail pharmacies and hospitals to validate the framework established by this research to measure SCQM, and its linkages with supply chain performance.

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