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Abstract

This pilot study strives to reach a more complete understanding of the key features of the medical technology supply chains in the European healthcare sector by contributing to the empirical foundation of the concept and employs a qualitative research design with structured interviews as the primary data collection technique. The target of this research is to identify the critical supply chain management factors in the medtech supply chain, in order for stakeholders participating in it to be able to identify which areas of improvement need to be addressed during the design and implementation of their supply chain strategies.

Keywords: Supply Chain Management; Medical Technology; Healthcare Supply Chain

Introduction

There is growing recognition of the relevance of the healthcare supply chain within the field of Operations Management, with the pharmaceutical supply chain being the focus of most research. However, the medical technology (medtech) supply chain has received little attention in comparison. This paper presents the initial findings of a pilot study that investigates the key characteristics of supply chains in the European medical technology sector. Particularly, it seeks to identify the characteristics that describe an optimal supply chain in medtech.

Medical technology is used specifically for diagnostic and/or therapeutic purposes and covers an extensive range of healthcare products such as equipment, devices and consumable products. There is a vast array of medtech products, ranging from items such as syringes and plasters, over more complex equipment such as wheel chairs and hearing aids, to extremely high tech devices such as artificial limbs, intelligent contact lenses and pacemakers (Medtech Europe, 2013). This sector has become increasingly important due to current demographic trends. Demand for medical products is expected to rise as the population grows, and as the growing population of the elderly uses a larger share of those resources (O'Keeffe, 2011). The expanding and ageing global

population is expected to result in increasing demand for healthcare products and services (Holtzman, 2012), posing an increasing challenge to the current supply chain structures.

Literature review

Medtech improves the quality of life of people in many ways. There are many definitions of what constitutes medical technology (Eucomed, 2013) with most authors not differentiating between the term "medical technology" and "medical device". For the purpose of this paper, the authors refer to the definition of the European Commission in their 'EU Medical Devices Directive': "*Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings. Devices are to be used for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or compensation for handicap, for investigation, replacement or modification of the anatomy or of a physiological process, or for control of conception."* (European Commission, cited in Eucomed, 2013).

As it provides a large number of high-quality jobs, attracts substantial inward investment and has created a hub for innovation, medtech is considered a substantial contributor to the economy in Europe. Based on calculations from Eucomed (2013), the European market size is estimated at roughly US$129 billion– around 30% of the world market, employing around 575.000 people, many of those in highly skilled jobs. There are almost 25.000 medical technology companies in Europe, and approximately 95% of them are Small and Medium sized Enterprises (SMEs), most of which reinvest in average around 8% of sales into product research and development (MedtechEurope, 2013).

The main drivers of the industry relate to the current demographic developments. The world population is expected to grow and get older in the next 20 years and beyond. Demand for medical products is expected to rise as the population grows, given that the growing share of elderly uses a larger share of those resources (O'Keeffe, 2011). Moreover, in view of the rising aesthetics trend, the segments of lifestyle healthcare are becoming increasingly attractive, which is being reflected by the higher consumption of products such as premium hearing devices and reconstructive dentistry procedures (Duncan, 2007). Finally, with obesity becoming a serious problem in many first world nations globally (Wang, 2008), an increased global demand for medical devices is expected (Holtzman, 2012).

The medical technology industry, along with the drug manufacturing sector, is an integral part of the healthcare supply chain (Burns et al., 2002). Despite well-documented evidence of significant competitive advantage and cost reduction resulting from supply chain management (SCM) practices, the healthcare industry has been extremely slow to embrace these practices (McKone-Sweet, et al., 2005). There is indeed a value chain in the healthcare industry yet it is not as clear as in other industrial channels because of the many third parties involved in the transactions. The manufacturers (producers) in the supply chain can be broadly classified into two groups namely, pharmaceutical and medical device manufacturers, the latter being the object of this study. The products from these producers are then purchased by group purchasing organizations (GPO), wholesalers, distributors and in some cases independent

contractors and delivered to providers like hospitals, integrated delivery networks (IDNs), physicians (individual clinics) and pharmacies. The customers (payers) in this supply chain are governments, employers and individuals. They pay the providers through fiscal intermediaries like insurers, health maintenance organizations (HMOs) and pharmacy-benefit managers (see Figure 1).

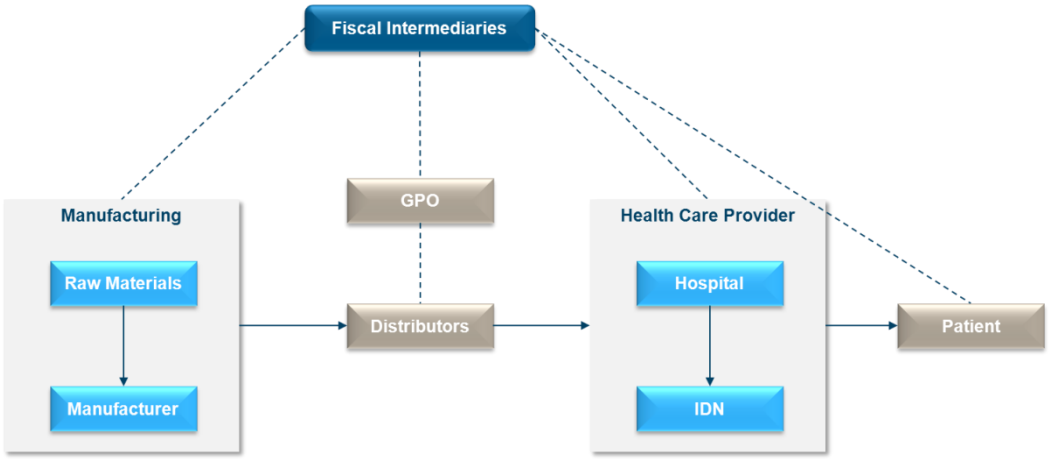

Figure 1: Detailed view of product, information and cash flows in the healthcare value chain (McCurry et al., 2005)

An interesting finding of the literature research was the fact that the term "healthcare supply chain" is not only being used to describe the flow of goods, services and/or information between organisations dealing with medtech or pharmaceutical products, but also to describe the internal patient flow in hospitals in the context of the so-called "internal supply chain" (Swinehart and Smith, 2005). With many authors relating to patient flow in hospitals, this would suggest that a shift in the research focus is taking place to more internal, end-customer orientated research in the healthcare supply chain field. In contrast, the medtech supply chain does not appear to be in focus of much research. Interestingly, during the course of the article selection stage for the literature review, the search on GoogleScholar of the terms "medical technology supply chain" or "medtech supply chain" did not deliver any relevant articles to be incorporated to the literature review. This suggests that the medtech supply chain is being understudied.

Understanding which factors are critical to the success of the medtech supply chains is important. As with other manufacturing supply chains, there are certain key factors which determine the success of operations in the medtech supply chain. The concept of success factors was first developed by Daniel (1961). This idea suggests that if certain factors, which are critical to the success of the organisation are not achieved, the organisation will fail (Huotari and Wilson, 2001). Rockart (1979) defines critical success factors as "the limited number of area in which results, if they are satisfactory, will ensure the competitive performance for the organisation" with Alazmi and Zairi (2003) describing them as "the limited number of areas in which results ensure successful competitive advantage". Rockart (1979) extended the concept of critical success factors to the supply chain and Porter (1985) combined critical success factors with the value chain concept. Gunasekaran and Ngai (2003) identified five functions with were evidenced as critical to a small logistics company: strategic planning, inventory management, transportation planning, capacity planning, and information

management. Furthermore, Power et al. (2001) identified seven success factors in agile supply chains: participative management, computer-based technology, resource management, continuous improvement, supplier relations, just-in-time methodology, and technology utilisation. Wong (2005) assessed critical success factors for knowledge management in small and medium enterprises and identified 11 separate activities grouped into: strategic planning, resource management, information management, human resources management, and continuous improvement. Pettit and Beresford (2009) identified ten critical success factors which were consistently identified as having a relevance to the implementation of successful humanitarian aid supply chains. These were: strategic planning, resource management, transport planning, capacity planning, information management, technology utilisation, human resources management, continuous improvement, supplier relations and supply chain strategy.

The application of the critical success factors to the medtech supply chain has not been addressed before in the literature and literature related to medtech supply chain improvement has not yet considered critical success factors as an important issue in their own right. Pettit and Beresford (2009) suggest however, that analysing the basic factors which are both critical for success and common to most industries and determining their relevance to the environment under study could provide organisations with ways of increasing the effectiveness of their activity. Therefore, in order to understand which factors are critical to the success of the medtech supply chains, the starting point for this analysis are the critical success factors discussed above.

Research objective

In light of the identified literature gaps, the research seeks to identify the critical success factors in supply chain management for medtech supply chain in the European healthcare sector. It is important to mention that the results described in this paper constitute the output generated during the pilot phase of this research. As Yin (2003) illustrates it, the purpose of the pilot study is to refine the data collection plans in regards to both the content of the data and the procedures to take place. The pilot study is not intended to serve as a pretest, but rather to assist the authors to evaluate and provide conceptual clarification for the research design. The findings of the pilot study are intended to be used in parallel with the on-going literature review, so that the next stages of the research will be informed by both the prevailing theories and the drawn empirical observations (Yin, 2003).

The expected benefit of the full-scale study is the establishment of the basis for a methodology to identify the degree of application of the critical factors aforementioned, in order to make appropriate implementation recommendations to improve supply chain operations in the medtech value chain. The following research questions are considered:

- *What are the critical success factors in the medtech supply chain of the European healthcare sector from a manufacturing perspective?*
  a. *Are the critical success factors the same for all medtech supply chains of the European healthcare sector?*
  b. *Are the perceived performance gaps of these factors the same for all medtech manufacturers in the European healthcare sector?*

Following the recommendations of Robson (2011), the research questions have been formulated specifying the population of interest (in this case the manufacturing organisations involved in the medtech supply chain of the European healthcare sector) and suggesting the nature of the study: exploratory rather than explanatory, as the focus of the research is to identify key variables (the aforementioned critical factors).

Methodology

This study employs a qualitative research design. Following Robson (2011), studies focusing their efforts to answering "what", "how" and "why" questions call for a flexible, qualitative research design strategy. Yin (2003) recommends a case study design when contextual conditions need to be covered as they are relevant to the phenomenon under study, the behaviour of those involved in the study cannot be manipulated, and the boundaries between the phenomenon and the context are not clear, among several other reasons. As this study seeks to develop detailed intensive knowledge about several organisations within their context, it employs the multiple case study design (Robson, 2011).

The primary data collection technique applied is that of structured interviews based on a questionnaire tool created for this study and consisting of 14 sections, with a total of 48 questions. The sections and questions were created according to the factors identified in the literature review, the identified gaps in the literature, the research questions, and discussions carried out by the authors with practitioners in the field. The questionnaire tool was designed following the approach of Watson and Frolick (1993) for structuring and performing interviews with executives. This approach consists of having respondents rate both the expected importance of a factor and its perceived performance. Such an approach makes the measurement of gaps between expected importance and perceived performance of factors possible. Questions were then graded for importance and performance on a Likert scale.

The use of a proper unit of analysis offers construct validity (Yin, 2003). For the purposes of this study, the unit of analysis has been defined as each of the organisations directly involved in the production of medtech devices. The number of cases suggested by several authorities differs. Generally speaking, the more cases utilised in a case study research, the higher the degree of certainty and therefore, external validity (Yin, 2003). Some authors argue that using a sample of less than four cases is considered difficult to generate theory (Yin, 2003); (Eisenhardt, 1989), and its empirical grounding is unlikely to be convincing (Eisenhardt, 1989). As of today, the sample consists of 15 respondents, each one having a management position in their respective companies. Companies are medium-sized, all belonging to the medtech sector in Europe. Confidentiality was an important prerequisite to perform all interviews and efforts have been made to ensure it.

To ensure consistency during the application of the method, all interviews during the pilot study were arranged, moderated and summarised by the researchers. Participants who consented to be interviewed were sent the questionnaire prior to the interview in order for them to have time to consider their responses in an effort to encourage more meaningful replies. Following the recommendations of Robson (2011), interviews took no longer than forty-five minutes and permission was sought from each participant to use a tape-recorder to record the interview. Interviews took place at the participants' place of work. Results were then after analysed using Microsoft Excel 2010.

Findings

This chapter provides an analysis and discussion of the initial results of the pilot study. As previously discussed, the purpose of the pilot study is to ensure that there is a link between the research questions, the collected data, and the analysis of the data, and to observe the first tendencies of the results obtained.

The literature review concluded with the statement that the starting point to find an answer to the research questions is to investigate exhaustively the critical success factors in SCM found in the literature, as analysing the basic factors which are both critical for success and common to most industries and determining their relevance to the environment under study can provide organisations with ways of increasing the effectiveness of their activity. By critically reviewing the works of Pettit and Beresford (2009), Rockart (1979), Gunasekaran and Ngai (2003), Power et al. (2001) and Wong (2005), it became apparent that there are a set of critical success factors that seem relevant in Supply Chain Management, independently of the focus of the Supply Chain (e.g. commercial supply chains, humanitarian aid supply chains). It is interesting to notice that to this date there has not been any publications found in the course of the literature review that deal with the subject of the critical success factors in Supply Chain Management for the medical technology sector.

The result of the review of the works of the aforementioned authors can be summarised in Figure 2.

Figure 2: The 14 critical success factors in Supply Chain Management under study

Figure 2 depicts the results of the literature review on the critical success factors and the output of the authors' discussions in this regard. The outcomes are 14 critical success factors in Supply Chain Management, clustered according to the processes of the SCOR model (Plan, Source, Make, Deliver, Return) (Lockamy III & McCormack, 2004) for easier reference. The critical factors "strategic planning", "sales and operations planning", and "information management" were allocated to the "Plan" process of the SCOR model. The factors "procurement strategies", "inventory management", and "building and maintaining strategic partnerships" were deemed to

be relevant to the "Source" process. Critical factors which subject matter stands in close relationship with the production of the medical devices were assigned to the "Make" process ("production system", "R&D process", "training and commitment of the staff").

The factors "customer relationship management", "supply chain agility", and "transport management" were consequently allotted to the "Deliver" process. Finally "green supply chain" and "reverse logistics" were allocated to the "Return" process. The questionnaire tool was then designed formulating appropriate questions for respondents to review the perceived importance and performance of these critical success factors. The answers were gathered and analysed using Microsoft Excel 2010.

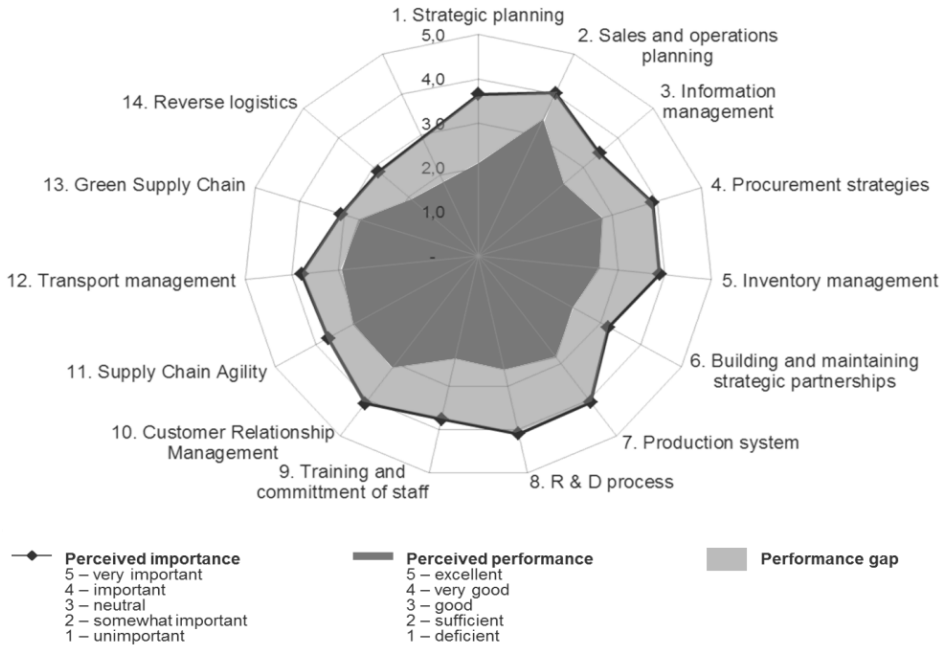

Figure 3: The critical success factors in the medtech supply chain of the European healthcare sector from a manufacturing perspective

Figure 3 illustrates in summarised form the average value of all answers provided by the respondents concerning the perceived importance and performance of their respective organisations in regards to the 14 critical success factors under review. At a first glance, 5 critical success factors seem to dominate the respondents' views regarding their degree of importance: "production system", "R&D process", "customer relationship management", "sales and operations planning", "inventory management", and "procurement strategies".

An analysis of the variability of the answers provided by the respondents was performed as well (see Figure 4). It is interesting to notice that there is a relatively high variability on what the respondents consider an important success factor in SCM. A closer look at the graphic reveals that the factors "production system", "sales and operations planning", "procurement strategies", and "inventory management" showed the smallest variability of the answers provided by the respondents, suggesting an agreed perceived importance of these factors. This leads to conclude that the factors "production system", "sales and operations planning", "inventory management", and "procurement strategies" are shared by the organisations of the sample in the context of the pilot study.

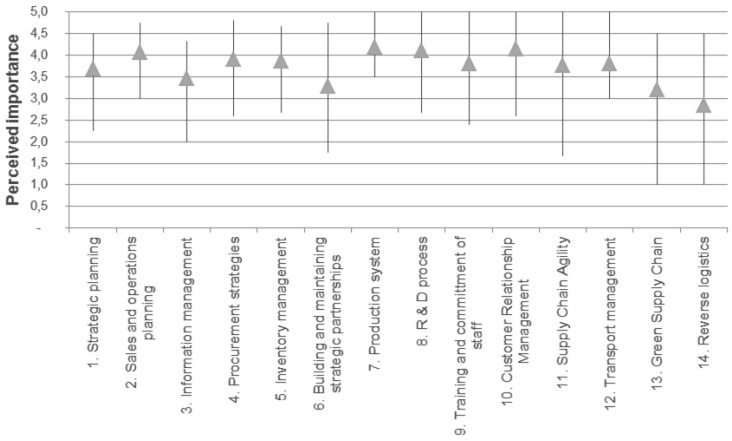

Figure 4: Variability analysis of the sample regarding the critical success factors in the medtech supply chain of the European healthcare sector

In regards to their companies' perceived performance, the average of all answers provided by the respondents shows that the factors perceived with the lowest performance levels in the organisations of the sample are "reverse logistics", "strategic planning", "building and maintaining strategic partnerships", "training and commitment of the staff", and "information management" (see Figure 3). However, these critical success factors have been given a different perceived importance by the respondents, ranging from "very important" to "unimportant". For this reason, the gap between the perceived importance and the perceived performance of the organisations interviewed was analysed as well (see Figure 3). According to the results of the graph, the factors with the widest gap between perceived importance and perceived performance are: "strategic planning", "R&D process", "training and commitment of the staff", "production system", and "inventory management". It is important to notice that, from the 5 aforementioned factors, 2 are regarded by the respondents of the sample as very important: "production system" and "inventory management" (see Figure 4).

Figure 5 reveals that, from the 5 factors mentioned before, "production system" and "strategic planning" appear to have a high level of variability in regards to the answers provided by the respondents.

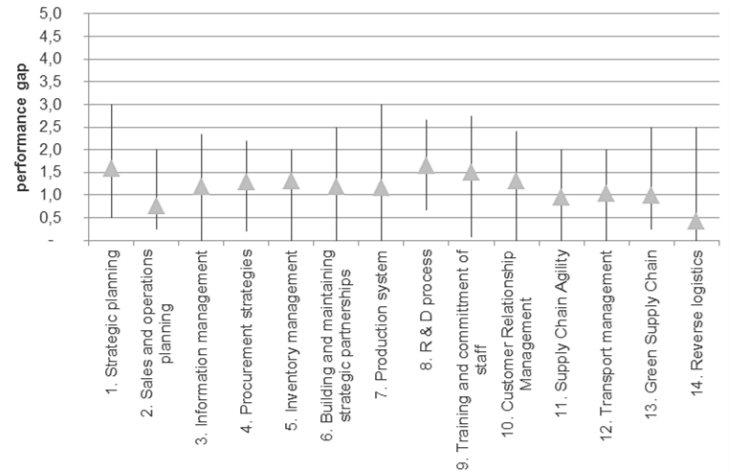

Figure 5: Variability analysis of the sample regarding the perceived performance gaps of the critical success factors in the medtech supply chain of the European healthcare sector

In contrast, “inventory management” and “R&D process” have a lower level of variability, leading to conclude that an important room for improvement in these two factors is shared by all the organisations surveyed in the context of the pilot study.

Conclusion

This paper discusses the results obtained during the pilot study in the framework of a research aimed at identifying the critical success factors in supply chain management for medtech supply chains in the European healthcare sector. It begins with the identification of current literature gaps in the context of the medtech supply chain. A first finding of the literature review is that the focus of most research on the healthcare supply chain, to which the medtech supply chain belongs, has been what Swinehart and Smith (2005) call the “internal supply chain”, meaning the internal patient flow in hospitals. Another important finding of the literature review is the notion that the medtech supply chain does not appear to be the focus of much research work.

As a means to contribute to the discussion on SCM for the medical technology sector, this research seeks to establish the base to identify the range of factors that are critical for the successful operation of their supply chains. A pilot study has been designed and executed in order to provide an answer to the questions addressed in the research objective section. As a first answer to the question: what are the critical success factors in the medtech SC of the European healthcare sector from a manufacturing perspective?, it can be concluded based on the 15 respondents of the sample that the factors “production system”, “R&D process”, “customer relationship management”, “sales and operations planning”, “inventory management”, and “procurement strategies” are highly regarded as critical success factors. After analysing the variability of the answers provided, critical success factors shared by all respondents appeared to be “production system”, “sales and operations planning”, “inventory management”, and “procurement strategies”. This gives a first indication to address question a: “are the critical success factors the same for all medtech SC of the European healthcare sector?” Finally, in response to question b: “are the perceived performance gaps of these factors the same for all medtech manufacturers in the European healthcare sector?”, both “inventory management” and “R&D process” are factors which offer an important room for improvement shared by all the organisations surveyed in the pilot study.

There are limitations to this pilot study that should be noted. Firstly, the nature of this research effort is an exploratory case study with a limited sample size, which means that the findings cannot be generalized beyond this study. As an exploratory study, the goal of this research effort is to seek greater understanding that can lead to building a foundation for more extensive research in the future. Another limitation of this study relates to the use of a fixed, inflexible, structured questionnaire, with verbal feedback for critical areas. Although a very systematic process is used for data collection and analysis to enhance the reliability and validity of the study, it may not have captured other data that is significant. In brief, these two aspects will be addressed in later stages of the research.

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