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Research Report: ZLC-2013-8 Risk Mitigation in Time and Temperature Sensitive Shipments in the Life Sciences and Healthcare Industry Samer Sharaiha and Luis Pastor For Full Thesis Version Please Contact: Marta Romero ZLOG Director

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Risk Mitigation in Time and Temperature Sensitive Shipments in the Life Sciences and Healthcare Industry

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Summary:

This thesis analyzes the effective utilization of the data generated from Life Science and Healthcare shipments managed by a major airfreight provider. It defines patterns and provides a risk mitigation strategy, identifying potential business applications, and optimizing the current temperature management service portfolio to be offered to customers.



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KEY INSIGHTS

- A risk index can be developed for cold chain shipments based on the key drivers of shipment quality (Origin-Destination, Carrier, Packaging type).
- A prototype tool developed to evaluate alternate shipment strategies, demonstrated that overall shipment risk could potentially be reduced as well as offering new options for sales people to propose to customers.
- For both the risk index and tool it is imperative that appropriate data be collected in an integrated process to support future decision making.

Introduction

Most temperature-controlled distribution channels operate efficiently; however incidents like the deaths of 128 children in India prompted agencies throughout the world to reexamine pharmaceutical good distribution practices [1]. It is estimated that 40% or more of the vaccines in the Sub-Saharan Africa have completely lost their effectiveness due to the inability to keep the product at a stable temperature, usually between 2°C and 8°C [2]. This is due to the lack of appropriate cold chain infrastructures in the region. In 2011, UNICEF procured around 2.5 billion doses of vaccines at a cost of \$1,030 million [3]. Assuming 40% of the procured vaccines are sent to Sub-Saharan Africa and the percentage of ineffective vaccines handled by UNICEF is the market average, the cost of the lost vaccines would be around \$165 million. Therefore, keeping a product within the required temperature range is one of the pre-eminent challenges in the Life Sciences and Healthcare [LSH] distribution channels.

Cold Chain in the LSH industry refers to the supply chain for a product that has to be maintained at a predetermined temperature range in order to preserve its potency and effectiveness [4]. Key challenges are controlling the proper temperature and humidity through the whole shipment, complying with the regulations established by different governments and agencies and the ongoing monitoring over the lifespan of the product while minimizing the overall cost.

Cost reduction is starting to become critical as over the last few years, patents of top selling pharmaceutical drugs have expired [5], thereby allowing generics to enter the market and reducing the branded pharmaceutical margins.

Problem statement and thesis scope

The main research objective of the thesis was to analyze shipment data in order to identify possible patterns and provide a risk mitigation strategy. This was done focusing on answering the following research questions:

1. Can we establish a process for Risk Mitigation in XYZ's approach to new cold chain opportunities with Life Sciences & Healthcare companies?

2. What are the most efficient means to build a tool that provides analytics to existing customers?

Therefore, the thesis analyzed historical shipment data and explained the patterns through the analysis of the shipment claim activity. Based on the analysis results, patterns obtained led us to define the main drivers that affect shipments' quality and analyze the various dimensions affected.

We provided a general framework to design a tool that will mitigate the shipment-associated risks. Furthermore, it will allow optimizing the current temperature management service portfolio, improve service levels through data analytics and make suggestions to shippers on alternative trade-routes or different types of packaging.

Additionally, we explored data integration methods to mitigate the risk of product damage and enhance the service level and quality offered to the customers by potentially including all the sources into one single risk factor. The risk index can help identify profitable trade-lanes where to strategically position and differentiate from competition.

Identified patterns

The study analyzed over 30,000 shipments done between 2007 and 2013 and identified those that have registered a case with a final impact on the customer:

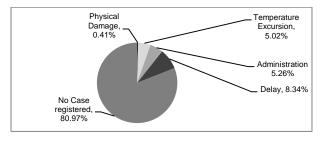


Figure 1. Customer impact rates

Based on the customer impact, analysis was done under the four major categories, trying to define the main drivers that affect to each of them.

- Temperature Excursion cases are registered when a shipment has a reading above or below the temperature range specified in the Standard Operating Procedure [SOP].

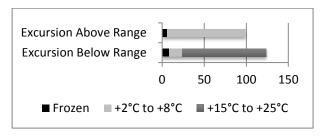


Figure 2. Temperature excursion by temperature range

- Delay cases are registered when a shipment departure is delayed two hours from its original schedule or if during the shipment the delay affects the next step in the SOP.

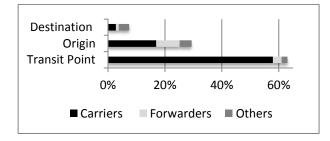


Figure 3. Delay responsibility distribution

- Physical Damage cases are registered when the packaging is damaged to the point that it can no longer maintain a stable temperature or when the product integrity is affected.

- Administration issues are registered whenever a shipment does not follow the instructions and guidelines established in the SOP.

% of Exports	Export Region	Case rate Import Region					
		AMLA	AMNO	ASPA	EMA	EURO	Grand Total
2.1%	AMLA	67%	24%	114%	12%	26%	51%
61.5%	AMNO	2%	20%	1%	1%	4%	3%
5.1%	ASPA	10%	5%	1%	0%	11%	6%
1.0%	EMA	6%	1%		0%	0%	1%
30.3%	EURO	15%	12%	11%	7%	1%	11%
	Grand Total	7%	12%	6%	2%	5%	6%
	Total IMPORTS	21.4%	14.5%	29.0%	8.9%	26.2%	

Table 1. Case rate per export/import region

Risk assessment tool and analysis

The risk assessment tool was designed to help the sales and field teams make better decisions about which airports, carriers and type of packaging are best suited for their client. It gives various alternatives for locations and carriers that have an overall low risk index than the current status quo.

Combining the indexes for origin, destination, carrier and packaging, the tool will provide a consolidated risk index for each optimized alternative. The algorithm follows the following relation, where risk indexes for the main issues are considered.

$$Risk \ score = \sum_{i=1}^{4} W_i \cdot I_i$$
$$Impact \ Index = \sum_{j=1}^{4} R_{ij} \cdot \left[CR_{ij} + EX_{ij}\right]$$

Since numbers can only tell half the story, the tool is intended to complement the existing knowledge and experience of the teams with historical shipments data analytics. The algorithm searches for alternatives to the current trade lane and optimizes the routes available.

System integration

Adding the proposed risk tool as a subsystem alongside other external databases to complement XYZ's existing database can potentially deliver an overarching functionality. Ultimately what would be expected from it would be to gather the information from all different databases available.

One way would be to integrate the information on existing storage facilities in the main airports utilized. This can help in many ways: first, potential patterns between cases and the absence of appropriate facilities can be evaluated; second, it can improve sales people's visibility to have real-time information about the existing facilities at each potential waypoint.

Integrating a flight database with the tool would provide the real time data of the carriers available, the type of aircraft used for the flight, and the actual cost charged by the carrier for each shipment. This information can be valuable when there are disruptions such as long delays or grounding flights because the system will readily provide alternatives for the given criteria

Real-time weather updates can avoid problems such as temperature excursions that could have been caused by forecasting errors. It could provide better insight to which packaging or insulation type from the different customers performs best under the different weather conditions. Moreover, having a real time weather report can help XYZ actively manage the shipments to the point where if gel packs or dry ice are needed at any point due to sudden changes in climate conditions, XYZ can act responsively.

Data integration can provide in-depth analysis and an overview of the root cause is with the integration of the data provided by the temperature sensors and the actual shipment temperature forecast data. Should there be an excursion on a certain shipment, it would be possible to pinpoint the exact location where the excursion took place. In Addition the resilience of the packaging can also be analyzed by comparing the change in the internal temperature of the package as a result of the variation in external temperature.

Data gathering improvement

Optimizing the available data for key measurements could give a company a competitive advantage in the cold chain airfreight and service providers market.

Based on the validity time, creating categories to consolidate passive packaging types across different customers will allow comparison between the different technological solutions used. The best performing solutions can be identified and proposed to other clients for each category. It can also provide feedback to the customers on packaging behavior and stability. For active containers categories, it could be useful to differentiate between dry ice and cooling fan solutions. Similar clusters should be done for the available passive packaging solutions.

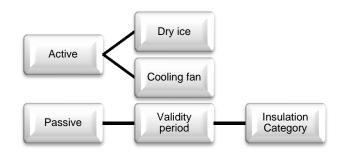


Figure 4. Proposed Packaging categories

Time on tarmac is one of the major drivers behind cases registered; by differentiating between passenger and cargo flights a significant risk reduction can be achieved. Time on tarmac for cargo flights is significantly lower than of commercial flights, since aircrafts tend to load and unload close to the airport warehouses and storage facilities. Furthermore, analytics should consider the root cause behind each issue registered, following a systematic procedure and performing analysis and correlation between the cases registered and the root cause. Linking the root cause with the final impact to the customer, will allow targeting improvements on the solutions that have the greatest impact. Moreover, both fields should be sufficient to give insightful information to the customers regarding the main causes affecting their shipments. It will also allow the sales force team to define best practices, and the quality team to be aware of the weaknesses of the chain and focus on those to provide a better service.

Conclusions

Designing a one-size-fits-all supply chain strategy for normal cargo can be worthwhile and can benefit from lowering costs through economies of scale. However this is not the case with cold chain as handling shipments tend be less flexible, and limited in the number of qualified carriers and lanes that can be used. Additionally, customers look for speed and reliability; rendering cost as a secondary factor.

By finding common denominators between different customers and integrating or adopting what a best performer might be doing can help minimize the risk for other clients. The data gathering improvement and system integration recommendations seek this improvement by identifying the main gaps in the data and highlighting the key measurements to be considered in the future.

Linking the information between the SOPs and the shipment database will allow the tool to analyze the information directly from the source, while the database will be checking for consistencies in data entry and avoid errors in the SOP documents

Once the tool considers all variables, the service provider should be able to provide customers with solutions for alternative trade routes, and packaging options that have the least amount of risk associated.

Conducting a tradeoff analysis between having a flexible SOP and the cost of that service is necessary. On one hand, Embarking onto long term agreements with a specific carrier to ensure a minimum quota on a certain route is definitively a way reduce shipping costs, but can also limit the flexibility for XYZ to select the best carrier for each shipment and provide the service level needed. The stability profile for each product is significantly different and therefore some products have higher tolerance for temperature excursions and delays than others. This has been considered when developing the tool, giving a certain weight to each customer impact, depending on the customer's input when establishing a new SOP.

Data is a core element in all operations. The ability to collect data that specifically addresses questions to improve service level is never an easy task. The most significant challenge is not gathering the data, but developing an integrated strategy that virtually allows everyone involved in supply chain processes to use the data for improved decision-making and improving the bottom line.

Bringing this together, the data collection, analysis, system integration and the risk tool are all part of achieving a strategic fit across the supply chain.

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