

## Safeguarding Pharmaceutical Shipments Using Internet of Things

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Author: Mohammad Shakhatreh

## Abstract

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<b>Abstract</b> <p>The pharmaceutical industry loses up to \$35 billion to damaged medicines due to temperature excursions. Most of these excursions are attributed to the pharmaceutical airfreight supply chain, thus leading to an increased preference for sea and rail transport. This study sought to establish the root causes of temperature excursions of pharmaceutical airfreight and to design software and hardware-based solution to enhance collaboration and visibility from end-to-end of the supply chain. The researcher used an integrated theoretical approach dubbed confirm, explore, empathize and build, and co-create and validate. Using a pragmatic approach and case study design, qualitative and quantitative data were collected and analyzed using multiple tools and techniques. In the confirm phase, the findings show that no temperature excursions occurred during ground transport, and though there were high-temperature excursions during the summer season, there were high-and low-temperature excursions during other seasons, all the excursions occurring at the origin, transit, or destination airports. This was further confirmed through a meeting of pharmaceutical companies. In the explore phase, the problem was established to be attributed to an uncoordinated drop-off of cargo by shippers. A further examination of the problem and stakeholder concerns during the empathize and build phase led to the conclusion that the problem is caused by the fragmentation and lack of coordination and visibility in the supply chain process, and that it can be effectively solved through a software-based alarm system using a serialized online data logger. The solution was further improved and validated during the co-creation and validation phase. Further, it was found to be commercially viable through a winning prototype, and funding of US\$110,000.</p>		
<b>Keywords</b> Temperature excursion, internet of Things, cold chain, pharmaceutical shipments, integrated supply chain		

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## 1 INTRODUCTION

The demand for shipping temperature-sensitive pharmaceutical products continues to increase on an annual basis. According to a report by Grand View Research, the pharmaceutical logistics market was valued at \$76.4 billion in 2018 and is expected to grow at 3.5 percent CAGR between 2019 and 2025. The cold chain market made up 25 percent of this market and is expected to increase as the demand for temperature-controlled pharmaceutical logistics increases (Grand View Research, 2019).

### 1.1 Background

While the temperature-sensitive shipping of pharmaceuticals keeps growing in demand, the disappointments associated with the need for product recalls due to temperature excursions are also on the rise (Chamlou 2019). The losses by pharmaceutical companies are estimated by IQVIA Institute for Human Data Science as totaling to about \$35 billion including the cost of lost product, clinical trials, the cost of replacement and the cost of wasted logistics and root-cause analysis (Aircargo News 2019b; Buxbaum 2018; Jafferri 2019). The huge losses have led various companies to prefer other means of temperature-controlled transportation (Buxbaum 2018). The survey reported by PR Newswire (2019a) also revealed that although air and ground transport are the most common modes of transporting temperature-sensitive pharmaceutical products, most of the respondents considered increasing sea and rail transport modes, which represents a major shift from air transport.

In yet another report, Aircargo News (2019b) established that more than 70% of key opinion leaders in the temperature-sensitive pharmaceutical shipment industry currently use sea transport, a third indicating they use it regularly. These statistics correspond to those provided by IATA (2018) which indicate that only 0.5 million tons of pharmaceutical products are transported by air compared to 3.5 million tones transported by sea. Compared to the statistics in 2018 which indicated the same volume for air and 2.5 tons for sea transport (Henry 2018), the implication is that the growth in the cold chain industry is largely benefitting sea and not air transport.

Even though temperature monitoring is required by regulators as a means of detecting and quantifying the cumulative period of the excursions to help estimate the resultant decline in remaining shelf life or acceptability of the products, this has not solved the problem of temperature excursions. Horak et al. (2017) posit that in commercial aviation, the temperature of medical equipment was found to be in the range of between  $-3.5^{\circ}\text{C}$  and  $42.4^{\circ}\text{C}$  between Copenhagen and Mombasa or Lagos. Moreover, Sharaiha and Pastor (2016) indicate that in

Sub-Saharan Africa, about 40% or above of vaccines lost their effectiveness completely as a result of the inability to maintain a stable cold chain temperature range as required.

In a study carried out in 2017 for UNICEF, the findings indicated that 38% of shipments to developed countries were below the recommended temperature (NJIT 2019). A survey conducted in 2019 by Pelican Biothermal further revealed that major temperature excursions are frequent, with 44.6% of the respondents positing they experienced multiple excursions every year, 41% also reporting that the excursions were above four degrees (PR Newswire 2019a). Further, IATA (2018) highlights that 25% of vaccines usually arrive at their destination degraded, with 50% of temperature excursions attributed to airports and airlines.

The industry and its stakeholders have responded swiftly to the problem of temperature excursion through various innovations. Such actions include the use of the Internet of things (IoT) in temperature monitoring, better packaging designs, as well as through various training and certifications. However, these have not significantly reduced or eliminated the problem of temperature excursions in pharmaceutical airfreight. Moreover, rather than taking a proactive approach to temperature excursion management, the most up-to-date solutions are based on historical analyses that are backward-looking, only enabling the pharmaceutical companies to investigate the cause of past excursions and provide recommendations for future actions and improvement (Aircargo News 2019d; Jafferri 2019).

In only a single case (Bollore Logistics), real-time temperature control permitted immediate action. However, this also had the challenge of time consumed in information dissemination between supply chain partners (Jafferri 2019). This enhanced transparency did not prevent valuable time from being lost. Despite the technology, the temperature excursion data is not visible to the stakeholders who are near enough to take immediate corrective measures. Instead, the data is sent to the people at the sending or receiving ends of the transportation chain, and only a few centers along the supply chain. Thus, losses due to damages are still sustained.

The motivation to undertake this study came from the researcher's work at a third world airport in the Middle East which exposed the researcher to the reality of the problem of temperature excursions. This generated sufficient interest to lead a team of professionals into undertaking a process re-engineering using the six sigma tools. The researcher, however, discovered that although the tools were useful in problem identification, designing a practical, workable, and acceptable solution required engaging the critical stakeholders in the end-to-end process of the supply chain.

Tackling the challenge of temperature excursion requires not just piecemeal or scattered efforts (Pharma Logistics IQ 2019), but a centralized and unified solution that taps into the

strength of each technology and process improvement. The goal must be to provide real-time temperature control that is visible to stakeholders that can implement corrective actions without delay. This would draw from the benefits of active and passive temperature control, the Internet of things (IoT), digitalization of temperature data, digital serial tagging for container and package identification and send alerts for abnormal temperature deviations from the product's specified temperature for examination before an excursion is reached. This would enable the identification of problems and their rectification beforehand.

## 1.2 Thesis objectives, research questions, and limitations

The aim of this study is to provide a practical, workable and commercial solution for temperature excursions through the use of IoT to enable the full integration of supply chains for high visibility and control across the end-to-end supply chain. Based on this aim, the research question is as follows:

How can IoT be used to enable the collaboration and full integration of air cargo supply chain for high visibility and to control across the end-to-end supply chain as a means of solving the temperature excursion problem in pharmaceutical shipments?

The sub-questions include:

1. Considering the entire air cargo supply chain, where do most temperature excursions of pharmaceutical shipments occur?
2. What are the root causes of temperature excursions in pharmaceutical shipments within the specified area?
3. How can IoT enhance real-time visibility, collaboration and better control from end to end of the supply chain to help solve the problem of temperature excursions?
4. How can the solution established be commercialized and what challenges exist in its commercialization?

Although this study examines the root causes and solutions for temperature excursions, it is limited to the pharmaceutical logistics, and thus will not cover other products that may require cooling during shipment. Furthermore, the study is limited to air shipping which combines both air cargo and road transportation. Other means of freight transportation are not examined.

## 1.3 Theoretical framework

In answering these research questions, the researcher integrates the use of six sigma tools with the concept of service design. This integration achieved through a theoretical design

methodology that encompasses confirm, explore, empathize and build, co-create and validate, and which overcomes the weaknesses of six sigma tools and enables the establishment of a solution for the problem, not only from the point of view of the researcher but also of the customer. Such a solution is more viable and acceptable and can be commercialized through the development of a new venture.

#### 1.4 Research methodology and data collection

The aforementioned theoretical approach is best implemented through a pragmatic philosophy encompassing a case study design that employs both primary and secondary methods. The primary data involved the observation of the processes within the airport, conducting meetings with stakeholders, and semi-structured interviews among the responsible stakeholders to obtain rich data that helped in establishing what the stakeholders think is the problem, what is really the problem, and their views and change requests as it pertains to designing the solution. The secondary methods involved obtaining data from temperature records as well as various investigations of excursion events.

#### 1.5 Thesis structure

The thesis is organized into six chapters, as displayed in the figure below.



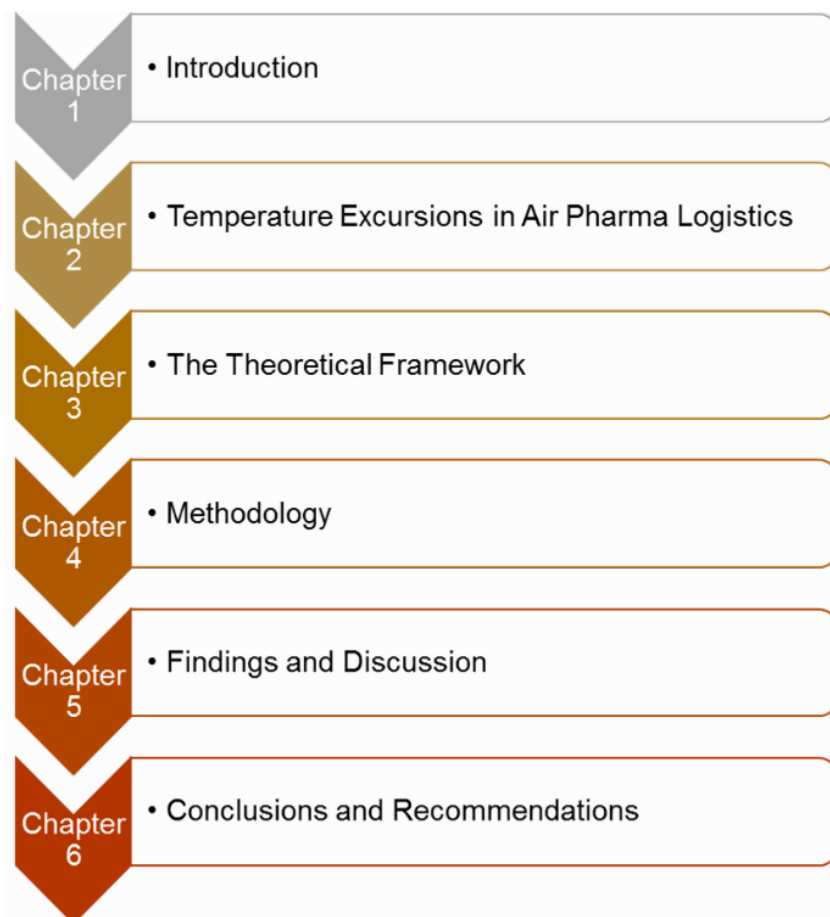


Figure 1. The structure of the thesis

The problem is introduced and discussed in the introduction, followed by the statement of the aim of the study and the research questions, as well as the motivation for conducting the study. The researcher introduces the theoretical framework and the methodology, all of which are explored comprehensively in other chapters. Chapter two furthers the problem through a step by step explanation of the concept of temperature excursion, temperature thresholds for pharmaceutical products, the challenges leading to excursions and the inadequate current solutions to prevent excursions. This chapter ends with the explanation of the gap that validates the need to conduct the study.

Following the presentation of this need, chapter three provides an overview of the theoretical framework used in exploring the questions. The combination of the six sigma's DMAIC methodology and the service design methodology through co-creation and validation of the solution are discussed. This leads to the discussion of the pragmatic philosophy adopted together with the case study design that introduces the multiple techniques used for data collection and analysis. The important issues in research such as ethical considerations, validity and reliability are further discussed.

In chapter five, the findings of the research are presented and discussed. These findings are shown in the sequence in which the data collection was conducted with sequential validations. The study is then concluded through a recap of the aim and methodology of the study, a summary of the findings from the aim of the research, an explanation of the limitations of the findings and recommendations for future research.

## 2 TEMPERATURE EXCURSIONS IN PHARMACEUTICAL AIRFREIGHT LOGISTICS

This chapter involves the discussion of the concept of temperature excursions in light of the pharmaceutical airfreight industry. It also introduces the need for temperature measurement and tracking through the entire logistics process, not just as a regulatory requirement but also as a tool used for investigating excursions and the extent of shipment damage. Further, the logistics challenges leading to temperature excursions are discussed, as indicated in the literature. This leads to the examination of the existing solutions and the gaps that are addressed in this study.

### 2.1 The concept of temperature excursion

Products that exhibit sensitivity to the conditions of transportation should be given special care so that their quality and potency remains unimpaired by the transport operations (Clénet 2018; NJIT 2019; Sharaiha & Pastor 2016). This sensitivity is required for environmental conditions such as temperature, light, shocks, humidity, oxygen, pressure, and vibrations (Kumar & Jha 2017). Lack of close monitoring and compliance with the manufacturer's label requirements may result in unintended compromises and possible degradation of the products.

The level of degradation depends on the environmental conditions stated, and the period of exposure to such conditions. Degradation may be insignificant when the deviations in the environmental conditions are small, and when these deviations occur for transient periods (very short periods and within the stability range of the products in the shipment). In this study, the products of the pharmaceutical industry (drugs and vaccines) are considered, and the sensitive parameter examined is temperature. Controlling for temperature ensures the integrity of the logistics and delivery processes.

A term that is often used when pharmaceutical products are exposed to temperatures outside their recommended range that potentially cause degradation is *temperature excursion*. This term is defined by the World Health Organization (WHO) as a circumstance entailing the exposure of a temperature-sensitive pharmaceutical product to conditions outside the predefined range for transportation and storage (Hernández & Yamaura 2017).

Temperature excursions over some time can result in the development of impurities that result from the degradation of the products and microbial growth. This adversely impacts the quality of pharmaceutical products (Kumar & Jha 2017). Other consequences of temperature excursions include loss of assay, separation of liquid products' layers, product discoloration, and changes in the dissolution patterns of solid dosages (Kumar & Jha 2017). These impacts could

render the products completely unsafe for human use as described in the above case of sub-freezing, or loss of their effectiveness.

Temperature is usually the main focus of discussions regarding environmental controls for pharmaceutical products on transit because of the sensitivity of all pharmaceutical products to temperatures outside their range of stability (Kumar & Jha 2017; Sadler-Williams et al. 2019). The importance of temperature also stems out of the trend in which the biologics and the biotechnology industries are increasingly developing therapeutic products that require distribution channels which are temperature controlled (Pelletier et al. 2018). Further, the importance of temperature control and considerations is acknowledged by the U.S. Pharmacopeia (USP) in their general guidance chapter 1079 where they indicate the uniqueness of temperature hazards to any given system (Sykes, 2018).

### 2.1.1 Temperature ranges for pharmaceutical products

According to Clénet (2018), the degradation of vaccines takes place when they are exposed to temperatures exceeding that which is recommended for storage. Such temperature limits are typically 5°C, 25°C, or 37°C. The possible degradations are not always due to heating, but can also be caused by allowing for cooler than the recommended temperatures (Lloyd et al. 2015). Sykes (2018) provides an example of such occurrence in August 2017 where a pharmaceutical company recalled its parenteral nutrition product due to exposure to subfreezing. According to Sykes, the product posed danger to the health of consumers and possible deaths because when frozen, its emulsion droplets become larger, thus forming aggregates that can obstruct pulmonary circulation. Such adverse impacts inform the need for the products to be kept within their range of tolerance during storage and transit.

The USP classifies the storage temperature range for pharmaceutical products into freezer, cold, cool, and control room temperatures. These ranges help define the limits of tolerance and represent different product classes and may also define shipping preferences.

- Freezer: The temperature range is maintained at -25°C to -10°C (Kumar & Jha 2017). Other scholars also indicate a possible lower temperature range known as cryogenic which ranges from 0°C to -150°C.
- Cold: Also known as cold chain, the temperature range of +2°C to +8°C needs to be maintained for certain products, such as vaccines, during distribution and storage (Hernández & Yamaura 2017; Wallace 2019).
- Cool: This refers to temperature ranges between 8°C and 15°C
- Control room temperature: One author indicated a computed mean kinetic temperature of 25°C, but also warned that pharmaceutical products under CRT conditions would

experience excursion if allowed to fluctuate within a range of 15°C - 30°C (Kumar & Jha 2017; Sharaiha & Pastor 2016). Sykes (2018) indicated that the temperature range, also known as ambient ought, to be 20°C -25°C which reduces the degree of fluctuations thus avoiding the extremes. However, Wallace (2019) extended the range to  $\leq 30^{\circ}\text{C}$ . It could be deduced, therefore, that the conditions for CRT may vary by-products, but appear to range between 20°C and 30°C, although this largely depends on the manufacturer.

In a 2015 survey of supply chain experts, the findings showed that out of the temperature-sensitive products that were shipped, 17% were frozen, 31% were refrigerated and 51% were in an ambient temperature range (Sykes 2018). Moreover, 32% of the products were indicated “must not be permitted to freeze.” Although the role of specialized pre-qualified shippers is to maintain the products within the range of temperature required, the temperatures sometimes get out of range during transportation.

### 2.1.2 The need for temperature monitoring

Guaranteeing the delivery of drugs to patients without losing their therapeutic attributes is the main concern to health authorities and the pharmaceutical industry (Hernández & Yamaura 2017). In many countries, the regulatory authorities hold the manufacturers responsible for ensuring that the quality of the drugs and vaccines delivered are maintained during the entire logistics and distribution chain and storage until they are used for treatment (Bhaskaran & Venkatesh 2019). They expect strict adherence to good manufacturing practices (GMP) as well as good distribution practices (GDP) which are considered as synonyms of a quality system in the pharmaceutical industry (Kumar & Jha 2017). For instance, the EU’s GDP guidelines document 94/C63/03 holds that the drugs should be in their right condition all the time during transport and storage (Kumar & Jha 2017). Moreover, the EU GDP chapter 9, ICH GCP E6 indicates that pharmaceutical firms must have the ability to track and trace their investigational medicinal products (IMPs) throughout their transportation (Segiel 2017). Lastly, the most recent EU GDP guideline, 2013/C 343/01 indicates the requirement for devices that record temperature (Sadler-Williams et al. 2019).

This means that the manufacturer must work towards decreasing the risk of defects in quality by ensuring that the temperature throughout the entire supply chain remains within the required range for sensitive products, and that the planned conditions of transport are maintained. The authorities expect pharmaceutical companies to monitor temperature – as a system placed by the manufacturer - for each shipment as a means of ensuring the required conditions are met (Kumar & Jha 2017). The failure to do this may not only harm the health of

patients but also the manufacturer's image if they are mandated to recall their products (Sykes 2018). It may also result in lawsuits due to substandard and damaged products, and distrust by shareholders that may cost more than just dollars. Aside from the costs associated with the lack of temperature monitoring, other reasons for monitoring include the need for process control, regulatory compliance and damage mitigation.

Monitoring provides decision-makers with the required data. According to Pelletier et al. (2018), the dynamic and fluid nature of shipping makes it hard to control even with the identification of all variables. This calls for monitoring as a means of determining the acceptability of products on arrival. The data enables effective decision making on the acceptance of products by Quality Assurance based on the comparison between the limits attained and product tolerance as indicated by the manufacturer. The growing importance of this comparison is because of the implications of not meeting the label directions which include: a) the consideration of the product as adulterated except where excursions are supported by stability data and the variability in temperature is well documented, b) questionable product efficacy and the non-acceptance of clinical data, c) the consideration of corrective actions as non-existent, and d) the consideration of storage conditions as being out of compliance (Sykes 2018). Moreover, the time and temperature history enable decision making concerning the shelf-life of the products and thus, decreasing uncertainties in product management.

As pharmaceutical companies strive to maintain GDPs, they are continually bombarded with the challenges of a complex supply chain environment (Sykes 2018). In many cases, the design and packaging of a product and transporting it to the customer can take several months, with numerous stakeholders involved including contract manufacturing firms, logistics service providers, distribution centers, and clinical sites. In many cases, the supply chain includes numerous countries, transportation legs, many months or days when the product sits in some storage shelf (Sadler-Williams et al. 2019).

The major challenge in pharmaceutical logistics is the control of temperature for the entire shipment and complying with the regulations of different governments and agencies while keeping the overall costs to the minimum (Sharaiha & Pastor 2016). Temperature-sensitive products are usually transported using pre-qualified shipping containers. However, these containers do not always perform as expected and significant deviations in temperature may occur without being detected. The loss of reliability is due to logistics challenges as well as issues related to the pre-qualified container and products.

## 2.2 Logistics challenges leading to temperature excursions

Logistics challenges risk the quality of the products making it difficult to maintain transport temperature and time, resulting in temperature excursions (Segiel 2017). These challenges arise because shipping containers are often handled by multiple stakeholders not under the control of the sender or any single party, increasing uncertain activities more than the controlled activities. These, combined with other uncontrollable factors, result in challenges that may cause temperature deviations (Pelletier et al. 2018).

The challenges include unpredictable weather changes, longer custom procedures, accidents, changes in transportation routes, stops at unsuitable places, malfunctioning of temperature control systems, defective sensors, and lack of information, or imprecise information (Pelletier et al. 2018). Moreover, the issues related to shipping containers include incorrect assembly of the shipping container, improper pre-conditioning of product, improper pre-conditioning of coolant, higher external temperatures than the design limits (Kumar & Jha 2017). There are also challenges associated with delays. These include traffic congestion between the airport and the destination, the material may be offloaded from a plane and put in a store for several hours, and there is a possibility that the customs officials could open the shipment storage and remove the temperature monitors (Segiel 2017; Sykes 2018). Of all these challenges, the highest risk to excursion occurs at the point of staging or product handling at airport locations or warehouses

## 2.3 Current solutions in the market

Several solutions have been adopted by pharma logistics stakeholders. These solutions are either active or passive, and are based on the attributes of their products, risk profile, and complexities in the trade lane. They include the use of traditional temperature monitoring devices, the adoption and use of digitized platforms for advanced analytics, the use of improved active and passive single-use or reusable cooling packages connected to the Internet of things, the adoption of best practices from IATA's CEIV certification program, and the newest solution – insurance.

### 2.3.1 The traditional temperature monitoring

The best way of ensuring that all the relevant information on the environmental conditions of transport is met is the inclusion of a temperature monitor, which enables the collection of primary data which includes accurate temperature reading that is linked to the time and date of measurement in transit and storage. The maintenance of high-quality temperature and time history as indicated in the guidelines of WHO and UNICEF is currently conducted through

many methods. These include temperature loggers, chemical-based indicators, electronic freeze indicators, and integrated digital thermometers (Hernández & Yamaura 2017).

#### Chemical-based indicators

Chemical indicators are chemical substances such as waxes, liquid crystals, lacquers and polymers which change their phase as a result of temperature changes (WHO 2015a). They are also referred to as phase-change indicators or markers or critical temperature indicators and are usually infused into a paperboard substrate. An example of an improved chemical-based indicator is the ThermaProx, a device developed by the New Jersey Institute of Technology which includes a proxy sensor and which mimics the temperature profile of the pharmaceutical products and changes color based on the type of temperature excursion. The device turns deep red if overheating occurs, and turns blue if frozen (NJIT 2019).

#### Electronic freeze indicators

An electronic freeze indicator is a small device that is usually placed together with freeze-sensitive vaccines during transportation (WHO 2015b). It has a built-in visual display that enables one to read whether a vaccine has been exposed to freezing. It is a one-time-use device, just like the chemical-based devices which are discarded once the alarm system has been triggered. According to WHO guidelines, the freeze indicator is only used as a backup and must never replace an electronic temperature and event logging device. Using a freeze indicator is routine for locating cold or hot spots in a cold room, but must not be used as a substitute for temperature mapping (WHO 2015b).

#### Electronic data loggers

Electronic data loggers, on the other hand, are small and portable devices that measure temperature and humidity at a preset interval. The measurements can be downloaded into a computer system for review, record, investigation, and evaluation (Kumar & Jha 2017). The devices have programmable alarms and integrated displays and can create graphs and reports which may be stored permanently, analyzed, and shared through propriety software, hardware, hosted databases or desktop applications (WHO 2015). These devices need to be periodically verified to ensure they are well-calibrated and that their software is up to date for uninterrupted and accurate data logging. They also need to be periodically cleaned, with caution taken to avoid damage or blockage of the sensor.

The use of electronic data loggers has made it hard for pharmaceutical companies to keep total oversight of products from the time they leave the manufacturer to their administration (Segiel 2017). It is, therefore, becoming challenging to provide the assurance that regulations



are met and the integrity of products is sustained. These methods essentially involve the manual assessment of temperature data which implies managing multiple software applications and vendors. Although the analysis of such data is highly valuable, it is time-consuming and labor-intensive, which sometimes leads to supply chain disruptions (Segiel 2017). Moreover, when the temperature data is reported at each location, it is stored in multiple, unrelated databases. As a result, there is no central point that provides complete oversight of the data throughout the life cycle of the product. This leads to the potential for unreadable data storage across the entire supply chain (Segiel 2017).

### 2.3.2 Data digitization efforts

Some companies have come up with ways of digitizing the temperature data collected and stored in various clinical sites. The platforms for real-time monitoring include the PharmaPort platform, which provides shipping containers that permit real-time monitoring of the temperature condition through the company's web-based system (Shanley 2019). The Almac Group in April 2019, launched its TempEZ™ software platform which provides data visibility, the flexibility of use and automation of excursion management (PR Newswire 2019b). The company considers its platform as the only company providing end-to-end data and visualization of the temperature history of drug products. The solution is provided, however, only in clinical sites. The company claims that the drug products take a longer time within the clinical sites as compared to transit points, and that the temperature history of products in such environments remains opaque. This warrants the effort to collect data at these points (PR Newswire 2019b). Another platform that is still under development is TraceLink with a Smart Product Excursion Tracking application, which enables real-time data collection on product conditions and the context of the patient during the consumption for the assurance of integrity and safety of specialty medicines (Healthcare Packaging 2019).

Aside from software platforms, another digitization solution is the use of digital tags. At the time of conducting this study, Unilode Aviation was in the process of completing the development and deployment of Bluetooth Low Energy technology for digital tagging to enable the linking of serial tags with container identity (Huq 2019; Jafferri 2019). Combined with temperature recording from the sensors within the solution, the digitized serialization aims to correctly identify packages which have been interfered with. It is not clear, however, whether the interference also includes temperature excursion.

Shanley (2019) reported a survey conducted in 2018 to establish the extent of the adoption of digitization efforts. The findings showed that 63% of the respondents were already using analytics, 37% advanced analytics, 29% were active users of AI while 35% were in the process

of implementing AI, and 19% were using IoT. The author further revealed that of these respondents, 54% had overspent in ensuring temperature control in more than a quarter of their shipments while 24% had underspent on the same.

### 2.3.3 Application of Internet of Things

The continuous monitoring of products in real-time is being conducted through the use of advanced data analytics, and by leveraging artificial intelligence (AI) and the internet of things (IoT) (Shanley 2019). The main idea that underlies the concept of IoT is that every physical thing can act as a computer that is linked to the internet. It is a vision in which the internet will cover the world through embracing and interconnecting objects through sensors, service, networking, and interface (Hernández & Yamaura 2017). Through programmed sensors, the IoT provides the possibility of having real-time monitoring of pharmaceutical products and the provision of timely warnings for operators to check the state of temperature in the storage areas.

It also enables the tracking of cumulative temperature excursions beyond the allowable range to maintain the viability and effectiveness of the products. According to Segiel (2017) the ability of a system to track all the excursions cumulatively for a specific shipment, product lot, or kit and perform the documentation of the product history and the ability to hold the preset allowances for excursion based on the stability of the product, can result in a more accurate and quick quality evaluations of the products. This is because the decision-making process and justification for those decisions are conducted upfront. This, in turn, can enable a robust and justified process for the disposition of products based on risk and data, as well as compliance with regulatory requirements, increased visibility, inventory, and product quality (Hernández & Yamaura 2017; Segiel 2017).

Furthermore, the ability to have real-time visibility in every part of the supply chain and throughout the journey of the product makes it possible to adopt a proactive approach. This approach drives more than just the enhancement of compliance, but also lowers the risk of temperature excursions that are unplanned, while controlling for the planned excursions (Segiel 2017). Planned excursions occur when the products are removed intentionally, from their ideal conditions to permit processing.

Shanley (2019) presented a case in which a real-time monitoring system was able to detect temperature excursion during truck transportation, even though the problem had not been detected by a data logger. This problem was traced to the failure to completely shut the back window following a customs check, allowing cold air into the truck. This shows the effectiveness of the real-time monitoring concept.

Improved packaging designs

Traditionally, ice has been employed in temperature-sensitive shipments to keep the products cool. However, this has led to issues such as freezing, condensation, and increased weight which also increases the cost of shipping (Microtek Laboratories 2019). Such problems have been contributing factors to temperature excursions which are now a huge concern in the pharmaceutical logistics industry.

Packaging providers have responded to the challenge of temperature excursions through the design of single and reusable packaging that offer active and passive temperature control methods (Shanley 2019; Jafferi 2019). Aside from insulation properties, some of the products in the market, such as SkyCell boxes have special rechargeable cooling technology and have IoT sensors (Aircargo News 2019e). Passive packages can operate from  $-65^{\circ}\text{C}$  to  $-25^{\circ}\text{C}$ ,  $+2^{\circ}\text{C}$  to  $+8^{\circ}\text{C}$ , and  $+15^{\circ}\text{C}$  to  $+25^{\circ}\text{C}$  for between 24 and 120 hours (Aircargo News 2019c; Jafferi 2019; Shanley 2019). CoolPall Flex for instance, which was released in July 2018, can provide temperature control for up to 144 hours while SkyCell provides up to 200 hours as a means of mitigating temperature excursion of pharmaceutical products (PELI Biothermal 2018; Jafferi 2019). Other temperature-control packaging solutions include Tempcell's ECO, a recyclable shipper made from corrugated paper materials that control the temperature between 0 and  $30^{\circ}\text{C}$ , Tempcell MAX that controls the temperature for up to 96 hours, and Silverpod MAX (Lowry 2019).

An example of active packaging innovation for mitigating temperature excursion is a range of Adaptek pouches and panels for thermal control during shipping (Microtek Laboratories 2019). According to the manufacturer, the pouches and panels can maintain a safe temperature within the threshold specified during transportation, are recyclable, and can be customized by size and temperature (Microtek Laboratories 2019). These containers are equipped with sensors that are connected to a data cloud for monitoring (Aircargo News 2019c).

A 2019 survey revealed that 37.6% of organizations currently use the re-usable rental containers for cold chain logistics, while 25% are considering this choice (PR Newswire 2019a; Aircargo News 2019b). Many organizations are now moving to the use of these containers. For instance, Singapore Airlines, United Cargo, Air France-KLM-Martinair Cargo, Cargolux, Emirates Skycargo signed a lease agreement with SkyCell for their passive temperature-controlled pharmaceutical containers in June 2019 (Aircargo News 2019c; Chamlou 2019). Jafferi (2019) further indicates that passive packaging is becoming more preferred to active cooling containers because of the number of hours of temperature control offered by passive packaging, although the active cooling packages have the advantage of unlimited runtime.

### 2.3.4 The CEIV certification by IATA

According to a report by IATA, temperature excursion contributes to only 20% of the damages and this is a result of a broken cold chain (Buxbaum 2018). The report further indicates that the brokenness of the cold chain is a result of the lack of accountability, standardization, compliance, and transparency and in most cases, temperature excursions take place during handling by airlines or airports (Buxbaum 2018). To resolve this problem, it is, therefore, logical to develop a set of regulations and standards and ensure compliance by airlines and airports as well as other pertinent stakeholders.

In response to the challenge, the IATA Center of Excellence and Independent Valuation (CEIV/Pharma) developed a global certification based on standards and best practices and ensures compliance through independent audits resulting in the harmonious and consistent delivery of quality services. Holders of the CEIV certification are rendered qualified to transport pharmaceutical products by air and the certification is achieved in two rounds of audits (Henry 2018). The first round enables a gap analysis, and the second round is for validation.

The components of the program are updated annually with training done according to best practices. These standards are applicable to chain partners including handlers, forwarders, and truckers, airports, and airlines. Other stakeholders such as regulators and shippers cannot be certified but take part as observers and are permitted to attend training sessions. Moreover, groups of service providers have taken up such training and implementation plans as communities. As of 2019, there were 12 communities, with 9 airports reported to be in the process of developing their communities (IATA 2018; Jafferi 2019). Firms benefit through increased quality, consistency, and integrity of services, and training, gap analysis as well as implementation plans (Sykes 2018).

So far, increased standards have been realized for instance, at Miami International Airport, a new custom cooling facility has been constructed which is equipped with temperature data recorders, alarm systems and CCTV monitoring (IATA 2018). Also, an airline – Delta Cargo reported increased volume since receiving its CEIV certification (Jafferi 2019). The same increases have been reported by Hong Kong International Airport (HKIA) which has been the busiest cargo airport since 2010 (Chan 2018). These benefits according to IATA (2018) are backed up by the pharmaceutical industry which sees transparency, certification, and standardization as an advancement in the aviation industry with endorsements from Merck Sharp and Dohme (MSD), the European Shippers Council, Baxter, and Zoetis, among others.

### 2.3.5 Insurance solutions

The stakeholders in the industry have also come up with insurance to help handle the losses associated with temperature excursions. The usual case has been that the pharmaceutical manufacturer takes all the risks associated with temperature excursion (Aircargo News 2019a). Backed by an insurance company, SkyCell with its product – Peace of Mind Insurance- now covers up to \$4 million worth of value for each container (Aircargo News 2019a). The valuation of the shipments, identification of risks and subsequent insurance is conducted by a transportation planner together with the shipper, airlines and freight forwarder.

### 2.4 The gaps in current solutions

As indicated above, the industry and various stakeholders have responded swiftly to the problem of temperature excursion through various innovations including the use of the Internet of things (IoT) as well as through various training and certifications. However, these have not significantly reduced or eliminated the problem of temperature excursions in pharmaceutical airfreight. Moreover, rather than taking a proactive approach to temperature excursion management, the most up-to-date solutions are based on historical analyses that are backward-looking, only enabling the pharmaceutical companies to investigate the already occurred excursions and provide recommendations for future action and improvement (Aircargo News 2019d; Jafferri 2019). Further, the temperature excursion data is not visible to those stakeholders who are near enough to take immediate corrective measures. The data is only given to the sending or receiving ends, and a few centers along the supply chain. Thus, the losses due to damages are not avoided, just confirmed. It is possible that the current solutions have failed because the root causes of temperature excursion have not been established, and thus, the current solutions are only superficial.

This study addresses these gaps by first establishing where temperature excursion takes place, zooming in on the processes within the risky touchpoints to establish the exact problem. Further, contributions from the critical stakeholders can be utilized to design a workable solution that can be commercialized. This effort promises to provide the real solution with a practical implementation, in view of the challenges indicated by the stakeholders. If implemented, the solution will go a long way into enabling the improvement of the efficiency of business processes and significantly reduce the losses associated with excursions. The solution does not operate in isolation, nor does it disregard the other existing solutions in the market, but integrates all of them to achieve the required success.

### 3 THE THEORETICAL FRAMEWORK

Having identified the gaps in the current solutions and the persistence of the problem of temperature excursions in the pharmaceutical airfreight industry, the two theoretical underpinnings that guide the identification of the exact problems and the design of the best solution possible is presented. These include the six sigma and service design methodologies. While the six sigma ought to enable the entire process of identification of the problem, design of the solution and its implementation and control, its weaknesses that lead to the integration with service design are discussed. This, therefore, justifies the use of an integrated theoretical approach to problem-solving.

#### 3.1 The Six Sigma Methodology

The six sigma idea was built on the total quality management philosophy and introduced first by Motorola in the 1980s. The concept has since been embraced by several organizations, and it has also evolved into different variants which are a combination of six sigma and other approaches. The DMAIC methodology which is an acronym for define, measure, analyze, improve and control, according to Mandelbaum, Hermes, Parker, and Williams (2017), is among the key pillars of six sigma and provides a roadmap for pursuing the opportunities for improvement. The DMAIC methodology is presented in the figure below.



Figure 2 The six sigma methodology

### 3.1.1 Define

This involves defining the problem, the goal, the process, and customer needs. These four definitions ought to lead to the development of four outputs: the problem statement, the goal statement, process maps, and customer requirements. The problem statement should comprise severity definition, impacts on business and the particular area or department. Moreover, goals need to be SMART. Process definition involves zooming into the processes using high-level process maps. The Suppliers, Inputs, Process, Outputs, and Customers (SIPOC) tool is often used. During this defining phase, the customer needs to be contacted for a better comprehension of their needs.

### 3.1.2 Measure

The measurement phase is enabled by a precise problem definition. The aim of this phase is to measure processes' actual performance to provide a definition of its exact state in order to prevent wrong measurements or the right measurements for the wrong parameter. For instance, in the situation where the improvement of reliability is the main problem, the primary measure would be the average and variance of the transit time. There is a need to prioritize these measures to enhance the clarity regarding which measures are the most important.

### 3.1.3 Analyze

The analysis stage involves the establishment of the source of the problem and the identification of the associated issues. This would involve issues that result in customer dissatisfaction, frustrations, unnecessary costs, and reduced margins. This phase involves a review of the data collected during the measurement phase, narrowing down in the analysis to identify the exact sources of the problem. The findings are visualized in graphs and charts for easier identification of the challenges in the process.

The analyses can be grouped into: a) time analysis, which involves the emphasis on the comparison between waiting time and processing time (when actual work is being done); b) value-added analysis which enables the discovery of the actual cost of doing business; and c) mapping of the value stream which is a combination of the process data with the map containing the value-added process to enable the determination of areas where waste can be eliminated. When working with teams, the sources of the problems faced can be identified through a structured brainstorming session using tools, for example, the cause and effect diagram. Another way of discovering the source of the problem is through the use of the design of experiments which enables the identification of the variations in reliability through controlling for factors such as the tendering, schedule and dispatch of shipments, the preparation, staging

and loading of shipments, delivery and pickup time, document processing and weather conditions. These details would not just help in discovering the problem, but also assessing the performance of processes and marking them for improvement.

#### 3.1.4 Improve

The objective of the improve phase is the establishment and the implementation of the solution that would mitigate the sources of the problems under research. Since change is complex and change processes take time in all organizations, the goal of the improve phase is to develop an organizational culture that supports improvement. Although many possible solutions may be available, there is a need to select the best two that align with the organization's resources and processes and the solutions ought to be tested for their practicality and greater benefits against costs incurred in developing and implementing the solutions. Tools such as the plan-do-check-act (PDCA) may be used during the testing and implementation processes.

#### 3.1.5 Control

Of all the DMAIC phases, the improve phase may require the largest effort. The control phase merely involves continuous monitoring of the improved system, to keep the key variables within acceptable limits. This should involve the definition of new variables and measures and worker training for the sustainability of the improvements. The emphasis is to eradicate possible complacencies and ensure that corrective actions are taken for measures out of the defined performance range.

### 3.2 Limitations of the six sigma

The six sigma methodology has its own limitations just like other TQM initiatives. First, quality data may be unavailable and this leads to a lot of time required for gathering data sufficient enough to begin the process. In the analysis phase, some of the aspects such as statistical applications may not be applicable in the service industry. For instance, failures are defined in the six sigma thinking as 3.4 failures per million which more suits large scale manufacturing. In the service sector, failure is anything that deviates from the expectations of consumers. This makes it illogical to use the sigma computation as a means to quantify service failure.

There are also situations where the solutions that are driven by the analyzed data cannot be used in the improvement phase because of the limited resources or their ability to return relative to the cost of implementation. Moreover, the initial cost of six sigma institutionalization into the corporate culture as required during the improvement phase may turn out to be a notable investment. Aside from the associated costs, the solutions designed are product-centric and



therefore, may enhance the efficiency of the current processes, but may not lead to the design of a totally new process or system that fully fulfills the needs of customers.

### 3.3 The service design methodology

This is a new method for the development of services as well as services businesses. It bears similar attributes with the goals of an iterative design and human-centered design and involves an iteration of designing, testing, measuring and redesign. The attributes of human-centered design are incorporated in the way in which unexpected insights are captured and innovative solutions are produced which reflect the wants of the consumer in a more precise way.

Service design involves three distinct phases including discovery and identification, building, conceptualization, and implementation phases. The discovery and identification phase involves gaining an understanding of the context of users, the service and the business environment. In this study, this was embodied in the concept of customer-centricity. The building, conceptualization, and creation concerns visualization, participatory design, co-creation, and prototyping. This was embodied in the concept of co-creation and solution validation phases. The last phase, implementation, involves many processes including the incorporation of the IT process, development of the service and training. The implementation phase of service design is not within the scope of this study. Following the end of the co-creation process, the researcher does not go beyond prototyping. This means that hardware and software development, or piloting the solution is outside the scope of this study.

#### 3.3.1 Customer centricity

The concept of customer centricity is defined differently by different researchers. However, the common themes in those definitions include a) the organizational unit of analysis, b) the emphasis on the interest of the customer, and c) the active prioritization of the customer. As it pertains to the organization as a unit of analysis, the majority of definitions consider customer-centricity from the level of the firm and thus, firms are considered as entities that portray customer-centricity, rather than processes or functions within those firms (Avilova, Gulei, & Shavyrina 2015; Hemel, & Rademakers 2016; Lee, Sridhar, & Palmatier 2015). Only a few studies emphasize on customer centricity at the functional or process level. These processes or functions include marketing, sales campaigns, or information systems with none focusing on product or service design or improvement programs (Camilleri 2016; Sauvola et al. 2015; Redding 2015).

Many definitions also conceptualize customer centricity based on a strong emphasis on the fulfillment of the needs of customers. Given that these needs vary from one customer to another, some studies consider customer-centricity from the view of segmentation based on the interests of customers. Moreover, for the third conceptualization, some authors consider customer centricity as the active prioritization of customer needs above the internal organization issues and concerns. For instance, some authors consider all the decisions made within an organization as beginning with the customer while others only consider customer centricity as the adaptation of the processes and structures in an organization to the interests of customers.

In this study, customer-centricity is understood through a strong emphasis on the fulfillment of customer needs through a complete understanding of the customer and customer journey, and mapping out the pain points for improvement. This is accomplished through the use of two tools: empathy and customer journey maps.

#### Empathy maps

The empathy map according to Ferreira, Barbosa, and Conte (2016) is a technique for creativity for the development of empathy for potential customers and new insights into their needs. In this study, the researcher did not design actual empathy maps, but during the solution validation process, empathized with stakeholders' needs and processes leading to solution redesign. Therefore, the researcher empathized with the customer and other stakeholders during the development of the initial solution, but more so, during the co-creation process. This occurred when the researcher kept adjusting the solutions based on the challenges identified with the applicability and practicality of the previously co-created solution. Therefore, the solution was not only driven by the need to solve the core problems, but to listen to design what is effortless and comfortable to use and ultimately acceptable.

#### Customer journey maps

This is a diagram that depicts the steps undertaken by the customer in engaging with a service. Journey mapping enables service providers to see their customers from outside in, and thus, enabling them to understand their pain points. Due to the involvement of many stakeholders in the shipment of pharmaceutical cargo, this study maps instead, the shipment journey, identifying the pain points through the identification of the risky touchpoints and the stakeholders in charge at each stage. Given that the customer – the pharmaceutical company is directly involved only at the shipment pick-up point, and because the entire process following the pick up is opaque to this customer, putting pharmaceutical companies at the core of each stage was impractical. On the contrary, the consideration of the shipment in the journey mapping enabled the researcher to consider the pain points as the points at which the shipment is at

risk of temperature excursions. At each of the stages, the liable party was identified, and the issues raised as possible causes of inefficiency were identified.

### 3.3.2 Co-creation

In co-creation, users of services work together with professionals in the design, creation, and delivery of services (Yim et al. 2019). Co-creation differs with co-production in the sense that customers are engaged in the planning process. A major assumption in co-production is that the process linear while in co-creation, the process is assumed to be iterative and dynamic where value is developed at the point of interacting with customers (Yim et al. 2019).

The concept of co-creation is also closely linked with participation as some authors highlight the idea of participative co-creation. This can be distinguished as the intention to enhance public service quality by inviting the contribution of customers during the strategic planning and design phases. In this study, the concept of participative co-creation is used as an element of customer-centricity to aid the development of a practical and acceptable solution to mitigate the problem of temperature excursions.

### 3.4 The integrated theoretical approach

The six sigma methodology provides the appropriate tools to zoom into systems and processes to identify those that deviate from the expected. It, therefore, works well in identifying the challenges with systems. However, as aforementioned, the use of the methodology in designing an appropriate solution is product-centric. This presents the challenge of coming up with solutions that do not align with the needs and resources of an organization, relative to the benefits of implementation. Therefore, in many cases, the solutions end up not implemented at all, and if implemented, then in small portions that do not bring about the intended level of performance and improvement.

This study involved the use of an integrated theoretical perspective. Before the use of theory to guide research, the researcher first used quantitative analysis to confirm the literature indicating that airports and airlines are responsible for most of the temperature excursions. This led to the use of the six sigma tools to examine processes and challenges with the airport in order to fully describe the real problem and attempt to find a solution. Because of the failure of the six sigma process in enabling a full solution that is acceptable to all the stakeholders, the researcher re-examined the problem in light of the stakeholders involved and the design thinking process to fully understand the customer and create a workable solution. This solution

was then co-created and validated with various stakeholders. This theoretical view of the process can be summarized as comprising four phases: confirm, explore, empathize and build, and co-create and validate, and is shown in the figure below.

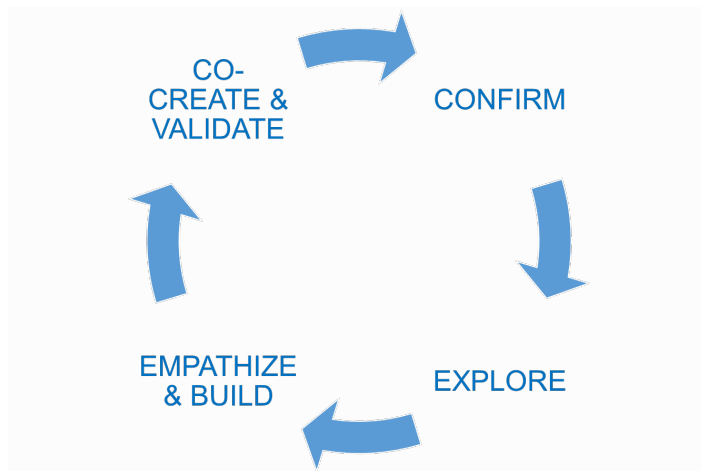


Figure 3 the integrated theoretical design view of the study

## 4 METHODOLOGY

The use of an integrated theoretical approach also means the amalgamation of different research methods to achieve the desired solution. This chapter discusses first, the research philosophy underlying the mix of methods, and how it impacts the entire research process. More particularly, the concept of pragmatism is discussed, followed by its alignment with the case study design and the qualitative and quantitative data collection methods. Moreover, the use of both primary and secondary data is discussed, together with the application of the integrated theoretical design tools for data analysis and solution design. These are discussed in the succeeding subsections.

### 4.1 The research philosophy

Research philosophy is defined by Saunders et al. (2015) as a system of assumptions and beliefs about knowledge development. The authors consider the research process as a knowledge creation endeavor. There are five major research philosophies. Two of these philosophies- positivism and interpretivism- are of the extreme opposites, while remaining three- critical realism, postmodernism, and realism- take from the two.

The positivist philosophy is the natural scientist's stance and holds that observable social reality ought to lead to the development of law-like generalizations, and promises accurate, unambiguous knowledge. Interpretivism, on the other hand, considers the difference of humans from social phenomena based on their ability to create meanings. Due to this, the study of humans must differ from social phenomena, by taking into account the variations in the experiences of humans based on their culture, circumstances, and social realities, all of which shape meaning. Interpretivism, therefore, opposes the positivist stance in requiring the richness of context.

In this study, both the objectivity of positivism and the subjectivity of interpretivism are required to properly establish where and why temperature excursions take place and to design a proper solution. This makes it of importance to choose a philosophy that supports both objectivity and subjectivity in a mix that allows for practicality. The pragmatic philosophy reconciles rigorous and accurate knowledge acquisition while taking the context of experiences into account. This is achieved by considering the elements of quantitative research including theories, ideas, and concepts based on their role as tools of action and thought and their practical consequences in particular contexts.

The pragmatic philosophy further aligns with the integrated theoretical methodology as the research commences with the identification of the problem, and ends with the validation of the

solution. It permits reflection, which is inherent in designing solutions. Further, it permits the use of multiple techniques as long as they permit credible, established, relevant and reliable data collection that validly contribute to the formulation of the desired practical solution.

#### 4.2 Case study design

In line with the need to develop practical solutions through the use of multiple data collection and analysis methods, the research strategy chosen is a case study design. A case study is defined as the study of a single case, particularly and taking into account its complexity in order to gain an understanding of its activities with situations of importance (George 2019). It also defined as the intensive evaluation of a unit with an emphasis on the developmental factors with respect to the environment (Yazan 2015). The versatility of case study design stems from its lack of assignment to any fixed methodological, epistemological or ontological position (George 2019). This enables the researcher to determine the methodology to be used. According to Yazan (2015), case studies can employ both qualitative and quantitative methods and thus supporting the pragmatic approach to inquiry.

This study establishes the root cause of temperature excursion by focusing on a single case: A third world airport in the Middle East. It leverages the contextualization and richness of data in case study design, as well as the use of multiple methods to analyze systems and processes to determine the root cause of the problem and to design an appropriate solution. The flexibility in the use of different methods permits the use of structured techniques and tools as well as various data collection methods, all of which lead to the desired result: a desired practical solution.

#### 4.3 Data collection

In this study, primary and secondary, qualitative and quantitative data were collected. The data were not collected at once but systematically first to identify where most temperature excursions take place, in six sigma methodology use and in the design of an appropriate and practical solution. The data collection process is visualized in the figure below.

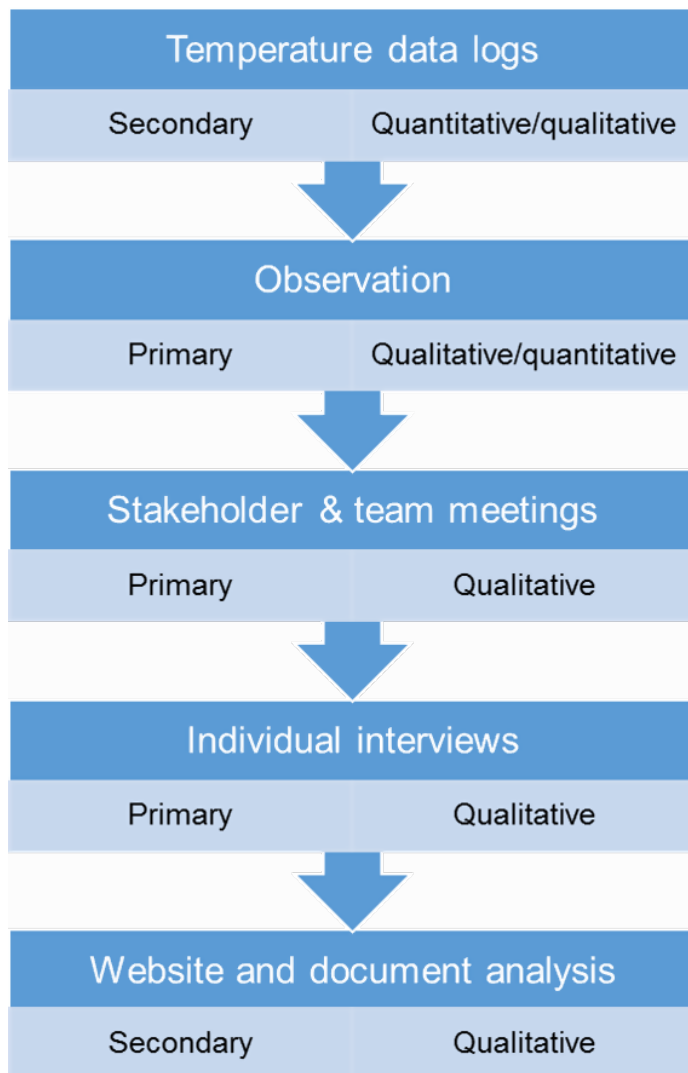


Figure 4 The data collection process and techniques

#### 4.3.1 Secondary data collection

The secondary data included:

- Temperature readings from data loggers from end-to-end supply chain
- Tracking number for all the shipments whose temperature data were provided
- Printed reports indicating the shipment temperature stability range
- Information on news and websites and policy documents

The purpose of the data was to help in establishing the location where most temperature excursions occur. The data were obtained from one Jordanian pharmaceutical company that provided access to temperature logs for 96 shipments. These shipments were all imported to Jordan from Belgium and the USA. The data were collected between January 19, 2019, and August 19, 2019. The researcher examined the temperature readings of each shipment and

whenever an excursion was discovered, the researcher entered the tracking number into the shipment tracking website and compared the time of the excursion with the location of the shipment at the particular time to identify the location of the excursion. Aside from the temperature reading, the date, and the time of the excursion, other parameters also examined included the location of the shipment, origin, transit, and destination airports, the shipping date, the arrival date, and the upper and lower temperature thresholds. The data were entered into an excel file.

The data obtained from news and websites were majorly to inform competitor analysis for examining the differentiation points of the designed solution. This, together with policy documents from IATA were also used to compare the designed solution with IATA's existing solutions and any special requirements for the proposed solution. Therefore, other than the information related to temperature logs, all other data collected were for validating and modifying the designed solution.

#### 4.3.2 Primary data collection

Primary data were obtained through observations, meetings, and interviews. Observation and meetings were critical during the application of the six sigma to identify the cause of temperature excursion inside the airports. Interviews were the main data collection technique during the co-creation process. These are discussed comprehensively in the succeeding subsections.

##### Observation

Observation is a data collection technique where a researcher examines processes and events as they occur. One important concept in observation is the position of the researcher during the process. The position could be covert where those observed are unaware they are being observed, or overt where the participants are aware they are being observed (Jorgensen 2015). Based on covert and overt observation techniques, an observer can be a *complete participant* who is a member of a group but observes other group members without their knowledge. The researcher can also be a *participant as an observer* who is a group member and observes other group members with their knowledge, or an *observer as a participant* where the researcher is not a member of the group but observes the group members with their knowledge. The researcher can also be a *complete observer* where the researcher is not part of the group and observes the members of a group without their knowledge.

In this study, the researcher took the position of an overt observer. Jorgensen (2015) indicates this is the most preferred way of making observations. Moreover, based on the four classifications, the researcher took the place of a participant as an observer. During that time, the



researcher worked at the airport and led a group of other employees in the identification of the problem using six sigma tools and therefore was a member. All the other members and stakeholders including the airlines, airport employees, and shipment handlers were all aware of the study and therefore aware they were being observed. As an observer, the researcher did not question or interfere with the processes.

The researcher's engagement in the process was of importance in gaining a deeper understanding of the work processes and functions. The process involved examining the flow of shipments inside the airport. Using a pen and paper, the researcher recorded: a) the time of arrival of shipments, b) their weight, c) the type of shipment (pharmaceutical or not), and d) the level of congestion at each stage during shipment processing.

According to Jorgensen (2015), overt observations have the challenge of a possible change of participants' behavior due to the awareness they are being observed. However, this may not have impacted this study because the focus of observation was not the people that run various processes and functions, but the processes. Moreover, in pharmaceutical cargo handling, there are many external players whose actions may not be controlled. Also, being an employee within the airport and in the same department, the researcher had experience of what the norm is and therefore, was in a position to notice any changes that could be attributed to the awareness of being observed.

### Meetings

Meetings were a crucial data collection technique for the six sigma process. Eight meetings were carried out, three of them with the team that was formed to help with the six sigma process, and five with stakeholders during the improvement process. The team formed to help with the six sigma process comprised 8 members drawn from different levels and functions including a) a driver, b) airport worker, c) the person responsible for weighing shipments, d) the person responsible for organizing the offloading process, e) the person responsible for preparing equipment inside the airport, f) field operator, g) airline employee, and h) airline supervisor.

On the other hand, the meetings with the stakeholders involved a) the shippers union, b) logistics managers of pharmaceutical companies, and c) security and customs. During these meetings, the researcher recorded only the main challenges raised, and the main solutions and resolutions arrived at. The series of meetings, persons involved, and the purpose of the meetings are presented in the table below.

Table 1 The series of meetings held with various groups and stakeholders

Meeting	Persons involved	The objective of the meeting
Meeting 1	Logistics managers from different pharmaceutical companies	Validating the existence of the problem established from the literature
Meeting 2	The six sigma team	Presented the confirmed problem and learning about the logistics process at the airport
Meeting 3	The six sigma team	Grouping the problems faced at each process using affinity diagrams
Meeting 4	The six sigma team	Understanding the root causes of the problem using interrelation diagram
Meeting 5	The shippers union	Validating the problem and initial establishment of solution
Meeting 6	Logistics managers from different pharmaceutical companies	Explaining the problem to get their support in organizing shippers to drop their shipments 24 hours to departure
Meeting 7	Security and customs	Enabling them to understand the problem and adjust their services based on the proposed improvement
Meeting 8	Shippers union	Informing and convincing them to embrace the booking process through emails as a solution

## Interviews

Interviews are a major way of qualitative data collection and classified as either semi-structured or fully structured, formal or informal. In this study, formal semi-structured interviews were conducted. The interviews had a conversational design, allowing the researcher to seek greater clarification about the answers provided by the participants. Semi-structured interviews are usually preferred because they permit the researcher to gather additional insights (Kallio et al. 2016). 10 interviews were conducted with different stakeholders, and mainly to validate the solution, identify stakeholder acceptance or modification requests, and reasons underlying their rejection of the solution. The stakeholders were identified through the use of the snowballing technique. According to Kallio et al. (2016), snowballing is a technique where

respondents are identified by recommendation, and this helps in creating rapport and trust beforehand, allowing the researcher to gather as much information as possible.

The interviews were conducted sequentially following developments in the design after the preceding interview. Most of them were conducted via telephone, with very few (those which were done with stakeholders at a third world airport in the Middle East) being face to face. The participants' responses were recorded on paper and factored in during the product co-creation process. The interviews and the persons interviewed are indicated in the table below.

Table 2 List of informants

Interviewee	Interview
Regional logistics manager of a pharmaceutical company	1, 2, 4, 11
Head of innovation at a courier company	3
Customs employee – at a third world airport in the Middle East	5
Head of a shipping company	6
In charge of receiving claims – an airline company	7
Lawyer of an airline company	8
Head of cargo – airport in the Middle East	9
Ground handler at a first-world airport in the Middle East	11

#### 4.4 Data analysis

The techniques used for data analyses differed based on the type of data collected. The findings from the temperature logs were analyzed using descriptive analyses and represented in bar charts and scatter plots. This was useful in demonstrating where temperature excursion takes place and the possible impact of weather conditions and the tolerance range of the pharmaceutical products. Since the researcher only asked questions that were helpful during each stage of the co-creation process, the researcher only noted the important points and factored them in the brainstorming and secondary research which was useful during the product development process. The interview findings, therefore, did not require analysis using software but were analyzed manually during the co-creation and validation process. Also, since the observation data was small and highly revealing, it also did not require further analysis.

The data obtained from meetings, and especially those conducted with the six sigma team members were thoroughly analyzed using certain tools. The tools used are summarized in the table below.

Table 3 Tools used to identify the problems at each stage of the six sigma process

Tool	Stage used	Purpose
Flowchart diagram	Meeting 2	To understand the flow of work processes at the airport
Affinity diagrams	Meeting 3	To group problems with certain similarities
Interrelation diagram	Meeting 4	To enable root cause analysis and establish the applicability of the 20/80

The researcher and the team used sticky notes that were stuck on a whiteboard as a means of recording and classifying the problems to validate the problem or the root causes, and to provide useful insights for the improvement phase of six sigma. Aside from the tool mentioned above, the research also used a customer journey map tool to identify the risky touchpoints and the pain points during the flow of shipments as an initial attempt to understand the customer and other stakeholders.

#### 4.5 Validity and reliability

The terms validity and reliability are more common in quantitative research. While validity refers to the ability of an instrument to measure what it was intended, reliability refers to the repeatability of the research (Noble & Smith 2015). Although this research employs quantitative data (secondary), the qualitative methods are more dominant. Therefore, it is more expedient to examine: a) whether the informants' responses were true and b) relevant to the research (Noble & Smith 2015).

The researcher ensured relevance through the selection of informants with knowledge about pharmaceutical airfreight. The most of the respondents either worked within the airport (members of the six sigma team), lawyer of airline, in charge of claims, customs and security, and head of cargo or had designations that reflected the relationship between their positions and topic under consideration for instance regional head of logistics in a pharmaceutical company, the shippers' union, among others. Only one interviewee did not have a designation reflecting

experience with pharmaceutical logistics – the head of innovation at a courier firm. The respondent provided critical information about the viability of renting the solution (product as a service) which was in line with the designation.

There are a number of ways through which truthfulness was maintained. First, in obtaining temperature readings, the researcher was provided with printed and signed forms indicating they were the true temperature logger readings for the 96 shipments. The researcher further confirmed the exact shipment with the tracking numbers. Another means of ensuring truthfulness was the engagement of stakeholders in multitudes through consultative meetings. Such are known to enhance the truthfulness of the respondents as they speak as a group, rather than as an individual. Lastly, truthfulness was enhanced through triangulation. More than a single research method was used, and the researcher did not find a disagreement between the respondents, or with data gathered from other techniques and thus fulfilling the need for triangulation (Turner, Cardinal, and Burton 2017).

#### 4.6 Ethical considerations

This study followed the followed ethical principles in all the research processes. These included obtaining informed consent, voluntary participation, maintaining the anonymity of the participants whenever it was expressed or deemed necessary, and keeping the confidentiality of information (Pacho 2015).

##### 4.6.1 Informed consent and voluntary participation

Informed consent was needed at every stage of the study, including obtaining temperature logs, analyzing processes at the airport using the six sigma methodology, and in interviewing different stakeholders during the process of co-creating the solution. In obtaining the temperature logs for shipments, the researcher contacted the general manager of a pharmaceutical importing company in Jordan, having been introduced to her by a third party. The researcher then arranged for a one-on-one meeting where the purpose of the research was explained, and following acceptance, the access to the temperature data logs together with their tracking numbers and the information regarding the stability range for all the drugs in the shipments were provided by the quality assurance manager.

For the study conducted at a third world airport in the Middle East, the researcher, by virtue of assignment, was permitted and provided with the contacts to all the relevant participants including those who made up the six sigma team, the customs, the shippers union, and pharmaceutical companies. Nevertheless, in each meeting session, the researcher explained the purpose of the study. The researcher, also, upon being referred to the individuals who agreed

to the telephone and face to face interviews, explained the purpose of the study after which permission was granted to conduct the interviews. All the consent provided were not in written form but rather implied. Moreover, even in the case of duty as in the six sigma team, participation was entirely voluntary.

#### 4.6.2 Maintaining anonymity

The researcher made due efforts to maintain the anonymity of the respondents by generalization, and where there was a need to distinguish between the respondents, pseudo names were provided. This followed an express request by most of the respondents to have their identity concealed as part of their conditions to consent participation in the study. It, therefore, became of importance to handle all the participants anonymously and thus protect their identity, as well as the identity of the institutions.

#### 4.6.3 Maintaining confidentiality

Confidentiality was attained in two main ways: by not recording the interviews and only noting the main points, and by concealing the identity of the participants through generalization. Although note-taking is traditionally a main and acceptable method of recording interviews and conversations, it became of great importance as a means of providing informant anonymity since today's technology allows for voice matching and tracing back to the informant. Further, all over the researcher's notes and analysis, the informants or their institutions were not mentioned but instead, participants were distinguished by their industry, country or occupation. The data were further not shared with unauthorized parties, except for the already analyzed information, which had already been factored within the co-creation process which presented in general without specific inference to the informant.

## 5 FINDINGS AND DISCUSSION

This chapter involves the presentation of the findings of the different stages in which data were analyzed, beginning with the findings of the review of temperature logs. This is followed by the findings of the six sigma analysis process and finally the findings of the solution design process. The discussions are integrated within the presentation process and encompass an analysis stakeholder acceptance of the solution as the major determinant of the viability of the solution for new venture creation.

### 5.1 The findings of temperature logger data review

The analysis focused on the temperature regimes of pharmaceutical shipments shipped from Western European or U.S. manufacturers to distribution warehouses in Amman, Jordan. Off-line monitors revealed the temperature extremes that were recorded for 96 different shipments of pharmaceuticals through the transportation chain. Each shipment went through five stages of a transport chain, as depicted below.

1. *Origin ground transportation:* Pharmaceutical cargo was shipped via ground transport from the manufacturer's warehouse to the cargo terminal storage facility at the airport of origin.
2. *Origin airport:* Pharmaceutical shipments arrived and were placed in temporary storage while waiting to be loaded onto an aircraft and flown from the origin airport to the transit airport.
3. *Transit airport:* Pharmaceutical shipments arrived and were placed in temporary storage while waiting to be loaded onto an aircraft and flown from the transit airport to destination airport.
4. *Destination Airport:* Pharmaceutical shipments arrived and were placed in temporary storage while waiting to be loaded onto ground transportation to the distribution center.
5. *Destination Ground transportation:* Pharmaceutical shipments were shipped via ground transport to be stored at the destination warehouse for eventual distribution to final consumers.

#### 5.1.1 A general view of the incidences of temperature excursions

Of these shipments, 58 experienced temperature excursions. This represents a 60% failure rate for all shipments in the sample. The researcher first separated the shipments into two:

those which experienced excursions due to a lower temperature than the threshold (low-temperature excursions), and those which experienced excursions due to a higher threshold than the threshold temperature (high-temperature excursions). More than half (43, or 50.7%) experienced high-temperature excursions while some (25) experienced low-temperature excursions. There are shipments (10) that experienced both high and low-temperature excursions. This is displayed in the figure below.

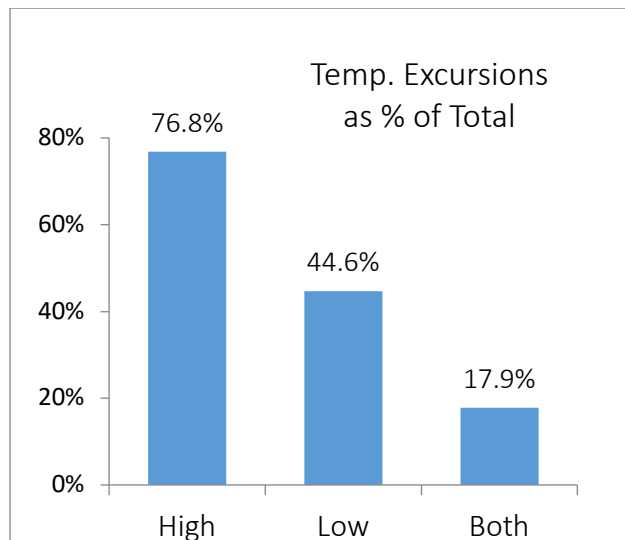


Figure 5 The incidences of high and low-temperature excursions

To further investigate the nature of these excursions, the researcher established a scale to enable the determination of low, high or extreme temperature excursions:

- Low-level temperature excursions: Temperature deviations exceeded the tolerance range by  $\leq 2^{\circ}\text{C}$ .
- High-level temperature excursions: Temperature deviations that exceeded the tolerance range by  $>2^{\circ}\text{C}$  and  $\leq 4^{\circ}\text{C}$ .
- Extreme temperature excursions: Temperature deviations that exceeded the tolerance range by  $>4^{\circ}\text{C}$

According to the findings, of the 25 low-temperature excursions, 13 were low-level (52%), 8 were high-level (32%) and 4 were extreme (16%). Of the 43 high-temperature excursions, 13 were low-level (30%), 21 were high-level (49%), and 9 were extreme (21%). This is shown in the figure below.



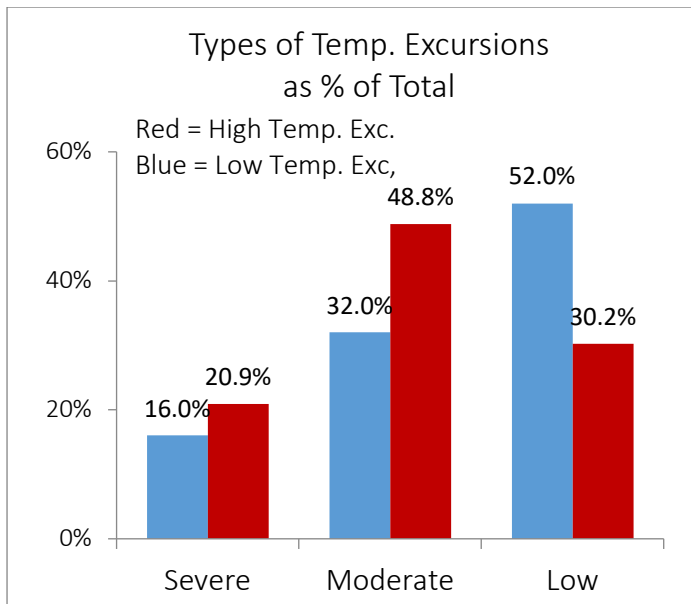


Figure 6 The incidences of low, high-level and extreme temperature excursions

### 5.1.2 The incidences of temperature excursions by location

The findings reveal that the origin airport contributed 2 excursions (3% of all excursion in shipments), the transit airport contributed 31 (46.3%) and the destination airport contributed 34 (50.7%). This is shown in the figure below.

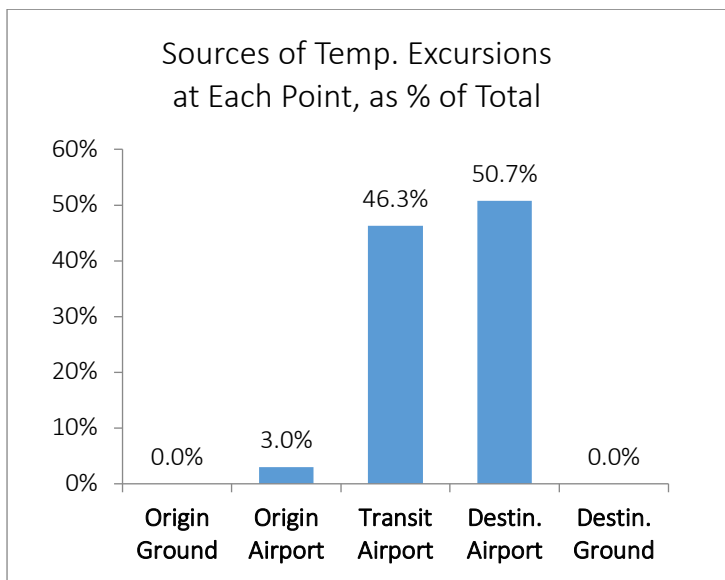


Figure 7 The incidences of excursions across the airport links in the transportation chain

Based on these findings, it is evident that no temperature excursions occurred during ground transportation, either from the origin warehouse to the origin airport or from the destination

airport to the destination warehouse. This means all the temperature excursions occurred at the origin, transit or destination airports.

The rates of temperature excursion were also determined based on the percentage of all the shipments in the sample handled by the particular airport. The origin airports which contributed the least temperature excursion included airports in the U.S., Germany, and Belgium. The two excursions that occurred at the origin airport were traced to Belgium Airport, amounting to 2.5% of all the shipments in the sample that originated from Belgium. Further, of the 31 shipments that experienced excursions in the transit airports, 27 excursions occurred at the Maastricht airport and 4 at the Dubai airport. This represents 64.3% of all shipments in the sample handled by Maastricht, and 67% of all shipments in the sample handled by Dubai. Finally, the 34 excursions at the destination airport (Amman) represented 35.4% of all shipments handled in the sample. These are shown in the figure below.

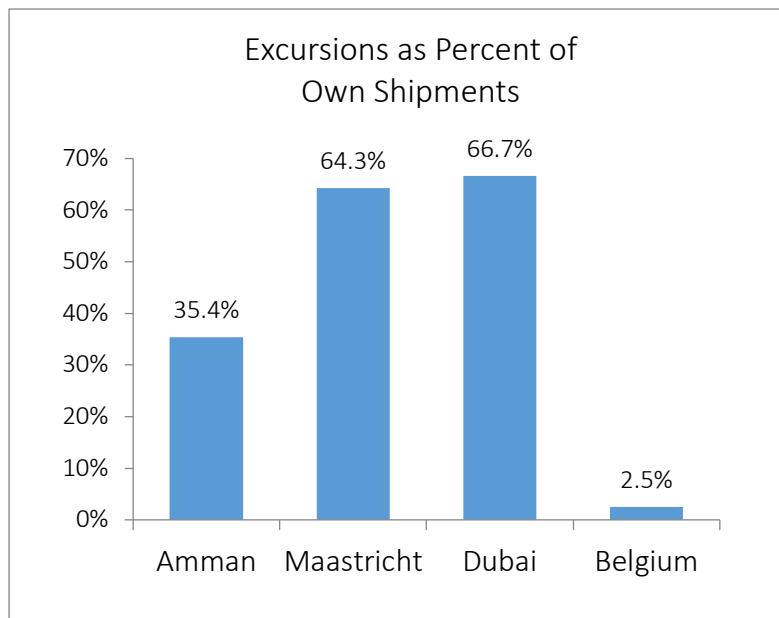


Figure 8 The incidences of excursions by origin, transit or destination airports

### 5.1.3 The incidences of temperature excursions by season

Due to the possible impact of environmental temperatures during different seasons of the year on the probability of excursions, the researcher separated the shipments that were transported during summer (May to August) from the rest and examined the rate of temperature excursion as a percentage of the total number of shipments in the sample handled by the airport. The excursions were further separated into high-temperature and low-temperature excursions.

All the temperature excursions at the transit airports (Dubai and Maastricht) and the destination airport (Amman) were high-temperature excursions. Only the origin airport (Belgium) recorded a single low-temperature excursion. The Amman airport experienced a high-temperature excursion on 28.7% of its shipments. The Maastricht airport experienced a high-temperature excursion on 42% of its shipments while the Dubai airport experienced a high-temperature excursion on two-thirds of its shipments. These are shown in the figure below.

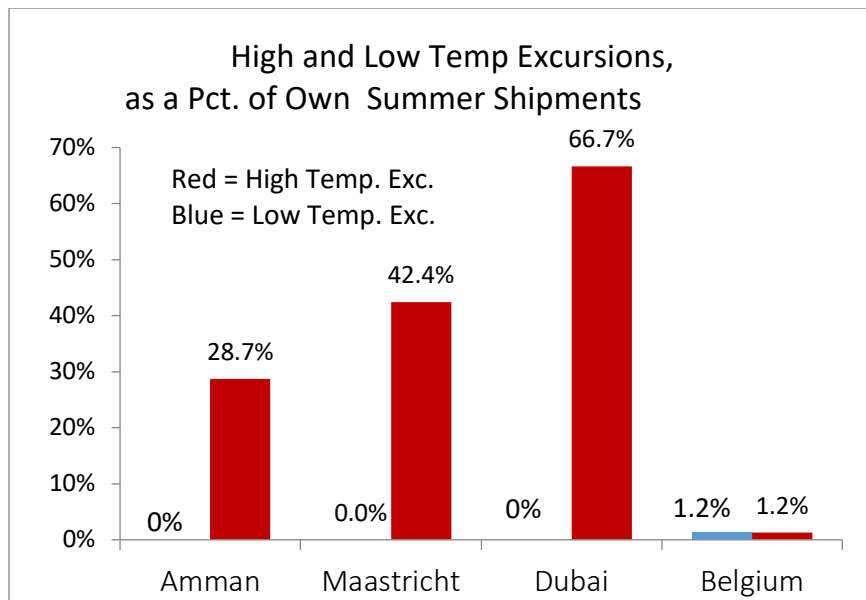


Figure 9 The incidences of temperature excursions during summer

Based on the findings, it can be argued that high-temperature excursions occur mostly during summer seasons, with the probability of low-temperature excursions being very low. The researcher also analyzed shipments outside the summer season to determine the rate of temperature excursions in each airport. The findings show that low-temperature excursions during non-summer months are limited to the transit airport (Maastricht). During the same period, two-thirds of the shipments that were transported through Dubai experienced high-temperature excursions, while for the remaining airports, very few or no incidence of excursions was experienced. This is shown in the figure below.

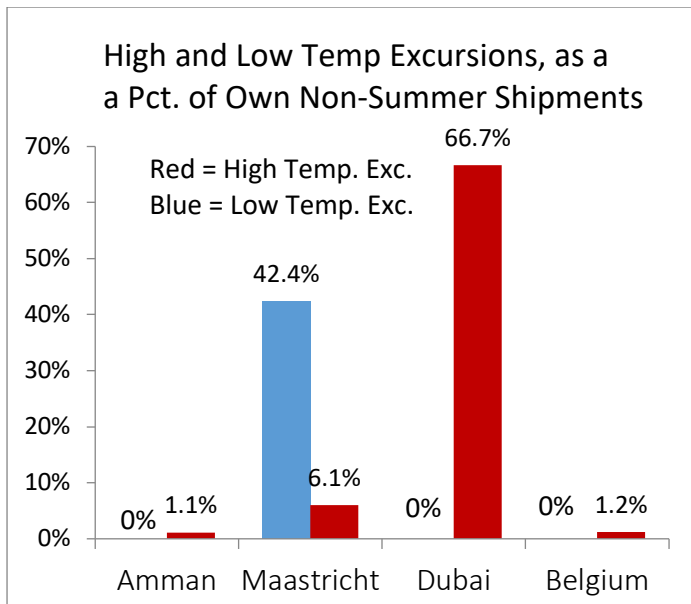


Figure 10 The incidences of temperature excursions during non-summer months

#### 5.1.4 The incidences of temperature excursions by the tolerance range of pharmaceutical shipment

The researcher also sought to establish the rate of temperature excursion by the type of pharmaceutical shipment. The pharmaceutical shipments were categorized by their temperature tolerance ranges. Out of the 96 shipments, 15 had a tolerance range of 2-8°C. Of the 15 shipments, 5 were exposed to a temperature above 8°C and 2 were exposed to temperatures below 2°C. One shipment was exposed to both high and low excursions. The number of excursions represents a 40% failure rate for pharmaceutical shipments within this tolerance range. This is represented in the figure below.

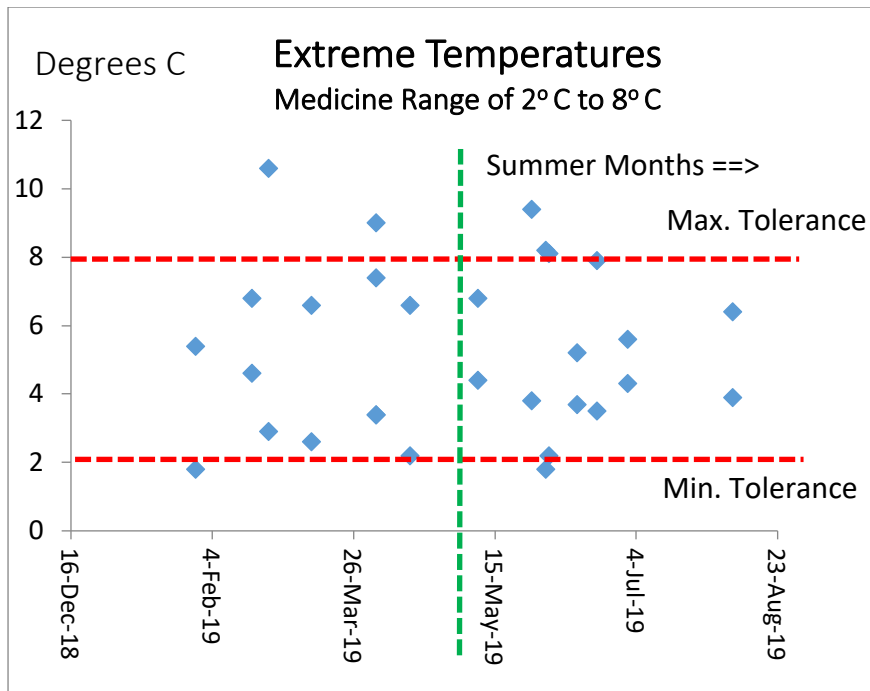


Figure 11 The incidences of temperature high and low-temperature excursions for the tolerance range of 2 to 8°C<sup>1</sup>

There were 11 shipments within the tolerance range of between 2°C and 25°C. Of these shipments, 6 were exposed to temperatures above 25°C and none below 2°C. These represent a 55% failure rate. This is shown in the figure below.

<sup>1</sup> Each shipment is arranged by the date the shipment left the origin warehouse along the x-axis. The temperature tolerance range is indicated by horizontal bands and the vertical line indicates the start of the warmer summer months when shipments experience higher temperatures.

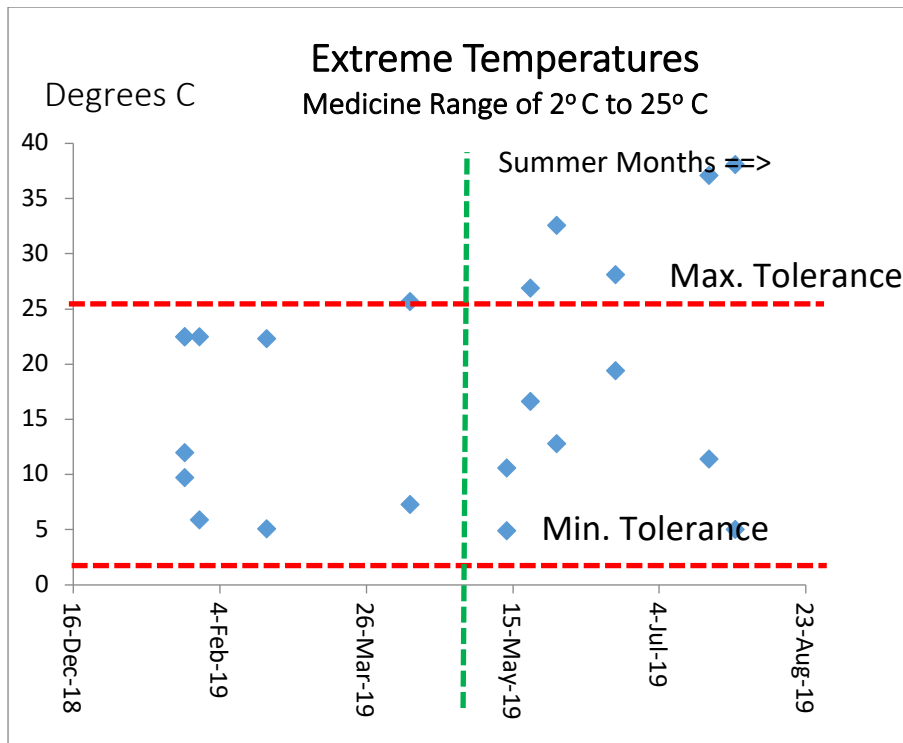


Figure 12 The incidences of temperature high and low-temperature excursions for the tolerance range of 2 to 25°C

Lastly, 70 shipments had a tolerance range of between 15°C and 25°C. Of these shipments, 37 were exposed to temperatures above the upper threshold and 28 shipments below the lower threshold. Nine shipments were exposed to both high and low-temperature excursions. This represents an 80% failure rate and is shown in the figure below.

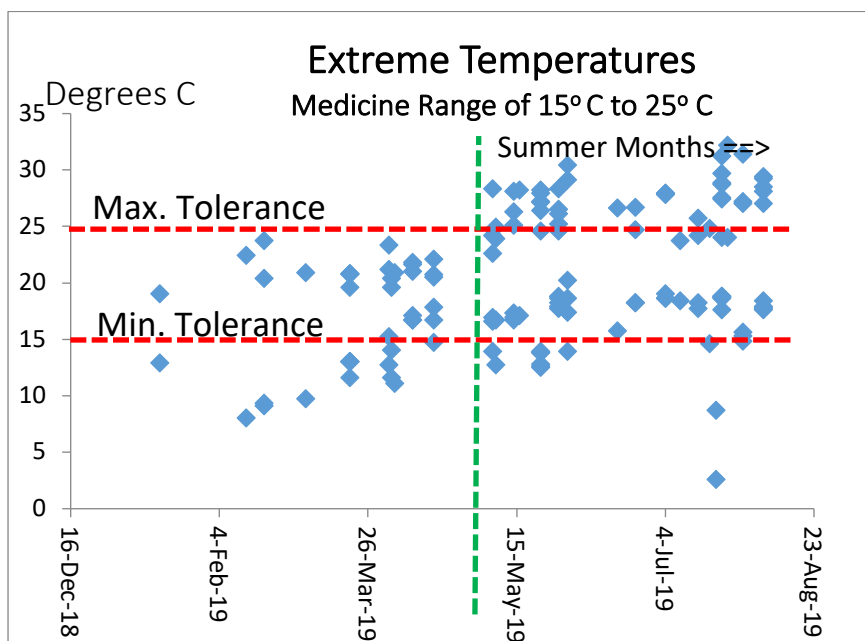


Figure 13 The incidences of temperature high and low-temperature excursions for the tolerance range of 15 to 25°C

The above findings demonstrate that all temperature excursions occur at the airports, agreeing with the claims in different research articles and correspondence (Buxbaum 2018; IATA 2018). The findings also show that most of these excursions (high-temperature excursions) occur during the summer season, and therefore, clearly showing the contribution of atmospheric temperature on the high-temperature excursions. However, it was also established both low-temperature and high-temperature excursions occur during the non-summer seasons and therefore, atmospheric temperature is not wholly responsible for the excursions at the airports. This introduces the need to examine comprehensively what happens at the airport to establish the real reason underlying the numerous excursions as observed in literature and the above findings.

## 5.2 The findings of the six sigma analysis

Following the establishment of the airport as the area where most of the temperature excursions take place, it became of importance to zoom into the processes and activities inside the airport to establish the root cause of the problem. This was done using six sigma tools, confirmed by observation and a meeting with stakeholders.

### 5.2.1 Problem definition

Before the formation of the six sigma team, a meeting with pharmaceutical companies in Jordan (meeting 1) was conducted to help validate the problem established through the analysis of the temperature logs. The pharmaceutical companies presented complaints about temperature excursions and presented documents with data logger readings and the tracking records of their shipments. These provided proof of their complaints and thus validating the airport as the location of the problem of the temperature excursions.

### 5.2.2 Problem measurement

To measure the extent of the problem, the researcher observed the processes at the airport. After noting the processes that occur around the clock and the issues around the problem, the researcher established that most shipments arrive around peak hours (within 2-3 hours), and most of the congestions take place on Thursday. This led the need to examine processes and procedures to establish a) why there are congestions and long waiting periods at the airport before shipments are cleared for departure and b) why the shipments arrive at peak hours.

### 5.2.3 Analysis of the problem

To further explore the problems at the airport, it became of importance to establish the processes at the airport and then allow the team members to list the challenges at each stage in the process. This was done using a flowchart diagram. Further, these problems were grouped using affinity diagrams based on the similarities between them in a bid to establish their common causes. Furthermore, the relationships between the common causes were further established to further distinguish the few problems that caused most of the problems (the 20/80 rule).

The flow of pharmaceutical shipments into a third world airport in the Middle East

It was established that the stages of pharmaceutical shipment include both ground and air freight transportation at the destination, transit and origin airport. The major stages at origin airport (a third world airport in the Middle East) are shown in the figure below.

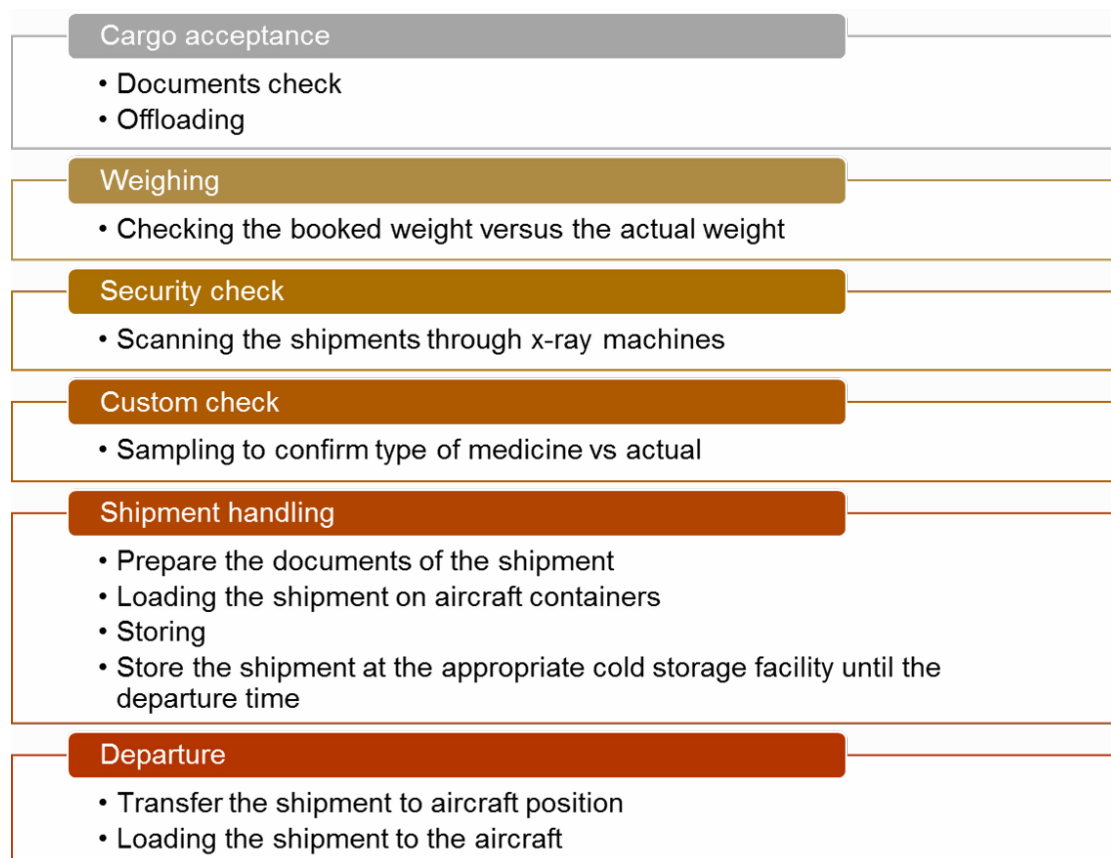


Figure 14 The flow of pharmaceutical goods at the origin airport

In the case of arrival, the flow of pharmaceutical shipments is shown in the figure below.



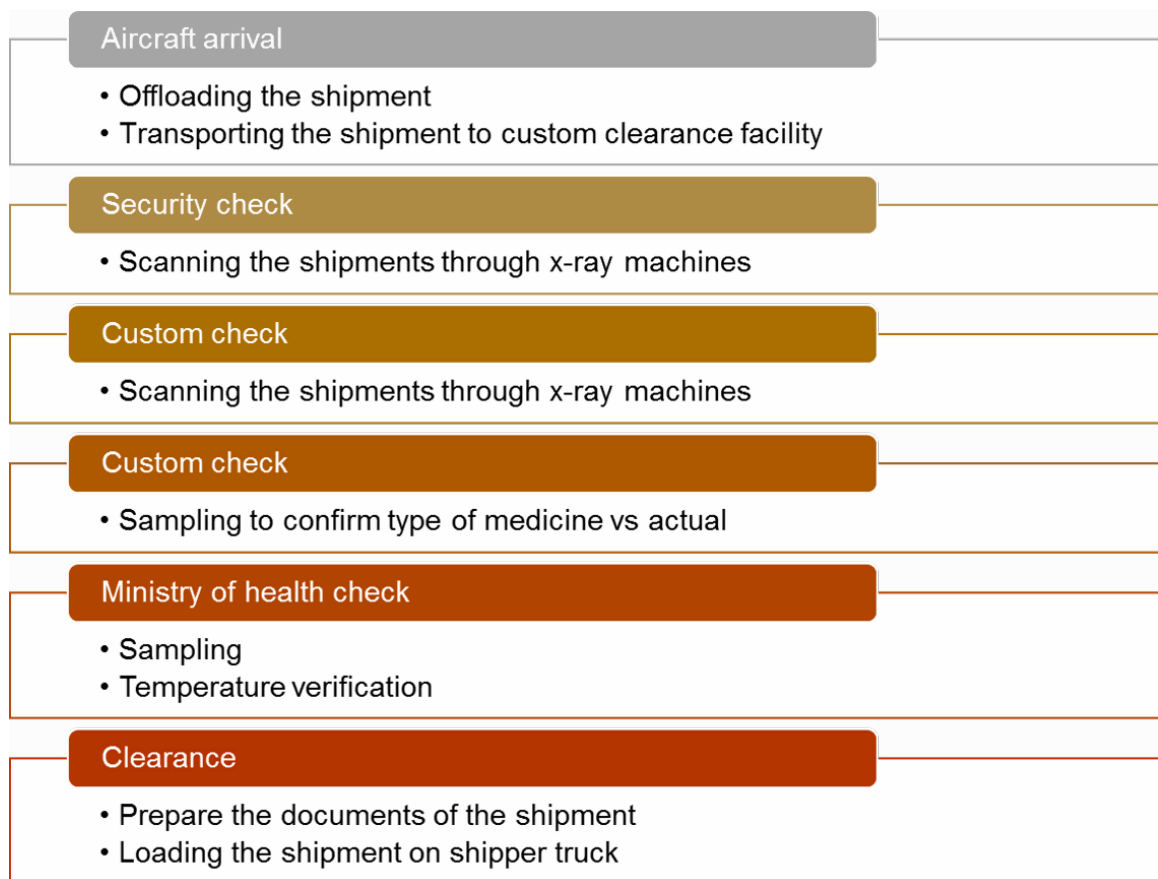


Figure 15 The flow of pharmaceutical shipments at the destination airport

In the case of transit, the flow of pharmaceutical shipments is shown in the figure below.

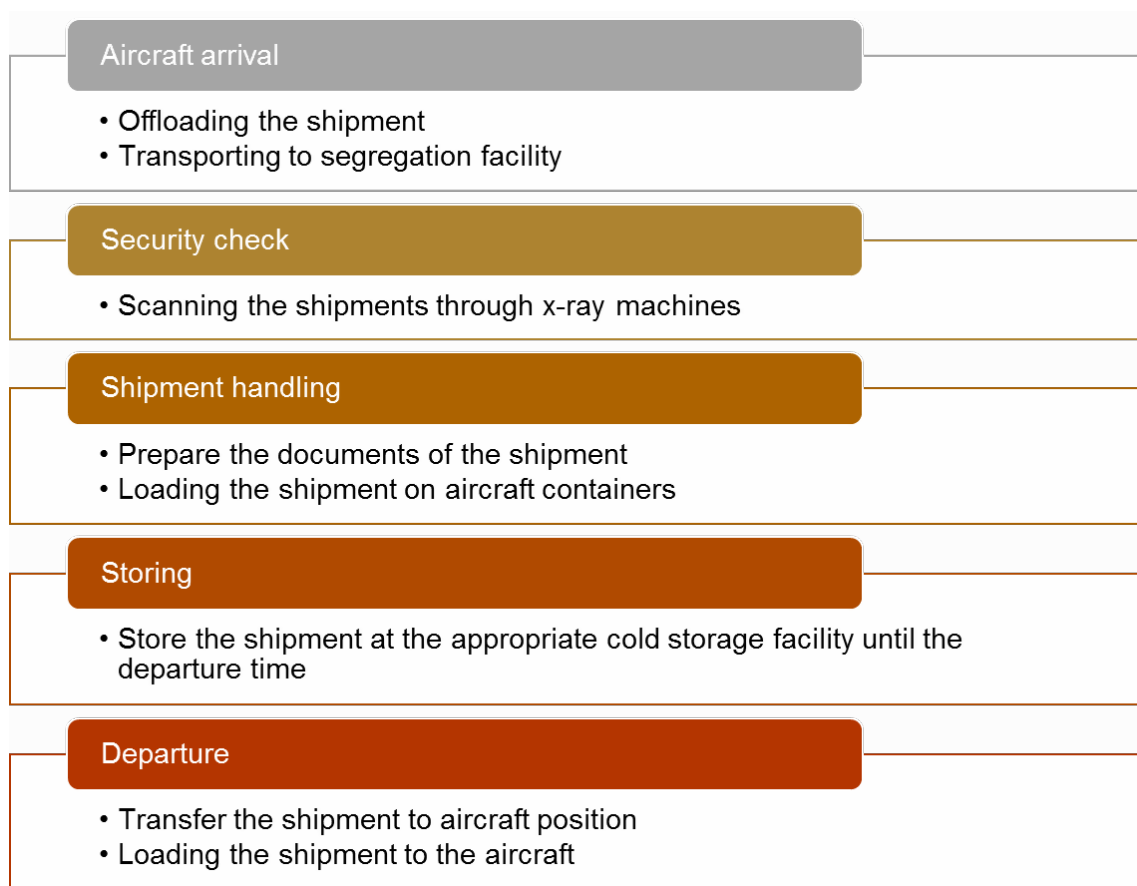


Figure 16 The flow of pharmaceutical shipment at the transit airport

Following the listing of the problems by the six sigma team, it became of importance to list the challenges encountered at each stage. The meeting chose the movement of the cargo at the origin airport as the model to explain to list the problems encountered at each of the stages. At cargo acceptance, the problems encountered include:

- Shippers drop their cargo for as long as 48 hours before the shipment's scheduled departure
- The airlines are not informed about the specific time that these shipments will be dropped
- The staff at the acceptance area are surprised by the arrival of shipments because they might arrive during peak hours
- There is no coordination between the shippers and the airport, and so and therefore, huge shipments may be received within two hours which is beyond the capacity to handle the shipment properly without excursions
- Sometimes there are longer hours minimal shipment, and then most the shipments are received within the peak hours

The problems mentioned above led to the realization that the biggest issue could be due to uncoordinated drop-off of shipments. The team went further ahead to list the challenges experienced at the weighing stage. These included:

- The huge number of shipments received within peak hours causes delays in checking the actual weight versus the booking and there is no cooling facility at this point
- There are only two weighing scales
- Space is limited and during peak hours, they could receive 10 fully loaded tracks with shipments which all have to be weighed
- Sometimes the scale gate is broken

It seemed that the surge of shipments during peak hours greatly impacted the weighing stage. The problem seemed to be further extended to the security check. The specific challenges listed by the six sigma team included:

- The security screening machines may not be sufficient to manage the flow of shipments during peak hours
- At the x-ray machine, sometimes there are four gates but only two operators
- Shortage of forklifts to carry the pallets and transport them to the storage facility
- The lack of efficiency of security operations

The problems identified at the customs-check include:

- The shipments to be cleared are more than what the customs can handle efficiently
- Shortage of workers
- Shortage of equipment
- Works on the priority of departure, because flights must not be delayed
- Even with the knowledge of shipments that need cold storage, the work must be completed before they are moved to cold storage, and the priority remains for shipments that depart in an hour

#### Classification of the challenges

Following the examination of the challenges listed at every stage of the process, the challenges impacting both shipment flow were categorized into the shortage of equipment, shortage of facilities, shortage of manpower, bottlenecks at peak hours and on the peak day. Similar challenges were grouped under these classifications as shown in the affinity diagram below.

Shortage of equipment	Shortage of facilities	Shortage of manpower	Bottlenecks during peak hours and on the peak day
<ul style="list-style-type: none"> <li>• Weighing scales</li> <li>• X-ray machines</li> <li>• Forklifts</li> <li>• Containers</li> <li>• Tugs</li> <li>• High loaders</li> </ul>	<ul style="list-style-type: none"> <li>• Acceptance area facility</li> <li>• Security check facility</li> <li>• Custom check facility</li> <li>• Preparation area facility</li> <li>• Cold storage facility</li> </ul>	<ul style="list-style-type: none"> <li>• Workers to offload the cargo</li> <li>• Forklift operators</li> <li>• Security and customs personnel</li> <li>• Ground handling employees</li> </ul>	<ul style="list-style-type: none"> <li>• Lack of communication and collaboration between shippers and airport cargo handlers</li> <li>• Unpredictable cargo flow due to lack of visibility of the flow of cargo arriving to the airport</li> <li>• Shippers allowed to drop cargo 48 hours prior the departure time</li> </ul>

Figure 17 Affinity diagram

#### Identifying the root cause of the problem

Following the grouping of the challenges, they were further explored to establish the relationships between them, as it pertains to which challenges cause what. The interrelation diagram was used to aid the identification of these relationships and the direction of causation (the arrow). These causations were established by the six sigma team following a critical view of the major classifications on the affinity diagram, and the determination of how the major concepts correlate. This is shown in the diagram below.

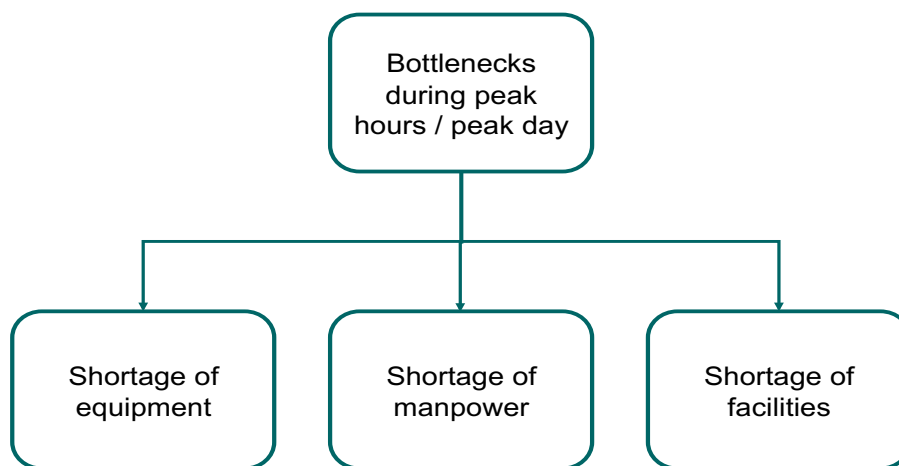


Figure 18 The root cause analysis diagram

The findings above show that the bottlenecks experienced during the peak hours and on the peak day are the root cause of all the other challenges cited as leading to temperature excursion at the airport. Considered in terms of the 20/80 rule, bottlenecks during peak hours and on the peak day (25% of the problem) leads to the remaining (75%) of the problem.

Exploring the underlying reason for shipment dropping at peak hours and on the peak day

Further exploration of the root problem identified led to the establishment of other findings. First, the researcher found that shippers are permitted to drop their cargo 48 hours before the departure time. Based on further observation of the cargo arrival time throughout the week, the researcher found that most shippers had the same pattern of workflow:

- Most of their shipments are dropped between 11 am and 2 pm while the morning shift at the airport commences at 7:30 am. This means that the airport facilities, manpower, and equipment remain underutilized for three and a half hours. This is the cause of the bottlenecks at every peak hour.
- Most of the shippers consolidate their shipments and drop them every two days and this may include different types of shipments (temperature-sensitive or not). Once the shipment arrives at the cargo terminal airport and considering the huge number of shipments in wait, the ground handler begins handling shipments based on their departure time, as opposed to the risk of temperature excursions.

- Most shippers drop off the shipments meant for Friday and Saturday on Thursday, as these two days are the official weekend in the third world country in the Middle East. This means that the airport facilities and manpower remain underutilized on Friday and Saturday, causing another bottleneck on Sunday when new shipments are dropped off.

This finding led to a shift in the consideration of shortage of equipment and manpower as the problem, to the realization that the problem was based on the unpredictable cargo drop-off patterns. Thus, the blame shifted from the airport and possible insufficiencies to shippers and their cargo consolidation and drop off. The rectification of this challenge became the theme of the improvement phase of the six sigma process.

#### 5.2.4 Improvement

Based on the identification of the unpredictable flow of the pharmaceutical cargo as the solution to the temperature excursion problem, the six sigma team identified booking as the most viable solution. This involved meeting and organizing the shippers to drop off their shipment by bookings of timing to allow for the coordination and planning of resources and capabilities. Thus, the first improvement proposed involved:

*Improvement 1. Organizing shippers to drop off their cargo by bookings*

The shippers union (in meeting 5) identified challenges they would experience if the solution proposed is implemented. These challenges included:

- If not permitted to drop their cargo 48 hours before departure, this will lead to increased costs for the shippers
- They have limited warehouses and therefore prefer to consolidate their shipments and ship together to the airport
- Transporting their shipment six hours before departure will mean more costs due to an increased number of trips to the airport
- Since Friday and Saturday are holidays, they would prefer to transport all their cargo on Thursday as is the norm

These findings indicated the clear resistance of shippers to the proposed solution. It, therefore, became necessary to engage pharmaceutical companies who have a higher purchasing power to compel shippers to comply. The meeting (6) brought together logistics managers from different pharmaceutical companies. The researcher explained the challenges at the air-

port and indicated the problems of temperature excursion originated from uncoordinated shippers that transport all their cargo during peak hours, and their unwillingness to be coordinated. This meeting led to the second proposed improvement:

*Improvement II. Having pharmaceutical companies release their shipments less than 24 hours to departure as a means of coordinating shippers and reducing congestion and ultimately temperature excursion at the airport*

However, they also introduced other challenges and concerns including:

- There is no visibility or coordination between pharmaceutical companies, ground handlers, and shippers and therefore after they provide their shipments, they do not know what happens
- Each shipper has a sole process and does not care about any other stakeholder, as long as they achieve their efficiency and profitability

Having made a significant stride in the improvement process with the pharmaceutical companies, the researcher found it fit to engage security and customs departments as core stakeholders at the airport through a meeting with both departments (meeting 7). After explaining the problem and the solution arrived at, the researcher noted they worked under the pressure of the airlines, and were not aware of the issue of temperature excursion and therefore concurred with the problem there being no visibility of the processes at the airport. They also noted that the visibility would enable them to organize their manpower and thus enhance their efficiency in service delivery.

As the first step to coordination and encouraging visibility of the processes (incoming shipments), the next improvement developed involved:

*Improvement III. Establishing a booking system where shippers send emails notifying the airport of their time of shipment drop-off.*

Having the support of the pharmaceutical companies, the researcher held another meeting with shippers in a bid to introduce the booking system. This was a promising solution for the improvement phase since, combined with the proposed improvement of releasing shipments only 24 hours to departure, it would have led to increased efficiency at the airport, thus significantly reducing temperature excursions. Although they agreed to be sending the emails, there was no commitment as the number of emails dwindled day by day until they were no longer sending any email. It was therefore evident that the attempts at improving the system by organizing the cargo drop-off by shippers had failed.

### 5.3 Customer centricity in solution design

The failure of the six sigma process is in line with several studies that consider the process as being inside out and therefore lacking customer-centricity (Antony et al. 2019). This is reflected in the attempt of the six sigma team as explained above to impose three thought of improvements to the shippers. The solutions imposed did not take into account the challenges expressed by shippers and particularly, the impact of the proposed solutions to their profitability and efficiency. Having identified this challenge, the researcher set out to outline the problem of temperature excursion from the perspective of the stakeholders through a shipment journey map and to find a suitable solution that empathizes with the stakeholders and is convenient, effortless, and easy from the customer's point of view. The shipment journey map is shown in the figure below.





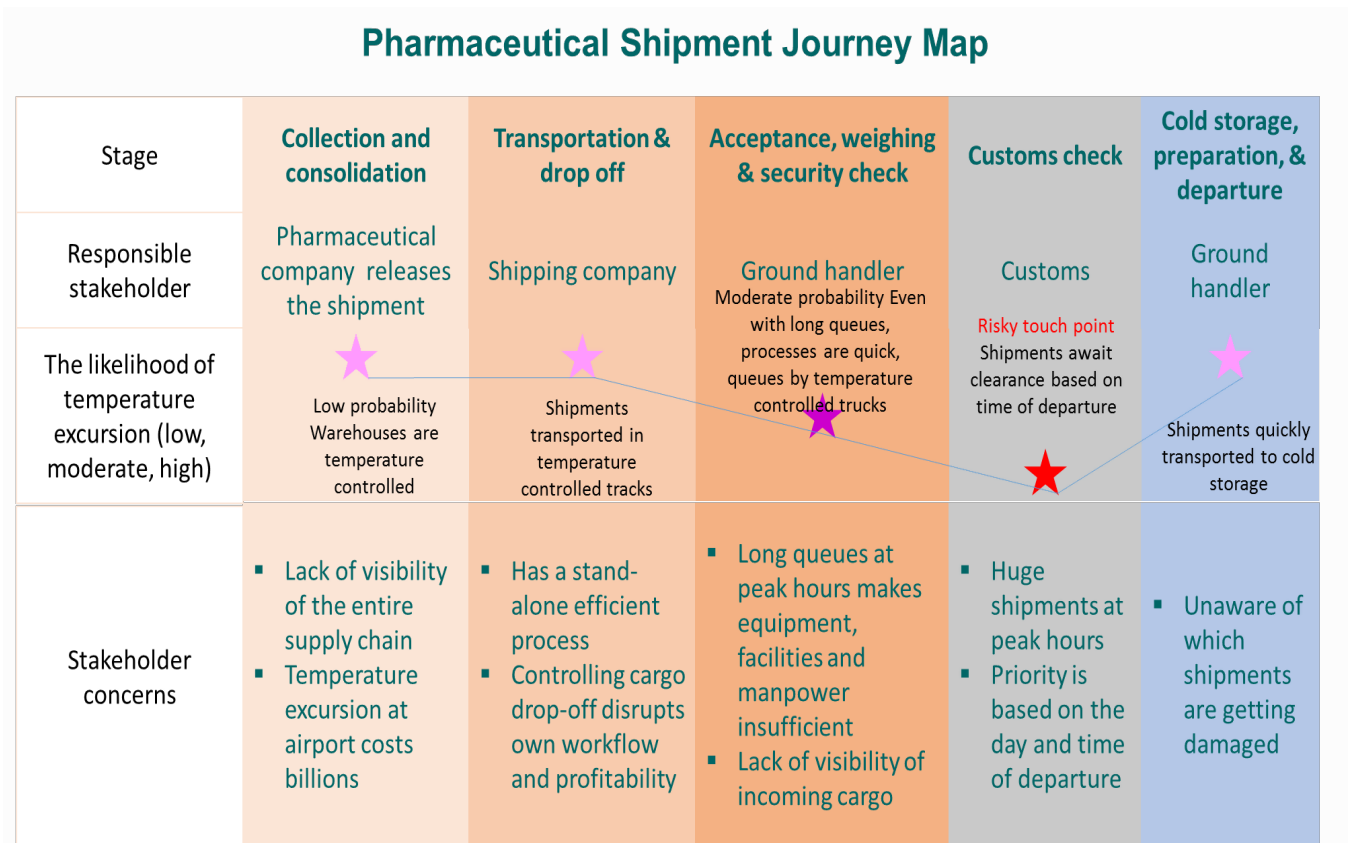


Figure 19 The shipment journey map

Following the process of identifying each stakeholder, their concerns, the risky touchpoints and the problems leading to temperature excursion, it became of importance to redefine the problem based on this new understanding. It was established that the problem is not due to shippers dropping their cargo at peak hours or on the peak day, but the lack of collaboration and coordination between the pharmaceutical supply chain stakeholders. This lack of coordination and collaboration leads to stress on facilities during the peak hours, and the problem is passed on from one stage of the cargo journey to the next.

While the queues at the acceptance are made by the cargo trucks, considerable time is spent during the processes of weighing and security checks because of the tons of different shipments transported in one truck, each which must be weighed. However, the process is quicker for each shipment, thereby causing the risk of excursion to be moderate. Moreover, the weighing is done sequentially based on come-first, serve-first. The biggest challenge is at the customs where the priority changes from the shipment queue by the arrival to the time of departure. By the time the cargo is picked by the ground handlers and shipped to the cold room, in some cases, excursions or even damages have occurred.

The next challenge is the lack of visibility of the entire supply chain. All the stakeholders are not aware of what is happening, and therefore, their focus is the maximization of their efficiencies. This lack of visibility makes the shippers appear like the villain, uncooperative and only concerned about their profitability. Having a clear view of the processes taking place at the airport, and especially at the risky touchpoints would enable them to re-organize their processes and shipment drop-offs in a way that is still profitable and convenient. Further, the visibility for customs and ground handlers would ensure better communication between them and incoming shipments and a change in the prioritization.

These new insights led to the establishment of a software-based alarm system to enhance visibility, collaboration and communication between the stakeholders as the most viable and acceptable solution. This alarm system would involve sending messages, and if after five minutes, no action is taken, the process owner receives a pre-recorded system call. The information regarding the process owners for each shipment will be pre-entered and updated from time to time. Moreover, the system will determine alarms through a combination of IoT and AI with the basic hardware being an online data logger. The system will identify process owners through the use of GPS and geofence technology. This solution is summarized as follows:

*Solution 1. To develop a fully integrated supply chain solution with temperature readings provided through an online data logger*

While this solution was considered to be based on an outside-in process and therefore acceptable, the researcher sought the validation of each stakeholder and the determination of whether there were any impediments for purposes of empathizing with the stakeholders and re-designing the solution to capture their needs and concerns.

#### 5.4 The findings of the co-creation process

The process of validation, empathy, and redesign took place through interviews with the various stakeholders. In each interview, the researcher presented the solution in its latest redesigned form. Following the first interview (1) with a regional logistics manager (the customer), the following insights were gained:

- Online data loggers exist and are in the market but lack value because the notifications are received by the pharmaceutical company which cannot correct the temperature excursion problem
- The online data logger solution derives its value from being connected to the airport
- The current data loggers cost 20 – 30USD
- Pharmaceutical companies are price sensitive, and are not willing to spend more than their current expenditure range for a data logger that is connected to the airport

Following a brainstorming session, and the consideration of the insights above, the researcher came up with a solution:

*Solution 2. To develop an online data logger that is integrated with the airport, and which is rented at the same price as the current data loggers*

With this new solution, the researcher interviewed the same respondent (interview 2) to determine the viability of the new solution. The respondent generated new challenges:

- Pharmaceutical companies have used data loggers in the past, and it was expensive to collect all data loggers from different regions and return
- Pharmaceutical companies prefer disposable data loggers because they are cheaper, and they do not have to worry about data loggers that are stolen or broken

The researcher through another brainstorming session determined that moving to disposable data loggers would counter some of the perceived benefits of the new product (environmental friendliness). This led to the establishment of another solution:

*Solution 3. To develop an online data logger that is integrated with the airport and which is rented at the same price as the current data loggers and collected from different destinations and returned by a courier service provider*

To check the viability of the solution, the researcher interviewed the head of innovation of a worldwide courier company (interview 3). The interviewee agreed on the possibility of collecting and returning all the data loggers at a reasonable cost that supports the desired profit margin and thereby validating the solution. The researcher then returned to cross-validate the solution with the regional head of logistics of a pharmaceutical company in previous interviews (interview 4). The interviewee agreed that the solution makes sense.

The researcher determined that there could be a challenge with the customs department as it pertains to fees that would be applied each time the data loggers are shipped back to Jordan. This led to the need to interview a customs official at a third world airport in the Middle East (interview 5). Following the explanation of the proposed solution, the researcher got a full assurance that the data loggers can be serialized to identify which is new and which is being returned to prevent the payment of extra fees. This led to the next solution:

*Solution 4. To develop a serialized online data logger that is integrated with the airport and which is rented at the same price as the current data loggers and collected from different destinations and returned by a courier service provider*

The success gained in the solutions developed led to an interview with a shipper (6). Following the explanation of the solution, the following concerns were raised concerning the alarming system:

- The driver is not permitted to use his phone while driving
- It is illegal to send him messages
- Even though the shipping company usually calls the driver, one cannot design a solution that violates the law, and therefore, the shipping company will not receive the messages or alarms, except for shipments within the warehouse.

The researcher discussed these challenges with a team of engineers and following a brainstorming session, established a suitable solution:

*Solution 5. To develop a serialized online data logger that is integrated with the airport and which is rented at the same price as the current data loggers and collected from different destinations and returned by a courier service provider. The solution uses Bluetooth technology, and during the cargo transportation and drop off, the alarm system will produce a beeping sound inside the driver's compartment as a warning signal in case of temperature excursions.*

During cross-validation with the shipment company, the stakeholder highly expressed interest in the solution. The researcher then sought an audience with the personnel in charge of

claims at an airline in Jordan (interview 7). The interviewee expressed the following concerns regarding the solution:

- The control station receives hundreds of emails every minute and therefore, there is a high chance they will not read emails in real-time
- They might be busy with priority messages and therefore, there is a high chance the messages will not be read until when the shipment is damaged
- Recorded calls are fine, but are not all that effective

Empathizing with this stakeholder, the researcher brainstormed and came up with a solution for the airline:

*Solution 6. To develop a serialized online data logger that is integrated with the airport and which is rented at the same price as the current data loggers and collected from different destinations and returned by a courier service provider. The solution uses Bluetooth technology, and during the cargo transportation and drop off, the alarm system will produce a beeping sound inside the driver's compartment as a warning signal in case of temperature excursion and visual and alarming system shown in the control station of the airport.*

The visual alarming system would be implemented as follows:

- The screen is set inside the control station and for any shipment being dropped off at the airport, the information regarding the shipment and temperature is shown on the screen
- The dashboard shows how long each shipment takes at each point
- The shipments and insights about them are shown in a colorful manner with green indicating the shipment is within the required temperature, and red indicating an excursion
- The screen produces an alarm to attract attention in case something is wrong (an excursion occurs)

The interviewee expressed satisfaction with the solution but indicated they would not accept to receive notifications from the serialized online data logger because of the high risk involved, and because an acknowledgment of claims would hold them accountable and liable to make compensations in case of product damages. The same statement was echoed by another interviewee – a lawyer of an airline (interview 8).

In a bid to determine if the refusal was widespread, the researcher interviewed the head of cargo of an airport in the Middle East (interview 9). The respondent accepted the solution

on condition that it is secured, and access is not granted to the insurance company. The led to a change of the solution to:

*Solution 7. To develop a serialized online data logger that is integrated with the airport and which is rented at the same price as the current data loggers and collected from different destinations and returned by a courier service provider, with secured access control. The solution uses Bluetooth technology, and during the cargo transportation and drop off, the alarm system will produce a beeping sound inside the driver's compartment as a warning signal in case of temperature excursion and visual and alarming system shown in the control station of the airport.*

In attempting to further argue with the respondent to push the solution without having to secure the data, the respondent gave additional insights:

- Airlines are likely not to buy-in to the solution
- An office may not be granted within the airport
- Establishing an office outside the airport may work, but the simple solution is to build it for the airline and deny access to the pharmaceutical company as this would help them a) reduce temperature excursions and b) protect them against litigation.

Based on these deliberations, the researcher found it more sensible to keep the solution secured. Therefore, the researcher sought to validate the solution with a manager at a ground handling company in a first-world airport (interview 10). The researcher sought their opinion regarding the solution if access would be denied to the insurance service provider. The respondent indicated they were ready to collaborate, and should be called upon when the solution is ready. The researcher established through desk research that there are five major ground handling companies that serve 80% of airlines in different countries throughout the world. Therefore, their buy-in would push the product into many countries.

The last validation was conducted with the customer, due to the changes that had taken place during the co-creation process. The researcher argued that the two stakeholders that would be the most important are pharmaceutical companies and insurance companies. For the insurance companies, in the previous solutions, it was determined that the solution would only be acceptable to the stakeholders at the airline if the insurance company does not have access to it. With this limitation, it became of importance to fully rely on the acceptance of the solution by the pharmaceutical companies. The researcher, therefore, conducted the last interview (11) seeking their buy-in and validation of the solution. The respondent, a regional logistics manager, indicated a positive response but with a request for an additional feature: the ability to enable the automation of information flow. In explaining the challenge faced with the current system, the interviewee listed the process as entailing:

1. The shipment arrives at the customer's warehouse
2. The quality assurance personnel collects the data logger from the shipment, write its serial number, ballet number, and take the temperature reading at the time of the collection and turns off the data logger
3. The data logger and datasheet are handed over to the quality assurance manager, who inserts the logger into the computer and prints its reading, attaches the printout with the shipment papers and scans all the documents, and sends to the in-charge of temperature
4. If there is no excursion, the shipment is cleared for temperature release, information sent by email. If there is an excursion, the documents are sent back to quality assurance which investigates the excursion versus the stability study of the shipment. A sample may be required for investigation, which is sent through courier services, with a data logger attached
5. Temperature release is then issued, sent to the customer by email, which the customer prints and attaches with the documents related to the shipment and sends to the food and drug administration for approval
6. The shipment is released to the market, while the information is archived for five years.

If an excursion occurs, this process may take up to 7 days from the shelf life of the products. The information flow process is summarized in the figure below. This would be eased with an online validation system since the online data logger system was not only connected to the airport but also had real-time data and built-in AI. After brainstorming, the researcher came up with the solution as encompassing the use of business intelligence to provide real-time data to reduce the time taken to investigate whether temperature excursion occurred and whether it exceeds the stability range. The final solution therefore became:

*Solution 8. To develop a serialized online data logger that is integrated with the airport and which is rented at the same price as the current data loggers and collected from different destinations and returned by a courier service provider, with secured access control. The solution uses Bluetooth technology, and during the cargo transportation and drop off, the alarm system will produce a beeping sound inside the driver's compartment as a warning signal in case of temperature excursion and visual and alarming system shown in the control station of the airport. The solution also provides an automated temperature release through business intelligence.*



The series of transformation in the solution during co-creation, empathy and solution redesign are shown in the table below.

Table 4 Changes in the solution from the initial solution

Solution	Changes	Insights by interview	Validated by interview
1	The initial solution –no change		
2	Integration with airport Rented at the same cost as disposable data loggers	1	
3	Data loggers collected from different destinations and returned by a courier company	2	3, 4
4	Serialization of online data loggers	5	
5	Bluetooth technology and beeping in the driver's compartment	6	6
6	A visual and alarming system inside the airport control station	7	7
7	Secure data, access control	9	9, 10
8	Automated temperature release through business intelligence	11	

## 5.5 The viability of the solution for a new venture creation

Following a series of co-creation and the validation of the solution, the researcher embarked on establishing the viability of the solution for a new venture. The viability was established based on a) stakeholder buy-in, b) approval by IATA, c) the unique value proposition, and d) the attractiveness of the idea for funding. These were achieved through desk research and the creation of a prototype and presenting to potential investors.

### 5.5.1 Buy-in by core stakeholders

To determine the stakeholders whose buy-in would be extremely necessary, the researcher conducted stakeholder analysis. This included the examination of the stakeholders and their relationship with one another. The stakeholders were found to include:

- Airfreight carrier –it is the ultimate carrier of the shipment, has lower power than the customer who is the shipper
- Ground handler – ultimately responsible for the excursions occurring at the airport. Is answerable to the airline
- Security – answerable to the airline and the ground handler, responsible for excursions
- Customs – coordinate with the airline and the ground handler to ensure efficient workflow, has lower power than the airline
- Shipper – responsible for ensuring shipments arrive in time. Passes the liability for temperature excursion to the insurance company, but has a lower purchasing power than the pharmaceutical company
- Pharmaceutical company – the ultimate customer, the purchaser or lessee of the data logger. Has a higher purchasing power, but has no control over the happenings at the airport
- Insurance company – has a high power as the one who compensates, can set rules for the shipper to reduce risk

Following the co-creation process, it was established that the solution would be acceptable to all the stakeholders, if the insurance company which is a third party, is denied access to the system. Therefore, a secure system would be highly acceptable and appreciated by the stakeholders. However, the implementation of the system requires the acceptance of only two critical stakeholders: the lessee of the online data logger (the pharmaceutical company), and the owner of the software system (a critical stakeholder at the airport). There are mainly two critical stakeholders: the ground handler who is responsible for all the ground operations, and the airline that employs the ground handler. Since there was buy-in from both, the researcher settled on engaging the ground handler solely because very few ground handlers (five) control the largest share in all markets. The stakeholder map is presented in the figure below.

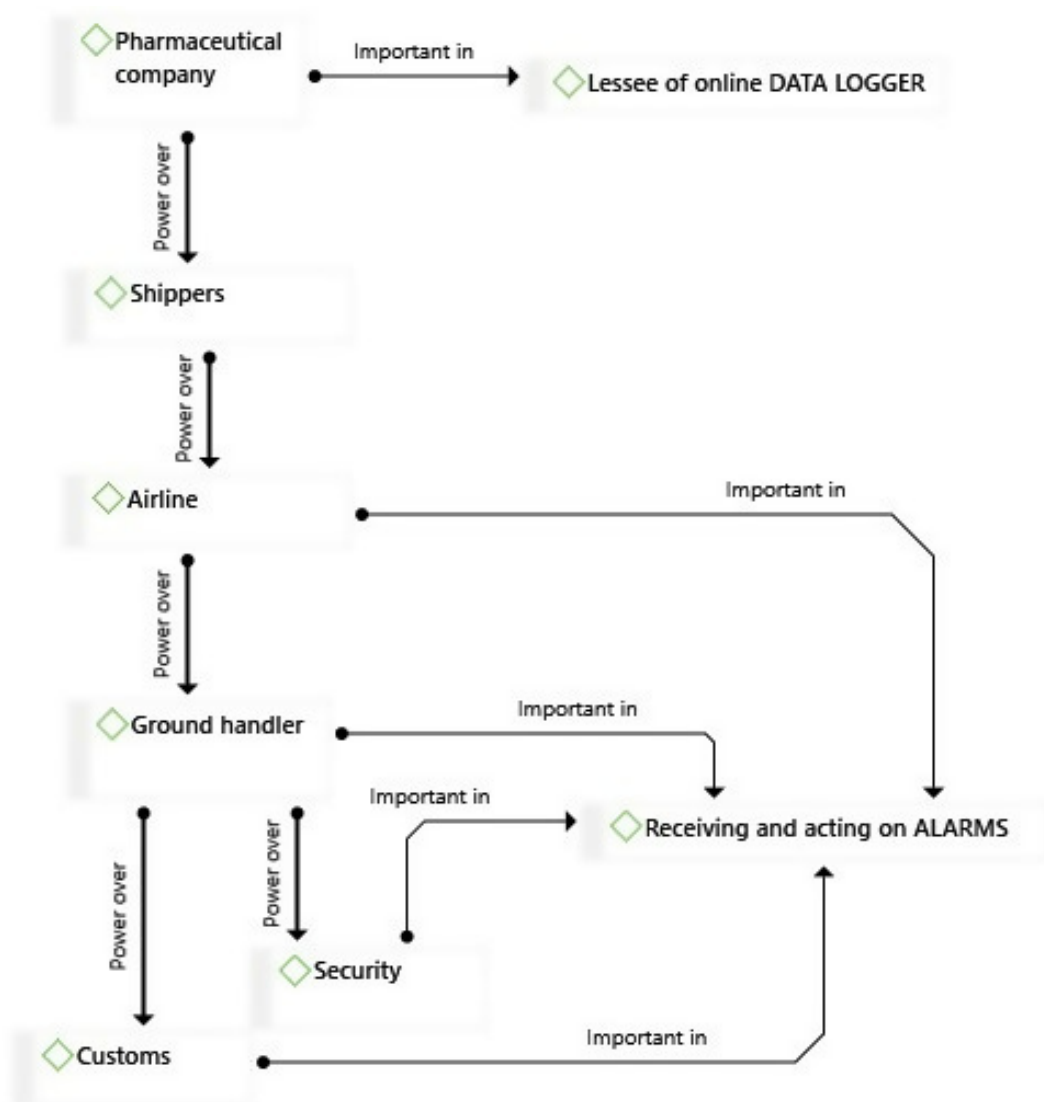


Figure 20 The stakeholder map<sup>2</sup>

### 5.5.2 Approval by IATA

Since the serialized online temperature data logger would be embedded in shipments on airfreight, it became of importance to examine any design barriers from IATA's regulations and policies. Following desk research, the researcher found that IATA has special hardware requirements for a device to be certified to be in an aircraft. These include: a) the battery used in the device should not be made of lithium which is considered an explosive and therefore dangerous to aircrafts, b) any device that transmits data not be permitted into an

<sup>2</sup> The insurance company has been omitted from the list owing to the need to secure the system and protect the airlines and the ground handlers from possible litigation

aircraft, and c) there must be two alternative solutions built into the device so that if one fails, the alternative can be used to stop the data transmission.

These requirements touch on the very core of the design of the current solution. However, following more desk research and brainstorming, the researcher established solutions. These include:

- The use of dry cells instead of lithium battery
- Method 1 to stop data transmission: have an accelerometer that reads the speed of the aircraft and switches the device to sleep for speeds above 100km/hr., since this is the minimum take-off speed.
- Method 2 to stop data transmission: have pressure sensors that switch the device to sleep mode when the atmospheric pressure in the aircraft changes.
- Have sufficient memory in the sensors so that readings taken during sleep mode can be pushed into the cloud once the serialized online data logger is switched to active mode on the ground

### 5.5.3 Unique value proposition

The product's unique value proposition was determined based on a comparison with its competitors. These competitors include hardware providers (companies that manufacture data loggers) and software providers (companies that deal in IoT and which offer data digitization for the temperature monitoring industry). Based on intense desk research, 39 data logger manufacturers were identified and a few software companies. These companies were found to offer inferior products compared to our solution because:

- The competitors do not fully understand the problem or the customer and therefore the solutions they offer are only superficial
- None of these competitors have a system that is connected to the airport
- The existing data loggers are disposable and therefore pose an environmental concern
- None of the manufacturers of the data loggers have a rental solution
- None of the competitors offers a solution that automates the process of temperature release

Aside from including all these, the proposed solution entails both hardware and software and:

- Complies with IATA's requirements
- Has memory

- Has GPS and geo-fence feature for ease of access of the shipment route
- Has an alarm system that works differently for the key stakeholders
- Solves the main problem of temperature excursions while taking into account, the adoption and use challenges

#### 5.5.4 The attractiveness of the idea for funding

As opposed to the traditional validation techniques such as the use of Porter's five forces, this study chose a more dynamic and practical way to validate the solution for a new business venture. The researcher developed a prototype and presented it to investors at the national, regional and international levels. The first, second, third and fourth validations are presented below.

- First validation: This involved a competition at the national level, organized by IoT Hacker Thorne. The jury included many investors and the researcher took the first position.
- Second validation: The researcher participated in the MIT startup for the Arab region. Following the presentation of the prototype of the solution, the researcher took second place. Moreover, 10 investors were ready to invest in the idea.
- Third validation: The researcher participated in global competition and presented the idea's prototype. The competition was held in Turkey and the researcher emerged the winner. The researcher also received 100 cards of investors willing to invest in the idea.
- Final validation: The researcher applied to a business accelerator in Bahrain and the idea received initial funding of US\$55,000.

## 6 CONCLUSIONS AND RECOMMENDATIONS

This study aimed to provide a practical, workable, and commercial solution for temperature excursions through the use of IoT to enable the full integration of the supply chain for high visibility and control across the end-to-end supply chain. The researcher adopted a pragmatic view to knowledge acquisition, with the use of a case study design to guide the methodology. Both primary and secondary qualitative data were collected using methods including desk research and document analysis for secondary data acquisition, and observation, meetings and individual semi-structured interviews for primary data collection. The data were analyzed and presented sequentially through the stages of confirming (frequency analysis of temperature logger data); exploring (the use of flow charts, affinity and interrelation diagrams to identify the problem and propose the initial solution); empathizing and designing (the use of customer journey map to fully understand the customer and design an acceptable solution); and co-create and validate which involved the manual analysis of interview responses, redesign of the solution in a manner that empathizes with the stakeholder, and validating the solution with the same stakeholder.

### 6.1 Summary of the findings

In fulfilling the aim, the researcher developed four sub-questions. In the first place, the researcher sought to explore the location of most temperature excursions. The findings from the review of temperature data logs exposed the airports (origin, transit, and destination) as the dominant areas where most of the temperature excursions take place, with the findings revealing that no temperature excursion took place during ground transportation. The findings of a stakeholder meeting also validated this finding, as the majority of the pharmaceutical companies provided evidence of excursions that had occurred at the airport.

The researcher also sought to understand the cause of temperature excursions in airports. Using the six sigma methodology coupled with observation, the researcher established that the root cause of excursions in the airports is the lack of coordination between the stakeholders, which leads to communication failures which in turn, results in a drop off of most shipments during peak hours. These trigger other issues such as perceived lack of sufficient facilities perceived insufficient human resource capacity, and a strong priority for shipments departing in an hour, rather than shipments indeed of cold storage to reduce the possibility of temperature excursions. An attempt to improve the processes failed, leading to the adoption of service design. The development of a shipment journey map and a deeper understanding of the customer further revealed that most temperature excursions occurred at the

airport because of the uncoordinated and fragmented supply chain, made worse by the lack of visibility of shipments from end to end. This led to an initial customer-centric solution.

The third question concerned how IoT can be leveraged to enhanced visibility and reduce temperature excursion. Following an intense journey of co-creation and validation, the final solution became the use of serialized online data loggers, coupled with the integration of the data loggers with the airports using a software system was. The solution promises to offer the pharmaceutical companies with the visibility of the happenings at the airports. It also promises to zoom the processes at the airport for stakeholders such as ground handlers, security and customs in a manner that would help in enabling them to organize their human resources and improve efficiency. It is the improvement of the efficiency of processes at the airport that will mitigate the challenge of temperature excursion, especially as it pertains to controlling for the cargo drop-off time and identifying and prioritizing shipments that experiencing temperature excursion at any point of the supply chain.

Lastly, the researcher was interested in understanding the viability of the solution for commercialization as the intention of the thesis was to use the findings as the base research to start a new venture. The researcher established that the solution is viable based on the buy-in of the critical stakeholders which was pegged on the following conditions: a) the access to the data on the cloud is secured and controlled, with accessibility denied to insurance companies; b) the cost of the serialized online data loggers be the same as the cost of the data loggers in the market; c) in renting data loggers, a courier service company be deployed to facilitate collection of the data loggers in destination countries and their return; and d) the system will be integrated with the airport to help enhance uncover inefficiencies and enhance systems that currently lead to excursions. Aside from the buy-in of the critical stakeholders, the solution was also established to provide unique and unmatched value to the customer, it meets the requirements of IATA. Lastly, it was largely accepted and applauded in different startup competitions, winning first place in two competitions, and the second place in one competition. The idea received funding totaling to US\$110,000.

## 6.2 Limitations and recommendations for future research

Due to the rigorous methodology employed in this study, the limitations only pertain to the scope of research and the unavoidable methodological limitations. First, as it pertains to the methodological limitations, these relate to the use of case study and qualitative techniques. While these guarantee the collection of rich data that are useful to the process of exploration, the key distinction of case study design is the emphasis on contextualization. This limits the transferability of findings. However, studies indicate that case studies are trans-

ferrable in similar contexts. The researcher identified that this case is no different from airports in other third world countries. Thus, the findings may be transferred within such contexts, and to other contexts with a lot of caution. Having pioneered the research into the causes of excursions within airports, future research may employ purely quantitative techniques that can be validly generalized.

Moreover, the solution in this research was accepted by the airlines and airports based on the condition that the data will be secured and thus inaccessible to insurance companies that are a third party. The airports and airlines in first-world countries may be open to the idea without having to secure the data, and especially those with improved processes (evidenced through CEIV certification) and which are confident enough not to fear possible litigations based on temperature excursions. Although the researcher plans to pilot the solution with airlines in such countries, future research may consider examining the correlation between the openness to the transparency of systems to thirds parties, and liability, and CEIV certification.



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