A toolkit to aid in the education and training of supply chain members for the efficient distribution of the COVID-19 vaccine: A South African case

by

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DECLARATION

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ABSTRACT

COVID-19 is an ongoing pandemic and South Africa is one of the many countries affected by it. Although the country has vaccinated citizens in the past, it now faces the challenge of vaccinating citizens against COVID-19, taking into consideration the vaccine's cold chain requirements and ensuring vaccines reach vaccination sites safely and uncompromised. The functionality and understanding of the COVID-19 vaccine supply chain is relatively new, because of its recent emergence, and the aim and purpose of this study is to allow distribution companies to have a better understanding of the requirements, education, training, and factors that need be taken into consideration when transporting, handling, or storing a COVID-19 vaccine.

This research study has five main objectives: firstly, to understand the functionality and components of a vaccine supply chain and the vaccine industry and secondly, identifying the COVID-19 vaccine supply chain stakeholders. Thirdly, to comprehend and clarify cold chain protocols for COVID-19 vaccines procured by the South African Government and the international best practices that can be implemented and applied to ensure vaccine safety and increase cold chain efficacy. Fourth, to identify and clarify the skill and training requirements of individuals at different employment levels and lastly using the inputs of these objectives in creating an educational toolkit that can be used by supply chain members regarding the effective distribution of COVID-19 vaccines in South Africa.

The study was exploratory and cross-sectional in nature and made use of both primary and secondary data. Research questions were answered and research objectives were met through information and data gathered from either a literature review, a stakeholder analysis or an interview process. The information from these sources served as an input to the educational toolkit, which is the outcome of the study. There are four tools in the educational toolkit namely, the COVID-19 vaccine supply chain stakeholders, the COVID-19 vaccine categorization and cold chain equipment, the COVID-19 vaccine handling, storage and delivery protocols and the COVID-19 vaccine supply chain required skills, training and education. These tools can be used by supply chain members to educate employees and serve as a basis for determining vaccine supply chain requirements. Although the toolkit should not be used as the only source of information, regarding the subject, its output can add value to the safe and effective distribution of COVID-19 vaccines in South Africa.

Keywords: Cold chain; COVID-19; COVID-19 vaccines; stakeholder analysis; vaccine supply chain.

OPSOMMING

COVID-19 is ’n voortdurende pandemie en Suid-Afrika is een van die vele lande wat daardeur geraak word. Alhoewel die land al in die verlede burgers ingeënt het, staan dit nou voor die uitdaging om burgers teen COVID-19 in te ent, met inagneming van die entstof se kouekettingvereistes en om te verseker dat entstowwe inentingsplekke veilig en sonder kompromie bereik. Die funksionaliteit en verstaan rondom die COVID-19-entstofvoorsieningsketting is relatief nuut, vanweë die onlangse verskyning daarvan, en die doel van hierdie studie is om verspreidingsmaatskappye in staat te stel om 'n beter begrip van die vereistes, opvoeding, opleiding en faktore te hê wat in ag geneem moet word wanneer 'n COVID-19-entstof vervoer, hanteer of geberg word.

Hierdie navorsingstudie het vyf hoofdoelwitte: eerstens om die funksionaliteit en komponente van 'n entstofvoorsieningsketting en die entstofbedryf te verstaan en tweedens om die COVID-19-entstofvoorsieningsketting-belanghebbendes te identifiseer. Derdens, om kouekettingprotokolle vir COVID-19-entstowwe wat deur die Suid-Afrikaanse regering verkry is, te verstaan en die internasionale beste praktyke te identifiseer wat geïmplementeer en toegepas kan word om entstofveiligheid te verseker en kouekettingdoeltreffendheid te verhoog. Vierdens, om die vaardigheids- en opleidingsvereistes van individue op verskillende indiensnemingsvlakke te identifiseer en te verduidelik en laastens die gebruik van die insette van hierdie doelwitte in die skep van 'n opvoedkundige gereedskapstel wat deur voorsieningskettinglede gebruik kan word met betrekking tot die effektiewe verspreiding van COVID-19-entstowwe in Suid-Afrika .

Die studie was verkennend van aard en het van beide primêre en sekondêre data gebruik gemaak. Navorsingsvrae is beantwoord en navorsingsdoelwitte is bereik deur inligting en data wat deur óf 'n literatuuroorsig, 'n belanghebbende-analise of 'n onderhoudproses ingesamel is. Die inligting uit hierdie bronne het gedien as 'n inset tot die opvoedkundige gereedskapstel, wat die uitkoms van die studie is. Daar is vier instrumente in die opvoedkundige gereedskapstel, naamlik die COVID-19-entstofvoorsieningsketting-belanghebbendes, die COVID-19-entstofkategorisering en kouekettingtoerusting, die COVID-19-entstofhantering, berging en afleweringsprotokolle en die COVID-19-entstofvoorsieningsketting vaardighede, opleiding en opvoeding vereistes. Hierdie gereedskap kan deur voorsieningskettinglede gebruik word om werknemers op te voed en dien as 'n basis vir die bepaling van entstofvoorsieningskettingvereistes. Alhoewel die gereedskapstel nie as die enigste bron van inligting gebruik moet word oor die onderwerp nie, kan die uitset daarvan

waarde toevoeg tot die veilige en doeltreffende verspreiding van COVID-19-entstowwe in Suid-Afrika.

Kernwoorde: Koueketting; COVID-19; COVID-19-entstof; belanghebbende-analise; entstofvoorsieningsketting.

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CHAPTER 1 : INTRODUCTION

1.1. INTRODUCTION AND BACKGROUND

Coronavirus, better known as COVID-19, is a current pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and originated in Wuhan, a city in China. The earliest cases of COVID-19 were reported in December 2019 and by March 2020, the World Health Organization had declared the virus a pandemic (Coronavirus disease pandemic, 2021). The Oxford dictionary defines a pandemic as, "a disease prevalent over a whole country or the world." The response to this disease caused international, societal, and economical disruption and led to the biggest global recession since the Great Depression (Coronavirus disease pandemic, 2021). It has changed what people view as their normal and led to the postponement or cancelation of events, panic buying, the closing of educational institutions, food shortages or agricultural disruption, widespread financial problems, and daily hardships (Coronavirus disease pandemic, 2021).

As of October 2021, more than 244 million COVID-19 cases have been confirmed worldwide with more than 5 million deaths (Coronavirus disease pandemic, 2021). The continuing infection of large numbers of people and the mutation of the virus strands have set in motion hundreds of research studies to try to develop a cure or treatment. The intense study of the coronavirus has produced several vaccines. Although at least five of these vaccines are being manufactured and distributed across countries, experts are predicting that the end of this pandemic is not yet in sight and won't be for quite a while (Coronavirus disease pandemic, 2021). Most of these vaccines are in a trial period and results are being captured, evaluated, and interpreted to conclude which of the vaccines hold the highest success or prevention rate. For this study, the researcher focusses on the vaccine cold chain and supply chain and not the development of a vaccine, as a biological product.

South Africa is one of the many countries impacted by the global pandemic and has lost 89 179 citizens to the fight against COVID-19, as published on 3 November 2021, and has reported more than 2.9 million cases (COVID-19 South African Resource Portal, 2021). The country received its first batch of COVID-19 vaccine doses in January 2021 (COVID-19 South African Resource Portal, 2021). The 1 million doses were from the Oxford University-AstraZeneca vaccine and came from the Serum Institute of India (SII). The country continues to receive more vaccines, mostly Johnson & Johnson and Pfizer, and the South African government chose to vaccinate its estimated 1.25 million

healthcare workers first. These healthcare workers either work at one of the 600+ public and private hospitals or at one of the ±4 300 healthcare facilities/clinics across the country (COVID-19 South African Resource Portal, 2021).

As the rollout of COVID-19 vaccines commences, both the global and South African logistics industry is facing one of its greatest challenges ever. These vaccines need to be transported around the country with their safety and efficacy uncompromised. The successfulness and effectiveness of the vaccine supply chain will determine whether all South Africans, should they choose to get vaccinated, have access to the vaccine at the right time and at the right place. Currently, the vaccine cold chain and all understanding, education and training around the transport, handling and storage thereof face many uncertainties and challenges. The newness and importance of the coronavirus vaccine cold chain makes it a fascinating and relevant field of study.

1.2. MOTIVATION FOR THE STUDY

According to Statistics South Africa (2020), the South African population consists of ±59.62 million people that are stretched out over about 1.22 million km^2. The reality of the country's current state of disaster and the promises made by President Cyril Ramaphosa means that approximately 40 million people, should they choose to get vaccinated, in all nine provinces will need to ultimately have access to a COVID-19 vaccine (COVID-19 South African Resource Portal, 2021).

The different vaccines for the COVID-19 have both cold chain and extreme cold chain requirements and their efficacy can be influenced by many factors along the supply chain (Vaccine cold chain Q&A, 2020). Early research shows that most COVID-19 vaccines will need to be kept at extremely cold temperatures ranging from -75°C to -20°C (Vaccine cold chain Q&A, 2020). Not only is the management of these extreme cold chains a challenge, but the lack of infrastructure in rural areas across South Africa propose significant challenges for transportation, handling and storage of the vaccine. The country's unreliable power grid will be one of the challenges that the vaccine cold chain faces, seeing that refrigerators and freezers used for cooling require a lot of continuous power/electricity (Immunization supply chain and logistics, 2020). If cold chain requirements are not met, spoilage of vaccines will occur, which means both time and money will be wasted, and lives might be lost. Tracking and tracing who has been vaccinated will contribute to the complexity of the supply chain as well as the process of determining who needs to be vaccinated first.

Companies transporting the vaccine will need to cover thousands of kilometres and reach millions of people to successfully deliver vaccines to assigned hospitals, clinics, and healthcare facilities. People, more specifically South Africans, including citizens (±59 million) and migrants, refugees, and asylum seekers (±4.2 million) are the intended recipients of the COVID-19 vaccine (Mavhinga, 2021). Their lives will be impacted if something during the vaccine lifecycle is left to chance. For this reason, research was done to understand the vaccine supply chain and information analysed and gathered was used to develop a toolkit explained in Section 1.4. It is of utmost importance to understand the protocols that need to be followed and to have relevant information available to train and educate all personnel involved in the lifecycle of the vaccine, for the vaccine to have the coveted impact.

Due to its recent emergence, the COVID-19 vaccine cold chain and all understanding around it, has not been researched fully within South Africa. This research study can have an impact on the effective distribution of the COVID-19 vaccine, highlighting distribution strengths and weaknesses and aid or educate companies when transporting, handling, or storing a similar product. This developing toolkit and basic understanding of the elements of a COVID-19 vaccine cold chain, may also assist companies and countries in the future. Research done will allow distribution companies to have a fundamental understanding of the requirements, education, training, and elements/components that need be considered when transporting, handling or storing a vaccine.

1.3. PROBLEM STATEMENT

COVID-19 has impacted the health and wellbeing of South Africans significantly. The development of vaccines gave people hope and the challenge lies in safely acquiring them for everyone who wants one. It is important that all South Africans, who want to be vaccinated, eventually have access to the vaccine irrespective of their location or economic and social standing. The South African Government plans to distribute the vaccine in three phases. Starting with frontline health care workers in phase 1 and moving onto essential workers, persons in congregated settings, persons older than 60 (first) and persons older than 18 (second) in phases 2 and 3 (Du Plessis, 2021).

For distributors to successfully deliver vaccines and follow set out phases, cold chain requirements and product sensitivity during transportation, handling and storage should be taken into consideration. Everyone handling the vaccine during its lifecycle must be trained and educated on the basics of its storage and temperature control requirements to ensure that the vaccine reaches its intended location uncompromised. The reality of South African roads, infrastructure, workforce,

and experience should be considered when distribution and vaccination plans are developed. South Africa is a developing country, which means that the rollout of the COVID-19 vaccines will be much more challenging here than in a developed country. The biggest challenge lies in understanding and adhering to the cold chain requirements of each specific, individual vaccine seeing that more than one exists.

Little to no research currently exists for a COVID-19 vaccine cold chain, within South Africa. Thus, this research addresses the gap in knowledge and the application thereof to aid efficient distribution. Distributing vaccines in such high quantities and importance, with such a critical time factor is not done regularly in South Africa.

1.4. AIM OF THE STUDY

The aim of this study is to aid the logistics industry in understanding the factors that play a role in the transport, handling, and storage of the COVID-19 vaccine. The study includes certain research objectives that support the understanding and alleviation of some distribution challenges associated with a COVID-19 vaccine supply chain in South Africa. The researcher aims to use existing literature and knowledge to aid the phased rollout of COVID-19 vaccines in South Africa from a logistics perspective, focusing on relevant capacity and infrastructure.

The research serves as a basic source of aid in the education and training of supply chain members in the efficient distribution of these specific COVID-19 vaccines. Basic guidelines are established in terms of required knowledge and skills to develop focused labour for successful last-mile distribution and attempt to overcome the many challenges on the South African side of the vaccine supply chain. The development of a toolkit for cold chain requirements and its importance is also established through the research and can be used in the education and training of distribution role players or focused labour for these specific vaccines. This toolkit consists out of a fixed set of procedures, guidelines etc., and needs to be applicable or easily adaptable to any COVID-19 vaccine that the South African government procures. The research and toolkit might also be useful in a wider cold chain environment.

1.5. RESEARCH QUESTIONS

For the researcher to achieve the desired aim and objectives of the research, the following research questions are investigated:

1. What current knowledge exists about similar cold chains and what successes or challenges have they had? For example, the distribution or distribution framework for Tuberculosis (TB) vaccines in South Africa.
2. What are the cold chain requirements and sensitivity of each requirement of a vaccine supply chain and how can they be categorised?
3. What are the specific cold chain protocols for each individual vaccine?
4. What best practices or metrics can be undertaken to ensure the effective management of temperature, humidity, vibration etc. along the different stages of the coronavirus vaccine supply chain?
5. What are the basic skills and knowledge requirements for personnel to safely and effectively transport, handle and store coronavirus vaccines?
6. What toolkit can be created or used to educate and train members of the vaccine supply chain?

1.6. OBJECTIVES OF THE STUDY

The objectives of this study can each be linked to one of the research questions and are used in achieving the aim of the study. The vaccine supply chain is categorized according to cold chain requirements and the sensitivity of each category is determined. Researching and understanding the vaccine supply chain and respective logistics cold chain requirements, through a stakeholders' analysis and a literature review, assisted in collecting information and data for analysis to support assumptions and conclusions drawn. In developing the toolkit, the researcher aims to understand and identify basic knowledge and skills required by COVID-19 vaccine supply chain members. Understanding and identifying the different cold chain protocols for COVID-19 vaccines procured by the South African government also contributed to the development of the toolkit. Familiarizing oneself with international best practices for the COVID-19 vaccine supply chain, contributed to the effectiveness of the toolkit and distribution.

The objectives and related research questions of the research topic are summarized in Table 1-1.

Table 1-1: Research objectives and related research questions

Research Question	Research Objectives	Addressed in Chapter(s)
1. What current knowledge exists about similar cold chains and what successes or challenges have they had? For example, the distribution or distribution framework for Tuberculosis (TB) vaccines in South Africa.	1. To synthesise the functionality and components of similar vaccine cold chains, through an extended literature review and interview process. This will enable the researcher to make use of previous research, tested knowledge and operations that can be used in the formulation of the vaccine supply chain and toolkit.	Three, Four and Six
2. What are the cold chain requirements and sensitivity of each requirement of a vaccine supply chain and how can they be categorised?	2. To conduct a Stakeholder Analysis to identify all stakeholders involved in a vaccine supply chain, to analyse the stakeholder relationship and to use their knowledge to identify supply chain links, vaccine cold chain characteristics and requirements.	Three, Four and Six
3. What are the specific cold chain protocols for each individual vaccine?	3. To comprehend and clarify cold chain protocols for COVID-19 vaccines procured by the South African government and why these protocols are in place as well as what value the maintenance of the cold chain has.	Three, Four and Six
4. What best practices or metrices can be undertaken to ensure the effective management of temperature, humidity, vibration etc. along the different stages of the coronavirus vaccine supply chain?	4. To identify what international best practices could be implemented to ensure vaccine safety and increase cold chain efficacy.	Three and Six
5. What are the basic skills and knowledge	5. To recognise and understand the basic	Three, Four and Six

requirements for personnel to safely and effectively transport, handle and store coronavirus vaccines?	requirements, such as skills or knowledge of transport and handling personnel for the effective distribution of COVID-19 vaccines in South Africa.	
6. What toolkit can be created or used to educate and train members of the vaccine supply chain?	6. To create a toolkit based on cold chain requirements of the COVID-19 vaccine and supply chain personnel requirements that can be used to educate members of the supply chain in transport, handling and storage of the vaccine.	Six and Seven
All research questions	To assemble the necessary data, analyse it, and provide or create a toolkit that can aid in the training and education of relevant supply chain members.	Three, Four and Six

1.7. CONCEPTUAL FRAMEWORK

The phrase COVID-19 or Corona has been on everyone's lips since December 2019 and this researcher strives to sufficiently understand the vaccine supply chain side of that phrase. Currently, most countries impacted by the pandemic have started their vaccination programs in an attempt to save lives and alleviate the enormous impact of the virus on their citizens and economy. There are at least five different COVID-19 vaccines that are being manufactured and countries are procuring the one's that best fit their country's needs and capacity or infrastructure.

The COVID-19 vaccine supply chain has recently entered the South African borders and government has set out a phased vaccination program. This plan needs to be executed and this research highlights the strengths and weaknesses related to the supply chain side of the execution process. The research strives to cover and understand the components that form part of the COVID-19 vaccine supply chain. Furthermore, the research aims to categorize and study the cold chain requirements of the vaccine supply chain and understand the sensitivity of each category. Knowledge and understanding of this specific topic will put forward or raise challenges that can then be focused on and overcome.

This study solely focusses on the vaccine supply chain and not the development of a vaccine, as a biological product. It considers the probability of human error and identifies the challenges associated with the distribution of a vaccine within a South African context. Although research and information from countries around the world were used, conclusions and practical implications are country, South Africa, specific. In developing a basic toolkit to aid in the education and training, the researcher focussed on COVID-19 vaccines that are procured by the South African government. The education and training toolkit focusses on the personnel involved in the transportation, handling, and storage of the vaccine. A diagram of the conceptual framework for the research can be seen in Figure 1-1.

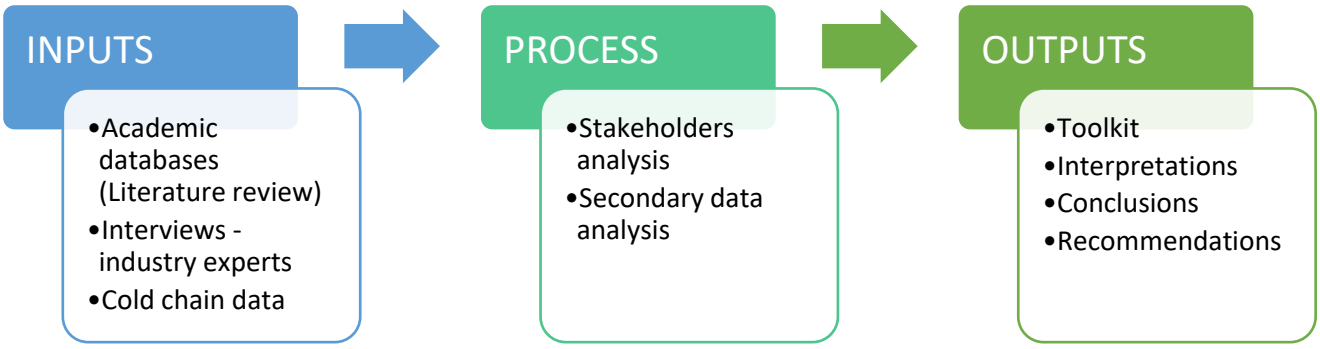

Figure 1-1: Conceptual Framework for the study

Source: Compiled by the researcher for the purpose of the study

1.8. CHAPTER OUTLINE OF THE STUDY

The remainder of the thesis is divided into the following chapters:

- Chapter 2 consists of the research design and methodology. This chapter explains how the stakeholder's analysis and study was conducted and how the data was collected. It further pinpoints potential problems of collected data, the primary and secondary data used for the research and the methods used to analyse and evaluate the data.
- Chapter 3 includes a full literature review containing various sub-sections. The sub-sections address different elements of the research. The purpose of this chapter is to provide an overview of what is already known within the field of study. It elaborates on relevant topics that are linked to different aspects of the research. Information in this chapter contributes to understanding supply chains, cold chains, vaccine supply chains and challenges associated

with these terms. This chapter aids the researcher and reader in understanding the overall topic and identifying potential knowledge and information gaps.

- Chapter 4 explains the vaccine supply chain and cold chain within the South African context. It continues to elaborate on the distribution of COVID vaccines in the country and how the rollout plan will commence. The chapter also addresses the statutory body responsible for COVID vaccines.
- Chapter 5 contains a discussion on conducting a stakeholder analysis. The chapter describes both the theoretical and practical tasks of the analysis.
- Chapter 6 focusses on data analysis from the literature reviews and stakeholder's analysis. It includes the data from interviews with different stakeholders in the industry and supply chain. This chapter contains the facts, knowledge and findings of the study as well as the data that can be extracted from the results. It explains the different methods that were used to analyse and evaluate the data and which data was used as an input to the toolkit.
- Chapter 7 includes the developed toolkit and elaborates on the achieved results. It also serves as a chapter to clarify the true, actual meaning and usefulness of the results and toolkit. The validation steps of the research are included as a section in this chapter.
- Chapter 8 includes the conclusions drawn from the toolkit output/results and the recommendations for the implementation of the toolkit, suggested by the researcher. The chapter also highlights possible suggestions or opportunities for future studies or research assignments.

CHAPTER 2 : RESEARCH DESIGN AND METHODOLOGY

2.1. INTRODUCTION

This second chapter outlines the research design and methodology undertaken in this study. The research design was formulated towards determining the required data and methods of data collection used in the study. The research methodology is discussed in terms of how the researcher systematically designed the study to ensure valid and reliable results were obtained that addressed both the aim and the objectives of the study. These topics are followed by the constructs and variables of the study, the reliability and validity of the results and lastly, the limitations of the study are summarised.

2.2. RESEARCH DESIGN

The researcher executed an analyses of existing literature to review what is already known within the field of study. This served as a basis to determine what knowledge gaps still exist and where and how the researcher can fill those gaps by means of a stakeholder analysis, interviews and further research, as part of a partial desktop study. The literature review also allowed the researcher to determine and define different terminology, processes and facts on which assumptions are based and conclusions drawn. The research followed a deductive approach to theory development. A deductive approach focusses on information, data and facts or theory that is already known within the specific field of study and then the researcher collects data to test or build on an existing theory. The researcher used a deductive approach, because of the recent appearance of COVID-19 vaccines and the fact that little data exists on the COVID-19 vaccine cold chain and the education and training of its supply chain members, but information regarding similar cold chains and the vaccine industry does exist.

The researcher made use of a mixed methods approach, which includes qualitative and quantitative research. The qualitative research included a stakeholder analysis, an interview process and a literature analysis of articles, annual reports and online sources or portals of various countries, companies and industries that form part of the COVID-19 vaccine supply chain. The quantitative research of this study includes secondary temperature data that was used to illustrate the effectiveness of COVID-19 vaccine packaging. The research can furthermore be classified as exploratory and cross-sectional in nature. This classification of nature, guarantees clarity in understanding what the current problem is and sheds light on new insights that are relevant at a

specific point in time. The study contains data from publicly available documents and online portals discussing the COVID-19 vaccine industry and supply chain.

2.3. RESEARCH METHODOLOGY

The research methodology typically refers to the "how" of the study or the way in which the study was structured to obtain results (Jansen & Warren, 2020). It includes the primary and secondary research that was conducted, the sample design of the study and the measurement instruments used. It lastly explains the phases of data analysis executed in this study, and the techniques used during analysis.

2.3.1. Primary and Secondary Research

Primary and secondary research methods are utilised in this research study to understand the COVID-19 vaccine supply chain and the elements that form part of the vaccine's transportation, handling and storage. These research methods are used to identify the cold chain requirements of the COVID-19 vaccine and how these vaccines should be managed based on their individual needs and composition. Primary and secondary research are also used to elaborate on the functionality of the cold chain, the knowledge and skills required for its handling and storage, and the distribution of COVID-19 vaccines in South Africa.

The primary research method that was used in this study is a stakeholder analysis. The stakeholder analysis included contacting companies that form part of the COVID-19 vaccine supply chain e.g., BIOVAC, DSV Healthcare, healthcare professionals, healthcare facilities and Imperial Logistics. Stakeholders for the study, summarised in section 5.2, were identified based on the information obtained from the literature review and explorative interviews with employees at Imperial Logistics. The identified stakeholders, if willing, had the opportunity to share their knowledge and information about the functionality of the COVID-19 vaccine industry and supply chain with the researcher. The researcher contacted these industry experts via telephone and email to schedule semi-structured interviews.

Secondary research was conducted by making use of the multiple information portals and documents on the Internet. Various websites, annual reports, books, academic publications, class slides and articles were used in the construction of the literature review. Information obtained from

these various sources allowed the researcher to answer certain aspects of research questions, assist in the formation of the toolkit and identify possible areas for future research.

2.3.2. Sample design

A sample design serves as the basis for the selection of a survey sample and generally refers to the way in which a target population is selected. The target population for this study includes organisations and stakeholders who in some or other way form part of or are affiliated with the COVID-19 vaccine supply chain in South Africa. The stakeholders identified for this sample were therefore, selected from the COVID-19 vaccine industry, Government officials, the medical profession, the logistics industry, and independent consultants. These stakeholder groups were identified based on explorative interviews and information obtained from the literature review.

2.3.3. Measurement Instruments

There were three measurement instruments used in this study to obtain insight and visibility into the distribution of COVID-19 vaccines in South Africa and its entire supply chain. The first measurement instrument was the literature review. This analysis of existing literature allowed the researcher to understand what elements are associated with effective distribution of the COVID-19 vaccine and which factors, operations and possible challenges could influence safe and effective handling, storage, and distribution. A stakeholder analysis was the second measurement instrument. This tool allowed the researcher direct access to the thoughts, recommendations and operations/processes of parties involved in the physical distribution of the vaccine in South Africa. The third measurement instrument was used to evaluate whether the researcher fully understood the COVID-19 vaccine supply chain functionality within South Africa and correctly identified the supply chain links. After the researcher constructed a visual representation of the COVID-19 vaccine supply chain, it was sent to employees at two different logistics/distribution companies, associated with the distribution of COVID-19 vaccines in South Africa, who then evaluated whether the researcher included all elements and links.

2.3.4. Data Analysis

In this study data was collected from a variety of sources. The stakeholder analysis served as a phase in the collection and analyses of data for the study.

The stakeholder analysis in this study was used to confirm certain aspects of the data collected in the literature review and to elaborate and build on collected facts and information. Interviews with

different stakeholders allowed the researcher to collect data from direct links in the COVID-19 vaccine supply chain. It also allowed the researcher visibility into the supply chain functionality. The process of the stakeholder analysis is explained in Chapter 5.

2.4. CONSTRUCTS AND VARIABLES

A construct is a broad concept and an abstract idea or topic that is specifically chosen to explain a given phenomenon (Bhattacherjee, 2020). Constructs need to be observable or measurable. The construct that this study focusses on are the cold chain operations and requirements as well as the elements associated with effective distribution of the COVID-19 vaccine and its supply chain.

A variable is a measurable representation of an abstract construct and is presented in the research questions and hypotheses (Bhattacherjee, 2020). One variable in the case of this study is the different factors or cold chain requirements, such as temperature, humidity or vibration that need to be monitored and managed in the COVID-19 vaccine cold chain. Another variable is the number and type of skills required for the effective distribution of the COVID-19 vaccine, within South Africa. The third variable refers to the operations and different links that form and configure the COVID-19 vaccine supply chain.

2.5. VALIDITY AND REALIBILITY OF RESULTS

These two terms, validity and reliability, are identified as the two important criteria for the evaluation of research. Validity in qualitative research serves as an indicator for the relevance and appropriateness of the different tools, procedures and information used in the study. According to Leung (2015:326) the term is used to determine, “whether the research questions are valid for the desired outcome, the choice of methodology is appropriate for answering the research questions and finally, the results and conclusions are valid for the sample and context.”

The validity of this research was tested by means of content, construct and concurrent validity. Content validity was achieved by basing the variables in the study on information gathered from both the literature review and the stakeholders’ analysis, in order to fully represent what the study aims to measure. Construct validity focuses on ensuring that the method of measurements matches the construct that the research wants to measure. This was accomplished by ensuring that supply chain measurements or measurements associated with the research questions were developed based on relevant, existing knowledge. Lastly, concurrent validity was realized by sharing results on

the SUCI platform and asking personnel at logistical stakeholder companies, focusing on health care, whether they agree with the obtained results.

The essence of reliability on the other hand, lies with consistency (Leung, 2015:327). The reliability of this study was based on using different analysis or evaluation methods for data and obtaining the same results from both. The researcher also used different resource portals to base conclusions and assumptions on.

Following the methodology and research design, as set out by the researcher, ensured the reliability and validity of this study.

2.6. LIMITATIONS

This study had four limitations that effected the data collection process. The first limitation is that not all the stakeholders who were identified in Chapter 4, could be contacted, or reached to schedule an interview. Most of these mentioned stakeholders included those associated with Government. The second limitation: there were a few stakeholders that were willing to assist, but they could not share data/information because of the rules and regulations implemented by Government in terms of the COVID-19 vaccine. The third limitation refers to the fact that employees interviewed at vaccination sites were limited to the Western Cape because of travelling requirements and time constraints.

Another limitation was the timing of the research within the very dynamic, uncertain pandemic environment. At the time of the research initiation in February 2021, large scale uncertainty was still present within the health care system on the planning specifics of the mass vaccination roll-out and the cold chain requirements from the various possible listed vaccines to be rolled out. The research journey was thus completed both in a largely uncertain environment parallel to the unfolding of the vaccine roll-out and done at considerable pace to ensure the outcome would be available at the soonest convenience to the industry. Despite this, the researcher had to take diligent care to ensure the rigour and validity of the research process and outcome.

2.7. CONCLUSION

To obtain results for this study, the researcher collected data through both primary and secondary research. The three data collection methods included a literature review, a stakeholder analysis,

and an interview process. The sample for the stakeholder analysis and interview process were organisations and individuals who form part of or is associated with the COVID-19 vaccine supply chain in South Africa. Employees from two different distribution companies, in South Africa and associated with the distribution of COVID-19 vaccines, assisted the researcher in identifying these stakeholders and evaluate the validity of the study. The results of the study were tested by means of three different validity aspects and reliability. A slight drawback in the study, also known as a limitation, was the fact that not all identified stakeholders in section 5.2, could be contacted to schedule an interview.

CHAPTER 3 : LITERATURE REVIEW

3.1. INTRODUCTION

The aim of this literature review is to link the research topic to previous studies and peer reviewed, tested knowledge. It is also used as an input to the development of a toolkit. It is compiled from various sources of literature to give the reader a comprehensive outlook on the topic and provide context surrounding the research area. The literature review provides an overview of supply chain and supply chain management as well as cold chain and cold chain management. These terminologies are defined in terms of operations, elements, components, challenges, requirements, etc. and are further classified into a vaccine supply chain and vaccine cold chain. The chapter elaborates on the COVID-19 vaccine industry, including the description of its supply chain and cold chain, and several other elements. COVID-19 vaccine cold chain requirements are identified to support research and conclusions in subsequent chapters.

3.2. SUPPLY CHAIN AND SUPPLY CHAIN MANAGEMENT

In 2013, the Council of Supply Chain Management Professionals (CSCMP) created the definition of a supply chain, and this definition is still used today in the Supply Chain Management Terms and Glossary (2013:186). It is defined as “a process starting with unprocessed raw materials and ending with the final customer using the finished goods.” This extensive network includes different activities, individuals, companies, data, and resources (Kenton, 2020). The supply chain is responsible for linking different companies, vendors, service providers and customers together. This linking process needs to be managed correctly and is essential to value creation and guaranteeing that products are delivered to their final destination effectively and/or efficiently.

The management of a supply chain is responsible for the preparation, scheduling and organisation or administration of all supply chain related activities involved in a supply chain process such as sourcing, procurement, warehouse management, etc. (Supply Chain and Logistics Terms and Glossary, 2010:115). Supply Chain Management (SCM) is a fundamental process involved in the flow of goods, data and finances related to the specific product or service supply chain (Kenton, 2020). Correct or appropriate management ensures that either effectiveness or efficiency within supply chains are achieved. Effectiveness and efficiency both serve as a standard of performance. Efficiency within supply chains is related with “doing things right” (Chan, 2019). Contrastingly, effectiveness within a supply chain is described as “the measure of how well one meets or exceeds the demands

of key stakeholders." Effective supply chains will portray characteristics such as visibility, consistency, and optimization to eventually encourage and expand customer satisfaction (Supply Chain Effectiveness, 2018). The comparison between an effective and efficient supply chain can be seen in Table 3-1. This table is a summary created by Yakoob (2019) based on the research done by M.L. Fisher in 1997. The nature of a vaccine supply chain's characteristics makes both efficient and effective supply chain management applicable.

Table 3-1: Comparison of Efficient vs. Effective (Responsive) Supply Chains

	Efficient	**Responsive**
Primary goal	Lowest cost	Quick response
Product design strategy	Min product cost	Modularity to allow postponement
Pricing strategy	Lower margins	Higher margins
Mfg strategy	High utilization	Capacity flexibility
Inventory strategy	Minimize inventory	Buffer inventory
Lead time strategy	Reduce but not at expense of greater cost	Aggressively reduce even if costs are significant
Supplier selection strategy	Cost and low quality	Speed, flexibility, quality
Transportation strategy	Greater reliance on low cost modes	Greater reliance on responsive (fast) modes

Source: Yakoob, 2019

Since the first mention of SCM in 1982, various supply chain models have been created to fit different needs of individual firms and achieve supply chain excellence and goals. These models as identified by Perez (2013) are an agile model, continuous flow model, customer configured model, efficient chain model, fast chain model and flexible model. The goal of these models is to evaluate and enhance supply chain performance (Bhardwaj, 2020). The SCOR framework is another model used to achieve supply chain excellence and has identified five different processes, which can also be considered the components of SCM. The components are - plan, source, make, deliver and return (Bhardwaj, 2020).

3.3. COLD CHAIN AND COLD CHAIN MANAGEMENT

A cold chain is a system that ensures temperature sensitive products are stored and transported within their required temperature ranges from start to finish (What is Cold Chain Management, 2020). This part of the supply chain typically consists out of thermal and refrigerated packaging methods, cold rooms, freezers or refrigerators and logistical planning. It can be summarized that a

cold chain is an uninterrupted, temperature-controlled system responsible for storage and distribution that needs to be managed correctly (Rodrigue, 2009). Rodrigue (2009:145) explains that the functionality of a cold chain consists out of the interaction between three main components, as seen in Figure 3-1. This interaction between product, distribution and origin allows various emerging countries and economies to partake in the international fresh/perishable products market. In current events, the cold chain allows COVID-19 vaccines to be transported between countries without losing its efficacy.

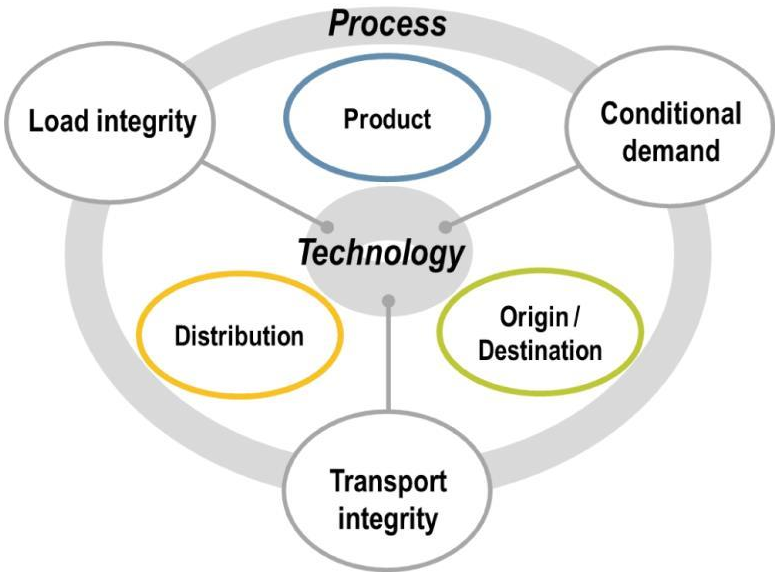

Figure 3-1: Elements of the cold chain

Source: Rodrigue, 2009

Cold chain management (CCM), as an essential to the cold chain, is defined by Rodrigue (2009:145) as: "the process of planning, implementing and controlling efficient, effective flow and storage of perishable goods, related services and information from one or more points of origin to the points of production, distribution and consumption in order to meet customers' requirements." It is fundamentally the management of the interaction between the elements of the cold chain, displayed in Figure 3-1. Management is, therefore, involved in every process and task from preparation to storage and transport (What is Cold Chain Management, 2020). Successful cold chain management (CCM) is dependent on being informed about shipping conditions or situations and how to distribute products based on their individual temperature requirements (Rodrigue, 2009:146). A lack of cold chain management could lead to temperatures fluctuating above or below the recommended range, which leads to product wastage and causes both the shipper and the client to lose money (What is Cold Chain Management, 2020).

3.3.1. Cold chain requirements

Cold chain requirements widely refer to the temperature levels at which products need to be transported, handled and stored. Perishable or temperature sensitive products require the maintenance of certain temperature ranges along their supply chain. Staying within the product temperature range enables and ensures the integrity of the product and optimal shelf life (Rodrigue, 2009:146). Cold chain requirements further refer to factors such as humidity, vibration, light sensitivity or shelf life that could have an impact on the effectiveness of the cold chain. Each product has their own cold chain requirements, and any deviation can cause an irreversible outcome and result in costly damages (Rodrigue, 2009:146).

It is noteworthy to mention, at this stage, that the key difference between a cold chain and a supply chain is the sensitivity of the product or material involved. The cold chain industry has developed four temperature standards that represents or groups the temperature ranges of nearly all products. These industry standards are “banana” (13 °C), “chill” (2 °C), “frozen” (-18 °C) and “deep-frozen” (-29 °C) (Temperature Standards for the Cold Chain, 2020). It is of utmost importance that the specific temperature range or temperature standard of products are maintained throughout all the stages of the cold chain to ensure optimal shelf life and the integrity of the product. If temperature standards are not met throughout the chain, products can lose market value or degrade (Rodrigue, 2009:146).

3.3.2. Cold chain components/elements

There are four key elements of a generic cold chain. According to Notteboom & Rodrigue (2020) they are:

- Cooling systems: These systems, also known as pre-cooling, are responsible for getting commodities to their proper temperature required for processing, storing, and shipping or transporting.
- Cold storage: These facilities usually contain freezers, refrigeration units, cold boxes etc. They are either used as an intermediate location for processing and distribution or as a storage facility over a period of time. According to UNICEF (2019) cold storage facilities used in the pharmaceutical industry need to comply with performance standards as defined by the World Health Organization (WHO).
- Cold transport: This entails having transportation accessible and available to distribute products or materials whilst maintaining the required temperature ranges and humidity

levels (Administrator, 2019). Stable environments mean that the integrity of the shipment is protected.

- Cold processing and distribution: This component provides the industry with facilities used for product transformation and processing, whilst ensuring sanitary conditions. This is where freight and load (crates, boxes, pallets) consolidation and deconsolidation take place.

Cold chain experts, from Logmore, suggests that an extra three cold chain elements can be added to this list. These include, packaging, monitoring and customs clearance (What is Cold Chain Management, 2020).

All activities, required infrastructure, required personnel and product characteristics that form part of one of these four or seven elements of each individual cold chain need to be identified and managed accordingly. Different product or material cold chains will have a unique composition based on the contents of each element.

3.3.3. Cold chain technologies

As mentioned earlier, temperature-sensitive products need to remain within a certain temperature range during distribution and storage to ensure product integrity. Maintaining temperature over a long period largely depends on the type of container and the cooling system that is used (Notteboom *et al*., 2020). When deciding on the type of packaging that is required, factors such as transit duration, shipment size and ambient (outside) temperatures experienced should be taken into consideration. Notteboom *et a*l. (2020) suggest that there are about six main cold chain technologies that are used in obtaining the appropriate temperature-controlled environment during transportation.

3.3.3.1. Dry ice

Dry ice or solid carbon dioxide is extremely cold and reaches a temperature of about -80°C and has the benefit of not melting. It is capable of keeping shipments frozen for long time periods and is mostly used in the distribution of pharmaceuticals, dangerous goods or food products. IPC (2019) suggests that dry ice is the best choice for keeping products frozen but should not be used in shipments where products are sensitive to freezing.

3.3.3.2. Gel packs

This technology contains phase changing substances to control an environment. They can change from a solid to a liquid form and vice versa. These packs are generally used for pharmaceutical and medical shipments because they have a "chill" temperature standard. The benefit of gel packs is that they do not reach extremely cold temperatures and can, therefore, be used in the transportation or storage of products that are sensitive to freezing (IPC, 2019). Subject to the transport requirements, gel packs are either in a refrigerated or frozen condition and according to IPC (2019), they can be used as an aid to prolong the life of dry ice.

3.3.3.3. Eutectic plates

Eutectic or cold plates is a technology similar to the gel packs principle. They are very flexible, can be used for either chilled or frozen products and makes financial business sense (EVERICED, 2018). These plates are full of liquid, can be reused and are mostly utilised in distribution vehicles to maintain temperatures levels for a short time frame.

3.3.3.4. Liquid nitrogen

This liquid is inert, colourless, odourless, non-flammable and extremely cold. It has a temperature of about -196°C and is applied to maintain the frozen state of products or packages over an extended time period. It is predominantly used in the transportation of biological cargo, for example, tissues and organs.

3.3.3.5. Quilts or Insulated Coverings

Quilts are insulated pieces that are used to cover freight and serve as a buffer in temperature changes or fluctuations, and they aid in maintaining stable temperature ranges or levels. This technology is best for local or short-haul shipments and can keep products at a constant temperature for a limited amount of time (Cold Chain Technologies, 2021). It also enables cost saving, because frozen freight can remain in that state when covered for a longer (limited) time, eliminating the need for more expensive refrigeration devices.

3.3.3.6. Reefers

This is the collective name used to group all temperature-controlled transport units. These units vary from a van to a small truck, semi-trailer or a standard ISO container. Notteboom *et al*. (2020) explain that these reefers are all insulated and have an independent refrigeration unit attached to

them to allow temperature-controlled air circulation. They are designed to distribute chilled air and their T-shaped decking allows the production of consistent and uniform air flow across the entire shipment (Manaadiar, 2015).

Each cold chain component/element should make use of the technology that suits their environment or infrastructure.

3.3.4. Cold chain operations

Establishing a comprehensive logistical process to uphold shipment integrity is required within each and all supply chains. This extensive process consists of several phases stretching from shipment preparation to final integrity verification of the shipment at the delivery point.

3.3.4.1. Shipment preparation

The first phase in a comprehensive logistical process is extremely important and the first step within this phase is to determine and assess the characteristics of the temperature-sensitive product that is being transported. This first step determines the direction of the rest of the preparation phase. During this phase, products are prepared for shipment according to identified, individual needs. They should already be at the required temperature and in the correct packaging. It is important for companies to understand that cold chain devices should not be used to bring a shipment to its correct temperature but only to maintain an already-obtained constant temperature (Notteboom *et al*., 2020). The preparation phase for each supply chain will look different, but there are certain aspects that should always be taken into consideration, such as the destination's weather conditions. The following general activities also take place during this phase:

- The load unit carrying the cargo is prepared;
- Refrigerated containers are cleaned to eliminate the possibility of bacterial contamination;
- Containers are prepared according to the specified temperature and humidity conditions of the shipper.

3.3.4.2. Modal choice

There are several key considerations when establishing which model will be used for transportation. According to Ballou (2004) and Bowersox, Closs, Cooper & Bowersox (2013), modal choice or transportation services are viewed and compared based on four characteristics/considerations namely:

- Price;
- average transit time;
- transit time variability; and
- damage and loss.

Price refers to: "the line-haul rate for transporting goods and any accessorial or terminal charges for additional services provided." Average transit time is calculated by taking the average time elapsed between the products point of origin and destination, during transportation. Transit time variability suggests the typical differences that happen between shipments by various modes such as weather, traffic, congestion, number of stops etc. Loss and damage are the primary customer service condition and important to consider when selecting a carrier (Ballou, 2004; Bowersox, Closs, Cooper & Bowersox, 2013). On top of these four considerations, Rodrigue *et al*. (2020) suggest that shipment size, weight and features are other key considerations.

3.3.4.3. Customs procedures

A cold chain can have three different geographic orientations. Local cold chains exists where the production site is close to the consumption site. Regional cold chains on the other hand are formed when the point of production and consumption is in the same country but in different regions (What is Cold Chain Management, 2020). As soon as country borders are crossed or products are moved overseas, the cold chain turns global, and customs become involved in the movement process. Customs might need to be cleared before suppliers are allowed to deliver shipments onto/to foreign jurisdictions. Products in a cold chain have a tendency to be time-dependent and more inclined to inspection than regular freight because of their nature. Rodrigue *et al*. (2020) explain that customs issues are frequently recognized as an important component in instituting dependable global cold chains.

3.3.4.4. The "Last Mile"

The last mile is the final phase of the delivery process of a product at its final destination. There are certain aspects to consider when organizing final delivery such as the intended destination, the timing of the delivery, the amount of space at the delivery point and operating hours of the product's destination. The product has made it this far and should not be exposed to any vulnerable areas during the transfer (from transport to storage facility) phase that could lead to a breach of product integrity (Rodrigue et al., 2020).

3.3.4.5. Integrity and quality assurance

Monitoring temperature throughout the cold chain is an important performance measure and indicator. After shipments have been delivered to their final destination, temperature monitors or recording devices should be analysed to gain insight into how well temperature was managed throughout the delivery process. This process within the logistical process creates trust, accountability and could assist companies if held liable for damaged shipments (Rodrigue et al., 2020). If device recordings indicate fluctuating temperatures outside of the recommended temperature range corrective actions should be taken to address the problem.

These five phases are carefully considered, applied and understood when the vaccine cold chain operations are identified and analysed. Challenges in each phase are identified and solutions are provided.

3.4. THE VACCINE INDUSTRY

A vaccine is defined as: "a substance used to stimulate the production of antibodies and provide immunity against one or several diseases. It contains tiny fragments of the disease-causing organism and other ingredients to keep the vaccine safe and effective." (What are the ingredients in a vaccine, 2020). Thousands of different vaccines exists and all of them form part of this industry. The vaccine industry is made up of businesses and corporations who are concerned with either research, development, manufacturing, sales, marketing or the distribution of vaccines (Gordon Douglas *et al*., 2017). Most vaccines are produced and distributed by private companies and the industry is regarded as relatively small, compared to the pharmaceutical industry (Gordon Douglas *et al*., 2017).

Sub-sets of the vaccine industry are found worldwide and although a certain vaccine may not be produced in a specific country, the country can still play a part in its industry. The largest vaccine production or manufacturing companies are predominantly based in the USA and Europe. These countries hold the dominant revenue-based share in the industry (Gordon Douglas *et al*., 2017). Gordon Douglas *et al*. (2017) explain that the vaccine business is capital intensive and substantial continuing investments is required in manufacturing, resources, amenities and/or facilities, research and individuals.

Balasubramaniam *et al*. (2014) describe vaccines as, "the most cost effective and equitable health intervention known to man." They protect and save millions of individuals each year and because of its importance to human health, the vaccine industry should be thriving. The industry does thrive in developed countries, but struggles in developing countries, such as South Africa. Developing countries have limited access to vaccines or vaccines available for immunization are not commonly found when and where needed. Limited access is usually the result of limited available funds for procurement or poor health systems and infrastructure (Balasubramaniam *et al*., 2014). The global vaccine industry is confronted with one big challenge, this being the continuing process of trial and error for the development of successful vaccines to battle diseases for example HIV, meningitis and tuberculosis (TB). Currently, the vaccine industry is facing one of its greatest challenges, namely the COVID-19 pandemic (Vaccines Market Size, Share & COVID-19 Impact Analysis, 2020).

3.4.1. Vaccine Management and Logistics support

Logistics support is a crucial component of any immunization campaign. The support function ensures the availability of proper equipment, sufficient source of excellent, quality vaccines and immunization-related materials. It consists out of three key areas, namely, vaccine management and monitoring, cold chain management and immunization safety (Logistics support, 2020). The first two functions are explained in sections 3.7.2 and 4.2.2. Logistics support programs need to be well-managed to avoid unnecessary vaccine wastage and wastage management or stock outs that could result in substantial operational program costs and an undesirable impact on public health.

3.4.2. The COVID-19 vaccine industry

COVID-19 vaccines are developed with the intention of providing immunity against COVID-19 (Vaccine News, Updates & Information Portal, 2021). The first appearance of a COVID-19 infection was reported in December 2019, urgent global research studies were started to prepare for the outbreak, understand the disease and develop a preventive vaccine. Early vaccine research and development were expedited because of the urgency of the situation and the rapidly growing infection rate. Global government co-operation and international alliances allowed the pooling of resources, which shortened vaccine development timelines (Coronavirus disease pandemic, 2021). In March 2020, four vaccine candidates were undergoing human evaluation and on 24 June 2020, China approved the first vaccination for limited use. By December 2020, Europe, Asia, the United States of America and some of Africa had limited access to at least one of several vaccines (Coronavirus disease pandemic, 2021).

The COVID-19 vaccine industry, started in February 2020 and refers to all the economic activity that is concerned with the process of converting raw materials into a useable vaccine (COVID-19 vaccines, 2021). It includes all companies, individuals and partners from around the world, involved in vaccine production and distribution. The rollout of at least seven different vaccines across three platforms has started across the world as of 18 February 2021. Since access to high quantities of vaccines are still limited, most countries are working towards procuring and vaccinating their vulnerable populations first (COVID-19 vaccines, 2021). While countries are currently procuring vaccines that best fit their needs, over 200 other vaccine candidates are in their development phase, of which 60+ have already entered clinical development.

This industry is relatively new, although vaccines have been around for years. The World Health Organization (WHO) and international partners have been working around the clock to get the industry on its feet and speed up the development of safe and effective anti-pandemic vaccines (COVID-19 vaccines, 2021). These fast-moving actions include the support function for the building of manufacturing capabilities and ensuring the fair and equitable allocation of the manufactured vaccines for all countries (COVID-19 vaccines, 2021).

3.4.2.1. The production of COVID-19 vaccines

Most vaccines are manufactured and sold by private corporations under contracts. Vaccine production takes place in different parts or stages and contracts can allow countries to partially take part in a production phase. Several middle-income countries such as India, Argentina and Mexico make use of this partial production opportunity to gain strategic leverage based on their adequate capacity. The production capacity of these countries allows them to procure or gain access to vaccines more easily (Dorfman, 2021).

It should be noted that more than one COVID-19 vaccine does exist, and individual vaccines are being tested, trialled and manufactured at various origins around the world. New manufacturing sites are approved as time goes by and demand increases. COVID-19 vaccine production predominantly takes place in Europe and Asia (Increase in vaccine manufacturing capacity and supply for COVID-19 vaccines, 2021).

3.5. THE VACCINE SUPPLY CHAIN

Vaccine and immunization programmes are one and the same and have been around for ages. They are built on functional, end-to-end supply chains and a range of integrated logistics systems that ensures their successful delivery (Essential Programme on Immunization, 2020). The ultimate goal and role of a vaccine supply chain is to guarantee the successful ad efficient storage, handling and stock management of the specific vaccine and to make sure exact temperature control takes place in every stage of the cold chain. A supply chain is also widely responsible for the maintenance of ample logistics management information systems (Essential Programme on Immunization, 2020).

Just like any other supply chain, the vaccine supply chain requires a system to achieve what we know as the six rights of supply chain management, i.e., the right product in the right quantity, delivered to the right place in the right condition at the right time and at the right cost. These rights are required to guarantee the uninterrupted flow and availability of quality vaccines from the manufacturer to service-delivery levels, to guarantee vaccination opportunities are not lost because of unavailability (Essential Programme on Immunization, 2020).

A generic vaccine supply chain, as shown in Figure 3-2, starts at a manufacturer and ends once consumers have access to vaccines or when vaccination takes place. Most vaccines in a supply chain have four pit stops before vaccination can take place. Vaccines are transported from the manufacturer to a national storage facility, whereafter they are moved to a regional hospital. Regional hospitals then transport smaller amounts to health centres and eventually to a vaccination outreach.

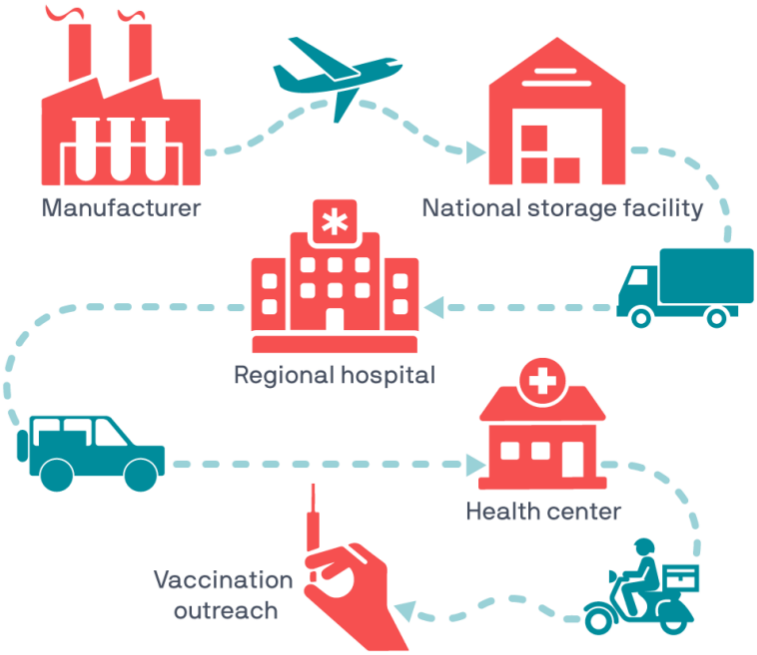

Figure 3-2: A generic vaccine supply chain

Source: Vaccine cold chain Q&A, 2020

3.5.1. Managing a vaccine supply chain

According to four industry experts (Bittinger, 2020; McKenzie, 2020; Martin, 2020; Wittman, 2020), there are five priorities that vaccine supply chain members have to manage in order to survive a supply chain crisis. They are:

- Agility;
- Sustainable supply chain reliability;
- Sustainable supply chain resilience;
- Cross-functional collaboration; and
- Accountability.

Agility is priority number one and is the term used to describe the combination between alertness, accessibility, decisiveness, swiftness and flexibility (Gligor, 2015). These five dimensions of agility cannot be achieved without end-to-end supply chain visibility and "smart sensing", when supply chains are in crisis. Supply chain members need to understand where vaccines are, the stage and condition they are in as well as small details around the vaccine shipment delivery and storage in order to have supply chain visibility (Bittinger *et al*., 2020). Once individuals have achieved visibility within their supply chain, good sensing is required to make intelligence out of it, which is called

smart sensing. The need to respond should automatically take action after sensing in order for members to achieve actionable sensing and alleviate problems.

The second and third priorities are sustainable supply chain reliability and resilience. The first states the degree to which a supply chain generates consistent performance (Barbosa-Pavoa, 2017). The latter explains the capability of the supply chain to be ready for any unforeseen risks; reacting and recovering quickly after interruptions and/or disruptions and growing or moving to a more preferable state (Barbosa-Pavoa, 2017). According to Wittman (2020), a reliable supply chain and execution stretches from demand sensing and visibility to product development and forecasting. In order for a supply chain to achieve agility, it needs to direct attention to reliability and defining the 3Cs of resilience, namely capacity, capability and competency (Chatterjee, 2020). Vaccine supply chain members should make use of interim measures in order to know what is required and expected of them every day, in terms of reliability and predictability (Chatterjee, 2020).

Cross-functional collaboration and accountability are priorities four and five. Both of these are used to improve team outcomes. The fourth priority refers to a group of individuals with different functional expertise who come together to work towards a common goal (Beck, 2017). This common goal within a vaccine supply chain is to ultimately get the downstream customer, and the patient, the correct product at the correct place and time. Collaboration within a vaccine supply chain is not just focused on profits, but the health and wellbeing of patients. Overall, accountability stretches throughout the supply chain, starting with supplier evaluation; transparency and traceability; establishing protocols and controls and ending with supply chain optimization and cost controls (Vizel, 2020). Managers or leaders should be using accountability within cross-functional collaboration and focus on using different measures to hold individuals responsible, both functionally and cross functionally to initiative teamwork and organizational focus (Bittinger *et al*., 2020).

Routine immunization programmes have achieved success for years, but the surge of new vaccine introductions, because of COVID-19, have strained the effective management of national vaccine supply chains. Suddenly, there is an increased need for new delivery strategies and the benefit of having access to new technological advances in cold chain equipment that can increase their effectiveness and efficiency. According to Bittinger *et al.* (2020), the COVID-19 pandemic has amplified long-lasting disruptions of the supply chain. Before the pandemic, the pharmaceutical

market circumstance consisted out of timely product development lead times, lengthy regulatory approval lead times and tolerated producers and marketers of pharmaceutical products to be a little complacent and unhurried to respond. Now, the supply chain and pharmaceutical market is in overdrive.

3.5.2. Best practices for a vaccine distribution

A vaccine supply chain is primarily responsible for getting vaccines successfully, effectively and efficiently from the point of production to the point of consumption. According to Conway (2021), there are five best practices that can be used in vaccine distribution. These were created and modified based on lessons learned from the past, different vaccines and vaccination campaigns. The five best practices are:

i. Minimize variation whenever and wherever possible. In a vaccine supply chain, there will always be some sort/degree of natural variation. The solution to this is to minimize the variation that supply chain members can control. For example, having control over how vaccines are distributed, identified, and tracked across the supply chain.

ii. Supply chain members need to leverage the tools that they have or in other words use what they have to their advantage. Most pharmaceutical and medical devices are inclined to have some form of an auto-identification carrier, e.g., a QR code or a barcode, explained in section 3.8.4.3. These carriers or devices simplify electronic information capturing and eliminates the need for manual capturing of product information.

iii. Vaccine supply chains need to invest in automation. Automation in a supply chain is defined as “the creation and application of technology to monitor and control the production and delivery of products and services.” This best practice builds on the previous one and refers to the standard operating practice of scanning barcodes on patients and medicines. It reduces medical errors and frees up time that can be spent on other tasks. Conway (2021) recommends that this should be how product movement and patient care is documented throughout the vaccine supply chain.

iv. The creation of multi-directional visibility. Many supply chain challenges arise due to the lack of demand and inventory visibility. Supply chain members need to manage their interdependency in order to extend upstream and downstream visibility. Members involved with raw materials need to be informed about demand forecasting at different locations, the location of health care facilities and the various suppliers involved, and vice versa.

v. The last best practice states "Call on the experts." Supply chain challenges can be overcome with the help of experienced and expert supply chain professionals, who are healthcare workers throughout the world. Their inputs are of extreme value because they know the different healthcare systems, they are experienced supply chain managers, and they are informed about the communities that they serve.

3.6. THE COVID-19 VACCINE SUPPLY CHAIN

The COVID-19 vaccine supply chain refers to all the processes involved in the manufacturing and distribution of the COVID-19 vaccine. This includes all activities, companies and individuals who play a part in the processes involved in the production of any COVID-19 vaccine, seeing that more than one exists. The supply chain, as displayed in Figure 3-3, starts at the manufacturer, and ends once vaccines reach the patient. A vaccines' destination can either be a hospital, clinic, pharmacy, or any other healthcare facility. The global pandemic is arising in the age where the extent of technology permits individuals to reinvent and distribute vaccines in a much more efficient and effective way (Supply chain traceability can ensure safe global distribution, 2020). It does, however, pose many challenges because vaccines are supplied to the global population. For these challenges to be managed and overcome and vaccine introduction to be executed smoothly, strong supply chain management is needed.

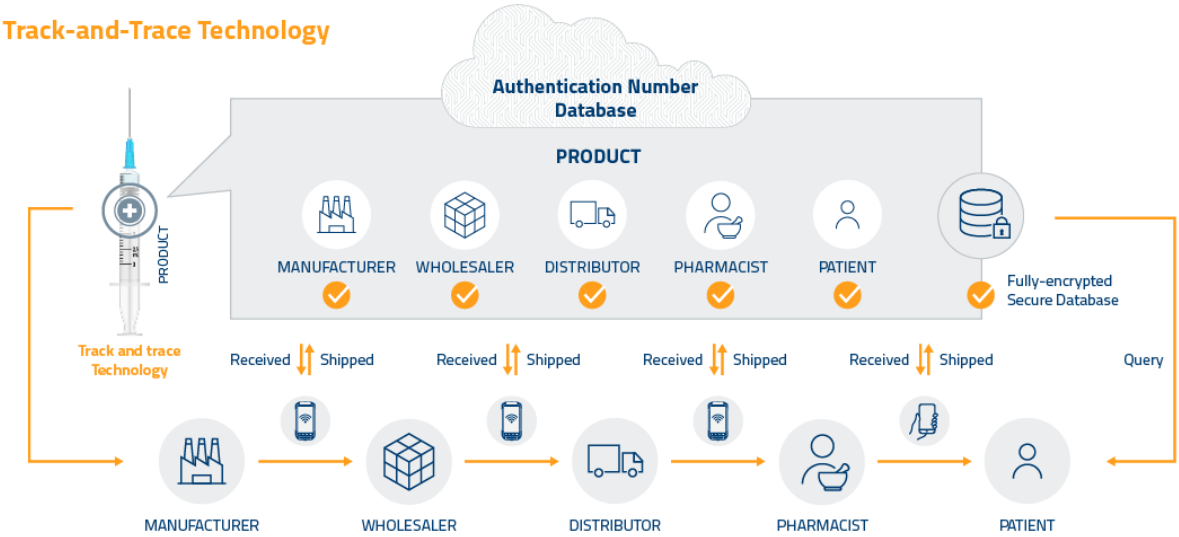

Figure 3-3: COVID-19 vaccine supply chain

Source: Supply chain traceability can ensure safe global distribution, 2020

According to the WHO (2021), there are eight steps in the deployment of COVID-19 vaccines. These steps are:

1. The reception of products, Personal Protective Equipment (PPE), and ancillary products.
2. Storage of vaccines and ancillary products.
3. Repackaging vaccines and ancillary items.
4. The production or purchase of coolant packs (cold chain equipment).
5. The transportation of vaccines.
6. Reverse logistics
7. The management of recalls.
8. The management of supply chain information.

These eight steps are not a once off, but a continuous effort that will be repeated each time countries receive big amounts of vaccines in various shipments from different manufacturers over a period. Management needs to occur at each of these steps.

3.6.1. COVID-19 vaccine supply chain management

Vaccine management includes two different functions, namely, managerial, and operational. These two functions are critical in ensuring the ample availability of high-quality COVID-19 vaccines for immunization. Both functions need to be managed and executed by a skilled, capable, and motivated team (Essential Programme on Immunization, 2020). Some of the elements of both functions fall into the supply chain side of immunization. Only the functions that are applicable to supply chain management are mentioned below.

3.6.1.1. Managerial functions of vaccine management

The managerial functions of vaccine management include the coordination, preparation and ordering of vaccines and vaccination equipment in a way that satisfies the six rights of supply chain management. It also includes the function of overseeing systems to ensure that they are being used in an optimal manner and that cold chain equipment and transportation is maintained (Essential Programme on Immunization, 2020). Vaccine management entails the establishment of standard operating guidelines for the authorisation and reception of products and the activity of physically receiving vaccines and managing stock levels. The latter activity also involves the management of all relevant documentation and according to the Essential Programme on Immunization (2020), managers are responsible for, “report-writing and record-keeping of archived documents.”

3.6.1.2. Operational functions of vaccine management

All the functions that have been identified as a sub-section of operational functions are applicable to supply chain management. Firstly, it includes the delivery function of vaccines in coordination with management. The sorting of vaccines and the sorting and allocation of vaccination-related equipment is the second function (Essential Programme on Immunization, 2020). It involves the functions associated with the updating of stock records and monitoring storage temperatures as well as other factors that could influence the efficacy of the product. The third function is the conducting of first-level maintenance to ensure that cold chain equipment is fully operational and up to standard. The final function is concerned with informing management of any apparent problem and ensuring that transparency between personnel and visibility in the supply chain is achieved (Essential Programme on Immunization, 2020).

3.6.2. COVID-19 vaccine supply chain challenges

The vaccine supply chain is delicate and fragile with many components of the supply chain subject to challenges and risks. According to Barnhill (2021), research done by Dr Robert Handfield and Dr Daniel J. Finkenstadt concluded that there are eight potential hiccups and bottlenecks that may occur at every stage of the global COVID-19 vaccine supply chain. These are:

- National security issues: COVID-19 vaccines are being described as liquid gold. The high value and importance of the product has the potential to cause a lot of security issues at different transfer points in the supply chain. These security issues include theft, sabotage and counterfeiting. The disposal of potentially damaged vaccines should be carefully monitored, because they carry the risk of ending up in the wrong hands and being sold on the black market.
- Shortage of personnel: Barnhill (2021) mentions that “as we think about the COVID-19 vaccine, we have to vaccinate the entire value chain.” This means that those who are executing the vaccination process, also need to be vaccinated. This not only includes healthcare workers but also key supply chain personnel. They need to stay healthy in order to get vaccines to their destination. If supply chain personnel are not healthy, vaccine manufacturing, distribution and administration will come to a stop. The lack or shortage of truck drivers is a major concern within the distribution of COVID-19 vaccines.
- Lack of Coordination: Each government has to clearly communicate their vaccination plan to all parties involved. If a plan doesn’t exist or isn’t communicated it cannot be executed by

supply chain and healthcare personnel. The vaccination plan or programme needs be clear in order to avoid risks such as potential shortages, hacking, inequities etc. Coordination also includes tracking and tracing who has been vaccinated. A clear communication portal needs to be established for this purpose, where data integration can take place.

- Shortage of supplies: Vaccines can only be manufactured if the correct raw materials are available. There has been a lack of critical materials such as vials, rubber stoppers and natural rubber, which could cause severe bottlenecks in production and is of major concern. It is important to emphasize that macro elements for example weather patterns and factory shutdowns that influences the functionality of the supply chain have always existed; managing these risks are just more important now than ever.
- Limited Capacity: This refers to the capacity restrictions on the production front and limited freezer capacity. The high vaccine demand has caused bottlenecks at fill-finish capacity. The terms represent the ability of the liquid vaccine to be put into vials for distribution. Not only is production capacity limited, but a few production and storage facilities are experiencing a shortage of skilled personnel.
- Vaccine damage: Most vaccine damage will probably occur in the cold chain. If correct temperature levels are not maintained at all stages of the cold chain, vaccines could become ineffective. Vaccines have a limit of two package repacks before there is no way to recover because too much temperature variation has taken place. The last-mile of the vaccine supply chain is extremely important and once vaccines are taken out of the cold chain only a five-hour window exists, before deterioration starts. Factors such as vehicle and equipment malfunctions during the delivery process, need to be considered and monitored, especially in rural areas.
- Gaps for Rural Areas: Rural areas propose major challenges for vaccine distribution and storage because of the lack of cold storage capacity. This is especially applicable to the South African setting. Barnhill (2021) suggests that temperature trials should be run at pallet level with vaccine carrying containers to test the ability of the temperature-controlled environments in rural areas. This should identify problem areas, which could then be addressed before significant amounts of COVID-19 vaccines are actually shipped to these areas.
- Misinformation about Vaccines and Tracking: Early research suggests that ±60% of a country's population is hesitant to get vaccinated against COVID-19, because of the mistrust

of their government and misinformation about the vaccine. Government and healthcare workers need to educate citizens on the importance of a COVID-19 vaccine and there needs to be complete transparency and open communication from government.

These challenges will probably vary, occur and reoccur as the vaccination process starts in each country. Collaboration and sharing of resources between governments could create a learning opportunity so that challenges are mitigated and overcome.

3.6.3. COVID-19 vaccine supply chain optimization

National healthcare systems around the world are working at a tremendous speed to secure and distribute COVID-19 related medical supplies and administer vaccines. This difficult task starts with acquiring enough doses, transporting them safely to multiple destinations, maintaining their required temperature and guaranteeing product integrity (Five ways to optimize the COVID-19 vaccine supply chain, 2020). According to a study done by KPMG (2020), there are five ways to optimize the COVID-19 supply chain. Those optimization tools include:

1. Planning is the key to success: Decent and sufficient planning is essential to understand the ability and capability of infrastructure and critical assets such as freezers and refrigerated trucks in the supply chain. Demand and supply chain planning is equally significant. The amount of required vaccines, vaccination equipment, vaccination locations, refrigerated trucks etc. must all be clearly identified and planned accordingly.
2. Keep vaccines at the correct temperature: This component will be elaborated on in section 3.8, because cold storage is a fundamental element of the COVID-19's, or any vaccines', supply chain. Healthcare systems are definitely being challenged with an increased need for cold storage facilities and temperature-controlled environments to maintain product integrity. Optimization can take place through managing end-to-end temperature logging, executing real-time monitoring, reporting and evaluation of temperature, shock and moisture and taking corrective action if required levels are not achieved. It is significant that supply chain managers are informed about the geographical setting and circumstances of the intended location of the vaccine doses in order to plan accordingly or make needed adjustments.
3. Tracking and tracing: Supply chain visibility is extremely important for supply chain managers to know exactly where available vaccines are and whether or not damage or theft has taken place. COVID-19 vaccine batches should be tagged, with each tag containing data on the location of the shipment and whether or not the vaccine has been administered. Stock can

also be identified based on their manufacturer and expiry date. Post-vaccination tracking places an important role in evaluating efficacy and the planning of a second dosage. If data is regularly captured, stored, transferred and processed, it simplifies the management of the vaccine supply chain.

4. Ensure product integrity: The COVID-19 vaccine will pass through many locations and hands before it reaches its final destination, which makes it vulnerable and exposed to counterfeiting, tampering, contamination or theft. These vulnerabilities can be addressed through serializing batches for easy identification and making use of Internet of Things (IoT) devices to monitor the chain of custody based on signed proof of pick-up and delivery. It is vital that all employees who come in contact with the vaccines should be trained in identifying counterfeits or mismanaged shipments.
5. Managing last-mile delivery, reverse logistics and post-vaccination tracking: The most significant part of the COVID-19 vaccine supply chain is the last-mile delivery. Last-mile delivery usually consists of smaller trucks and carriers, making multiple deliveries to healthcare centres, hospitals or pharmacies. In order to avoid wastage at these locations, accurate volume flow is required because of on-site capacity limits and the cold chain requirements of vaccines. According to KPMG (2020), last-mile carriers, "must be equipped with cold chain storage and precious cargo facilities, commandeered by licensed drivers and integrated into track and trace systems to assure 24/7 visibility for both delivery and returns."

Governments, supply chain managers and healthcare systems can use these optimization tools to overcome some of the challenges mentioned in the section above.

3.7. THE VACCINE COLD CHAIN

Hundreds of manufactured vaccines need to be delivered to vaccination programs or clinics and healthcare facilities around the world and stay safe and uncompromised until they're required (Vaccine cold chain Q&A, 2020). They are biological products and if the active ingredient of a vaccine gets too hot or too cold it can degrade and become less effective. Thus, vaccines need to be placed in a cold chain because of their characteristics, sensitivity, and viability requirements. According to Maurya (2016), the cold chain, "is a system of keeping vaccines at their recommended temperature from the point of manufacturing to the point of vaccination of the beneficiary."

The vaccine cold chain consists out of a global network of cold rooms, freezers, refrigerators, cold boxes and carriers, as displayed in Figure 3-4. These vaccines need to be kept at the exact, required temperature during each link of the supply chain (Vaccine cold chain Q&A, 2020). The cold chain usually starts once products are placed in the cold chain at the manufacturer and ends once patients are vaccinated. The elements of a generic vaccine cold chain can be seen in Figure 3-5. This cold chain consists out of four or five components/facilities that are linked together through a variety of transport modes and cooling systems. The facilities or components include the manufacturing site, primary storage facilities, national storage, district level or provincial storage facilities, primary health care centres and sub-health care centres.

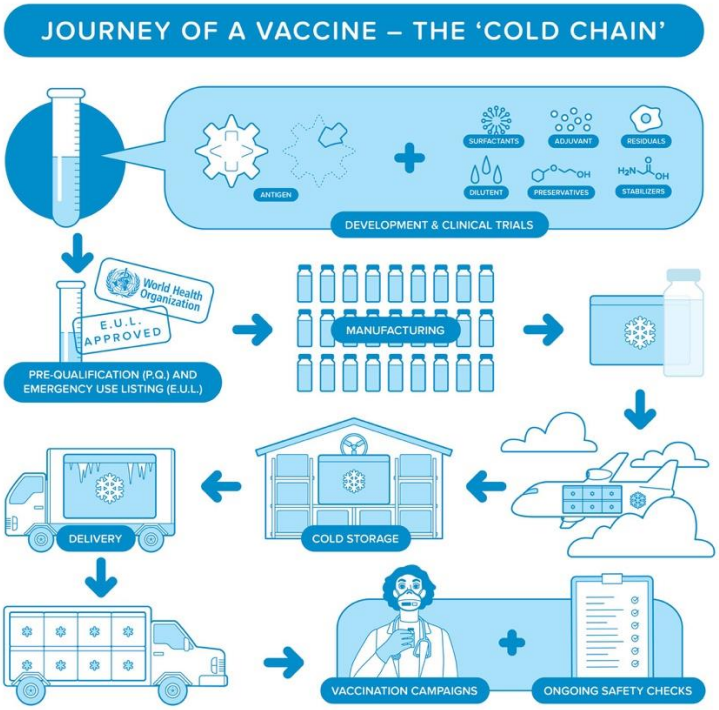

Figure 3-4: Temperature controlled environments of a vaccine cold chain

Source: PAHO, 2020

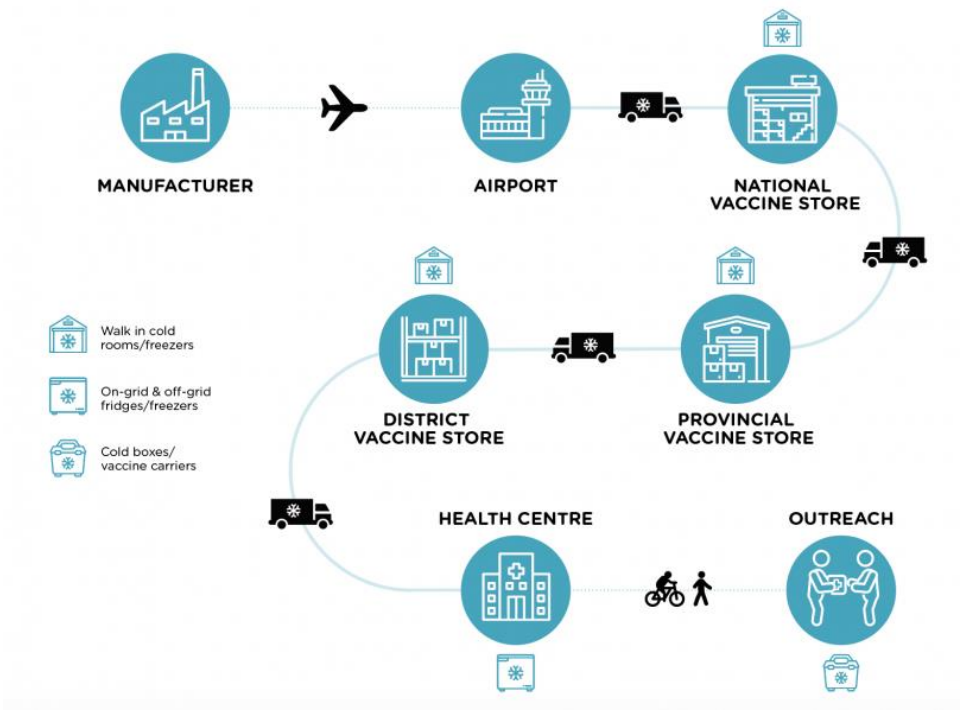

Figure 3-5: Product flow of a generic vaccine cold chain

Source: Peters, 2020

3.7.1. Vaccine cold chain requirements

As mentioned earlier, vaccines are biological products and are very sensitive to temperature fluctuations. If they are exposed to temperature levels outside of their recommended temperature range, they can become less effective, or even destroyed (Maurya, 2016). Maintaining the vaccine cold chain is extremely important because human beings are involved, and vaccines suffer a loss of potency every time they are exposed to temperatures outside of their required temperature range. Research done by Maurya (2016) revealed that, "repetitive exposure to heat episodes results in a cumulative loss of potency that is not reversible." Vaccines are vulnerable to both heat and freezing. The individual temperature requirements of each different vaccine should be known to all personnel who are responsible for either transport, handling or storage and should be clearly indicated on all documentation. Any break in the vaccine cold chain can put patients at risk.

According to several industry experts, vaccines should be stored at their precise temperature requirement from the instance they are produced till they are administered. Most vaccines are stored at a temperature between 2°C and 8°C, with an ideal average of 5°C (Greenwood, 2021). Other vaccines have extreme cold chain requirements ranging from -75°C to -15°C. According to Greenwood (2021), "Many live-virus vaccines can tolerate freezing temperatures and rapidly

deteriorate once defrosted." Inactive vaccines on the other hand more generally require a stable temperature range of 2°C - 8°C.

Temperature is not the only factor that could influence vaccine efficacy and potency. Some vaccines such as the vaccine against Measles, Bacille Calmette-Guérin (BCG) and Rubella (MR) are very sensitive to light. If these vaccines are exposed to strong light, it could cause a loss of vaccine potency. Light sensitive vaccines need to be kept away from sunlight or should be protected from UV-light with the appropriate packaging (Pan American Health Organization, 2019). The vulnerability of each vaccine can be summarised in terms of heat, light and freezing (Maurya, 2016). Other factors that should be monitored based on each vaccine's requirements are vibration, humidity, shelf life and tilt.

3.7.2. Vaccine cold chain management

There are three elements that need to be combined if proper vaccine transport, storage and handling is to take place. The first element is trained personnel and refers to all personnel throughout the supply chain that comes into contact with the vaccine (Maurya, 2016). The second element is transport and storage equipment. Equipment needs to be functional and able to reach or provide the required temperature levels. Transport vehicles need to be serviced regularly and the operational ability of freezer units should be monitored. The last element is the efficient management of procedures (Maurya, 2016). This element is required to ensure that the first two elements are managed, monitored, and executed according to required standards.

For vaccines to be stored efficiently there are certain steps that need to be taken by cold chain participants/members. The Centre for Disease Control and Prevention (CDC) recommends that each of these members should develop and maintain a comprehensive transcribed plan for the following activities involved with the distribution and storage of a specific vaccine: ordering, acceptance, handling, storage, and accounting for emergency storage locations (Greenwood, 2021). These comprehensive plans could assist in avoiding situations such as storing vaccines over their expiry date or deep freezers being too warm (higher than -14°C) and refrigerators being too warm (higher than 8°C). According to Arnot (2019), managers in the cold chain are responsible for monitoring and managing these eight sections:

- The storage temperature under refrigeration;
- Logs, including temperature and refrigerator logs;

- Vaccine inventories;
- Separation of stock locations;
- Freeze indicators;
- Assessing vaccines on arrival;
- Packaging vaccines for transit;
- Management of temperature excursions; and
- Refrigerator specifications.

The detail and specifications of each section will differ with each vaccine. These eight sections are used and applied, in the next section, to the South African COVID-19 vaccine setting because this framework was developed for other vaccines by the Western Cape government in South Africa. It is one of the ways in which the tasks included in cold chain management of a COVID-19 vaccine can be summarised.

3.7.3. Vaccine cold chain infrastructure and equipment

Different equipment and infrastructure are needed at different steps or phases of the vaccine cold chain. They range from walk-in coolers to ice packs, each used to maintain the specific temperature requirement of the vaccine being stored and transported. Walk-in coolers and freezers are usually located at regional or provincial level and are used at manufacturing facilities, primary storage locations or national, provincial and district locations (Maurya, 2016). Walk-in coolers maintain a temperature range between 2°C and 8°C, walk-in freezers on the other hand uphold a temperature range of -25°C to -15°C. Both are used to store vaccines for up to three months.

The next extensively used equipment is a 300ℓ/140ℓ deep freezer. Deep freezers are mainly used at district level or district storage facilities and primary health centres like hospitals and clinics (Maurya, 2016). These freezers are predominantly used to store and prepare ice packs, but can also be used for vaccine storage and maintain a temperature range between -25°C and -15°C. The 300ℓ storage capacity enables them to store between 15 000 and 20 000 vaccine doses and the 140ℓ storage approximately 20-25 ice packs. It is very important that deep freezers are used and packed in the correct way to ensure that proper airflow and freezing is obtained.

Ice lone refrigerators (ILR) are primarily used and utilized for storing vaccines for up to one month. They have a temperature range between 2°C and 8°C with a storage capacity of 25 000 to 60 000 doses, depending on the vaccine. Maurya (2016) recommends that ILR's and deep freezers should

be kept in a cool room away from direct sunlight, the equipment must be clearly labelled and should be locked and only opened when necessary. Personnel should avoid over filling deep freezers and ILR's, because it damages the equipment and could shorten their life span and usefulness (Maurya, 2016).

Cold boxes are another piece of equipment that is used to transport vaccines between links of the cold chain. The most common sizes of cold boxes that are used are 5ℓ and 10ℓ. These can maintain a temperature betwixt 2°C and 8°C and are very convenient because they require no power/electricity. Ice packs in a frozen state are packed at the bottom and on the sides of the cold box whereafter vaccines are placed on top of them (Maurya, 2016). Avoid packing or positioning vaccines in direct touch with ice packs and keep vaccines in their carton or polythene bags. Vaccine carriers are very similar to cold boxes, but much smaller and are used to carry small quantities of vaccines for a certain vaccination session. Their holdover time is ±12 hours and their capacity allows a maximum of 20 vials and four ice packs (Maurya, 2016).

Ice packs are one of the most useful pieces of cold chain equipment. They are used to line the walls of vaccine carriers, cold boxes or even day boxes. Approximately 48 hours is required for them to fully freeze in a deep freezer whereafter, they can be used to regulate temperature between 2°C and 8°C. Ice packs should be regularly checked for leakage and should be allowed to "sweat" at room temperature for fifteen minutes before they are used (Maurya, 2016). This allowance prevents freeze-sensitive vaccines from freezing when put in contact with ice packs. The last piece of cold chain equipment that is used throughout the vaccine cold chain in almost all other cold chain equipment is a thermometer. Thermometers verify the temperature of cold chain storage on a daily basis and are used to easily identify fluctuations in temperature. A summary of the different cold chain equipment can be seen in Figure 3-6.

Research done by Maurya (2016) concluded that there are a few basic guidelines that should be followed when cold chain equipment is used in vaccine storage facilities or in transit. For example:

- Follow the "First-in-First-out" (FIFO) rule as well as the "First to expire – First out" (FEFO) rule.
- As mentioned earlier, vaccines should be stored according to their individual temperature need and cold chain equipment should be changed accordingly.

- Vaccine appearance does not change even if product efficacy is lost due to exposure to temperature above the recommended range. Damage cannot be reversed by re-freezing vaccines.

Figure 3-6: Summary of cold chain equipment

Source: Maurya, 2016

3.7.3.1. Vaccine cold chain technologies

Cold chain equipment can further be supported and specified through cold chain technologies. Dry ice is one of the most common cold chain technologies that is used throughout the cold chain of several vaccines. It can keep extremely low temperatures and it does not melt. Gel packs are also used to control the temperature environment of vaccines during transportation. Depending on the

transportation modus that is being used these gel packs are either in a frozen or refrigerated state. Eutectic plates are very similar to gel packs and in vaccine cold chains they are used in delivery vehicles that cover a short distance or time period. For example, delivery vehicles that are used to transport vaccines from primary health care centres to smaller clinics or local centres could make use of eutectic plates. As displayed in Figures 3-4 and 3-5, refrigerated containers (reefers) are used throughout the vaccine cold chain and the cold chain could not exist without them. Reefers will vary from cold chain to cold chain depending on the quantity and size of the shipments.

3.7.4. Vaccine cold chain operations

A vaccine cold chain consists out of the same cold chain operations that were mentioned in section 3.3.4. These operations are required to ensure and uphold vaccine product integrity. The first phase in vaccine cold chain operations is shipment preparation. This phase predominantly takes place at manufacturing sites and primary storage facilities. Shipment preparation is used to determine the exact characteristics and cold chain requirements of the vaccine that is being transported and stored. The phase is used to make sure that vaccines are in the correct packaging and at the required temperature before they are shipped to their destinations or the next cold chain link. During preparation, the load unit carrying the vaccine shipment is prepared, refrigerated containers used in transportation and storage are steam cleaned and containers are prepared according to the temperature requirements of the specific vaccine.

The next operation is modal choice. The type of transport modes that are used in a vaccine cold chain will largely depend on the location of vaccine production and the final destinations or the location of patients. Air transport is predominantly used to transport vaccines from continent to continent. The critical time factor of vaccines makes this the most obvious choice for international delivery. Road transport will usually follow, once vaccines have reached their intended continent or country. Road transport is used to transport vaccines from one facility to the next and includes trucks, refrigerated vans and even motorbikes, for smaller deliveries. Transport modes such as rail, pipeline and maritime are not commonly used in a vaccine cold chain.

Custom procedures are the third cold chain operation and are applicable on every vaccine cold chain. Once vaccines cross borders they are subject to certain customs. Time spent in inspection at customs must be monitored and managed because of the time-sensitivity of vaccines. Each different vaccine cold chain will need to adhere to a certain set of customs that are subject to change,

depending on their individual scenario. Each country will have their own customs' requirements for each vaccine entering their borders. The "last mile" is the fourth cold chain operation and refers to the last stage of the vaccine delivery process, when vaccines are moved from district storage facilities to healthcare centres and finally to patients. Many industry experts like Dr Robert Handfield and Dr Daniel Finkenstadt are of the opinion that this is the most challenging, yet important component of the vaccine cold chain. Refrigerated vans or even motorbikes equipped with vaccine carriers are used in this stage. Each vaccine cold chain will face different challenges and operations in their last mile.

The final vaccine cold chain operation that should be considered is product integrity and quality assurance. Temperature monitoring takes place at every supply chain link of the vaccine cold chain with the help of monitoring/recording devices. The data produced by these devices should constantly be analysed and interpreted to take rectifying action when needed. If temperature is managed throughout the vaccine cold chain, it supports the integrity and quality assurance of the vaccine.

3.7.5. Vaccine cold chain challenges

Both vaccine cold chains and ultra-cold chains have certain challenges associated with them. According to PAHO (2020), the biggest challenge for either is electricity. A lot of cold chain equipment such as refrigerators and freezers require a consistent power source. Ultra-cold freezers, required for certain vaccines, need even more. The biggest challenge associated with vaccines' power need is an unreliable power grid and the use of generators. Some storage facilities in certain countries are not guaranteed electricity and incur higher costs to operate generators and store vaccines at their required temperature (PAHO, 2020).

Storage capacity throughout the vaccine cold chain is another challenge and is made even more difficult by the need for ultra-cold formulations. This factor is especially earning a lot of focus because of the COVID-19 pandemic and the vaccines' demand for storage. Almost all international, national, and domestic cold storage capacity is already being used for the storage of routine vaccines (PAHO, 2020). The pandemic demands the multiplying of materials, cold chain infrastructure, logistics operations and coordination, which causes a bottleneck in the industry. The challenges associated with storage capacity need to be overcome without removing storage space from critical

vaccines that are currently making use of the existing cold chains' infrastructure and equipment (PAHO, 2020).

The third challenge associated with vaccine distribution is time. In most vaccine cold chains, a period of four to six months passes before vaccines reach their intended location. COVID-19 has created an immediate need for vaccines which lead to a more compressed timeline ranging between one and two months, from production to patient. This compressed timeline benefits earlier delivery, but it does not allow governments and health care centres a lot of time to prepare cold chain equipment (PAHO, 2020). The last challenge linked to a vaccine cold chain, according to PAHO (2020), "is the unprecedented level of collaboration this will all require." For a vaccine cold chain to function properly both material components and human beings are required. People need to be connected and able to rely on each other to effectively use cold chain equipment (PAHO, 2020). The challenges that the industry currently face because of COVID-19 requires all cold chain members to work together to overcome them.

3.8. THE COVID-19 VACCINE COLD CHAIN

All COVID-19 vaccine candidates need to be placed in a cold chain because of their characteristics and temperature sensitivity. The cold chain, if managed effectively, allows these vaccines to be transported between continents and countries without losing their efficacy. The COVID-19 vaccine cold chain stretches over international borders and each link in the supply chain needs to be held accountable for ensuring the safety and integrity of a vaccine shipment. More than one COVID-19 vaccine exists, which means that these cold chains will look slightly different for each vaccine depending on their cold chain requirements, manufacturing location and destination. An example of a COVID-19 vaccine cold chain can be seen in Figure 3-7. The elements and components of these cold chains, displayed in Figure 3-7, are different because of their individual temperature requirements. According to Peters (2020), "most COVID-19 vaccine related research is focused on developing, testing and manufacturing an effective vaccine, little attention is given to distribution requirements."

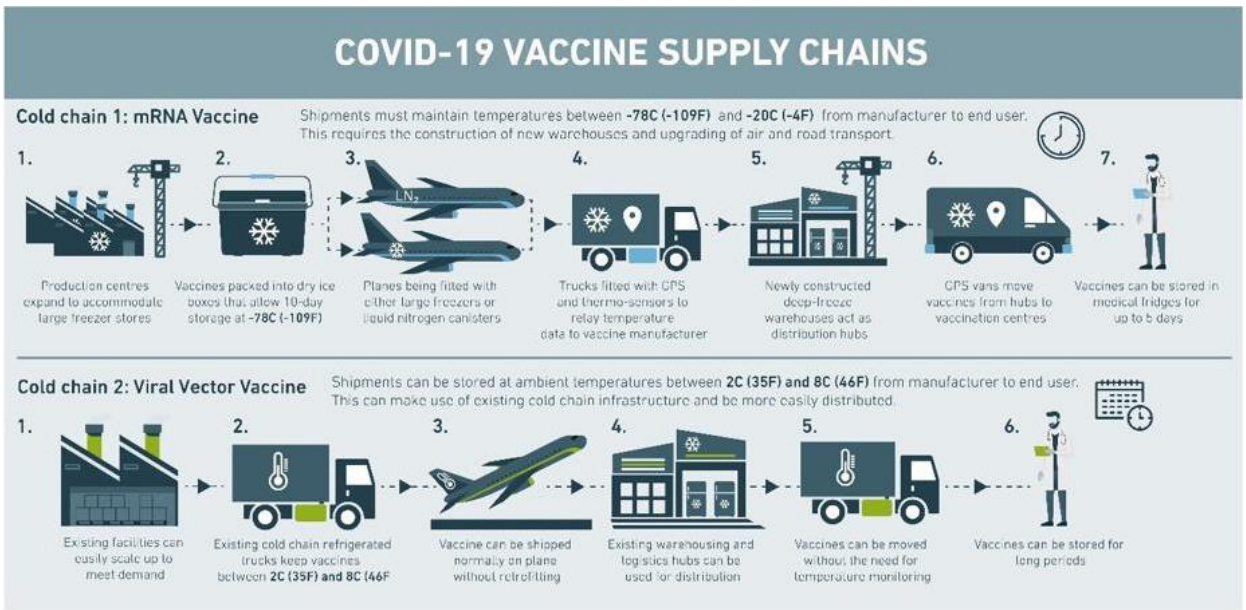

Figure 3-7: Example of a COVID-19 vaccine cold chain

Source: Wood, 2021

Figure 3-7 indicates that a COVID-19 vaccine cold chain starts once vaccines are manufactured and ends at the final health care facility or vaccination location. Air transport is used to deliver vaccines to different countries and road transport is used once vaccines need to be transported from the airport or between different storage facilities. A variety of cold chain equipment including walk-in freezers and refrigerators, deep freezers, cold boxes, vaccine carriers and ice packs are used at storage facilities or during transportation.

3.8.1. COVID-19 vaccine cold chain requirements

Although individual COVID-19 vaccines have different cold chain requirements, all of them are temperature sensitive. According to PATH (2020), most COVID-19 vaccines must be kept frozen at about -20°C. Information from the WHO (2021) indicates that there are three storage requirements that COVID-19 vaccines are grouped by. These are summarised in Table 3-2. COVID-19 vaccines that fall into category 3 require a major capital investment because of their ultra-cold chain storage requirement and the additional training or upskilling of personnel for the handling of these vaccines and associated equipment (WHO, 2021).

Table 3-2: COVID vaccine categories

Category	Temperature Standard	Temperature (°C)	Type of equipment needed

1	Chill	2°C - 8°C	Cold chain equipment
2	Frozen	-20°C	Cold chain equipment
3	Deep Frozen	-70°C, ±10°C	Ultra-cold chain equipment

Source: WHO, 2021

Shelf life is another cold chain requirement that varies from vaccine to vaccine. This requirement should be considered when a COVID-19 vaccine candidate is procured and stored. Most COVID-19 vaccine candidates can last for at least six months if stored in a temperature-controlled environment (WHO, 2021). Although humidity is suggested to have an effect on the transmission of Coronavirus, it is not yet shown to have an impact on the vaccine itself. Early studies suggest that caution should be taken to minimize shaking or agitation during transportation or movement of the Covid-19 vaccines. This is due to the fragility of the products and each type of Covid-19 vaccine will have its own guidance regarding the amount of shaking/vibration or agitation it can handle during transportation or movement (COVID-19: Vaccine Storage and Handling Guidance, 2021). Most COVID-19 vaccines should be protected from light during storage. Exposure to direct sunlight and ultraviolet light should always be avoided and exposure to room light should be minimized during storage. Packaging can be used as method to protect vials from light during storage (WHO, 2021).

3.8.2. COVID-19 vaccine cold chain infrastructure and equipment

According to the guidelines established by the WHO (2021), “Pharmaceutical warehouses, including cold chain facilities, need to be efficiently laid out and should contain all the necessary storage areas, goods assembly, packing, receiving, dispatch bays, offices and ancillary accommodation needed for the effective operation of the store.” Most COVID-19 vaccine cold chains consist out of the same cold chain equipment. Equipment and their temperature range will vary slightly based on the specific need of the vaccine in transit or storage. There are some exceptions such as the Pfizer-BioNTech COVID-19 vaccine that requires ultra-cold chain equipment (WHO, 2021). Cold chain equipment used during transportation should be developed and utilized in such a way that shaking and agitation is minimized during the transit stage. During transportation and storage, vaccine vials should always be kept upright. According to the COVID-19 vaccine guideline created by the WHO (2021), all cold boxes or vaccine carriers should be labelled “Fragile: Handle with Care, Do Not Drop”.

Although the temperature requirements of COVID-19 vaccine candidates differ, all manufacturing facilities make use of either walk-in freezers or walk-in refrigerators to store vaccines. During storage, deep freezers and ice-lined refrigerators are used to maintain the essential temperature range at either a national, provincial, district or private storage facility (WHO, 2021). Most COVID vaccines requires a temperature range of between 2°C and 8°C when they are being transported. This entails cooled or reefer vehicles, cold boxes, vaccine carriers and ice packs to maintain the required range (WHO, 2021).

3.8.2.1. Cold chain technologies

Refrigerated water packs and conditioned ice packs are used to assist storage and transportation equipment to uphold the desired temperature level, between 2°C and 8°C. These two pieces of equipment need to be stored in a refrigerator for a minimum of 24 hours preceding storage or transportation activities (WHO, 2021). According to the WHO (2021) guidelines, ice packs should be conditioned at room temperature for one to two hours before they are used and should never be positioned in direct contact with a vaccine vial. Ice or gel packs are used to maintain a temperature of -20°C during transportation and storage and must be completely frozen prior to use (minimum of 24 hours spent in refrigerator). Bagged or loose ice should never be used during storage or transportation to maintain a certain temperature.

3.8.3. COVID-19 vaccine cold chain operations

There are five cold chain operations that need to be considered in the COVID-19 vaccine cold chain. These operations are shipment preparation, modal choice, custom procedures, last mile and product integrity and quality assurance. COVID-19 vaccine cold chains will have similar or basic cold chain operations, but operations will vary when individual vaccine characteristics and cold chain requirements are considered. Cold chain operations of COVID-19 vaccines that are applicable to the South African setting will be identified and elaborated on in Chapters 4 of the research.

3.8.4. COVID-19 vaccine cold chain management

COVID-19 vaccine cold chain management is a crucial factor for ensuring that the distribution of COVID-19 vaccines is done in a safe and effective manner. It entails the management and maintenance of required temperature levels in processes such as manufacturing, storage, transportation and distribution for highly sensitive vaccines (Eisenhart, 2020). Cold chain managers need to manage and monitor temperatures throughout transportation and storage and make sure

that adequate cold chain technologies are in place. In the COVID-19 vaccine cold chain there are various stakeholders including pharmaceutical manufacturers, logistics providers, healthcare providers and laboratory equipment manufacturers. Vaccine cold chain managers are responsible for the coordination and cooperation among these stakeholders (Eisenhart, 2020).

The WHO (2021) suggests that these are some of the primary activities that should take place through the management of a COVID-19 vaccine cold chain:

- Individuals and appropriate entities should be assigned to receiving and acceptance responsibilities.
- The cold chain capacity of each country, warehouse and facility should be determined to assist decision-making in the selection of vaccines.
- The responsibility of mapping all cold chain storage points.
- Monitoring the temperature range at specific public and private storage points.
- Perform a gap analysis to identify/establish the exact cold chain storage requirements.
- Activities involved in the preparation of warehouse storage and transport before and during the vaccination campaign.
- Reverse logistics.

If cold chain managers identify a specific need or gap during these primary activities appropriate action should be taken. For example, if storage capacity is insufficient, cold chain managers should attempt the leasing of a private facility, procure ice lined refrigerators and/or cold boxes and vaccine carriers or split the shipments and increase delivery frequency (WHO, 2021).

3.8.4.1. Transportation of vaccines

Whether air transport or road transport is being used in the vaccine transportation process, temperature levels need to be monitored and managed. Data loggers are the preferred temperature monitoring option as they are responsible for monitoring the temperature of the vaccine vial during the delivery process (WHO, 2021). For the first, temperatures should be checked at the beginning and end of the trip and for the latter, temperature should be checked at least twice during the trip.

During the COVID-19 vaccination campaign, the availability of all transport resources and operators should be monitored and fuel should be readily available. Timelines should be established, and the progress of shipments should be monitored while taking into consideration security problems,

climate conditions and road conditions that could affect delivery periods. The refrigerator units of delivery vehicles need to be checked regularly to determine functionality or fault (WHO, 2021).

3.8.4.2. Reverse logistics

According to the WHO (2021), reverse logistics refers to, "the process of retrieving unused vaccines and other supplies either to dispose or reuse." In COVID-19 vaccine cold chain management, this activity is crucial for safety and accountability reasons. Most COVID-19 vaccines, in early production, have a manufacturing date but not an expiry date. It is important to guarantee that all vaccine vials are properly accounted for in every single healthcare or storage facility and that any unused vials are returned to a central or provincial storage facility. Cold chain managers need to enforce exact stock management, vaccine inventory management, correct storage and transaction recording at all supply chain links. These practices need to be enforced during and after the vaccination campaign, during a possible temporary pause and if the vaccine is recalled for any reason (WHO, 2021).

3.8.4.3. Management of supply chain and cold chain information

Successful COVID-19 vaccine deployment is dependent on the close management of supply chain information, including cold chain information. The following three information management matters assists successful distribution of vaccines. Firstly, information regarding the monitoring of cold chain capacity and performance should be managed to guarantee safe storage space availability at distribution points. Secondly, to confirm the right number of vaccines are transported to every site, information regarding stock distribution and consumption should be monitored. Lastly, cold chain information should be managed closely to ensure sufficient distribution (vehicles, carriers, etc.) capacity to deliver vaccines on schedule, as promised (WHO, 2021). Four areas exist from which supply chain information/data are collected, recorded and analysed in order for supply chain and cold chain management to deliver. These are cold chain storage capacity, cold chain performance, supply chain and reverse logistics. Table 3-3 provides a summary of the activities that is related to reporting information in each area.

Table 3-3: Information/data requirements

Area	**Key data for review**
Cold chain storage capacity	• Current available cold chain storage capacity at target sites.

	• Forecasted storage need for COVID-19 vaccine and current available capacity.
Cold chain performance	• Temperature monitoring log for any cold chain equipment (CCE) storing COVID-19 and Expanded Programme on Immunization (EPI) vaccines. • Functionality of CCE required vaccines. • Performance/functionality of generators supporting CCE.
Supply chain	• Performance of delivery timelines. • Proportion of planned target deliveries confirmed as delivered. • Stocks and consumption rate of COVID-19 vaccine. • Location of stocks.
Reverse logistics	• Tracking of all vials (open, unopened and used). • Report to collect and record after each round of vaccination.

Source: WHO, 2021

Management information systems (MIS) are used before and during vaccination campaigns. During the COVID-19 vaccine rollout, this system is used to contact warehouses and mobilize personnel, track and trace vaccines through barcodes, dispatch vehicles and operators, report on insufficient personnel and to monitor the delivery of vaccines. Monitoring delivery allows cold chain management to identify delays due to any external factors such as climate, traffic etc. (WHO, 2021).

Barcodes and QR codes are used in the tracking and tracing of vaccines by providing rapid, in-time information on their whereabouts, origin, expiry date etc. QR codes are displayed on secondary and tertiary packaging containers but are not present on all vaccine packaging. When scanned they display the following information regarding the vaccine: real-time shelf life; heat stability and new information on vaccine profiles. Barcodes on the other hand, when scanned, display manufacturer's information, lot/batch numbers and an expiry date (WHO, 2021). The problem with barcodes is that they are only included on secondary packaging and not on the vaccine packaging itself. This means that the ability to scan a barcode is lost if a shipment is removed from its secondary packaging. For example, if smaller vaccine quantities, removed from their secondary packaging, are sent to rural communities, all vaccine-related information must be handled manually because no barcode is present (Conway, 2021). The absence of a barcode or tracking system also requires vaccinated individuals to retain a piece of paper in order to know which vaccine they received, when and where.

According to Conway (2021), "proper documentation is also vital in monitoring for adverse event reactions."

3.9. VACCINE PACKAGING

In 2005, the WHO published a document called 'Guidelines on the international packaging and shipping of vaccines' that was created by the Access to Technologies team of the Department of Immunization, Vaccines and Biologicals. This document provides the basic guidelines for packaging standards, temperature monitoring devices, storage volume standards, labelling and packaging and standard shipping and arrival procedures.

3.9.1. Insulated packaging standards

The document states that vaccines are classified into one of three categories based on their thermostability and presentation, each category with its own insulated packaging standards (Guidelines on the international packaging and shipping of vaccines, 2005). Class A packaging is applicable to any vaccine that's highest temperature inside the insulated packaging should not rise above 8°C, whilst a vaccine in Class B's insulated packaging should not be higher than 30°C. Both of these insulated packaging should be able to maintain the indicated temperature for at least 48 hours when exposed to temperatures of 43°C. Class C packaging on the other hand, has the same requirements as Class B, but has the exception that the vaccine's coolest storage temperature should not be lower than 2°C in a continuous external temperature of -5°C (Guidelines on the international packaging and shipping of vaccines, 2005).

3.9.2. Temperature monitoring devices

It is important that all vaccine shipments, including COVID-19 vaccines, need to include temperature monitoring devices, no matter the vaccine's class, destination, origin or characteristics. According to the WHO (2005), these devices have mainly two functions:

- It serves as a quick reference to aid recipient countries in knowing whether or not parts of or the whole shipment has been exposed to temperatures that would influence their efficacy or potency.
- It supports the procurement agency to determine when, where and to what extent temperature limits have been exceeded.

The WHO guidelines, recommend that temperature monitoring devices should be checked at all stops in the supply chain and recipients should make sure temperature limits where not exceeded, before accepting a shipment.

3.9.3. Labelling and packaging

Vaccine packaging consists out of three levels, namely primary, secondary and tertiary packaging. Primary packaging represents the first level of vaccine packaging and refers to the vaccine vial or ampoule. Secondary packaging includes any intermediary packaging that holds the primary packages (e.g., vaccine vials). Materials used for this level needs to be clearly labelled and indicate the following information: vaccine type, name of the manufacturer, presentation, batch number, date of manufacture, expiry date, quantity and storage conditions (WHO, 2005). The third level or tertiary packaging is the outer box and refers to the shipping container that contains the secondary packages. Tertiary packaging is usually insulated packaging and their external surface should either be white or a natural colour of corrugated carton. All labelling must be attached to all four sides of the package and must be written in a language appropriate to the destination country. Any shipment in its three-level packaging should always be accompanied by its appropriate shipping documents (WHO, 2005).

The WHO is responsible for the preparation of labels for vaccine vials and packaging. When COVID-19 vaccines came into production, the WHO developed a working position for vial and carton label requirements to unify the labelling of vaccines supplied through the COVAX facility (Model packaging for carton for vials for COVID-19 vaccines, 2020). An example of labelling requirements for COVID-19 vaccine for carton packaging is displayed in Figure 3-8 and for vials in Figure 3-9.

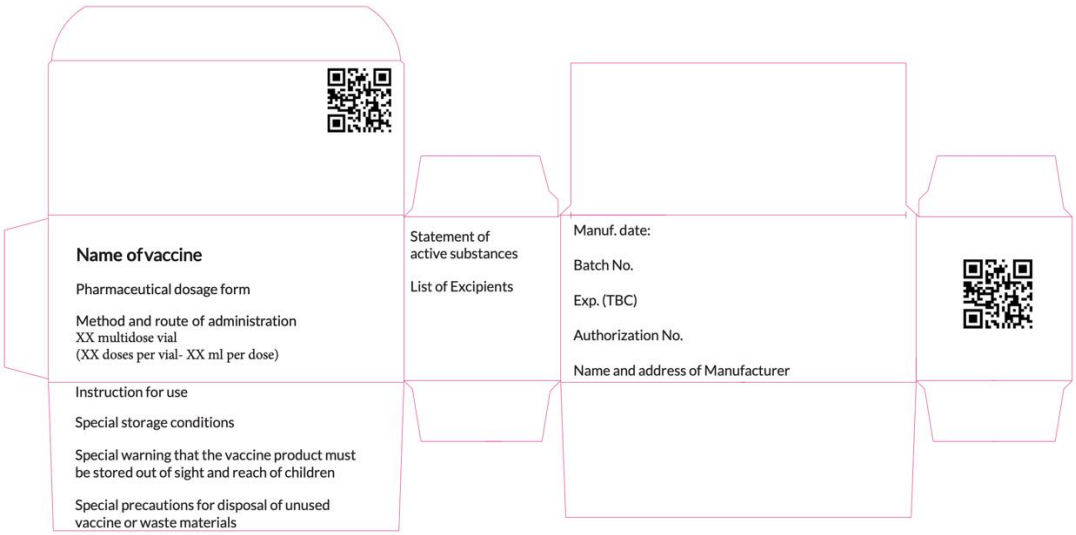

Figure 3-8: Carton packaging labelling requirements

Source: Model packaging for carton for vials for COVID-19 vaccines, 2020

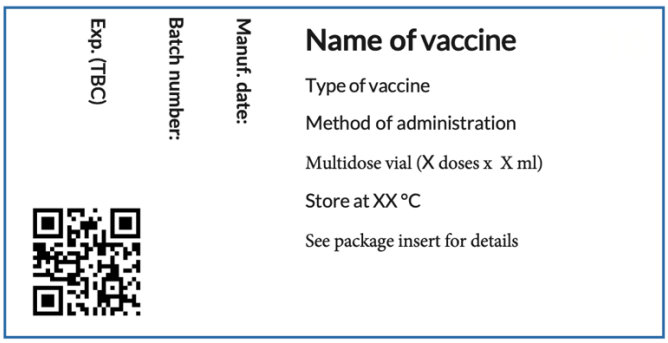

Figure 3-9: Vial packaging labelling requirements

Source: Model packaging for carton for vials for COVID-19 vaccines, 2020

3.9.4. Vaccine packaging materials

The most used material in primary packaging of vaccines is borosilicate glass. Coated aluminosilicate Valor glass is another material used and undergoes an ion-exchange process that aids the minimization of breakage, fractures, and particulate contamination. According to Forcinio (2020:48), "the coating lowers the coefficient of friction and eliminates cosmetic flaws." Stoppers and seals are also used on the primary packaging level. Materials used for secondary and tertiary packaging is explained in section 3.7.3.

3.10. CONCLUSION

An overview of supply chains, cold chains, supply and cold chain management and the vaccine industry are discussed in this chapter to support assumptions about the COVID-19 vaccine supply chain and the elements that should be taken into consideration and managed during its transport, handling and storage. This chapter highlights the importance of knowing the different factors that could influence the efficacy of COVID-19 vaccines throughout its supply and cold chain. Elements such as cold chain technologies, infrastructure, equipment and operations are discussed in terms of the broader vaccine industry and then narrowed down to the COVID-19 cold chain. Broader knowledge regarding vaccines, their requirements and packaging is provided to illustrate how COVID-19 vaccines fit into these sectors and industries.

CHAPTER 4 : THE SOUTH AFRICAN COVID-19 SETTING

4.1. INTRODUCTION

This chapter aims to provide information on the South African vaccine industry and how vaccine supply chains and cold chains function within the country. Due to recent events, the COVID-19 vaccine supply chain and cold chain now form part of the South African vaccine industry, therefore, this topic is elaborated on. The chapter includes distribution challenges that are faced by both the private and public sector in the country because of the importance of administering the product in a short timeframe and its' cold chain requirements. The chapter concludes with the importance of the applicable statutory body in South Africa and the role it plays.

4.2. THE SOUTH AFRICAN VACCINE INDUSTRY

There are several vaccines that are produced, distributed and used in South Africa. These vaccines stretch from routine vaccines such as Chickenpox (Varicella), Flu (influenza) or Polio to vaccines used for Hepatitis A & B, Malaria, Measles, Rabies, Typhoid and Yellow Fever (South Africa Traveler View, 2020). South Africa is a developing country and as a result the South African vaccine industry faces many challenges. Not only is accessibility a problem, but the industry itself is in its infancy state (Dorfman, 2021). The effect of the country's state of infancy was especially felt when the COVID-19 pandemic entered the South African borders.

4.2.1. The production of vaccines

According to Dorfman (2021), South Africa doesn't comprise of significant vaccine manufacturing ability or capacity that would have allowed the country to gain strategic leverage, which could permit easy vaccine access. Although the country has dealt with the production and distribution of vaccines for many years, it is not nearly where it should be, compared to the global vaccine market.

The Biovac Institute is a public-private partnership that exists between a consortium of South African healthcare companies and the South African government. Their goal is to increase vaccine production to have more secure and available childhood vaccine supply for South Africa (Dorfman, 2021). Although efforts are made towards this goal, the industry is currently in its beginning stage and very small in comparison to the global COVID-19 vaccine market (Dorfman, 2021).

Globally, the pharmaceutical industry is larger than that of the vaccine industry, and this fact does not differ when comparing the two industries in South Africa. Aspen Pharmaceuticals is a publicly traded South African-owned global company that operates four pharmaceutical manufacturing and packaging plants in the country. They are currently expanding their market by moving into vaccine packaging because of the high demand caused by the COVID-19 pandemic (Dorfman, 2021). This high demand has caused private vaccine manufacturing companies in South Africa to reconsider their position and size in the global market.

According to Dorfman (2021), South Africa should focus their efforts on rethinking the extent of financial, technical, and strategic resources allocated to vaccine manufacturing if they are serious about supplying anti-pandemic vaccines in the future. Increased resources, allocated to both private (Aspen Pharmaceuticals) and public (Biovac) institutions could allow the country to have adequate vaccine production capacity to use as strategic leverage when negotiating for access to future anti-pandemic vaccines.

4.2.2. Vaccine management and monitoring

Vaccine management, especially proper storage and handling procedures, forms the basis on which excellent immunization practices are built in South Africa (Vaccine Storage and Handling, 2017). Storage and handling errors can contribute largely to the improper management of vaccines during its lifecycle. It can cost companies or countries thousands in wasted vaccines and revaccinations. It can also lead to loss of patient confidence and according to PAHO (2017), it is better not to vaccinate than to administer a dose of vaccine that has been mishandled. South Africa should focus on building excellent practices concerning COVID-19 vaccine management. Vaccine management and monitoring is done by the Department of Health in South Africa.

4.3. THE SOUTH AFRICAN COVID-19 VACCINE INDUSTRY

The South African Government is responsible for sourcing, procuring, distributing and overseeing the rollout of the COVID-19 vaccine. They operate as the sole purchaser of vaccines and assign the product to provincial governments and the private sector (COVID-19 South African Resource Portal, 2021).

The limited vaccine production capacity of the country forces the South African government to procure COVID-19 vaccines from other countries. This is not ideal because access is limited, procurement costs could be high and indirectly South Africa is just fuelling another country's economy while it could be boosting its own (Dorfman, 2021). The effect of the lack of vaccine production capacity stretches all over Africa and not just South Africa. African countries are so focused on internal supply that there is no opportunity for exports to take place. There is no immediate readiness to repurpose facilities for production, due to the restricted, limited number of COVID-19 vaccines that are available. This basically means that Africa, including South Africa, is struggling to get in front of the immunization and accessibility curve or wave (What is Africa's vaccine production capacity, 2021).

South Africa procured its first shipment of COVID-19 vaccines in January 2021. The shipment consisted out of 1 million doses of the Oxford University-AstraZeneca vaccine that was manufactured by the Serum Institute of India (SII). The vaccines were set to be used to vaccinate the country's projected 1.25 million healthcare workers (COVID-19 South African Resource Portal, 2021). The South African government has, however, put off the use of the AstraZeneca's COVID-19 vaccine after information disclosed it offered minimal protection against mild-to-moderate infection of the specific virus strain in South Africa. The country, nevertheless, kick- started its first phase of vaccination, on 18 February 2021, by distributing and vaccinating citizens with the Johnson & Johnson's vaccine (Everything you need to know about the Johnson & Johnson vaccine, 2021).

Aspen Pharmaceuticals is set to start the production of Johnson & Johnson COVID-19 vaccines by March 2021 outside of South Africa. Although these vaccines are transported back to Johnson & Johnson for international distribution, the South African ownership of the company allows nine million doses to remain in South Africa for local use (Dorfman, 2021). The Government has managed to secure 11 million doses of the Johnson & Johnson vaccine of which 2.8 million doses will be delivered in the second quarter of 2021. The rest of the shipment will be received and spread throughout the year (COVID-19 South African Resource Portal, 2021).

Other vaccine suppliers include the COVAX facility who will provide 12 million vaccine doses to South Africa, through the African Union's Vaccine Acquisition Task Team facility. Vaccine candidate choice will be based on availability and appropriate fit to the South African setting as described in section 4.3.1. Another supplier, namely, Pfizer (supplied by COVAX) has committed to delivering 20 million

vaccines to South Africa by the end of the first quarter of 2021 (COVID-19 South African Resource Portal, 2021).

4.3.1. The COVID-19 vaccine program

According to Dr Anban Pillay (2021), there are six key considerations in the selection of COVID-19 vaccines for the South African setting. These considerations include:

- Availability;
- Safety, efficacious and good quality;
- Ease of use and schedule, including the number of required doses;
- Stability during storage and distribution;
- Supply and sustainability, for example, supplier capacity; and
- Cost.

Every newly developed vaccine is evaluated based on these considerations and the vaccine that best fits the South African setting is procured and used in the vaccination program (Du Plessis, 2021). The South African COVID-19 vaccine program includes all activities involved in procurement, distribution, vaccination, monitoring, communication and mobilization. All of these activities need to be executed by individuals, companies, global partners and the South African government (COVID-19 South African Resource Portal, 2021).

The South African Health Department aims to vaccinate 67% of the population, which equates to 40 million South Africans that are stretched out over 52 districts and 280 wards. This is the largest vaccination campaign that the country has ever undertaken (COVID-19 South African Resource Portal, 2021). The country aims to achieve herd immunity through the COVID-19 vaccination program. Herd immunity means that enough people in the community develop a resistance to the disease which prevents them from becoming ill and slows down the spread of an infectious disease, such as COVID-19 (Schoub, 2021). The rollout of COVID-19 vaccines will take place in three phases, as displayed in Figure 4-1 and according to the Deputy Director General, Dr Anban Pillay (Health Regulation and Compliance) the following groups will be targeted in each phase:

- Phase 1: Healthcare workers
- Phase 2: Essential workers, persons in congregated settings, persons older than 60 years and persons older than 18 years with comorbidities
- Phase 3: Other persons older than 18 years

As of April 2021, the country is in Phase 1 due to a limited number of vaccine doses being available.

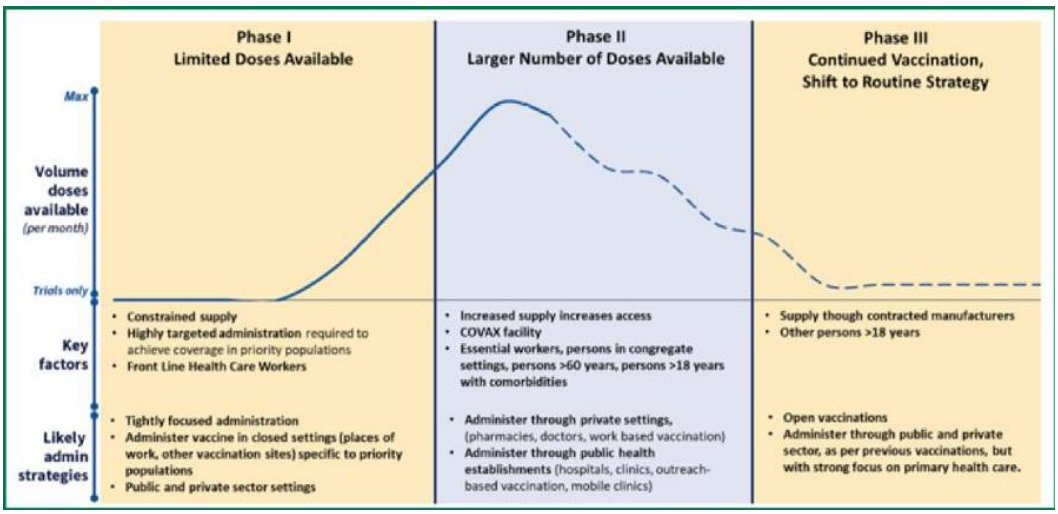

Figure 4-1: South Africa phased rollout plan

Source: Du Plessis, 2021

Figure 4-2 summarizes which populations will be targeted or vaccinated at each phase of the rollout plan. An estimated of 1.25 million health care workers will be vaccinated first, followed by essential workers, persons in congregated settings, persons older than 60 years, persons older than 18 years with comorbidities and other persons older than 18 years in phases 2 and 3.

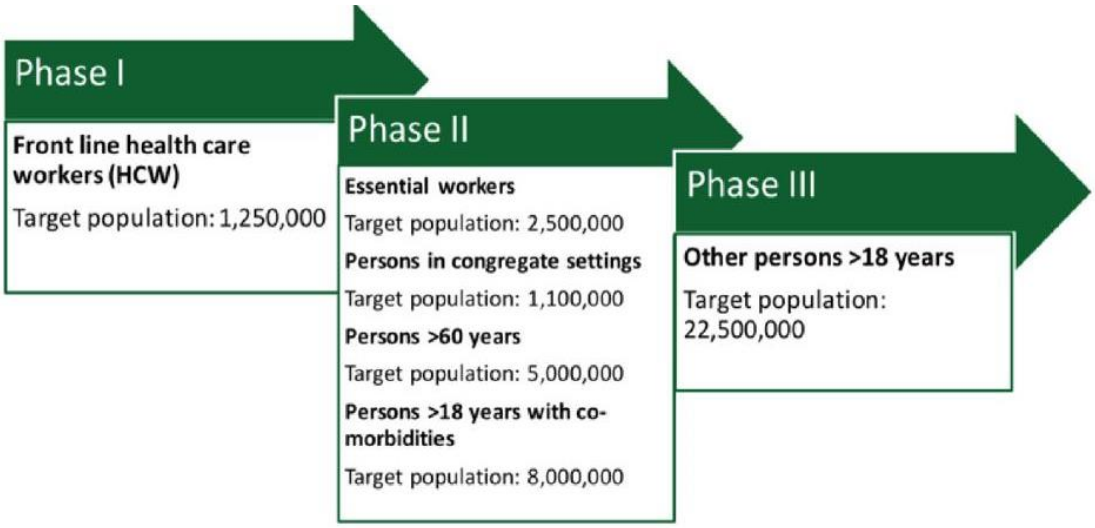

Figure 4-2: Three phase distribution of vaccines

Source: Du Plessis, 2021

Figure 4-3 and Figure 4-4 gives a brief overview of where vaccinations will take place during each stage and which platforms will be used. In phase 1, as displayed in Figure 4-3, work-based vaccination takes place at district level private and public hospitals. Both outreach work-based vaccination programs and remote vaccination centres will be used.

1. **Work Based Vaccination program:**
Venue: District level public & private hospitals
- Most suitable for hospital linked healthcare workers

2. **Outreach work based vaccination program**
Venue: Mobile teams move from facility to facility
- Most suitable for healthcare workers in primary healthcare, Community healthcare workers and private medical centres

3. **Vaccination centres: Remote or facility based**
Venue: Vaccination centres, e.g. community pharmacies
- Most suitable for independent healthcare workers

Figure 4-3: Phase 1 distribution platforms

Source: Du Plessis, 2021

Figure 4-4 indicates which vaccination platforms will be used during phases 2 and 3. There are four main platforms, namely public facilities, vaccination centres, the outreach vaccination programme (provided by mobile clinics) and the work-based vaccination programme. During these two phases, citizens, who are included in the targeted population, will need to travel to the nearest pharmacy, health facility, community hall or school that is being used as a mass vaccination location to be vaccinated (COVID-19 South African Resource Portal, 2021).

1. **Public facilty vaccination:** Primary health care
- suitable in rural settings for community access

2. **Vaccination Centres:** Remote or facility based vaccination centres e.g. community pharmacies, GPs or NGOs
- Suitable in urban settings for community

3. **Outreach vaccination programme:** Service provided via mobile clinics
- Suitable for congregated settings e.g. old age homes

4. **Work-based vaccination programme**
- Suitable for Essential workers e.g. mining sector, industry & departments

Figure 4-4: Phase 2 and 3 vaccination platforms

Source: COVID-19 South African Resource Portal, 2021

Vaccinations in all three phases are administered based on a pre-vaccination registration and appointment system at a specific vaccination site. To simplify tracking and tracing who has been vaccinated, all South Africans who have received a COVID-19 vaccine receives a vaccination card and are placed on a national register (COVID-19 South African Resource Portal, 2021).

The availability of storage or cold chain related materials, infrastructure and capacity are extremely important if the South African government wants to achieve the goals of phased vaccination. The South African health system cannot seize infrastructure from existing vaccines or the vaccine schedule to distribute COVID-19 vaccines. The vaccine schedule of other illnesses is however required simultaneously. This necessitates that many things needed for the phased vaccinations will have to be added or purchased such as: freezers; refrigerated shipping containers or temperature monitoring systems (Irfan, 2020). The cold chain of COVID-19 vaccines, within the South African setting is discussed in section 4.4.

4.3.2. The containment strategy

On 3 June 2021, health24 reported that South Africa is no longer aiming towards full community protection, also known as herd immunity, through the COVID-19 vaccination program. The South African Health Department has now shifted their sights on a new goal namely containment or the containment strategy. According to Schoub (2021), “The containment strategy aims to immunise just enough people so that Covid hospital admissions put no more strain on the health system than any other illness would.” The change in strategy is a direct result of the stop-start nature of the vaccine roll-out, which stems from the limited supply of vaccines and new variants circulating in the country (Schoub, 2021).

Herd immunity and its variables can be defined quite precisely for other acute viral infections but identifying and defining them for COVID-19 becomes difficult. After extensive planning and forecasting it become evident that it is impossible to accurately state and determine the figure of herd immunity for COVID-19 vaccination in South Africa. As a result, the country is now trying to contain the virus to a bearable level, so that it causes minimal hardship. The desirable level of containment could be reached by 2022, if the vaccine roll-out goes according to plan and without too many problems (Schoub, 2021).

4.4. THE SOUTH AFRICAN COVID-19 VACCINE COLD CHAIN

The country kick-started its first phase of vaccinations, on 18 February 2021, by distributing and vaccinating citizens with the Johnson & Johnson's vaccine. This vaccine has a long shelf life of two years when stored at -20°C and can safely be stored in a domestic fridge for a month. The cold chain requirements of the vaccine make it suitable for widespread rollout in South Africa as ultra-cold freezers are not needed (Everything you need to know about the Johnson & Johnson vaccine, 2021).

As of 26 April 2021, the South African government has secured enough COVID-19 doses to vaccinate at least 45 million people living in South Africa. The number of vaccines is made up by 31 million Johnson & Johnson (J&J) vaccine doses and 20 million Pfizer doses (each person requires two doses of this vaccine). It is significant to note that about 22%, 9 million, of the 41 million vaccines arrived in South Africa between April and June 2021. After putting a stop to the use of AstraZeneca vaccines, because data disclosed it offered minimal protection against mild-to-moderate infection, and new information came to light about the effects of the Johnson & Johnson vaccine, the government has diversified by procuring Pfizer/BioNTech vaccines instead (Karim & van Dyk, 2021). As mentioned in section 4.3.1, the cold chain requirements of a COVID-19 vaccine play a role in its selection for the South African setting and this Pfizer procurement decision affects the required cold chain equipment.

Before explaining how South Africa will manage an ultra-cold chain, it is important to start by looking at the flow of temperature-sensitive vaccines within the country's borders. COVID-19 vaccines are transported via air transport onto South African soil. From the airport, Johannesburg OR Tambo International Airport, the doses are taken to a central storage facility where the South African National Control Laboratory (NCL) is responsible for the quality assurance processes. After this, a trained team sorts them according to different recipient storage facilities based on a pre-planned list with quantities awarded to each specified storage facility (Karim *et al*., 2021).

Where the vaccines go next is fully dependent on the kind of agreement that the government has with a distribution company. Some vaccines are delivered to a central, provincial depot while others are delivered directly to administering/vaccination sites, which is called "fine distribution". The vaccine orders delivered to a depot will then be collected by clinics (Karim *et al*., 2021). There are over 900 distribution sites across the country that are being used as storage facilities. These sites

are either already a vaccination centre or storage hubs from where vaccines will be distributed to vaccination facilities (Mkhize, 2021). According to the media statement by Dr. Zwelini Mkhize on 26 April 2021, more than 3 338 vaccination sites had been identified by provinces of which 2 369 are now registered on the Master Facility List and undergoing various stages of approval.

Trucks, that can support the vaccine's cold chain requirements, are used to transport vaccines from the airport to the primary storage facility and to a provincial depot. According to Karim *et al*. (2021), the transport schedule for delivery trucks is developed and structured in such a way that all facilities, no matter their location, receive their delivery before the end of the workday. In the case of fine distribution, special containers are used to store vaccines inside a truck at a temperature of -20°C. "That way, the containers can be loaded onto trucks at the provincial depot and then head out to the clinics". It is vital to know that each COVID-19 vaccine procured for South Africa will have its own or adjusted vaccine cold chain seeing that they all have different cold chain requirements.

4.4.1. Ultra-cold chain management

Certain COVID-19 vaccines, such as the Pfizer vaccine candidate requires ultra-cold storage. Initially this vaccine needed to be stored at -70°C, which made it difficult to procure for a country such as South Africa (Karim *et al*., 2021). This is because most immunization programme vaccines in South Africa are kept between 2°C and 8°C, which means that the country has the storage capacity, infrastructure, and equipment for vaccines with relatively the same temperature requirements. Most rural areas in South Africa do not have ultra-cold freezers that are required to maintain a well below frozen temperature. New data on the Pfizer's vaccine has, however, shown that the doses can be stored in a standard freezer for shorter time periods. Three options exist for the storage of these vaccines:

Firstly, vaccines can be temporarily stored in shipping containers. Specialised thermal shipping containers can keep a temperature of -70°C for up to 30 days if dry ice is refilled every five days. After the 30 days, doses can be transferred to a normal refrigerator that maintains a temperature range of 2°C to 8°C (Karim *et al*., 2021). The problem with this solution is the availability of an unlimited supply of dry ice. Restocking containers with dry ice is not a medium or long-term option/solution for South Africa. The second option is to store vaccines short-term in standard freezers. The vials can be stored between -25°C and -15°C for a period of up to two weeks. Vials will only stay effective if they are frozen throughout this period. South Africa will aim at storing Pfizer

vaccines at -20°C at certain facilities. These vaccines can also be kept in a defrosted state for five days in a fridge, but they must then be used in that time period (Karim *et al*., 2021).

The last option is long-term storage in ultra-cold freezers, which South Africa had to make use of when the 6.75 million Pfizer vaccines arrive between April and June. The South African setting makes it impossible to administer all those doses in two weeks, thus, the country needed specialised freezers to keep vials at -70°C for up to six months. According to South African health minister, Dr Mkhize the country has secured ultra-cold storage facilities, but their locations are still unknown to the public (Karim *et al*., 2021).

Another solution to ultra-cold storage and transportation came to light on 15 February 2021, by the South African domestic natural gas and helium producer, Renergen. The company designed and developed a product called Cryo-Vacc. The Cryo-Vacc has a temperature range of between -150°C and 8°C and can keep vaccines at their recommended temperature for up 30 days, allowing transport vehicles to cover longer distances and reach remote areas (Liedtke, 2021). This solution is ideal to the South African setting because of the demographics, social factors, and power supply challenges of the country. The logistics of moving COVID-19 vaccines in South Africa can be simplified through this product because recommended temperatures can be maintained for more than four weeks, and it does not require any power supply. Renergen's creation combined with best-in-class cold chain monitoring and asset tracking technology can be used to provide accurate temperature reading of vaccines in transit and ensure an audited chain of custody through the global positioning system tracking (Liedtke, 2021).

According to Renergen CEO, Stefano Marani, "The Cryo-Vacc is suitable for both air and ground transportation, as it uses liquid nitrogen to transport by road and helium to transport by air." The composition of helium makes it ultra-light weight, which drastically reduces airfreight cost, and it can accommodate ±12 times more vials per flight than other cryogens. As mentioned earlier, no tender contract has been awarded for the distribution of COVID-19 vaccines in SA, but DPD Laser and Renergen has teamed up for this contract (Liedtke, 2021).

4.4.2. COVID-19 vaccine distribution challenges

Most of the challenges mentioned in section 3.6.2 are applicable to the South African setting. Certain challenges can be added to that list and the flow of COVID-19 vaccines in South Africa can

be hindered because of the country's healthcare systems, geographical and economical setting, and governance. There are three main concerns regarding the distribution of vaccines in South Africa.

The first is the lack of pharmacists in South Africa. Pharmacists are the only people that can sign off on delivery received at final destinations. They are responsible for the paperwork associated with the delivery and checking the temperature of the cargo that is delivered (Karim *et al*., 2021). If cargo temperature is not up to standard, the distribution company will be held liable. In South Africa, some facilities do not meet the accreditation requirement needed for vaccine reception because of the shortage of pharmacists. Qualified pharmacists are also not distributed equally, and the effects are especially felt in the Free State, North-West, Mpumalanga, Kwazulu-Natal and Limpopo (Karim *et al*., 2021).

The next challenge is ordering backlogs and stock outs. The vaccine ordering system in South Africa has been labelled "haphazard" by Makhoana, Deputy Chief Executive Officer of The Biovac Institute. The management of stock levels has always been a problem within the South African health system because of the absence of a central co-ordination system for the nine provinces. The mismanagement of stock levels leads to stock outs, which causes government to incur unnecessary costs. Karim *et al*. (2021) suggests that although South Africa has ordered enough COVID-19 vaccines, the stock levels at provinces and individual facilities need to be managed carefully to prevent local level stock-outs.

Thirdly, the uneven supply of vaccines or the lack thereof is one of the biggest challenges preventing the achievement of either herd immunity or containment, as explained in 4.3.2. In third world countries, like South Africa, the effects of wealthy countries hoarding vaccine supplies are directly felt. Wealthier countries, who could secure vaccines early in their development process, are delaying the roll-out of vaccines in South Africa because they possess the majority of vaccines produced (Schoub, 2021).

4.4.3. COVID-19 vaccine distribution partners

The country's health department has recruited private companies to aid with the distribution of vaccines by means of importation, warehousing, transportation, and storage (Daniel, 2021). As of 24 April 2021, Imperial Logistics and Pfizer were chosen as South Africa's preferred private import service providers of COVID-19 vaccines. Daniel (2021) reported that Imperial Logistics and Pfizer

together with the government-partner, Biovac, will be solely responsible for importing vaccines and providing "cold chain solutions" for temperature-sensitive vaccines. This preferred importer holds the requisite licence for importing medicines and will issue a quote every instance a shipment is ready for collection. According to Daniel (2021), Imperial's import contract states that they are responsible for "collecting COVID-19 vaccines from the manufacturer's production site and facilitating international carriage to South Africa, covering import and export documentation, foreign airport charges, insurance, and customs clearance."

Although Imperial Logistics and/or Pfizer is responsible for import logistics, DSV Healthcare and Biovac have been named the health department's preferred transportation, warehousing, and distribution partners within South Africa. There are two distribution categories, the first is for vaccines with a temperature requirement of 2°C and 8°C (Biovac), and the other for vaccines in the -70°C (DSV) temperature range. DSV consists out of more than 60 individual Pharma companies in South Africa and until 31 December 2022, DSV will be primarily responsible for transporting and storing vaccines, which need to be kept at extreme cold temperatures of -70°C (Daniel, 2021).

4.4.4. COVID-19 vaccines, procured by the South African Government, cold chain requirements

As mentioned earlier, the South African Government has decided to procure two vaccines for their vaccination programme. The first is the Jansen (Johnson & Johnson) vaccine and the second the Pfizer-BioNTech COVID-19 vaccine. Both of these fall within two different cold chain requirement categories and are distributed by two different companies in South Africa.

4.4.4.1. Janssen (Johnson & Johnson), COVID-19 vaccine, cold chain requirements

This vaccine requires a storage temperature of between 2°C and 8°C and is stored and distributed by Biovac in South Africa. According to the storage and handling guide created by the CDC (2021:1), the vaccine cartons arrive at the storage facility at a temperature of between 2°C to 8°C in a qualified shipping container. The shipment is examined for any signs of damage and employees remove the instruction card for the temperature monitor immediately to read the monitor.

Vaccines are removed from shipping containers and placed in a refrigerator with a temperature range of 2°C to 8°C. Unpunctured vials can be stored in the refrigerator until their expiry date. It is important to know that the expiration date is not printed on the vaccine vial or carton and employees need to scan the QR code on the outer carton to determine the date. The expiration date then needs to be written on the carton. Unpunctured Janssen vials can alternatively be stored

between 9°C and 25°C for up to 12 hours. Punctured vaccine vials may only be stored for up to 2 hours at room temperature (CDC, 2021:2).

These vaccines should not be frozen and needs to be protected from light during storage and transportation. Full vaccine cartons may be transported at refrigerated temperatures (2°C to 8°C) by means of a portable unit or a qualified container (CDC, 2021:2).

4.4.4.2. Pfizer-BioNTech, COVID-19 vaccine, cold chain requirements

In South Africa, DSV Healthcare is responsible for the storage and last mile distribution of the Pfizer vaccine. This vaccine needs to be stored in an ultra-low temperature freezer between -80°C and -60°C, with a preferred storage temperature of -70°C. Although there are numerous cold chain requirements or factors that could influence the efficacy of the Pfizer vaccine, the South African government only requires DSV to monitor temperature within the cold chain. The FDA (2021:2) recommends that during storage of these vaccines, exposure to room light should be minimized and exposure to sunlight and ultraviolet light should be avoided. The vials of this vaccine should never be refrozen if/when thawed (FDA, 2021:3).

Pfizer vaccine vials arrive in thermal containers, covered with dry ice, and should be removed immediately, upon arrival, from the thermal container and placed in ultra-low temperature (-80°C and -60°C) freezer. Vaccine vials can safely be stored in an ultra-low freezer until their expiry date. Vials can alternatively be stored at -25°C to -15°C for up to two weeks and may be returned to ultra-low storage once. The third storage option, if neither of the other two options is available, is to temporarily store the vaccine vials in the thermal containers, in which it arrived, and to consistently top up the container with dry ice (FDA, 2021:3).

According to the fact sheet for healthcare providers released by the FDA (2021:3), full cartons containing vaccines should preferably be transported between -90°C to -60°C. Vials can alternatively be transported in a temperature range of -25°C to -15°C, but any hours transported at this temperature range counts against the two-week storage limit of the vaccines.

4.5. STATUTORY BODY

The Cambridge dictionary defines a statutory body as: “an organization with the authority to check that the activities of a business or organization are legal and follow official rules.” It can also be an

organization that has been created by a parliament. All industries and trade within the global economy have a certain statutory body that they must adhere to. Statutory bodies differ from country to country and product to product.

The South African Health Products Regulatory Authority (SAHPRA), established by the Medicines Act, is the statutory body for all medicines and healthcare products in South Africa. According to Bernstein (2020), they are responsible for, "ensuring efficient, effective and ethical evaluations; registration and control of all clinical trials; medicines and other healthcare products." No trials may be conducted, or medicines may be prescribed, sold, or marketed in South Africa without the prior approval of SAHRA. The body does not undertake any ethical or safety trials in its own capacity as a regulator, but rather approve those conducted by pharmaceutical researchers and manufacturers (Bernstein, 2020).

As soon as vaccines have successfully finished their development phase, they must be registered with SAHPRA. Vaccines may only be prescribed, administered, or sold in South Africa after receiving SAHPRA approval (Bernstein, 2020). Although most COVID-19 vaccines have received approval from a foreign drug-regulatory authority, SAHPRA approval is still required, irrespective of whether offshore approval was granted. Bernstein (2020) states, "if offshore approval has been granted by a stringent regulatory authority, which SAHPRA recognizes as being particularly thorough, such as the Food and Drug Administration in the United States, SAHPRA may accelerate local approval."

In South Africa, the COVID-19 vaccine rollout programme is being overseen by the Inter-Ministerial Committee (IMC) on Vaccination at the highest level. The committee is chaired by Deputy President, David Mabuza. The purpose of the committee is to assist the vaccine rollout and strategy with swift decision-making to guarantee the smooth implementation of the programme (COVID-19 South African Resource Portal, 2021).

4.6. CONCLUSION

This chapter provides a basic understanding of how COVID-19 vaccines are distributed within the South African borders, and which challenges the supply and cold chain face because of the country's economic, geographical, and physical state. The three-step phased rollout of COVID-19 vaccines are explained, focusing on the fact that there are six key considerations influencing which vaccines are procured by the South African government. It further explains that the nature of these procured

COVID-19 vaccines forced the South African health department, government, and logistics companies to create options and solutions for cold chain and ultra-cold chain management. The chapter identifies Imperial Logistics as being the government's preferred import partner of COVID-19 vaccines and DSV healthcare as the preferred transportation, warehousing, and distribution partner, both working in cooperation with BIOVAC.

CHAPTER 5 : STAKEHOLDER ANALYSIS

5.1. INTRODUCTION

The content of this study is used in the building and creation of a toolkit that can aid supply chain members in the education and training of their employees. The researcher conducted a stakeholder analysis to determine the important stakeholders involved in the supply chain of a COVID-19 vaccine. Identifying these stakeholders and collecting relevant information from them, assisted the researcher in gaining visibility into the vaccine supply chain to formulate the toolkit that is aimed at a subset of the stakeholder pool. These stakeholders are predominantly based in South Africa because of the focus area of the study.

5.2. STAKEHOLDER ANALYSIS

Before explaining the process of a stakeholder analysis, it is important to understand what a stakeholder is. The term stakeholder is used to describe any individual, group, or organization that is actively involved in a project or whose interests may be positively or negatively affected by the project outcome or by organizational achievements (Smith, 2000). Based on the understanding of what a stakeholder is, Smith (2000) found that a "stakeholder analysis typically refers to the range of techniques or tools to identify and understand the needs and expectations of major interests inside and outside the project environment." This understanding can be elaborated on from a wider perspective, as the process of identifying stakeholders in an organization, industry, or process; assessing their influence and interests on the topic at hand; to formulate strategies for managing relationships with them (CMI, n.d.).

A stakeholder analysis is thus, an essential technique used in the identification of stakeholders and the analysis of both their needs and insights. This technique can best be managed in four steps:

1. Identify the stakeholders or stakeholder groups;
2. Analyse the stakeholder relationships;
3. Develop a stakeholder strategy;
4. Engage and communicate with the stakeholders.

This four-step process is flexible, could have subsets and the stakeholder relationship might change. In this study, stakeholders are analysed relative to the COVID-19 vaccine roll out. Each step of the process is explained and covered.

Step 1: Identify the stakeholders

To be classified as a stakeholder, the person, group or organization must have some level of influence or ability to influence. Most stakeholders are identified based on their relevant importance to the outcome. In this study, the levels of influence or power was determined by the importance and involvement of the stakeholder in the COVID-19 vaccine supply chain. These stakeholders were identified based on their involvement in the COVID-19 vaccine industry and the various stakeholders who are directly participating in its supply chain. The researcher used information obtained from the literature review to identify stakeholders for this study and personnel from two different logistics companies, associated with the distribution of COVID-19 vaccines in South Africa, provided some more insight into the identification of certain stakeholders.

The researcher decided to compile two different lists of stakeholders. The first in Table 5-1 identifies the stakeholders for this study on a national level. Not all these stakeholders directly contributed or benefitted from the aim of this study, but they do form part of the vaccine supply chain and industry.

Table 5-1: National Stakeholders related to the COVID-19 vaccine industry and supply chain

Stakeholders	Definition	Power and interest	Type of stakeholder
Government – Department of Health	The core function and responsibility of the Department of Health, in all nine provinces, is to deliver a comprehensive package of health services to South Africans. The Department of Health is one of the most important stakeholders, because they have the authority to make decisions regarding COVID-19 vaccines such as which vaccines are procured, the quantity and how these vaccines are distributed and by who.	High levels of power High levels of interest	Pivotal stakeholder
Government – Inter-Ministerial Committee (IMC) on Vaccination	The purpose of this committee is to assist the vaccine rollout and strategy with swift decision-making and is chaired by the Deputy President. This	High levels of power High levels of interest	Pivotal stakeholder

	committee has important influence directly linked to the distribution of COVID-19 vaccines.		
Government – South African National Control Laboratory (NCL)	NCL is a quality control laboratory responsible for testing and releasing vaccines for human use in South Africa. Once COVID-19 vaccines enter South African borders quality assurance processes are completed by the NCL where after, vaccines are dispatched to the various provinces.	High levels of power High levels of interest	Pivotal stakeholder
Government - South African Health Products Regulatory Authority (SAHPRA)	The statutory body responsible for all medicine and healthcare products in South Africa. No COVID-19 vaccine may be distributed in South Africa without SAHPRA approval. This means that this statutory body has authority over which vaccines are distributed within South Africa.	High levels of power Low levels of interest	Dormant stakeholder
The South African Medical Association (SAMA)	SAMA is a non-statutory, professional association for medical practitioners in both the public and private sector in South Africa. They act as a trade union and are focused on empowering doctors to bring health to the nation. Their platform can be used to access multiple individuals within the industry.	Low levels of power Low levels of interest	Marginal stakeholder
Vaccine industry	The vaccine industry has a vested stake in the research because the COVID-19 vaccine supply chain forms part of this industry.	Low levels of power High levels of interest	Interested stakeholder
Air freight/cargo	Air freight involves the shipment of products, in this case COVID-19 vaccines, through an air carrier. Air freight has been used as the preferred transport mode of	Low levels of power High levels of interest	Interested stakeholder

	vaccines for many years. Transport by air is fast, has strategic importance and can reach a number of locations while protecting vaccines from spoilage and ensuring that it is handled at the correct temperatures.		
Freight forwarders	A freight forwarder is an agency that receives freight from a shipper and arranges for transportation through other carriers to the final destination. They also arrange imports and exports.	Low levels of power High levels of interest	Interested stakeholder
Customs Clearance Agent	A customs clearance agent or broker is responsible for facilitating the export and import of goods. They oversee various tasks to ensure authorised passage of packages, shipments, or goods.	Low levels of power High levels of interest	Interested stakeholder
Logistic Service Providers (LSP's)	The term LSP refers to a third party to whom logistics operations are outsourced to. A LSP provides and manages logistics services such as packing, billing, shipping, distribution, warehousing and freight forwarding.	Low levels of power High levels of interest	Interested stakeholder
Healthcare facilities e.g., hospitals, clinics, and vaccination sites	Hospitals are responsible for treating patients with COVID-19. Some hospitals and majority of clinics are used as COVID-19 vaccinations sites. Other public and private facilities in South Africa have been identified as vaccination sites.	Low levels of power High levels of interest	Interested stakeholder
Local security companies e.g., NATJOINTS	Security companies are responsible for escorting vaccine deliveries to their final destinations. No COVID-19 vaccine is ever transported without the support of a security provider.	Low levels of power High levels of interest	Interested stakeholder

BIOVAC	A bio-pharmaceutical company based in Cape Town, established for local vaccine manufacturing capabilities to ensure national health management and security. They work in partnership with Imperial and DSV in distributing and managing the COVID-19 vaccine rollout.	Low levels of power High levels of interest	Interested stakeholder
Pfizer	Pfizer is a multinational pharmaceutical and biotechnology corporation, responsible for providing several COVID-19 vaccines to South Africa. A lot of communication takes place between the National Department of Health and Pfizer South Africa on the procurement front. The Pfizer QA team are involved with the temperature monitoring devices and the release of products once NCL has done their work.	High levels of power High levels of interest	Pivotal stakeholder
DSV Healthcare	DSV consists out of 60 individual Pharma companies in South Africa and has been named the health department's preferred vaccine transportation, warehousing, and distribution partner within South Africa. They play an integral part in the COVID-19 vaccine cold chain.	High levels of power High levels of interest	Pivotal stakeholder
Imperial Logistics	An African focused provider of integrated market access and logistics solutions who will be solely responsible for importing COVID-19 vaccines and providing "cold chain solutions" for temperature-sensitive vaccines. Imperial hands products over to either DSV Healthcare or Biovac for further distribution in the country.	High levels of power High levels of interest	Pivotal stakeholder

Pharmacists	Pharmacists are the only people that can sign off on COVID-19 vaccine delivery received at final destinations in South Africa. They are responsible for the paperwork associated with the delivery and checking the temperature of the cargo that is delivered.	Low levels of power High levels of interest	Interested stakeholder
Healthcare workers	Healthcare workers aid in educating vaccine recipients to ensure public awareness. The key responsibilities of nurses include physical vaccinations, communication, administrative safety and follow-up.	Low levels of power High levels of interest	Interested stakeholder
Patients	Patients or the public refers to those individuals who have been vaccinated; are awaiting vaccination or form part of the targeted groups in one of the three vaccination phases. There are two distinct camps when it comes to patients, those who want the be vaccinated and those who don't. In this analysis, we focus on those patients who want to be vaccinated.	Low levels of power High levels of interest	Interested stakeholder

Source: Compiled by the researcher for the purpose of this study

The second list in Table 5-2 is the stakeholder group or set that the researcher focused on most. This is because these stakeholders are the ones that the outcome of the study is aimed at. They form part of the physical distribution, handling, and storage of the COVID-19 vaccine in South Africa. These groups of individuals were identified based on the information obtained from the literature review and personnel at two different logistics companies, associated with the distribution of COVID-19 vaccines in South Africa, about the flow of COVID-19 vaccines and the hands that these products go through.

Table 5-2: Stakeholders involved in the distribution, handling, and storage of the COVID-19 vaccine

Stakeholder	Employee activity/role	Definition	Power and interest	Type of stakeholder
Imperial Logistics, Pfizer (South Africa) or Biovac	Port operators	Personnel responsible for clearing the port before products can be moved into the country. This includes the role of freight forwarder and customs clearance agent.	High levels of power High levels of interest	Pivotal stakeholder
	Receive shipment	These person/persons are responsible for receiving the shipment at the airport (South Africa).	Low levels of power High levels of interest	Interested stakeholder
	Road transport operator	All employees who are responsible for operating a vehicle transporting COVID-19 vaccines from a local airport to a central storage facility.	Low levels of power High levels of interest	Interested stakeholder
DSV Healthcare or Biovac	Receive vaccine shipment	These person/persons are responsible for receiving the shipment at the central storage facility.	Low levels of power High levels of interest	Interested stakeholder
	Offload shipment	Includes all personnel responsible for transferring the shipment from the transport vehicle to the facility.	Low levels of power High levels of interest	Interested stakeholder
	Unpack shipment	This activity includes those personnel	Low levels of power	Interested stakeholder

		responsible for unpacking the shipment and transferring vaccine trays from their packaging into the facility freezer.	High levels of interest	
	Resource allocator	This refers to those personnel responsible for receiving orders from DOH and planning deliveries to vaccination sites.	Low levels of power High levels of interest	Interested stakeholder
	Picking and packing shipments	These employees are responsible for removing vaccine trays from the freezers and picking and packing them according to order quantities for different vaccination sites.	Low levels of power High levels of interest	Interested stakeholder
	Transport operator	Employees that are responsible for transporting the vaccines from the storage facility to vaccination sites.	Low levels of power High levels of interest	Interested stakeholder
Vaccination sites (clinics, hospitals, or outlets)	Receive vaccine shipment	Pharmacists, nurses, or any other personnel responsible for receiving and signing paperwork upon shipment arrival at the vaccination site.	Low levels of power High levels of interest	Interested stakeholder

Source: Compiled by the researcher for the purpose of this study

Step 2: Analyse stakeholder relationships

The next step in the process, after identification, is to analyse the relationship between the project at hand and the stakeholders. In the context of this study, the project refers to the COVID-19 vaccine supply chain and the formation of a toolkit to aid in the training and education of supply chain members. The analysis of the process requires important assessments about the level of power and interest that different stakeholders have in the project. Figure 5-1 compiled by Venter & Oosthuizen (2018:326) illustrates the different types of stakeholders in a stakeholder analysis, based on their interest and power.

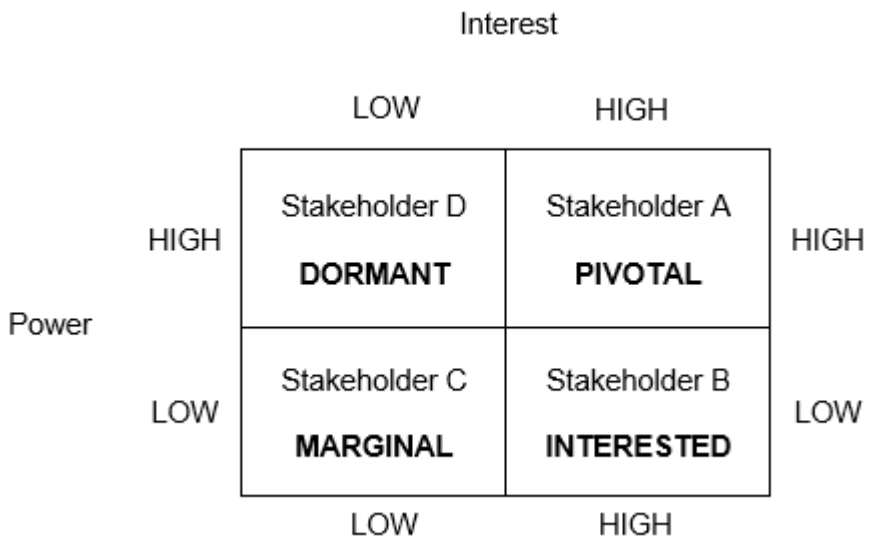

Figure 5-1: Different types of stakeholders highlighted by stakeholder analysis

Source: Venter & Oosthuizen, 2018:326

Venter and Oosthuizen (2018: 326) identified four types of stakeholders, namely pivotal, interested marginal and dormant. These terms are defined as:

a) *Pivotal stakeholders*: These stakeholders play a key role in the project because they have a high level of both power and interest. The project in this study refers to the COVID-19 vaccine selection, management, and supply chain. If these stakeholders have a favourable attitude towards the project, they are proponents and if they have an unfavourable attitude, they are considered opponents. For the purpose of this study, the following are considered pivotal stakeholders, namely Government, DSV healthcare, Imperial Logistics etc.

b) *Interested stakeholders*: These stakeholders have high levels of interest but low levels of power. Their low level of power regards them as supportive if they show a favourable attitude towards the project and non-supportive if they show an unfavourable attitude. This study has quite a few interested stakeholders such as air freight/cargo, freight forwarders,

logistics service providers, SAHPRA, the vaccine industry and BIOVAC, healthcare workers, patients, certain employees at Imperial Logistics and DSV Healthcare and healthcare facilities.

c) *Marginal stakeholders*: This term refers to stakeholders who have relatively low levels of power and interest. As a result, these stakeholders are not really concerned about most issues and the project can operate without them and their favourable or unfavourable attitude. In this study SAMA is a marginal stakeholder.

d) *Dormant stakeholders*: These stakeholders hold high levels of power but low levels of interest. This specific stakeholder can be difficult to manage and can be the most distressing because although they have low levels of interest, they still have the power to influence decision-making. Currently, there are no dormant stakeholders in the study or related project.

Step 3: Develop the stakeholder strategy

Once identification and analyses are completed, the insights gained from those first two steps can be used in the development of stakeholder strategies. Venter and Oosthuizen (2018: 328), developed the following stakeholder strategies in response to the level of power and interest of stakeholders:

a) *Collaborative with pivotal stakeholders*

Pivotal stakeholders are referred to as key stakeholders and with high levels of power and interest. They are best managed through collaboration. Collaboration will require upfront negotiation, to ensure alignment between stakeholders' interest and the formation of the toolkit.

b) *Keep the interested stakeholder informed*

It is very important to keep interested stakeholders informed about major decisions and developments in the project. The high level of interest that these stakeholders have could be used advantageously by including them in decision-making.

c) *Monitor the marginal stakeholder*

The low level of both power and interest of these stakeholders means that they require minimal effort to manage. They should, however, be monitored because their level of power and interest can change over the course of the project.

d) *Keep the dormant stakeholder satisfied*

Dormant stakeholders should always be kept satisfied. Their interest is low, if they are satisfied but as soon as they become dissatisfied, their interest could increase, which moves them into the pivotal stakeholder group. It is important to understand and manage the specific issues that could activate the interest of the stakeholders. The researcher should keep these stakeholders informed and consult them before any major decisions relating to these issues are made.

Step 4: Engage and communicate with the stakeholder

The final step of the process is to engage and communicate with the identified stakeholders. This entails guaranteeing that the strategies developed, in the previous step, are implemented appropriately. These strategies need to be implemented carefully because it is possible for the relationship of the stakeholders to change.

A fundamental part of this step is to get to know the stakeholder, understand what motivates them, what their priorities are and whether they have a positive view of the study.

5.3. RESEARCH QUESTIONS RELATED TO THE STAKEHOLDER ANALYSIS

As part of step 4 in the stakeholder analysis, communication and engagement between the researcher and the identified stakeholders took place. This assisted the researcher in answering her research questions and creating a cold chain distribution educational toolkit. The research objectives and research questions served as a basis from which the researcher generated the questions asked during interviews with different stakeholders. The researcher used the COVID-19 vaccine supply chain, illustrated in Figure 6-1, together with Table 5-1 and Table 5-2 to identify which stakeholders should be approached for the different research questions. Table 5-3 summarizes which stakeholders were approached to aid in answering certain research questions.

Table 5-3: Research questions linked to stakeholder inputs

Research question	Stakeholders
Q2: What are the cold chain requirements and sensitivity of each requirement of a vaccine supply chain and how can they be categorised?	• DSV Healthcare • Imperial Logistics • Doctors and/pharmacists (Healthcare workers at vaccination sites)

Q3: What are the specific cold chain protocols for each individual vaccine?	• Healthcare workers at public and private vaccination sites • Imperial Logistics • DSV Healthcare • Pharmacists
Q4: What best practices or metrics can be undertaken to ensure the effective management of temperature, humidity, vibration etc. along the different stages of the coronavirus vaccine supply chain?	• DSV Healthcare • Imperial Logistics
Q5: What are the basic skills and knowledge requirements for personnel to safely and effectively transport, handle and store coronavirus vaccines?	• DSV Healthcare • Imperial Logistics • Doctors • Nurses • Pharmacists • Other personnel at vaccination sites (e.g., operations manager)

Source: Compiled by the researcher for the purpose of this study

The researcher started the interview process by searching for individuals to interview through viewing the stops in the supply chain and making use of existing contacts that she had at her disposal. The researcher tried to interview at least one person at each core link in the supply chain, to gain visibility into the protocols and procedures followed at the different stages of the supply chain. The interviewees were individuals at different management levels and at different companies or vaccination sites. Healthcare workers and operations managers at vaccination sites were easily reachable but the researcher did struggle to connect with companies or individuals at the start of the supply chain.

The researcher focussed on ensuring that the stakeholder that was being interviewed had the ability and appropriate supply chain role/position to answer the specific interview questions related to the stakeholder group. The interview guide in Appendix A explains which questions were asked and aimed at which stakeholders interviewed. It is important to note that the researcher tried to get a variety of expertise, but she was limited to only interviewing individuals at vaccination sites in the Western Cape. The rest of the stakeholders interviewed were in either the Western Cape or Gauteng

province. To protect the privacy of the individuals that shared their opinions and expertise, the stakeholder's name is not mentioned but the number of stakeholders interviewed at each stage in the supply chain is listed below in Table 5-4.

Table 5-4: The number of stakeholders interviewed

Step in the supply chain	The number of stakeholders interviewed
Import, Customs Clearance & Freight Forwarders	1 x Managing Director
Central storage facility	1 x CEO 1 x Managing Director 2 x General Manager 2 x Operations Manager
Vaccination sites	2 x Operations Manager (Public & Private sector) 2 x Nurse (Public & Private sector) 1 x Pharmacist (Public sector) 3 x Pharmacists (Private sector) 1 x Doctor (Public sector)

Source: Compiled by the researcher for the purpose of this study

The researcher processed the answers received in each interview, by rereading the notes taken during the interview and listening to the recording. Each interviewee granted permission to be recorded. She then categorised the individual responses, to the interview questions, according to the research questions. Answers, opinions, and recommendations received from interviewees were used in conjunction with information from the literature review. The stakeholder responses and comments are combined and summarised based on the subsections discussed in section 6.3 and section 6.4.

5.4. CONCLUSION

The four-step process of a stakeholder analysis was conducted to determine which individuals and organizations form part of the COVID-19 vaccine supply chain. The researcher compiled two separate sets/lists of stakeholders because of the nature of the toolkit and the aim of the study. In this research study, information from approximately 16 national stakeholders/stakeholder groups and 10 domestic stakeholder groups, were used to help in the formation of a toolkit. Their

knowledge and interest assisted the researcher in understanding elements of the vaccine supply chain and the components that play a part in its distribution.

CHAPTER 6 : DATA ANALYSIS AND TOOLKIT INPUTS

6.1. INTRODUCTION

This chapter discusses the analyses of the qualitative data collected through both the literature review and the stakeholder analysis. The qualitative data was used to answer the research questions and objectives as stated in Chapter 1. The first two sections of this chapter discuss the way in which the literature review and the stakeholder analysis contributed to and assisted the researcher in collecting and analysing the qualitative data. Information from the literature review formed the basis on which assumptions were drawn. It also influenced the approach to the stakeholder analysis and pinpointed the data needed through the stakeholder interviews. The stakeholder analysis section shortly discusses which stakeholders were interviewed and how information from the interviews were used to illustrate and describe the COVID-19 vaccine supply chain. The last section provides information from both the literature review and the stakeholder analysis that systematically answer the research questions. This chapter allows the researcher to validate information and to summarise and categorise the inputs to the toolkit.

6.2. LITERATURE REVIEW

The literature review was used as a basis for concepts, terminology, and processes to determine what information, linked to the research study, was already available. The literature review contained facts and knowledge from various sources, online portals, articles, and information booklets. These sources allowed the researcher to identify and prioritise what information should be gathered from interviews with certain stakeholders. The literature review formed the foundation against which the researcher drew assumptions from and compared information from interviews with.

Information from the two methods, namely the literature review and stakeholder analysis, correlated in some cases and in other instances individuals interviewed, shed more light on the actual flow of COVID-19 vaccines and the activities involved during handling, storage, and distribution specifically as is found in South Africa. The dissimilarity of information from these two methods, in certain instances, and the lack of visibility from just conducting a literature review, highlighted that the researcher needed information from other sources as an input to the toolkit and not just peer reviewed and published information.

6.3. STAKEHOLDER ANALYSIS

The researcher conducted semi-structured interviews with several stakeholders. These stakeholders form part of either the national stakeholder group or the group that is directly involved in the storage, handling, and distribution of vaccines. The researcher focused on gathering information, facts and valuable inputs from stakeholders summarised in Table 5-2, because they are directly involved in the distribution of the vaccines and the aim of the study is focussed on these stakeholders. The process of identifying stakeholders and the number of stakeholders interviewed at each link of the supply chain is described in section 5.3.

The stakeholder analysis assisted the researcher in several ways. Not only did it serve as a contributing input to the toolkit, but it allowed the researcher insight into the functionality of the COVID-19 vaccine supply chain in South Africa, which is explained below. Other insights, knowledge and explanations from stakeholders are discussed and summarised in the third section of this chapter. To protect the privacy of the stakeholders interviewed, Table 6-1 provides the anonymous title and job description of everyone interviewed for this research study. The researcher references the stakeholders by their anonymous title in the sections to follow.

Table 6-1: Stakeholder reference title

Anonymous reference title	Job description	Supply chain position	Link to study
Manager 1	Key account and Project Manager, Health Science	Import and warehouse	Works at a Logistics company that distributes many types of vaccines & tendered for the import contract of COVID-19 vaccines.
Manager 2	Key account and Project Manager, Health Science	Warehouse / storage	Manages the key accounts at a Logistics Company for vaccine manufacturing clients.

Manager 3	General Manager: Solutions & Commercial	Warehouse / storage and distribution	Works for a company that distributes COVID-19 vaccines in South Africa.
Manager 4	Managing Director	Warehouse / storage and distribution	A Managing Director at a company that distributes COVID-19 vaccines in South Africa.
Manager 5	Assistant Manager COVID-19 vaccine control tower	Distribution	Works for a company that is distributing Pfizer COVID-19 vaccines in South Africa.
Pharmacist 1	Pharmacist at private pharmacy	Vaccination site – pharmacy	Manages the administration of COVID-19 vaccines at a private pharmacy.
Pharmacist 2	Pharmacist at public clinic	Vaccination site – pharmacy	Manages the administration and requirements of COVID-19 vaccines at a public clinic.
Pharmacist 3	Pharmacist and business owner at private pharmacy	Vaccination site – pharmacy	Manages the administration of COVID-19 vaccines at a private pharmacy.
Pharmacist 4	Pharmacist at public hospital	Provincial depot – pharmacy	Manages the administration of COVID-19 vaccines at a public hospital

			and assigns vaccines to different vaccination sites in the area.
Doctor 1	Doctor and site manager at public vaccination site	Vaccination site – manager	Manages the operations at a public COVID-19 vaccination sites.
Nurse 1	Nurse and general manager at public clinic	Vaccination site – administer	Manages operations & personnel and administers the COVID-19 vaccine at a public clinic.
Nurse 2	Nurse at public hospital	Vaccination site – administer	Administers COVID-19 vaccines at a public hospital.

Source: Compiled by the researcher for the purpose of this study

6.3.1. The flow of COVID-19 vaccines from manufacturing sites to central storage facilities

There are several supply chain links or stakeholders in the vaccine supply chain who play a vital role in its functionality. For this study, there are a few stakeholders that the researcher focused on, due to their direct involvement in the handling and distribution of the vaccines. With the help of individuals at different stages of the supply chain, the researcher was able to illustrate and validate the COVID-19 vaccine supply chain. Figure 6-1 illustrates the flow of COVID-19 vaccines in South Africa, from the point of production to the point of vaccination.

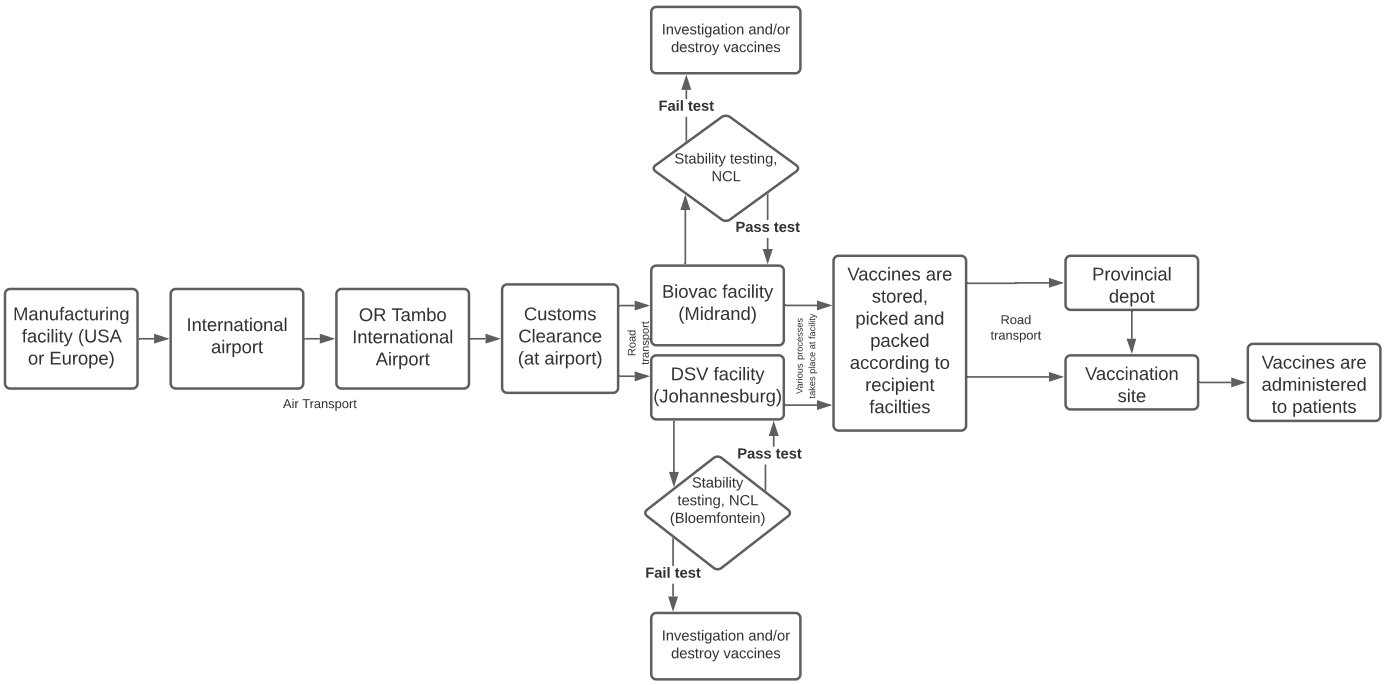

Figure 6-1: COVID-19 vaccine supply chain - South Africa

Source: Compiled by the researcher for the purpose of this study

Figure 6-1 illustrates that COVID-19 vaccines have approximately 4 to 7 physical stops before they reach their intended location or patient. At each of these stops, there are several processes that take place, as discussed below. The COVID-19 vaccine supply chain in South Africa is similar to a generic vaccine supply chain (displayed in Figure 3-2), because the starting point is the manufacturer and the chain ends once vaccines are administered to patients. It does, however, differ from the global COVID-19 vaccine supply chain (displayed in Figure 3-3) because of the structure of procurement and distribution in South Africa.

Companies or supply chain members involved in the COVID-19 vaccine supply chain are continuously chasing a shorter timeline due to the stability factor of vaccines, post leaving the factory and a need to try and vaccinate people as soon as possible (Manager 1, 2021). Both the literature review and stakeholders confirmed that in South Africa, the Department of Health is the sole procurer of COVID-19 vaccines and have identified certain private and public partners to assist them with the distribution of vaccines in the country. As the vaccine role out program began, the researcher learnt, from stakeholder interviews, that those partners identified in section 4.4.3, are not necessarily the only partners being used in the distribution of vaccines in South Africa.

There are a limited number of companies responsible for importing COVID-19 vaccines in South Africa for example, Imperial Logistics, Biovac and Pfizer (Manager 4, 2021). These companies wait upon the South African Government to inform them, when and where they have procured vaccines. They, or freight forwarders that they outsource to, are then responsible for transporting vaccines from a manufacturing facility or factory, mostly in Europe and the USA, to the local port in South Africa, via air transport (Manager 1, 2021). Once vaccines arrive at OR Tambo International Airport customs clearance agents are responsible for facilitating the import process and ensuring authorized passage of vaccine shipments. Currently, OR Tambo International is the only South African airport to which COVID-19 vaccines are transported (Manager 3, 2021). Vaccine shipments are transported, via road transport, from OR Tambo International Airport to a central storage facility. There are two central storage facilities in the country, either the Biovac storage facility in Midrand or the DSV facility located in Johannesburg (Manager 3, 2021).

6.3.2. The flow of COVID-19 vaccines from central storage facilities to vaccination sites

The researcher received information from the DSV team to summarize the process followed at their central storage facility. Most protocols followed at the two central storage facilities are relatively similar, except for the cold chain storage equipment that is used and the temperature ranges that are maintained. Vaccines requiring a storage temperature of 2°C to 8°C are transported to the Biovac facility whereas vaccines that fall into a -70°C storage requirement category are transported to the DSV facility, from the airport by a freight forwarder (Manager 3, 2021). Vaccines that are manufactured in South Africa are transported from manufacturing facilities to the Biovac storage facility via road transport.

Once vaccine shipments reach the storage facilities they are placed in cold storage. The processes that take place within the DSV Healthcare facility, from receiving shipments to delivering them, are summarized in Figure 6-2. The figure consists of three swim lanes. Each lane represents an ongoing process that takes place simultaneously to the other two lanes. The first lane displays the flow of vaccines as part of the entire supply chain (this is just a snippet). Lane 2 describes the activities that form part of the physical handling of the vaccines in the DSV facility and lane 3 shows other activities that need to take place to have the correct resources allocated to the distribution process.

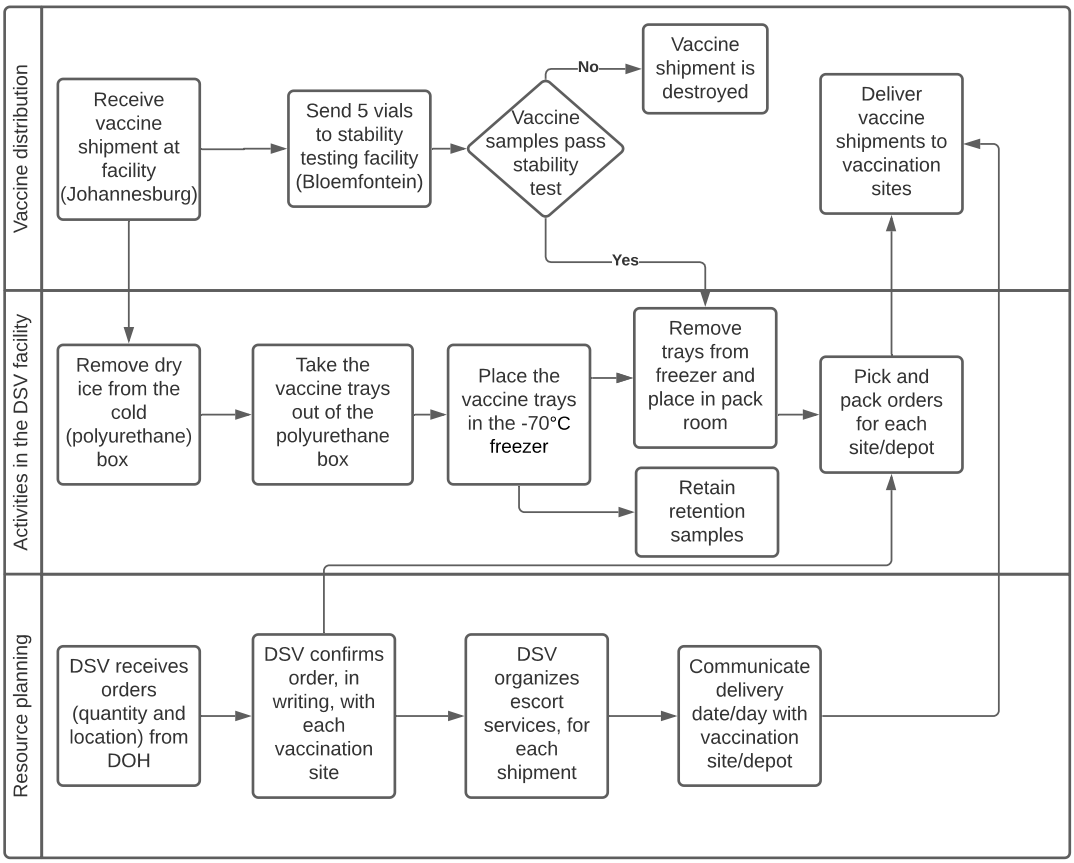

Figure 6-2: DSV Healthcare COVID-19 vaccine flow

Source: Compiled by the researcher for the purpose of this study

DSV receives the vaccine vials from Pfizer in a polyurethane box that is packed inside a carton box. The polyurethane box has got dry ice on top of it as well as a temperature monitoring device (Manager 4, 2021). The DSV team has got five minutes to transfer the vaccines from a -70°C environment to a -70°C storage facility (ultra-cold freezer). It is important to remember that DSV employees work in an environment with an ambient temperature (where unpacking of shipments take place) of between 18°C and 25°C (Manager 4, 2021). The process of transferring the vaccines is quite robust and a team of employees is used during the process, with each employee having a different role to fulfill. These roles include:

- Opening and closing the ultra-cold freezer (the freezer may only stay open for 30 seconds at a time and once closed will only be able to reopen after 5 minutes);
- Monitoring the stopwatch;
- Taking the dry ice off the cool box; and
- Removing the shipment from the box.

Employees need to fulfill these roles very precisely because of the significant value of each shipment. One tray, per cooler box, is about 195 vials. Each vial can vaccinate six people, which calculates to about 1170 vaccinations per tray (Manager 4, 2021). Pfizer, the company, bills medical aids R354,75 per dose of the Pfizer vaccine and the cost of the J&J vaccine is around R330 per dose (De Wet, 2021). The cost of these vaccines and the fact that it is being administered to humans, emphasizes the care that should be taken during the cold chain.

Effectively, the Department of Health is the client of DSV, who communicates with the company how many vaccines they will receive and when. COVID-19 vaccine shipments usually arrive on Sunday nights at the DSV facility, whereafter five vials are taken to a laboratory in Bloemfontein for stability testing on the Monday morning. These samples and their results are usually released mid-afternoon on Wednesdays to allow the flow of vaccines to continue or to stop the entire shipment. While stability testing takes place, the Department of Health sends DSV a list of vaccination sites or facilities as well as the quantity per location that vaccine trays need to be transported to. There are about 120+ facilities that DSV delivers to, and the company only delivers vaccine shipments in full trays (Manager 3, 2021). Depending on the province, shipments are either delivered to a provincial depot or directly to a vaccination site.

After receiving order quantities from the Department of Health, DSV directly contacts the different vaccination sites or depots to confirm in writing that it is what they want. They also establish when the vaccination sites will receive their shipment based on their location. Between Monday and Tuesday, DSV personnel are also in contact with certain escort/security services about their delivery schedule, to organize and plan enough resources to escort DSV trucks during the delivery process (Manager 4, 2021). Although some shipments are sent out on a Wednesday evening, the majority of trays are picked and packed on a Thursday. DSV tries to flush out all trays by the end of week, except some retention samples that are retained, to prepare for the next shipment and to avoid becoming a long-term storage site (Manager 4, 2021).

According to Manager 4 (2021), DSV uses polyurethane cold boxes to ship the vaccine vials to vaccination sites. These polyurethane boxes, if unopened, will maintain a temperature of -70°C or a temperature range between -60°C and -80°C for up to 72 hours and they fit perfectly into the specialized carton boxes. Any individual who receives the box at any given time in the supply chain, needs to check the temperature monitoring device, on top of the polyurethane box, and document

it. If at any time, the temperature monitoring device shows a temperature fluctuation above -60°C or below -85°C they should red flag the shipment and indicate a deviation. DSV will not deliver the "red flagged" product/shipment to its intended location, but will quarantine it in the correct storage conditions (Manager 3, 2021). The temperature data of the shipment will then be investigated to determine why the temperature range went above or below the required range and for how long. If, after investigation, the shipment is still viable it will re-enter the supply chain, otherwise compromised vaccines will be destroyed (Manager 4, 2021).

Figure 6-3 and Figure 6-4 illustrate the temperature profile, for a 48-hour period, during the delivery of two separate Pfizer COVID-19 vaccine shipments. These graphs are used to demonstrate how the cold chain equipment and technology, namely the polyurethane box and dry ice, that the vaccine vials are packaged in, maintains the vaccine cold chain. Manager 4 (2021) explains that vaccine vial trays are taken out of the ultra-cold freezer, placed in the packaging explained above and the temperature monitoring device is activated. The first temperature reading, displayed on the graph, is taken ten minutes after the temperature monitoring device is activated. This ten-minute time delay allows sufficient time for the device to reach equilibrium inside the environment (Manager 4, 2021).

Figure 6-3: Temperature data of vaccine shipment 1

Source: Manager 4, 2021

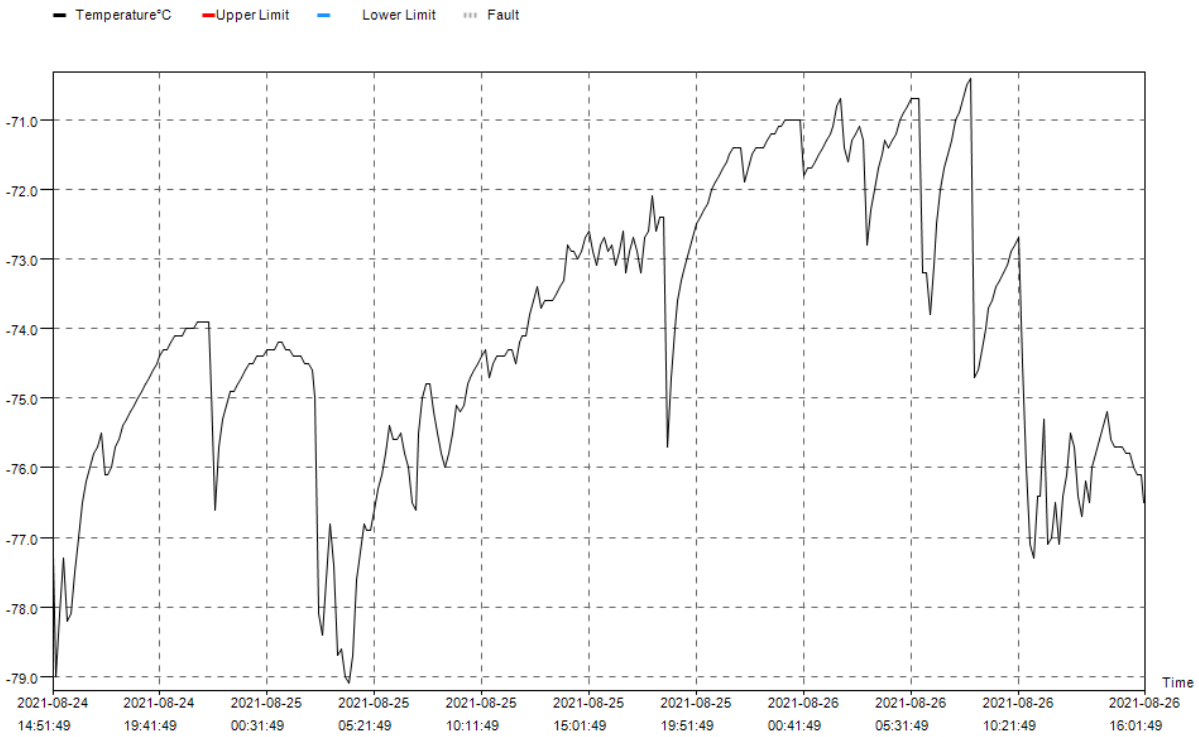

Figure 6-4: Temperature data of vaccine shipment 2

Source: Manager 4, 2021

The temperature data in the first example, Figure 6-3, reached a maximum of -69.1°C and a minimum of -76.3°C with an average temperature of -72.2°C. The temperature data in the second example, Figure 6-4, reached a maximum of -70.4°C, a minimum of -79.1°C and an average of 73.6°C. Although the temperatures in both examples fluctuate around -70°C, the temperature levels never rise above -60°C nor below -85°C. Temperature data in both examples fall well within the required temperature range and illustrate the ability of the cold chain packaging to maintain the required temperature range of a Pfizer vaccine. The fluctuations in temperature around -70°C can be the result of the sublimation and movement of the dry ice over time inside the box (Manager 3, 2021).

It is important to note that the company tries to avoid reverse logistics as far as possible because of the complexity of the product. They do, however, have 13 cross-dock hubs around the country, stocked with a supply of dry ice in the unfortunate situation of a need for reverse logistics (Manager 4, 2021). If there is an issue with any shipment, it either goes back to the facility in Johannesburg (if

it is close enough) or to one of the DSV cross-dock hubs, where the shipment is restocked with dry ice (which gives the shipment an additional 72 hours).

The rest of the supply chain and the importance, role and responsibility of each link is explained in the various sub-sections below.

6.4. TOOLKIT INPUTS & ANSWERED RESEARCH QUESTIONS

This chapter includes results from both the literature review and the stakeholder analysis that assisted the researcher in answering the research questions. Information from stakeholder interviews is further analyzed in this section, to answer aspects of the research questions that could not be answered through the literature review. The researcher used the research questions and research objectives as a basis from which interview questions were generated, as seen in Appendix A. Insights gathered from stakeholders were most valuable in determining which elements should be included in the toolkit. Facts and knowledge from stakeholders were used to correlate or differ from the basic assumptions made, based on the literature review.

The researcher divided this section into six sub-sections. Each sub-section, the title or term, was derived from one of the research questions. The researcher did this to categorize results and simplify the answering of the research questions. Each sub-section contains an amalgamation of answers and knowledgeable facts from various individuals, either in the same or a different stakeholder group.

6.4.1. Handling, distribution, and skills-requirements of similar vaccine supply chains

South Africa has dealt with the distribution and administration of vaccines for many years. Although Pharmaceutical experts' reason that the industry is in its infancy state, distribution companies have learned and grown significantly in the effective distribution of vaccines in the country (Dorfman, 2021). Individuals from distribution companies are very aware that in South Africa there is a vast variety of situations and circumstances regarding distribution locations. Each Province and even municipality or regional area are in different development phases and has dissimilar availability of resources and infrastructure. This is one of the biggest challenges when distributing and storing vaccines. Power shortages, seasonal weather changes, environmental challenges and human error are some of the major concerns that distribution companies need to anticipate (Manager 1, 2021).

The widespread distribution of vaccines in the past, over all nine provinces in South Africa, gives distribution companies in the pharmaceutical industry the advantage of having dealt with temperature sensitive products and their requirements during distribution. Imperial Logistics, a stakeholder in this study, has distributed vaccines manufactured by GSK for many years. The international manufacturing company, GSK, have a vaccine portfolio of over 20 different vaccines that help protect people from a range of diseases throughout their life (Manager 1, 2021). DSV Healthcare on the other hand distributes a range of pharmaceutical products manufactured by SANOFI, their focus being Tuberculosis (TB) medicines. Information from literature review and these examples indicate that distribution companies in South Africa have adequate experience in distributing vaccines and pharmaceutical products that require certain temperature ranges and this assists them in the distribution of COVID-19 vaccines (Manager 3, 2021). The Pfizer vaccine's temperature requirement did require distribution companies to purchase appropriate cold chain equipment and PPE and additional training and/or upskilling of employees needed to take place (Manager 4, 2021).

Manager 2 (2021) explained that through their company's years of distributing vaccines with a temperature requirement of 2°C to 8°C they have established a few primary processes that takes place in any of their warehouses. These phases, processes or steps are identified, by them, as the basic processes for every vaccine and are summarized in Figure 6-5:

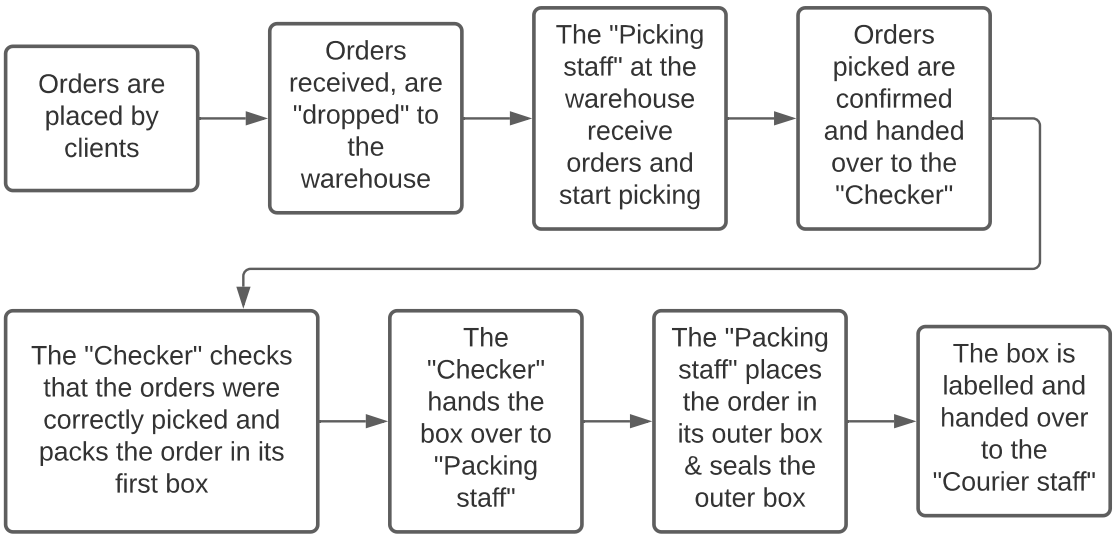

Figure 6-5: Vaccine handling processes

Source: Compiled by the researcher for the purpose of the study

According to Manager 2 (2021) there are between five and six groups of people who handle a vaccine in a warehouse. These groups stay relatively the same for any vaccine but the tasks for the employee groups might differ based on the vaccine's requirements or order specifications:

1. Admin staff:
    - Receive orders placed/dropped at warehouse;
    - Assign tasks to picking staff
2. Picking staff:
    - Receive picking task;
    - Go to a bin;
    - Work according to a first-in-first-out system;
    - Confirm order, after task is completed, and hand order over to checking staff.
3. Checking staff:
    - Check that the order is correctly picked;
    - Place order in its' first box (this box can keep a 2°C to 8°C temperature range for 19 hours);
    - Hand order over to packing staff.
4. Packing staff:
    - Place first box in the outer box;
    - Seal the box;
    - Label the box.
5. Label and handling staff:
    - Responsible for labelling orders and general handling of boxes on the distribution floor.
6. Courier staff:
    - Receive boxes from packing, labelling and handling staff;
    - Load the transport vehicle and deliver orders.

Manager 1 (2021) suggests that there is one skill that has always contributed to a successful vaccine supply chain and always will. That skill is cold chain expertise and refers to having validated solutions that have been tried and tested. Manager 3 (2021) supports this opinion because in her capacity she believes that cold chain distribution expertise is the key to a successful cold chain, no matter the product. This expertise stems from previous experience and educating personnel around the

importance of certain cold chain aspects. Employees need to understand the characteristics of the product and its cold chain, for example, how long can it be stored and how the packaging should be done. Cold chain expertise is a structured methodology and science and has years of data that supports the manner in which activities are performed. Thus, an integral part in overcoming many cold chain challenges (Manager 1, 2021). Basic cold chain expertise and knowledge created through years of experience, data and education are applied to the management of the COVID-19 vaccine cold chain and addresses challenges that arise.

In the early stages of the COVID-19 vaccine worldwide rollout, industry experts predicted that there are eight potential obstacles and bottlenecks that might occur at every stage of the global COVID-19 vaccine supply chain, explained in section 3.6.2. Manager 4 (2021), assisted in explaining which of these challenges, vaccine supply chains in South Africa have faced, and how companies have tried to overcome these challenges throughout the COVID-19 vaccine rollout:

- National security issues: Not all vaccine deliveries in the country need security escorts during the transportation leg. The value, delivery location and importance of the vaccine determines this need. In the case of COVID-19 vaccines, DSV does not do any deliveries without the support of NATJOINTS (The National Joint Operational and Intelligence Structure) as well as the support from their own security providers who do armed escorts. The company makes use of unmarked vehicles to transport the vaccines and tracks their delivery trucks at all times.
- Security services at vaccination sites: Doctor 1 (2021) commented that their vaccination site always has a security team on site during vaccination timeslots. The researcher observed that a security guard or security guards was/were also present at the public clinic, two private pharmacies and public hospital.
- Lack of coordination and resources: Supply chain members of the South African vaccine industry have experience in communicating vaccination plans and schedules across supply chains. Although the rollout of COVID-19 vaccines in South Africa have not been executed according to the original, proposed timeline, individuals at Imperial Logistics argue that regardless of the negative publicity, the vaccination program in South Africa is fairly efficient. Individuals working at vaccination sites, interviewed by the researcher, support this statement made by Imperial Logistics in commending the efficiency of the rollout program. A problem in terms of the lack in resources was, however, noted by Nurse 1. Nurse 1 (2021) mentioned that nurses and other staff at local clinics need to administer COVID-19 vaccines

on top of their other daily tasks. This makes it difficult to balance which activities should receive top priority.

- Vaccine damage: Most vaccine damage normally occurs due to a break in the cold chain. In South Africa, COVID-19 vaccine write-offs because of spoilage or contamination have been minimal. This success can be linked to the strict cold chain protocols that are followed by supply chain members, the stability testing by NCL and constant temperature monitoring (Manager 1, 2021). The characteristics of vaccines give a small window of grace if anything were to go wrong during the supply chain and supply chain members need to manage this window by making use of available infrastructure and resources (Manager 5, 2021).
- Gaps for Rural Areas: According to Statistics South Africa, the rural population in the country in 2020 was estimated at 19 361 915 people. These citizens need access to vaccination programs, including the COVID-19 vaccination program. Many initiatives in South Africa, for example, the Unjani clinics, have made it possible to bring healthcare to rural areas (Pharmacist 1, 2021). The biggest challenge in rural areas, in terms of the COVID-19 vaccine, is the lack of sufficient cold storage capacity. This challenge can, however, be overcome by cold chain expertise and the variety of cold chain equipment available in which COVID-19 vaccines can be stored until needed**,** explained in section 3.8.2 and summarized in Table 6-2.
- Misinformation about Vaccines and Tracking who has been vaccinated: The South African Government tracks who has been vaccinated through a national registry (Pillay, 2021). Various opinions and news articles on social media and the internet have created two groups of people when it comes to vaccination. First, the group choosing to get vaccinated and second, the group choosing to not get the vaccine (Manager 3, 2021). The researcher chose to focus her study on those who want the COVID-19 vaccine. Manager 3 (2021) noted that a key challenge that needs to be overcome in the COVID-19 vaccine supply chain is increasing the demand amongst the public.

Nurse 1 (2021), Nurse 2 (2021) and Pharmacist 4 (2021) mentioned from a practical point of view, the fact that clinics and hospitals in South Africa have dealt with the administration and storage of vaccines for many years, assisted in the COVID-19 vaccination program. Most of these immunization vaccines need to be stored in a refrigerator (2°C to 8°C), thus, those nurses responsible for vaccination know the importance of keeping vaccines within the correct temperature range. Pharmacist 3 (2021) and Nurse 1 (2021) stated that most nurses have experience with carrying out an immunization campaign as it is part of their formal qualification, and they did not need a lot of

additional training for the COVID-19 vaccine rollout. Their experience together with the insights of distribution companies contributes to a successful vaccine roll out program (Pharmacist 1, 2021).

6.4.2. Cold chain requirements & categorization

The most important cold chain requirement when it comes to COVID-19 vaccines is temperature. This statement is supported by information from the literature review and every single stakeholder interviewed. According to various sources, apart from temperature, shelf life, shaking/vibration or agitation and sunlight are also cold chain requirements that should be monitored within a vaccine supply chain (Pharmacist 1 and 4 and Manager 2, 2021) .

The Department of Health (DOH) in South Africa only requires companies involved in the distribution, storage, and handling of COVID-19 vaccines to monitor temperature (Manager 4, 2021). There are three temperature elements that should be monitored and managed in a vaccine supply chain. The first referring to the temperature monitoring of stock by making sure vaccines stay in the correct and recommended temperature range, examples are illustrated in Figure 6-3 and Figure 6-4. The second is the monitoring of vaccine's freezing, in most vaccine supply chains – the avoidance thereof and the last element is the management of consumables used in the vaccine cold chain (Manager 2, 2021). Information booklets from the FDA do, however, also recommend that distribution companies need to monitor and manage the expiry date (shelf life) indicated on the packaging of COVID-19 vaccines.

During the tender process for the distribution of COVID-19 vaccines in South Africa, the DOH categorised vaccines according to their temperature requirement, and companies could tender for either one category or both. The first category was for vaccines that require a storage and handling temperature range of between 2°C to 8°C and the second category was for vaccines requiring a storage, handling, and distribution temperature of -70°C. The Jansen (Johnson & Johnson) vaccine falls into the first category and the Pfizer vaccine into the second.

Individuals from the stakeholder groups DSV, Imperial Logistics and healthcare workers at vaccination sites (pharmacists, nurses & a doctor) agree that this is the easiest way to categorize and summarize vaccines and their cold chain requirements. Manager 3 (2021) stated, "It is a logical basis of classification." Although Manager 1 (2021) supported this categorization, he just noted that for South Africa temperature and storage is a crucial component of the supply chain. The country

faces many challenges because of load shedding, poor access, hot weather etc., and when sending vaccines to certain areas, distribution companies need to be aware of environmental challenges. He, thus, suggests that vaccines should be categorized according to temperature and storage.

Table 6-2 summarizes the requirements of the two categories, based on information from these three stakeholder groups and the literature review. While the storage temperature range of the two categories differ, stakeholders and organizations warn that exposure to light (sunlight or ultraviolet light) should be minimized for both vaccines. It is, however, not required to monitor the amount or intensity of light exposure during storage and handling. Vaccines that fall in Category 1 have two options during storage. They can either be stored in a refrigerator until their expiry date or they can be stored at an ambient temperature for up to 12 hours. Vaccination sites that do not have refrigerators at their disposal, make use of the 12-hour storage gap. Four stakeholders, involved at vaccination sites, confirmed that vaccine expiry dates are not shown on vaccine vials and that barcodes need to be scanned to view the expiry date.

Vaccines in Category 2 can be stored in one of three different cold chain infrastructures, based on the availability of certain equipment. Vaccines can be stored until their expiry date in ultra-cold freezers, for up to one month in a freezer and for up to two weeks in a refrigerator. It is important to note that for both categories, shelf life is determined and based on unpunctured vials. Punctured vaccine vials that have already been mixed, with other liquids, are viable for up to six hours at room temperature (Doctor 1, 2021).

Table 6-2: Vaccine cold chain requirements categorised

Category	Temperature range	Storage and handling temperatures	Shelf life – unpunctured vials	Shelf life – punctured vials	Other cold chain requirements
1	2°C to 8°C	• Refrigerator: 2°C to 8°C • Ambient: 9°C to 25°C.	• Refrigerator: Until expiration date • Ambient: Up to 12 hours. (The expiry date is not printed on the vaccine vial; employees need to	Two to six hours, at room temperature	Minimize light exposure during storage.

			scan the QR code on packaging.)		
2	-70°C	• Ultra-cold freezer: -80°C to -60°C • Freezer: -25°C to -15°C • Refrigerator: 2°C to 8°C	• Ultra-cold freezer: Until expiration date • Freezer: Up to one month • Refrigerator: up to two weeks	Two to six hours, at room temperature	Minimize exposure to room light during storage. Avoid exposure to sunlight and ultraviolet light.

Source: Compiled by the researcher for the purpose of this study

6.4.3. Cold chain protocols

Individuals at each link in the supply chain, illustrated in Figure 6-1, have different roles, responsibilities, and protocols that they need to follow to maintain the vaccine cold chain. As mentioned in section 3.6, the WHO (2021) identified eight steps in the deployment of COVID-19 vaccines:

1. The goods receiving of products
2. Storage of vaccines
3. Repacking vaccines
4. Purchase of cold chain equipment
5. Transportation of vaccines
6. Reverse logistics
7. Management of recalls
8. Management of supply chain information

These steps are applied to Table 6-3 to summarise what tasks or steps each of the cold chain links are responsible for. Some steps are applicable to every supply chain link whereas others are only fulfilled by a few links. There are generally four to five stops before vaccines are administered to patients. The researcher mainly interviewed those stakeholders that form part of the domestic stakeholder group to establish which protocols are followed during storage, handling and

distribution by employees and individuals at the respective supply chain links, in South Africa. The links and stakeholders are summarised in Table 6-3 and ordered in the natural flow of distribution.

Table 6-3: Supply chain links, roles and responsibilities

Supply Chain Link	Company / stakeholder example	Role & Responsibility	Steps
1. OR Tambo International Airport	Pfizer, Imperial Logistics and Biovac	Importing and receiving shipments at local ports	1, 4, 5, 8
2. Customs Clearance & Freight Forwarding	DHL, Kuehne and Nagel (K&N)	Forwarding and clearing of shipments imported	1, 4, 5, 6, 8
3. Central Storage Facility	Biovac and DSV Healthcare	Receive shipments, store shipments, pick & pack orders, deliver orders	1, 2, 3, 4, 5, 6, 8
4. Stability testing	NCL	Determine safety and efficacy of vaccine shipments	1, 7, 8
5. Vaccination sites	Pharmacists, nurses, and doctors	Receive vaccine shipment and administer to patients	1, 2, 4, 8

Source: Compiled by the researcher for the purpose of this study

6.4.3.1. OR Tambo International Airport

The companies that are responsible for importing vaccines either do the importing themselves or they have a freight forwarder that does the job on their behalf. Freight Forwarders are responsible for arranging transport services and preparing the relevant documents. Companies responsible for importing, collect the COVID-19 vaccine shipments in their tertiary packaging at the manufacturing facility. On departure, the company's employees are responsible for checking whether the product is in fact in the correct packaging, the correct paperwork is included, and the correct number of vaccines are ready to be transported around the continent safely (Manager 1, 2021). In the case of most COVID-19 vaccines, the manufacturer will stipulate the amount of dry ice needed for the supply chain or distribution leg (Manager 5, 2021). Vaccine shipments are transported by means of road transport to international airports and flown in on air transport to OR Tambo International Airport.

Once vaccines touch down in South Africa, customs clearance agents and freight forwarders fulfill their roles. Clearing agents act on behalf of the shipper and arrange or facilitate the customs

clearance of the vaccine shipment that has been imported. These agents calculate the import duties and taxes/VAT that is payable on the shipment as well as framing and submitting the Bill of entry (BOE) to SARS (Push Button Import Export, n.d.). All these activities take place at the airport and clearing agents arrange the customs clearance/release of the vaccine shipment after the relevant requirement stops have been passed e.g., port health exams. Freight Forwarders need to have the relevant paperwork/documents in place and assist clearing agents with the shipment hand over (Push Button Import Export, n.d.). In the case of Pfizer vaccine shipments, DHL perform both the clearing and forwarding activities for Pfizer. DHL is responsible for transporting vaccines from OR Tambo airport to the DSV central storage facility in Johannesburg (Manager 4, 2021). It is important to note that transport from the airport to the central storage facilities is arranged by the National Department of Health (Manager 5).

6.4.3.2. Central storage facilities

There are two central storage facilities in South Africa that are used to store, handle, and deliver COVID-19 vaccines, operated by DSV and Biovac. Both are in the Gauteng province with a centralised storage solution and have the capacity to deliver vaccines to anywhere in South Africa in three to four days (Manager 4, 2021). When a company like DSV tendered for the distribution contract, the company modelled based on the assumption that if they were to distribute those vaccines that require a storage and distribution temperature range of 2°C to 8°C, they would need to deliver to between 800 and 900 vaccination sites. In the case of the -70°C temperature range category, they would deliver to about 100 vaccination sites. The reason for fewer vaccination sites in the -70°C category is the lack of appropriate storage capacity at vaccination sites or other depots.

The fact that DSV stores and distributes the Pfizer vaccine (-70°C temperature requirement) with a different temperature requirement than the Johnson & Johnson vaccine (2°C to 8°C temperature requirement) distributed by Biovac, means that certain basic processes followed are the same, but handling protocols differ at each facility. According to information from both the literature review and distribution companies, employees at these facilities are responsible for:

- receiving and assessing the vaccine shipment upon arrival;
- offloading shipments from road transport vehicles of the freight forwarders;
- unpacking the carton boxes and taking vaccine trays out of tertiary packaging;
- placing the vaccine trays in cold storage;
- monitoring and managing the storage temperature under refrigeration or freeze indicators;

- logging the temperature data of cold chain equipment;
- checking paperwork and updating vaccine inventories;
- checking the expiry date of vaccines;
- receiving orders from DOH, stipulating quantity and location of delivery;
- taking vials out of storage for picking, and packing vaccines for transit according to orders received;
- loading their own delivery vehicles;
- delivering vaccines to location.

These activities need to take place, while maintaining the recommended storage and handling temperatures (Manager 3, 2021). The procedures that are followed at the DSV facility in Johannesburg in terms of product flow are explained in section 6.3.2, and the processes that occur at the Biovac facility are very similar. The temperature requirements of both the vaccine categories require individuals at the storage facility to follow exact procedures and time schedules. It is important to note that DSV prefers to always ship vaccine vials in full trays and vials are delivered to either a provincial depot or a vaccination site. The destination that vaccines are delivered to is determined by each province and the private sector. Some provinces and companies want the distribution partners to deliver directly to vaccination sites, whereas others prefer delivery to provincial depots or company depots.

DSV and Biovac receive vaccine shipments from manufacturers and the freight forwarders in its tertiary packaging. Vaccines trays are then removed from the polyurethane boxes and placed in cold storage. Manager 4 (2021) explains that once orders are received, confirmed and scheduled the following standard packing procedure takes place, in the pack room with an ambient temperature:

- vaccine trays are placed in the polyurethane box;
- they are covered with dry ice;
- a temperature monitoring device is placed around the vials and dry ice, but the actual temperature logging unit is placed on top of the polyurethane box, once it is closed (to avoid freezing);
- the polyurethane box is closed; and
- placed in a carton box.

Carton boxes are loaded onto trucks and transported to either provincial depots or vaccination sites. The vials are taken out of the polyurethane boxes at destination facilities and put into cold storage. Polyurethane boxes, belonging to DSV, are returned to the DSV central storage facility to reuse up to five times (Manager 3, 2021).

6.4.3.3. Vaccination sites

In South Africa, COVID-19 vaccines are either delivered to a provincial depot or directly to the vaccination sites. According to Manager 5 (2021), this delivery option is dependent on the preference of the province and the cold storage facilities available at vaccination sites. COVID-19 vaccines delivered to a provincial depot is stored and delivered to different vaccination sites daily, based on the vaccination site's forecasted demand (Pharmacist 4, 2021). The researcher conducted interviews with personnel in the private and public sector. Each sector has general procedures that they follow when receiving vaccines from either DSV, Biovac or their provincial depot and some instances where protocols differ, as explained below.

Public sector: Nurse 1 (2021) is the operations manager at the local clinic in a rural area in the Western Cape and a qualified medical nurse, who shed some light on the protocols that she and her personnel follow at their vaccination site. The clinic collects Pfizer COVID-19 vaccines from the Day Hospital in a town close by, their nearest Sub-District medical centre, on Monday mornings. The number of vaccines received are solely dependent on the number of vaccines available and awarded to the rural clinic. An employee at the clinic, usually the general manager or pharmacist, collects the vials in a polyurethane box from the sub-district medical centre, signs the necessary paperwork and transports the vials in a vehicle to the clinic. At the clinic, the polyurethane box is immediately taken to the clinic pharmacy where the pharmacists remove the dry ice, checks the number of vaccine vials in the box and logs the temperature displayed on the temperature monitoring device (Pharmacist 2, 2021).

Vaccine vials are then placed in a refrigerator that retains a temperature range of 2°C to 8°C. An assigned nurse is responsible for checking and logging the temperature of the refrigerator twice a day. If anything should happen that could jeopardize the safety and efficacy of the vaccines, e.g., vaccines are exposed to temperatures outside the recommended storage temperature, Nurse 1 (operations manager) or Pharmacist 2 calls the Day Hospital to report the incident and awaits further instructions. Between 12 and 24 COVID-19 vaccines are administered to patients everyday

between 11:00 and 13:00 at the clinic. Vials are taken out of the refrigerator 15 minutes prior to it being administered. The pharmacist is responsible for updating the stock card once vaccines are taken out of the refrigerator to be administered. Nurse 1 is responsible for returning unused vaccine vials to the Day Hospital on Fridays, because the clinic is closed on Saturdays and Sundays and the vaccine vials cannot be left unattained throughout the weekend. Unused vials are placed in the polyurethane boxes that they came in when transported back to the Day Hospital. It is important to note that at the clinic vaccines are administered on a first come, first serve basis.

Doctor 1 (2021), operations manager at a public vaccination site in an urban town (area), explained that their pick-up protocol is very similar to the rural clinic. The public vaccination site collects their vials every Monday to Friday morning from the town's Provincial Hospital (their nearest Sub-District medical centre). The number of vials they receive are based on previous daily demand. The vials are transferred at the hospital from cold storage into the vaccination site's portable freezer, filled with big ice blocks, that is then loaded into the vehicle of the employee collecting the vials for the vaccination site. The vials stay in the portable freezer until they are administered, and all unused vials are returned to the Provincial Hospital at the end of that day. Once the portable freezer arrives at the vaccination site, the temperature is checked and logged. This protocol is followed every time the freezer is opened and closed.

Private sector: Pharmacist 1 and Pharmacist 3 are qualified pharmacists who work at pharmacies in a town and urban area respectively. These pharmacies form part of the private sector and administers the Pfizer COVID-19 vaccine to citizens. Their operations vary a bit from the process explained above because COVID-19 vaccines are administered based on an appointment-system and the pharmacies receive vaccines directly from DSV, after placing an order directly to the DOH. Personnel at these pharmacies receive a call from DSV confirming their vaccine order placed at the DOH and the day that the vaccine shipment will be delivered.

When vaccine shipments arrive, one of the pharmacists at the pharmacy is responsible for signing the paperwork and immediately logging the temperature of the shipment received. Pharmacist 3 (2021) mentioned that their pharmacy receives a USB device with each vaccine shipment, providing the temperature data of the temperature monitoring device attached to the shipment. Pharmacist 3, pharmacist, and pharmacy owner, is responsible for checking the temperature data,

downloading, and storing it for any future use or reference. After vaccine vials are received, they are removed from their tertiary packaging and placed in a freezer with a temperature of between -25°C and -15°C. Most pharmacies also have a refrigerator at their disposal, which they use to store the vaccines in before administering it to patients.

6.4.3.4. Basic protocols

Through the interviews with the supply chain links, a few protocols can be listed and summarized as the basic protocols that need to be followed by anyone who handles a COVID-19 vaccine shipment at any time in the supply chain. The protocols applicable to the research topic are summarized below:

- Be informed and educated about the temperature and storage requirements of the COVID-19 vaccine that are handled or stored.
- Always check the temperature monitoring device, upon receipt and handover, to make sure that the correct temperature range is being upheld.
- Monitor and log temperature data of both the temperature monitoring device and the cold chain equipment being used e.g., refrigerator or freezer on a regular basis.
- Sign and complete the necessary paperwork.
- Red flag a shipment as soon as a temperature fluctuation is detected in storage or handling circumstances.

6.4.4. Best practices

Section 3.5.2 in the literature review provided five best practices that Conway (2021) recommends for vaccine distribution. The first is to minimize variation whenever and wherever possible, to try and control these variations. In South Africa, the DOH tries to minimize variations by being the sole procurer of COVID-19 vaccines and only using a handful of companies to import and distribute the vaccines in the country, as explained in the sections above (Manager 1, 2021). The companies responsible for the distribution of vaccines follow certain set out protocols, mentioned in section 6.4.3, that contribute to minimizing variation in the supply chain.

The second and third best practice can be combined and focus on using technology to the advantage of the supply chain. Not only do distribution companies and vaccination sites make use of barcodes to track and trace vaccine vials, but temperature monitoring devices follow shipments from

manufacturing to vaccination. These devices allow visibility into the supply chain, best practice four, and if correctly monitored can inform supply chain links exactly when, where and for how long temperature fluctuations took place (Manager 4, 2021). The temperature logger allows data to be downloaded onto a USB device, which means temperature data can be viewed and stored. Temperature monitoring devices or temperature loggers play an integral part of managing and upholding the vaccine cold chain and is extremely useful, since temperature is the only COVID-19 vaccine cold chain requirement companies are obligated to monitor in South Africa.

Manager 2 (2021) suggests that automated electronics manufacturing services (EMS) systems are extremely valuable and important in managing cold chain requirements and elements. These systems are used to monitor and manage the cold chain, allowing companies to highlight human error and have better control. Technology can simplify the monitoring process and have the advantage of warning employees as soon as temperature or humidity levels of cold chain equipment or products, fluctuate outside of the recommended or required ranges.

Best practice five, states to "call on the experts" and according to Manager 4 (2021), a cold chain expert, following basic cold chain protocols can be labelled as a distribution best practice. It contributes significantly to getting vaccines safely and effectively from manufacturing facilities to patients. Pharmacist 2 (2021) suggests that communication between supply chain links and communication from the DOH should be marked a necessity and a way of contributing to best practices during vaccine distribution. Pharmacist 2 (2021), Nurse 1 (2021) and Nurse 2 (2021) mentioned this because at the clinic and hospital in a rural area, management never knows how many people will turn up for their COVID-19 vaccination based on the vaccination message citizens receive from the DOH. People are referred to a certain vaccination site without the DOH informing personnel at the vaccination site how many people were referred to their site. This creates the problem of an insufficient number of vaccine vials and having to turn people away. Pharmacies in the private sector do not necessarily experience this problem but do support the notion that communication around vaccine administration should be linked to a best practice (Pharmacist 1, 2021).

6.4.5. COVID-19 vaccine cold chain education and training

As mentioned earlier, distributing, and administering vaccines is not something new in South Africa and according to most supply chain links, they used previously developed skills and knowledge to

approach their role in the COVID-19 vaccine supply chain. Distributing companies like DSV, DHL and Imperial Logistics used what Manager 1 (2021) described as cold chain expertise to understand and fulfill their distribution role in the supply chain. DSV used knowledge from public spheres, e.g., FDA information booklets, and information sharing from Pfizer South Africa to understand the protocols that need to be followed during distribution and storage of a second category (-70°C) vaccine. Previous experience, information from public sources and Pfizer South Africa allowed DSV to educate their employees, at all stages of the supply chain, on the importance of maintaining the COVID-19 vaccine cold chain and the critical role their actions play in assuring vaccines reach their destination safe and uncompromised (Manager 3, 2021).

The NCL facility/laboratory have been testing the safety of vaccines for human use in South Africa since 1998. Biologists, chemists, scientists, and other laboratory personnel are well trained in handling vaccines that require a certain temperature range to remain viable. The researcher is not aware of any additional training that these individuals needed to receive to be prepared for the stability testing of COVID-19 vaccines, except knowing the basic cold chain characteristics and requirements of the specific vaccine.

At the end of the supply chain, nurses and doctors are already trained and educated around the administration of temperature sensitive vaccines and pharmacists understand the storage temperature that needs to be upheld and logged. According to Nurse 1 (2021) and Nurse 2 (2021), staff at their facility did attend an information session about the storage and handling protocols of Pfizer vaccines that was presented by a primary healthcare representative of the provincial department of health and the chair of the local clinic and hospital. Information regarding vaccine supply, characteristics of the category two vaccine (Pfizer), administer procedures and basic protocols were communicated to nurses, administrative staff, cleaners, and the pharmacist. Doctor 1 (2021) explained that she and her admin staff received training on how to use the information system and all employees at the vaccination site received basic COVID-19 protocol training. The site also receives updated training material in the form of videos that need to be watched by all personnel at the vaccination site. Neither pharmacy interviewed in the public sector received any training from Government officials (Pharmacist 1, 2021 & Pharmacist 3, 2021).

6.4.6. Required skills and training

The literature review and composition of the supply chain highlighted that there are numerous different roles being played and fulfilled in the COVID-19 vaccine supply chain. The researcher tried to focus on the roles involved in the product and information flow in the supply chain and not necessarily the roles associated with the financial flow of vaccines. Both Manager 1 (2021) and Manager 3 (2021) share the opinion that each role requires either a formal qualification e.g., supply chain qualification or a health qualification, or is best suited based on experience. Individuals working at an operational level do not necessarily require a formal qualification, but they need experience and practical skill to perform their daily tasks and role in the supply chain. Manager 1 (2021) mentioned that on-the-job upskilling is crucial. This term refers to the process of teaching current employees' new skills or reskilling employees and starts with companies researching what skills are currently needed or will be required in the future. These skills are then developed through training and education of individual or groups of employees (Andriotis, 2018). In the COVID-19 vaccine supply chain, employees handling vaccine shipments and vaccine vials need to be trained on how to execute tasks and adhere to basic protocols.

Individuals interviewed on the distribution leg of the COVID-19 vaccine supply chain, suggest that cold chain expertise is the number one skill that employees in a management position should have. The term cold chain expertise, as explained in section 6.4.1, allows management personnel to use their experience and assembled knowledge to make decisions on a tactical and strategic level. It also allows these individuals to educate employees working at an operational level about protocols, decisions, actions, and characteristics associated with the handling, distribution, and storage of the specific product. Manager 3 (2021) believes that for someone who plays a middle to upper-level management role in this supply chain, it is critical to view the end-to-end supply chain and to understand how all the elements work together. Planning is critical and individuals in a management role need to be adaptable due to the high number of unknowns during the planning phase. Manager 1 (2021) suggests that individuals that form part of either upper, middle, or lower-level management need to give attention to detail and should be able to apply problem-solving techniques and skills.

In a vaccine supply chain, there are usually four levels or categories of training that employees on an operational level need to go through. These four levels were explained by Manager 2 (2021):

1. Standard Operating Procedure (SOP) training: This refers to the training of employees to perform day-to-day tasks.

2. System and device training: Employees are taught how to use the different systems and devices such as computers, scanners, and equipment.
3. Product specific training: This training is usually done by the client, teaching employees the relevant tasks related to their specific product.
4. General knowledge training: This training is focused around educating employees on the "why", why it is important to maintain the cold chain, why temperature levels should not fluctuate, etc.

Training on levels 1, 2 and 4 are relatively the same in every vaccine supply chain, only level 3 of training varies from product to product. System and device training, level 2, might vary if specific devices or equipment is required to handle or store a vaccine. Manager 2 (2021) mentioned that training of company employees at all stages of the supply chain either takes place on-site or at a training facility, based on the company. In the COVID-19 vaccine supply chain, employees handling the vaccine at a storage site need to be trained on all four levels and Pfizer or Biovac need to facilitate training on level 3. Employees involved in the handling, storage and distribution of COVID-19 vaccines also need to be able to read, write and count. Although these are basic requirements, they should never be underestimated or overlooked because these skills enable employees to execute daily tasks (Manager 2, 2021).

According to Pharmacist 1 (2021) and Nurse 2 (2021) there are normally four groups of employees at vaccination sites, namely pharmacists, nurses, administrative personnel, and cleaners. Pharmacists and nurses require a formal qualification to be classified as medical personnel during the vaccination process and their knowledge stems from these qualifications, training and experience. Both of these groups require the skills they already developed in terms of knowing basic vaccine protocols for both handling and storage. The two groups did not need to be trained in administering the COVID-19 vaccine. Nurse 1 (2021) did mention that her team at the clinic had to familiarize themselves with additional protocols applicable to the Pfizer vaccine, for example, administrative personnel needed to be informed about temperature and data logging. Nurse 2 (2021) and both public pharmacists suggested that those in charge of logging patient and vaccine data need to know how to operate the information system used in the vaccine rollout program.

Doctor 1 (2021) stressed that employees at vaccination sites need to have good people skills. Many citizens arrive stressed or anxious at vaccination sites and it is so important to put these people at ease and make them comfortable. Not only is people skills important but attention to detail is

another critical skill that employees at the end of the supply chain should have. Attention to detail is especially important when drawing up the exact amount of liquid needed per administration/vaccination. Pharmacist 3 (2021) confirmed these skills mentioned by Doctor 1 (2021) and added that supply chain links and companies should prioritize using an employee's natural abilities and specific skills. Pharmacist 4 (2021) suggested that employees at provincial depots need to be able to follow instructions, whether these instructions are verbal or in writing.

An important aspect mentioned by a few stakeholders is that employees at all levels should be proactive in knowing what they need to do and how they need to do it. Management personnel need to take up their responsibility and make sure that employees working under them understand their role and responsibility. Individuals should also know who to contact if there is a disruption in the supply chain.

6.5. CONCLUSION

This chapter served as an input to the toolkit, created in the next chapter, and through Chapter 6 most research objectives have been met and the researcher has enough information to create the educational toolkit. Information from the literature review and answers from the stakeholder interviews, allowed the researcher to understand and report on information related to each research question. The flow and functionality of the COVID-19 vaccine supply chain, in South Africa, is illustrated, explained and used as a basis to categorise and summarise cold chain protocols and requirements by, at each link in the supply chain. End-to-end supply chain visibility is critical and in South Africa temperature loggers is the primary tool used to evaluate and monitor the effectiveness of the vaccine cold chain. Management at all levels of the supply chain need to be able to apply problem-solving techniques, be adjustable to change and pay attention to every detail.

CHAPTER 7 : TOOLKIT

7.1. INTRODUCTION

This chapter serves as a summary of the output of the study. The output was achieved through collecting, analyzing, and comparing inputs gathered and explained in Chapters 3, 4 and 6. Chapter 7 explains what a toolkit is and how the researcher decided which elements to include in this specific toolkit. Some of these toolkit elements include, the stakeholders involved in the COVID-19 vaccine supply chain and their role, the cold chain characteristics and requirements that should be taken into consideration when distributing a COVID-19 vaccine and the skills required by employees throughout the supply chain to effectively manage, handle and store the vaccine in South Africa. The researcher included the toolkit elements that she found most applicable to the study and the target group. The toolkit was created and compiled with the aim of contributing to the education and knowledge of supply chain members in the vaccine cold chain industry, specifically, but not exclusively, in the COVID-19 vaccine cold chain.

7.2. A TOOLKIT

A toolkit is a fixed set of procedures, guidelines, protocols, criteria, etc., that is established to ensure a desired or required result is obtained. It consists out of a set of tools that is designed to be used together or for a particular purpose and addresses a target audience (Yalsa, 2017:1). Toolkits are the outcome of the process of analyzing resources and determining what content, on a specific topic, is the most relevant and important and presenting this information in a meaningful and simplified way (Lesly, 2015). A toolkit creation guide created by Yalsa (2017:1) explains that "toolkits can help translate theory into practice and are meant to offer practical advice and guidance regarding a specific issue or topic."

To establish which elements should be included in this specific toolkit, the researcher used the topic of the study as a basis, the literature review as a guide and the answers from various stakeholders as confirmation and input. The research questions, in section 1.5, were used as the foundation from which the researcher could extract key words and elements that now form part of the educational toolkit. The toolkit presented below is a combination of theory, practical advice and tools that can contribute to the understanding of the COVID-19 vaccine supply chain and the education around its functionality and requirements.

7.3. AN EDUCATIONAL TOOLKIT DEVELOPED FOR COVID-19 VACCINE SUPPLY CHAIN STAKEHOLDERS/MEMBERS

7.3.1. Introduction

The roll out of the COVID-19 vaccination program required citizens, healthcare workers, government officials, companies, and any other stakeholder groups to work together to achieve the South African Government's vaccination goal of herd immunity. This goal necessitated individuals to educate themselves on the COVID-19 vaccine's requirements, protocols, supply chain, etc. On 8 November 2021, the South African COVID-19 online news portal reported that 5.5 million Johnson & Johnson vaccines and 17.75 million Pfizer vaccine doses have been administered to South Africans since February 2021.

The aim of this toolkit is to aid stakeholders involved in the COVID-19 vaccine supply chain in the education and training of each employee or supply chain member that handles, stores, or distributes the COVID-19 vaccine in South Africa. The COVID-19 vaccine supply chain came into existence in South Africa in early 2021. Prior to that no knowledge, protocols, understanding or education and training existed for this specific vaccine cold chain. Although many distribution companies in the country have transported, handled, or stored vaccines and other pharmaceutical products, none have dealt with the distribution of a COVID-19 vaccine until January 2021. The same is applicable to pharmacies, pharmacists, nurses, and other healthcare workers at vaccination sites, at the end of the supply chain. These professionals have stored and administered vaccines for many years, but none had administered a COVID-19 vaccine until the vaccine rollout program commenced in South Africa.

The newness and importance of the vaccine supply chain created a gap for the researcher to understand the concepts and use inputs to create a set of tools that can be used to understand the supply chain and its content. The urgency of vaccinating citizens, if they choose to get vaccinated, and the extreme cold chain requirements of some vaccines, created a need for information and education of both the public and private stakeholders and sectors. Most tools in the toolkit are aimed at a subsection of the stakeholder group and some of these tools were created to illustrate and explain the functionality of the South African COVID-19 vaccine supply chain to any interested individual. There are four tools in this specific toolkit, starting with identifying the stakeholders and

the roles that need to be filled and ending with aspects pertaining to the education and training of supply chain members. The four tools are:

1. The COVID-19 vaccine supply chain stakeholders
2. The COVID-19 vaccine categorization and cold chain equipment
3. The COVID-19 vaccine handling, storage and delivery protocols; and
4. The COVID-19 vaccine supply chain required skills, training and education

7.3.2. COVID-19 vaccine stakeholders

Supply chain members, in both the public and private sector, need to identify stakeholders or stakeholder groups that are responsible for either procurement, evaluation, distribution, storage, handling and safety of the COVID-19 vaccine. Table 7-1 provides a list of stakeholders that need to be considered when studying the functionality of the COVID-19 vaccine supply chain in South Africa. These identified stakeholder groups can also serve as a basis to work from when identifying stakeholders in any other vaccine supply chain.

The first column of the table categorizes stakeholders according to the level that they operate on which is either a national level, mostly government, or a domestic/provincial level. The second column identifies the general stakeholder groups and provides examples of companies that form part of those stakeholder groups. The role of each stakeholder group, in column three, is linked to one or more of the following vaccine supply chain processes, derived from the SCOR framework's five basic supply chain management components, namely plan, make, source, deliver and return:

- Make
- Procurement / source
- Import
- Store
- Testing (stability & safety)
- Deliver
- Administer
- Return

The last column ranks the stakeholder groups according to their level of involvement in the physical distribution, handling, and storage of the COVID-19 vaccine. The two levels of involvement are:

- Low: minimum to no involvement
- High: medium to high-level involvement

Table 7-1: COVID-19 vaccine supply chain stakeholder groups

LEVEL	STAKEHOLDER GROUP	SUPPLY CHAIN ACTIVITY	INVOLVEMENT LEVEL
National or Government	The Department of Health	Procurement / source	High
	Inter-Ministerial Committee on Vaccination	Procurement / source	Low
	South African National Control Laboratory (NCL)	Testing (stability & safety)	High
	South African Health Products Regulatory Authority (SAHPRA)	Testing (stability & safety)	Low
Domestic or Provincial	Manufacturing e.g., Biovac and Pfizer	Make	High
	Air Freight e.g., Imperial Logistics and Pfizer	Import	High
	Freight forwarders e.g., DHL and K&N	Import	High
	Customs Clearance Agent e.g., DHL	Import	High
	Logistic Service providers e.g., DSV Healthcare	Store Deliver Return	High
	Healthcare Workers e.g., pharmacists, nurses, and doctors	Store Administer	High
	Security e.g., NATJOINTS and SAPS	Deliver	Low
	Patient		Low

Source: Compiled by the researcher for the purpose of this study

Each of these stakeholder groups with a high level of involvement, in the physical distribution, handling, and storage of the COVID-19 vaccine, can be assigned a position in the COVID-19 vaccine supply chain as displayed in Figure 6-1. There are between eight to ten basic/main supply chain processes in the product (vaccine) flow that take place from point of manufacturing to point of vaccination. The steps or processes and stakeholders involved in each step/process is summarized in Table 7-2.

Table 7-2: Stakeholders involved in supply chain step/processes

SUPPLY CHAIN STEP/PROCESS	STAKEHOLDER GROUP INVOLVED
1. Vaccines are manufactured and/or procured (orders are placed).	The Department of Health and Manufacturing
2. Vaccine shipments are transported from manufacturing facilities to an International Airport.	Freight Forwarders
3. Vaccine shipments are transported from an international airport (USA or Europe) to OR Tambo International Airport (South Africa).	Air Freight
4. Shipments are received and customs clearance process takes place.	Freight Forwarders and Customs Clearance Agents
5. Shipments are loaded onto road transport vehicles and transported to a central storage facility.	Freight Forwarders and Logistic Service Providers
6. Shipments are received at a central storage facility, handled, and stored in appropriate cold storage equipment at the required temperature range.	Logistics Service Providers
7. Sample vaccine vials are sent for stability and safety testing.	South African National Control Laboratory (NCL)
8. Orders are received, shipments are removed from cold storage, picked, and packed according to recipient facilities.	Logistics Service Providers
9. Shipments are loaded onto road transport vehicles and transported to either a provincial depot or a vaccination site.	Logistics Service Provider and Security
10. Shipments are received at provincial depots or vaccination sites. Provincial depots store vaccines until they are distributed to vaccination sites or collected by healthcare workers for specific vaccination sites.	Logistics Service Providers and Healthcare Workers
11. Vaccines at vaccination sites are stored, in appropriate cold storage equipment at the	Healthcare Workers

required temperature range, until they are administered to patients.	

Source: Compiled by the researcher for the purpose of this study

It is important to note that vaccines that are manufactured in South Africa will skip steps two to four.

7.3.3. Vaccine categorization and cold chain equipment

There are many cold chain requirements that need to be considered and monitored when distributing and handling vaccines. In South Africa, the Department of Health stipulates that temperature is the only cold chain requirement that needs to be monitored and managed in the COVID-19 vaccine supply chain. COVID-19 vaccines in South Africa are categorized according to their temperature requirement. Vaccines in category one require a storage, handling, and distribution temperature range of 2°C to 8°C while vaccines in category two require a -70°C environment. Cold chain infrastructure and equipment is used to maintain the recommended and required temperature range for each specific COVID-19 vaccine in the cold chain. The most basic and widely used cold chain equipment in both temperature categories is the polyurethane box that is placed inside a carton box, an example displayed in Figure 7-1. These boxes are used during distribution, from manufacturing facilities to last mile distribution.

Figure 7-1: Polyurethane box

Source: Polyurethane Cooler Boxes, 2021

There are four types of cold chain equipment, apart from the polyurethane boxes, that are used for vaccines in the first category and seven types in the second category. Table 7-3 summarizes the cold

chain equipment used in the different vaccine temperature categories. There is only one cold chain technology that is used during distribution of vaccines in category two, namely dry ice. COVID-19 vaccines are transported in delivery vehicles with an ambient temperature; they are not transported in a refrigerated truck. The polyurethane box and dry ice are responsible/used for maintaining the required temperature levels.

Table 7-3: COVID-19 vaccine cold chain equipment and technology

VACCINE TEMPERATURE CATEGORY	COLD CHAIN EQUIPMENT AND/OR TECHNOLOGY	FUNCTION
Category 1: 2°C to 8°C	Walk-in refrigerator	Storage, maintaining a temperature of 2°C to 8°C
	Portable refrigerator	Storage and transportation of small shipments
	Refrigerator (Medical or Health Facility)	Storage at vaccination sites
	Polyurethane box	Distribution (both inbound and outbound), maintaining a temperature of 4°C
	Temperature monitoring device	Monitors the temperature of the shipment
Category 2: -70°C	Bank freezers (ultra-cold)	Storage, maintaining a temperature of -70°C
	Portable freezer (ultra-cold)	Storage and transportation of small shipments (usually used at vaccination sites)
	Freezer (-25°C to -15°C)	Storage for up to one month
	Refrigerator (2°C to 8°C)	Storage for up to two weeks
	Polyurethane box	Distribution (both inbound and outbound), maintaining a temperature of -70°C
	Dry ice	Forms part of temperature-controlled packaging, aid in maintaining a temperature of -70°C

	Personal Protective Equipment (PPE) for employees	The equipment protects those individuals handling the vaccine in a -70°C environment
	Temperature monitoring device	Monitors the temperature of the shipment

Source: Compiled by the researcher for the purpose of this study

7.3.4. COVID-19 vaccine handling, storage, and delivery protocols

The next tool provides a summary of the basic or general handling, storage, and delivery protocols. These protocols are focused on maintaining the vaccine cold chain and need to be followed by employees at different stages in the COVID-19 vaccine supply chain to ensure vaccines reach their intended location safely and uncompromised. Table 7-4, Table 7-5 and Table 7-6 can be used as a basis for determining protocols, but it is important to note that protocols can be added or changed according to different companies or manufacturer requirements. Figure 7-2 provides a step-by-step guide, explaining the packaging procedure of COVID-19 vaccines.

Table 7-4: Protocols for employees in a warehouse or central storage facility

BEFORE ARRIVAL	HANDLING (IN WAREHOUSE)
• Be informed and educated about the temperature requirement of the COVID-19 vaccine arriving at the facility. • Be informed about the storage temperature range required by the specific COVID-19 vaccine. • Review and prepare the relevant documentation to receive vaccine shipment. • Ensure cold chain equipment is clean and sanitised. • Ensure sufficient storage is avalaible for the number of vaccines arriving. • Ensure cold chain equipment is at the required temperature levels and accesible.	• Check the temperature monitoring device upon shipment arrival. • Confirm and document the number of vials received. • Check the shipment for any damage. • Sign and complete necessary paperwork. • Monitor the time and exposure to ambient temperature when transferring the vials into cold storage. • Monitor and log the temperatures of the cold chain equipment, regularly. • Wear appropriate PPE when handling a vaccine at a temperature lower than room temperature. • Pick orders according to a first-in-first-out system. • Ensure that orders are correctly picked according to the picking task received. • Follow the correct packing procedure as displayed in Figure 7-2. • Red flag a shipment if you notice a temperature flucation* outside the recommende temperature range.

Source: Compiled by the researcher for the purpose of this study

*For the Johnson & Johnson vaccine, a temperature below 2°C or above 8°C is considered a fluctuation. For the Pfizer vaccine, a temperature above -60°C or below -85°C is considered a fluctuation.

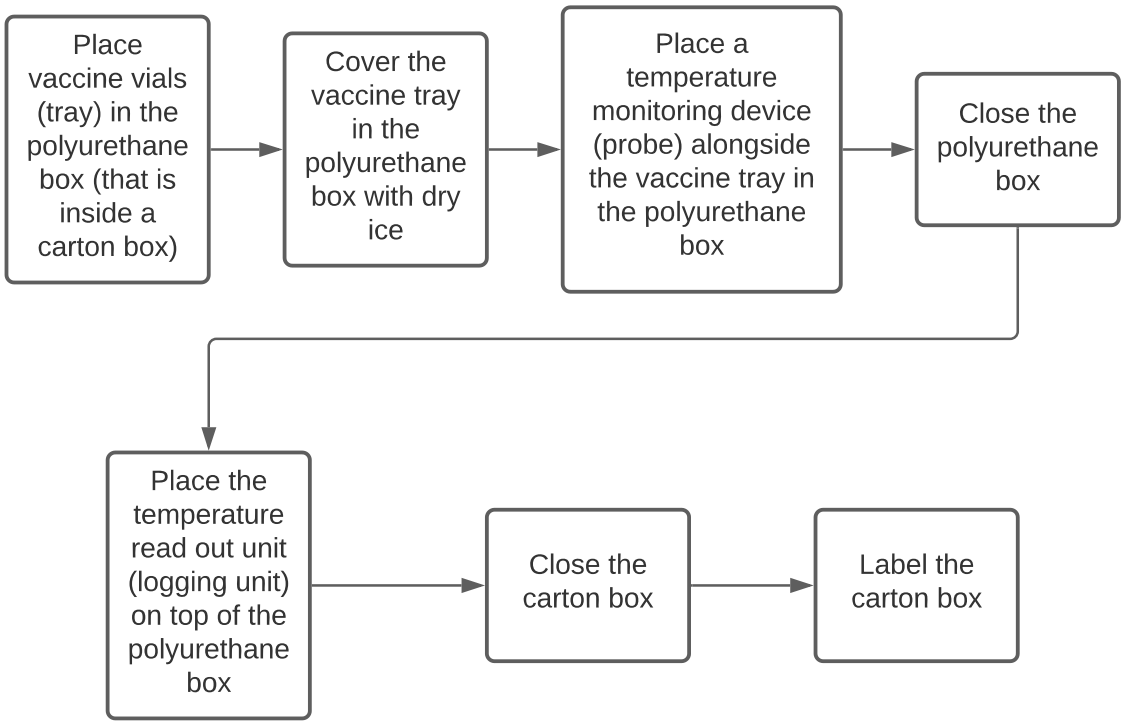

Figure 7-2: COVID-19 vaccine packaging procedure

Source: Compiled by the researcher for the purpose of this study

Table 7-5: Protocols for employees that form part of the delivery team of a vaccine shipment, either to a central storage facility, provincial depot or vaccination site

COLLECT SHIPMENT	DELIVER SHIPMENT
• Sanitise and clean the delivery vehicle before loading the shipment. • Ensure the correct number of vaccine vials are loaded onto the delivery vehicle. • Check the shipment for any damage. • Load the delivery vehicle in the correct way, without disrupting air flow. • Handle boxes, containing vaccine vials, wih care - they are fragile. • Ensure all vehicle doors are properly closed. • Sign the neccesary paperwork upon collection. • Ensure the paperwork needed for delivery is in order and you know the exact delivery location. • If security or police escort services were arranged, never leave the airport or warehouse without it.	• Deliver to the exact address as stipulated by each company, depot or vaccination site. • Ensure that the corect number of vials, as stipulated, is unloaded/delivered to the corresponding address. • Ensure that the appropriate or specifically assigned person signs for the shipment received after checking and confirming the number of vials in the shipment received. • Hand the temperature data logger over to the person receiving the shipment. • Get the polyurethane boxes back after vials are transferred to the facility's cold storage. • Check that all vehicle doors are properly closed before leaving the delivery location. • Red flag a shipment if you notice a temperature flucation* outside the recommende temperature range.

Source: Compiled by the researcher for the purpose of this study

*For the Johnson & Johnson vaccine, a temperature below 2°C or above 8°C is considered a fluctuation. For the Pfizer vaccine, a temperature above -60°C or below -85°C is considered a fluctuation.

Table 7-6: Protocols for handling and storage at COVID-19 vaccination sites (Public and Private):

BEFORE ARRIVAL	UPON ARRIVAL	ADMINISTER
• Confirm the number of vials arriving at the facility and make sure there is adequate cold storage for the number of vaccines. • Sanitise, clean and prepare the necessary cold chain equipment. • Schedule vaccination timeslots (private sector). • Prepare the necessary administration/vaccination equipment. • Ensure adequate personnel are available during the vaccination time-slots.	• Check, confirm and document the number of vials received. • Check whether the shipment has any damage • Sign for the shipment received. • Log the temperature of the shipent upon arrival or collection. • Download the temperature data of the temperature logger and confirm whether the required temperature levels were maintained before arrival. • Transfer the vials from the polyurethane box into the appropriate cold storage equipment and return the polyurethane box. • Monitor and log the temperature of the cold chain equipment every time it is opened. • Red flag a shipment if you notice a temperature flucation* outside the recommende temperature range	• Remove vials from cold storage at the appropriate time before administering the vaccine. • Use punctured vaccine vials within six hours from exposure to room temperature.

Source: Compiled by the researcher for the purpose of this study

*For the Johnson & Johnson vaccine, a temperature below 2°C or above 8°C is considered a fluctuation. For the Pfizer vaccine, a temperature above -60°C or below -85°C is considered a fluctuation.

7.3.5. Required skills and training

The next two tools explain and summarise the skills and training required at different employment levels or by different stakeholders in the COVID-19 vaccine cold chain's, product flow. It is important to note that these are not the only skills and training required by employees handling, distributing,

or storing a COVID-19 vaccine, but the skills and training requirements mentioned are considered essential, by different stakeholders, in the COVID-19 vaccine supply chain.

7.3.5.1. Skill requirements toolkit

A skill, in this case, refers to the ability of an employee to do a task or job, associated with the handling, distribution or storage of a COVID-19 vaccine properly and correctly. Efficiently performing a task, because employees have the correct skill set contributes to keeping vaccines safe and uncompromised. The skills that are required by individuals are categorised according to hard and soft skills. Hard skills can be measured and learned through schooling or on the-job-training, while soft skills are universal, less defined skills that do not apply to only one specific job. Employees in the COVID-19 vaccine supply chain either need a formal qualification to fulfil their role or they need to have the relevant experience and training.

Table 7-7: Skills requirements

LEVEL OF EMPLOYMENT	EXAMPLE OF AN EMPLOYEE	QUALIFICATION REQUIRED	HARD SKILLS REQUIRED	SOFT SKILLS REQUIRED
Operational level at the airport	- Employees receiving shipments - Employees transferring shipments from an airplane to a truck	No formal qualification required	- Operate equipment and infrastructure - Read & write	- Pay attention to detail - Perform assigned task and/or duty
Operational level at a warehouse or storage facility	- Picker - Packer - Checker - Employees receiving vaccine shipments - Employees transferring vials to cold storage - Employees monitoring cold chain equipment temperature	No formal qualification required	- Read & write - Operate equipment or infrastructure	- Listen - Follow instructions - Pay attention to detail - Report - Perform tasks
Distribution, operational level	Truck drivers	No formal qualification required	- Appropriate license to operate the vehicle - Read and write - The ability to understand and operate a GPS or tracking system	- Communication skills - The ability to follow instructions
Management level e.g., in a warehouse, at the airport, at the company head office	- Key Account Manager - Project Manager - Managing Director - Operations Manager - General Manager	Formal qualification or relevant experience and/or training required	- Cold chain expertise - The ability to view the end-to-end supply chain - Analytical Abilities	- The ability to explain - Communication skills - Decision-making skills - Problem-solving skills - Planning skills

				- Adaptability - Attention to detail - Conflict resolution
Operational level at a vaccination site	- Admin personnel - Cleaners - General help	No formal qualification required	- Read & write	- Attention to detail - Follow instructions - People skills
Management level and vaccine administration personnel at a vaccination site	- Operations Manager - Head Nurse - Doctor - Pharmacist	Health qualification required	- Medical skills (learned through formal qualification for administering vaccines) - The ability to understand and operate the COVID-19 information and logging system - The ability to read, interpret and understand the temperature logger and temperature data it records.	- The ability to explain - Communication skills - Planning skills - Attention to detail - People skills

Source: Compiled by the researcher for the purpose of this study

7.3.5.2. Training requirements toolkit

The researcher focused on the training and education required by four groups of people in the COVID-19 vaccine supply chain. These individuals form part of the physical distribution and handling of a COVID-19 vaccine shipment and either work at the airport, in a warehouse (including truck drivers), at a provincial depot or at a vaccination site. The researcher then explains the basic roles that management personnel should fulfil and the abilities that they should have.

GROUP 1: WAREHOUSE, OPERATIONAL TRAINING AND EDUCATION

The type of tasks performed by employees working in a COVID-19 vaccine warehouse vary from picking orders, packing orders, operating warehouse equipment, monitoring cold storage to receiving orders and transferring shipments to courier vehicles. The training and education required by these individuals is categorised according to the four basic levels of training:

- Level 1: Standard Operating Procedure (SOP)
- Level 2: System and device training
- Level 3: Product specific training
- Level 4: General knowledge training

Level 1: Standard Operating Procedure (SOP)

This level refers to training employees to execute or perform day-to-day tasks. Employees fulfilling different roles need to be trained in their specific task or procedure. Examples of this include training employees how to pick and pack orders, how to label correctly and how to check orders. Most employees working in a warehouse are already trained in these specific tasks. The following training, summarised as a checklist in Table 7-8, is required specifically for a COVID-19 vaccine warehouse in terms of SOP.

Table 7-8: Level 1, COVID-19 specific training checklist

ACTIVITY	CHECKLIST
Pick orders according to a first-in-first-out system (FIFO) or according to the first to expire – first out (FEFO) system.	☐
Pack vaccine shipments/orders according to Figure 7-2.	☐

Handle vaccine shipments with care because the product is fragile.	☐
Teach employees how to check whether the order received correlates with the paperwork and if the number of vials received are correct.	☐

Source: Compiled by the researcher for the purpose of this study

Level 2: System and device training

On this level of training, employees are taught how to use the different systems and devices such as computers, scanners, and equipment. Most employees working in a warehouse are familiar with the use of scanners. There are, however, some COVID-19 vaccine specific systems, equipment and device training that should take place as summarised below in Table 7-9 in a checklist format.

Table 7-9: Level 2, COVID-19 specific training checklist

ACTIVITY	CHECKLIST
Teach employees how to read and understand the temperature monitoring device of different cold storage equipment.	☐
Train employees how to log temperature data displayed on different cold storage devices.	☐
Teach employees which protocols to follow when the temperature of cold storage equipment fluctuates above or below the recommended temperature.	☐
Train employees how to use the computers that shipment data and temperature data are analysed and stored on.	☐
Teach employees the importance of minimizing the amount of time cold storage is opened and closed.	☐
Teach employees how to activate or operate the temperature monitoring device (probe and read-out unit) that is placed alongside the vaccine vials in the polyurethane box.	☐
Truck drivers should already know how to operate and drive their delivery vehicles.	☐

Source: Compiled by the researcher for the purpose of this study

Level 3: Product specific training

This level of training is usually done by the client or product manufacturer and employees are taught the relevant tasks related to the specific product. In the South African scenario, employees will either be trained on the requirements of a Pfizer vaccine or a Johnson & Johnson vaccine. The information provided in Table 7-3 can be used to educate employees about the different cold chain equipment and technologies that are used in maintaining the cold chain of these vaccines. It is important that employees at a management level educate operational employees on the importance of maintaining the vaccine cold chain and the important role that these employees play in ensuring vaccines are safe and uncompromised. Table 7-10 summarises the COVID-19 specific training required by employees in group 3.

Table 7-10: Level 3, COVID-19 specific training checklist

ACTIVITY	CHECKLIST
Educate employees on the required temperature ranges of the specific COVID-19 vaccines.	☐
Inform operational employees which COVID-19 vaccine they will be handling.	☐
Show employees what an intact vaccine shipment looks like for them to be able to identify when and if a shipment has incurred any damage, upon inspection.	☐
Teach employees the importance of keeping vaccines in the correct temperature range.	☐
Train employees to wear the appropriate PPE when working with a -70°C vaccine shipment.	☐
Train employees to monitor the time that vaccine shipments are exposed to ambient temperature during the transfer from packaging to cold storage.	☐
Train employees how to pack the vaccine orders correctly and where to place the dry ice and the temperature monitoring device.	☐
Inform employees who to report to when a problem arises during the handling or storage of the vaccine.	☐

Source: Compiled by the researcher for the purpose of this study

Level 4: General knowledge training

This level of training is focussed around educating employees on the “why”. The most important “why” in the South African vaccine scenario is the “why” around maintaining the specific vaccine temperature requirements. Temperature is the biggest influencer on vaccine safety and potency

and the only cold chain requirement that needs to be monitored by stakeholders in the COVID-19 vaccine supply chain, as stipulated by the National Department of Health.

The following information can be used as a starting point on the education of "why":

- Any deviation from the set-out vaccine cold chain procedures, roles and responsibilities could lead to temperatures fluctuating above or below the recommended range, which leads to product wastage and causes both the client and the manufacturer to lose money.
- COVID-19 vaccines are biological products, which means that they are very sensitive to temperature fluctuations. If they are exposed to temperature levels outside of the recommended range, they become less effective, which ultimately means they are not able to have the coveted impact.
- Staying within the product temperature range enables and ensures the integrity and safety of the product. Remember that humans are the recipients of the COVID-19 vaccine, and their safety is of utmost importance. Thus, not reporting any deviances could have a serious impact on a human's health.

GROUP 2: AIRPORT, OPERATIONAL TRAINING AND EDUCATION

Employees who work at the airport do not necessarily need any COVID-19 specific training, but the following basic training can be noted and checked, as summarised in Table 7-11. It is important to understand that these training guidelines are based on operational employees who handle and transfer vaccine shipments to and from the aircraft and not on pilots or aircraft personnel.

Table 7-11: Group 2, basic training checklist

ACTIVITY	CHECKLIST
Teach employees how to complete the necessary paperwork and manually log the paperwork onto a digital device or scan the shipment barcodes.	☐
Train employees where to check for and how to identify any shipment damage.	☐
Train employees how to read the temperature monitoring devices and how to download and/or log the temperature data from the monitoring device.	☐
Emphasize the importance of "handle with care" when vaccine shipments are transferred from an airplane to a road vehicle.	☐

Source: Compiled by the researcher for the purpose of this study

GROUP 3: PROVINCIAL DEPOT TRAINING AND EDUCATION

This group includes those employees who work at a provincial depot or a provincial storage site. Most of the roles that are fulfilled at these storage sites/depots are the same as those in a central warehouse. One of the only differences is that some of these operational employees need to know and understand how the logging system of COVID-19 vaccines work and how to interpret and understand the orders that are received by the DOH. Table 7-12 summarises the COVID-19 specific training required by individuals in group 3.

Table 7-12: Group 3, COVID-19 specific training checklist

ACTIVITY	CHECKLIST
Train employees how to use the COVID-19 vaccine information/data portal and how to log the correct, requested vaccine shipment related information.	☐
Train employees how to correctly re-pack a COVID-19 vaccine shipment, if smaller amounts need to be sent to vaccination sites.	☐
Educate packer employees, according to the manufacturing guidelines, the correct amount of dry ice that should accompany a vaccine tray, when packaged for a vaccination site.	☐
Train employees how to use the specific vaccine cold chain equipment and educate them on the importance of keeping temperature levels in the recommended temperature range.	☐
Train employees to pay attention to detail.	☐
Educate and inform employees who they should report to and who they should approach if they see any temperature fluctuation or process deviation in the cold chain.	☐
Train employees to follow both verbal and written instructions.	☐

Source: Compiled by the researcher for the purpose of this study

GROUP 4: VACCINATION SITE TRAINING AND EDUCATION

There are four groups of employees that work at either a private or public vaccination site namely, pharmacists or doctors, nurses, administrative personnel, and cleaners. Pharmacists, doctors, and

nurses have administered vaccines for many years, so most of their training has already occurred as part of their formal qualification. It is important to note that the vaccination site's operations manager is usually a doctor, pharmacist, or nurse. It is these individuals who place vaccine orders, sign off on vaccine shipments received, train their team at the vaccination site and log, and interpret the temperature data of the shipments received. The COVID-19 specific training or education required by these employees is summarised in Table 7-13.

Table 7-13: Group 4, COVID-19 specific training checklist

Employee group/title	Activity	Checklist
Pharmacists and/or Doctors	Train and inform pharmacists how and where to place a COVID-19 vaccine order. It will either be directly to the DOH or to the nearest Sub-district hospital or clinic.	☐
	Teach and educate pharmacists on the basic requirements and characteristics of the COVID-19 vaccine being administered at their vaccination site for them to educate their other employees.	☐
	Train and educate these individuals how to download the temperature data from the temperature read-out unit (monitoring device).	☐
	Educate them on how to read the temperature data and what classifies as a temperature fluctuation outside the recommended temperature range.	☐
	Train pharmacists how to log the information of COVID-19 vaccine receipt and administration on the COVID-19 vaccine information portal.	☐
Nurses	Inform and train nurses around the specific vaccine specifications, according to information from the manufacturer. Such as the amount of time a vaccine needs to be at ambient temperature before it is administered to patients and	☐

	the protocol that patients should follow, after receiving their vaccination.	
	Train specific nurses how to read and log the temperature monitoring device/unit of the cold storage that the vaccines are stored in. Inform nurses how many times a day the temperature of the cold storage equipment should be monitored and logged.	☐
	Educate nurses about the characteristics of the vaccine that they are administering to patients.	☐
	Educate and train nurses around the basic COVID-19 protocols that should be followed in terms of sanitising, distancing, and information sharing.	☐
	Train and remind nurses to pay attention to detail, especially when drawing up the precise amount of liquid for a vaccination.	☐
Administrative personnel	Train these employees how to log patient information on the COVID-19 vaccination portal.	☐
	Train employees how to complete patient vaccination cards.	☐
	Teach employees to speak clearly and have good communication and people skills.	☐
Cleaners	Educate cleaners on the basic COVID-19 protocols in terms of cleaning and sanitising.	☐
	Teach employees how many times a day they should sanitise certain spaces and how it should be done.	☐

Source: Compiled by the researcher for the purpose of this study

MANAGEMENT PERSONNEL:

This group refers to any individual that is in a middle to upper-level management position in the COVID-19 vaccine supply chain. These employees need to be informed and educated about the requirements and characteristics of the specific COVID-19 vaccine that they are handling or

distributing for them to educate the employees who work under their management. The COVID-19 specific training requirements of Management personnel are summarised in Table 7-14.

Table 7-14: Management, COVID-19 specific training checklist

REQUIREMENTS	CHECKLIST
Informed and educated about the characteristics and requirements of the specific COVID-19 vaccine, cold chain expertise.	☐
Trained in problem-solving and decision-making skills.	☐
Trained in analytical abilities to analyse and interpret the relevant data and make decisions or changes.	☐
Trained in the ability to view the end-to-end supply chain to have supply chain visibility.	☐
Trained in the ability to give instructions and be adaptable to change.	☐
Informed about how the COVID-19 vaccine supply chain functions and how all the links contribute to ensuring vaccine safety through a well-maintained cold chain.	☐
Trained in the ability to delegate and assign tasks and communicate instructions to employees.	☐

Source: Compiled by the researcher for the purpose of this study

7.3.6. Conclusion

This toolkit serves as an aid in educating and training COVID-19 vaccine supply chain employees on the functionality of a COVID-19 vaccine supply chain. The tools mentioned in this toolkit are focussed on maintaining the vaccine cold chain, in other words keeping the temperature levels at the recommended ranges, and not on the protocols or requirements of a vaccine as a biological product. This toolkit can be used as a basic input in the education and training process and should not be used as the only tool to educate and train employees working in the COVID-19 vaccine supply chain. Vaccine manufacturers are required to educate and inform those handling, distributing, or storing their vaccines about the vaccine's general handling protocols, cold storage requirements and information logging. These manufacturer manuals can be used in collaboration with the educational toolkit described above to effectively distribute COVID-19 vaccines to the public.

7.4. CONCLUSION

The educational toolkit described in Chapter 7 consists out of four basic tools that can be used by COVID-19 vaccine supply chain members in the education and training of supply chain employees. This toolkit starts with an introduction to the COVID-19 vaccine supply chain, elaborates on the supply chain members involved, the various cold chain, skills and training requirements and ends with a conclusion. The tools provided can be used in collaboration with manufacturer protocols, guidelines, and product manuals to contribute and/or ensure effective and safe distribution of COVID-19 vaccines from the point of manufacturing to the point of vaccination. This chapter contributes to reaching the final research objectives of the study and answers research question six.

CHAPTER 8 : CONCLUSIONS AND RECOMMENDATIONS

8.1. INTRODUCTION

The aim of this study was and is to aid the logistics industry and its stakeholders in understanding the factors that play a role in the COVID-19 vaccine supply chain and the training and/or education required by individuals to handle, store, and distribute these vaccines correctly and effectively. This chapter discusses whether the inputs gathered through the research study contributed to achieving the aim and purpose of the study and which information, of the research, can be used to address the different research questions and objectives. This final chapter thus focusses on the conclusions and recommendations of the study as well as possible, recommended future research projects.

8.2. CONCLUSIONS

The next two sections discuss the competence of the research study to meet the research objectives and answer the research questions as stated in Section 1.5. It also summarises in which chapters the information pertaining to each objective and question can be found.

8.2.1. Did the study meet the research objectives?

This sub-section lists each specific research objective, as summarised in Table 1-1, and discusses and determines whether the study met them.

1. *To synthesise the functionality and components of similar vaccine cold chains, through an extended literature review and interview process. This will enable the researcher to make use of previous research, tested knowledge and operations that can be used in the formulation of the vaccine supply chain and toolkit.*

Chapter 3 explained, summarised, and illustrated the functionality of a generic vaccine supply chain and cold chain. Chapter 4 discussed the functionality of a vaccine supply chain and the vaccine industry in South Africa. These two chapters allowed the researcher visibility into a vaccine supply chain and aided in determining and illustrating the COVID-19 vaccine supply chain.

2. *To conduct a Stakeholder Analysis to identify all stakeholders involved in a vaccine supply chain, to analyse the stakeholder relationship and to use their knowledge to identify supply chain links, vaccine cold chain characteristics and requirements.*

Chapter 5 explained and summarised the stakeholder analysis process. It allowed the researcher to follow basic steps, which aided in identifying COVID-19 vaccine supply chain stakeholders and

analysing the role that they play. Individuals in the different stakeholder groups were contacted or approached to conduct an interview with. Information from stakeholder interviews allowed the researcher to collect and analyse data. Chapter 6 served as a contributing input to the educational toolkit developed in Chapter 7.

3. *To comprehend and clarify cold chain protocols for COVID-19 vaccines procured by the South African government and why these protocols are in place as well as what value the maintenance of the cold chain has.*

Information gathered from stakeholder interviews and answers analysed, in Chapter 6, allowed the researcher insight into basic vaccine handling protocols and the COVID-19 vaccine handling and storage protocols in the vaccine supply chain. Information from manufacturer manuals, Chapter 3 and 4, provided the researcher with specific COVID-19 vaccine handling, storage, and distribution requirements and recommendations. Chapters 3 and 4 provided insight into the importance of maintaining a vaccine cold chain and the role that employees throughout the supply chain play in contributing to vaccine safety and efficacy. A tool in the toolkit, shown in Chapter 7, provides summary tables to list the different protocols for employees handling, storing or distributing vaccines.

4. *To identify what international best practices could be implemented to ensure vaccine safety and increase cold chain efficacy.*

Throughout Chapter 3, international best practices were provided in terms of vaccine safety and increased cold chain efficacy. Section 3.5.2 explains five specific best practices for vaccine distribution. In Section 6.4.4, these five best practices were used as a basis for explaining how South Africa implemented and executed best practices during the rollout of COVID-19 vaccines, as experienced by the stakeholders interviewed.

5. *To recognise and understand the basic requirements, such as skills or knowledge of transport and handling personnel for the effective distribution of COVID-19 vaccines in South Africa.*

Chapter 6 provides a summary of the basic skills and training required by employees at different stages and employment levels in the COVID-19 vaccine supply chain. The stakeholders interviewed provided visibility into the skills needed at their respective level of work or the training required for the role that they play in the vaccine supply chain. There is a tool in the toolkit, in Chapter 7, that provides a summary of these skills and training requirements.

6. *To create a toolkit based on cold chain requirements of the COVID-19 vaccine and supply chain personnel requirements that can be used to educate members of the supply chain in transport, handling, and storage of the vaccine.*

Chapter 7 provides and explains four different tools that could contribute to understanding the COVID-19 vaccine supply chain in terms of stakeholders involved, the role they play, the cold chain equipment used, temperature requirements and the skills and training required and recommended for employees or companies handling, storing, or distributing COVID-19 vaccines. Chapter 3, 4 and 6 served as the contributing input to the toolkit in Chapter 7.

7. *To assemble the necessary data, analyse it, and provide or create a toolkit that can aid in the training and education of relevant supply chain members.*

This objective was reached throughout the research study. Data, inputs, and knowledge gathered in Chapters 3, 4, 5 and 6 contributed to the creation of the educational toolkit in Chapter 7.

8.2.2. Did the study answer the research questions?

This sub-section states the six different research questions and determines whether the specific questions were successfully answered through the research study.

1. *What current knowledge exists about similar cold chains and what successes or challenges have they had? For example, the distribution or distribution framework for Tuberculosis (TB) vaccines in South Africa.*

Chapter 3 identified the processes, requirements and roles involved in a vaccine supply chain and identified general successes and challenges that these cold chains have experienced. Chapter 4's information is specifically focussed on the South African vaccine industry and supply chains, providing the functionality and challenges of existing vaccine supply chains, therefore, answering the research question successfully.

2. *What are the cold chain requirements and sensitivity of each requirement of a vaccine supply chain and how can they be categorised?*

Chapter 3 identified and defined different cold chain requirements, vaccine cold chain requirements and their sensitivity and COVID-19 vaccine cold chain requirements and their sensitivity. Chapter 6 identified temperature as the most important COVID-19 vaccine cold chain requirement and categorised COVID-19 vaccines according to this. Through the identification and explanation in Chapter 3 and the categorisation in Chapter 6, the research questions were successfully answered.

3. *What are the specific cold chain protocols for each individual vaccine?*

Firstly, the different stages/steps in the South African COVID-19 vaccine supply chain were identified and explained in Chapters 4, 6 and 7. Thereafter these stages/steps were used to group certain protocols and processes by. South Africans are vaccinated with either the Johnson & Johnson vaccine or the Pfizer vaccine, as identified in Chapter 3. The research study does focus more on the protocols for the Pfizer COVID-19 vaccine, because the majority of citizens are vaccinated with this vaccine and its temperature requirement, requires specific protocols. A tool in the Chapter 7 toolkit provides basic protocols that can be followed for both vaccines in terms of handling and distributing; therefore, this question was answered successfully.

4. *What best practices or metrics can be undertaken to ensure the effective management of temperature, humidity, vibration etc. along the different stages of the coronavirus vaccine supply chain?*

Throughout Chapter 3, various best practises were identified in terms of vaccine cold chain requirements, vaccine cold chain management and emphasizing five best practices for vaccine distribution. Sub-sections in both Chapters 6 and 7 explain and identify the different processes or best practices applied to the COVID-19 vaccine supply chain, therefore, answering the research question successfully.

5. *What are the basic skills and knowledge requirements for personnel to safely and effectively transport, handle and store COVID-19 vaccines?*

Through the stakeholder interview process, described in Chapter 5 and summarised and analysed in Chapter 6, the researcher was able to determine the basic skills, training and education needed for employees handling a COVID-19 vaccine. Both the literature review and stakeholder analysis inputs allowed the researcher to establish a tool that stipulates the training and skill requirements at different stages and employment levels in the COVID-19 vaccine supply chain, thus, answering this research question successfully.

6. *What toolkit can be created or used to educate and train members of the vaccine supply chain?*

An educational toolkit was developed and provided in Chapter 7 that can aid supply chain members in the education and training of employees around the handling, storage, and distribution of a COVID-19 vaccine, for both the Johnson & Johnson and Pfizer vaccine.

8.3. RECOMMENDATIONS

This section provides recommendations for the implementation and use of the educational toolkit provided and explained in Chapter 7. As mentioned in the toolkit conclusion, it is important that the toolkit is used in collaboration with existing knowledge, cold chain expertise and manufacturer manuals and/or guidelines/protocols.

8.3.1. Tool 1, COVID-19 vaccine supply chain stakeholders

The first tool in the educational toolkit provides a summary of the different role players/stakeholders in the COVID-19 vaccine supply chain, each responsible for fulfilling a role at different stages. It is important for anyone working within the COVID-19 vaccine supply chain to understand and identify those who are responsible and play a part in the safe and effective handling, storage, and distribution of a COVID-19 vaccine shipment in South Africa. The researcher recommends that all individuals involved in the vaccine cold chain understand who their co-supply chain members are, to comprehend the role each of them play and contribute to safely and effectively distributing COVID-19 vaccines. This tool can be used to emphasize and explain what activities or processes supply chain members are responsible for and what their level of involvement is in the physical distribution of COVID-19 vaccines in South Africa.

8.3.2. Tool 2, COVID-19 vaccine categorisation and cold chain equipment

The information in this tool needs to be understood by all supply chain members and clearly communicated to all employees, from manufacturing facilities to vaccination sites. This tool is a quick reference to understanding the main cold chain requirement, namely temperature, and the different cold chain equipment used for the two different COVID-19 vaccines that are distributed in South Africa. The researcher recommends that supply chain members should firstly identify in which temperature category the vaccine is that they are dealing with and should then understand the cold chain equipment required for that temperature category.

8.3.3. Tool 3, COVID-19 vaccine handling, storage, and delivery protocols

Supply chain members need to understand where in the supply chain they are executing and performing activities and/or processes (Tool 1). Once they have done that the researcher recommends that they use Tool 3 as a basis and checklist for understanding and following different protocols applicable to their position in the COVID-19 vaccine supply chain. The researcher recommends that this tool is used in collaboration with manufacturer stipulated guidelines and

product protocols to maintain the COVID-19 vaccine cold chain. Employees at a management level can make use of the information in Chapters 3, 4 and 6 to educate employees on the important role that they play in maintaining the vaccine cold chain by following set out protocols. The researcher lastly, recommends that protocols are clearly communicated to employees in a way and language that they understand.

8.3.4. Tool 4, COVID-19 vaccine supply chain skill and training requirements

The researcher recommends that this tool is used as a starting point for all COVID-19 vaccine supply chain members in determining the skillset and training required by employees at different levels and stages of the vaccine supply chain. Using the skill requirements tool can aid supply chain members in ensuring that the employees they appoint, upskill, or employ have the necessary skillset to perform the required cold chain activities. The training tool enables supply chain members to execute or request the required COVID-19 specific and general training. The researcher recommends that both the skill and training tools are used as a basis when trying to determine what abilities are required from individuals for the successful and efficient flow of COVID-19 vaccines in South Africa. The researcher also recommends that the probability and effect of human error should be considered and minimized wherever and whenever possible.

8.3.5. Future work

This study, firstly, focussed on understanding the flow and requirements of COVID-19 vaccines in South Africa and those who are involved in its supply chain. It then focussed on determining the skills and training required by individuals handling, storing, or distributing these vaccines in South Africa. The data gathering and overall research study was mostly theory based on qualitative data; thus, the researcher recommends a more quantitative or numerical data approach. Executing or running temperature trials to determine and evaluate the effectiveness of the COVID-19 vaccine cold chain could contribute to gaining even more visibility into the product flow. Analysing temperature data could allow a researcher to determine where in the cold chain adjustments, improvements or change can or should be made. This could also contribute to understanding where in the supply chain more training or education is required.

8.4. VALUE TO THE INDUSTRY

Because of the pandemic's recent emergence, the COVID-19 vaccines and their cold chain requirements are new to the vaccine industry and supply chain both locally and internationally. The literature review and stakeholder analysis done during this research study aided in understanding

the functionality of the COVID-19 vaccine supply chain and elements of the industry, closing the current knowledge gap. The research study identified the stakeholders involved in the supply chain, the cold chain requirements of the vaccine and their sensitivity, the processes or roles associated with each stakeholder and the training and skill requirements of individuals at different employment levels and stages of the COVID-19 vaccine supply chain. The information from this research study is valuable to those interested or involved in the distribution, handling, and storage of the COVID-19 vaccine because it provides the requirements needed to contribute to safe and effective distribution. The educational toolkit created in Chapter 7 can be used to educate supply chain members in the industry and serve as a starting point in identifying and following protocols, skills, and training requirements.

8.5. CONCLUSION

This research study achieved its aim and purpose by answering the research questions and meeting the research objectives. Possible recommendations for the use and implementation of the educational toolkit were provided to assist stakeholders in the distribution, handling and storage procedures and requirements. The researcher mentioned and identified a possible future research study, which focusses more on quantitative data and measuring how well the COVID-19 vaccine cold chain is managed and maintained.

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APPENDIXES

Appendix A

Stakeholder interview guide

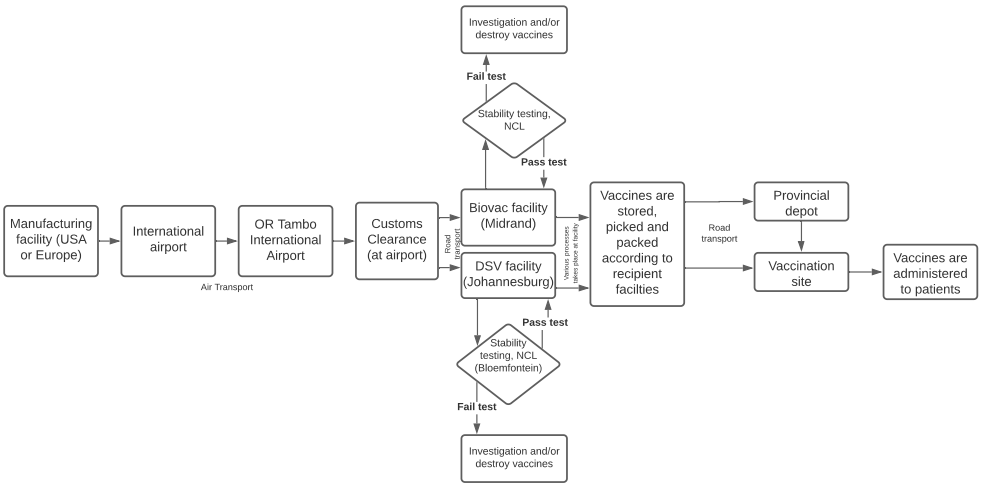
The following interview guide served as the basis for questions asked in the stakeholder semi-structured interviews. The questions were divided into six subsections, each subsection served as a grouping of questions around a specific research question.

1. Introduction questions
   - What is your name?
   - What is your profession?
   - What is your education and experience?
2. Q1: *What current knowledge exists about similar cold chains and what successes or challenges have they had? For example, the distribution or distribution framework for Tuberculosis (TB) vaccines in South Africa.*
   - Do you handle, store, or distribute any other vaccines, apart from the COVID-19 vaccine?
   - If yes, what skills or knowledge that you use for the handling, storage or distribution of these vaccines is applicable or can be used in the COVID-19 vaccine handling/distribution?
   - If yes, what do you find most challenging when handling, storing or distributing these vaccines, including the COVID-19 vaccine?
3. Q2: *What are the cold chain requirements and sensitivity of each requirement of a vaccine supply chain and how can they be categorised?*
   - Do you understand what is meant by a cold chain requirement? (If not – explain, otherwise continue)
   - According to you, which cold chain requirements should be monitored when handling, distributing a vaccine?
   - Which of these cold chain requirements is applicable to the handling, storage and distribution of a COVID-19 vaccine?
   - Which of these COVID-19 vaccine cold chain requirements, if mentioned more than one, is the most important and should be closely monitored?

- The South African Government categorises the COVID-19 vaccines according to its temperature requirement. There are two categories. One for a 2°C -8°C vaccine and the second for a -70°C. Do you agree with these categories?
- How sensitive are COVID-19 vaccines to a fluctuation in their cold chain requirements?

4. Q3: *What are the specific cold chain protocols for each individual vaccine?*

This is the basic flow of COVID-19 vaccines in South Africa:



- What role do you play in the COVID-19 vaccine supply chain?
- Do you work with a vaccine that requires a storage temperature of 2°C -8°C or -70°C?
- When in the supply chain do you handle the COVID-19 vaccine?
- What cold chain technologies/equipment do you use or have to your access to, to maintain the cold chain?

Example of cold chain technologies and infrastructure:

- What protocols do you need to follow when receiving the vaccine shipment/vials?
- What protocols do you need to follow when storing the vaccine shipment?
- What protocols do you need to follow when distributing a vaccine shipment? (Only asked to employees at distribution companies and not to individuals at vaccination sites)
- What protocols do you follow when you realise there is something wrong with the shipment? For example, the vials were exposed to temperatures outside of their recommended temperature range.

5. Q4*: What best practices or metrics can be undertaken to ensure the effective management of temperature, humidity, vibration etc. along the different stages of the coronavirus vaccine supply chain?*
   - In your professional opinion, are the distribution of COVID-19 vaccines effectively done in your supply chain to your vaccination site?
   - What would you recommend can make the distribution/roll-out of COVID-19 vaccines run smoother?
   - What metrices do you follow to ensure that cold chain requirements are met during your role in the supply chain?
   - Were your role and responsibilities clearly communicated to you?
6. Q5: *What are the basic skills and knowledge requirements for personnel to safely and effectively transport, handle and store coronavirus vaccines?*

- What do you understand around the concept: safe and effective transport? Handling? Storage?
- Did you have to receive any training for the role you play in the COVID-19 vaccine supply chain?
- If yes, please explain.
- In your opinion, and based on your profession, what are the most important skills an employee involved in the COVID-19 vaccine supply chain should have? (Focussed: that fulfil the same role as you?)
- What knowledge should a person involved in the COVID-19 vaccine supply chain have? And how should the transfer of the required knowledge take place? (Basically, how should employees be educated with the necessary knowledge?)

7. Anything important that I missed or should have asked?