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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

Authors:
Suzanne Stofberg-Müller[1]
Leila L. Goedhals-Gerber[1]
Joubert van Eeden[2]

Affiliations:
[1]Department of Logistics, Faculty of Economics and Management Sciences, Stellenbosch University, Stellenbosch, South Africa

[2]Department of Industrial Engineering, Faculty of Engineering, Stellenbosch University, Stellenbosch, South Africa

Corresponding author:
Leila Goedhals-Gerber,
stofbergsuzanne@gmail.com

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Background: Since the roll-out of coronavirus disease 2019 (COVID-19) vaccines worldwide, South Africa has had to adjust and overcome challenges associated with the safe and effective distribution of COVID-19 vaccines to its citizens. Vaccines are biological products, and many supply chain factors could influence product integrity and efficacy. This study focuses on aiding the logistics industry in understanding the COVID-19 vaccine supply chain around its handling, storage, and transportation requirements.

Objectives: The study had five objectives. Firstly, to understand the functionality and components of a vaccine supply chain and, secondly to identify the stakeholders involved and their roles. Thirdly, the researchers wanted to comprehend and clarify the cold chain protocols for each category of the COVID-19 vaccines procured and the appropriate international best practices. The last two objectives were to identify the skill and training requirements of stakeholders on all levels, and using these inputs in creating an educational toolkit, aimed at operationally involved supply chain stakeholders.

Method: The researchers made use of both primary and secondary data, focusing mostly on collecting data through a literature review, stakeholder analysis, and interview process.

Results: The study outcome was a COVID-19 vaccine educational toolkit with four tools addressing the research objectives: (1) An identification of all vaccine supply chain stakeholders, (2) vaccine categorisation according to type and equipment required, (3) handling, storage, and delivery protocols, and (4) vaccine supply chain skill and training requirements.

Conclusion: These tools can be used as a basis when educating and/or training COVID-19 vaccine supply chain employees on different levels and stages.

Keywords: cold chain; COVID-19; education and training; toolkit; vaccine supply chain.

Introduction

The roll-out of coronavirus disease-2019 (COVID-19) vaccines caused both the global and South African logistics industry to face one of its greatest challenges ever. These vaccines need to be transported around the country with their safety and efficacy uncompromised (Essential Programme on Immunization 2020). The successfulness and effectiveness of the vaccine supply chain determines whether all South Africans, should they choose to get vaccinated, have access to the vaccine at the right time and at the right place. South Africa received its first batch of COVID-19 vaccine doses in January 2021 and started its vaccination programme (COVID-19 South African Resource Portal 2021). This programme includes all activities involved in procurement, distribution, vaccination, monitoring, communication, and mobilisation and is executed by either the South African government or identified public and private partners (Pillay 2021).

According to Dorfman (2021), the pharmaceutical and health industry in South Africa has manufactured, distributed, and administered vaccines for many years. Most of these vaccines have a temperature requirement between 2 °C and 8 °C. The South African Government, the sole procurer of COVID-19 vaccines, procured both the Johnson & Johnson (J&J) and Pfizer vaccine candidates for local distribution in the country (Karim & Van Dyk 2021). Although South Africa has the infrastructure, equipment, and ability to accommodate a vaccine with a temperature requirement of 2 °C – 8 °C (J&J) it has never distributed, handled, or stored a vaccine with a –70 °C (Pfizer) cold chain requirement (Karim & Van Dyk 2021).

Note: Special Collection: Impact of COVID-19 on the transport and logistics management.

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). This is the largest vaccination campaign that the country has ever undertaken (Mkhize 2021). A big challenge, besides inaccessibility and third world country characteristics, lies in maintaining the different cold chain and extreme cold chain requirements of COVID-19 vaccines, while managing the many factors along the supply chain, that could influence the efficacy of the product (Vaccine Cold Chain Q&A 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 (Rodrigue 2009:146). According to Rodrigue and Notteboom (2020), everyone handling a vaccine during its lifecycle must be trained and educated on the basics of its protocols, storage, and temperature control requirements to ensure that the vaccine reaches its ntended location uncompromised and have the desired impact.

This research study started in parallel with the roll-out of COVID-19 vaccines and thus little to no research existed for a COVID-19 vaccine cold chain. The newness and importance of the coronavirus vaccine cold chain made it a fascinating and relevant field of study. Research done addresses the knowledge gap and will allow distribution companies to have a fundamental understanding of the requirements, education, training, and elements and or components that need be considered when transporting, handling, or storing a vaccine.

Aim of the study

The aim of this study was to aid the logistics industry in understanding the factors that play a role in the transport, handling, and storage of the COVID-19 vaccine, in parallel to the roll-out of the vaccines during 2021. The study included research objectives that supported the understanding and alleviation of some initial distribution challenges associated with a COVID-19 vaccine supply chain in South Africa. The researchers aimed 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 development of a toolkit for cold chain requirements and its importance was established through the research and can be used in the education and training of distribution role players or focused labour, emphasising the knowledge and skills requirements, for these specific vaccines. This toolkit consists of a fixed set of procedures, guidelines, and similar things, 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 prove to be useful in a wider cold chain environment. The research study had one primary research question:

- What toolkit elements can be created or used to educate and train members of the vaccine supply chain?

This research question was answered through, stakeholder analysis, explorative interviews, and in the formation of the toolkit. All inputs for the answering of this question were gathered through the analysis of the data and synthesising information from the literature review, explorative interviews, and stakeholder analysis.

Objectives of the study

The objectives of this study can each be linked to answering the primary research question and were used in achieving the aim of the study. The research objectives are the following:

- To synthesise the functionality and components of similar vaccine cold chains, through an interview process. This enabled the researchers to make use of previous research, tested knowledge and operations that can be used in the formulation of the vaccine supply chain and toolkit.
- 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.
- 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 integrity of the cold chain has.
- To identify the international best practices that could be implemented to ensure vaccine safety and increase cold chain efficacy.
- 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.
- 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.

The vaccine supply chain was categorised according to cold chain requirements and the sensitivity of each category was determined. Researching and understanding the vaccine supply chain and respective logistics cold chain requirements, through a stakeholders' analysis, assisted in collecting information and data for analysis to support assumptions and conclusions drawn. In developing the toolkit, the researchers aimed 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. Familiarising oneself with international best practices for the COVID-19 vaccine supply chain, contributed to the effectiveness of the toolkit and distribution.

Research methods and design

The research design of this study was formulated towards determining the required data and methods of data

collection used in the study. The researchers executed an analysis of existing literature to determine what is already known within the field of study; the results of this research method are not extensively included in this article. This execution served as the basis to determine what knowledge gaps still existed and where or how the researchers could fill those gaps by means of a stakeholder analysis and interviews, as part of a partial desktop study. The researchers made use of a mixed methods approach, including both quantitative and qualitative research.

A stakeholder analysis was included in the qualitative research. Secondary temperature data was used to illustrate the effectiveness of COVID-19 vaccine packaging in this study's quantitative research. In addition, the research can be characterised as exploratory and cross-sectional. This classification of nature ensures that the current problem was understood clearly, and it provided clarity on fresh discoveries that were pertinent at the time. Data from publicly available documents and online portals detailing the COVID-19 vaccine industry and supply chain was used in the study. Both primary and secondary research and/or data was used in the study to ensure that valid and reliable results were obtained that addressed both the aim and the objectives of the study.

Primary and secondary research

The primary research method used in this study was a stakeholder analysis. This included contacting companies that are part of the COVID-19 vaccine supply chain in South Africa, such as BIOVAC, DSV Healthcare, and Imperial Logistics, as well as healthcare professionals and healthcare facilities to form part of the stakeholder interview process. Stakeholders for the study were identified using information from the literature review and exploratory interviews with employees from Imperial Logistics. If willing, the identified stakeholders had the option to share their knowledge and information with the researchers about the COVID-19 vaccine industry and supply chain, including the role that they play. To organise these semi-structured interviews, the researchers contacted these industry experts via phone and email.

Secondary research was conducted by using a variety of Internet-based information portals and publications. The literature study was built using a variety of websites, yearly reports, books, academic publications, class slides, and articles. The information acquired from these many sources enabled the researchers to answer some elements of the research questions, contribute to the development of the educational toolkit, and identify potential areas for future research. Citations will be provided in the results section to indicate the source of literature input as it has been combined with information obtained and strengthened through the physical interviews. The entirety of the literature review is not included in this article.

Sample design

The target population for this study included 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. The sample design was derived from the stakeholders listed in Table 1. These stakeholder groups were identified based on explorative interviews with experts, in the pharmaceutical and healthcare industry, and on information obtained from the Vaccine News, Updates & Information Portal (2021) and Pillay (2021).

The researchers divided the stakeholders, who were willing to participate, into three subsections. These subsections were based on the step in the supply chain that the stakeholder is involved in. In the first supply chain step, which relates to import, customs clearance, and freight forwarder the researchers interviewed five people. In the sixth and eighth supply chain steps, which relates to the central storage facility, six people were interviewed. In the

TABLE 1: COVID-19 vaccine supply chain stakeholder list (Toolkit element 1).

Level	Stakeholder group	Supply chain activity	Involvement level	Interviewee reference title
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	Manager 3
	South African Health Products Regulatory Authority (SAHPRA)	Testing (stability & safety)	Low	
Domestic or Provincial	Manufacturing, for example, Biovac and Pfizer	Make	High	Manager 3
	Air Freight, for example, Imperial Logistics and Pfizer	Import	High	Manager 1, 2
	Freight forwarders, for example, DHL and K&N	Import	High	Manager 4
	Customs clearance Agent, for example, DHL	Import	High	Manager 5
	Logistic Service providers, for example, DSV Healthcare	Store Deliver Return	High	Manager 1, 2, 3, 4, 5
	Healthcare workers, for example, pharmacists, nurses, and doctors	Store Administer	High	Pharmacist 1, 2, 3, 4. Doctor 1 and Nurse 1, 2
	Security, for example, NATJOINTS and SAPS	Deliver	Low	
	Patient		Low	

10th and 11th supply chain steps, which relates to vaccination sites, 10 people were interviewed. Both public and private vaccination sites were visited, located at either pharmacies, clinics, hospitals, or public spaces where nurses, operations managers, pharmacists, and doctors were interviewed.

Table 1 summarises the supply chain members or stakeholders who were identified in step one of the stakeholder analyses and were identified as stakeholder groups who are responsible for either procurement, evaluation, distribution, storage, handling, and safety of the COVID-19 vaccine. The first column categorises stakeholders according to the level that they operate on, the second column identifies the general stakeholder groups and provides examples. Column three summaries the role of each stakeholder in the supply chain or the process they are a part of, and the fourth column ranks the stakeholder groups according to their level of involvement in the physical distribution, handling, and storage of the COVID-19 vaccine. The last column assigns an anonymous reference title to each of the interviewees, whose inputs are discussed in the results section and links their expertise and insights to the supply chain process that they are involved in. They have been anonymised to protect their identity. Empty cells in the last column indicates that the researchers did not interview individuals in these stakeholder groups due to their unavailability.

Data collection

Three methods of data collection were used in this study. The first two methods were used to obtain insight and visibility into the distribution of COVID-19 vaccines in South Africa and its entire supply chain. The first of these methods was the literature review. This analysis of existing literature allowed the researchers 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. The data was collected through online resources, articles, presentations, and so on, and served as secondary data collection.

A stakeholder analysis was the second data collection method. This tool allowed the researchers direct access to the thoughts, recommendations and operations and processes of parties involved in the physical distribution of the vaccine in South Africa. The third method used for data collection was semi-structured interviews with stakeholders. The researchers used information from the literature review and the research questions as a reference from which questions were created to ask during the stakeholder interview process. The answers to these questions served as contributing input to the educational toolkit. The key issue in the collection of data from the stakeholders was the lack of participation and sharing of information or resources.

There were four basic steps the researchers followed in the execution of the stakeholder analysis. These were as follows:

- Identify the stakeholders or stakeholder groups.
- Analyse the stakeholder relationship.
- Develop a stakeholder strategy.
- Engage and communicate with the stakeholders.

A fourth method, also considered a measurement instrument, was used to determine, and evaluate whether the researchers fully understood the functionality of the COVID-19 vaccine supply chain within South Africa and correctly identified the supply chain links. After the researchers constructed a visual representation of the COVID-19 vaccine supply chain it was sent to senior supply chain management employees at DSV Healthcare and Imperial Logistics, who then validated whether the researchers included all elements and links.

Data analyses

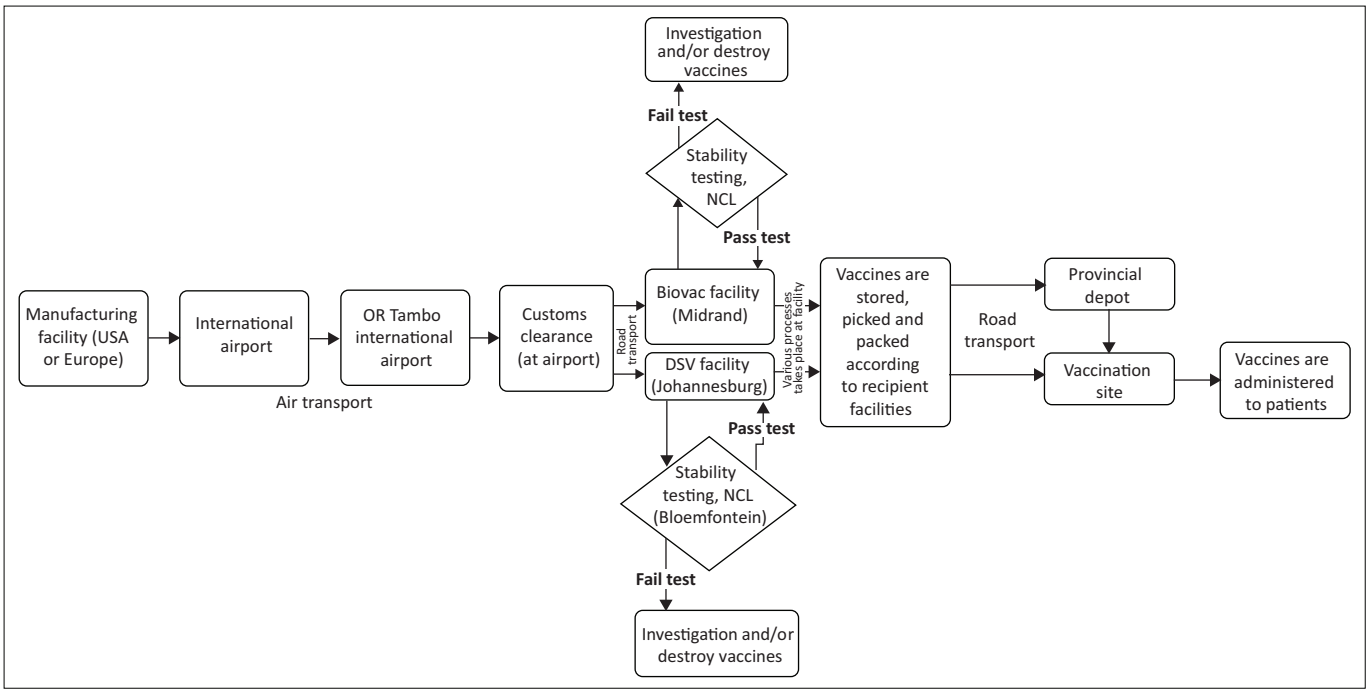
The literature review served as a basis for secondary, qualitative data collection. After consulting a variety of internet authors, articles, books, and information portals, the literature review was written. The analysis of these sources and materials, yielded qualitative information and data. The assumptions made, based on the qualitative data collected from the literature review, were drawn from multiple sources.

In this study, the stakeholder analysis was used to confirm specific parts of the data collected through the literature review and to elaborate and build on collected facts and information. The researchers were able to obtain data from direct sources in the COVID-19 vaccine supply chain through interviews with various stakeholders. These interviews and information exchanges gave the researchers access and visibility into the functionality of the vaccine supply chain operations.

Validity and reliability

Two criteria were used in the evaluation of this research study, namely, validity and reliability. 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, to fully represent what the study aims to measure. There were three main variables in this study, namely, (1) different factors or cold chain requirements that need to be monitored and managed in the COVID-19 vaccine supply chain, (2) number or type of skills required for effective distribution and (3) operations and different links that form and configure the COVID-19 vaccine supply chain.

Construct validity focuses on ensuring that the method of measurements matches the construct that the research wants



NCL, National Control Laboratory.

FIGURE 1: COVID-19 vaccine supply chain – South Africa.

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 realised by sharing results with industry experts and asking personnel at logistical stakeholder companies, focusing on healthcare, whether they agree with the obtained results.

The reliability of this study was based on using different analysis or evaluation methods for data and obtaining the same results from both. The researchers also used information from different stakeholder sources to base conclusions and assumptions on, which allowed credibility. Authenticity was realised by conducting the research in a genuine and credible way and ensuring that the results contribute to the field of study.

Findings

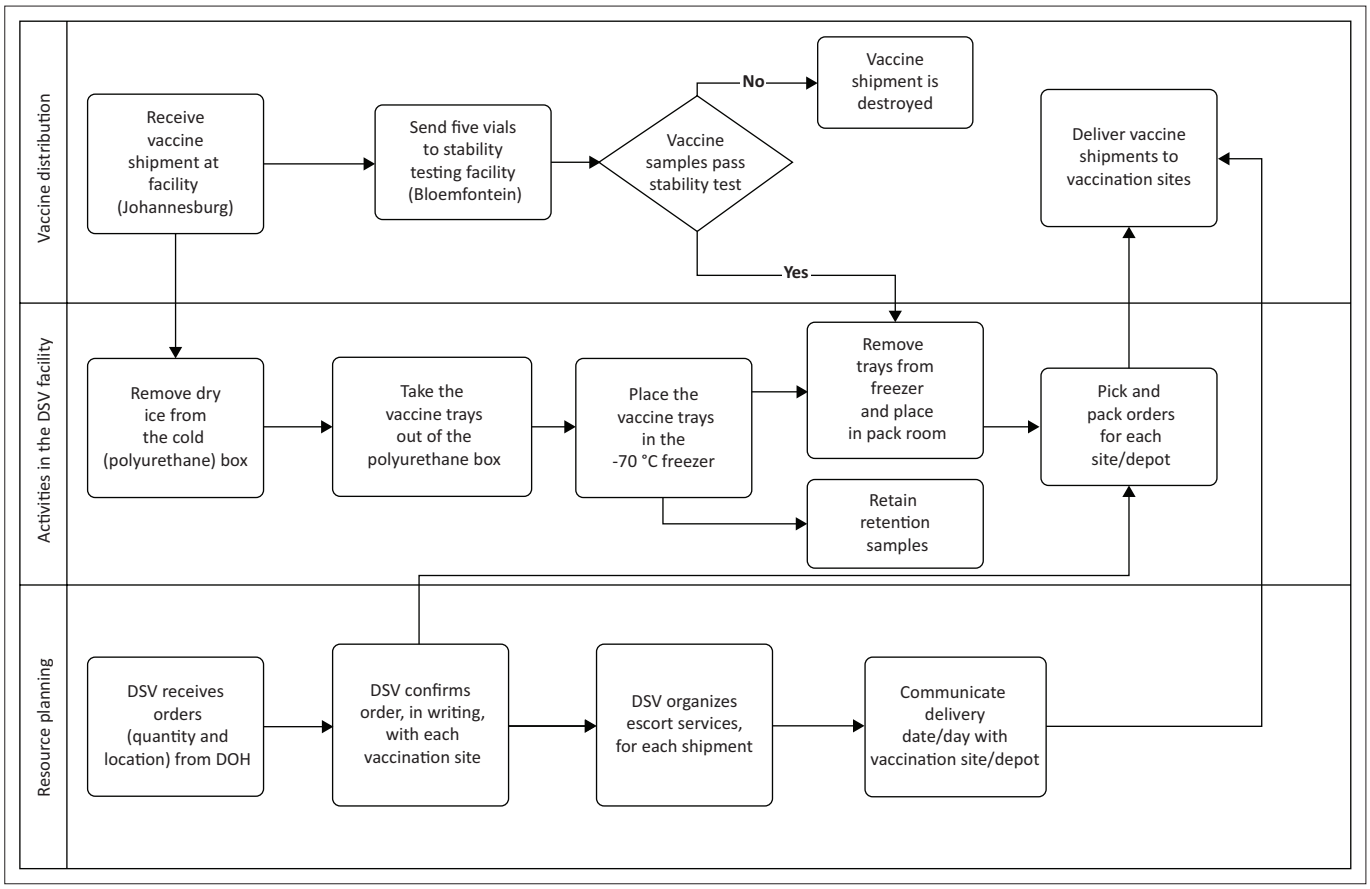
The findings of this study can be divided into two sections. The first being the information and data that was the result of the explorative interviews, literature review and stakeholder analysis and the latter being the use of these results as an input to the formation and creation of the educational toolkit, which was the actual output of study.

COVID-19 vaccine flow and supply chain

The first important result to discuss is the flow of COVID-19 vaccines from manufacturing sites to vaccination sites in South Africa. 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 researchers focused on, due to their direct involvement in the handling and distribution of the vaccines. With the help of anonymous individuals/stakeholders at different stages of the supply chain, the researchers were able to illustrate and validate the COVID-19 vaccine supply chain, as illustrated in Figure 1. This illustration was used as an aid to achieve the objectives associated with understanding the functionality of the vaccine supply chain and identifying stakeholders.

Figure 1 illustrates that COVID-19 vaccines have approximately four to seven physical stops before they reach their intended location or patient. At each of these stops, there are several processes that take place. The COVID-19 vaccine supply chain in South Africa is like a generic vaccine supply chain 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 because of the structure of procurement and distribution in South Africa. In the global market, both governments and public and/or private companies are used to procure and distribute COVID-19 vaccines.

Information from both the literature review and stakeholders confirmed that in South Africa, the Department of Health (DOH) 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 (COVID-19 South African Resource Portal 2021 and Manager 1, 2021). Identified companies wait upon the South African government to inform them, when and where they have procured vaccines so that they can start with the freight forwarding and clearing process (Manager 1). Vaccines are transported from manufacturing facilities around the continent, mostly incoming from Europe or the USA, to the local port in South Africa, via air transport. Upon arrival



DOH, Department of Health.

FIGURE 2: Central storage facility COVID-19 vaccine flow.

at OR Tambo International, Airport customs clearance agents are responsible for facilitating the import process and ensuring authorised passage of vaccine shipments (Manager 3). Shipments are then transported, via road transport through a freight forwarder, to either the Biovac central storage facility, in Midrand, or the DSV central storage facility, located in Johannesburg (Manager 4).

According to Manager 1 and Manager 3 (2021), vaccines that require a storage temperature of 2 °C – 8 °C are transferred to the Biovac facility, whereas vaccines that require a storage temperature of –70 °C are transported to the DSV facility. Vaccines manufactured in South Africa are delivered by road from the manufacturing site to the Biovac storage facility (Dorfman 2021). 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 summarised in Figure 2. These processes are similar to the processes in the Biovac facility. Figure 2 consists of three swim lanes. Each lane represents an ongoing process that takes place simultaneously to the other lanes. The first lane provides a basic flow of vaccines as part of the entire supply chain. 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 2 shows that DSV receives the vaccine vials from Pfizer in a polyurethane box that is packed inside a carton box. The polyurethane box has dry ice on top of it as well as a temperature monitoring device (Manager 4, 2021). The DSV team has 5 min 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 fulfil (Manager 3, 2021). Some of these roles include: (1) opening and closing the ultra-cold freezer, (2) monitoring the stopwatch, (3) taking the dry ice off the polyurethane box and (4) removing the shipment from the box.

Supply chain employees need to fulfil 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 R35 475 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, emphasises the care that should be taken during the cold chain (Manager 2, 2021).

Effectively, the DOH is the client of DSV, who communicates with the company about how many vaccines they will receive and when. After a shipment arrives, five vials are taken to a laboratory in Bloemfontein for stability testing (Manager 3, 2021). These samples and their results are released to either allow the flow of vaccines to continue or to stop the entire shipment. While stability testing takes place, the DOH sends DSV a list of vaccination sites or facilities as well as the quantity per location that vaccine trays need to be transported to (Manager 4, 2021). 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.

DSV contacts the various vaccination sites or depots directly after obtaining order quantities from the DOH to confirm in writing that it is what they want. Based on their location, they also determine when the immunisation locations will receive their supply (Manager 3, 2021). DSV workers are in contact with specific escort/security firms about their delivery schedule to prepare and plan enough resources to escort DSV trucks during the delivery procedure (Manager 4, 2021).

DSV transports vaccine vials to vaccination sites using polyurethane cold boxes, according to Manager 4 (2021). If left unopened, these polyurethane boxes will keep a temperature of –70 °C or a temperature range between –60 °C and –80 °C for up to 72 h. The temperature monitoring device on top of the polyurethane box must be checked and documented by anybody who receives the box at any point in the supply chain (Manager 3, 2021). They should red-flag the cargo and advise a deviation if the temperature monitoring device displays a temperature variation above –60 °C or below –85 °C. The 'red-flagged' product/shipment will not be delivered to its designated location; instead, it will be quarantined in the correct storage conditions (Manager 4, 2021). Temperature data of the shipment is then 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 vaccines are destroyed (Manager 3, 2021).

The understanding and visualisation of the supply chain and its components served as a basis for answering certain aspects of the research questions.

Toolkit and answered research questions

The following subsections discuss the inputs obtained from the stakeholder interviews and literature review. Facts and knowledge from stakeholders were used to correlate or differ from the basic assumptions made, based on the literature review. This section also includes elements of the toolkit, such as tables or figures, which was the ultimate output of this research.

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

South Africa has dealt with the distribution and administration of vaccines for many years (Pillay 2021). Although pharmaceutical experts reason that the industry is in its infancy stage, 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 (Manager 2, 2021). Each province and even municipality or regional area are in different development phases and has dissimilar availability of resources and infrastructure (Schoub 2021). 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 (Dorfman 2021). The Pfizer vaccine's temperature requirement has led distribution companies to purchase appropriate cold chain equipment and Personal Protective Equipment (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 – 8 °C, they have established a few primary processes that take place in any of their warehouses. These phases, processes or steps are identified, by them, as the basic processes for every vaccine and are summarised in Figure 3.

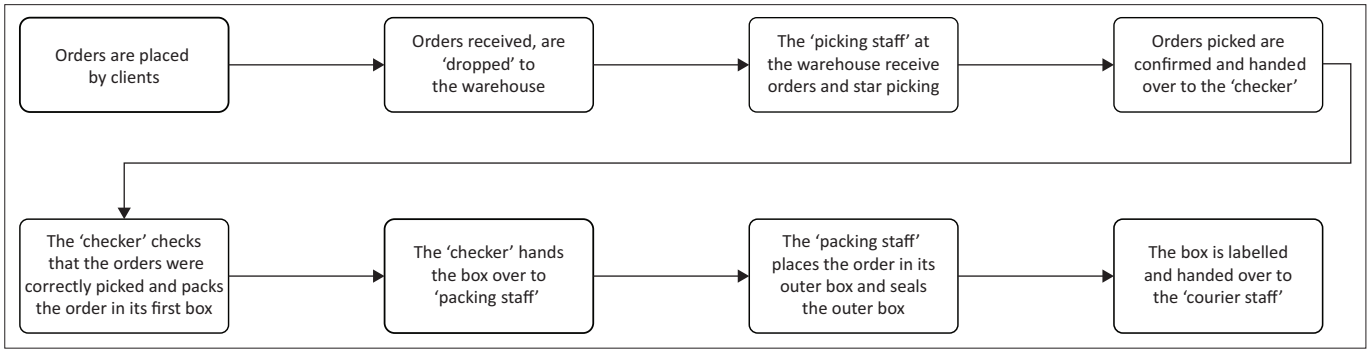


FIGURE 3: Vaccine handling processes (Aspects of toolkit element 3).

TABLE 2: COVID-19 vaccine categorisation (Toolkit element 2).

Vaccine temperature category	Other cold chain requirements	Cold chain equipment and/or technology	Function
Category 1: 2 °C – 8 °C	Shelf life of unpunctured vials if refrigerated is until the expiration date, if in ambient temperature, up to 12 h.	Walk-in refrigerator	Storage, maintaining a temperature of 2 °C – 8 °C
		Portable refrigerator	Storage and transportation of small shipments
	Shelf life of punctured vials is 2 h – 6 h at room temperature.	Refrigerator (Medical or Health Facility)	Storage at vaccination sites
		Polyurethane box	Distribution (both inbound and outbound), maintaining a temperature of 4 °C
	Minimise light exposure during storage.	Temperature monitoring device	Monitors the temperature of the shipment
Category 2: –70 °C	Shelf life of unpunctured vials is until the expiration date in ultra-cold freezers, up to 1 month in a freezer and up to 2 weeks in a refrigerator.	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)
	Shelf life of punctured vials is two to 6 h at room temperature.	Freezer (–25 °C – 15 °C)	Storage for up to 1 month
		Refrigerator (2 °C – 8 °C)	Storage for up to 2 weeks
	Minimise exposure to room light during storage.	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
	Avoid exposure to sunlight and ultraviolet light.	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

According to Manager 2 (2021), there are between five and six groups of people who handle a vaccine in a warehouse, namely, admin staff, picking staff, checking staff, packing staff, label and handling staff and courier staff. These groups stay relatively similar for any vaccine but the tasks for the employee groups might differ based on the vaccine's requirements or order specifications. There are certain key skills that have always contributed to the successful distribution of vaccines and one of those skills is cold chain expertise, according to Managers 1 and 3 (2021). This refers to having the validated solutions that have been tried and tested, that stems from previous experience and educating personnel around the importance of certain cold chain aspects. The first research objective was thus reached, using previous experience and knowledge to understand the functionality of a vaccine supply chain.

Cold chain requirements and categorisation

The most important cold chain requirement when it comes to COVID-19 vaccines is temperature (PATH 2021). Shelf life (expiry date), shaking/vibration or agitation and sunlight are also cold chain requirements that should be monitored within a vaccine supply chain (WHO 2021). The 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. The second is the monitoring of vaccine's freezing and in most vaccine supply chains this type of monitoring is done to avoid freezing. The last element is the management of consumables used in the vaccine cold chain (Manager 2, 2021).

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 (Manager 1, 2021). The first category was for vaccines that require a storage and handling temperature range of between 2 °C and 8 °C and the second category was for vaccines requiring a storage, handling, and distribution temperature of –70 °C (Manager 5, 2021). The Jansen (J&J) vaccine falls into the first category (CDC 2021:2) and the Pfizer vaccine into the second (FDA 2021:3). Individuals from distribution companies agree that this is the most practical and logical way to categorise COVID-19 vaccines. Manager 1 (2021) suggested that storage should also be a categorisation element because of the challenges faced in South Africa, for example, load shedding, poor access, and hot/warm weather. These interviews with stakeholders enabled the researchers to identify and categorise cold chain requirements, thus achieving objective two. Table 2 summarises the cold chain requirements of the two vaccines, the cold chain equipment and/or technologies used, and the function of the equipment used.

Cold chain protocols

The third research objective was to clarify cold chain protocols for procured vaccines in the South African setting. The information from stakeholders interviewed, clarified the cold chain protocols that need to be followed by everyone who distributes, handles, stores or transports a COVID-19 vaccine shipment or vial. Although protocols differ at each link in the supply chain, the following protocols are considered the basic protocols applicable to the research topic (Aspects to Toolkit Element 3):

- 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, for example, 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.

Best practices

Conway (2021) recommends five best practices for vaccine distribution. The first is to minimise variation when and where possible. In South Africa, the DOH, tries to minimise variation by being the sole procurer of the COVID-19 vaccine and only using a handful of companies to import and distribute the vaccines in the country (Manager 1, 2021). 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 (Pharmacist 1 and 2, 2021). These devices allow visibility into the supply chain, which is 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). Temperature monitoring devices or temperature loggers play an integral part in managing and upholding the vaccine cold chain and are extremely useful, because temperature is the only COVID-19 vaccine cold chain requirement companies are obligated to monitor in South Africa (Pharmacist 4 and Manager 3, 2021).

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. Clear, open, and frequent communication between supply chain links should also be labelled a best practice (Doctor 1, 2021). These identified best practices address the fourth research objective.

Skill requirements

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 (Manager 1). Efficiently performing a task, because employees have the correct skill set, contributes to keeping vaccines safe and uncompromised (Manager 3 and 4). The skills that are required by individuals are categorised according to hard and soft skills (refer to Table 3). 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 (Gerencer 2021). 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 (Manager 1 and 3). The information in this sub-section addresses research objectives five and six and contributed to the final toolkit elements.

TABLE 3: Skills requirements (Toolkit element 4).

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 licence 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, for example, 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

GPS, Global Positioning System.

The listed skills were assembled through answers and insights from the stakeholder interviews.

Training requirements

The researchers focused on the training and education required by four groups of people in the COVID-19 vaccine supply chain, and these are also included in the final toolkit element. These individuals form part of the physical distribution and handling of a COVID-19 vaccine shipment:

- **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. These employees need to be trained on four basic levels, namely, standard operating procedures, system and device training, product specific training and general knowledge training.
- **Group 2: Airport, operational training, and education.** Employees who work at the airport do not necessarily need any COVID-19 specific training and includes operational employees who handle and transfer vaccine shipments to and from the aircraft and not on pilots or aircraft personnel. Basic training in terms of completing paperwork, checking the shipment, reading the temperature monitoring devices and how to handle shipments with care should be focussed on.
- **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.
- **Group 4: Vaccination site training and education.** There are four groups of employees who 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.
- **Management personnel:** This group refers to any individual who 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.

TABLE 4: Toolkit tools.

Toolkit tools/elements	Article links
The COVID-19 vaccine supply chain stakeholders	Shown in Table 1.
The COVID-19 vaccine categorisation and cold chain equipment	Shown in Table 2.
The COVID-19 vaccine handling, storage, and delivery protocols.	Described in Sections Cold chain protocols and Best practices.
The COVID-19 vaccine supply chain required skills, training, and education	Described in Sections Skill requirements and Training requirements.

Discussion

The key findings of this study are the four basic tools that were created as an output of the study as listed in Table 4.

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.

It also includes knowing that although many stakeholders form part of the COVID-19 vaccine supply chain, there are ± 15 stakeholder groups who are involved in the physical handling, distribution, and storage of these vaccines in South Africa. The DOH is the sole procurer of either J&J vaccines or Pfizer vaccines for the South African population, should they choose to get vaccinated. The DOH have identified both public and private partners who assist them in one of the following supply chain processes: import, store, testing (safety & stability), deliver, administer, and return.

Vaccines in South Africa are categorised according to their cold chain requirements. There are two temperature groups. Category 1 includes all vaccines with a temperature requirement of 2 °C – 8 °C while vaccines in category 2 require a –70 °C environment. Although temperature is not the only cold chain requirement that should be monitored and managed, the DOH only requires companies to monitor temperature in South Africa. To maintain the vaccine cold chain, protocols should be implemented, followed, and monitored. Employees working in either a central storage facility, warehouse or vaccination site should follow certain protocols before arrival of vaccines, during the handling and storage of vaccines, upon receival and during administering. Employees who form part of the transportation leg should know the protocols to follow when collecting and delivering a shipment.

Employees handling, storing, or transporting vaccines are divided into six groups based on their level of employment. Each group have a different qualification requirement, hard skills requirement, and soft skills requirement to fulfil their role in the COVID-19 vaccine supply chain. Training related to the handling, storage and transportation of COVID-19 vaccines are also divided into subsections based on the place where employees work and the roles, they play in the vaccine supply chain. It is very important that management personnel are informed and educated about the characteristics and specifications or requirements of specific COVID-19 vaccines and that they are trained in decision-making, problem-solving and analytical abilities. They should also communicate

instructions and facts clearly and be able to instruct or teach those employees that report to them.

Limitations

This study had four limitations that affected the data collection process. The first limitation is that not all the stakeholders who were identified could be contacted or reached to schedule an interview within the research timeframe. Most of these mentioned stakeholders included those associated with government, specifically the DOH. The second limitation is that there were a few stakeholders who 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 healthcare 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 researchers had to take diligent care to ensure the rigour and validity of the research process and outcome.

Recommendations for 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 who are 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 researchers recommend 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 researchers 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.

Conclusion

The cold chain requirements of COVID-19 vaccines are new to the vaccine industry and supply chain both locally and internationally. The literature review and stakeholder analysis aided in understanding the functionality of the COVID-19 vaccine supply chain and elements of the industry, closing the current knowledge gap. Researchers 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 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.

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Competing interests

The authors declare that no competing interest exists.

Authors' contributions

S.S.M. wrote the methodology, did the formal analysis and investigation as well as the writing of the original draft. Authors L.L.G.G. and J.V.E. contributed to the conceptualisation, validation, supervision and funding of the acquisition. They also did the writing in terms of review and editing.

Ethical considerations

This article followed all ethical standards for research without direct contact with human or animal subjects.

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Data availability

The data that supports the findings of this study are available upon reasonable request from the corresponding author, L.L.G.G. A supplementary document was submitted containing the toolkit, output, of the study.

Disclaimer

The views and opinions expressed in this article are those of the authors.

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