

Immunization supply chain of India

(A Case study on challenges for COVID-19 vaccination)

Master Thesis Report

By

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Acknowledgement

The master's degree thesis programme finally culminates with the conclusion of my TWO-YEAR post-graduation in logistics and supply chain management at one of the premier institutions of Northern Europe i.e., Lund University. It was a great feeling to have graduated out of such a prestigious university with lot of hard work, dedication, and passion. It is therefore needless to that my sojourn at this place has left me with fond memories and everlasting impression of lifetime.

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Mahesh Praveen Kashyap

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Inspiring quotes

Vaccines are one of our important tools for preventing outbreaks and keeping the world safe. While most children today are getting vaccinated, far too many are left behind. Unacceptably it often those who are at risk- the poorest the most marginalized, those touched by conflict or forced from their homes- who are persistently missed.

Dr Tedros Adhanom Ghebreyesus

WHO Director

Vaccine are the Tugboats of the preventive health

William Foege

American Physician

Life or death for a young child too often depends on whether he or she is born in a country where vaccines are available or not

Nelson Mandela

South African revolutionary

Investments in Immunization yield a rate of return on a par with educating our children- and higher than nearly any other development intervention

Seth Berkley

CEO, Gavi the Alliance

Abstract

Background

The COVID 19 pandemic has subjected a lot of countries to economic and social turmoil. This has contributed to socio economic as well as psychological challenges undermining the economies of many countries. Immunization is the key in this crucial phase of pandemic that can save a lot of precious lives. But imminent challenges in immunization supply chain of world countries to the native population across the world are manifold. This must be enhanced to enable the world to come back to normalcy. Problems in distributing vaccines are aplenty depending on the adversity in each country. By studying this phenomenon, many solutions could be found that can benefit the concerned stakeholders.

Problem definition

Distribution of vaccines is often a challenge in developing countries, this is due to several shortfalls in the immunization supply chain setup like cold chain distribution, lack of infrastructure for last mile delivery and shortage of adequate staff for administering the vaccines and storage capacities at distribution centres which makes it challenging to conduct immunization.

Aim of the study

This study will identify the challenges in the COVID-19 immunization supply chain of India and identify the main challenges it faces in immunization its population against COVID-19 and describe how it can be mitigated by identifying suggestions from theory for future that will aid in strengthening the immunization supply chain. This analysis will be made in comparison to the routine immunization programme that happens in India.

Research methodology

To study the immunization supply chain of India, the case study research methodology is followed. A single case study is adapted to study the challenges of COVID-19 vaccination in India. The study on a higher levels follows an abductive approach to achieve the purpose of answering the research question. The qualitative data for the study is mainly collected through secondary sources such as Journals, articles and newspapers relevant to COVID-19 vaccination in India. Primary data is not utilized as there were challenges collecting data from the health care workers in India.

Conclusions

The challenges for COVID-19 immunization supply chain of India is much more than routine immunization supply chain. All the activities of immunization supply chain in India face challenges starting from planning the immunization supply chain, cold chain distribution till vaccine administration. Hence most of the challenges identified resemble theory which states the problems in immunization supply chain for developing countries. The only dissimilarity from theory is the vaccine procurement and information systems where India has achieved self sufficiency in vaccine procurement and has integrated information system in place in all its vaccine stores.

Contribution

The study will help the stakeholders to understand the main challenges in COVID-19 immunization supply chain and areas requiring attention for overall improvement. The identified challenges faced may be of some help for the stakeholders in India to tide over the shortcomings and ways & means

to improve during the COVID-19 vaccination. Unless efforts are put at each stage of the vaccination drive, the challenges cannot be met with success; there could be downward trend in India's immunization program in future. But since it is a pandemic, it could take time to implement considering the vastness of India's immunization program and at present it looks like India is on the way to achieve its desired goal. This is also a way to help stakeholders for future immunization in India.

Key words

Immunization supply chain, COVID-19 vaccination, routine immunization, Vaccine distribution in developing countries, Health care workers for COVID-19 vaccination, Vaccine administration.

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Abbreviations

ANM	Auxiliary nurse midwives
ASHA	Accredited social health activists
CHCs	Community health centres
CCP	Cold chain points
COVAX	COVID-19 vaccines global access
EPI	Expanded Programme on Immunization
EVIN	Electronic vaccine intelligence network
GMSD	Government medical stores depot
HOs	Humanitarian organizations
LSPs	Logistics service providers
MIS	Management information systems
PHCs	Primary health centres
SCRM	Supply chain risk management
SARS-COV-1	Severe acute respiratory syndrome coronavirus 1
SARS-COV-2	Severe acute respiratory syndrome coronavirus 2
UIP	Universal Immunization programme
UNICEF	United Nations children’s education fund
VDS	Vaccine Distribution System
WHO	World Health Organization

1) Introduction

This section will give an introduction to COVID-19 pandemic in general and how it has affected the general population of the world. This is followed by introduction to immunization in India with brief discussion on problem definition, research question, aim of the thesis and structure of the report

1.1) COVID-19 Pandemic

COVID-19 known as corona virus is an acute disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-COV-2). The biologists/virologists have speculated that the virus had its origin from the bat population. Even though the initial outbreak was confined to China in December 2019, it soon spread its tentacles across many countries breaking every available geographical boundary due to unrestricted movement of men and materials. The rapid transmission of the virus across Europe and USA was quite alarming and by the end of May/June 2020 it had spread to the entire world leading to precious loss of human lives. This has prompted the WHO (The World Health Organisation) to declare it as a pandemic and guidelines were issued to combat the pandemic. The precautionary guidelines were in the nature of wearing masks, maintaining social distancing and washing hands with sanitizers to prevent the spread of the disease. The WHO also declared that people with co-morbid conditions like diabetes, Blood Pressure, Kidney disease, Cancer and other immune deficiency disorders are the most vulnerable people of the large population and are required to take precautions. Depending upon the gravity of the pandemic, countries across the world started shutting down the economic activities like travel industry, hospitality, tourism, education sector and business etc. This has also led to widespread closure of trading and other allied activities. The emergence of this virus is not the first of its kind affecting mankind in general. In the year 2003 (SARS-COV-1) had the same resemblance genetically with the present COVID-19 virus (WHO, 2021; Chakraborty and Maity, 2020; Jackson et al., 2020).

The pandemic has resulted in the collapse of world economy which has affected the employment of many people. This is especially true for lowly paid worker/labourer in all developing countries who depend on daily wages for their livelihood. In order to overcome this challenge, a cohesive and vibrant supply chain management is needed for quick and fast distribution of basic commodities, food, clothing, medicines etc. apart from other necessities. However, due to bottlenecks in transportation and other distribution networks, it is expected that some disruptions may be encountered at certain point of time which needs to be addressed to achieve the targeted goal. In this context, the many countries are fighting to combat the rapidity of the pandemic by enforcing a lot of reforms in their political and economic systems. (Chakraborty and Maity, 2020; Jackson et al., 2020)

At present, the focus of the world countries is in equitable distribution of vaccines. This will involve challenges for stakeholders (Government Agencies, Pharma companies, organisations in supply chains etc) at every level in collection, storing and distribution of vaccines to the needy population. Hence, it is important that a well-structured distribution network if managed professionally would help the targeted immunisation programme function much faster. This will help the world bounce back to normalcy.

1.1.2) Immunization

Vaccination is a major contributor to the public health, from the past many years' deaths have been averted through vaccination against different diseases like swine flu, hepatitis, and influenza (Duclos et al., 2009). EPI also called as **Expanded programme on immunization** was launched by WHO in the year 1974 aimed to immunize all the population critically affected by diseases. Since then, it has been a success story which has mandated all the world nations to vaccinate its native population to eradicate severe pandemics (Shen et al., 2014).

Despite the immunization programmes in the world, challenges in distributing vaccines are many. The shipping, storing, and delivering vaccines in a cost-efficient way remains a major hurdle in most of the pandemics. This is relevant to the developing countries that often face shortages in resources and technologies (Yang et al., 2021). Hence, timely distribution of vaccines is important to combat the pandemic more quickly, but in many developing nations the vaccine supply chains are severely strained and the possibility to distribute vaccines are low putting many lives in risk (Kaufmann et al., 2011).

1.1.3 Immunization in India

Immunization in India is also called **Universal Immunization programme**. This was launched by the government of India in 1985. The aim of the programme was to vaccinate children and pregnant women against diseases like BGT, hepatitis, measles, and tetanus. The routine immunization programme of India was launched with the following objectives in mind (CFPI, 2021):

- 1) Increase immunization coverage
- 2) To improve quality of services
- 3) To establish a reliable cold chain system to the health care facility
- 4) Monitoring of performance and to achieve self-sufficiency in vaccine production

There were specific challenges with the launch of immunization programme in India. Following independence of India in 1947 from British, there was a rapid outbreak of tuberculosis and smallpox which motivated the government to increase the infrastructure of immunization in India. Despite becoming the largest producer and exporter of vaccines in the world, India was home to one third of unimmunized people in the world. There were several problems associated with it (CFPI, 2021):

- A) Lack of standard operating procedure.
- B) Insufficient government tools and machinery (Inadequate infrastructure)
- C) Insufficient cold chain infrastructure
- D) Poor turnout of masses due to lack of awareness.

All these led to inefficiencies in the Logistics and vaccine management leading to wastage of vaccines. This posed a challenge for the government to augment its cold chain capabilities. Since then, it has progressed to increase the immunization coverage in the country (CFPI, 2021).

UIP has benefitted from a number of international organizations like WHO, UNICEF and Gavi alliance. In the past UNICEF has worked closely with the Government of India to advance the cold chain logistics and supply systems for the vaccines in the country (CFPI, 2021).

Recently, there has been new initiatives undertaken by the UIP to advance the immunization coverage. Mission Indra Dhanush was launched in year 2014 to increase the immunization coverage to children to around 90%. Advancements in vaccine cold chain and logistics have been strengthened along with capacity building. Electronic vaccine intelligence network (E-vin) is introduced to track the stock of vaccines, their logistics and their temperature from the national to the rural level. This enables managers to have a real time view of the vaccines in stock (National Health Mission, 2021). The figure 1 represents the immunization supply chain in India from manufacturers to the last cold chain points with various levels of vaccines stores.

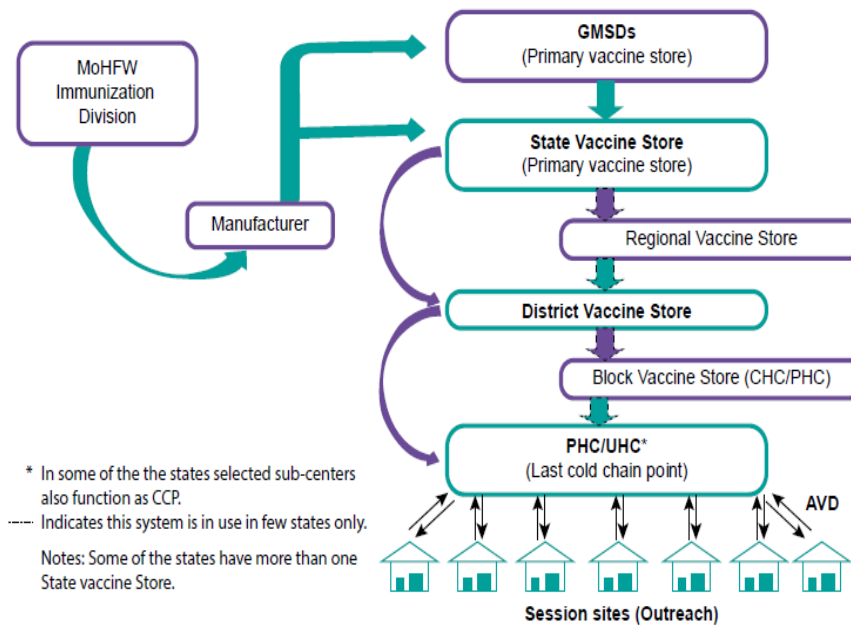


Figure 1- Immunization supply chain in India (Cold chain handbook, 2016, p.3)

1.2) Problem Definition and aim of the thesis

Distribution of vaccines is often a challenge in developing countries, this is due to several shortfalls in the immunization supply chain like cold chain distribution, lack of infrastructure for last mile delivery and shortage of adequate staff for administering the vaccines and storage capacities at distribution centres which makes it challenging to conduct immunization (De Boeck et al., 2019).

Hence this study will identify the challenges in the COVID-19 immunization supply chain of India and describe how it can be mitigated by identifying suggestions from theory that will aid in strengthening the future immunization supply chain. This analysis will be made in comparison to the routine immunization programme that happens in India.

Vaccination of people against COVID-19 is very crucial and it helps save a lot of lives. The world countries have started their immunization programme and hence the immunization supply chain pose a lot of challenges. This aspect will be interesting to study as it will give the stakeholders involved to map a new perspective of their Immunization supply chain. By identifying the key differences and similarities with the routine immunization the complexities associated with the COVID-19 vaccines can be identified. Hence, by understanding the theoretical backdrop of immunization supply chain in developing nations, solutions could be investigated for India's immunization supply chain.

To fulfil the aim of the study and to understand the main challenges, the following research question is proposed-

What are the challenges in India's COVID-19 immunization supply chain in comparison to routine Immunization supply chain of India?

1.3) Focus of the research

The focus of the research is to study the immunization supply chain in India and investigate different aspects like Vaccine Procurement, Vaccine distribution system, Cold chain distribution of vaccines, Transportation of vaccines and other important factors of Immunization supply chain and find out how it is configured for the COVID-19 vaccination. This would assess the preparedness of India for the COVID-19 vaccine rollout and how it is different from the routine immunization.

1.4) Structure of the report

The structure of the report follows the below stated flow of contents-

The next part of the report will motivate on the type of research methodology chosen and Part 3 will discuss the theoretical frameworks of this study.

Then, Part 4 will motivate on the different types of secondary data collected for the study and will describe Immunization supply chain of India and how it is configured for the COVID-19 vaccination.

Part 5 will analyse the data and compare it with the theoretical frameworks to answer the research question and will summarise all the challenges for COVID-19 immunization supply chain.

Part 6 will conclude and answer the research question.

2) Research Methodology

This study will utilize case-based research method to answer the research question as this is the best choice to analyse the immunization supply chain of India. This section will motivate the choice for case-based research method.

2.1) Scientific approach to research

All the research carried out in the scientific world should focus on achieving best conclusions as much as possible. Based on this perception, the research in logistics also carries the same positive approach. The reality in positivistic approach is tangible, fragmented and fragmentable (Gammelgaard, 2004).

Arbnor and Bjerke (1997) presents three different ways for choosing the scientific approach in logistics research, they are classified as analytical approach, systems approach, and actors approach (Figure 2).

	Analytical approach	Systems approach	Actors approach
Theory type	Determining cause-effect relations. Explanations, predictions. Universal, time and value free laws	Models. Recommendations, normative aspects. Knowledge about concrete systems	Interpretations, understanding. Contextual knowledge
Preferred method	Quantitative (qualitative research only for validation)	Case studies (qualitative and quantitative)	Qualitative
Unit of analysis	Concepts and their relations	Systems: links, feedback mechanisms and boundaries	People – and their interaction
Data analysis	Description, hypothesis testing	Mapping, modelling	Interpretation
Position of the researcher	Outside	Preferably outside	Inside – as part of the process

Figure 2- Different scientific approaches in logistics research (Gammelgaard, 2004, p.482) based on Arbnor and Bjerke (1997)

The analytical approach impinges closer to the reality of things. It explains reality as a single entity in which we can identify the patters without distorting it. This goes on to explain further that reality can be split into patterns in which finding a relationship between the cause and its effect is possible. This approach moves closer to the quantitative approach (Gammelgaard, 2004).

The systems approach has a different meaning to the reality of things, it explains that decomposing the reality into parts is meaningless. Hence the researcher must identify the parts in the system and try to establish their casual relationships by creating an understanding of the world. The systems approach is said to be pragmatic in nature, rather than searching for absolute truth, the researcher tries searching for solutions that could have effect in the actual world (Gammelgaard, 2004).

According to *actors approach*, the reality is not objective. The reality is seen as construction and the knowledge to be socially constructed. This approach is highly contextual, and it argues that it is impossible to understand the cause-effect relationship, therefore the understanding of reality requires investigation of intentions (Gammelgaard, 2004).

The systems approach is found most relevant to this study. To investigate the challenges in the Immunization supply chain of India for COVID-19 vaccination, this entity is considered as the system (figure 3) and this will be studied to dwell deeper into its parts. They are vaccine procurement, cold

chain distribution of vaccines till the last activity which is vaccine administration. The challenges in each of them for COVID-19 vaccination will be investigated.

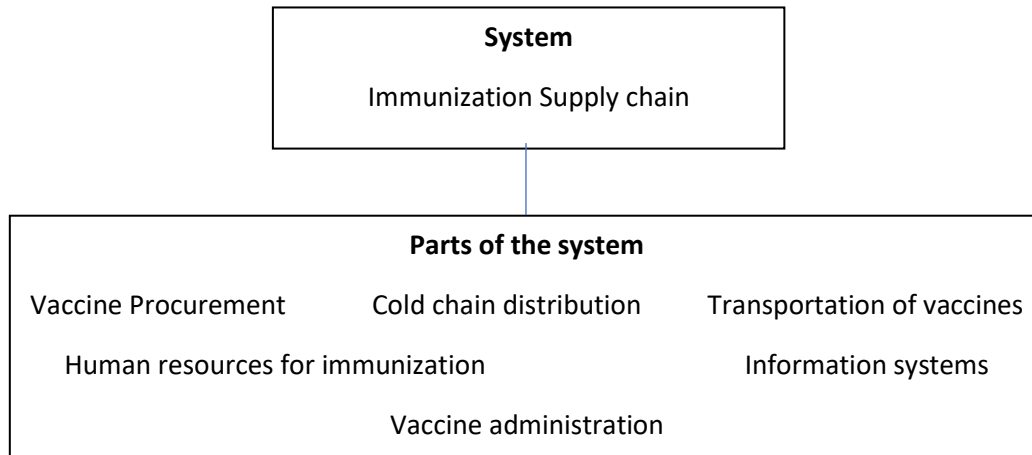


Figure 3- Systems approach for this study

2.2) Research approach

The research approach starts with selecting inductive or deductive approach (Figure 4 and Figure 5). The inductive approach begins by collecting the data and then theorizing it which paves way for new theory generation. Contrary to the inductive approach, deductive approach begins by discussing the theory relevant to the research questions and then collecting the empirical data which gives rise to refinement of theory based on the existing theoretical framework (Voss et al., 2015; Kovacs and Spens, 2005).

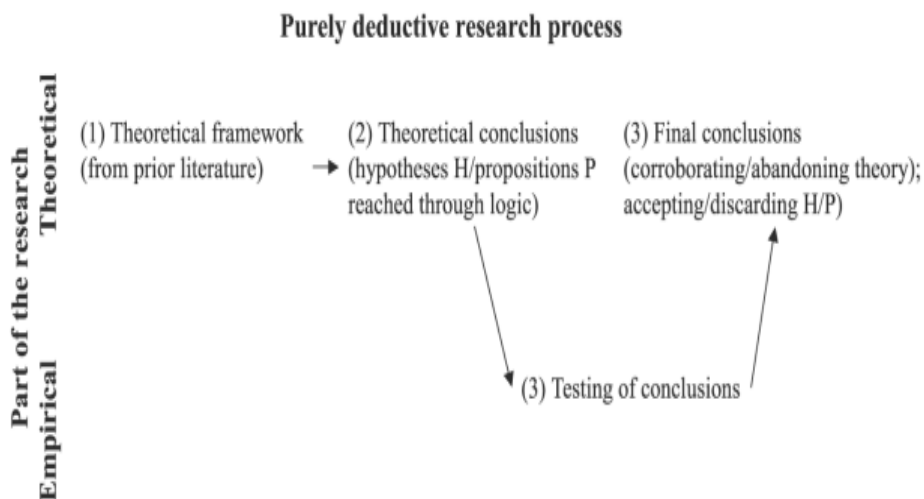


Figure 4- Deductive approach (Kovacs and Spens, 2015, p.137)

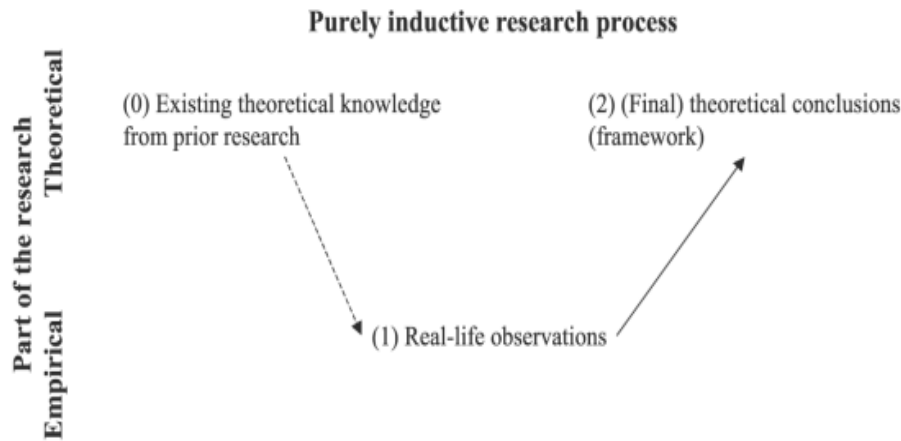


Figure 5- Inductive approach (Kovacs and Spens, 2015, p.137)

Apart from the two types of reasoning stated above, there is a third category of reasoning in logistics research termed as abductive reasoning. This is neither inductive nor deductive, but a combination of both to arrive at a conceptualization. Abductive reasoning emphasises the findings of the theory to an empirical observation and at the same time data is collected to find the suitable theory (Kovacs and Spens, 2005).

The thesis has followed an *abductive approach* (Figure 6). The data was collected after defining the theory on immunization supply chain in developing countries. Further based on the secondary sources on the activities of immunization supply chain in India, the theory was added in proportion to the collected data. This helped the research to answer the research question that is addressed for the study. Abductive reasoning was the most suitable for this research as the secondary data fetched is not always what the theory defines. Hence the theory had to be refined accordingly.

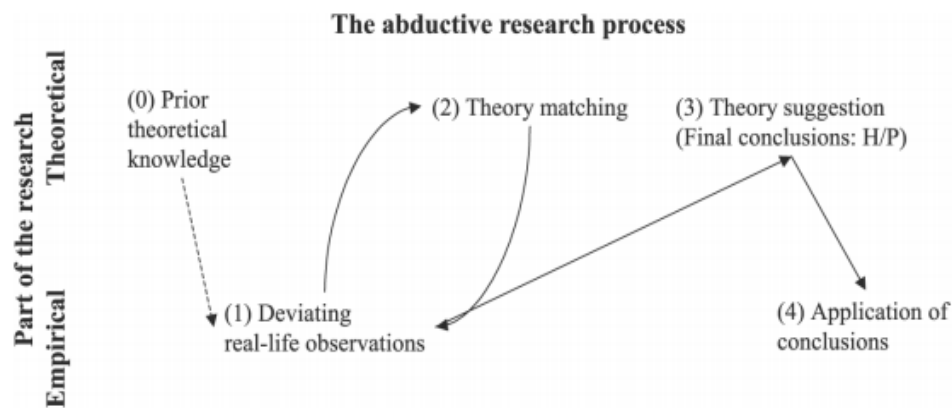


Figure 6- Abductive approach (Kovacs and Spens, 2005, p.139)

The following steps were taken in this abductive study:

- 1) Use data bases like google scholar, EBSCO Host to search for theory on immunization supply chain in developing nations
- 2) Develop theory based on the sources for conceptual framework
- 3) Collect data on Immunization supply chain in India
- 4) After collecting data, search for the missing theory on Immunization supply chain in developing countries

- 5) Add the theory
- 6) Find the conclusions based on theory and secondary data

Further, there are different types of case-based research. As classified in Baxter and Jack (2008), it could be explanatory, exploratory and descriptive. The type of each method used is dependent on the research questions of the study.

The explanatory research tries to explain a phenomenon based on the principle of cause and its effect relationship (Kahkonen, 2014). The exploratory type of case study will test the feasibility of the research procedure and will study the desired research question and the hypothesis and on the other hand, descriptive is a process where there is a complete description of the phenomena under study (Kahkonen, 2014; Baxter and Jack, 2008).

This research will be exploratory in nature as it will explain the research questions by studying the existing theory and making some suggestions based on the available secondary data generated in this study. The general challenges in the immunization supply chain of India is discussed to shed light on the vulnerabilities of India for COVID-19 vaccination which will help in understanding how different it is with the routine immunization. In this manner it will aim to answer the research question which is the goal of the exploratory research.

2.3) Types of methods in logistics research

Ellram (1996) points at different types of methods in logistics research (figure 7). This can be primarily qualitative or quantitative depending on the type of problem to be solved.

		Type of analysis	
		Primarily quantitative	Primarily qualitative
Empirical	Survey data, secondary data in conjunction with statistical data		Case studies, participant observation, ethnography
	Factor analysis		Characterized by
	Cluster analysis		Limited statistical analysis
	Discriminant analysis		Often nonparametric
Modelling	Simulation		Simulation
	Linear programming		Role playing
	Mathematical programming		
	Decision analysis		

Figure 7- Classification of research methods (Ellram, 1996, p.96)

The empirical way of research can be quantitative or qualitative, it incorporates real world data into it which helps in giving practical solutions. This study on immunization supply chain will be

qualitative in nature as it is descriptive. The case study is the chosen mode of method for this research as it allows the author to understand the main challenges for COVID-19 vaccination in India in relation to routine immunization. This method allows the author to investigate in depth the analysis of a phenomena under observation which is immunization supply chain of India. Hence by focussing on a single area, more understanding of the phenomena can be achieved which is not possible in other methods. The issue of COVID-19 vaccination in India is a vast area to be studied considering the huge population of India. Hence better understanding could be achieved by using a single case study.

2.4) Case based research method

This section describes in detail about the approach taken for case-based research method (Figure 8) The main steps chosen in this study will follow the guidelines given by Yin (2014).

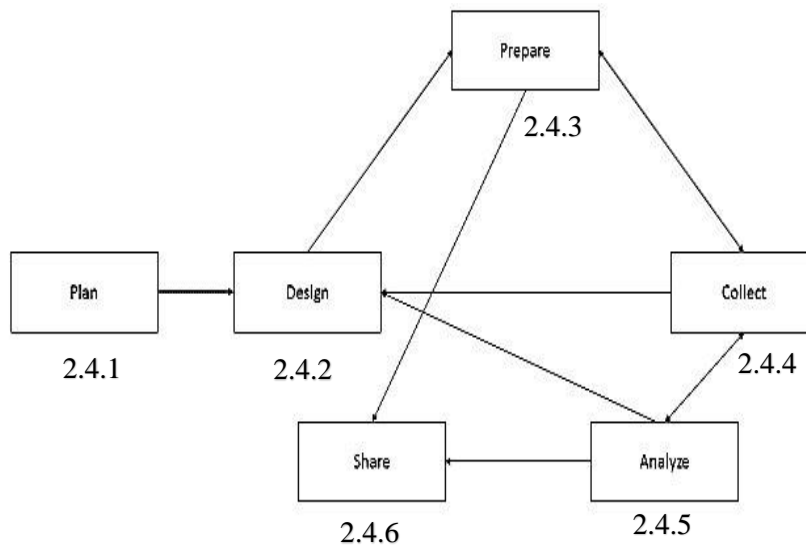


Figure 8 – Case study approach (Yin, 2014, p.24)

2.4.1) Research Plan

The choice of a research method highly depends on the nature of the research problem, and this will pave way for several questions on the research method (Noor et al., 2008). The case-based research method starts with defining the research questions followed by identifying the relevant theoretical frameworks that will benefit the progress of the study (Stuart et al., 2002). Therefore, the theory building in case study is very crucial and it contributes to cohesive research (Nagel, 1963).

According to Voss et al. (2015), the starting point for case research is the research questions and starting point of how and why question that comes up to the researcher. Also, in theory building, the view of general constructs and categories are essential, no matter how inductive the approach is in a case study.

The theory building is a building block for case research, and it has different stages. They are definition of concepts and variables and setting in which the theory can be applied and specific predictions which can be made. The theory is viewed as a system of constructs and variables where the system is interlinked with each other by propositions and variables and hence without proper theory, it is impossible to generate empirical data to create a case study (Voss et al., 2002).

The research in area will start from identifying the relevant theoretical framework, hence it organizes all the literature in a specified field of study. Literature review helps in the following way in a research (Rowley and Slack 2004):

-It helps in the identifying the research topic and the relevant research questions.

-It will identify the literature to which the research will contribute.

-It will enhance understanding of theoretical concepts for the research

-It will help in analysing and interpreting the results

According to Durach et al. (2017) there are lot of idiosyncrasies when trying to conduct systematic literature review. When interpreting the results of the study, it is very much essential to consider the theoretical boundaries. This will help the study focus on what is important while negating nonessentials. Petersen and Autry (2014) also mentions that theoretical divergence within the research study poses a lot of challenges. Due to this theoretical divergence, the study will focus on diverse issues that will limit the findings of the study. The theoretical frameworks also has influenced the unit of analysis. By defining the frameworks, we can easily define the unit of analysis and limit the scope of the study thereby enhancing the findings of the research.

The main sources of references in this study are identified from

- 1) Google scholar
- 2) EBSCO Host
- 3) LU library

The literature or theoretical framework in this study will limit to Immunization supply chain in developing countries. Different topics like vaccine distribution system, cold chain system/distribution and other relevant theoretical aspects will be discussed in this study. These discussions will benefit the findings of the study which depends on the identified theoretical frameworks.

The next step in case research after identifying the research questions and theory building is the refinement of theory, this involves testing the theory based on the available empirical data. This will enable the research purpose to refine the existing theory to introduce new frameworks and suggestions (Hyer et al., 1999).

The research plan was executed in the same way as the literature states. The research questions are clearly stated in the first section of this study and has helped in defining the theory relevant to it. With the help of research questions, several papers relevant to immunization supply chain in developing countries was found and the theory was generated for the research. Eventually, the theory generation on immunization supply chain led to the formation of conceptual framework from which the secondary data was collected. Finally it was compared with the theoretical framework to answer the research question.

2.4.2) Research design

The design of case-based method follows the approach suggested by Yin (2003). The important aspects to be considered here is the decision on unit of analysis and whether to employ single case or multiple case studies (figure 9). These factors depend on the nature of research questions in the study.

Selecting the number of cases is often a challenge in case-based research method. Single vs multiple case studies have their own merits and demerits. A single case study is chosen when the phenomenon under observation is limited. A single case represents a critical study that needs explanations for further research, On the other hand multiple case studies have a broader horizon and will validate the theory on a larger scale giving rise to contrasting and interesting conclusions (Ellram, 1996). Yin (1994) explains the multiple case studies as the addition of individual case studies that are compared in the end to draw conclusions and suggestions. In a more specific sense, each individual case is

separately described and in the end all the cases are cross linked. This will increase the horizon of research and will be less biased as compared to single case study.

Single case studies are less time consuming and better if the writer wants to create a better theoretical framework in a single area of focus. This will create a bigger picture of the merits and demerits associated with the study (Gustafsson, 2017).

Dyer and Wilkins (1991) argues that a single case study produces better theory and will enhance the quality of the theoretical framework. Yin (1993) states that in a single case study, multiple units can be analysed paving way for a larger description of the case units.

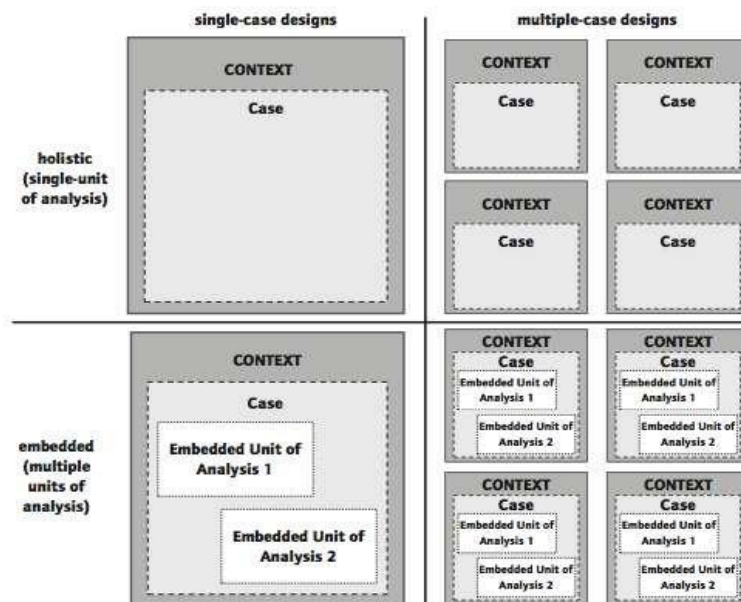


Figure 9 – Single vs multiple case studies as given (Yin, 2003, p.40)

Single case study is used in this study as it will dwell deep into the research question to assess the immunization supply chain of India. This mode of study will help in producing better analysis of the challenges in a single area of focus. The study can go in depth to understand the challenges in immunization supply chain of India which is not possible in multiple case study with too many areas of focus. Single case study will also help in producing more theory related to immunization supply chain in developing nations. Therefore, a single case study will enable critical analysis of all the immunization supply chain activities which will create a better understanding of all the challenges in it. Hence it was the best choice for this study to evaluate the existing challenges for COVID-19 vaccination and to recommend theory based suggestions for future immunization. Yin (2003) states that a single case study is utilized when the researcher wants to study only a single thing. Based on this rationale, the study will encompass in depth observation of immunization supply chain of India which will be studied to answer the research question.

The unit of analysis in a case-based research is the subject under study that is to be explored based on the proposed research questions. This will enable the research to focus on that aspect which has to be studied (Grunbaum, 2007). According to Yin (1994), the unit of analysis could be single or multiple depending on the level of analysis made in the research study.

According to many researchers, there seems to be an ambiguity among the terms case and unit of analysis. Grunbaum (2007) states that unit of analysis focuses on what the case study is focussing which could be individual, group or companies. Miles and Huberman (1994) mentions the case to be the unit of analysis. Yin (1993) also has the same idea regarding case as unit of analysis. Stake (1995)

also agrees with Miles and Huberman (1994) and Yin (1993) regarding the perception of case and unit of analysis as similar.

Hence, we can argue that the unit of analysis can be termed as the process that will intensify the study. Therefore, unit of analysis could be same as case study or not, it all depends on the nature of research (Grunbaum, 2007).

Based on the arguments stated above, the main unit of analysis for this study would be **challenges in Immunization supply chain of India** for the COVID-19 vaccination (Figure 10) which will be compared to the routine immunization supply chain of India:

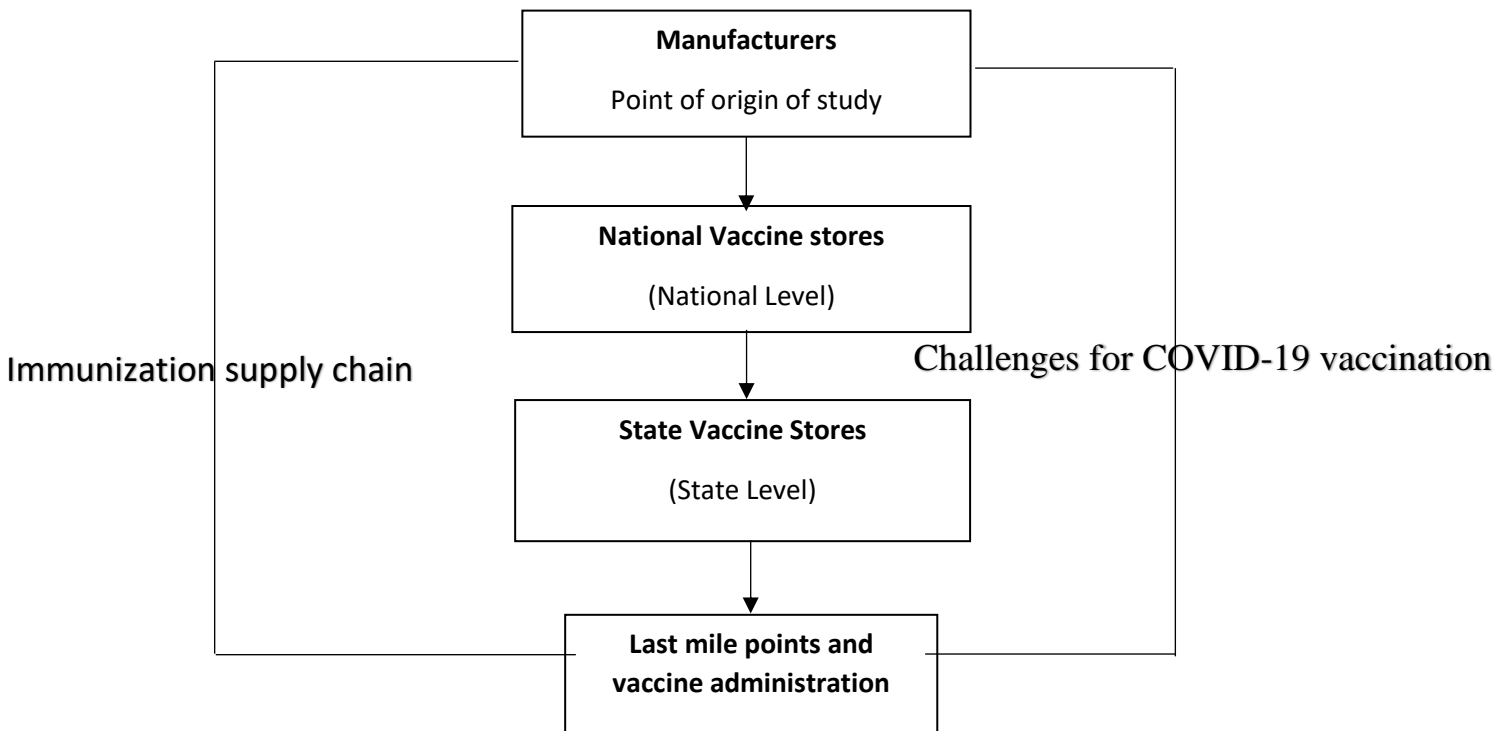


Figure 10- Unit of Analysis for this study: challenges in immunization supply chain of India for COVID-19 vaccination

2.4.3) Preparing the case study

Preparing the case study according to Yin (2003) involves getting the grasp of the situation in the case study. This involves formulating steps or procedures for collecting data and finding a good way to analyse it. Good listening capabilities is highly emphasised as it helps trap the correct answers without being biased on the topics being researched.

The preparation of this case study was done systematically and some of the important websites and government reports were thoroughly searched to fetch the most important data relevant to COVID-19 vaccination in India. All the collected data was rigorously studied and checked for relevance in this study before the analysis was done.

2.4.4) Data collection

Data collection plays a key role in analysing the empirical data for the research. The common forms of data collection include interviews, questionnaires, and observations. The interviews could be structured or semi structured (Barrat et al., 2011). The data collection can be from a single source of information or even from multiple sources, it depends on the depth of the research. Using multiple

sources of data can help in triangulation and helps in achieving greater validity of the research (Eisenhardt, 1989). All the types of the data collection mentioned above are categorized as primary data (Voss et al., 2002). Johnston (2017) also mentions another category of data called secondary data from which the analysis could be made. They are not collected by the principal researcher and it includes compilations of reports and journals from multiple sources. The disadvantages of using this type of data will include lack of proper understanding of the contents from the secondary sources.

After narrating the available data sources, the data for the thesis is collected from the secondary sources which are through journals, newspapers, periodicals and authentic websites disseminating factual information. The importance of print and visual media is of high importance in this research. The efforts made to obtain information from primary data could not bear positive results due to several reasons. Therefore, the present method adopted to obtain data from secondary sources stems from the fact that there exists a barrier with regard to sharing of information on COVID-19 vaccine management and associated protocols from primary stakeholders like doctors, paramedics, nursing professionals etc in India. This deprives valuable primary data required for this thesis. On this front, there is no standard operating procedure for health care professionals or frontline workers to share vital information with students and academicians for proper analysis and research. Since COVID-19 is termed as a health emergency, availing feedback on some of the concepts for project work could not materialise. However, in the near future application of COVID-19 vaccine management in academic and education front may be a reality. The government of India directive to concerned stakeholders and others not to disclose sensitive data and information forbids the author from collecting primary data. Hence secondary data information is being gathered in an accurate and authentic way duly supported by facts and figures.

The secondary sources of data for this study was mainly searched on google search engine with key words like *Immunization supply chain of India, routine immunization in India*” etc. The website of ministry of Health and family welfare of India was accessed to get leads on government reports on immunization. The sources on COVID-19 vaccination was also searched using google search engine with key words *“COVID-19 vaccine distribution in India, logistical challenges of COVID-19 vaccine distribution in India, cold chain infrastructure in India*” etc. Based on the above key words following were the reports that were found (Table 1) that helped in forming a foundation of data collection for this study.

Title of the document	Main theme
TECHNO-ECONOMIC ASSESSMENT OF ELECTRONIC VACCINE INTELLIGENCE NETWORK	The report which addresses the important challenges in Evin system implemented across the states and union territories in India.
INDIA’S HISTORIC VACCINATION DRIVE: EVALUATING THE STAKES, HURDLES AND OPPORTUNITIES	The report evaluates the challenges for India in terms of the logistics needed for conducting COVID-19 vaccination.
IN-DEPTH ANALYSIS OF COLD CHAIN, VACCINE SUPPLY AND LOGISTICS MANAGEMENT FOR ROUTINE IMMUNIZATION IN THREE INDIAN STATES	Evaluated the cold chain distribution in India and talks about the challenges in three states of India namely Gujarat, Kerala and Bihar
COVID-19 OPERATIONAL GUIDELINES	The report that outlines the operational preparedness of India for the COVID-19 vaccination.
COVID-19 VACCINE: DEVELOPMENT, ACCESS, AND DISTRIBUTION IN INDIAN CONTEXT	The report evaluates how the distribution of COVID-19 vaccines could be conducted in India and what are its challenges.

Table 1- Main sources of secondary data for this study

2.4.5) Data analysis

The core of theory building is data analysis, it helps in comparing the empirical data with the identified theoretical framework (Eisenhardt, 1989; Yin, 1989). The analysis of empirical data should simultaneously work in parallel with data collection, this will help the researcher to grasp the reality of the available empirical data (Baratt et al., 2011). The time which is taken to analyse the data and present it in identifiable forms is very time consuming. Hence, identifying patterns from the information in a qualitative analysis is to extract is to sense from the chaos (Stuart et al., 2002).

Yin (2003) suggested three different analytical strategies of treating data for carrying out the data analysis in a case study. They are “relying on theoretical propositions, thinking about rival explanations and developing the case description”. The first analytic method which is relying on theoretical propositions is utilized to carry out the analysis. The theoretical propositions on immunization supply chain developed in this study helped the author to analyse the secondary data for higher findings which is to understand the main challenges in COVID-19 vaccination in India and to identify suggestions from theory.

The secondary data generated in this study is analysed by identifying similarities in patterns of the qualitative data with the theory. This is mainly done to understand if the immunization supply chain of India and its challenges resemble to what is stated in theory which addresses the challenges in developing nations. First the key challenges were identified in each of the immunization supply chain activities for developing nations using theory. These challenges were described in the conceptual framework in a systematic way for each activity. The collected data was later investigated to find similar challenges in each activity for the COVID-19 immunization supply chain of India. Finally if the challenges were similar, it was described in the analysis of each supply chain activity to the literature it resembles in the challenges.

Explanation building is also another form of data analysis in this study to answer the research question using the generated secondary data. This method is used mainly to explain why the challenges exist in the immunization supply chain activities like cold chain distribution of vaccines, transportation, human resources for immunization to carry out COVID-19 vaccination in India. The explanation building is developed by understanding the challenges in each activity and how these could affect the COVID-19 vaccination. For example, the study has made reference to cold chain infrastructure in India and how it shows disparity in many states of India. With this the study goes on to explain more in detail on the likely impact of such a state for COVID-19 vaccination. Similarly, all the challenges in each activity of the immunization supply chain which are identified are explicitly described in the analysis.

2.4.6) Sharing the case study

The final step in the case research methodology is to circulate the research to all the important stakeholders of the research. This will help in gaining important feedback and opinion on the research that will help the researcher in the future work (Yin, 2003).

This study will be uploaded on the LUP data base and will be accessible to all stakeholders involved in the immunization research.

2.5) Quality of the research

According to Yin (2003) the final stage in the case study method is on the aspect of quality of research (Figure 11). Research quality is of utmost importance when undertaking a research. There are different methods of judging the research quality. They are construct validity, internal validity, External validity and reliability.

Tests	Case study tactic	Phase of research
Construct validity	<ul style="list-style-type: none"> • multiple sources of evidence • establish chain of evidence • Have key informants review draft case study reports 	Data collection Composition
Internal validity	<ul style="list-style-type: none"> • do pattern matching • do explanation-building • address rival explanations • use logic models 	Data analysis
External validity	<ul style="list-style-type: none"> • use theory in single case designs • use replication logic in multiple-case designs 	Research design
Reliability	<ul style="list-style-type: none"> • use case study protocol • develop case study database 	Data collection

Figure 11 – Research Quality criteria (Yin, 2003, p.34)

2.5.1) Construct validity

The construct validity is the extent to which the research has operational measures in place. The interviews, questionnaires must be documented properly and presented in the journal. There are several measures to enhance construct validity. First is to gather enough evidence of the collected data and the key informants to review the draft report, also the study should help other researchers with same data to arrive at the same summary of different constructs in the study (Stuart et al., 2002).

Multiple sources of evidence are used in the study which includes news articles that mentions about the challenges faced by India in COVID-19 vaccination. Quantitative data is also used in this study which include the number of cold chain points in each state of India to understand the challenges in cold chain distribution. To enhance construct validity, multiple sources of news articles are used to prevent wrong usage of quantitative data. Also, one of the drawbacks of using the news articles are differences in the information that they publish for the same topic. For example, the cold chain points quoted in one news article may not be the same in another news article. Hence to avoid discrepancies, the information from the news articles are expressed as they are quoted.

2.5.2) Internal validity

Internal validity refers to the ability to arrive at a causal relationship in a research where one condition leads to another condition in research. When we consider a single case study, proposed patterns should match the actual data patterns. If the patterns match similar cases, then internal validity is stated to be high in a case study. Dissimilar cases do not show similar patterns (Yin, 1989; Stuart et al., 2002).

The results of the research should be related to reality based on the empirical data. Hence if the results as realistic as possible, the internal validity will increase (Ellram, 1996).

The secondary data in this study was matched with the generated theory of this study. In most cases, the data patterns resemble the theory as India is a developing country and the theory in this study addresses the issues relevant to a developing country. Explanation building is also of emphasis in this study which enhances internal validity of this research.

2.5.3) External validity

The external validity refers to the ability of the research to generalize beyond what is studied in each area of what is being researched. The higher the number of cases or samples for the research, the greater is the ability to generalize the samples (Yin, 1989). The multiple case studies usually have higher external validity, but single cases have less. But selection of cases as stated previously depends on the nature of the research questions (Stuart et al., 2002).

The external validity in this research would be limited to some extent as it is a single case study. But to augment external validity as much as possible, a large amount of theory on immunization supply chain is utilized to understand the challenges that each factor poses which would be common in any immunization supply chain research. The challenges studied would be generalizable to any developing economy in the world in its immunization supply chain.

2.5.4) Reliability

Reliability refers to the extent in which the results of the study can be repeated to obtain the same results. The study should be reliable as it will enable the future researchers to proceed with same results or data which is obtained (Ellram, 1996; Yin, 1989). The ability of researchers to proceed with a given set of data and produce same results is known as replicability (Bryman et al., 2008).

The collected data will be stored as a data base which includes the data collected from the secondary sources. Thus, it will enable other researcher to access the data and proceed with their analysis.

One of the main constraints of this research would also be the reliability of the data. Since there are very few sources to refer like news articles, journals to understand the challenges for COVID-19 vaccination and hence reliability could be limited in this study. Also, many articles that are published relevant to COVID-19 vaccination may also be biased on the issues which are being addressed. This can also lead to misalignment of information which may not reflect the actual reality. Since the news articles are key to this study, the reality of challenges are described as per the articles without any bias by the author in this study.

3)Literature review

This study will investigate the immunization supply chain of India for COVID-19 vaccines by looking into various aspects like Cold chain distribution, Transportation and last mile delivery of vaccines, Information sharing in immunization supply chain etc. Hence different aspects related immunization supply chains will be studied.

3.1) Immunization supply chain

Immunization supply chain consists of all the people, systems and equipment involved in the distribution of vaccines from the point of origin to point of destination who are the beneficiaries (Kaufmann et al., 2011). The introduction of vaccines in developing nations is always filled with a lot of uncertainty and there are problems with logistics and supply of vaccines. This creates problems of immunizing the country's population to fight against the vaccine preventable diseases. There are various bottlenecks in the vaccine supply chain that needs to be addressed in terms of capacity at national, state and district levels related to storage and distribution of vaccines (Zaffran et al.,2013). The immunization supply chains are often characterized by the lack of objectives and independent decision making mainly as silos in each part of the supply chain. Hence developing nations should aim to configure its immunization supply chain by rectifying its problems to increase its immunization coverage (Duijzer et al.,2018). The figure 12 is an illustration of immunization supply chain components by De Boeck et al. (2019) which shows the importance of each stage in an immunization supply chain. The process starts from research and development, filling ,shipping till the national stores from where it is dispatched further downwards in the supply chain network all the way till it reaches the beneficiaries where vaccines are administered.

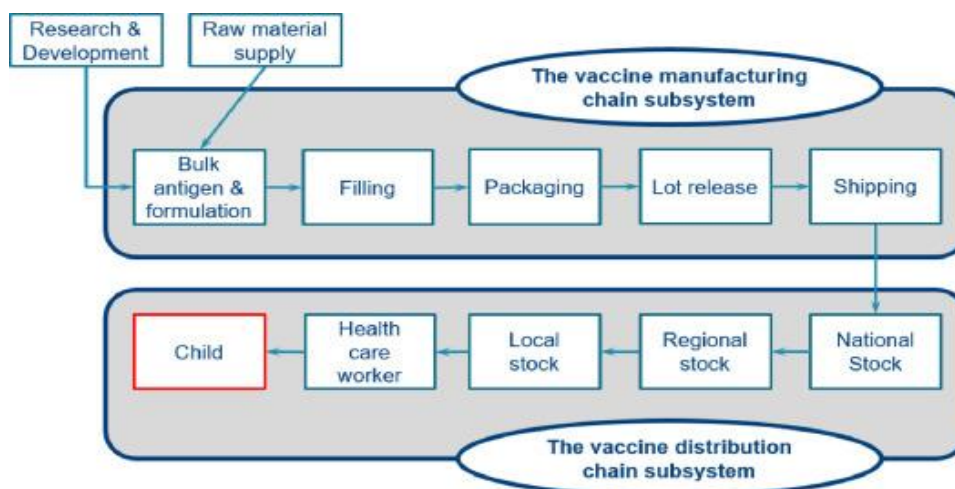


Figure 12- Immunization supply chain (De Boeck et al., 2019, p.3)

The immunization supply chain components differ from the perspective of each author. Duijzer et al. (2018) represents the immunization supply chain as the combination of four components which are product, production, allocation and distribution (Figure 13).

	Product	Production	Allocation	Distribution
	What kind of vaccine should be used?	How many doses should be produced and when?	Who should be vaccinated?	How should the vaccines be distributed?
	<i>Right product (decision)</i>	<i>Right product (realization), Right time</i>	<i>Right place (decision)</i>	<i>Right place (realization), Right time</i>
Similarities	<ul style="list-style-type: none"> - Product development (R&D) 	<ul style="list-style-type: none"> - Long production time - Uncertain demand - Pull process: initiated by the customer (i.e., public health organisation) - Uncertain yields 		<ul style="list-style-type: none"> - Inventory control - Facility location - Routing - Supply chain design - Perishable product - Temperature controlled chain
Unique characteristics	<ul style="list-style-type: none"> - Decentralized decisions: product is determined by public health organizations, not by the supplier - Public health organizations are non-profit, whereas supplier is for-profit - Product changes very frequently (yearly for annual influenza vaccine) - Product decision is made under time pressure and high demand uncertainty 	<ul style="list-style-type: none"> - Demand externalities due to disease dynamics and the protective power of vaccinations for non-vaccinated people 	<ul style="list-style-type: none"> - Complex decision making: political interests, equity considerations - End customer (i.e., 'patient') does not pay for the product in most cases - Push process: initiated and performed in anticipation of end customer need - Decentralized decisions: end customer has no power in this phase 	<ul style="list-style-type: none"> - Mass distribution under time pressure

Figure 13- Immunization supply chain (Duijzer et al., 2018, p.176)

The product and production is out of scope for this study as it deals with challenges from the stakeholders perspective which are Public authorities, Logistics service providers and Health care professionals for COVID-19 vaccination. Hence manufacturing perspective is not discussed in the literature review.

3.1.1) Planning the immunization supply chain

Planning the immunization supply chain plays an effective role in the prevention of many infectious diseases in a pandemic. For effective planning of immunization supply chain, fulfilling the demand of the end users is the utmost priority. This phase consists of planning the essential factors such as identifying cold chain infrastructure, resources, and manpower for delivering the vaccines to the end users. This is done in relation to the number of people to be immunized in a nation. Hence, planning the immunization supply chain is very challenging as it involves multiple decisions such as deciding on cold chain requirements, identifying human resources and deciding on mode of transportation. This has influence on various stakeholders such as public decision-making authorities at various levels of the planning hierarchy. Therefore, this needs proper supply chain mechanism in place to achieve the highest utility (Gharote et al., 2015).

During the planning phase, adequate vaccine management strategy is needed at all levels of vaccine distribution levels to achieve a successful immunization programme (Iwu et al., 2020). Vaccine management is a managerial and operational level planning that monitor the stock of vaccines and ensure the quality of vaccines available at the health centres (WHO/UNICEF, 2015). Studies from Lydon et al. (2017) shows that in many developing countries, the percentage of vaccine stock outs reported were around 31% at national level and around 26% at the district level. Hence, proper planning and management of distribution network along with coordination among different players with effective vaccine management should be enforced in practise. This will help in better availability of vaccines at all the levels in the distribution network (Iwu et al., 2019).

3.1.2) Vaccine procurement

The procurement of vaccines is often a challenge in many developing nations where there is high imbalance in power between developing nations and humanitarian organization to procure vaccines (Pazirandeh, 2011). The main bottleneck in many developing nations is the lack of sufficient funds for procuring vaccines. There could also be bureaucratic delays in the procurement process that could

lead to vaccine stock outs creating disruptions in the vaccine distribution. Hence this issue needs to be addressed to enable timely supply and distribution of vaccines (Lydon et al.,2017).

The purchase of vaccines for developing nations often occurs through humanitarian organizations or they directly procure from the manufacturers. Most often the vaccines are viewed as donor supplied commodities that is often not accorded enough importance (Pazirandeh and Norrman, 2014). Therefore developing nations should achieve self-sufficiency in the procurement of vaccines which ultimately helps them in mitigating the crucial bottlenecks in the immunization programs of their nations (Woodle, 2000). Health organization in the world have tried to bring the vaccines into the markets of developing nations using their donor funds which has led to substantial increase in immunization coverage across many developing nations. The future for immunization in developing nations is dependent on a good procurement process that ultimately helps save a lot of lives (Martin et al., 2020).

3.1.3) Allocation of vaccines

Allocation is a crucial stage in immunization supply chain after the procurement of vaccines. It is a stage where vaccines are given to the beneficiaries depending on the vulnerability of the population in a pandemic. This stage is specifically important when there is a sudden outbreak of a disease/pandemic leading to problems in allocation. The important challenge for the government will be on whom should be vaccinated? It is important to distinguish between high-risk individuals and low risk individuals to prioritise vaccination to the general population. There are instances where it could lead to unequitable allocation of vaccines due improper decision making involving multiple people. This in not desirable for the nation's health especially in an outbreak where all the population must be vaccinated. The government of different nations use many models to understand different ways of vaccine allocation especially in a country with vulnerable population. Hence allocation of vaccines means to create priority groups and make the logistics efficient (Duizjer et al., 2018). The allocation process for an immunization supply chain is followed by distribution of vaccines (figure 13).

3.1.4) Vaccine Distribution in a pandemic

Distribution in a pandemic is often characterized by uncertainties and lack of proper planning that complicates the distribution process. Hence proper coordination is needed between the governments and other stakeholders to efficiently plan the distribution points (Oloruntoba and Gray, 2006). Further, Tomasini and Wassenhove (2009) mentions that in a humanitarian relief chain, the delivery of important lifesaving cargoes is often delayed which hinders the efficiency of the distribution operations.

The delivery of relief material in a pandemic should focus on the reduction of lead time to achieve higher response time and to minimize the losses. This will greatly depend on the network design, vehicle routing and the location of the facilities in the network (Safeer et al., 2014). Hence better relief distribution is very essential for meeting the demand of the pandemic and reducing the unmet demand thereby playing a pivotal role in saving a lot of lives. Due to uncertainties, maximum distribution can be achieved by efficient planning by mandating all the important stakeholders to take informed decisions and charting out plans for effective delivery of relief materials (Safeer et al., 2014; Caunhye et al., 2012).

It is stated that in a pandemic, there is generally less cooperation with different stakeholders leading to lack of synchronized decision making (Tatham et al., 2010). Effective coordination of core competencies of both private and humanitarian sector can contribute to increased preparedness in a pandemic (Tomasini and Wassenhove, 2009). With the growing number of pandemics, the relationship with stakeholders specifically with LSPs become critically important (Jensen and Hertz,

2016). The LSPs are generally a private corporation aiming to generate profits, this is not always desirable in the humanitarian field, but they do bring in a lot of expertise and experience needed to respond to a situation, and it adds to their social cause in the form of CSR initiatives. In any pandemic, response phase is when they come into picture. This will fetch them some important media attention that can add to their brand image (Sigala and Walkobinger, 2019). Also, some of the important activities undertaken by the LSPs during pandemic include transportation, warehousing, fleet management etc (Baharmand and Comes, 2019).

Vaccine distribution is the downstream part of the immunization supply chain (Figure 12 and Figure 13) that plays a key role in distributing vaccines to the end user (Lim et al., 2019; De Boeck et al., 2019). According to De Boeck et al. (2019), the vaccine distribution chain is divided into four different categories which are sourcing of vaccines at the national level, storage of vaccines, transportation of vaccines and administration of vaccines. All the four components must be synergized for an effective immunization system that help in saving a lot of lives.

Efficient delivery of vaccines is timely, and it helps in eradicating a disease or a pandemic more quickly. The traditional network design of vaccine distribution system typically has a central store, regional stores and many local stores that distributes vaccines at the outreach area. But often the design of these networks is often constrained by the administrative decisions of that country which influences optimality of the distribution networks. Hence by carefully planning and deciding on facility locations and storage areas can lead to greater efficiency of distributing operation in an immunization supply chain network (Lim et al., 2019).

3.1.4.1) Vaccine distribution system

The primary objective of a vaccine distribution system (VDS) is to increase the immunization coverage in a country. There are several challenges that it faces, hence it should be resilient enough to sustain uncertainties. Challenges are introduction of new vaccines, changes in government policies and lack of skilled workers to handle vaccines (Chen et al., 2014). There are specific characteristics associated with the VDS such as high uncertainty in demand and supply and as it acts in a pressure situation this gives rise to misaligned objectives and lack of time to act immediately (De Boeck et al., 2019).

The number of levels of VDS differs between each country. The number varies between 3-5 (Lee et al., 2015) In example of Niger there is first a central store that receives the shipment from UNICEF and then moves the stock down from central store to regional stores before it is shipped to district store and individual clinics (Chen et al., 2014).

To understand the general set up of VDS, Yang et al. (2021) made a thorough investigation of how the vaccine distribution network looks like. In most of the developing countries it looks as shown in figure 14.

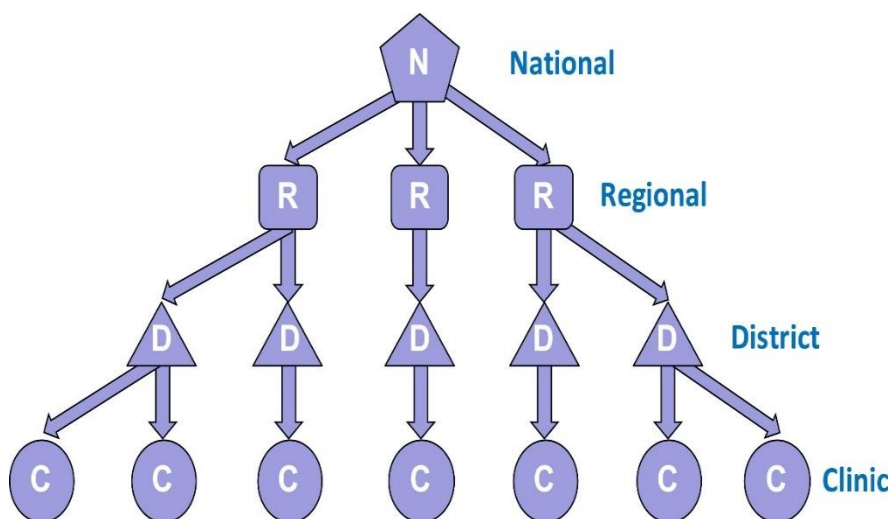


Figure 14- Four tier vaccine distribution network (Yang et al., 2021, p.2)

The vaccines are procured from the manufacturers are shipped to the national stores. From the national stores, it is shipped by truck to the regional stores. This process continues till it reaches the local health centres in a district. This distribution network is similar for most developing countries as mentioned by Chen et al. (2014). Yang et al. (2021) mentions that designing the vaccine distribution network is critically important especially when handling a lot of uncertainties. Hence, a good network will facilitate easy flow of vaccines and carry out immunization more effectively.

To ease the burden, the decentralization of the distribution will avail a lot of benefits for a country's immunization programme. Decentralization will help the local workers to gain sufficient skills, build on local capacities and shorten the lead time of delivery. But in many lower middle-income countries the local capacities have often not been utilized effectively (Molemodile et al., 2017).

The most significant challenge is that number of resources and funding available for VDS is limited in developing countries. Hence a lot of immunization programmes are introduced each year and the health care sector in these countries should be equipped with additional capacity to manage the immunization (Lee et al., 2016). Yadav et al. (2014) talks about the integration of the immunization supply chains with other health commodity supply chains. This will enable to reduce the cost of distribution in developing countries and products with common temperature requirements could be integrated into the shipment of other medical products to achieve economies of scale and scope. But there are different problems which this set up might face as transport integration is not easy and it requires a streamlined flow of information between different stakeholders.

To understand the decision making in VDS, Yadav (2015) mentions that in many Sub-Saharan African countries, the vaccine distribution is handled by government through Central medical stores. How this is done is different in many countries, often associated with heterogeneity. Central medical stores are mandated to take care of warehousing and storage and delivery to the district health centres. Often having too much magnitude of work, they become incapable of handling surges in demand.

VDS should be mandated to increase their storage and handling capacities. This will enable the local governments to support their local immunization programmes to reach more population. This will eventually help in combating a disease or a pandemic. Thus the vaccine distribution systems should be upgraded for handling future requirements (Brooks et al., 2017).

3.1.5) Cold chain distribution of vaccines

According to a literature survey by Matthias et al. (2007), the number of vaccines wasted all around the world due to lack of cold chain is common in high income and low-income countries. Hence irrespective of the adversity, problem exists in all immunization supply chains. Cheriyan (1993) pointed that in most of the times, the monitoring of temperature is generally overlooked and not found important.

Most often it is mainly due to the nature of vaccines. The vaccine instability is primarily because of the complexity associated with the components present in the vaccine. This renders it highly sensitive to the external temperature making the storage and distribution difficult (Kartoglu and Milstien, 2014). The need for maintaining the required temperature was a grave concern right from when the immunization started in the world. There has been a lot of effort in upgrading tools and technologies for supporting the vaccine distribution. EPI launched by WHO was the first effort in developing the cold chain systems for the vaccines. There were challenges associated with it, it was absence of systems to monitor the temperature of thermosensitive vaccines and lack of capacity to store and transport vaccines (Lloyd and Cheyne, 2017).

The vaccine cold chain contains series of steps that will help the end users to utilize the vaccine for immunization purposes. Comes et al. (2018) shows how the cold chain of vaccines are maintained throughout the distribution network in figure 15.

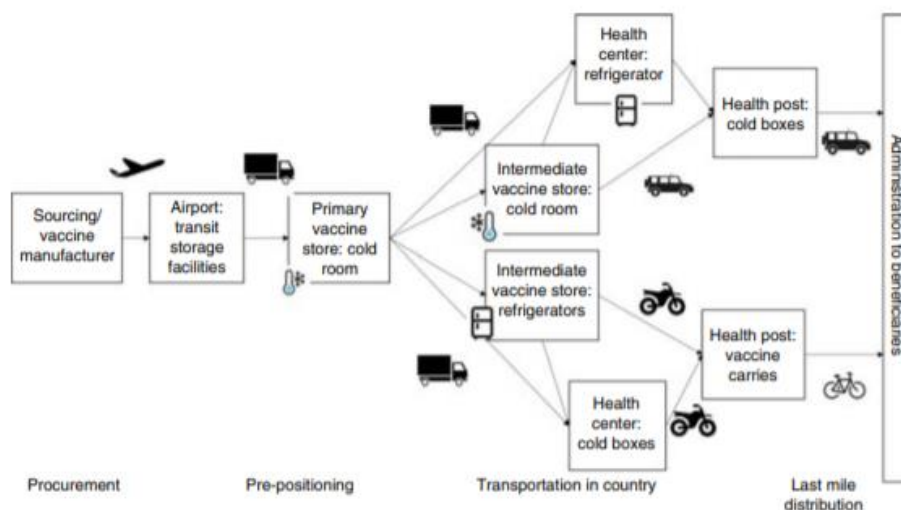


Figure 15- Vaccine Cold Chain system (Comes et al., 2018, p.51)

As we can observe, all through the distribution network to the health care centres, the vaccines must be in different temperature requirements for it to be rendered to the end users. The cold storage equipment differs in each stage of the distribution process. It also depends on the transportation provider who is responsible for distributing the vaccines (Comes et al., 2018). Lloyd and Cheyne (2017) states that in a vaccine distribution system, the cooling equipment adds to 50% of the total costs. There are different types of cooling equipment in practice. It is classified as passive coolers and active coolers. Active coolers are refrigerators and off grid coolers that play an active part in maintaining the required temperature for vaccines. For its functioning, reliable use of technology is very much essential. Passive coolers are equipment that support or aid the active coolers for its functioning. They include cold boxes and vaccine carriers (Comes et al., 2018). Erdogan et al. (2017) mentions that vaccine carriers are used when the quantity of vaccines are small to transport. Cool

boxes can be used for larger storage space and it is generally transported by the means of bicycle or by foot in the last mile delivery (Comes et al., 2018).

Ashok et al. (2017) discusses the factors contributing to cold chain problems:

- 1) Most of the cold chain systems do not have sufficient data collection techniques to monitor inventory which leads to lack of adequate capacity. This can lead to disruption in the delivery of vaccines.
- 2) Poor forecasting for the demand of vaccines which can lead to many vaccines not being monitored.
- 3) Often lack of resources leads to lack of upgradation of technology to accommodate all the vaccines for future pandemics.

There are problems in the active and passive cooling devices. Schoub and Cameron (1996) mention that there could be power shortages and disruption in the electrical equipment leading to breakage of cold chains while distributing. The information gaps in the cold chain system are another problem leading to lack of proper decision making in the cold chain (Lloyd et al., 2015). Lastly, there are problems when the management is not able to take decisions when there are disruptions in the devices, impact is not able to recover from it leading to vaccine wastages (Trostle et al., 2003).

Kartoglu and Milstien (2014) suggest mitigation strategies that could help the decision makers in improving the stability of the vaccine cold chain:

- 1) The information on the stability of vaccines needs to be documented and sent to all the stakeholders.
- 2) Apply risk management tools to identify the distribution risks in the cold chain.
- 3) Use better temperature control tools.

Yakum et al. (2015) also mentions some important strategies for risk mitigation in the vaccine cold chain:

- 1) Ensure relevant training to all the health care workers to identify breaks in the cold chain.
- 2) Record all the information and data pertaining to the temperature sensitivity of vaccines.
- 3) Establish a communication plan where all the responsible stakeholders share information to each other on how the vaccines are being monitored.

3.1.6) Vaccine stock management and information sharing

Vaccine stock management is an important factor contributing to a successful immunization programmes around the world. The stock outs of vaccines at the health centres are a common cause of disruption in the vaccine distribution. The vaccine stock outs are commonly known as lack of adequate vaccines at the point of delivery to the customers. The **effective vaccine stock management** is a principle created by the WHO in aiding the practises to reduce the stock outs of vaccines. The EVSM has laid out different principles which can help in better stock management of vaccines, it has three steps (WHO, 2006):

- 1) Checking vaccine consignments when they arrive at the national and local storage facilities
- 2) Adequate monitoring of vaccine stocks during their time at the storage facilities
- 3) Checking vaccine consignments when they leave the storage points to different health care centres in a region
- 4) Regular stock taking and adopting FIFO (First In-First Out) method of inventory valuation. This method also reduces vaccine wastages considerably.

The occurrence of stock outs is at the lowest level in immunization supply chain, but due to lack of availability of sufficient information management systems, most of the stock outs are unreported

leading to a higher risk of unsuccessful immunization (Iwu et al., 2020). Therefore, shortage at the national directly affects the stock at the local level and the level of stock outs is directly linked to the failures in the distribution chain. The availability of stocks round the clock can be ensured with if sound planning is envisaged at all levels. Periodic stock taking facilitates replenishment of stock at regular intervals (Brown et al., 2014).

Information sharing is a critical aspect in a pandemic. The quality of information is crucial in responding to the needs immediately. The information shared will have a drastic impact on the efficiency and effectiveness of the pandemic response that is initiated (Saab et al., 2008). The information sharing in a pandemic response comprises of quality, accuracy and timely information that helps different stakeholders to understand the gravity of the situation (Deghedi, 2014).

In immunization supply chains, quality of the information shared must be of the highest precision. This will enhance the effectiveness of the immunization programmes and requires a good information system in place as it will enable the stakeholders to keep track of the inventory status at each level. This will facilitate uniform distribution of vaccines for all the regions. Yadav et al. (2014) illustrates how information systems could be integrated across multiple levels and functions in immunization supply chains (Figure 16).

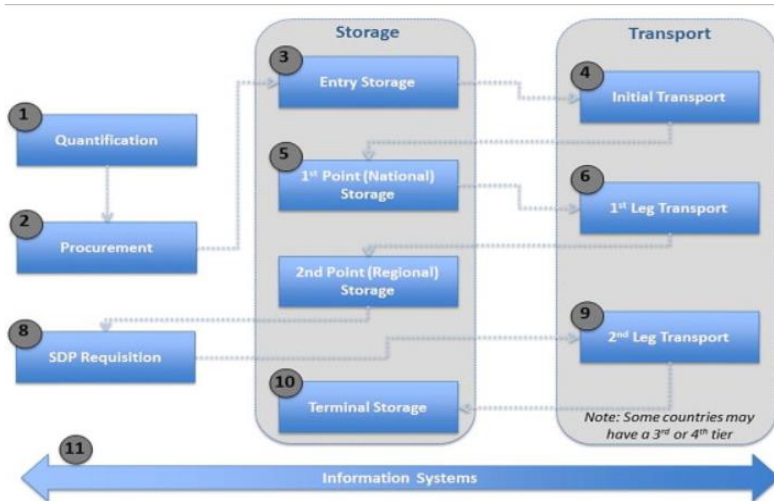


Figure 16- Information system across immunization supply chains (Yadav et al., 2014, p.6728)

Kaufmann et al. (2011) states that to enhance frequent deliveries of vaccines from manufacturers to national health centres and to local health centres will need good quality of shared information between different stakeholders. Lloyd et al. (2015) places a special emphasis on the information gaps in vaccine distribution. Therefore, without much information different stakeholders in the distribution network will not pay heed on monitoring the temperature of vaccines that will ultimately lead to a lot of vaccine wastages.

Comes et al. (2018) mentions three areas that will help information sharing across cold chain systems in immunization supply chain:

- Facilitate coordination of information across national and regional health centres
- Focus on real time decision making to comply with the required vaccine temperatures
- Data collection across multiple tiers in vaccine distribution system that all the stakeholders will benefit

Due to the vast complexity in vaccine distribution system and huge number of stakeholders involved, it is always difficult to act on the numerous information regarding vaccines which are available across national and regional health centres (Gralla et al., 2013). The local capabilities will also need to be assessed, often rural health centres will not be equipped enough on various technical grounds regarding IT system to receive huge data of information. Hence local health centres need to be continuously updated to avail all the key information on vaccine temperature and other decisions about distribution (Comes et al., 2018).

Hence, the COVID-19 immunization supply chain will entail all the stakeholders in the vaccine distribution system to share real time data so that they can comply with the regulation of vaccine temperatures. This study will focus on the challenges of information sharing for COVID-19 immunization in India.

3.1.7) Vaccine handling and storage

Vaccine handling and storage creates problem in most of the immunization supply chain networks with risk of vaccines losing its potency due to lack of enough care given to it (Bell et al., 2001). Most of the vaccines in usage must be stored at a temperature of 2-8 degree Celsius. The most speculated reason for the breakage of the cold chain link in the vaccine distribution is because the refrigerators are too hot or too cold for the required vaccine storage. This could hamper the contents of the vaccine, but could be mitigated using max-min thermometer which continuously monitors the temperature of vaccines. The temperatures should be recorded and reset daily (Weir and Hatch, 2004). A combined refrigerator-freezer with one external door is insufficient to maintain the temperature of vaccines. The refrigerator and freezer must have proper temperature regulators to adjust the temperature range which will help in maintaining the vaccine potency. The refrigerator and freezer should have separate doors to ensure temperatures are properly maintained. There should also be rooms to store frozen packs in the freezer (Rogers et al., 2010).

3.1.8) Human resources in Immunization supply chain

An important part of the Immunization supply chain is the essential training giving to the health care workers on how to vaccinate the identified eligible groups. This is very critical challenge in many developing countries where there is dire shortage of training given to the staff to administer the vaccines (Chen et al., 2014). It is to be ensured that the standard operating procedure on modalities for vaccine administration is laid down for health care workers for adherence and carefully following the protocol. Vaccine will need different handling capabilities and different schedules to immunize the affected people. Hence it is vital that all the health care workers are exposed to all the essential training to handle vaccines and their specific requirements (Zaffran et al., 2013).

The human resources across health care facilities are often loosely defined. This makes it difficult to take decisions of considerable impact related to distribution. Hence recruiting and motivating health care workers on importance of immunization will play a key role in reminding the health workers on maintaining the required temperature and potency of vaccines (Kasonde and Steele, 2017). Zaffran et al. (2013) states that there should be different levels of supervision to ensure that all health care workers adhere to the standard operating procedures in administering vaccines.

COVID-19 vaccine administration will need more intense training to health care workers as vaccines need a higher freezing temperature and the number of people affected are more. There could be challenges in training human resources in developing countries to handle COVID-19 vaccines. This will be one of the areas of focus when describing the human resources for COVID-19 immunization in India for this study.

3.1.9) Vaccine administration and last mile delivery

Administration of vaccines is the final step in immunization supply chain. It involves arrival of vaccines at the local health care facility and then carrying out the immunization by health workers (Karp et al., 2015). The difficulties are multiple in poor countries where vaccines are transported by foot by the health care workers (Van den ent et al., 2017). Outreach is a common phenomenon in some countries where health facility is positioned in a way that is accessible to all (Figure 17). It shows that in many developing countries the health care worker will have to carry vaccines to a certain distance closer to where the patients are located to conduct immunization.

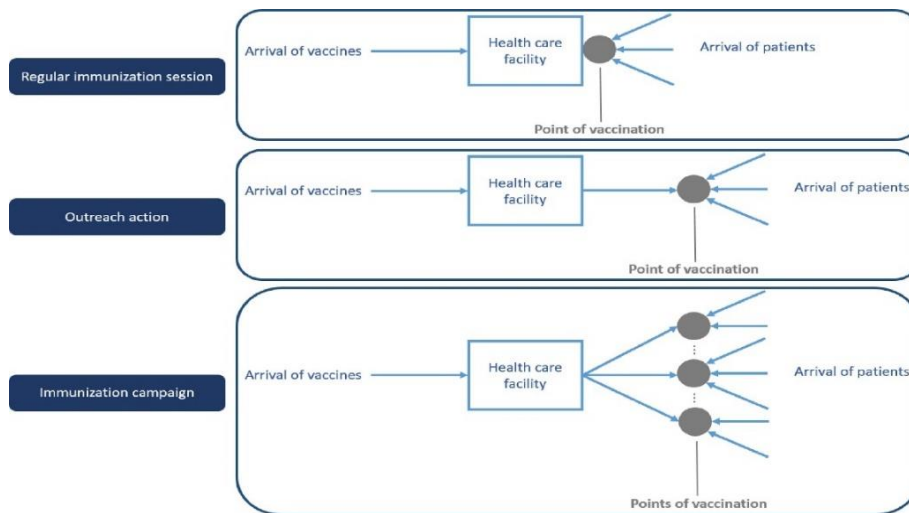


Figure 17- Outreach Immunization in developing countries (De Boeck et al., 2019, p.6)

The last mile delivery is the final leg of the distribution process in a pandemic where the goods are transferred from the local health centres to the required beneficiaries. This is the most difficult part in any pandemic where the required goods must reach the most interior parts of the affected regions where the resources are often limited (Balcik et al., 2008). The amount of time and resources allocated in the last mile directly influences the service of delivery. With equitable distribution between time and resources, delivery of service can be increased (Huang and Rafiei, 2019).

There are different decisions that commonly influence the last mile distribution in pandemics. They are facility location which influence the position where inventory is concentrated, inventory management to monitor the flow of materials through various facility locations, transportation decisions to move in a vulnerable place and distribution decisions on who should distribute the materials (Roy et al., 2012). Balcik et al. (2008) shows how last mile distribution is performed in a pandemic response (figure 18):

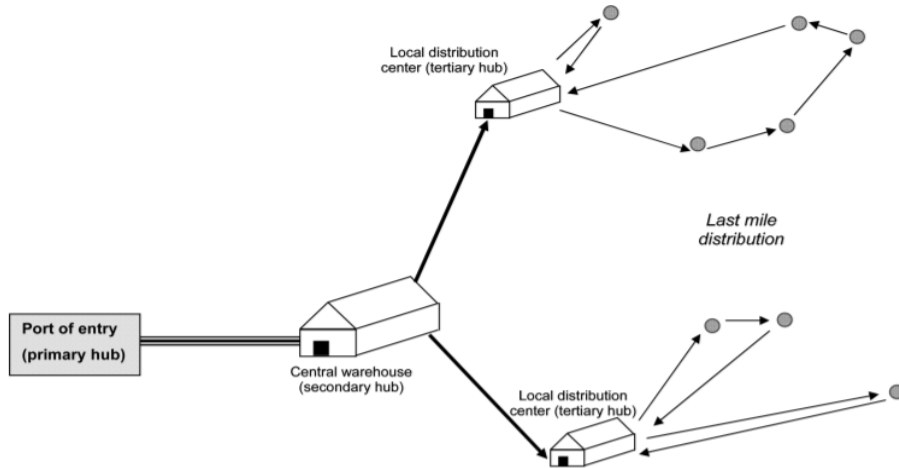


Figure 18- Last mile distribution from tertiary hubs in a pandemic (Balcik et al., 2008, p.52)

There are several factors that must be considered in the last mile distribution (Maghfiroh and Hanaoka, 2018):

- 1) Location of the demand: The location should be accessible with any mode of transportation.
- 2) Road infrastructure: The routes of the last mile distribution should be convenient for safe arrival of materials.
- 3) Information system: The information conveyed from the preceding node in the distribution network should be clear to avoid confusions in the decision making at the last mile delivery.

The last mile travel is highly crucial for vaccine delivery. But there could be disruptions due to bad weather and road conditions in adverse settings which is a key challenge (Huang et al., 2017). This is particularly a challenge in developing countries where sufficient cold chain capabilities are not present and most of the time, due to the tropical climatic conditions the vaccines are vulnerable to the external temperature (Lemmens et al., 2016). As stated in Balcik et al. (2008), the most common problem in last mile delivery will be the bad roads and lack of poor infrastructure which affects the outreach of the final delivery. Hence the key aspect is to increase the thermostability of the vaccines so that it remains potent until it reaches the point of outreach which could be local health centres (Levin et al., 2007).

The last mile distribution will be very crucial to the COVID 19 immunization supply chain this would be different in each country depending on the level of adversity. The challenges in India will be discussed in this case study and how it will affect the COVID-19 immunization programme. Therefore, last mile connectivity and delivery is the key criteria to ensure effective and optimum immunization coverage for COVID-19 vaccination in developing countries.

3.2) Critical factors, vaccine wastage and risk management in immunization supply chain

This section discusses the critical factors which are very essential for immunization supply chain. They are very important to carry out successful immunization in a country. The vaccine wastages are also discussed which occur majorly during vaccine administration. The final of this section topic is immunization supply chain risk management which is important to identify and mitigate risks for successful immunization

3.2.1) Critical factors in immunization supply chain

There are many authors who have made strides in investigating what contributes to a successful immunization supply chain in enhancing the immunization coverage in a nation. Lemmens et al. (2016), Chen et al. (2014) and Yang et al. (2021) mentions that good network characteristics in vaccine distribution system could play a pivotal role. This means that facility location and good network of health centres near the vicinity of the affected area helps in eradication of pandemic more easily. It also comments on disruptions that could affect the vaccine distribution. Slow movement of vaccines are a prime cause of concern especially if there is a bottleneck in the DC's that distribute vaccines. Unreliable transportation is also another factor that inhibit the vaccine distribution.

Cold chain is a critical component of immunization supply chain as it plays a key role in maintaining the required temperature for vaccines to be affective (Karp et al., 2015). This is often a challenging task in poorer settings and hence a lot of vaccines have been wasted in the past (Azimi et al., 2017). Transportation is another important factor in vaccine distribution. It can be done with the help of trucks, aircrafts and 4x4 trucks in developing nations (Lee et al., 2016). A key challenge is that there could be disruptions due to bad weather and road conditions in adverse settings (Huang et al., 2017).

A key role is played by the third-party logistics service providers as they will have capacity for cold storage and transportation. But even this is a difficulty in poorer settings (Sarley et al., 2017). Aina et al. (2017) states that outsourcing can reduce a lot of costs associated with vaccine distribution. The logistics service providers have a key role in ensuring that supplies reach in a timely basis. This is done in cooperation with local governments of the respective country. The LSPs are mainly classified as actors, tools and members which proves the importance of their presence in a pandemic (Baharmand and Comes, 2019). Their participation has become very crucial in a pandemic context as they support the local government, NGOs, and other key players in accomplishing their mission (Vega and Roussat, 2015).

Vega and Roussat (2015) mentions some of the important roles of LSPs in the humanitarian aid:

- 1) Operator: The LSPs perform the role of providing services in a pandemic by providing crucial services.
- 2) Coordinator: Plays a key role in coordinating between different stakeholders in a pandemic relief.
- 3) Partner: Partners with key players and ensures a responsive action to combat the pandemic.

As mentioned in Jensen (2012), they can also play the role of decision makers by taking important decisions that can affect the response mechanism in a pandemic. But it has a lot of drawbacks in a humanitarian context as the number of resources available for HOs in information management is still scarce which has a lot of effect on the relationship between the HOs and the LSPs (Tatham et al., 2017). This can be increased by increasing the level of trust between HOs and LSPs in a pandemic. Due to their different nature of working, the idiosyncrasies exists and hence attention needs to be given to the building of trust between the two entities in a pandemic (Tatham et al., 2010).

Pertaining to the vaccine distribution, the logistics service providers have a key role in delivering the vaccines to the required local health care centres by providing a robust cold chain system comprising of both transportation and equipment to sustain the potency of the vaccines until it reaches the end user (Comes et al., 2018).

COVID-19 immunization supply chain will need a lot of logistics service providers in transporting the vaccines to the required areas, this study will identify the key logistics service providers who are actively involved in the transportation of vaccines in India.

3.2.2) Vaccine wastage in immunization supply chain

Vaccine wastages are a highly relevant issue in an immunization supply chain, this is often associated with lack of technology to monitor vaccine temperature or adverse road conditions that could damage the quality of the vaccines. As a result of this vaccines cannot be used as it becomes inactive and often amounts to revenue loss for the stakeholders (Guichard et al., 2010).

According to a study by the world health organization, 50% of the total vaccines are wasted when they are in the distribution phase. This amounts to a huge revenue loss for the organizations carrying out the immunization programmes. Logistical aspects of vaccine wastages are highly related to lack of compliance of vaccine cold chain and quality (WHO, 2005). The most common thing in any immunization practice to avoid vaccine wastages are to promote single dose vials rather than multi dose vials. Most of it occurs at the clinical level when administering the vaccines to the patient. For example, in a scenario with a health care worker that opens a multi dose vial and there are 10 doses to be administered. If opened, all the 10 doses should be administered within a given point of time or else the doses will expire (Assi et al., 2011).

Finally, the costs related to the wastages are a common concern to a lot of immunization programmes. It also depends on the area that needs to be vaccinated (Wallace et al., 2018). There are several reasons for the wastages of vaccines (Setia et al., 2002):

- 1) Expiry before usage
- 2) Cold chain breaks
- 3) Multi dose vials
- 4) Physical damage due to crushing, dropping

Hence, vaccine wastages must be taken care of by organizations and distributors to significantly reduce costs associated with it and to promote more effective immunization (Parmar et al., 2010).

3.2.3) Immunization supply chain risk management

Risk management in immunization supply chain is important to ensure that quality of vaccines is maintained all through the chain until it reaches the end user. There have been incidents in the world that have endangered the lives of many people due to bad quality of vaccines due to mismanagement and bad coordination among stakeholders (Sudarmin and Ardi, 2020).

SCRM or also called supply chain risk management has 4 different steps (Figure 19) as classified by Fan and Stevenson (2018).

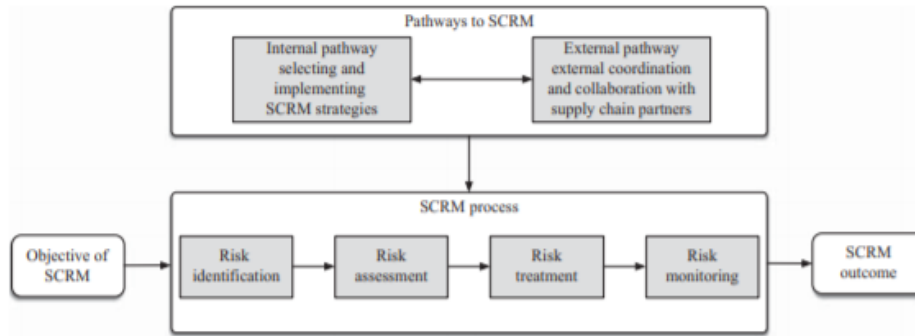


Figure 19- SCRM process in supply chain management (Fan and Stevenson, 2018, p.210)

Risk Identification

The purpose of risk identification is to identify uncertainties that occur in the supply chain process which can help in mitigating them more quickly. This will help the stakeholders to respond to the risks and act accordingly making the risk mitigation easy to manage (Fan and Stevenson, 2018).

Risk Assessment

Risk assessment is the quantification of uncertainties, and it is involved in the determination of likelihood of each factor. Uncertainties can be assessed by objective information and probability distributions for each supply chain risks. If the objective information is not available, subjective information can be used to approximate distributions (Xie et.al., 2011).

Risk Treatment

The most common strategies for risk treatment are acceptance, transfer, sharing and prevention since in any organisation certain amount of risk forms an integral part of its functioning (Fan and Stevenson, 2018). However, the strategies for mitigating the risks are commonly applied at the operational level, and as per the ground realities. This will have financial implications as per the budget of the organisation (Xie et al., 2011).

Risk Monitoring

This is one core area where organisations have to continuously monitor probable risks which are likely to arise and devise ways and means to combat the same in order to minimise the losses in supply chain. This is the final stage of risk management process. (Pires et al., 2019; Xie et al., 2011).

Hence, the upstream and downstream side of immunization supply chain faces a lot of risks. The following are the list of risks faced in an immunization supply chain (Sudarmin and Ardi, 2020)

Upstream risks

- 1) Lack of proper communication between actors and chain of links in the immunization supply chains
- 2) Limited partnerships with the vaccine suppliers
- 3) Delivery reliability of suppliers to deliver vaccines

Downstream risks

- 1) Disruptions due to disaster or man-made activity that will disturb the distribution setup of vaccines
- 2) Problems in storage and warehousing of vaccines
- 3) Geographical proximity of health care centres to the outreach areas and cold storage infrastructure
- 4) Poor road conditions and bad weather might damage vaccines

Therefore, managing the risks in the immunization supply chain is of utmost importance to protect the efficacy of vaccines and ensure its timely delivery. Due to the inherent risks in the logistical aspects of immunization supply chains, a risk management framework is needed to mitigate the risks and increase the efficiency of all logistical operations in vaccine distribution (Sudarmin and Ardi, 2020).

3.3) Conceptual Framework for challenges in Immunization supply chain of developing countries

Conceptual framework presented below is the summary of different aspects discussed in the literature above and the challenges identified in each of the supply chain activities

The conceptual framework presented in figure 20 is a culmination of all the supply chain activities for immunization supply chain in developing countries. For each of the activities identified, there are challenges that a developing nation faces. Based on the discussion of these challenges, secondary data will be collected on all the immunization supply chain activities for routine and COVID-19 immunization supply chain in India. This will be done to assess the challenges that India's immunization supply chain will face during the COVID-19 vaccination which is ultimately the goal of this study. The challenges identified for India will be compared to the theory based on the challenges identified in the conceptual framework.

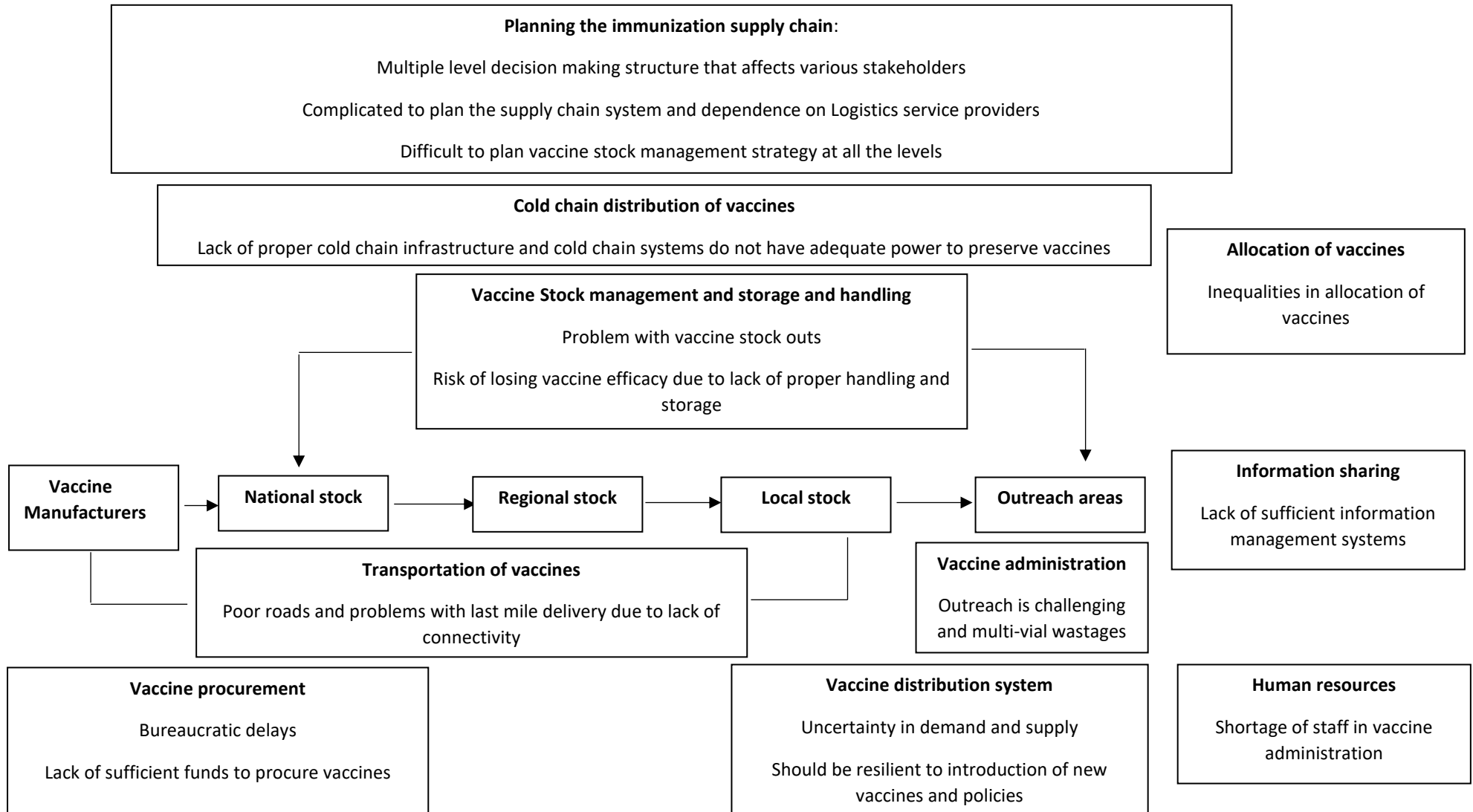


Figure 20- Conceptual framework of this study

4) Case description

The case description will first explain the routine immunization supply chain in India and how different aspects like planning the immunization supply chain, vaccine procurement till vaccine administration is conducted in India

4.1) Routine immunization supply chain of India

India's immunization programme is one of the largest in the world serving around 26.7 million infants and 30 million pregnant women on an annual basis. Despite its vast network of immunization system, it has still failed to reach a larger section of infants/pregnant women leading to very low immunization coverage. The recent policies have strived towards enhancing immunization coverage to a greater number in all India states (nhp, 2021).

Universal immunization programme (UIP) in India is mandated to vaccinate children and pregnant women against the vaccine preventable diseases. Currently under UIP, 8 vaccines are being administered to avoid vaccine preventable diseases (nhp 2021; CFPI 2021):

- 5) BCG for Tuberculosis
- 6) DPT
- 7) OPV (Oral polio vaccine)
- 8) Measles
- 9) Hepatitis B
- 10) TT (Tetanus Toxoid)
- 11) Japanese Encephalitis vaccination
- 12) Hib which has pentavalent vaccine

Seven other vaccines that are administered in India apart from UIP vaccines (INCLIN Trust, 2018):

- 1) MMR
- 2) MR
- 3) IPV
- 4) PCV
- 5) Rotateq
- 6) Rotarix
- 7) ROTAVAC

The routine immunization supply chain in India comprises of different levels of vaccine stores starting from the national level to the outreach areas (Figure 21). The vaccine that are manufactured are sent to the national stores or directly to the state stores from where it is delivered to the primary health centres/community health centres for routine immunization. The routine immunization supply chain also has few private beneficiaries that receive vaccines. The point where vaccines are administered are called sub centres/outreach area where the beneficiaries are immunized. The administration of vaccine can also take place at Primary health centres (PHCs) and Community health centres (CHCs) (Technet, 2021).

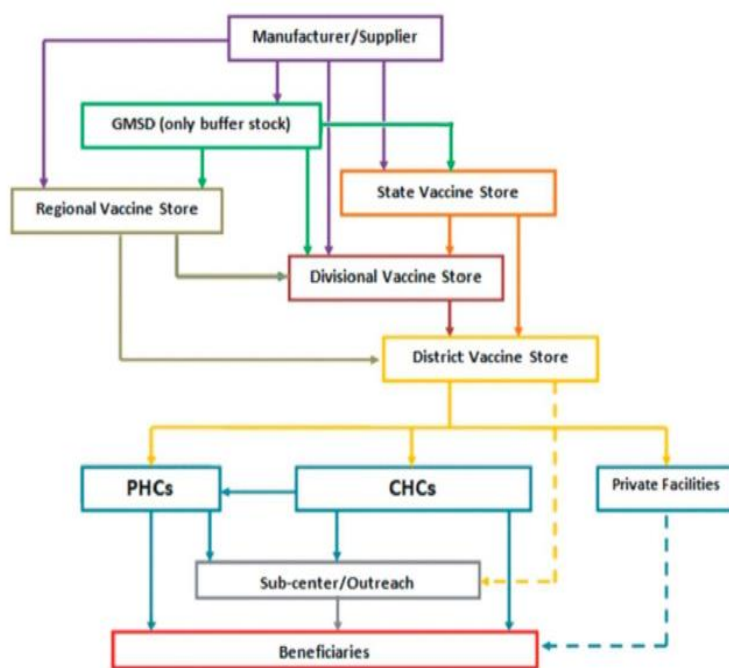


Figure 21- Routine immunization supply chain in India (INCLIN Trust, 2018, p.8)

4.1.1) Decision making structure for planning the distribution of routine vaccines

The central government of India has the mandate to plan the distribution of vaccines to the primary health centres/Community health centres. There is no involvement of the state government machinery in the planning of routine vaccines. National immunization schedule prepared by ministry of health and family welfare charts out the exact time frame in which the immunization is to be conducted to children and pregnant women (See Appendix 1) (INCLIN Trust, 2018).

4.1.2) Procurement of routine vaccines

The authority to procure routine vaccines lies with the government of India under the *ministry of health and family welfare*. It is the highest authority that mandates procedures to conduct procurement activities for conducting immunization in India. Ministry of health and family welfare is the nodal authority that funds and procures vaccines from the manufacturers. Routine vaccines are procured at the central level without the involvement of the state governments. Vaccines to treat the children and pregnant women against the vaccine preventable diseases are procured from multiple suppliers (National vaccine policy, 2011; ORF, 2020).

4.1.3) Allocation of routine vaccines

The priority groups for the allocation of routine vaccines is children and pregnant women in all the states/UTs of India. The vaccines are allocated to around 10 million immunization sessions each year across the country that happens majorly in the rural areas of India (mohfw, 2021).

4.1.4) Vaccine distribution system for routine vaccines

The present system for routine immunization operates with four government medical stores depot/GMSDs that functions as the main hub for storing vaccines for use to the entire nation. They are concentrated across four different zones of the nation (Figure 22) (Cold chain handbook, 2016).

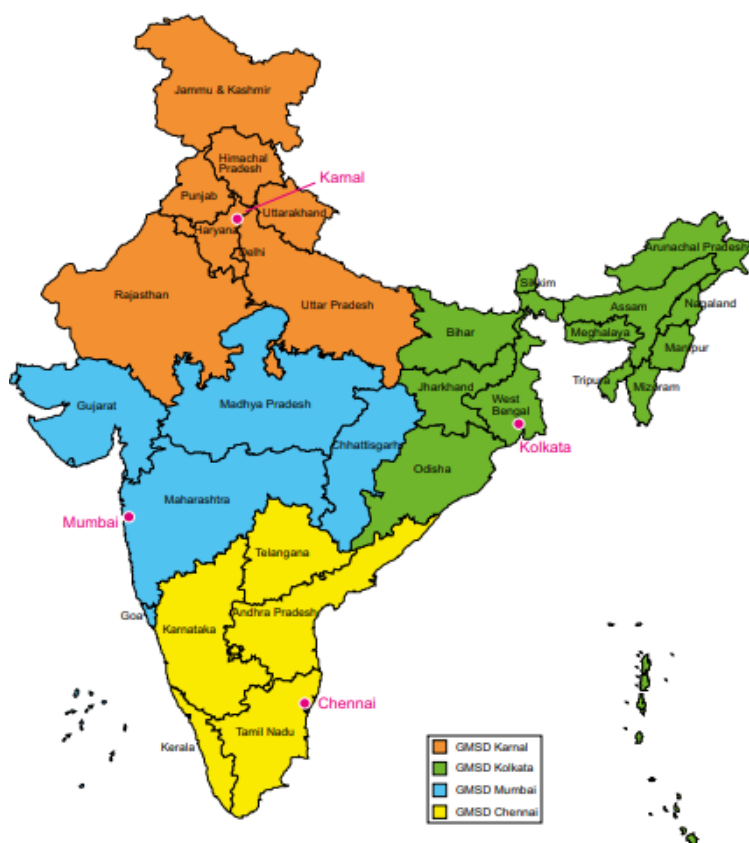


Figure 22- GMSDs in India across all four regions (Cold chain handbook, 2016, p.2)

- 1) Kolkata (North-eastern region)
- 2) Karnal (Northern region)
- 3) Chennai (Southern region)
- 4) Mumbai (Central and periphery region)

GMSDs store the vaccines for routine immunization. Some percentages of vaccines are stored as buffer stocks in these locations. Most of the time, vaccines are shipped to the central medical stores only if area of delivery of vaccines are far and it needs to pass through these central stores. The buffer stocks stored in these locations are supplied to the lower echelons of the vaccine distribution system. Their role is of prime importance in the immunization supply chain as they help the state governments handle surge in the demand of vaccines by having safety stock in place for the entire nation (Live Mint, 2021; Hindustan Times,2021; INCLIN Trust;2018).

The GMSDs in India are located to serve specific regions. The table 2 represents the allocation of GMSDs to the different states/UTs in India (INCLIN Trust, 2018):

GMSD Chennai	GMSD Mumbai
Tamil Nadu Karnataka Telangana Lakshadweep Pondicherry	Maharashtra Chhattisgarh Goa Gujarat Madhya Pradesh Daman and Diu Dadar and Nagar Haveli
GMSD Kolkata	GMSD Karnal
Bihar West Bengal Jharkhand Assam Meghalaya Manipur Tripura Mizoram Orissa Arunachal Pradesh	Haryana Punjab Delhi Himachal Pradesh Jammu and Kashmir Rajasthan Uttarakhand Uttar Pradesh

Table 2- Distribution of GMSDs to states in India (INCLIN Trust, 2018, p.9)

53 state vaccine stores follows the GMSDs (Figure 21) and are spread across the nation. They receive vaccines from manufacturers and from the buffer stock in the GMSDs. Each state vaccine store is responsible for supplying to its respective states. Most stock of the vaccines arrive directly to the state stores from the manufacturers and the remaining small number goes to the GMSDs. Since the decision is centralized, this enables the state stores to rely on the central government on a timely basis to get its share of vaccines. The regional vaccine stores receive the vaccines directly from the state vaccine stores from which it is disseminated to district vaccine stores. Then they are shipped to PHCs/CHCs and to the outreach areas. There are few private beneficiaries which also receive vaccines from state vaccine stores (Live mint, 2021; Hindustan Times, 2021; INCLIN Trust, 2018).

The vaccine distribution mechanism in India is based on the strategy of push and pull (National eVIN report, 2018) meaning that vaccines are pushed from higher echelons to the lower echelons of the vaccine distribution chain (Figure 23). Sometimes, vaccines are out of stock in lower echelons, hence they are pulled from the GMSDs based on the situational needs and the demand from the lower echelons. Due to large scale demand of the vaccine requirement higher levels of buffer stocks are needed at the GMSDs. This will ensure equity in distribution of vaccines on a timely basis. For a few states that may not have state vaccine stores the stock will disseminate from regional vaccine stores.

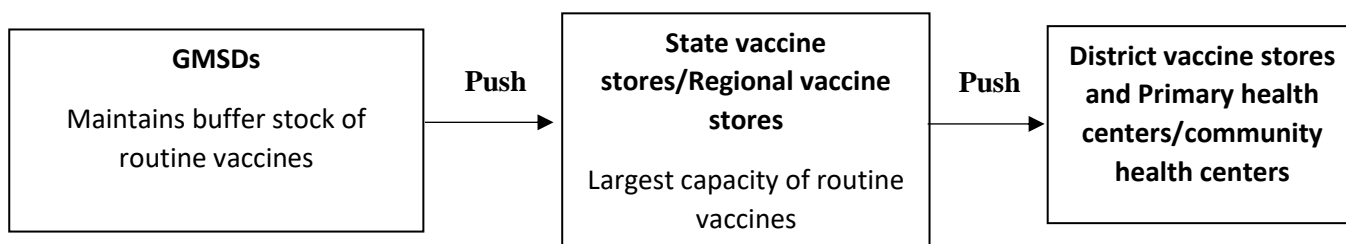


Figure 23- Vaccine distribution mechanism of India (Developed by author)

The vaccines are supplied to the vaccine stores to be stored for at least one or more months across all the levels of VDS (Table 3). Hence the routine vaccines which are received from the manufacturers will be used for a year in vaccinating to children and pregnant women in all the PHCs/ CHCs of India.

GMSDs	State vaccine store	Divisional vaccine stores	District vaccine stores	Primary health centre	Immunization area
3months buffer stock	3 months	2 months	2 months	1 month	1 month

Table 3- Storage of routine vaccines in India (INCLLEN Trust, 2018, p.9)

4.1.5) Cold chain infrastructure in India

The cold chain infrastructure in India comprises of around 29,000 cold chain points which delivers vaccines to the required beneficiaries. The number of cold chain points mentioned are used for routine immunization programmes. The cold chain infrastructure in India for routine vaccines contains numerous cold chain devices (ORF, 2021):

- 1) Number of cold chain points in accurate numbers- 28932
- 2) Walk in Freezers- 70
- 3) Walk in cooler- 240
- 4) Ice lined refrigerator-44246
- 5) Deep freezer-40792

Most of the cold chain equipment are part of the Universal Immunization Programme. 90% of these cold chain devices are operated below the district level according to the ORF report (2021). Primary health centres/Community health centres across the nation have the highest number of cold chain devices.

The concentration of cold chain equipment differs across each state in India. Some have higher concentration of cold chain equipment and others have below average numbers. Hence the challenges in terms of cold chain infrastructure are different from the perspective of each state. A recent study by INCLLEN trust (2018) showed Kerala has the highest immunization coverage with Gujarat in the middle and Bihar with the lowest immunization coverage. This could be indirectly related to the cold chain infrastructure in these states.

4.1.5.1) Distribution of cold chain points and equipment in states of India

Six states in India out of 36 states/UTs in India account for almost 1/6th of the total cold chain equipment in the entire country (Table 4).

State	Cold chain Points	Cold chain equipment
Karnataka	2870	7285
Tamil Nadu	2599	5483
Rajasthan	2405	2208
Gujarat	2291	5076
Andhra Pradesh	1650	4431
Maharashtra	3247	8643
Other states and Union territories	13860	52496

Table 4- Distribution of cold chain points in India (TOI, 2021)

There are few states in India like Bihar, Uttar Pradesh which have less immunization coverage (NFHS 2015-16) where shortages in cold chain points could be difficult to conduct COVID-19 vaccination. The north-eastern states in India which are difficult to reach (LEADS, 2019) and conduct outreach sessions also could face significant challenges in COVID-19 vaccination. Mandate to increase the capacity of cold chain infrastructure is being conducted by government of India to enable vaccination of all people in these vulnerable states (COVID-19 operational guidelines, 2019).

The government of India has mandated the respective states to increase their current capacity and cold chain equipment will have to be procured for additional capacity and for covering all the population in all states (Economic times, 2021; Live mint, 2021).

The statistics shows how the cold chain is not sufficient to handle large scale vaccination in India. Live mint (2021) shows how the cold chain points are concentrated in many states of India (Table 5). The states which have less cold chain points are on the vulnerable side of getting immunized. It is due to their shortage in cold chain points which could be difficult to conduct large scale vaccination.

State	CCP per 100,000 people
Jharkand	1
Uttar Pradesh	1
Bihar	1
Madhya Pradesh	2
Chhattisgarh	2.5
Assam	Around 3
Odisha	3.5
Rajasthan	3.5
Gujarat	4
Manipur	5
Nagaland	Around 8

Table 5- Cold chain points in states of India (Live mint, 2021)

There are various types of cold chain equipment that are used under UIP India mainly with different technical specifications as summarized in table 6 (Cold chain handbook, 2016; Park's textbook of preventive medicine, 2015) and with more details in the appendix 2:

Type of equipment for storage and handling of vaccines	Description
Walk in freezer	It is a type of cold room with two identical refrigeration units and a generator to supply power in case of power outage. The temperature in the WIF is maintained between -15 to -25 degree Celsius. They are commonly used in National, state level vaccine stores for immunization in India.
Walk in cooler	They are like WIF, but it is used to store large quantities of vaccines. The temperatures in WIC are commonly between +2 to +8 and between -15 to -25 degree Celsius. It is used in national stores and state vaccine stores. Large amounts of UIP vaccines are commonly stored in WIC.
Deep freezers	It is a device which utilizes vapour compressors like the conventional refrigeration system. The temperature in Deep freezers is between -15 to -25 degree Celsius. They are generally independent of the number of ice packs present in the system. Deep freezers are commonly present in district vaccine stores in India. They are commonly used for OPV vaccines.
Ice lined refrigerator	They also operate with the vapour compressors just like the conventional refrigeration system. It is used to store large quantities of vaccines as compared to Deep Freezers. Lining of ice on its walls provide more stability to the efficacy of vaccines present in it. It can also sustain without power for a longer duration of time.
Solar refrigerators	These cold chain devices are powered by solar energy that helps in storage of vaccines. It is the most sustainable form of cold chain devices that could be used for storing vaccines. India has utilised solar refrigerators for the routine vaccines as a supplement to the electrical driven cold chain devices.
Reefer trucks	They are customized forms of trucks which carry vaccines at a specified temperature. The reefer trucks are used for routine vaccines to carry vaccines from state medical stores to district vaccine stores and primary health centres in India.
Vaccine carriers	They carry vials of vaccine from the primary health centres to the outreach sessions. The temperature of vaccines is maintained between +2 to +8 degree Celsius.

Table 6- Description of cold chain equipment used in India

The classification of the cold chain devices is given in table 7:

Electrically powered devices	Non electrically powered devices
Walk in freezer Walk in cooler Deep Freezer Ice lined refrigerator	Vaccine carriers Solar refrigerators

Table 7- Types of cold chain equipment

Comes et al. (2018) separates the devices into active and passive devices-

1) Active devices (Major power consumption)

-WIC, WIF, deep freezer and ice lined refrigerator

2) Passive devices (Used for last mile delivery)

-Vaccine carriers

4.1.5.2) Cold chain flow of routine vaccines in India

The representation of cold chain flow given (Figure 24) is inspired by Comes et al. (2018). The cold chain of routine vaccines in India begins with the vaccine manufacturers. The vaccines are airlifted to the respective Government medical stores depot (GMSDs) and State vaccine stores by maintaining temperature between +2 to +8 degree Celsius and between -15 to -25 degree only for oral polio and rotovac vaccines (INCLIN Trust, 2018) (see appendix 3). The commonly used cold chain devices for routine vaccines in GMSDs are WIC and WIF. As stated above, only some percentage of vaccines arrive at the GMSDs. Most of the routine vaccines are sent directly to the respective state vaccine stores from where it is carried by reefer vans in the optimum temperature to the district stores. Again, these reefer vans carry vaccines to the Primary health care centres where they are stored in Deep Freezers. The final point in the cold chain is the outreach areas or sub centres where vaccines are carried in vaccine carriers and the immunization is conducted. The primary health centres and community health centres will be the last point where electrical cold chain equipment will be utilized. These PHC/CHCs form the bulk of the cold chain distribution of vaccines in India (Live mint, 2021).

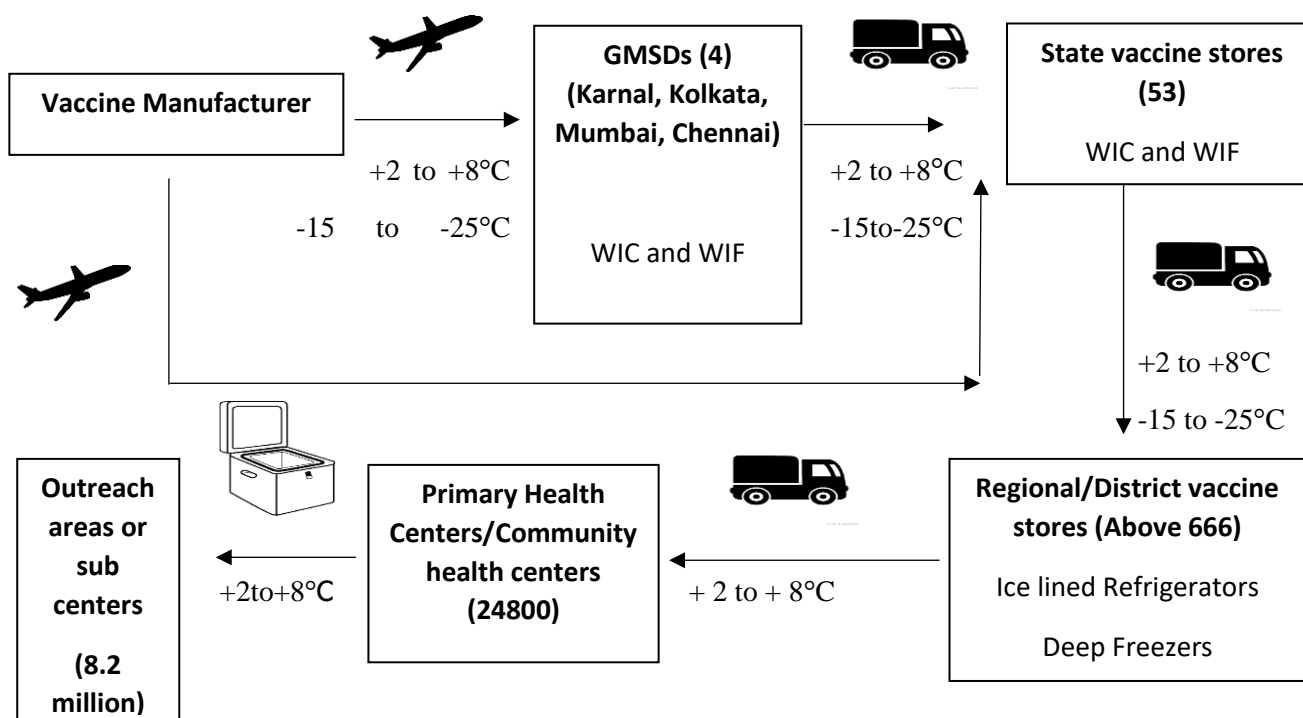


Figure 24- Cold chain flow of routine vaccines

There are around 30,000 primary health centres in India in which approximately 24,800 serve the rural population and around 5000 serve the urban population (Business standard, 2021). There are approximately 8.2 million outreach/sub centres where the vaccines are administered to the beneficiaries in India (Live mint, 2021).

4.1.6) Transportation of routine vaccines

The transportation of routine vaccines in India is done by the Central government with the help of reefer trucks outsourced from private players. There is involvement of Logistics service providers in the transportation of routine vaccines in terms of outsourced trucks and manpower. This is due to the resource crunch at State vaccine stores to procure reefer trucks on their own and hence it is a challenging task to run their transportation system (National EVM assessment, 2018).

4.1.7) Vaccine stock management of routine vaccines

The *electronic vaccine intelligence network (eVIN)* is a tool that is implemented in 32 states across the nation for improving vaccine stock visibility for all the stakeholders in the immunization supply chain of India (India today, 2021; News Indian express,2021). The observed benefits of this system are (National eVIN report, 2018):

- Improved stock management
- Increased visibility of vaccine levels
- Adequate temperature monitoring
- Reduction in vaccine wastage

This system was recently implemented in all the states of India making the vaccine stock management digital and accessible to all the stakeholders. Previously it was manual without an IT system making the vaccine management cumbersome and difficult to the stakeholders. The application of IT concept ensured accuracy and saving precious time. The IT system functions from the national vaccine stores/GMSDs to the last mile points of India where the stakeholders will have information about vaccine stock and temperature at all junctures (National eVIN report, 2018).

The key bottleneck with the IT system is that there are various problems with internet connectivity at the rural PHCs where the access to the IT systems for vaccine stock monitoring is not always possible. There is also a shortage of dedicated manpower to handle the systems and absence of monitoring at PHC/CHCs level (Mukherjee, 2021). This is problematic in states with low immunization coverage. Also 26% of the eVIN points have reported instances of stock outs (Live mint, 2021) leading to instances of less vaccination to children and pregnant women.

4.1.8) Human resources for routine immunization

The network of professional health workers called ASHA (Accredited social health activists) are involved in administering vaccines to children and pregnant women. India also has a network of Auxiliary nurse midwives who are key human resources in the immunization of India as they actively administer vaccines to children and pregnant women in the rural PHC/CHCs of India (Journals of India, 2020). The Print (2021) explicitly mentions that there is 1 doctor for 1511 people and 1 nurse for 670 people in India which clearly conveys the bottlenecks in the health care system of India.

The human resource for the routine immunization also include immunization leaders at all levels of vaccine distribution system and cold chain handlers responsible for maintaining the cold chain equipment at all the cold chain points and to maintain the stock of vaccines for timely immunization (See appendix 4). The Cold chain handbook (2016) addresses the list of duties of cold chain handlers in maintaining the cold chain equipment and for protecting the efficacy of vaccines by avoiding freezing or heating of vaccines. At present the number of vaccine cold chain handlers are around 55,000 in India (Live Mint, 2021). According to Mukherjee (2021), the amount of sufficient manpower needed in the vaccine stores like vaccine handlers, cold chain technicians were missing in 30% of the vaccine stores.

4.1.9) Administration of routine vaccines

The outreach sessions for routine immunization in India was conducted by the PHC/CHCs in the vicinity of people where they are concentrated in rural areas of India. The ASHA workers help in conducting the outreach sessions along with other health care workers in the rural areas of India (Das et al., 2018). During the administration of routine vaccines several states have experienced vaccine wastage (Oberoi et al., 2021). Further, the routine vaccines can be partially reused if the vials are opened. This practise is termed as *open-vial policy* which is mandated by the government of India from the year 2011 (see appendix 5) (Open vial policy, 2015).

4.2) COVID-19 immunization supply chain of India

The COVID-19 immunization supply chain is similar to routine immunization supply chain except for few parameters that needs additional capacity to sustain the scale of vaccination

4.2.1) Decision making structure and their activities for planning COVID-19 immunization supply chain

The government of India has formulated key administrative and decision-making roles at national, state and district level for planning and the enforcement of COVID-19 immunization supply chain to conduct immunization across all the states in India (Table 8). The synchronized decision making at all the levels of administration for COVID-19 pandemic is emphasized mainly to avoid pitfalls in immunizing people against COVID-19 (COVID-19 operational guidelines, 2019):

Decision making structure	Role
National expert group on vaccine administration	Main body which mandates the vaccine distribution strategy for the entire nation. It is headed by the chairperson of NITI AYOOG along with the secretaries of 19 important ministries in India
State level expert group	It is the state level body for monitoring the vaccine distribution strategy. It receives instructions from the national expert group and is headed by the respective chief secretary of a state. It is also involved in assessing the preparedness of each states in term of cold chain infrastructure to immunize its population
District level expert group	Responsible for reviewing preparedness of each district in a state for vaccine distribution.
Block level expert group	Final decision-making body that helps in preparing the last mile points for distribution and enhancing its cold chain capacity. It will help in identifying the outreach areas in the respective blocks by ensuring all the vaccine logistics in place.

Table 8 -Decision making structure and their roles (COVID-19 operational guidelines, 2019)

The decision-making structure is designed to operate in a hierarchy to manage all the activities related to vaccine distribution (Figure 25):

MULTI LEVEL GOVERNANCE MECHANISM

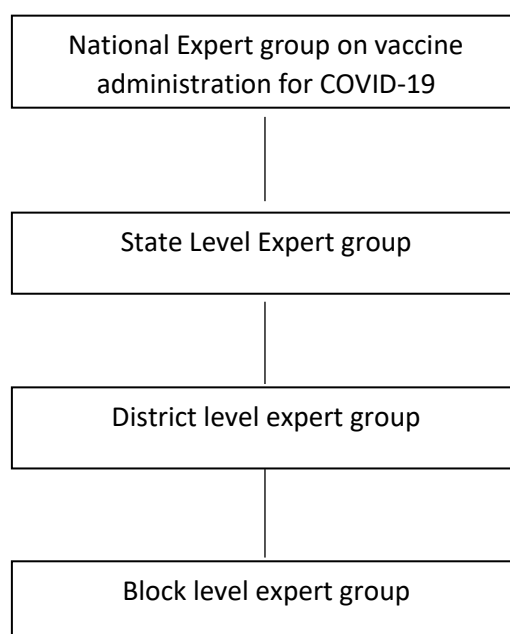


Figure 25 -Hierarchy of COVID-19 vaccine distribution planning team (Developed by author)

4.2.1.1) Key International organizations for COVID-19 immunization supply chain planning

There are international organizations helping the central and state governments in India to devise vaccine distribution strategy (Table 9) and help in overall preparedness of the nation to combat COVID-19 pandemic (COVID-19 operational guidelines 2019):

International organizations	Role
WHO India	WHO's office in India will play a key role in partnering with the Indian government in planning vaccine introduction by mapping important areas in a state and district. It will also track the implementation of vaccine rollout by identifying key bottlenecks by collaborating with state and district level players.
UNICEF India	UNICEF in India will play a key role in ensuring vaccine rollout and to help state governments to devise a proper vaccine distribution strategy. It will also help in building capacity and provide training to health care work force to administer vaccines effectively.
UNDP India	UNDP is playing a key role in improving technical support for vaccine distribution in terms of improving the information systems for better vaccine stock management.
John snow research group	It is helping states and districts in microplanning the distribution strategy and capacity building to promote better immunization services to all citizens in the nation.
Other groups	Red cross and rotary clubs are helping government in planning and implementing the vaccination drive. All these help in capacity building and better preparedness for achieving higher immunization levels.

Table 9- International organizations involved in planning COVID-19 immunization supply chain (COVID-19 operational guidelines, 2019)

4.2.2) COVID-19 Vaccine Procurement in India

Procurement of COVID-19 vaccines will be done on the central level similar to the routine vaccines. The COVID-19 is a large-scale pandemic and the number of vaccines that are procured is high. To vaccinate 1.3 billion people in the nation will require right procurement of vaccines on a timely basis. For phase 3 of vaccination in India, states will be given partial control of the vaccine procurement directly from the manufacturers. States will have the power of floating tender to the manufacturers in case of vaccine shortage (Indian Express, 2021).

The funds for procuring vaccines have been allocated and manufacturers of COVID-19 vaccines in India have been issued tenders to supply vaccines to Government of India (Livemint, 2021). The procurement of vaccines is the start of vaccine distribution chain as stated in De Boeck et al. (2019). Hence to prevent imbalance in supply and demand of COVID-19 vaccines, coordination is being emphasised by the government with the key suppliers and this will be the key to achieve higher immunization coverage. The pandemic has also made India one of the largest producers and buyers of vaccines in the world. This also corresponds to the massive population and need for proper principles in immunization supply chain for COVID-19 vaccines which is being implemented by the Indian government to promote effective immunization (TOI, 2021; BBC, 2021).

The two main manufacturers and suppliers of COVID-19 vaccines are **Serum Institute of India** and **Bharat biotech**. Apart from sourcing vaccines from these suppliers, there are many other suppliers who are testing vaccines which are in the clinical trial phase (See Appendix 6). Subject to approval, it will all be sourced locally from the manufacturers in India. The main reason to prefer many suppliers is due to demand of the vaccines for the COVID-19 vaccination in India as this nation conducts one of the largest immunization campaigns in the world (BBC, 2021).

India has procured 1600 million doses as of December 2020 (Figure 26) making it the largest buyer of COVID-19 vaccines (TOI, 2021).

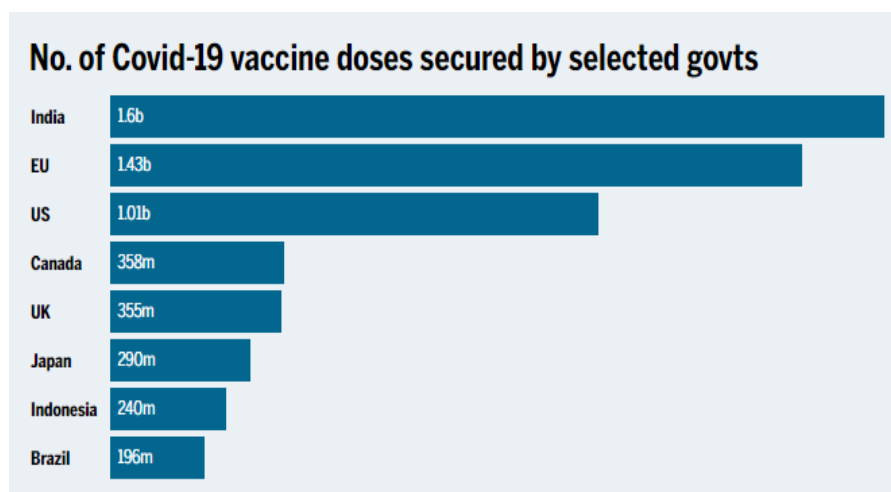


Figure 26- Total number of COVID-19 vaccines procured by world countries (TOI, 2021)

4.2.3) Allocation of COVID-19 vaccines

The allocation of COVID-19 vaccines in India is a huge logistical challenge. To vaccinate its large population, priority groups have been made to systematically immunize all the population. The allocation of vaccines is done in the order of priority of risk groups. For the phase 1 of vaccination drive following were the high-risk groups (The Hindu, 2021).

- 1) Health care professionals (Doctors, medical staff)
- 2) Frontline workers (Army, Police, municipal workers)

3) People above 50 years of age with morbidities and high-risk individuals

This phase will cover around 300 million people with 30 million health care workers and 270 million high risk individuals

For Phase 2 (First Post, 2021)

1) Elderly population above 60 years of age (100 million people)

For Phase 3 (Financial Express, 2021; Live mint, 2021)

1) General population of India (Rest of Indian population)

The allocation will thus be made based on the vulnerabilities of the citizens to COVID-19. This will help the common citizens and government to systematically prioritize and ensure equitable distribution to all in the country. The total population of India is 1.3 billion and hence 3 or more phases of distribution are needed to cover all the people. Therefore, to immunize its entire population requiring 2 doses, it might take many years to achieve the desired goal. Currently the vaccination drive is in the third phase which will vaccinate the general population of India in the age group of 18-44. Recently, the government has raised the interval between the first dose to second dose from 6-8 weeks to 12-18 weeks ostensibly on the scientific evidence showing higher efficacy rates. The total number of people covered under this drive is around 900 million population which is nothing but daunting and first of its kind in independent India which has never been tried before (Financial Express, 2021).

Furthermore, despite the government's priority on the equitable vaccine distribution strategy, there are inequalities noted for COVID-19 vaccines. The table 10 shows the allocation of vaccines to the states of India as per the latest data available in the month of April 2021 (Money control, 2021):

States of India	% of the doses allocated to the state	% of the population which are administered with the vaccine
Gujarat	16.4%	14.9%
Kerala	16.1%	14.7%
Chhattisgarh	15.8%	15.2%
Chandigarh	15.7%	10.7%
Himachal Pradesh	14.8%	14
Rajasthan	12.9%	12.3%
Goa	12.1%	8.7%
Uttarakhand	12%	12.3%
Haryana	10.5%	8.8%
Delhi	10.4%	9.9%
Karnataka	10.1%	9.2%
Jammu and Kashmir	9.9%	10.2%
Odisha	9.2%	9.2%
Maharashtra	8.5%	8.6%
West Bengal	8.4 %	8.3%
Punjab	7.3%	6.4%
Madhya Pradesh	6.8%	7.3%
Tamil Nadu	6.4%	4.6%
Jharkhand	6.4%	6.3%
Telangana	6.3%	5.6%

Assam	5%	4.9%
Andhra Pradesh	4.1%	4.2%
Uttar Pradesh	3.9%	4%
Bihar	3.7%	3.9%

Table 10- Allocation of COVID-19 vaccines to states of India (Money control, 2021)

4.2.4) COVID-19 vaccine distribution in India

The COVID-19 vaccine roll out in India was launched on January 16, 2021. Two vaccines are distributed by the Indian government (mohfw, 2021):

- 1) **Covishield** vaccine manufactured by Serum Institute of India
- 2) **Covaxin** manufactured by Bharat Biotech

The Covishield vaccine manufactured by Serum institute of India is generally preferred compared to the one manufactured by Bharat biotech due to higher efficacy percentage. The biological parameters of both the vaccines differ right from production to administering. However, this is in no way undermining the efficacy of Covaxin. There were many vaccines that were on the priority list for getting approved. The possibility of approval of these vaccines were highly scarce due to the requirement of larger freezing temperature needed to maintain its potency. Hence vaccines that could be kept between 2-8 degree Celsius have been approved by the Indian Government. Overall, the COVID-19 vaccines have the same temperature compliance similar to routine vaccines. Hence the same distribution mechanism will be utilized to distribute COVID 19 vaccines in India as the logistics seemed easier with these vaccines (Indian Express, 2021)

4.2.4.1) Vaccine distribution system for COVID-19 vaccines

The VDS for COVID-19 vaccines is similar to routine immunization supply chain except that there are many private and government hospitals as the last mile points where the vaccines will be delivered and administered to the people. These Private hospitals and other beneficiaries receive vaccines from the state vaccine stores/regional vaccine stores depending on the vicinity at which they are located. Many private hospitals in India are selected for being the COVID-19 care centres in many states. One of the prominent being Apollo Hospitals (Hindustan Times, 2021; Business Standard, 2021).

There are various challenges inherent in this vast network. Maintaining cold storage all through the distribution chain and delivering it until outreach areas in rural India is a big challenge. It should be understood that many states in India do not have full immunization coverage due to loopholes in the health care infrastructure (NFHS 2015-16). This must improve in the response to the COVID-19 vaccination and to avoid disruptions in the routine immunization programmes even further.

Furthermore, the vaccine distribution mechanism is similar to routine vaccines and the forecast for COVID-19 vaccines would be decided on a weekly basis at all the levels of VDS (Mukherjee, 2021).

4.2.5) Cold chain flow of COVID-19 vaccines in India

The cold chain of COVID-19 vaccines (Figure 27) begin from manufacturers Serum institute of India and Bharat biotech from where the vaccines are airlifted to GMSDs or directly to the state vaccines stores in the temperature between 2-8 degree Celsius in the cargo deck of the aircraft. The rest of the flow is similar to routine vaccines. But one major difference is that COVID-19 vaccines are also transported by reefer trucks from the manufacturers to the state vaccine stores/regional vaccine stores in the required optimum temperature.

The cold chain flow of COVID-19 vaccines also include many private hospitals which play a key role in immunizing people against COVID-19. Most of these private hospitals are situated in major cities of India and they help in maintaining the cold chain. Vaccines in these hospitals are stored between 2-8 degree Celsius in Deep Freezers. Apart from these private hospitals, there are government run hospitals that functions as COVID-19 care centres in districts and cities of India which are also crucial for the cold chain. Given its vast network of operations, there are key challenges that are to be addressed in the cold chain systems for COVID-19 vaccination (Business Today, 2021; Hindustan Times, 2021).

The future vaccines suppliers in the cold chain of COVID-19 vaccines have been listed (NDTV, 2021):

Cadila Pharma- Ahmedabad

Dr Reddy's and Biological E- Hyderabad

Aurobindo Pharma- Telangana

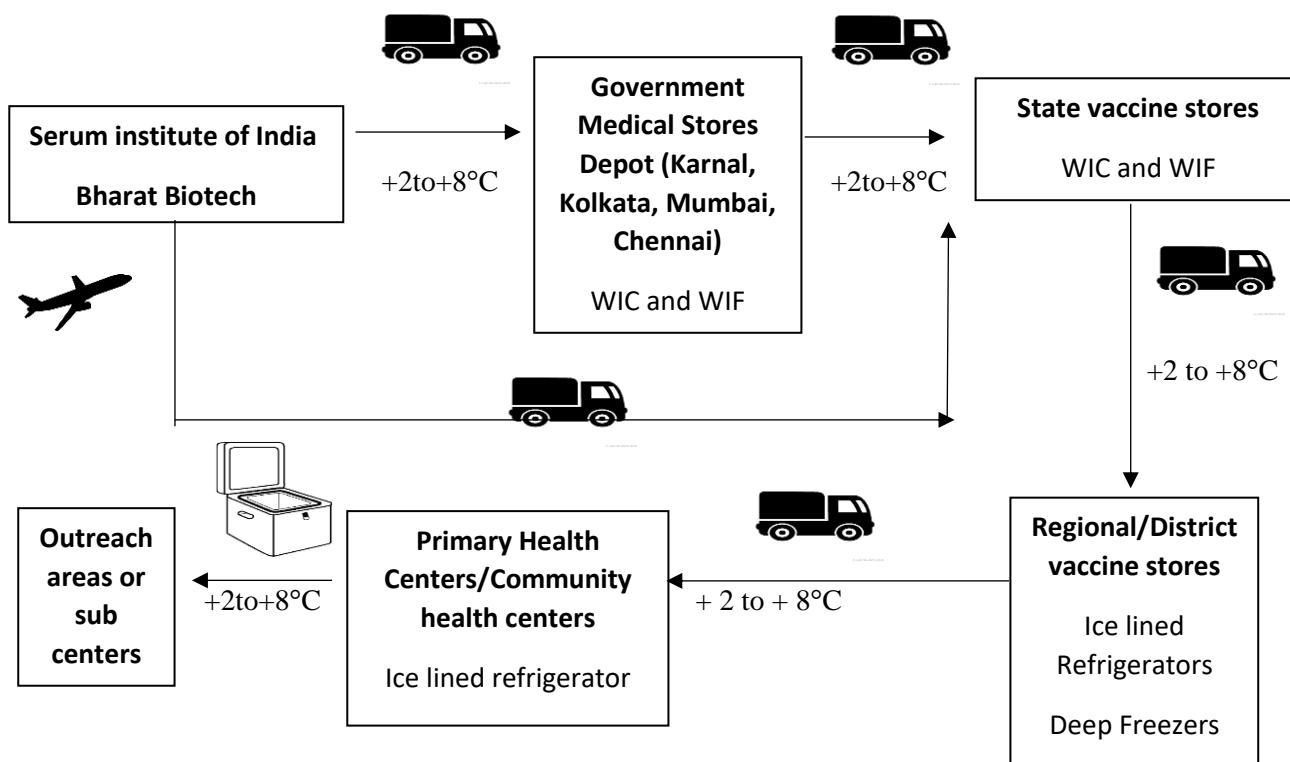


Figure 27- Cold chain flow of COVID-19 vaccines in India

The cold chain devices discussed above for routine immunization will also function as part of the COVID-19 vaccination drive in India. The devices mentioned previously are compatible with vaccines developed by Oxford and AstraZeneca which is manufactured by Serum Institute of India. It is also compatible with vaccines manufactured by Bharat Biotech. Also the cold chain infrastructure mentioned for routine vaccines will be similar for COVID-19 vaccines. The National EVM assessment (2018) found that cold chain equipment in many states of India have become obsolete due to absence of advanced technology. With the influx of COVID-19 vaccines, the current cold chain systems are not sufficient to handle or vaccinate all the population. Keeping in mind the regular immunization programmes, the present infrastructure might lead to disruptions in the routine immunization for children and pregnant women. The 29,000 cold chain points should function for

both the UIP and COVID-19 vaccines which is a significant challenge. ORF (2021) shows the disparity among different states of India in terms of having cold chain equipment (Figure 28):

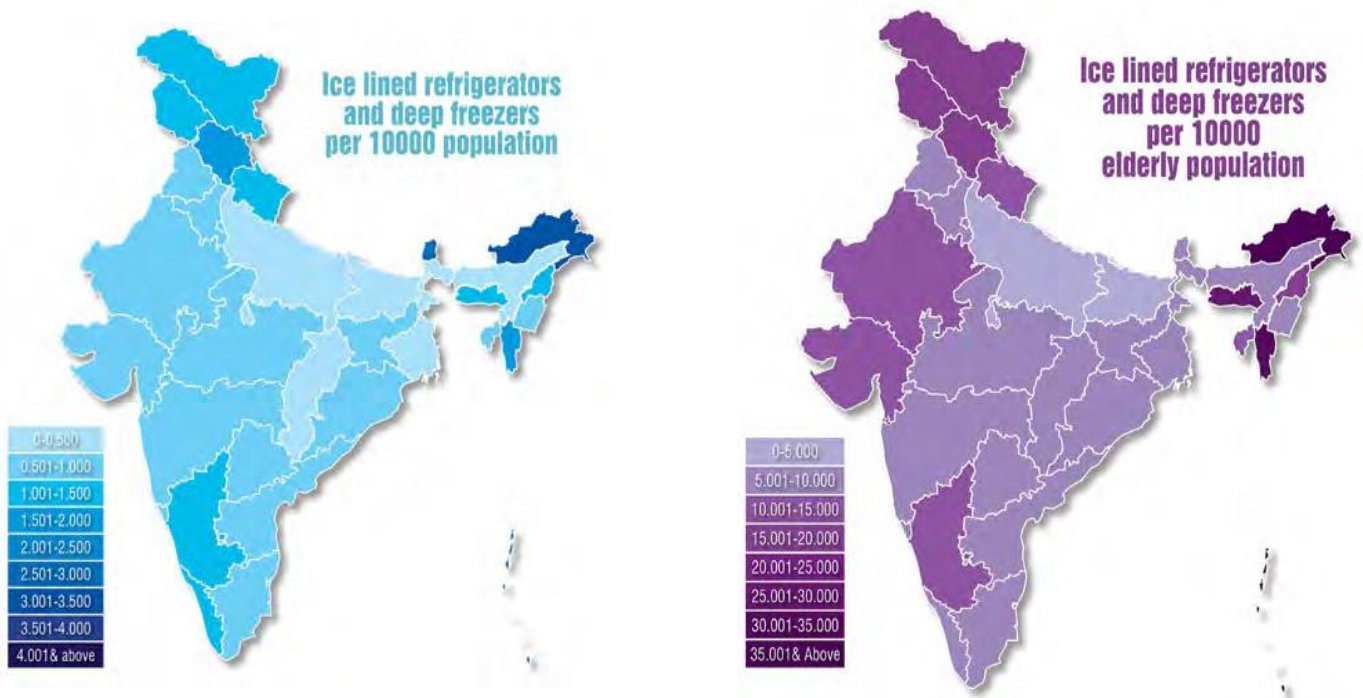


Figure 28 - Cold chain distribution in India (ORF, 2021, p.14)

India Today (2021) points the key bottleneck in the cold chain of COVID-19 immunization supply chain that many PHCs in India does not have adequate electricity (Table 12):

State	Percentage of PHCs without electricity
Karnataka	1.4%
Maharashtra	1%
Himachal Pradesh	1.4%
Haryana	2.1%
Meghalaya	2.7%
Mizoram	3.5%
Chhattisgarh	4%
Rajasthan	4.3%
West Bengal	5.8%
Assam	6.7%
Manipur	8.2%
Uttar Pradesh	10.7%
Nagaland	11.3%
Odisha	12.6%
Arunachal	12.9%
Uttarakhand	14.4%
Jharkhand	55.2%

Table 12- Percentage of PHCs in India without electricity (India Today, 2021)

4.2.5.1) Plans for strengthening the cold chain Infrastructure

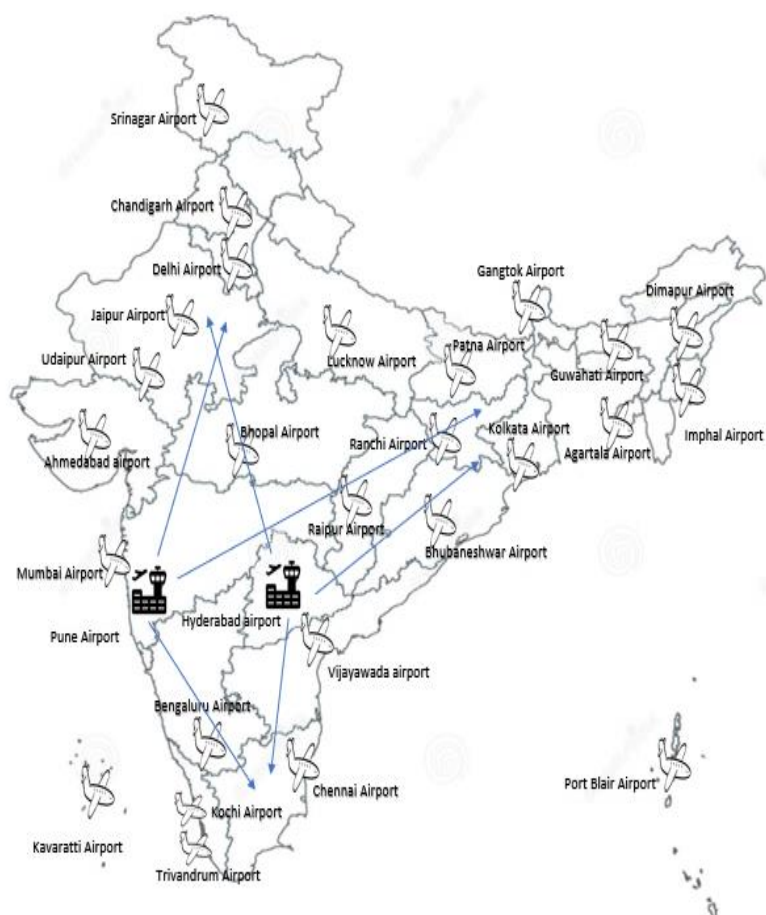
The government of India has laid out plans for strengthening the cold chain infrastructure for the COVID-19 vaccination. The demand and supply for COVID vaccines are highly variable which puts pressure on the government to scale up the capacity. Thus, it is particularly important to upgrade the cold chain equipment that protects the efficacy of vaccines. The government has laid out the following plans for scaling up cold chain infrastructure in the country (COVID-19 operational guidelines, 2019).

- Install more WIC and WIF to suit the storage of COVID-19 vaccines
- Identify the sites that need scaling up of cold chain infrastructure mainly to store more vaccines for immunization
- Reduce lead time of delivery of cold chain equipment
- Ensure training to all the health care professionals on the newly installed cold chain equipment

The challenges to achieve equitable distribution of vaccines in all the states will also need equity in the number of cold chain equipment in each state depending on its population. This will be in emphasis for COVID-19 vaccination drive for the Indian government.

4.2.5.2) Important cold chain corridors for COVID-19 vaccine distribution

Airports play an important role in collecting and distributing the COVID-19 vaccines across all the states in the nation at the same time which was not the case with routine immunization. Many airports in India have ramped up their cold chain infrastructure to help maintain the efficacy of vaccines for the distribution of vaccines to all the states. Maintaining the appropriate temperature of vaccines is essential as it passes through the main airports of the respective states. Hence it is important for this pandemic as the scale of vaccine distribution is huge. Therefore, airports have to act as the primary gateway for receipt and despatch of vaccines to the respective state/regional vaccine stores (Itln, 2021). The figure 29 represents the cold chain corridors for COVID-19 vaccines in India:



State Airports



Main Point of dispersion of vaccines in Pune and Hyderabad to other airports

Figure 29 – Cold chain airports and points of dispersion to individual states

4.2.6) Vaccine stock management for COVID-19 vaccines

The COVID-19 vaccine management will function as part of the existing stock management guidelines that was part of the UIP. Additionally, a new platform is created which is termed as Co-WIN that enables the list of beneficiaries to get themselves registered for getting vaccinated. Co-WIN along with Arogya Setu mobile app are digital tools where the beneficiaries register initially with their phone numbers to get information on slot availability and nearest centre (Figure 30). Post selection of the same the message is transmitted to local authorities to ramp up the stock of vaccines accordingly. This platform will be beneficial to maintain adequate stock of the vaccines depending on its demand from the end users. Following are some important features of this digital platform (COVID-19 operational guidelines, 2019).

- It will track the beneficiaries at the target vaccination site.
- Supply and demand could be well managed.
- Immunization at a large scale can be well managed.
- Update of the vaccine stock on a timely basis.
- Will issue certificates post vaccination and prompt the beneficiary in case of due date for second dose. The real time requirement of vaccines can be forecasted well in advance.

The vaccine stock management in respect of COVID-19 vaccines is a herculean task as the total number of people getting vaccines are relatively high. Hence this digital platform/app would come in handy for beneficiaries as they can register at their convenience to get the vaccine shots at their nearest outreach area or hospital depending on the location in which the beneficiaries are residing (COVID-19 operational guidelines, 2019).

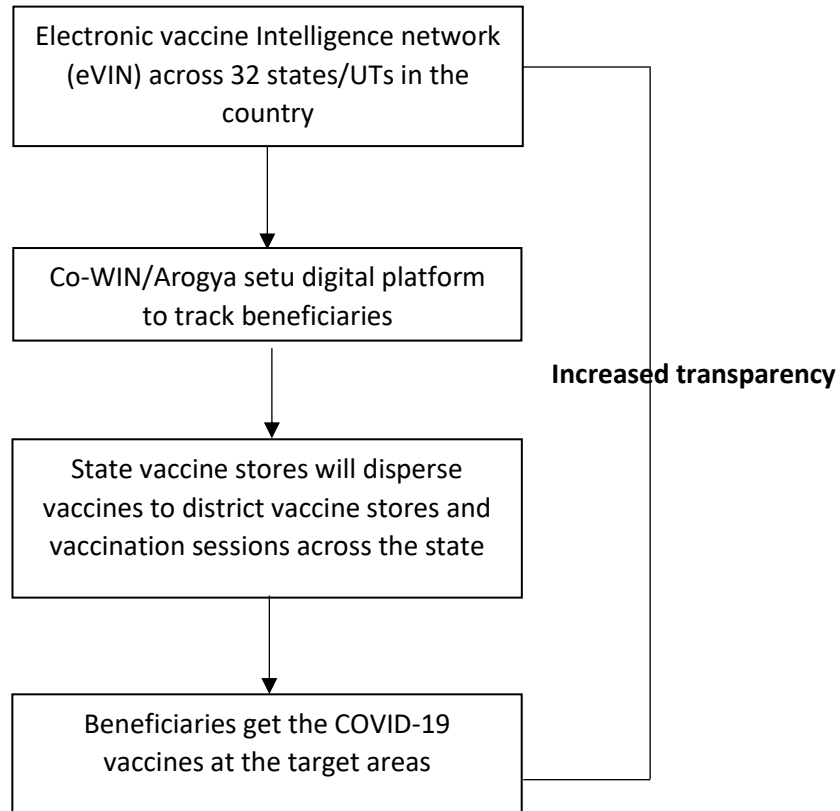


Figure 30- IT system for COVID-19 vaccines (Developed by author)

4.2.6.1) Process flow of The IT system (Co-WIN)

The Co-WIN App performs all the functions that are needed to help the stakeholders at all the levels of VDS to monitor vaccine stock and other vaccine related information for COVID-19 vaccine management as it is an extended version of the eVIN system (Figure 31). But the most observed challenge in the system was related to the glitches in the newly created app (India today, 2021; Economic Times, 2021).

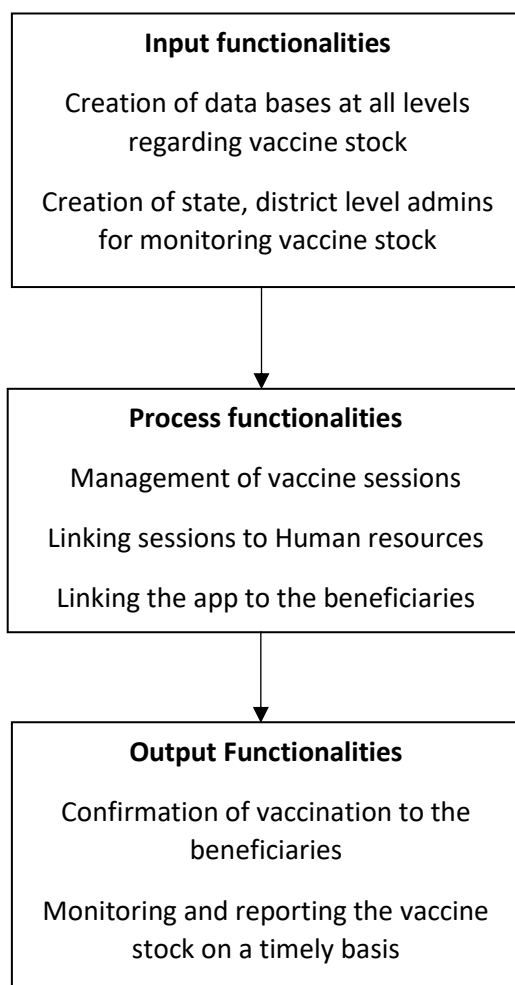


Figure 31- Process flow of the Co-WIN app for COVID-19 vaccination (COVID-19 operational guidelines, 2019)

4.2.7) Transportation of COVID-19 vaccines and Logistics Service Providers

The prime mode of transportation of COVID-19 vaccines in India will be undertaken by reefer vans that are custom built to carry vaccines from one place to another (News 18, 2021). The adversity of transportation depends on the road conditions/network in each state. It is pertinent here to mention that there exists demarcated national highways, state highways crisscrossing each other at certain points in addition to district and rural roads. The consignment of vaccines must navigate these roads to reach the destination. However, this is being outsourced to Logistics service providers (Mukherjee, 2021) who provide the government with reefer trucks and sufficient manpower for handling and storing the vaccines in their private warehouses in the country. The transportation of vaccines from the manufacturers to the state vaccine stores will be the responsibility of the central government and from the state vaccine stores to the primary health centres will be the responsibility of the state government (News 18, 2021).

The distribution network for the COVID-19 vaccines have been designed by the central government for the transportation of vaccines. Pune and Hyderabad will be the main hub from where the vaccine will be transported. From the airport in Pune and Hyderabad, reefer vans of specific LSPs will be utilized to transport vaccines from the manufacturing site. There were 41 sites identified for the transportation of COVID-19 vaccines in India. Also, Mini Hubs were created in different regions that

can aid in transportation of vaccines. The mini hubs in the regions are designated only to supply or store buffer vaccines specifically for COVID-19 vaccines (Figure 32). Mini hubs for each region are as follows (Livemint, 2021):



Figure 32- Mini hubs for COVID-19 vaccine distribution in India (Live mint, 2021)

The additional mini hubs like Hyderabad, Delhi and Guwahati specified above was not functioning for the routine vaccines but were created exclusively for COVID-19 vaccines. It is quite evident that the journey of COVID vaccines from National stores/state stores to the outreach areas will encompass the strenuous work comprising skilled manpower right from handling, storing, and delivering it to the outreach areas. Hence the logistics service providers are playing a key role in the transportation of vaccines almost to all the remote and inaccessible areas often encountering challenges in moving vaccines all around the country (Figure 33). A few different logistics service providers transporting COVID-19 vaccines in India are described below:

4.2.7.1) Aircraft carriers

Spice Jet is an airline company in India which has aircrafts for carrying passengers from one place to another. Its role is pivotal in COVID-19 vaccine distribution as it is responsible for airlifting the vaccines from the manufacturing site to the respective state airports. It has signed pact with other logistics service providers to effectively transport vaccines to length and breadth of the nation (Business standard, 2021). The other carriers are Indigo, Go air who are actively involved in transporting vaccines to the respective states from the manufacturers in Pune and Hyderabad (Financial express, 2021). The DGCA (Director general of civil aviation) of India being the regulatory body has given direction to the aircraft carriers on how to safely airlift vaccines to different state destinations (Live Mint, 2021; Business standard, 2021).

4.2.7.2) Snowman Logistics

Snowman logistics is one of the leading providers of cold chain logistics in India. The COVID-19 vaccines are being transported majorly by snowman logistics in India. It has signed pact with Spice jet to ferry covid-19 vaccines all around the country. It will provide services like ground duties, transportation and cold chain warehouses across the length and breadth of the country. It can handle transport of around 300 million vaccines in immediate circumstances. Also, it has close to 12,000 pallets at its disposal immediately whereas its total pallet capacity is 100,005 for the entire country. It is also involved in storage and packaging of vaccines all through its journey to destination. The main challenge that snowman logistics foresees in this pandemic is the lack of clarity on the total volume of vaccines to be distributed and time constraints associated with the delivery lead time (Bloomberg quint, 2021).

4.2.7.3) Kool ex private Limited

Kool ex private limited is also a cold chain logistics service provider in India. It is handpicked by the government to transport vaccines to different locations in the country depending on its capacity. It has many fleets of reefer trucks which provide the necessary temperature of vaccines. Kool ex will be transporting vaccines from the manufacturing sites to various state depots which will then be used for storage and dispersion to district level stores (India Today, 2021).

4.2.7.4) Other Logistics service providers

Transport corporation of India (TCI), Blue dart, Mahindra Logistics and Om logistics are some of the other 3PL logistics service providers in the country who will be part of transporting, storing, and delivering the vaccines to the required beneficiaries through their outsourced activities. They must enhance their handling capacity to match the scale of immunization as it is much tougher than routine immunization. This requires immediate response by all the logistics service providers (ORF, 2021). Also, Companies like Tata and Daimler Benz are developing cold chain trucks specifically to carry vaccine all around the country (Economic Times, 2021).

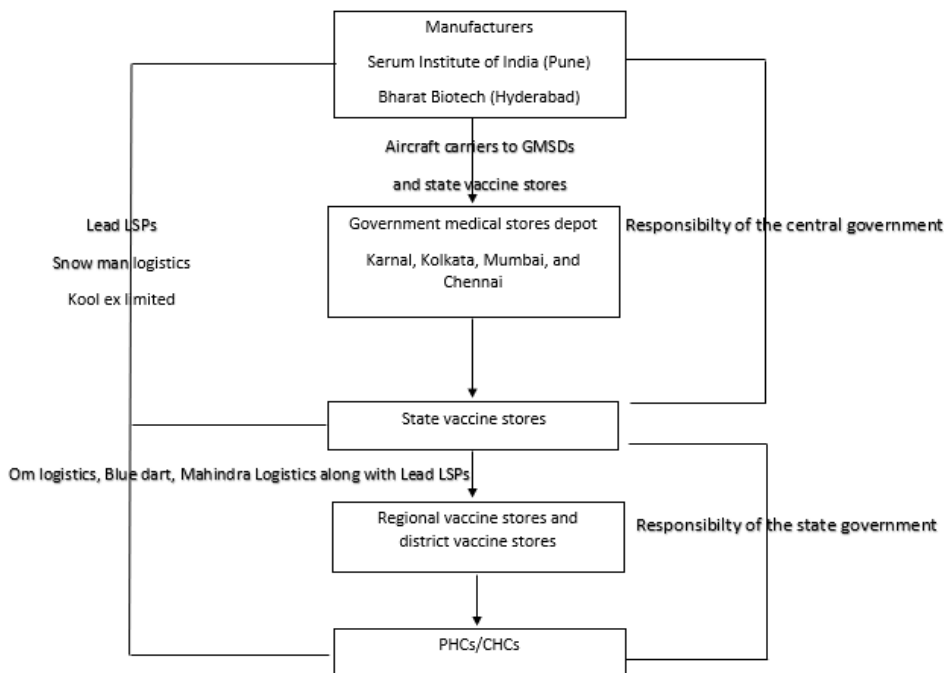
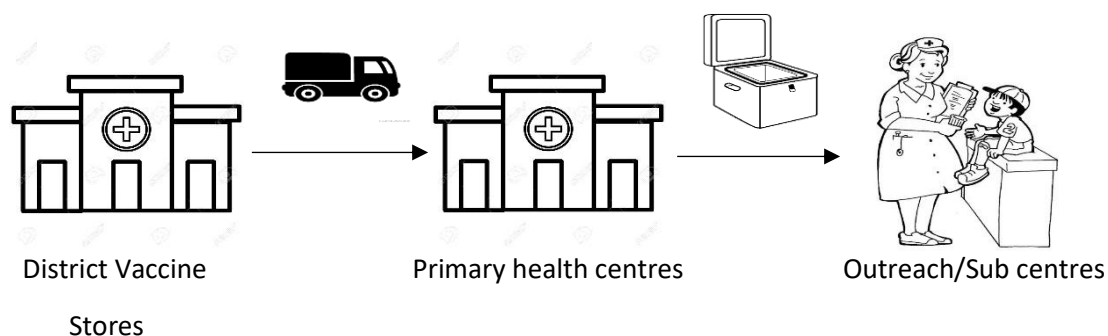


Figure 33- Transportation flow of COVID-19 vaccines in India (Developed by author)

4.2.7.5) Last mile delivery of COVID-19 vaccines in India

The rural India comprises of almost 65.5% of the Indian population (World Bank, 2019). India has around 6.3 lakh villages with 7935 towns. The connectivity issues are particularly high in these areas where vaccines will have to be distributed. The government of India is also estimating the possibility of rail network which has better connectivity to last mile points in rural areas as compared to road network (Hindu Business Line, 2020). The last mile delivery of COVID-19 vaccines from district vaccine store to Primary health centres will also be conducted by outsourced reefer vans that are deployed by the state for its routine immunization. Therefore, reaching all the primary health centres of India will take more time and all the logistics service providers have been roped in to handle the vaccine delivery till the primary health centres (Hindustan times, 2021; Economic Times, 2021).

Rural Setting



Urban Setting

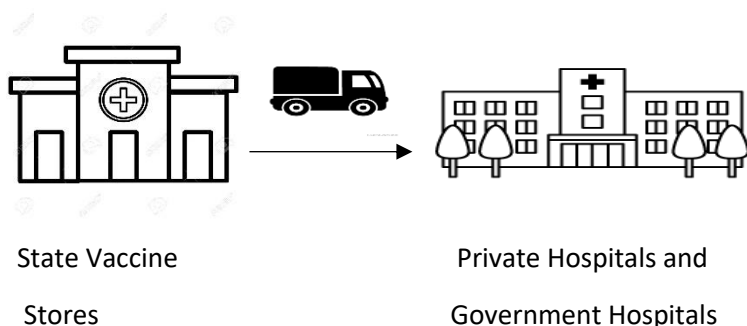


Figure 34- Last mile delivery of COVID-19 vaccines in India

In the urban setting, last mile delivery will comprise the distribution of vaccines from the state vaccine store to the private hospitals in big cities and to government hospitals in towns (Figure 34). The COVID-19 vaccination has involved a lot of private players who are actively participating in vaccinating the vast population of people in India (Hindu Business Line, 2021).

One of the key drawbacks of the last mile delivery of COVID-19 vaccines are that PHCs in the states of India are not well connected with roads (Table 13) that will affect delivery of vaccines at these points (India today, 2021):

State	PHCs in India not connected with roads
Odisha	0.9%
Mizoram	1.8%
Rajasthan	3%
Chhattisgarh	5%
Maharashtra	5.1%
West Bengal	6.7%
Haryana	6.7%
Manipur	7.1%
Karnataka	7.6%
Kerala	8.6%
Madhya Pradesh	8.8%
Himachal Pradesh	9.5%
Assam	10.6%
Meghalaya	11.8%
Jharkhand	14.8%
Nagaland	18.5%
Jammu and Kashmir	19.6%
Uttarakhand	21%
Uttar Pradesh	23.1%
Arunachal Pradesh	25.7%

Table 13- PHCs in India without road connectivity (India Today, 2021)

4.2.8) Human Resources for COVID 19 vaccine administration

The basis of a successful immunization programme during a pandemic is the availability of dedicated human resources. The immunization of this scale needs proper training of health care workers to administer the vaccines. The ORF report (2021) highlighted that the amount of health care workers needed to immunize people across the country is far below the actual margin. The total number of health care personnel stand at 3.07 million which translates to 1.7 health care professionals per 1000 for India. The WHO norms point to 3 per 1000. The health care professionals have been given sufficient training to administer COVID-19 vaccines across all the states. But states with low health care systems will have substantial challenges in augmenting its capacity and work force. Uttar Pradesh, Bihar have the lowest health care system in the country (Anand, 2014), hence they will have complexities in training more health care professionals for COVID-19 vaccination in a situation where there are shortages already in its human resources. The other states like Jharkhand, Chhattisgarh, Madhya Pradesh have a very skewed health care work force that can take a toll on the doctors who are on duty (The Print, 2021). This could be problematic in other states of India as well.

The ASHA workers and Auxiliary nurse midwives who hitherto functioned for routine immunization are given training to administer COVID 19 vaccines as well. Ministry of health and family welfare is also training additional health care work force for the administration of COVID-19 vaccines across all the states in the nation (ORF, 2021).

There are cold chain handlers and immunization officers at national, state and district levels to handle the stock of vaccines and to maintain cold chain systems/equipment for ensuring that all the necessary systems are in place for conducting COVID-19 vaccination. Apart from these human resources the government is also training health care workers for working at the vaccine administration site. They

are termed as vaccination officers (figure 35) who are designated with roles to monitor administration sites (COVID-19 operational guidelines, 2019).

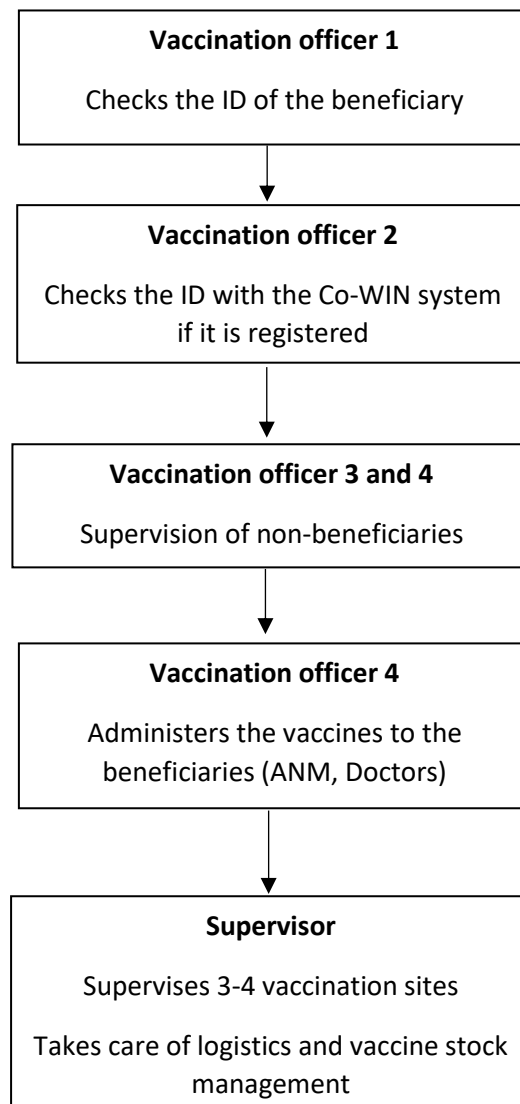


Figure 35- Human resources for the COVID-19 vaccine administration (COVID-19 operational guidelines, 2019)

4.2.9) Administration of COVID-19 vaccines

Covishield and Covaxin the two vaccines used for COVID-19 vaccination have different clinical parameters when it comes to administering them to the masses in terms of the technology utilized to manufacture them (Table 14). But the administration of these vaccines at the last mile points will need the same cold chain requirement. At present, the level of administration of the vaccines is dependent on people's willingness to get immunized since the government has not made this a mandatory vaccination for general population. This is true for people getting immunized at primary health centres and last mile cold chain points in India (TOI, 2021):

Vaccine	Temperature	Shelf life	Technology
Covishield	2-8 degree Celsius	6 months	It Uses Viral Vector Technology which does not contain inactivated corona virus, but a harmless different virus
Covaxin	2-8 degree Celsius	6 months	Inactivated COVID-19 vaccine technology which uses inactivated corona virus

Table 14- Technicalities of COVID-19 vaccines that are presently administered (TOI, 2021)

The two vaccines have less logistical challenges in terms of cold chain configuration and transportation of vaccines till the last mile point as they have the same temperature requirement as that of routine immunization vaccines. Despite the temperature compliance, there are challenges in vaccine administration for COVID-19 vaccination as it will be a mass campaign.

The outreach session for COVID-19 vaccines will be conducted at the last mile points especially in the vicinity of PHCs and sub centres of India and in government and private hospitals of India in urban areas and semi urban areas of India. The plans of vaccine administration will resemble an election campaign where there will be many community halls and booths which will be set up to immunize people (Hindustan Times, 2021).

There are many other vaccine candidates that could be approved in the future (Table 15). All these vaccines are mainly manufactured to be stored between 2-8 degree Celsius considering the complexity involved with other vaccine candidates like Pfizer and Moderna which could create a huge logistical challenge in India (Business Today, 2021):

Vaccine Candidate	Temperature
Zydus Cadila	2-8 degree Celsius
Biological E	2-8 degree Celsius
Novovax	2-8 degree Celsius
Sputnik V	2-8 degree Celsius

Table 15- Vaccine candidates for future administration (Business Today, 2021)

The states have a dynamic rate at which the vaccine wastages are being experienced. Multi-vial dosage of COVID-19 vaccines have a wastage limit of 10% as mandated by the Indian Government and should not exceed beyond this limit (The Federal, 2021). As of April 2021, the total amount of vaccines that are wasted is estimated to be around 4.6 million for the entire country (Business Insider, 2021). The vaccine wastage for India at present is at 23% as on April 2021 for the COVID-19 vaccines (Money control, 2021) which is highly undesirable in the COVID-19 vaccination. Also, the vials should be used within 4 hours of opening (Indian Express, 2021).

The table 16 shows the wastage rates of COVID-19 vaccines in states of India as of March 2021 (Indian Express, 2021):

State	Vaccine wastage
Tamil Nadu	3.7%
Bihar	4%
West Bengal	4.8%
Gujarat	5.3%
Assam	5.5%
Rajasthan	5.6%
Jammu and Kashmir	6.6%
Karnataka	6.9%
Uttar Pradesh	9.4%
Andhra Pradesh	11.6%
Telangana	17.6%

Table 16- Vaccine wastage rate in states of India for March 2021 (Indian Express,2021)

The wastage rate keeps changing every month as few states may decrease or tend to increase their wastage rate as this is a dynamic issue in a pandemic. The vaccine wastage rate for April 2021 is shown (Table 17) (Business Insider, 2021):

State	Vaccine Wastage
Tamil Nadu	12%
Haryana	9.4%
Punjab	8.1%
Manipur	7.8%
Telangana	7.5%

Table 17- Vaccine wastage rate for April 2021(Business Insider, 2021)

5) Case analysis

This chapter will analyse the case study by analysing challenges in supply chain activities of the immunization supply chain for COVID-19 vaccination in comparison to routine immunization supply chain. The final part of the analysis will identify the main challenges of the COVID-19 immunization supply chain and how the routine immunization is affected by COVID-19 vaccination.

5.1) Analysis of immunization supply chain in India

National EVM assessment (2018) compared different aspects of routine immunization in India as of year 2018 with target values (Figure 36):

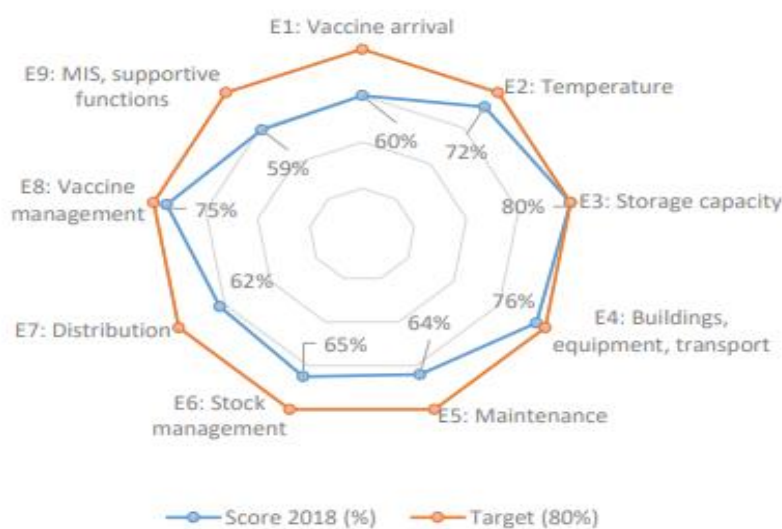


Figure 36- Statistics on routine immunization in India (National EVM assessment, 2018, p.15)

The case analysis will first analyse the performance of the routine immunization supply chain (figure 36) that will have direct impact on the COVID-19 immunization supply chain. It shows the challenges in the routine immunization supply chain of India and the need to improve many supply chain activities for immunization. In comparison to the conceptual framework in this study, these challenges shows a developing nation where many activities of the immunization supply chain will have to be rectified. This can have direct impact on the COVID-19 immunization supply chain in India as most of the parameters are below the 80% mark. Added with this complexity of the routine immunization supply chain, there are issues to be resolved for COVID-19 immunization supply chain.

We can analyse the following challenges from figure 36:

-The Management information system (MIS) and supportive function has the weakest performance among all the activities (59%) which could be problematic to maintain vaccine stock visibility across all the levels of vaccine distribution system

-Distribution and vaccine arrival is rated at 62% and 60% respectively which signifies problems in the movement of vaccines between different levels of vaccine stores of India.

-Stock management is at 65% which shows that guidelines for periodic stock taking is not followed which could lead to vaccine stock outs and maintenance of cold chain systems is rated at 64% which means that preventive maintenance is not executed on a regular basis.

-Temperature control of vaccines is at 72% which could result in wastage of vaccines to some extent. It is below 80% mark which is not beneficial for routine immunization in India.

-Vaccine management, building and equipment and storage capacity is rated better among the rest other parameters. But challenges would significant even these parameters for COVID-19 vaccination.

As we can state that performance of routine immunization supply chain is still not satisfying, there should be additional efforts to ensure that current performance and challenges do not affect on how the COVID-19 vaccination will be conducted since this comes under prioritised activity.

The wide disparity among different activities of Immunization supply chain across all the levels of VDS (Figure 37) is particularly alarming as many of these activities will have to be resolved for COVID-19 immunization supply chain. There could many bottlenecks in terms of increasing the immunization coverage for the pandemic. Many activities at different levels are very vulnerable for routine immunization supply chain (Marked in red in figure 37) such as aspects related to GMSD and the MIS and supportive function at all levels. Supply chain aspects below 80% mark needs to be improved. This analysis of routine immunization supply chain gives an understanding of how complicated it will manage COVID-19 immunization supply chain when already having many challenges in routine immunization supply chain.

Sr. No.	Global Criteria (Minimum target is 80%)	India Consolidated scores	GMSD	PVS	Sub National Stores	Lowest Delivery Stores	Service Point Stores
1	Vaccine Arrival Process	60%	80%	58%	N/A	N/A	N/A
2	Vaccine Storage Temperature	72%	41%	62%	67%	78%	78%
3	Storage Capacity	80%	57%	65%	61%	82%	94%
4	Building, Cold Chain Equipment & Transport	76%	66%	69%	66%	81%	81%
5	Maintenance & Repair	64%	37%	65%	65%	66%	65%
6	Stock Management	65%	60%	72%	66%	66%	60%
7	Distribution	62%	76%	70%	65%	68%	52%
8	Vaccine Management Practices	75%	42%	71%	70%	71%	83%
9	MIS & Supportive Functions	59%	46%	68%	59%	65%	52%

Figure 37- Performance of routine immunization across all the levels of VDS (National EVM assessment, 2018, p.18)

Needless to say, the COVID-19 vaccination has created a lot of stress for the immunization supply chain in India. The plan of continuing with the supply chain configuration is indeed a good decision given the scale of the pandemic. The ability to configure a new supply chain would have been difficult considering the sudden impact of the pandemic situation. The comparison of challenges above between the routine and the COVID-19 immunization supply chain shows the intense capacity needed for COVID-19 vaccines.

The state uses 29,000 cold chain points for immunizing around 57 million people including children and pregnant women in the routine immunization programme. Even though this programme is more than 5 decades old and has achieved creditable success, the challenges are still there to achieve full immunization coverage in most of the states due to below average performance (Figure 37).

Also in the COVID-19 immunization supply chain, the government uses the same cold chain points to vaccinate 1.3 billion people. Hence, we can infer a clear shortage of capacity which needs expansion of the current public distribution system. If the present capacity is not upgraded with the

actual requirement, it will result in delays in the vaccination process and it may take many years to reach the full coverage. Therefore, challenges are particularly high for COVID-19 immunization supply chain in each of its supply chain activities.

5.1.1) Comparison of challenges in the supply chain activities of routine and COVID-19 immunization supply chain

There are many key differences in challenges between routine and COVID-19 immunization supply chain that could be analysed from the case description

The table 18 compares the intensity of challenges in COVID-19 immunization supply chain compared to routine immunization supply chain. As routine immunization supply chain already has many challenges from figure 36 , the intensity would be greater for the COVID-19 immunization supply chain in each of its activity. This comparison is mainly done to understand the higher complexity for COVID-19 vaccination in India. Few activities in routine immunization like planning the immunization supply chain, allocation of vaccines may not be problematic as it can be seen, but it is problematic in all the activities for COVID-19 vaccination in India as it can be seen below:

Activity	Routine	COVID-19
Planning the immunization supply chain	The routine immunization is more than 50 years old and there exists time tested planning and execution. The planning was done for the routine immunization by the Ministry of health and family welfare by executing the immunization schedule of vaccines. It has fewer challenges as the time frame to chart the distribution plan is as per the standard operating procedure. However, this programme needs to keep pace with the ever-increasing child population	Since this is a new pandemic, the vaccine rollout and distribution may suffer lack of co-ordination and mismanagement due to enormous number of cases and lack of proper implementation of the distribution strategy. Forecasting exact requirement for distribution may suffer from inaccuracies. The state task forces may experience problems in managing and coordinating the distribution to all the last mile points.
Vaccine Procurement	Highly centralized procurement leaving aside states for decision making. All the procurement decisions are at the discretion of the centre	Applies the same principle for procurement as routine immunization. But there could be imbalance in supply due to high demand of vaccines for the COVID-19 vaccination.
Allocation of vaccines	The allocation of vaccines was clear as they had less volume of vaccines to be distributed with priority groups being either children or pregnant women. The quantity of vaccines under this category is comparatively less.	Allocation of vaccines will meet a lot of bottlenecks due to misjudgement about the priority groups despite clear directions from the central government. This is bound to happen in a pandemic as population of people to be vaccinated are more. Most populous states in India with low health care like Uttar Pradesh, Bihar will be the most vulnerable to plan vaccine allocation.
VDS	Weak distribution capacity noted only at last mile points across the VDS which signifies delivery challenges to the outreach areas. Distribution to the service points is only 52% while it is 62% in general (Figure 37).	Highly challenging across all the levels of VDS which could affect the distribution of COVID-19 vaccines between the vaccine stores.

Cold chain distribution	Shortage in cold chain systems in some states and deep disparity in cold chain points. Cold chain performance is at 76% which is among the best benchmark, but it is still below 80% mark (Figure 36).	Heavy imbalance could occur in the cold chain systems due to the storage of COVID-19 vaccines. There will not be enough space to accommodate all the COVID-19 vaccines in the vaccine stores.
Information sharing	eVIN system was implemented in all states very recently. Hence the IT system is still picking up pace in many states. MIS gets only 59% in total (Figure 36).	Integration of all beneficiaries in the e-portal is daunting and may not reach the rural population because of prevalence of high percentage of illiteracy and lack of internet connectivity in rural India.
Transportation of vaccines	Transport infrastructure is reasonably well oriented but there is still scope for improvement.	Last mile delivery could be challenging as many states in India is still yet to develop proper road infrastructure added with the complexity of transporting routine vaccines.
Human resources	Availability of quality health care professionals is scarce due to challenges faced in working at rural areas and there could be visible changes in urban-rural working environment	Requires Human resources with more skills and expertise to handle COVID-19 vaccines coupled with crisis handling capabilities. It is also pertinent to mention that there is visible shortage of health care staff in India for COVID-19 vaccination at present.
Vaccine Administration	Vaccine Wastages were observed in many states for routine vaccines. Also very low practises in GMSD is observed (Figure 37).	Highly challenging to conduct vaccine administration due to vast population keeping in mind the vaccine wastage rate.

Table 18- Comparison of differences in challenges between routine and COVID-19 immunization supply chain

5.1.2) Similarity and differences between routine and COVID-19 immunization supply chain

Comparing the similarities and differences between the routine and the COVID-19 immunization supply chain, many challenges for COVID-19 immunization supply chain can be identified

The table 19 lists the main similarities and differences between routine and COVID-19 immunization supply chain. The differences point out the complexity for managing the COVID-19 vaccination in India as listed below:

Activity	Similarity	Differences
Planning the immunization supply chain	Centralized planning by ministry of health and family welfare for both the immunization programme	In planning COVID-19 immunization supply chain there is involvement of many government machineries including state governments which is not the case for routine vaccines
Vaccine Procurement	For both the immunization programmes the procurement of vaccines is done on the central level. The rationing exercise for the vaccines is mandated by the national vaccine policy that gives guidelines on the procurement at the central level	In case of routine immunization there could be multiple tenders issued for the same vaccine with different manufacturers to ensure vaccines do not run out of supply. On the other hand, COVID-19 vaccines have limited suppliers and there are no options of issuing multiple tenders.
Allocation of vaccines	Clarity in priority groups	Allocation of COVID-19 vaccines are more complex than routine vaccines

VDS	Similar set up for both the vaccines	Forecasting for routine vaccines was on an annual basis while for COVID-19 vaccines forecasting is on a weekly basis at all the VDS levels. The weekly forecast of COVID-19 vaccines can be inferred as vaccination being carried out on a daily basis at all the vaccination centers
Cold chain distribution	Similar cold chain flow with the same temperature requirement for vaccines except OPV and rotovac which needs -15 to -25 degree celsius	More vastness of the cold chain for COVID-19 vaccines as there are many private/government hospitals for conducting vaccination
Information sharing	The Same IT system are used for routine and COVID-19 vaccines	An additional app is created to monitor COVID-19 vaccines
Transportation of vaccines	Outsourced activity	Even higher dependence on LSPs with enhanced capacity for COVID-19 vaccination which is otherwise impossible
Human Resources	Similar network of human resources is used	Additional capacity is required for COVID-19 vaccine administration due to large scale vaccination
Vaccine administration	Multi-vial form of dosage Vaccine wastage is observed for both the vaccines	Maximum Wastage rate for COVID-19 vaccines is lower than routine vaccines due to the reason that higher wastage rate is not desirable in a pandemic COVID-19 vaccines have lesser shelf life than routine vaccines, hence it is more prone to wastage

Table 19- Similarities and differences between routine and COVID-19 immunization supply chain

5.2) Analysis of COVID-19 immunization supply chain in comparison to theory

This section discusses key challenges in different aspects of the COVID-19 immunization supply chain and compare it with theory. Key suggestions based on theory are given for improving future immunization keeping in mind routine and COVID-19 vaccines. The aspects discussed following the conceptual framework is planning the COVID-19 immunization supply chain, vaccine procurement till the vaccine administration for COVID-19 vaccines

5.2.1) Planning the COVID-19 immunization supply chain

The key challenge for planning the COVID-19 immunization supply chain is the identification of right quantities of vaccines to be shipped which should be within the capacity of vaccine stores at various levels of the distribution system. According to COVID-19 operational guidelines (2019) the tasks forces are mandated to identify cold chain points and the necessary infrastructure. This might be a challenge to plan across the entire nation for the stakeholders. As observed, there is planning at multiple levels of the Immunization supply chain leading to coordination problems will be the biggest challenge. The hierarchy of the decision-making structure shows that it is a complicated task to manage for planning immunization supply chain at all the levels. It will be even more challenging at the district and block level where their task is to identify outreach areas and mobilize people for vaccination. One key drawback that could be inferred from the decision-making structure is that there is no involvement of private entities like the LSPs who will play a key role in the transportation of vaccines. How the communication is achieved between stakeholders and LSPs is not clear.

One positive aspect to infer is the presence of many international bodies like UNICEF, UNDP who are helping the central and state government in planning the vaccine distribution effectively. Key support from these international organizations should be utilized that will help India achieve a better distribution strategy. Without their crucial support, it would near be impossible to achieve highest level of planning. Some of the key technical support is being availed out of this partnership which is beneficial for the vaccine distribution.

Gharote et al. (2015) mentions the challenges of immunization supply chain planning that most of the stakeholders face when introduction of a new vaccine such as preparing the right cold chain requirements, mode of transportation to use, preparing schedules and the costs associated with the vaccines. The planning of COVID-19 immunization supply chain in India could be a complex task where the stated challenges needs to be well managed by the stakeholders. The planning will need proper communication between all the levels in the decision-making structure to achieve highest utility in the immunization supply chain system of India for COVID-19 vaccination. Hence in line with the theory, India will face issues with preparedness during its planning as all the levels of decision-making structure should be prepared to handle the uncertainties in COVID-19 vaccination.

Planning the COVID-19 immunization supply chain in a country like India cannot be executed in a sudden pandemic environment without understanding the topography of the regions. Unlike normal immunization where the supply chain can be streamlined as per demand to a targeted population beforehand, in a pandemic situation the population density in urban and rural areas has to be identified and vaccination distribution needs to be channelized as per the requirement. The distribution system has to take cognizance of an areas remoteness which consumes lot of time. The program initiated is optional and thus more awareness especially rural population has to be created in order to avoid erratic distribution.

Gaps identified for COVID-19 vaccination

Multiple levels of planning with lack of coordination between the states may be the biggest gap as this hinders effective information sharing between states due to a vertically integrated planning structure for COVID-19 vaccination.

Suggested way forward

The pandemic planning often takes into account a lot of issues which are related to proper implementation of a vaccine distribution strategy (Buccieri and Gaetz, 2013). Regis Hernandez et al. (2017) emphasises vertical and horizontal coordination in humanitarian logistics which stresses the importance of effective information sharing between the decision-making bodies. This should be the key for India during its planning phase. The last mile points are the most vulnerable when it comes to receiving information from the upper echelons as they function in the remotest part of India. Hence horizontal coordination in terms of information sharing between different last mile points from the same district could prove beneficial to conduct vaccination in rural India. This could prove a boon for future immunization.

Irrespective of the challenges in the multi-level decision making, vulnerable groups should be prioritized over other factors to help the nation in achieving faster response to a pandemic (Buccieri and Gaetz, 2013). Thus, India should aim to achieve higher immunization coverage based on giving priority to the vulnerable groups in its planning strategy which will help it to combat COVID-19 pandemic more quickly and help the most vulnerable population to be safe and lead a healthy life. Future immunization should also have this strategy that ensures equal access of vaccines to all the beneficiaries to protect against vaccine preventable diseases.

5.2.2) COVID-19 vaccine procurement

The central government has solely taken responsibility to handle the procurement of vaccine for all the states in the COVID-19 vaccination. This centralized way of procurement seems not beneficial during the pandemic as there are no separate procurement principles for the states. This means that the states have no option to procure vaccines creating a waiting time for the vaccines to be delivered to the states. This is the case with phase 1 and Phase 2 of the vaccination. Phase 3 of the vaccination may have many positive sides as states are given partial control for the procurement of vaccines. This will enable the states to procure vaccines by having their forecast of people to be vaccinated. This will reduce the dependency on the centre as states are made to wait to receive the vaccines in phase 1 and phase 2 of the COVID-19 vaccination.

The positive aspect of the COVID-19 vaccination in India is that the vaccines are sourced locally from the Indian suppliers which reduces the lead time of delivery to the central government. The number of vaccines that are procured may also increase in the future depending on the necessities as the population to be vaccinated is high. India is one of the largest producer and buyer of vaccines in the world as stated from the case description, this is not a surprise as procuring large volumes of vaccines would be beneficial in COVID-19 vaccination. As of now if 1.6 billion is the total amount of doses procured, the total volume of doses to be procured may go up to 3 billion or more as people will have to be vaccinated twice in a span of 3 months. This is stated keeping in mind about the safety stock and vaccine wastage.

Woodle (2000) states that procurement of high-quality vaccines have direct impact on the national health of a country. The developing nations should move towards self-sufficiency rather than depending on the funds from developed countries. From a theoretical perspective India has achieved self-sufficiency in vaccine procurement which is beneficial for the COVID-19 vaccination.

Pazirandeh (2011) discusses local sourcing and global sourcing of vaccines and states that local sourcing of vaccines is advantageous as it reduces the lead time of delivery and increases the growth of the local markets. In line with the literature, the COVID-19 vaccines are locally sourced and has increased the global market for Serum Institute of India and the indigenous producer Bharat Biotech. Also, other vaccines might be approved for use in future. The vaccines are provided at an affordable price to the government of India enabling all common to afford at least a single dose of the vaccine.

In comparison to Woodle (2000) and Pazirandeh (2011) the vaccine procurement function of India seems to well be developed in comparison to other developing nations. But there could be delays for COVID-19 vaccines in India due to high demand of vaccines in line with Lydon et al. (2017) stated for developing nations.

It is presumed that procurement of COVID-19 vaccines from the manufacturers may seem a bottleneck in India due to large volumes of vaccines to be ordered from the manufacturers. The main challenge lies in meeting the huge demand which has already put an immense burden on the manufacturer. The production of vaccines must be in direct correlation with the number of people identified for immunisation. Even though India has enough capacity to produce indigenous vaccine production as per the quantum of population, it is a herculean task to achieve. It is however not out of the stakeholders reach due to continuous government support and robust infrastructure including supply chain management. This is an advantageous position as far as India is concerned. Adversity brings out the best in a challenging situation like COVID-19 pandemic.

Identified gaps

There are many major suppliers in the vaccine market for manufacturing COVID-19 vaccines in India. As of now the government of India has sanctioned only two private sector manufacturers to produce vaccines for COVID-19 vaccination. It is expected that there may be shortfalls in production and meeting the actual requirements due to the sudden onset of the pandemic and the time gap taken for planning and initiation of clinical trials leading to vaccine manufacture. Even though the manufactures are reaching their optimum level of production, the supply of crucial vaccine may see retrograde step in view of the huge demand for vaccines. This is due to government's decision to bring more categories of people under the ambit of vaccination. This in turn is expected to put lot of strain on their production capacity and indirectly responsible for the escalation in mortality rates.

Suggested Way forward

The government of India has to prioritise the vaccine procurement function keeping in mind the huge number of identified citizens to be vaccinated. The procurement function is progressing well for the COVID-19 vaccination programme which augurs well for India and its population. It is pertinent here to mention that quality of vaccines should not be compromised in the name of achieving targeted population (Pazirandeh, 2011). This area needs to be thoroughly managed by the Indian government making no compromise on the quality of vaccines procured that could affect the lives of many individuals.

5.2.3) Allocation of COVID-19 vaccines

The most observed challenge for India in terms of allocation of COVID-19 vaccines are the inequalities in how the vaccines are supplied to the states from the centre (Table 10). Allocation is not in direct proportion to the beneficiaries in each state. Since the states have very little role in the procurement, they are mandated to receive the supplies sent from the central government. Hence this type of allocation could result in inequalities between the states where they might not get the vaccines in proportion to its population. In addition, the states will have to plan re-allocation to its respective population after receiving the vaccines. This creates a logistical challenge. We can state from the data

on allocation of vaccines that there is no mandate given by the central government in planning allocation based on the population. This is left to the discretion of the respective states after they receive vaccines. States like Maharashtra and Uttar Pradesh with larger population than Gujarat received lesser than their required quota. The most populated states receiving fewer vaccines may expose its population to the vulnerable disease. This must be immediately addressed by the stakeholders. The other complex issue noted with allocation of vaccines is the earmarked priority groups. Without accurate data of people who fall into different categories of priority groups like health care workers it becomes difficult to allocate vaccines in proportion to the population density of each priority group. This will be a challenge since India has a huge population density among different priority groups.

Phase 3 of the COVID-19 vaccination should have more equal allocation of vaccines as states will get its required doses of vaccines. This will ease the logistical burden of waiting for supply from the centre.

Duizjer et al. (2018) mentions inequalities that can occur during the allocation of vaccines. With many decision makers in the vaccine allocation process that can influence the way in which vaccines are allocated to various regions resulting in unequal allocation. This is true for India having 36 states/UTs where the vaccine allocation could have disparity. Hence, the inequalities in allocation of COVID-19 vaccines are in line with what Duijzer et al. (2018) mentions about the vaccine allocation process.

Gaps identified in allocation of vaccines for COVID-19 vaccination

Strict mandate is not enforced to allocate vaccines based on logic as shown (Table 10). Inequalities could result in unequal immunization coverage in the Indian states. This would delay the rate of curbing the COVID-19 pandemic.

Suggested Way forward

The inequalities in the allocation of vaccines needs to be curbed immediately. As Buccieri and Gaetz (2013) stresses the importance of equitable vaccine distribution strategy which is based on good allocation decisions. Hence this is important for India and all the states should be treated equally when distributing vaccines as this is good for eradicating the pandemic equally in all the states. The motto should be to eradicate this dreaded pandemic with firm conviction and resolve across India with equanimity.

As a keynote, states in India do not have equal immunization coverage, hence to improve future immunization rate, this strategy of equitable distribution should be aimed which ensures vaccine equality to all the states.

5.2.4) VDS for COVID-19 vaccines

The key challenge observed for COVID-19 vaccine distribution system is the storage capacity at all the levels of the vaccine stores with the influx of large quantities of vaccines that has never been seen before. This will be problematic at all the government run vaccine stores as well as in both the private and government hospitals as they have never stored large quantities of vaccines of this scale before. Hence the additional complexity observed for VDS of COVID-19 vaccines is the presence of innumerable private hospitals and government hospitals that receive COVID-19 vaccines. VDS should be smooth enough to supply vaccines to these points from the state-run vaccine stores which is a big logistical challenge.

India has a 5-tier vaccine distribution system that serves a vast population. The states of India also have about 3-4 tier distribution system starting from the state vaccine stores/regional vaccine stores

configured in relation to the population of each state. Starting from the GMSDs which serve as the nodal point for the entire country, there could be overload of vaccines that might create problems in accommodating all the COVID-19 vaccines. We can state that the distribution from manufacturers to GMSDs does not seem to be a bottleneck as the vaccines are manufactured indigenous in the country and delivery lead time is less. Compared to the other developing nations, most of nations do not manufacture their own vaccines creating a logistical challenge for receiving COVID-19 vaccines to other nations which is avoided in case of India (Figueroa et al., 2021).

Corroborating theory in most developing nations states that the vaccine distribution system receives its stock from the upper echelons. There is a distinction between push and pull and this transition is termed as push pull boundary (Yadav, 2015). Also, Chen et al. (2014) explicitly mentions that VDS could be either push or pull based. India's VDS also has a push pull boundary, and the transition is seen at the lower echelons at PHCs where the vaccines are pulled due to low demand and pushed from the state vaccine stores via district vaccine stores depending on the need for immunization. The GMSD is pulled only for buffer stocks as shown in the case description. But one of the drawbacks during the COVID-19 vaccination is that this mechanism may not function as smoothly as expected due to the complex nature of the situation. This structure of VDS in India should be as resilient as possible for the pandemic as all the vaccine stores are made to function at the same time due to the complexity of the situation.

Going further, there seems to be disparity in how the COVID-19 vaccines are being distributed among the lower echelons. Some states in India may not have state vaccine stores. This makes it more difficult to plan the distribution to regional stores without having a central storage access where vaccines could be dispersed in the beginning. The biggest challenge lies in distributing vaccines to the last mile points. For routine immunization the current performance is low 52% (Figure 36). This will affect the way in which the COVID-19 vaccines are distributed to last mile points. As discussed previously primary health centres are large in numbers in the immunization supply chain of India and hence more focus should be given on the distribution between district stores to primary health centres and the outreach areas in many rural areas of India. Hence, in comparison to Yadav (2015) and Chen et al. (2014), the VDS in India for COVID-19 vaccines is vertically integrated at all its levels. Therefore, this can contradict with theory since vertically integrated structure may not be very effective and there needs to be horizontal coordination between the vaccine stores on the same level that can aid in faster response to vaccinate people from the perception of the author.

Gaps identified in VDS for COVID-19 vaccination

There is no interaction between the vaccine stores on the same level, which is very much necessary during a pandemic. This could possibly result in lack of information on how the other vaccine stores are managing their vaccine stocks. Also, there could have been more transparency between the states in how they handle large quantities of vaccines in their vaccine stores.

Suggested Way Forward

As it can be seen the VDS in India is vast and managing the vaccine distribution at all the levels might be a daunting task for many stakeholders. One solution investigated (Yadav et al., 2014) is integration of this system to other health care commodity supply chains. This could be practised to enhance the efficiency of vaccine delivery. But this integration also needs the support from various stakeholders involved in Immunization supply chain in India. Considering the higher costs in COVID-19 vaccination incurred by the stakeholders, this step could prove beneficial. All the medicines/vaccines with similar cold chain requirements could be integrated to achieve higher efficiency. The crucial thing to note is on which level this integration can be achieved which could be a question for future research. Building on this recommendation, the vaccine distribution system in India could be privatized to some extent with the pharmaceutical supply chains. This would be similar to how

medicines reaches all major hospitals and clinics in India not depending solely on the public distribution system. All the major private players could help the government in conducting immunization by providing key technical and human resources support. It is a good step to increase immunization coverage in the future.

5.2.5) Cold chain distribution of COVID-19 vaccines

The most observed challenge in the cold chain flow of COVID-19 vaccines is the difficulty in maintaining the vaccine temperature all the way till the outreach areas as the scale of the vaccine to be distributed are high. The actual scale is almost 10 times higher than routine vaccines. The most difficult aspect is to maintain this cold chain from the point of origin i.e., manufacturers to the last mile point which is very challenging in this unexpected scenario.

The cold chain flow for the distribution of COVID-19 vaccines in India is bound with a lot of disparities among different states in India. This is alarming as the nation must vaccinate all the population not just children or pregnant women. According to national EVM assessment (2018) the cold chain performance of India overall stands at 76% (figure 36). As the performance across the higher levels of the vaccine distribution system is not up to the mark, it needs revamp. The challenge with the cold chain is that routine immunization already needs such a vast infrastructure, so with the influx of COVID-19 vaccines the capacity is not sufficient to handle nationwide vaccination.

The cold chain distribution of India in Figure 28 exemplifies that states are not equally upgrading the cold chain capacity. This can be compared to the cold chain infrastructure related to number of cold chain points/equipment present in states of India (Table 4 and Table 5). Some states have a better cold chain points like Maharashtra, Karnataka, Tamil nadu and Gujarat. With the present state of cold chain distribution, there are possibilities of shortage in capacity to handle bulk volumes of COVID-19 vaccines. Many states in India like Uttar Pradesh, Bihar, Chhattisgarh have less cold chain devices in proportion to its population. The densely populated states in north India will suffer the most due to inadequate cold chain systems in place.

We can state that vulnerable states in India have a clear shortage of cold chain points for routine Immunization (Table 5) that can directly affect the COVID-19 vaccination to people. Thus, it is highly challenging to vaccinate all the people of a particular state. Hence rapid expansion of CCPs is needed for COVID-19 vaccination. Else, the cold chain points may be insufficient to handle the vast population across states in India. It can be concluded that with less cold chain points, there will be rapid influx or crowding of people at the CCPs creating bottlenecks to vaccinate the people. It could also result in mismanagement of vaccination centre leading to improper immunization at CCPs. The expansion of CCPs will at least result in meeting the demand of the people to get vaccination on time.

The absence of cold chain systems lead to disruption in immunization services across many states in India for COVID-19 vaccination. The unserviceable inventories tend to occupy space leading to congestion in many vaccine stores. This must be taken care of by state and district level authorities. It is particularly important for COVID-19 vaccination as the scale of immunization is much higher and non-functioning equipment only lead to large scale disruption of vaccination in addition to wastage of large quantities of COVID-19 vaccines. Therefore, we can say that the number of challenges that lie with the cold chain systems for COVID-19 are immense especially in a country like India with a vast population. Developing nations often struggle to increase the capacity and equipment to manage a large-scale pandemic because of resource constraints affecting immunisation programme.

The problems with cold chain systems could be stated from the study by INCLIN Trust (2018) that studied cold chain of three states in India Viz. Kerala, Gujarat and Bihar. There are many important issues in the cold chain equipment including poor quality of cold chain systems and inadequate

refrigeration capacity. Temperature monitoring of the vaccines and vials were not done accurately leading to losses of vaccines. Sometimes losses exceeded more than the average limit for the routine vaccines (Mukherjee, 2021). This scenario will be highly vulnerable for COVID-19 vaccines if the cold chain systems are not adequately prepared to handle high volumes of vaccines. The options available to configure cold chain equipment are limited in case of outbreak of pandemic. This is due to lack of preventive maintenance and noncompliance of repair schedules as mentioned in De Boeck et al. (2019). This is true for India as well. The COVID-19 vaccination has made it clear that for effective immunization, the cold chain equipment and system must be in place in proper working condition. Therefore, the government of India must regulate meetings with cold chain handlers on a regular basis. This can be done on district level or in block levels as they house the maximum cold chain equipment. In pandemic like COVID-19, proper liaison should be more regular so that cold chain equipment is functioning at optimum level for successful immunization.

The present cold chain facilities spread across India caters to regular immunization programmes only and the present capacity may not be sufficient to immunize its entire population. Therefore, the current outbreak of pandemic has mandated the government to procure more cold chain equipment. On this front, proper review and inspection of all cold chain points should be carried out and resource mobilized to procure new ones in upgrading the existing capacities in all the states.

Comes et al. (2018) states that usage of solar powered cold chain equipment in developing countries will reduce a lot of power consumption and will also be cost effective. India has deployed solar powered cold chain equipment in the form of many solar refrigerators. This step is a good strategy to save power and keep the vaccines at sufficient temperature to avoid vaccine wastage. These PHCs are the last point of access for COVID-19 vaccines to many Indians in rural areas.

A high number of PHCs in India have no electricity which is an alarming number especially for the COVID-19 vaccination. State with the most predominant number of PHCs without electricity is Jharkhand followed by other states (Table 12). Hence Government should focus on providing alternative power supply to the PHCs mainly to avoid power outage to cold chain equipment leading to vaccine wastage. This aspect is important during pandemic as most of the cold chain points are located below the district level in states and most of them run out of power during critical phase.

Guillermet et al. (2017) has recommendation for horizontal distribution of vaccines between vaccine stores at the same level. This is not followed in India at present. But it can be beneficial in the future mainly with respect to malfunctioning of cold chain equipment in the lower levels of the vaccine distribution system. Hence the stakeholders should aim to achieve this horizontal coordination between states of India that can benefit the concerned beneficiaries and prevent loss of vaccines due to cold chain equipment that are not functioning due to lack of alternative power supply.

In terms of comparison to literature, the cold chain distribution of India complies with Comes et al. (2018) in having solar cold chain equipment as a sustainable way of storing vaccines. It is not in line with Guillermet et al. (2017) for the lack of horizontal distribution of vaccines. Schoub and Cameron (1996) mentions power outages in last mile points that could affect the life of vaccines, this is applicable due to power shortages in certain PHCs of India along with De Boeck et al. (2019) for lack of adequate preventive maintenance of cold chain systems in India.

Gaps identified with cold chain distribution for COVID-19 vaccines

States are not treated equally in upgrading their cold chain infrastructure which has a dire impact on COVID-19 immunization. This means that the number of cold chain devices does not match with the population of each state leading to inadequate storage capacity for COVID-19 vaccines. Looking at the government's mandate to increase the cold chain infrastructure, it is understood that all the states have dire shortage of cold chain devices for COVID-19 vaccination except few states. Confirming to

the fact that 6 states in India having maximum cold chain points, there is an urgent requirement to bring parity and offset imbalances between haves and have-nots solely on the basis of population density and exact requirement.

Suggested Way forward

It is hugely challenging to maintain cold chain systems for a huge country like India. Also, there are many PHCs without electricity that would be critical to the life of many COVID-19 vaccines. Hence one of the dimensions stated by Kristensen et al. (2017) and Lee et al. (2012) is to make the vaccines thermostable. This is from the perspective of the vaccine manufacturers. Since India has a lot of indigenous manufacturers, this step could prove useful, and it could reduce some of the inherent challenges in the cold chain systems of India for future immunization. Also, government can mandate the use of more passive devices that consumes less power as investigated by Comes et al. (2018). This could be of use in the future immunization as we can see that India has cold chain devices that mainly run-on power consumption which is creating the biggest bottleneck.

5.2.6) IT system for COVID-19 vaccines

The information sharing in the immunization supply chain of India was earlier maintained through manual system of records. All the records of vaccine stock, temperature and monitoring were maintained manually through registers. The bottlenecks in maintaining thousands of records were felt and it was decided to implement eVIN in all the states. As observed, with the implementation of this information system, it has become a boon for the COVID-19 vaccination as it would have been difficult without an integrated information system in place for monitoring all the technicalities related to vaccine stock management. But National EVM assessment (2018) reveal that only 59% of the information systems are functional (Figure 36) which conveys that they suffer glitches leading to lack of compliance of vaccine temperature monitoring. Further, in many of the eVIN points in India instances of erroneous display of vaccine stock-outs due to technical glitch have been reported which does not augur well for COVID-19 vaccine management. Hence incorrect stock outs status on the system will render the whole system malfunctioning defeating the role of E-inventory.

Yadav et al. (2014) shows that the information systems are very crucial for vaccine stock management and for monitoring product flow information. But despite the features of IT system in India, the states with recently implemented information systems could take time to obtain results, this could have an impact on COVID-19 immunization. The most inferred challenge in information systems for COVID-19 vaccination is the surge in the data of vaccine stock to the information systems for the pandemic. As the vaccine levels are higher to monitor the stock, the temperature monitoring at each juncture of the distribution network could be a challenge for the stakeholders.

The Co-WIN platform was designed specifically to keep track of the COVID-19 vaccine stock and the list of beneficiaries. The platform was integrated with the existing e-VIN platform to reap all the benefits of information systems put in place. To properly demarcate routine and COVID-19 vaccine information in the IT system could be a challenge for the stakeholders. When looking at the process flow of the IT system (Figure 31), it is hugely challenging to maintain large data bases across all the levels of VDS and challenges are even higher as many hospitals in private as well as in government are interconnected with IT network.

It can also be stated that instance of the technical glitches in the IT system could hamper the process of vaccination to the individuals at their centres. Major improvements are needed to clearly define a proper roadmap for Information systems in place as inferred from the routine immunization. Highly vulnerable are those in the last mile points where the stock management could be susceptible to data error due to fragile information system network. Since PHCs are the last point of contact for individuals to get vaccinated, more priority should be given to fix information systems in place for

effective COVID-19 vaccination in all the last mile points. To keep track of all the beneficiaries and maintain the stock accordingly will be challenging as millions are to be vaccinated in all the phases.

The states with low immunization coverage should be the focus for improving the information systems as they have poor IT systems in their PHCs due to lack of proper internet connectivity, and it is still improving as it can be observed. One major drawback due to lack of connectivity may result in non-display of correct stock position that is much essential during a pandemic. This may result either in display of excess stock or less stock obstructing smooth vaccine programme.

During the COVID-19 vaccination all the beneficiaries should be educated about the functioning of this app. This also applies to all the rural areas of India where there is a high level of vaccine hesitancy due to poor awareness and lack of knowledge about the vaccination. Hence more awareness is to be created to mobilize people for vaccination by helping them to register on the app. Sometimes they may not have the resources like mobile phones where they can go and get registered. This could be resolved by helping them register manually at the outreach areas and scheduling a time and slot for vaccination. As there are around 8.2 million outreach sessions in rural areas of India, this would be a cumbersome task for the stakeholders.

Digitalization of COVID-19 immunization supply chain will avail a lot of benefits for India's immunization programme. Due to vast repository of stakeholders, each of the entities will have independent thought processes leading to quick decision making (Hotaran, 2009). Hence taking decisions by using the common digital platform for COVID-19 immunization will help stakeholders take informed decisions that have synergy with the other stakeholders. This will improve vaccine stock management and ensure compliance of temperature required for vaccines. As we can infer, it is digitalized to some extent in the immunization supply chain of India, but there must be rapid improvements in the newly implemented states.

Hence conclusion drawn from theory on information systems for immunization is that it should be integrated at all levels of immunization supply chain (Yadav et al., 2014; Anderson et al., 2018; Zaffran et al., 2013). Currently this is in practise in India from the national stores to PHC/CHCs for monitoring the temperature and stock levels and in helping the lower echelons to be informed of stock levels adequately for immunization. But there are improvements to be made to increase the functioning of IT systems such as data visualizations for monitoring COVID-19 vaccine stocks on a dashboard as mentioned in Molemodile et al. (2017). COVID-19 vaccination will put this to test on the level of information sharing between the stakeholders. Therefore, it is a good opportunity to improve the IT systems even for future immunization drives as well. Hence the integration of the information systems are well followed in line with Yadav et al. (2014) and Zaffran et al. (2013) in all the vaccine stores of India. Also, as stated in Gralla et al. (2013) regarding numerous vaccine stock information, the stakeholders in India may find it difficult to access vaccine stock information at all levels of VDS for COVID-19 vaccination which will be disadvantageous and needs to be well managed.

Gaps identified in IT systems for COVID-19 vaccination

Presently the information dissemination through Co-WIN portal and app-based portal needs to be streamlined as there are server issues, connectivity problems encountered at each centres preventing access to factual information and data. The whole IT systems integration needs to be well organized to cater to the immunization programme. Failing with real time data collection would be a herculean task. A successful programme needs dedicated software for all stakeholders. The envisaged road map should have clear vision under an integrated software module Since the IT system for COVID-19 vaccination is an extended version of the routine immunization, there needs to be a demarcation between routine vaccines and COVID-19 vaccines.

Suggested way forward

The other unclear aspect of the IT system in India is the lack of integration with procurement and the transportation activity of the immunization supply chain. The integration is achieved at all the levels of VDS, except with the procurement and the transportation function of the immunization supply chain. Yadav et al. (2014) has a framework which is also utilized in the literature section of this study which shows how the information systems should also be integrated with various tiers of transportation that will help in better visibility of vaccine stock (Figure 16). This will create better transparency of the vaccine stock when it is with the LSPs/reefer trucks for transporting vaccines to all the distribution points. But it also has its cons with this implementation as the integration is not an easy task and there are multiple reefer trucks that ply to all the points. Later after COVID-19 vaccination to all the citizens in the country, this could be given a thought for enhanced visibility of vaccine stock as the stakeholders will have time to implement some changes.

The integration of the IT system with the procurement function may not be feasible to India as it sources vaccines from many suppliers either for routine vaccines or for COVID-19 vaccines in the future. Hence this could be difficult to achieve with multiple entities. *Serum institute of India* is a manufacturer in India which supplies multiple vaccines to India's immunization programme. Therefore, this integration could be attempted with key strategic suppliers.

5.2.7) Transportation of COVID-19 vaccines

The transportation of COVID-19 vaccines could be a significant challenge in this vaccination drive. India with a huge network of road and rail infrastructure, the logistical challenges are aplenty. The transportation for routine immunization vaccines is round the clock service each year depending on the immunization schedule and stock levels. However, this is not the case with COVID-19 vaccination as the transportation of vaccines should be quick and fast. According to an estimate by ORF (2021), the transportation of COVID-19 vaccines across India will need approximately 11,500 reefer trucks/vans. However, this is not readily available at any given time. This requires intelligent coordination among private players who will perform the transportation of vaccines on behalf of the Government of India and their role cannot be underestimated. The proactive stance of private players has benefitted the program to a large extent and utilising their services will help deliver large quantities of vaccines to all the distribution centres.

For the first time many aircraft carriers are also part of this vaccination drive hitherto not associated with routine immunisation. This could be the first transportation challenge where vaccines must be properly stored in vaccine boxes with required temperature in the cargo deck of the aircraft. The other main challenge involves packaging associated with COVID-19 vaccines in the aircrafts. Proper use of dry ice in vaccine boxes should be followed to avoid preventing loss of efficacy of vaccines. Other challenge would be in giving sufficient training to the air crew in handling the vaccine boxes with care.

Airports have played the role of transit hubs during COVID-19 vaccines shipment to the respective states as stated from the case description depending upon their handling capacity and cargo space. The bigger airports like Mumbai airport, Kolkata Airport and Delhi airport has served as some of the important cold chain corridor in the country. There should be efforts taken by the airport authorities to increase the cold chain capability in all the airports across India. It should be ensured that the ideal temperature at the airport storage is in tune with the requirement before despatching the same to the state vaccine stores. The airports may have prior experience with the cold chain distribution for Pharma products, but COVID-19 vaccination requirement may be a challenge for faster processing at the airports. Hence there are challenges with airport authorities to ensure protection of COVID-19 vaccines.

After the unloading of vaccines at airports from the manufacturers, the transportation of vaccines will solely depend on the distribution network of COVID-19 vaccines. The main challenges that we can infer in the distribution network is the allocation of vaccines equally to all the regions depending on their population for which transportation infrastructure is the key. The delivery of vaccines must be to the desired destination as per prior planning. The routine immunization did not create additional hubs for the transportation of vaccines which indicates the complexity for the COVID-19 vaccines.

As observed from the case description, currently the government of India faces lot of issues with regard to transportation of vaccines on a larger scale due to limited capacity and shortage of time. There could be other issues as well in terms of sensitisation of truck drivers regarding the cold chain of vaccines. Necessary on job training should be imparted to them on the importance of driving etiquette while ferrying vaccines and protecting the efficacy. This aspect is very important since the drivers are exposed to strenuous working hours where they will have to drive for long hours without break often involving multiple trips.

During transportation of vaccines, Setia et al. (2002) mentions instances in developing nations where the vaccines are damaged due to breakage or dropping leading to wastage. This should be given importance to prevent unexpected damages to the vaccines especially considering the road conditions in interior parts of the rural India. Handling large volumes of vaccines is not an easy task; any breakage during transport in the rural areas of India will lead to vaccine wastage.

The overall planning regarding distribution of vials by the end of 2021 may undergo many changes bringing with it more challenges. Hence, there is a need for extensive collaboration between the stakeholders from the start of transportation of vaccines right from manufacturers till the end users. The main players are the LSPs who will need to collaborate with manufacturers, airport authorities and Government officials to ensure timely delivery of vaccines. Hence, central government has sanctioned many LSPs like Snowman logistics, Kool ex limited and other important service providers for the transportation of vaccines. But as observed from case description, LSPs may have limited knowledge on how many doses of vaccines to be transported to a particular centre. The government should give directions on exact doses to be delivered that will help the LSPs in enhancing their storage capacity accordingly. This being a new concept, there are challenges faced by LSPs in upgrading their capacity in terms of having more reefer trucks and warehouses to store COVID-19 vaccines.

Bealt et al. (2016) emphasises on the importance of collaboration in a pandemic for timely delivery of the relief materials. Hence with extensive collaboration with the private players, transportation system could be enhanced. This will be important for the COVID-19 pandemic in India as addressed in the theory. As the routine immunization involves very little private participation and largely government controlled, emphasis on involvement of private stakeholders needs to be underscored for a successful COVID-19 vaccination programme.

The responsibility of transporting vaccines safely to all corners of the nation lies with the LSPs. It includes safeguarding from thefts, pilferage enroute. This can be ensured if the reefer trucks/lorries are adequately sealed before commencing their journey. The LSPs should ensure non-stop conveyance in order to reach the destination at the prescribed time. During journey, the safe custody of original invoice, lorry receipt and details of consignment should be produced by the driver to the concerned authorities if stopped for checking as is the norm on national and state highways in India. The other important aspect to consider here is the speed limitation on Indian roads together with slow toll collection booths which may hinder faster movement of vaccines. The national average on distance covered by trucks on Indian roads is around 300 kms per day which is far below the international standards. This will drastically increase vaccine wastages on account of reduced refrigeration level to the required temperature on account of above factors.

Therefore, all the truck drivers have the utmost responsibility in ensuring that vaccines reach safely without delay and on time. The capacity of the LSPs like Snowman logistics and Kool ex limited to undertake the transportation on a large scale is itself a challenge. To be able to deliver vaccines all over the country at the same time will need more capacity of cold chain systems inside the reefer vans. As there are many companies manufacturing reefer trucks with enhanced capacity in India, this step will be beneficial for all the LSPs in upgrading their transportation capacity.

The responsibility of the LSPs in transporting vaccines culminates with handing over the consignment to the Primary Health Centres who are the end users, but in many parts of rural India encountering improperly maintained rural roads is a stumbling block during this pandemic. The table 13 shows that there are states in India where PHCs might pose problems in the last mile delivery of vaccines. This will affect the COVID-19 vaccination in these PHCs where vaccines will have to be carried by foot or by motorcycle in proper conditions to conduct vaccine sessions for the common public. Kaufmann et al. (2011) and Lim et al. (2017) describes the same for the developing countries where there are inherent problems in transportation of vaccines to the last mile points. In most cases, it is carried by foot and by motorcycles to the outreach areas. Hence the prevailing conditions in certain PHCs of India would remain the same for COVID-19 vaccination.

The state of Arunachal Pradesh has the highest number of PHCs without proper accessibility due to insufficient road connectivity (Table 13). This north-eastern state is in remote corner of India with some of the places inaccessible and will have many challenges in its last mile distribution. Also, table 13 conveys the fact that last mile distribution is a problem in many northern Indian states which will be very challenging for the stakeholders. Hence the LSPs must be well prepared to handle the uncertainties in transportation of vaccines. As most part of India is rural which conveys that maintaining vaccines temperature is very critical during its transport to all the PHCs and not all the last mile points are accessible by road. Good usage of rail network will be beneficial in reaching all the rural areas of India. The vaccines could be carried in the refrigerated compartments of the train that will help in maintaining the cold chain. This is yet to be utilized by the Indian government to its full capacity. But this step will ease the burden on the LSPs to carry large volumes of vaccines. This must be given a thought for future transportation of vaccines.

In comparison to the theory e.g., (Lemmens et al., 2016; Lee et al., 2016), the challenges faced by India in its transportation sector is similar to the problems encountered in other developing nations. When it comes to the road conditions Balcik et al. (2008) mentions about bad roads and infrastructure that could hinder transportation of vaccines for each Indian state as they have challenges in its rural areas like other developing nations. Also, last mile logistics as addressed above is an inherent challenge due to lack of connectivity in India that will impact the transportation of vaccines. The COVID-19 vaccination has shown the stakeholders in India that there are urgent reforms that needs to be done to improve transportation of vaccines even for future immunization. Compared to Lemmens et al. (2016), India does not have sufficient cold chain capability in the PHCs that can affect last mile delivery of vaccines. But one of the advantages with the transportation of COVID-19 vaccines in India is that they are outsourced to LSPs which is beneficial in saving costs (Melomodile et al., 2017; Sarley et al., 2017).

Gaps identified for transportation of vaccines for COVID-19 vaccination

Indian government is not equipped with adequate transportation capacity which could delay the transportation of COVID-19 vaccines. This will put extreme pressure on the LSPs to solely manage the transportation of COVID-19 vaccines. Also, there are very few cold chain logistics providers in India like Snowman logistics, Kool ex limited etc. Hence transporting required doses of vaccines will encounter unexpected delays.

Suggested way forward

The only way forward for India in transporting vaccines to all the last mile points is coordination with LSPs irrespective of the number of cold chain providers as emphasised in Tomasini and Wassenhove (2009) and Vega and Roussat (2015). This will also enable better reach of vaccines to all the population of India in a faster span of time with less stress on the Indian government as it can focus on other related challenges.

5.2.8) Human resources for COVID-19 vaccination

The human resources for COVID-19 vaccination will form the core of vaccination drive in India. To vaccinate 1.3 billion people adequate number of health care professional are needed to be trained and managed to effectively conduct immunization in India. The routine immunization had a dearth of human resources for administering the vaccines. In addition, the challenges are now even higher for vaccinating all the population at one go during COVID-19 vaccination. Hence adequate number of health care professionals must be trained and deployed in field and an equal number should be on the reserve strength to tide over non availability of regular health care workers. It is explicitly conveyed that the number of human resources at present is strained to handle large scale vaccination for a 1.3 billion population.

Therefore, ASHA workers and ANMs who are administering vaccines to pregnant women and children are very crucial to help mitigate the COVID-19 pandemic in India. Due to the sudden impact of the pandemic, it would be difficult for them to act in emergency situations as the pandemic of this scale has never happened before.

The routine immunization sessions are conducted round the year and many children and pregnant women are vaccinated (ORF Report, 2021). The COVID-19 vaccination is designed to be a daily vaccination drive requiring more number of health professionals for deployment. The government therefore should draw an action plan to hire qualified nurses, midwives and other health care workers at urban as well as rural centres to successfully address the health issue. It should prepare budgetary provision by raising estimate of expenditure towards infrastructure, salaries and other overhead costs. The success of any program depends on the augmentation of human resources and COVID-19 programme is no exception. This is true for all the states with low health care like Bihar and Uttar Pradesh where there is dire shortage of health care staff even for routine immunization. There are other states as mentioned in the case description where skewed health care work force will generally lead to chaos and inability to handle large scale vaccination. Therefore, additional recruitment and training of health care work force is already undertaken by the Indian government, priority towards this vaccination will help in achieving higher targets of immunization.

Zaffran et al. (2013) places emphasis on human resources in the immunization supply chain as it is the most essential part of the system after the vaccines have reached the last mile points for administration. At present human resources in India is bit of a limited capacity considering the fact that COVID-19 pandemic is a sudden onset. Challenges must be met by scaling up funds to train health workers in case of pandemic and its aftereffects. This is not followed in India at present. There must be future scope for reserving additional work force to operate in emergency or pandemic.

Due to the absence of many cold chain handlers in the vaccine stores as observed from the case description, this situation is very vulnerable as insufficient manpower in the vaccine stores may cause hindrance to the COVID-19 vaccination drive. This will hinder adequate maintenance of cold chain systems which are crucial for the life of vaccines. The government should accord more attention to appoint more cold chain handlers in order to combat this pandemic effectively.

The duties of cold chain handlers involves monitoring of temperature level right from national vaccine stores till it reaches primary health centres. Cold chain equipment for COVID-19 vaccines will have to be additionally installed and maintained at all levels of VDS. This requires a qualified and experienced cold chain handler and they play an important role in VDS. There are vaccination officers at the administration site as stated from case description; this would mean training additional staff all over India to handle vaccination at the administration site. This means setting up logistics in place at administration site would be complex in terms of arranging for syringes, needles and vaccine carriers and hence it will be a difficult task for the human resources.

Kasonde and Steele (2017) states that human resources form an integral part of immunization in a country's immunization supply chain. The complex nature of immunization exercise due to explosive population in a country like India demands well trained manpower who can manage stress and anxiety in emergent situations. Dedicated human resource talent is a steppingstone for a successful immunization effort. In comparison to India, this situation is applicable as human resources are completely understaffed, over strained beyond their capacity. However, the duties are properly demarcated across all the levels of VDS like cold chain handlers for maintaining cold chain systems, immunization leaders to manage vaccine stock along with ANMs and ASHA workers for vaccine administration which is beneficial for India immunization against COVID-19.

Gaps observed in human resources for COVID-19 vaccination

Deployment of trained human resource is scarce in a country like India and the current pandemic has put the entire human resource machinery to severe scrutiny. The massive scale of vaccination has put additional burden on cold chain handlers who may find it difficult to keep pace with the requirement and may find deficiencies in their service. This needs to be revamped, since there are 29,000 CCPs to be handled by the immunization leaders and cold chain handlers at all the levels of VDS.

Suggested way forward

To improve the way immunization is conducted in developing countries, Zaffran et al. (2013) mentions about training adequate staff and human resources for immunization supply chain with adequate skills to handle new vaccines. The duties should be properly defined to handle different types of work in immunization supply chain and the work should not be overlapping in nature. It is therefore suggested that India should properly allocate work to its human resources by giving them adequate skills in their area of work to handle immunization especially in emergency situations which otherwise proves to be an exercise in futility.

5.2.9) Administration of COVID-19 vaccines

The administration of COVID-19 vaccines will need a skilled health care work force that is specifically trained to handle these new types of vaccines. The health care professionals are required to manage huge number of beneficiaries at the centres on daily basis and should be mentally and physically agile in order to overcome anxiety and psychiatric issues due to strenuous working hours. At present, all individuals above the age of 18 are covered under this drive involving around 900 million population. It is especially a daunting task as it is a two-dose vaccination drive.

Thus, the administration of COVID-19 vaccines in India will be conducted mainly at PHCs/CHCs, sub centres and in outreach sessions in the rural areas of India. It will also take place at Private hospitals and Government hospitals in urban and semi urban areas. The administration of COVID-19 vaccines in India will have substantial challenges in order to educate and address the issue of vaccine hesitancy among the common masses of urban and rural areas in India. This is attributable to one or two stray cases of vaccine reaction in some patients which were rather due to other medical history than on the vaccine itself. The general fear and anxiety associated with any new vaccine and

pessimistic tendencies associated with humans in general are to be addressed on war footing. The rural masses have to be taken into confidence by establishing effective communication and general awareness campaign that should be conducted in view of their low literacy rate. This is the total responsibility of the respective outsourced agency in all rural areas of India. The Indian sub-continent consists of majority rural parts and therefore administering a mass immunisation camp is a huge responsibility for all stakeholders.

The two vaccines that are launched at present in India may seem to be easy to administer because of the required temperature as compared to other globally used vaccines in the picture like Pfizer and Moderna. The challenges with these vaccines are high as it needs much lower temperature and may be a logistical issue that could hinder vaccination drive in India.

Further, the outreach sessions for COVID-19 vaccines will be conducted in a similar way at the vicinity of the rural PHCs, sub centres of India like the regular immunization sessions where rural people are concentrated. The outreach sessions in urban and semi urban areas will be organised through camps which are organized by the hospitals in collaboration with local authorities. Due to paucity of proper ventilated rooms in PHCs, the drive is being conducted in government schools, private institutions, and community halls by prior intimation through local newspapers and mobile based apps. This is more akin to conducting general elections where the entire apparatus is used to tide over space constraints. The arrangement of infrastructure and other paraphernalia have to be organised methodically for successful vaccination.

In rural areas especially in the interior parts of the nation, vaccines will have to be carried by the health workers to the session sites by maintaining the integrity of vaccines all throughout as detailed in COVID-19 operational guidelines (2019). As we can observe, this will have to be repeated many times in stark contrast to routine immunization. Hence challenges are more for the health care workers to be as efficient as possible in carrying vaccines and administering them at the session sites.

The future does look assuring, and it is presumed that more vaccines are likely to be launched and administered to people as shown in the case description. However, it may complicate the planning and forecast in case multiple vaccines are launched in future. People may prefer to get different vaccine jabs as an individual preference. Hence, vaccination in outreach areas should be logistically prepared to store and handle all types of vaccines.

The other logistical issue of vaccine administration are the wastages encountered while conducting drive. The states in India have already started to experience this wastage rate which needs to be curbed in order to avoid overhead costs and increase its utility.

The wastage rate is specific to COVID-19 vaccines. The alarming rate at which it is progressing needs to be curbed immediately to reduce wastage that might affect the immunization drive. The states with higher than 10% wastage rate needs to immediately take precautions to reduce unnecessary wastage of COVID-19 vaccines as it is detrimental to its immunization drive. It is explicitly conveyed that states with higher wastage rate are either not forecasting the vaccine sessions accurately or the vials are opened without proper mandate. Since handling of COVID-19 vaccines are different from routine vaccines, human resources at the vaccination centre may find it difficult to minimise the wastage rate as they are handling the COVID-19 vaccines for the first time.

Drain et al. (2003) states that vaccine wastages are common in any developing nations as they might have complexities in handling the vaccines during vaccine administration. The COVID-19 operational guidelines (2019) has listed a number for recommendations for reducing the wastage like issuing vaccines based on the beneficiary list and usage of vaccine vials with oldest manufacturing date and the stock should be exhausted as per First-in First-out method. Despite the guidelines many states have experienced wastages at a much higher rate. This needs to be addressed by training the

vaccine administrators on the details of how to use vaccines once it is opened. The multi-vial dosage of vaccines is prone to wastage rate higher than single vial vaccines (Dhamodharan et al., 2011) and hence addressing this issue will be a challenge for India's immunization against COVID-19.

As far as India is concerned, wastage may be due to improper planning on the vaccine sessions where no head count is taken on the number of people. Even though people have to register and obtain confirmation number via internet or mobile apps (Co-WIN), it could be stated that people do not turn up at the centres in spite of having registered for a particular day and session resulting in miscalculation of exact vials required for administration. The other disadvantage noted with the COVID-19 vaccines is that they must be used within 4 hours of opening or else the vials gets wasted. With a vast population like India this issue has to be addressed seriously, hence without proper mandate and planning this wastage of vaccines cannot be controlled.

The vaccine wastage for COVID-19 vaccination in India has similarity in comparison to the literature multi-vial policy for vaccines is commonly advocated as the reason for vaccine wastages in many developing countries (Assi et al., 2011; Yang et al., 2014). The wastage rate is not healthy for country's immunization drive especially during a pandemic as it increases the overall costs and ultimately its purchase price.

The vaccine administration in India is similar to what literature mentioned with respect to developing nations. The outreach sessions are conducted in a similar way across the other developing nations by health care workers who carry the vaccines in vaccine carriers by foot or in motorcycles to reach people and carry out immunization (Van den ent et al., 2017; Lemmens et al., 2016). The literature also addressed the intensity of the session sites which depends on the population of people present in the region (Lemmens et al.,2016). This indeed holds good for India as there are challenges in equitable allocation of vaccines to all the outreach sessions depending on the population of each rural area. This will be a challenge for the stakeholders to ensure equity in vaccine distribution for COVID-19 vaccination to all government hospitals, private hospitals, and outreach areas. Further, the vaccine wastage for India is in line with Assi et al. (2011) where multi vial wastage is observed for COVID-19 vaccines.

Gaps identified in COVID-19 vaccine administration

Lack of planning the vaccine sessions is the significant gap in the vaccine administration. This is possibly because people do register on the apps, but due to misinformation about vaccine, efficacy and its side effects they prefer not to take the vaccines. Therefore, many people do not turn up to the session sites leading to multivial wastage of vaccines.

Suggested Way Forward

The outreach sessions in India are vast with a huge network which operates all over the country. Lemmens et al. (2016) recommends good allocation decisions to be made to the outreach areas so that vaccines are not wasted, and they are administered in line with the population. Similarly, this allocation rule is based on the intensity of outreach sessions that should be formulated in India as it will prove beneficial to administer vaccines in line with the population of each outreach area. It will also help in reducing vaccine wastage which is undesirable for the vaccination programme. But this is a complicated task to implement in India's immunization programme. Vaccine vials in the session sites could be opened after all the registered beneficiaries have turned up for vaccination instead of opening with just few beneficiaries present at the session site. This should also be practised in all the urban vaccine administration sites.

The other suggestion from the theory is the manufacturing of vial size of the vaccines in proportion to the session site under administration (Assi et al., 2011). This practically means to fill the vaccines

with required doses just to administer it to the registered beneficiaries. Here stakeholders should manually design the doses of vaccines. This could be a good step in reducing wastage of vaccines at the session sites. But it requires accurate forecast and thorough planning from the manufacturers end. Considering the intensity of COVID-19 vaccination in India, this could be quite hard to implement in this strenuous situation but could be advocated for future immunization.

5.3) Summary of challenges in COVID-19 immunization supply chain of India from the analysis

This section pinpoints key challenges in the COVID-19 immunization supply chain of India in comparison to what is observed for other developing nations in its immunization supply chain based on the theory referred in this study

The table 20 summarises the challenges in COVID-19 immunization supply chain of India in each of the supply chain activities. There are challenges in all the immunization supply chain activities for COVID-19 vaccination:

COVID-19 immunization supply chain of India	Challenges in supply chain activities identified from the analysis
Planning the immunization supply chain	Vertically integrated multi-level decision making structure Deals with complex supply chain mechanism comprising of 29,0000 cold chain points
Vaccine procurement	Strained capacity of the manufacturers leading to delays in procurement
Allocation of vaccines	Inequalities in the allocation of COVID-19 vaccines due to improper decision making
Vaccine distribution system	Uncertainty in demand and supply across all the levels of VDS as there are larger volumes of COVID-19 vaccines to be stored in all vaccine stores
Cold chain distribution	Shortage in cold chain points in many states of India Lack of power supply in many PHCs of India
Information sharing	Regular technical glitches of the app
Transportation of vaccines	Lack of sufficient cold chain trucks to manage transportation of COVID-19 vaccines Last mile delivery problems due to lack of connectivity at rural PHCs
Human resources	Shortage of staff in all levels of VDS including cold chain handlers along with ASHA workers and ANMs
Vaccine administration	Vaccine outreach is a challenge in rural and urban areas as there are large quantities of vaccines to be administered Multi-vial wastage of COVID-19 vaccines

Table 20- Challenges in COVID-19 immunization supply chain of India

The summary of challenges for COVID-19 immunization supply chain in India clearly shows the similarities it has with the theory in terms of challenges that a developing nation may face in its immunization supply chain. There are however some supply chain activities that seem to be better developed in comparison to other developing nations. The vaccine procurement is one such activity that may be more advanced than what other developing nations have. Also, IT system for vaccine stock management is well integrated at all the levels of VDS in its vaccine stores which is not the case with other developing nations as mentioned in the theory. The remaining activities resemble the challenges as stated in theory for immunization supply chain in developing countries. Some challenges identified in the table 20 can also be categorized as the risks of COVID-19 immunization supply chain of India and can hinder effective vaccination of people. With reference to Sudarmin and Ardi (2020), risk identification is done and the following challenges could be categorized as risks in the COVID-19 vaccine supply chain

-Limited supplier availability and complicated governance process as upstream risk

-Limited cold chain, transportation and human resource capacity and improper planning of vaccine administration as downstream risks

Hence, we can conclude that there are many challenges that lie ahead for India as a developing nation to achieve higher immunization coverage for COVID-19 keeping in mind the routine immunization programme that is already strained due to COVID-19 vaccination. With the help of these challenges stated above, issues will have to be resolved at a steady pace that will also help India in its future immunization programme. Due to the vastness of the immunization supply chain system, the challenges may take many years to subside.

Therefore, it can be said that challenges posed by the immunization drive for COVID-19 vaccination should be in tandem with regular immunization without any deviating approach as both were concerned with health issues. Further, the challenges may crop up in the initial stage or in between or may be encountered at the vaccination stage. But it should be foreseen, and remedial measures must be put in place for professionally addressing the whole drive. The entire system needs to be integrated and no system should give rise to knee jerk reaction to an unforeseen circumstance. This can go a long way for India to organize a better immunization programme. Having said that, the challenge may remain unaddressed in spite of better planning due to vast area of network, sudden climatic conditions, natural calamities etc. However, the focus should be on achieving full immunization in the near future which may be a step to become a self-sufficient nation that will enable its citizens to be protected against vaccine preventable diseases. Along with the challenges there are few complexities noted with the COVID-19 immunization supply chain of India that has disrupted the routine immunization programme of India.

5.4) Disruptions in the routine immunization during the COVID-19 vaccination

The COVID-19 vaccination in India has not only led to increase in the complexity of the immunization supply chain, but also disruptions in the routine immunization that targets the children and pregnant women. Due to the impact of the pandemic, the regular way of conducting the immunization like door-to-door campaign, setting up camps for vaccinating children has been disrupted leading to lack of vaccination given to the children against vaccine preventable diseases. There are instances which conveys that more than 100,000 to 200,000 children have missed their opportunities to get vaccinated with BCG and other pentavalent vaccines in India (Shet et al.,2021).

There are many barriers that can be observed in the terms of lack of health care work force and low availability of supplies (Routine vaccines) from the manufacturers that could be one reason where the vaccination coverage might have been disrupted. The other reasons could also be due to the lack of transportation capacity which is dominated by the COVID-19 vaccines in India at present.

Therefore, the main reasoning is that balancing both the routine immunization and COVID-19 vaccination is a trade-off as the present capacity to manage both the services is not adequate in India. This will significantly affect the immunization coverage among children and pregnant women. Hence the immunization supply chain in India should be configured to handle surge in the capacity which is ultimately missing.

5.5) Increase in complexity of vaccine distribution network

The vaccine distribution network of COVID-19 vaccines in India has led to increase in complexity from the previous routine immunization distribution network. The increase in complexity could be related to increase in the total supply chain costs of the immunization supply chain which can be described in the following ways:

- Increase in the inventory of COVID-19 vaccines
- Increase in the number of cold chain facilities
- Increase in the transportation costs

Therefore, we can conclude that the overall logistical costs of the distribution network has increased due to the influx of COVID-19 vaccination. The increase in costs will have impact on states with poor economy due to additional burden of providing vaccines to its citizens for free. Business today (2021) mentions that the total costs incurred for Phase 1 that could have been incurred by the Indian government is at 140 billion INR. The World bank is also funding some part of the expenses for India. The biggest help for a 1.3 billion population is take help of the COVAX initiative by WHO to fund vaccination to poorer states in India. Also by taking help of private partners who can outsource some key distribution activities will have to be advocated rather than relying only on public distribution system of India. Public Private partnership could be the key for achieving higher immunization for future immunization programmes in India.

6) Conclusion and contribution

This section will summarise on how the study answered the research question along with the theoretical and practical contribution of this study for future research

6.1) How is the research question answered

The overall aim of this thesis was to find the challenges for COVID-19 immunization supply chain of India in comparison to routine immunization supply chain. Aligned with this aim, the research question was proposed for the study. The RQ of this study is “*What are the challenges in India’s COVID-19 immunization supply chain in comparison to routine immunization supply chain of India ?*”

This research question was answered by identifying the relevant theoretical frameworks related to immunization supply chain in developing countries. A conceptual framework was developed which included all the immunization supply chain activities and its challenges for COVID-19 vaccination in India. The analysis was done by studying the existing routine immunization supply chain of India and then finding what are the areas requiring improvement. Applying the same framework and also by making reference to various articles pertaining to COVID-19 vaccine distribution in India, challenges were described for different immunization supply chain activities. Suggestions were also given for each of the supply chain activities of the immunization supply chain based on theory which could be a basis for future immunization. Based on this discussion we also identified challenges as risks in the COVID-19 immunization supply chain. As a conclusion disruption in the routine immunization was mentioned along with the complexity of the distribution network for COVID-19 vaccines.

The main finding of the study was that there exists challenges in all studied activities of India’s immunization supply chain from procurement, cold chain distribution to administration of COVID-19 vaccines that needs to be well addressed to be able to increase the immunization coverage in future. One important aspect is the vertically integrated immunization supply chain that is not as effective as it should be in a pandemic environment. It should also be horizontally integrated between the vaccine stores on the same hierarchy for making the structure intact during an emergency. The challenges in all the activities indicate that the immunization supply chain of India was not prepared for a large scale pandemic. This needs to be considered to effectively mitigate all the challenges for future pandemics.

The challenges that India is facing is similar to other developing nations which face problems in the immunization supply chain. De Boeck et al. (2019) and Duizjer et al. (2018) mention all the key areas of immunization supply chain where the finding of this study could be tested. The only difference is the vaccine procurement and information systems that are well developed for India in comparison to other developing nations

The figure 38 summarises the main challenges for COVID-19 immunization supply of India for all the activities. It shows the topics reviewed in the literature section of this study and the challenges in each of the activity for COVID-19 vaccination:

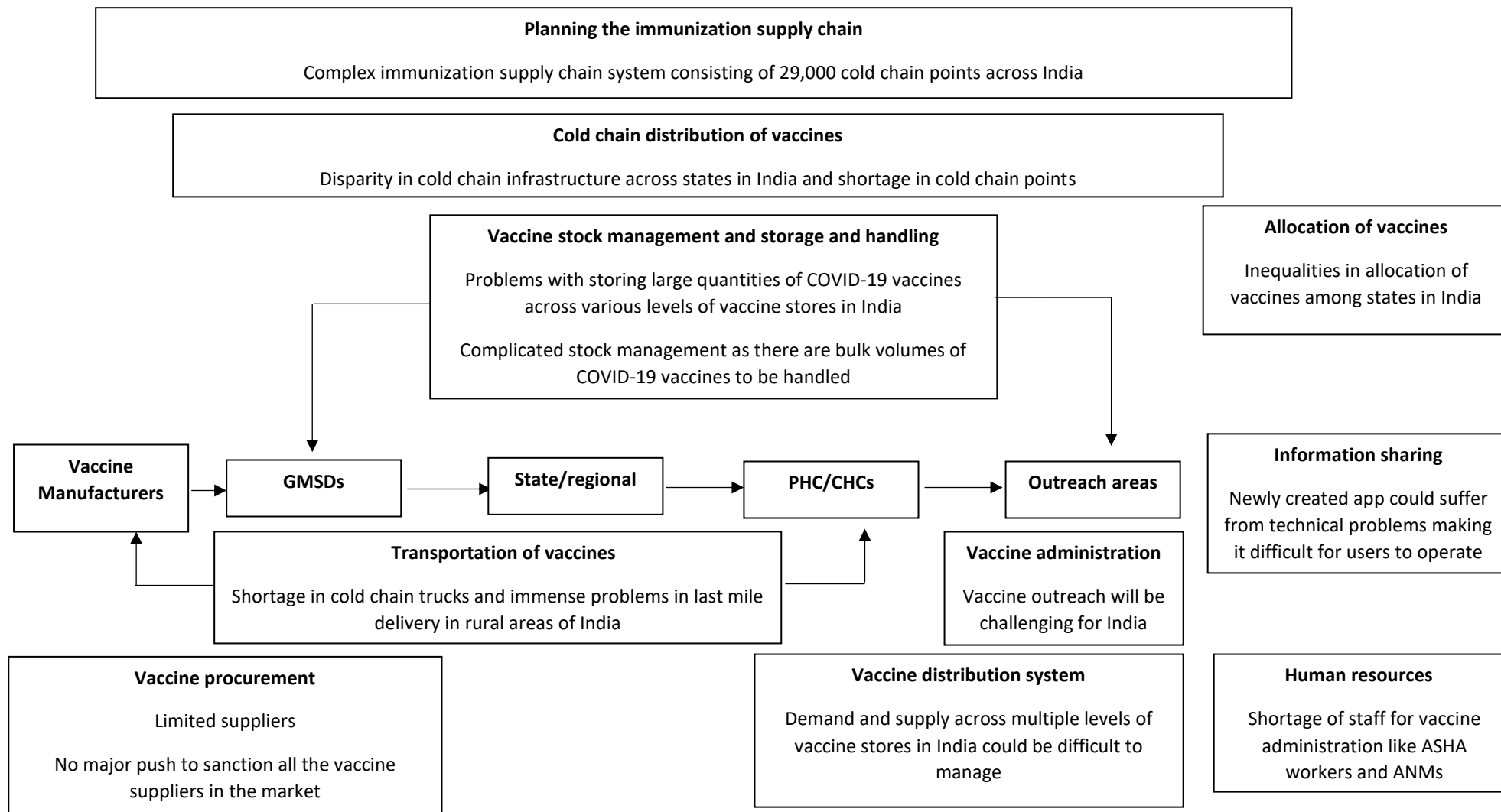


Figure 38- Challenges in COVID-19 immunization supply chain of India

6.2) Theoretical Contribution

The topic of research is as new as COVID-19 vaccination which is still an issue to be solved by most world countries. The study discussed much theory that is relevant to the immunization supply chain in a developing country in general and its applicability to India in particular. Therefore, the findings from this study and research can be applied to any middle income country which faces challenges in COVID-19 immunization supply chain. This could pave way for future researchers to explore in detail the immunization supply chain theory for developing countries across the world. The challenges described theoretically in this study such as shortages in cold chain, lack of sufficient vaccine storage capacity, human resource constraints and lack of proper IT systems would help other research in this field for future immunization programs. The study also provided details of compiled data regarding COVID-19 immunization supply chain in India which will help a reader to understand the overall complexity in the COVID-19 immunization supply chain management.

With the general understanding of key research papers in vaccine distribution like Comes et al. (2019) and Lemmens et al. (2016) and other papers identified in the literature section, the challenges in vaccine distribution can be identified and this approach will be of help to the future researchers. The study did not reveal any new challenges in COVID-19 immunization supply chain of India as it was the confirmation of the old ones stated in the literature.

6.3) Practical Contribution

The study will help the stakeholders to understand the main challenges in COVID-19 immunization supply chain and areas requiring attention for overall improvement. The identified challenges faced may be of some help for the stakeholders in India to tide over the shortcomings and ways and means to improve during the COVID-19 vaccination. Unless efforts are put at each stage of the vaccination drive, the challenges cannot be met with success. There could be downward trend in India's immunization program in future. But since it is a pandemic, it could take time to implement considering the vastness of India's immunization program and at present it looks like India is on the way to achieve its desired goal.

6.4) Limitations

The data collected is limited to journals, newspapers and web-based information network and other sources. The facts and figures enumerated as data would vouch for its veracity and correctness, it can also be a handy guide for future research programme in the same area of activity. However, this may not be equivalent to study carried out involving primary data for COVID-19 vaccination in India, which could have had more practical insight into the challenges faced by India in this vaccination drive.

The secondary data in this research are mainly obtained from the news articles, journals websites and government publications that formed the foundation of the source for this study and gave an insight into the challenges faced by states in India in general. This study could not describe the challenges in detail pertaining to each state as the data available was limited and not exhaustive to answer the research question. The study is explorative in nature, in as much the same is confined to general information and for understanding purpose only. The accuracy of the data, information and literature appended here is certified for its authenticity as it was collected by the author with utmost care and dedication.

6.5) Future research

Any immunization/vaccination-based research that considers various topics and subjects as a groundwork for this study are anything but complex in nature. This kind of study is limited in a vast country like India. It is due to several factors considering the federal structure of the government

where there is divergent views on policy decisions across states in India which often overrides issues concerning society at large. With the influx of COVID-19 vaccination, this aspect needs to be researched more to understand the implications of pandemic and how the immunization supply chain in India can be focussed to alleviate the ill effects of pandemic. The current research provided one such foundation that will help future researchers to carry forward the conclusions drawn from this study. Since the study may seem generic in nature, future researchers should adopt both primary as well as secondary data to study the implications of COVID-19 vaccination and define how the immunization supply chain in India could be configured to arrive at a defined goal.

The study also proposes the following questions that could be relevant for future research:

- 1) How can the vaccine distribution system be integrated with other medical and health care products in the public distribution system of India?
- 2) What are the main benefits of public-private partnerships in the immunization supply chain of India?
- 3) How can cold chain infrastructure be upgraded to handle future pandemics in India?

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Appendix

1) National Immunization schedule for routine Immunization from INCLIN TRUST (2018)

Vaccine	When to give	Dose	Route	Site
For Pregnant Women				
TT-1	Early in pregnancy	0.5 ml	IM	Upper arm
TT-2	4 weeks after TT-1*	0.5 ml	IM	Upper arm
TT- Booster	If received 2 TT doses in a pregnancy within the last 3 years	0.5 ml	IM	Upper arm
For Infants				
BCG	At birth or as early as possible till one year of age	0.1 ml (0.05 ml until 1 month of age)	ID	Left upper arm
Hep B Birth Dose	At birth or as early as possible within 24 hours	0.5 ml	IM	Antero-lateral side of mid-thigh
OPV-0	At birth or as early as possible within the first 15 days	2 drops	Oral	Oral
OPV 1,2 & 3	At 6 weeks, 10 weeks & 14 weeks	2 drops	Oral	Oral
DPT 1,2 & 3 [†]		0.5 ml	IM	Antero-lateral side of mid-thigh
Hep B 1,2 & 3		0.5 ml	IM	Antero-lateral side of mid-thigh
Hib 1,2 & 3 [†]		0.5 ml	IM	Antero-lateral side of mid-thigh
Measles 1 st Dose	9 completed months-12 months (give up to 5 years if not received at 9-12 months age)	0.5 ml	SC	Right upper arm
Vit A 1 st Dose	At 9 months with measles	1 ml (1 Lakh IU)	Oral	Oral
JE 1 st Dose **	9 completed months	0.5 ml	SC	Left upper arm
For Children and Adolescents				
DPT Booster	16-24 months	0.5 ml	IM	Antero-lateral side of mid-thigh
OPV Booster		2 drops	Oral	Oral
JE 2 nd Dose (with DPT/OPV Booster)		0.5 ml	SC	Left upper arm
Measles 2 nd Dose		0.5 ml	SC	Right upper arm
Vit A**** (2nd to 9th dose)	16 months with DPT/OPV booster then, one dose every 6 months up to the age of 5 years	2 ml (2 lakh IU)	Oral	Oral
DPT Booster 2	5-7 years	0.5 ml.	IM	Upper Arm
TT	10 years & 16 years	0.5 ml	IM	Upper Arm

* Give TT-2 or Booster doses before 36 weeks of pregnancy. However, give these even if more than 36 weeks have passed. Give TT to a woman in labor, if she has not previously received TT.

** JE Vaccine (SA 14-14-2) is given in select endemic districts after the campaign is over in that district.

**** The 2nd to 9th doses of Vitamin A can be administered to children 1-5 years old during biannual rounds, in collaboration with ICDS.

[†] In select states, DPT (1,2,3) and HepB (1,2,3) vaccines at 6, 10 and 14 weeks has been replaced with DPT-HepB-Hib (Pentavalent) vaccine. It is expected to be expanded countrywide soon.

2) Technical specifications of the cold chain equipment from Immunization handbook (2017)

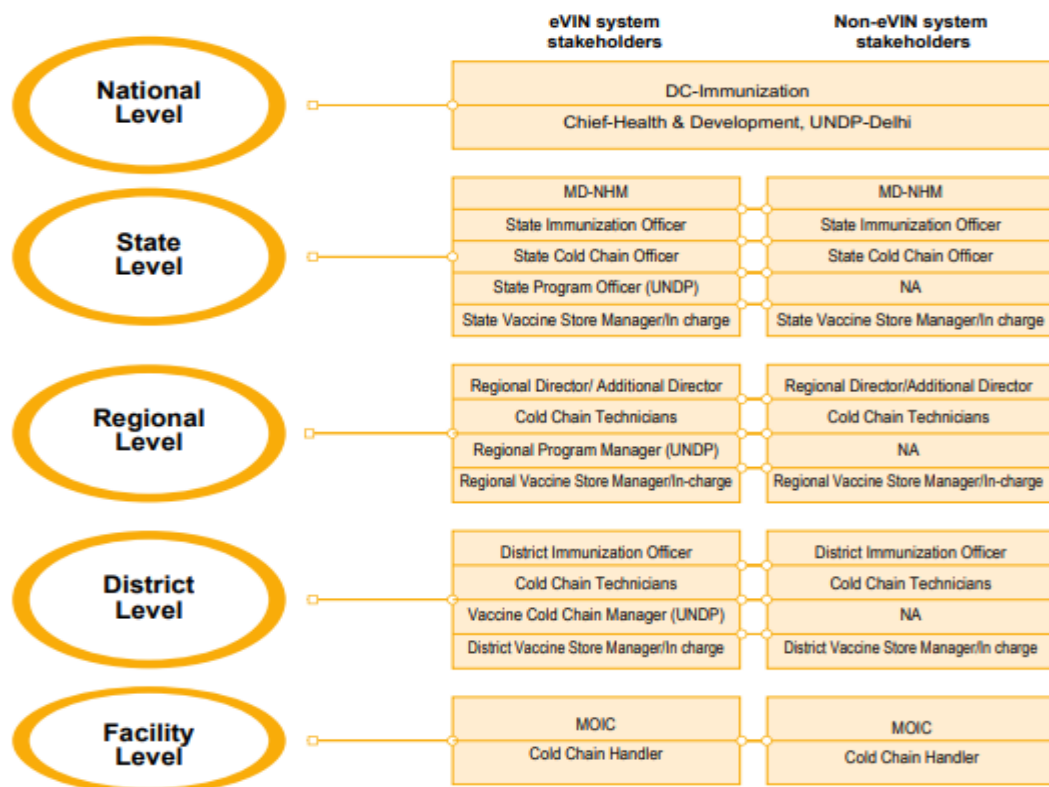
Equipment	Temperature	Storage Capacity	Holdover time
Electrical			
Deep Freezer (Large)	-15°C to -25°C	Ice packs or OPV stock for 3 months (275 to 300 Litres)	At 43°C for 2 hrs 30 mins (minimum)
ILR (Large)	+2°C to +8°C	BCG, OPV, IPV, RVV, DPT, TT, Measles/ MR, Hep-B , Penta, IPV, Vaccine stock for 3 months (135 to 160 litres)	At 43°C for 20 hrs (minimum)
Deep Freezer (Small)	-15°C to -25°C	Ice packs (105 to 125 litres)	At 43°C for 2 hrs 30 mins (minimum)
ILR (Small)	+2°C to +8°C	BCG, OPV, IPV, RVV, DPT, TT, Measles/ MR, Hep-B vaccine stocks for one month (90-105 litres)	At 43°C for 20 hrs (minimum)
Non-electrical			
Cold Box (Large)	+2°C to +8°C	All vaccines stored for transport or in case of power failure (20 to 25 litres)	At 43°C for 96 hrs (minimum)
Cold Box (Small)	+2°C to +8°C	All vaccines stored for transport or in case of power failure. (5 to 8 litres)	At 43°C for 48 hrs (minimum)
Vaccine carrier (1.7 litres)	+2°C to +8°C	All vaccines carried for 12 hours (4 conditioned Ice packs & 16-20 vials)	At 43°C for 36 Hrs (minimum)

3) Recommended storage temperature of routine vaccines from INCLIN TRUST (2018)

WHO Norm	Vaccine	Primary	Intermediate			Health Centers (CHC/PHC/UHC)
		GMSD	State	Division	District	
UIP Vaccines	OPV	(-15°C to -25°C)				+2°C to +8°C
	BCG	+2°C to +8°C				
	JE					
	HepB					
	DPT					
	DPT-Hib-HBV (Pentavalent Liquid)					
	TT					
	Measles					
Additional Vaccines	MMR	+2°C to +8°C				
	MR					
	IPV					
	PCV					
	Rotateq (RV-5)					
	Rotarix (RV-1)	(-15°C to -25°C)				
ROTAVAC (116E)						

Diluents vials must NEVER be frozen. If the manufacturer supplies a freeze-dried vaccine packed with its diluents, ALWAYS store the product at between +2°C to +8°C. If space permits, diluents supplied separately from vaccines may safely be stored in the cold chain between +2°C to +8°C.

4) Cold chain handlers at all the levels of VDS from National eVIN report (2018)



Note- eVIN is implemented in all states, hence human resources in non eVIN may be integrated

5) Shelf life of routine vaccines from INCLIN TRUST (2018)

Vaccine	Doses per Vial	Manufacturer	Shelf Life (Months)	
			+2 to +8 ^o C	-20 ^o C
UIP Vaccines				
OPV	20	Serum Institute of India Ltd	6	24
BCG	10	Serum Institute of India Ltd	24	
Measles	5	Serum Institute of India Ltd	24	
DPT	10	Serum Institute of India Ltd	24	
Hep B	10	Serum Institute of India Ltd	36	
TT	10	Serum Institute of India Ltd	36	
Pentavalent	10	Serum Institute of India Ltd	24	
JE	5	Chengdu Institute of Biological Products Co. Ltd	18	
Additional Vaccines				
IPV	10	Sanofi Pasteur	36	
Rotarix	1	GlaxoSmithKline, Belgium	36	
Rotateq	1	Merck Sharp and Dohme Corp, USA	24	
Rotavac	1	Bharat Biotec	6	24
MMR	10	Serum Institute of India Ltd	24	
MR	10	Serum Institute of India Ltd	24	
Typhoid	20	Sanofi Pasteur	36	
Pneumococcal	1	Wyeth, USA	24	

6) COVID-19 Vaccines manufactured in India by COVID-19 Operational guidelines (2019)

S. No	Product	Indian Manufacturer	Collaborator	Current stage
1	Covishield (Chimpanzee Adenovirus)	Serum Institute of India, Pune	Astra Zeneca	Phase II/III
2	Covaxin (Inactivated Virus)	Bharat Biotech International Ltd, Hyderabad	Indian Council of Medical Research, India	Phase III (advanced)
3	ZyCoV-D (DNA vaccine)	Cadila Healthcare Ltd, Ahmedabad (Zydus Cadila)	Dept of Biotechnology, India	Phase II (advanced)
4	Sputnik V (Human Adenovirus vaccine)	Trialed and manufactured in India by Dr. Reddy Lab.	Gamaleya National Center, Russia	Phase-II over, Phase-III to start
5	NVX-CoV2373 (Protein Subunit)	Serum Institute of India, Pune	Novavax	Ph III under consideration in India
6	Recombinant Protein Antigen based vaccine	Biological E Ltd, Hyderabad	MIT, USA	Phase I plus II human clinical trials started
7	HGCO 19 (mRNA based vaccine)	Genova, Pune	HDT, USA	Pre clinical animal studies over.
8	Inactivated rabies vector platform	Bharat Biotech International Ltd, Hyderabad	Thomas Jefferson University, USA	Pre-clinical (Advanced)
9	Vesiculo Vax Platform	Aurobindo Pharma Ltd, Hyderabad	Aurovaccine, USA	Pre-clinical (Advanced)

Note- Covishield and Covaxin is already in use