PROJECT REPORT

A STUDY ON COVID-19 VACCINE COLD CHAIN STORAGE, TECHNOLOGY AND DISTRIBUTION IN INDIA

PROJECT REPORT SUBMITTED IN THE PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE AWARD OF

MASTER OF BUSINESS ADMINISTRATION

INTERNATIONAL TRANSPORTATION AND LOGISTICS MANAGEMENT

SUBMITTED BY

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UNDER THE SUPERVISION OF

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DECLARATION

I ALFRED MANUEL HEREBY DECLARE THAT THE PROJECT REPORT TITLED "A STUDY ON COVID 19 VACCINE COLD CHAIN STORAGE, TECHNOLOGY AND DISTRIBUTION IN INDIA" IS A BONAFIED RECORD OF WORK DONE BY ME UNDER THE GUIDANCE AND SUPERVISION OF DR JAYAN P A, HEAD OF THE DEPARTMENT, SCHOOL OF MARITIME MANAGEMENT, INDIAN MARITIME UNIVERSITY, KOCHI CAMPUS.THIS REPORT NEITHER IN FULL OR PART HAVE BEEN SUBMITTED FOR AWARD OF ANY DEGREE OF EITHER THIS UNIVERSITY OR ANY OTHER UNIVERSITY

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CERTIFICATE

This is to certify that, this project titled "A STUDY ON COVID-19 VACCINE COLD CHAIN STORAGE, TECHNOLOGY AND DISTRIBUTION IN INDIA" submitted to School of Maritime Management, Indian Maritime University, Cochin Campus by "ALFRED MANUEL" for the partial fulfilment of the requirements for the award of the degree of MASTER OF BUSINESS ADMINISTRATION IN INTERNATIONAL TRANSPORTATION AND LOGISTICS MANAGEMENT is a BONAFIDE record of work carried out by 'his/her' under my guidance.

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EXECUTIVE SUMMARY

The covid -19 pandemic has effected the world in its every sphere. People where restricted from their daily routine. The fear of death , the loss of live of dear ones and lack of ability to contain the spread made the situation even worse. It has also lead the world trade to the worst phase it has ever experienced in the history of mankind. The effects of the virus are far reaching. Some of the nations have not even moved from the problems caused by the virus. In India for example the GDP has contracted by 7.3% in 2020- 21.

The only way to fully survive from this situation is to bring the life of the people to the normal ways , which could be done only through the mass vaccination program throughout the country.

The procedure required to follow in the development of vaccine is actually very lengthy process. The protocol need to follow in vaccine development is subjected to varies restrictions imposed by the government. But in the case of covid vaccine, because of its necessity , the vaccine companies were able to bypass these lengthy process to make the way for the vaccine into the market. The vaccine production companies where able to get financial support from the government in its development and manufacturing stage. But one of the main problem initial lies in it , was the need for large cold chain network in order to support its distribution actives.

Since a number of vaccines have been developed around the world , which requires a specific temperature to be maintained ,while it is in storage , the need for a large and efficient sophisticated cold chain network is of paramount importance .A cold chain is a temperature-controlled supply chain. An unbroken cold chain is an uninterrupted series of refrigerated production, storage and distribution activities, along with associated equipment and logistics, which maintain quality via a desired low-temperature range.

Therefore , it is important to understand the procedure followed , the different stage involved and the effects that the cold chain network play in flow of vaccine across country , the limitations faced by the networks , the ways to overcome those limitation and how its current functions in the country , compare to its counterparts in other parts of the world.

ABBREVIATION

The following abbreviations have been used in this document.

AD	auto-disable (syringe)
Co-WIN	Covid Vaccine Intelligence Network
CDC	Centre for disease control and prevention
CCM	Cold chain Monitor
EEFO	earliest expiry first out
EPI - (WHO)	Expanded Programme on Immunization (WHO)
eVIN	Electronic Vaccine Intelligence Network
FCI	Food corporation of India
ILR	Ice-lined Refrigerator
VVM	vaccine vial monitor
NCCMIS	National Cold Chain Management Information System
NEGVAC	National Expert Group of Vaccine Administration for Covid-19
RTM	Remote Temperature Monitoring
SAGE	Strategic Advisory Group of Experts on IMMUNIATION
SKU	Stock Keeping Units

SOP	Standard operating procedure
TOR	Terms of reference
UCC	Ultra low temperature cold chain
ULT	Ultra low temperature
UN	United Nations
UNICEF SD	United Nations Children's Fund Supply Division
VAR -	vaccine arrival report
VIRAT	Vaccine Introduction Readiness Assessment Tool
WHO	World Health Organization
WICR/FR	walk-in cold room/freezer room
WIRF	walk-in freezer room
WMF	wastage multiplication factor

CHAPTER-1

INTRODUCTION

1.1 INTRODUCTION

One of the largest manufactures of vaccine in the world is located India , but still , currently India is the country lagging in the distribution of vaccine to its citizens. There are some many reasons that attribute to this situation , some are relating to the political policies , some are purely logistical . India has ample manufacturing capacity (about 2.5 bn doses) that would be sufficient to meet both domestic and export demand, however, the key bottleneck is in the cold chain .What India lacks currently is the lack of available infrastructure to support the cold chain for the effective storage and distribution of vaccine , which needs to be maintained at a lower temperature ranging from -70^{o} c to 8^{o} c depending on the types of vaccine used from point of origin to the point consumption.

A cold chain is a temperature-controlled supply chain. An unbroken cold chain is an uninterrupted series of refrigerated production, storage and distribution activities, along with associated equipment and logistics, which maintain quality via a desired low-temperature range .The cold chain infrastructure that india lacks is the transportation facilities , although the storage facilities are merely enough to support the Covid vaccination program .

Vaccines that are currently available in india include sputnik V from Russian direct investment fund, Covid shield from Serum institute of india ,Covaxin from Bharat bio tech. These are currently used vaccines in India , each requiring specific temperature along the cold chain network.The lack of transport infrastructure support can overcome by in cooporating private Entities into the distribution program , mainly those work in the distribution of perishable goods like fruits and vegetable , involving redesigning of their vehicle to support the cold chain needs .Great care and coordination needs to be made for the effective distribution of covid-19 vaccine , in order to achieve the mass vaccination program undertake by the government .A single break in the cold chain , could disrupt the flow and could result spoilage , which should not be allowed , in country were people are looking to get vaccinated at the earliest . Therefore it is important to understand the technologies involved in the storage and distribution of covid-19 vaccine cold chain.

1.2 SCOPE OF STUDY

India being the largest manufacturer of vaccine s in the world still lacks behind in effectively distributing it to its citizen. One of the main reason behind this situation is the under development of cold chain infrastructure in the country.

This paper presents current and future prospects of Indian cold chain network ,the various process , technologies involved in its storage , transportation and distribution stages and the challenges it faces in its effective functioning. The main focus of this paper is to understand how vaccine cold chain networks function in this time of pandemic and to find a solutions to the various problem its faces.

1.3 OBJECTIVE OF THE STUDY

1TO UNDERSTAND THE VARIOUS PROCESSES ,TECHNOLOGIES INVOLVED IN VACCINE COLD CHAIN IN INDIA

2.TO DETERMINE THE FUNCTIONING OF COVID VACCINE COLD CHAIN NETWORK IN INDIA

3. TO PROVIDE SOLUTIONS FOR EFFECTIVE COLD CHAIN DISTRIBUTION OF VACCINE IN INDIA

1.4 RESEARCH METHODLOGY

Research methodology is the specific procedures or techniques used to identify, select, process, and analyse information about a topic. For the purpose of achieving the above mentioned objectives , the majority of the necessary information has been collected using secondary data.

1.5 .LIMITATION OF STUDY

Due to covid 19 pandemic and the restrictions imposed in the form of lockdowns and restricted number employees in work space , collection of data was restricted with webinars , journal , websites , newspaper articles , Discussions and research works available on online based on the selected topic.

CHAPTER-2

LITERATURE SURVEY AND METHODOLOGY

2.1 REVIEW OF LITERATURE

.In India the supply chain of pharmaceutical products , mainly that of vaccines are loaded a large number of issues and challenges . In order to understand these challenges and issue , it is important to study the cold cold chain infrastructure in India. The main purpose of this paper ,is to details these problems and to resolve solutions to overcome these issues.

- .According to **soumi saha , pharmacist , published on premier(2019)** ; "For health-care supply chains, extreme cold chain is uncharted ground. As a result, distributing this vaccine and getting it to the correct spot while keeping the product's integrity is a completely new logistical problem.".
- .**In an article published by Daine reynolds in network effort beyond supply chain** (2020), it was stated that "The Cold Chain will take on increased significance in the coming year, with vaccines at the forefront. Supply chain management is difficult enough, but maintaining constant temperature control across the chain is far more difficult. Yet, for temperature-sensitive products such as vaccines, pharmaceuticals, meals, and some chemical products, this is exactly what is necessary. Vaccines, like temperature-sensitive foods like seafood and steak, are perishable and require a cool environment to keep their quality. The bulk of COVID-19 vaccines now in development, including those from Moderna and Pfizer, are RNA-based and will need to be kept refrigerated at extremely low temperatures in order to remain effective. They can spoil, just like fresh foods."
- .**T. Sundararaman, New Delhi-based coordinator of the People's Health Movement, an organization that works with academics and civil society(2020)**. "said that Because the current cold chain capacity is insufficient for current immunisation programmes, we need to invest in cold chains on the order of five to ten times what you're doing presently. Purchasing, distributing, allocating, operating, and training so much cold equipment is a major undertaking.
- **Archana Chaudhary & Ragini Saxena(2020)** , in their article Vaccines such as the Pfizer injection must be stored at ultra-low temperatures of -70 degrees Celsius, thawed, and injected within five days, according to the article "**India faces cold chain logistics issue for Covid-19 vaccination**." Moderna claims that its vaccination can be kept in the refrigerator for up to a month, but that it needs to be kept in the freezer for longer periods of time. However, in terms of storage, transportation, and distribution, India lacks the necessary infrastructure to sustain these super vaccines."

- .**The All Things Supply Chain(2020)** article goes on to say that,“ Normally, quality-related difficulties may be solved by delivering extra vaccine, but the COVID-19 vaccine will be in such high demand that every lost or spoiled dose will be felt by medical professionals and patients alike. Both tracking and final-mile handoff will be required to protect the usage rate of supplied vaccines.”

- .**According to Dr soumya Rathore** (2020), The Indian cold chain is fragmented, and establishing technology-enabled cold storage facilities that can cover the entire value chain from procurement to refrigerated truck transportation to retail outlets in cities will require major investment. She also stated that. The majority of cold storage investments in India have been made in states such as Uttar Pradesh, Uttaranchal, Maharashtra, Gujarat, Punjab, and West Bengal. Second, the cold storage facilities that have been established can only handle single commodities, which is a huge bottleneck. That is the case with the Covid 19 vaccination. Which necessitates a complete overhaul of the infrastructure

- In a study conducted by **Prof. Haritha S on COLD CHAIN INDUSTRY IN INDIA-CHALLENGES & OPPORTUNITIES(2020)** , it was stated that One of the most significant challenges of the cold chain is the much higher operational expenses; the cost of cold storage per cubic metre in India is $ 60, compared to $ 30 in the West. According to data from 2014, India has approximately 31.82 million tonnes of cold storage space, with a gap of 3.28 million tonnes in cold storage space, of which only 26.8 million tonnes were in use, resulting in an 8.25 million tonne gap.

2.2 COLLECTION OF DATA

These statistics and data were not gathered from Primary Sources and had previously been gathered and used, so they cannot be considered distinct in character. There are a variety of ways to obtain secondary data, including websites, journals, organisation reports, reviews prepared by researchers, reviews of a variety of connected business, industry, and so on . Secondary statistics were gathered for this work from the

company's websites and reviews, as well as an television interviews . The information can be gathered in two ways:

1.Primary data is the information that obtained directly from primary sources by scholars, whereas secondary data is the information collected from primary sources and made publicly available for scholars to use in their own studies. However, no such primary data was employed in this project.

2. Secondary Data refers to the data collected by someone other than the scholar, such as statistical information from project, government surveys or survey details. To identify on-the-ground problems and opportunities, the data is gathered through taking notes from various corporate televison interviews, journals , firms websites etc .

2.3 TOOLS FOR ANALYSIS

Research instruments are devices that are used to gather data, are measurable and observable for data analysis and interpretation, and are created by the scholar depending on the objectives.

1.Descriptive analysis. Descriptive statistics are short descriptive values that summarise Given sample of population- Descriptive statistics are used to explain the essential aspects of data in a given data set, which can be a reflection of the full population or a subset of it.

2.Correlation—The analysis also looked into the relationship between the study's dependent and independent variables.

CHAPTER-3

COLD CHAIN BASIC COMPONENTS AND PARTICIPANTS

3.1 COMPONENTS OF THE COLD CHAIN

1.Transportation and Storage of Vaccine

In order to ensure the effectiveness of vaccine , it is important to maintain it in the proper temperature. A person who act as a coordinator for the vaccine operations must ensure proper cold chain adherence during the three phases such as transport , shipping and receipt of vaccines .It is also important to provide information necessary to preserve and maintain the integrity of vaccine and there must be a standard operating procedure for providing directions in the process of vaccine personnel training , evaluation of staff performance and procedure for proper storage and handling .

All vaccines are sensitive biological substances , when exposed to outside temperature beyond their accepted range lose their potency and integrity.The use of a properly packed cooler helps to maintain the vaccine temperature within accepted range . Special care must be given in the use of quantity and placing of ice packs inside the cooler packs . Since the usage of fewer ice packs leads to failure of maintaining internal cooler temperature and usage of excess of ice packs leads to freezing of vaccines .

The centres for diseases control and prevention developed a chart that provides the details of ice pack use in different climate around the world. In order to prevent vaccine from freezing and losing potency with lower temperature ice pack placement plays a crucial role. There should be a barrier in the form of bubble wrap , crumpled brown wrap between the vaccine and the cold packs.The vaccine transport personnel should monitor the internal temperature of transport container on an hourly basis with the usage of a ISO certified thermometer. Makes sure that the thermometer is placed near to the vaccine rather than close with the cold pack .The contents inside the cold pack must be assembled in the following order from top to bottom: refrigerated cold packs, barrier material, vaccine, thermometer, and another barrier layer. Vaccines should remain inside its original packing and the preparation of doses in advance should not be allowed . A legible description of vaccine including the name of the vaccine , number of vitals , date , time and recorded temperature while placing inside the cooler must be displayed outside the cooler.Vaccine are not allowed to carried inside the trunk of the vehicle as the temperature inside the trunk cannot be controlled and it effects the internal temperature of the vaccine , there by reducing the potency of the vials .

Nurses may be required to transfer vaccination to locations such as off-site clinics by hand. Vaccines must be carried in containers that are suitably insulated. It is sufficient to use Styrofoam® with 2-inch thick walls and certified hard-sided coolers transport on a short-term basis The vaccine shipping containers from the vaccine manufacturer can also be retained and utilised for off-site shipment. Styrofoam® containers with thin walls and soft-sided coolers are insufficient to keep vaccines cold during transit.

Table 1

Refrigerated/Frozen Pack Needs for Different Climates

Outside Temperature	*Number of Faces[a] Covered With Packs*	*Temperature of Packs*	*Comment[b]*
> 75°F to 110°F (> 24°C to 43°C)	2[c]	23°F (-5°C)	Up to 48 hours of delivery with 10 hours at 110°F (43°C)
32°F to 75°F (0°C to 24°C)	2[c]	23°F (-5°C)	Up to 48 hours of delivery
	4	41°F (+5°C)	Up to 24 hours of delivery
< 32°F (< 0°C)	4 to 6[d]	50°F (+10°C)	About 24 hours of exposure to mix of outdoor and heated areas
0°F (-18°C) or colder	6[d]	68°F (+20°C)	Prolonged, 24 to 48 hours of continuous exposure to 0°F (-18°C)

Note. *[a]Faces would include the interior surfaces of the box, including the walls, floor, and lid (above the vaccines and insulating material). [b]Applies when high-quality insulated boxes with walls of 1¾ to 2¼ inches of expanded polystyrene, 1 inch of isocyanurate, or 3 inches of polyurethane insulation were used. [c]Three for medium-sized box tested by the Centers for Disease Control and Prevention (10 × 10 × 7 inches—interior dimensions). [d]Essentially the entire surface area is covered with packs. [Source: Centers for Disease Control and Prevention. (2008).* CDC: Vaccine storage and handling toolkit *(Fact sheet). Retrieved from*

Shipping

The health workers and nurses will be required to ship vaccines to the other clinic due to the shortage of inventory .During the shipping of vaccine the health care workers and nurses need ensure that the proper vaccine cold chain procedures and requirements have been followed during the shipping stage. Which include proper packing with ice packs and barrier material like bubble wrap, temperature monitoring of the ice packs and recording of the temperature on regular basis and notifying the variation and identifying the breach. Reefer containers or small sized containers capable of maintaining the acceptable temperature range for a minimum 48 hours should be used for shipping the vaccine. Cold chain monitors (CCMs) should used to monitor vaccine temperatures during shipping and ensure that the vaccine hasn't been exposed to temperature outside accepted range to ensure its potency .

Three basic types of CCMs are available: one indicates if the vaccine reached temperatures above 50°F or 10°C, one indicates if the vaccine reached temperatures of 32°F or 0°C, and one indicates the vaccine temperature con-tinuously during the entire shipping process. Heat indicator CCMs are for single use, are temperature sensitive, and should be placed in the refrigerator prior to use to ensure that the dye is in a solid state before activation. A heat indicator CCM releases a colored dye into the windows of the device when the activation temperature has exceeded the set range (indicated on the device). over time dye moves through the windows gradually. If the temperature drops below the threshold again, the dye stops moving but does not disappear; therefore, the indicator also shows the length of time, in hours or days, that the

temperature has exceeded the desired range.
When ready for use, the heat indicator CCM is removed from the refrigerator and placed in the environment being monitored. If the environment being monitored is above the temperature threshold of the indicator, the heat indicator CCM will activate prematurely; therefore, the indicator must be attached directly to the vial or the vaccine box promptly. Freeze indicator CCMs are also for single use and release a colored liquid dye when exposed to freezing temperatures (32°F or 0°C). However, they do not indicate the length of time the vaccine is exposed to the undesired temperature range. Some types of freeze indicators require preconditioning .

Digital data loggers are small, programmable, battery-operated, electronic devices available in single- and multi-use models. These devices have external lights alerting the user when the appropriate temperature occurs and when a temperature either too hot or too cold has occurred.The approval for the further use of vaccine shipment to be given , only after the interpretation of temperature data .The digital data logger requires a special software program that interprets the data and reveals if the vaccine has reached temperatures outside the recommended range .When shipping a vaccine, it is critically important to review the vaccine insert carefully, noting the manufacturer's recommended temperature range. At least 6 pounds of dry ice should be used for vaccine that must remain frozen. Dry ice should not be used for vaccine that is to remain unfrozen. Live vaccines generally tolerate freezing well and deteriorate rapidly when removed from the freezer. Consequently, health care workers especially nurses should administer the vaccine immediately after removing it from the freezer . When shipping expired vaccine back to the manufacturer for a refund or disposal, the health care workers handling the vaccine should contact the vaccine manufacturer for shipping instructions and authorization. Cold chain monitoring is unnecessary for expired vaccine. Vaccine that is damaged or expired is considered medical waste and must be properly disposed of in accordance with existing regulation of the country .

Receiving

During the receiving stage of the vaccine cold chain , proper inspection must be carried to make sure that the cold chain has been maintained . The vaccine shipment must be undergone through the stages of receiving , inspection and storage as soon as it reaches the destination. Upon the arrival , examine whether the container and its content are free from damages . Make sure that the vaccine consignment has been received within the time span of 48 hours since dry ice and barrier become ineffective , once this time span is over . The expiration date of the vaccine vials are noted to identify old vials. The cold chain monitors are also verified for ensuring vaccine integrity . Make sure that the coldness of the dry ice is intact and barrier exist between the package and the vaccine . Mere visual inspection is enough to check for the integrity of the vaccine . If the inspection personnels have doubts regarding whether the vaccine has been compromised or not , the vaccine must be marked do not use and must be separated from other vaccine once the integrity is verified

Storage Equipment

In order to ensure that vaccine temperature is maintained ,Proper storage equipment is essential . Equipment necessary for routine storage and handling of vaccines includes refrigerators , freezers, calibrated thermometers, and alarms. In the selection storage equipment a, a consideration must be made in the amount of inventory needed to be stored . If the equipment purchased is a combined refrigerator -freezer, then there must be seperate doors to ensure that the temperature is maintained properly . The frozen packs should be stored in the freezer and the water bottle must be stored in the refrigerator. A unit similar to dormitory style with one external door is not sufficient for vaccine storage, because of the lack of temperature regulation . The selected refrigerator-freezer must have a temperature regulator that can be adjusted to appropriate temperature ranges. The temperature of the refrigerator unit should be maintained between 2ºC and 8ºC, and the temperature of the freezer unit should be -15ºC or lower. Health care workers and nurses should monitor the temperatures of both the freezer and the refrigerator twice daily: once in the morning and once before the end of the daily shift .A certified calibrated thermometers must be used for monitoring storage unit temperatures. Thermometers are calibrated during manufacture and again from an appropriate agency . These thermometers generally receive a 2-year certification from these agencies.

The certificate should be maintained throughout the usage and the vaccine providers should monitor for their expiration date. The health care workers should determine which type of thermometer and recorders should be used depending on the vaccine requirement.Labels assist workers in properly storing and handling vaccine. Labels placed on external refrigerator doors provide instructions about the correct storage location for each vaccine in the inventory and inform workers not to store food or beverages in designated vaccine refrigerators and freezers. In addition, vaccines should be stored in separate labeled bins in refrigerator-freezer units to reduce the risk of retrieving the wrong vaccine ..

3.2 KEY PARTICIPANTS AND THEIR ROLE IN COVID 19 VACCINE COLD CHAIN

The key participants in covid 19 cold chain network includes

- Specialized laboratory equipment manufacturers (temperature gauges, sensor devices, hospital-grade freezers)
- Laboratory equipment manufacturers - specialised in the production of climate-controlled packaging and container materials
- Logistics providers
- Healthcare providers and point-of-care (POC) retail pharmacies
- pharmaceutical manufacturers.
- Government Authorities

For the effective management of cold chain network , there is a requirement of varying degree of coordination and cooperation among the various stakeholders in the networks. Effective cold chain management entails not only maintaining constant temperatures to keep vaccines viable, but also ensuring that suitable technology are in place to allow stakeholders at various points in the vaccine storage, transport, and distribution chains to verify temperature stability.

PHARMACEUTICAL MANUFACTURERS

The pharmaceutical manufacturers , mainly the covid 19 vaccine manufactures plays a huge role in the distribution of vaccine around the country. The current shortage that the country faces , in terms of vaccine availability is mainly due to the limitation that the vaccine manufacture have , to provide the quantity demanded in excess of their current capacity. SII – Serum institute of india has a current capacity of 1,6 billion per annum. They have sought a grant of 3000 crores from the government to increase their production capacity to 100 million per month doses from the current 60 million doses per month. Another major manufacturer like Bharart Bio tech also envisaged plans to expand their production capacity by installing plans in Hydrabad and Bengaluru .

SPECIALIZED LABORATORY EQUIPMENT MANUFACTURERS

The proper monitoring of the vaccine vials temperature is crucial to the effective distribution of vaccine . Since most of the covid 19 vaccine distributed in india , needs to be maintained at a temperature of $2^{o}c$ to $8^{o}c$, the monitoring process becomes a crucial factor in its effectiveness. The usage of temperature gauges, sensors and hospital grade freezer and their quality becomes important. A minor error or variation in the temperature reading could disrupt their entire supply chain . These equipments needs to be purchased from the certified manufactures.Players like Blue star plays an important role in it , as they are major player in the production low and ultra low temperature equipments **.**

LABORATORY EQUIPMENT MANUFACTURERS

Apart from the monitoring aspect , the quality of the material used to sustain the temperature in the cooler for vaccine storage need to be considered .The container used to store c=vaccine while in transist and the cold packs inside the cooler needs to be specially managed to protect the vaccine integrity . Any defect in the vaccine storage containers could lead to huge wasteage.

LOGISTICS PROVIDERS

logistics providers gives an end to end distribution from the point of origin to the point of consumption. Providers like mahindra logistics , snowman ,blue darts and allcargo are all set for the national wide

distribution of covid vaccine. Their own fleet of reefer trucks could become a great factor for the effective cold chain distribution in the country.

TCI , snow man, KOOL EX are one of the major player in this sector.

GOVERNMENT AUTHORITIES

The government authorities could play a great role in the effective cold chain distribution of covid 19 vaccine. From providing financial assistance to manufacturers to adminidtering the vaccine to the citizens of the country.

The regulations made by these authorities should be aim at the direction of the proper distribution of vaccine , both for the free and paid version made available in the market .issuing special clearance to vaccine consignment. Removal of tariff barrier for materials related to the production and distribution of vaccine etc. Could also lead to effectiveness of cold chain network .

NCCVMRC

The National Cold Chain and Vaccine Management Resource Centre (NCCVMRC), part of National Institute of Health & Family Welfare (NIHFW) New Delhi, is the apex body of MoHFW, GoI to offer technical assistance with the country's immunisation supply chain The centre was founded in 2013 as a collaboration between the Ministry of Health and Family Welfare (MoHFW), the National Institute of Health and Family Welfare (NIHFW), and UNICEF. On March 9, 2015, the Union Minister of Health and Family Welfare, Government of India, formally inaugurated it. .

NCCVMRC is under the direct supervision of the Nodal Officer (Immunization), NIHFW, with functional control given by the Ministry of Health and Family Welfare's Immunization Division. UNICEF also assists the institute with GAVI-HSS initiatives by providing technical assistance.NCCVMRC is India's principal resource centre for all research, training, planning, and policy initiatives connected to the vaccination supply chain. The centre has also been appointed as the secretariat for the evaluation of effective vaccination management (EVM) and the standards for cold chain equipment. At all levels, the institute works to develop the ability of programme managers and policymakers. CCVMRC also collaborates with the National Cold Chain Resource Centre (NCCRC) in Pune to provide Cold Chain Technician training (CCTs).

3.3 BENEFITS FROM A WELL CONNECTED COLD CHAIN

AVAILABILITY

The lack availability of vaccine across the country is one of the problem that we are currently facing. Some of the state are excess of vaccine , while some states are scare with it . The deciding factor for this situation is the level od establishment of cold chain infrastructure in these states. The moderating parameters like temperature , humidity and atmospheric composition along with utilizing proper handling procedure, the cold chain can improve and the integrity of vaccine , which helps to hold their value longer, and leads to their transportability and availability

AFFORDABILITY

A well connected cold chain network reduce the loss incurred in vaccine degradation and ultimately makes the vaccine at a affordable price . If significant portion of the vaccine produced degrades due mismanagement in the cold chain , the ultimate barrier is imposed on the shoulders of the citizens of the country. Since currently all expenses for vaccine are bound by people themselves.

ACCESSIBILITY

Access to the vaccine is another issue faced by the people today. Lack of vial distribution centre and walk in coolers , freezers makes the situation worse. despite of the current incapability of covid shield and covaxin manufacturers to produce vaccines to stipulated demand , installment of these infrastructure helps improve accessibilty of vaccine and reduce the situation in which piling up in outnumber vaccination centre for getting vaccinated **.**

QUALITY

If sufficient storage and handling facilities were provides , it eventually leads to maintaining the quality and integrity of vaccine without degradation.

3.4 Cold chain Storage Equipment

Cold Room

A refrigerating chamber, often known as a cold room, is a warehouse where a specified temperature is maintained artificially. It is typically used to store things in an environment that is cooler than the ambient temperature. These rooms are beneficial for a variety of things, regardless of the objects they contain:

Goods reception;. Businesses, such as warehouses and restaurants, are required by hygienic regulations to maintain a suitable temperature for receiving raw materials, which will then be distributed to various locations. In these situations, a good cooling system is essential.

Storage and products handling:. This enables for increased production and marketing, as well as product transformation and shelf life extension.

Products display;. In these circumstances, walk-in or reach-in doors are particularly prevalent, as they allow the final consumer to quickly access things while also providing a far more appealing point of sale.The temperature ranges from +2 to +8 c

Walk in coolers

A walk-in cooler is essentially a large-scale refrigerator, similar to the ones you might have at home, except that you can walk into it! Every restaurant and fast food chain has a walk-in cooler where all of their perishable foods are kept. A Walk-in cooler, on the other hand, has a far stronger refrigeration system than a domestic refrigerator, allowing them to keep their food at optimal temperatures in order to fulfil particular FDA regulations and to ensure that it satisfies local safety and food handling codes.Walk-in coolers are used by a wide range of businesses, from Floral Boutiques to Breweries to Medical Research Facilities. The temperature is between +2 and +8 degrees Celsius.

Walk in freezer

The walk-in cold/freezer room is a custom-made product that meets the needs of medical services, scientific research, agricultural, biological and chemical industries, and other industries. It is used to store vaccinations, medications, blood plasma, and chemical reagents, among other things.

The Key Features

1. Microprocessor controller with high-precision temperature sensors for automatic temperature regulation at 2°C, 8°C, or -15°C, 25°C, with 0.1°C resolution

2.A digital LED display ensures long-term storage in high-temperature environments (Optional LCD touch screen)

3. A refrigerant system that uses forced air cooling maintains a consistent temperature.

4. Dual system design: when one of the refrigerant units fails, the other refrigerant unit ensures that the interior temperature is maintained.

5. Installation is simple with a monoblock refrigerant unit (below 40m3).

6.Auto-defrost makes maintenance a breeze.

7. A high/low temperature alarm system promotes storage safety.

Ice lined Refrigerator

Vaccines, pharmaceutical items, blood bags, and samples, among other things, are stored in ice-lined refrigerators that have a temperature range of 2°C to 8°C. In a 24-hour period, an ILR can maintain a temperature of +2°C to +8°C with as little as 8 hours of power supply. If the refrigerator's power goes out, the ice liner keeps the temperature inside the fridge at a safe level for vaccines.

Deep freezer

Deep freezers are pieces of testing equipment that are used to keep food, medical equipment, blood samples, pharmaceuticals, and injections, among other things, frozen for a long time. The temperature is between -15 and -25 degrees Celsius.

Cold box

A cold box is an insulated container which can be lined with water packs to maintain vaccines and diluents in the proper temperature range while being transported or stored for a short period of time. When tested at a steady +43 °C, current prequalified cold box types have a maximum cold life of two to seven days.

Vaccine carrier

Vaccine carriers are insulated containers that keep vaccines and diluents cold during transit when coated with coolant packs. They are lighter and smaller than cold boxes, making them easier to carry while walking. Place the vaccinations and diluents in the cold box or carrier's centre. Place a foam cushion on top

of the conditioned ice packs in vaccination carriers. Place conditioned ice packs on top of vaccines in cold boxes. Close the cold box's or vaccine carrier's lid tightly.

Refrigerated vans

Vaccines are transported in bulk via refrigerated vehicles between storage locations. They have a refrigerated unit as well as an enclosed cargo compartment. The type of refrigerants used in medical cold chain equipment is usually determined by the vaccines/temperature medicine's control requirements. . The majority of deep-frozen systems (up to -80°C) are located upstream in the medical chain, for example. Synthetic HFC refrigerants, natural refrigerants like ammonia (R-717) and carbon dioxide (R-744), and cascade systems that use both natural and synthetic refrigerants can all be used in deep-frozen systems. Synthetic HFC-based systems such as R-134a, R-404A, and others are used for refrigeration applications in the downstream that typically demand positive temperature ranges (2°C to 8°C). Natural refrigerant systems based on hydrocarbons are likewise becoming more popular on the global market..

The COVID-19 response may necessitate the construction of new cold chains or the reinforcement of existing ones. Importing countries would have to analyse this obligation and ensure that their technological choices do not jeopardise their Montreal Protocol commitments and have the least possible impact on energy and climate.

3.5 Guidelines for Storage

A primary vaccine coordinator should be selected, usually an occupational and environmental health nurse, with a secondary coordinator assigned to monitor vaccine storage and handling issues as necessary.

The principal vaccine coordinator is unable to assist. Written guidelines on adequate vaccine storage and handling for vaccine employees should be available from the occupational and environmental health nurse. Those administering or storing vaccinations should have easy access to the recommendations, which should be prominently displayed. These guidelines should include the following::

1. The vaccine coordinators' contact information.

2Resource or vendor contact information (e.g., vaccine manufacturers; refrigerator, freezer, and maintenance companies).

3 descriptions of the vaccination coordinator's job and responsibilities

4.Vaccine storage requirements summaries.

5. Instructions for monitoring the temperature of vaccine storage units, including where vaccine should be placed within the units.

6. Transporting and receiving vaccination supplies instructions.

7. Vaccine inventory management instructions.

8. Directions on how to properly dispose of vaccines and supplies.

9.Vaccine administration instructions

10.Troubleshooting instructions

11.Sample forms used in the vaccine program

3.6 IMPORTANCE OF COLD CHAIN TECHNOLOGY IN COVID-19 VACCINE

About 50 varieties of vaccines from around the world are currently awaiting regulatory approval for their trials as per data provided by world health organisation . Most of these vaccines are highly temperature sensitive and are needed to be stored at lower temperature , So in order to ensure safe and effective delivery of vaccine to their citizen. The government authorities and private organisations need to develop efficient cold chain network with highly sophisticated technology to support it . As most of the currently available vaccines are required to be transported and stored in refrigerated mode , such as for Pfizer at -70oc and covid shield at 2Oc, in large quantities , presents huge challenge in their tracking , monitoring and real time alert process. All these issues can be overcome by advancements made in technology in the cold chain network.

Vaccines are highly sensitive and fragile drugs which requires strict temperature control to avoid their spoilage along the chain. M ore than half of the vaccines produced around the world are getting wasted , because of the lack of measures taken in their proper carriage. The vaccine loss their effectiveness and potency , when they are exposed to temperature outside their prescribed range.The process of end to end monitoring and automations for effective vaccine distribution can be achieved by using IOT based technology which provides Detailed sight with respect to temperature during each leg of the cold chain , validation of temperature which helps to take remedies as required , Automation which improves efficiency along cold chain etc.

3.7 COLD CHAIN TECHNOLOGY

Cold Chain Monitoring Platform

A cold chain monitoring platform spported on the basis of internet of things (IoT), artificial intelligence (AI), and block chain technology aids in improving security and many compliance elements. It also helps to avoid wastage in the cold chain caused by inadequate temperature monitoring in the cold chain unit.

In the event of a temperature spike, IT prevents waste by giving geographic notifications with the help of GPS in real time. Excursion Sensor based on IoT enables to regularly check several characteristics of the vaccination unit, such as temperature and humidity, to ensure its integrity. The sensors transmit data in real time thanks to the IoT's connectivity. The system also allows for the storage of temperature data from the sensors in the event of a network outage. The platforms' blockchain technology provides immutable notifications, and AI makes the necessary decisions to protect the unit's integrity.

The advantages of a cold chain monitoring platform The advantages of a cold chain monitoring platform include: The advantages of a cold chain monitoring platform include:

• Reduces medicine deterioration during the shipping phase of the cold chain with a highly accurate temperature monitoring system

; • Demonstrates robustness throughout the cold chain and provides speedier notifications in the event of an emergency.

Data Loggers

Data loggers are electronic devices that continuously monitor and record environmental factors, allowing for the measurement, documentation, analysis, and validation of conditions. The data logger has a sensor that collects data and a computer based chip that stores it. The use of internet of things (IoT) technology to continuously monitor temperature-sensitive products being transported in a "cold chain"—that is, a supply chain of perishable and/or temperature-sensitive products such as pharmaceuticals, biologics, food, and beverages—is known as cold chain monitoring.

e-VIN RTM

e-VIN is a low-cost remote temperature monitoring (RTM) system that includes a sensor unit that is installed in vaccine storage freezers (ILR). Temperature data is collected by this sensor device and sent to eVIN. CT5 takes temperature readings from the top, centre, and bottom of the ILR.

RFID:

RFID (Radio Frequency Identification) is a technology that uses radio waves to identify goods and collect data on them without the need for human intervention or data entry. Additional sensors, such as temperature, humidity, and gas, can be added to RFID sensors/labels to record their history across the supply chain. RFID temperature tags are as accurate as traditional temperature data loggers and also offer improved performance due to speedy data recovery and live access at any point in the supply chain. This aids in the inspection and decision-making process, resulting in better inventory management and fewer batch rejections.

Wireless sensor networks (WSN) and Internet of Things (IoT):

WSN is made up of sensors, microcontrollers, and radio frequency handsets. At a local level, these components communicate with one another. A diverse set of WSNs are connected through the Internet to serve as IoT sensory organs. The internet of things (IoT) is a network that connects numerous objects to transfer data for the purposes of object locating, tracking, monitoring, and management, using RFID tags, sensors, actuators, and other control systems. The Internet of Things (IoT) provides a perfect platform for

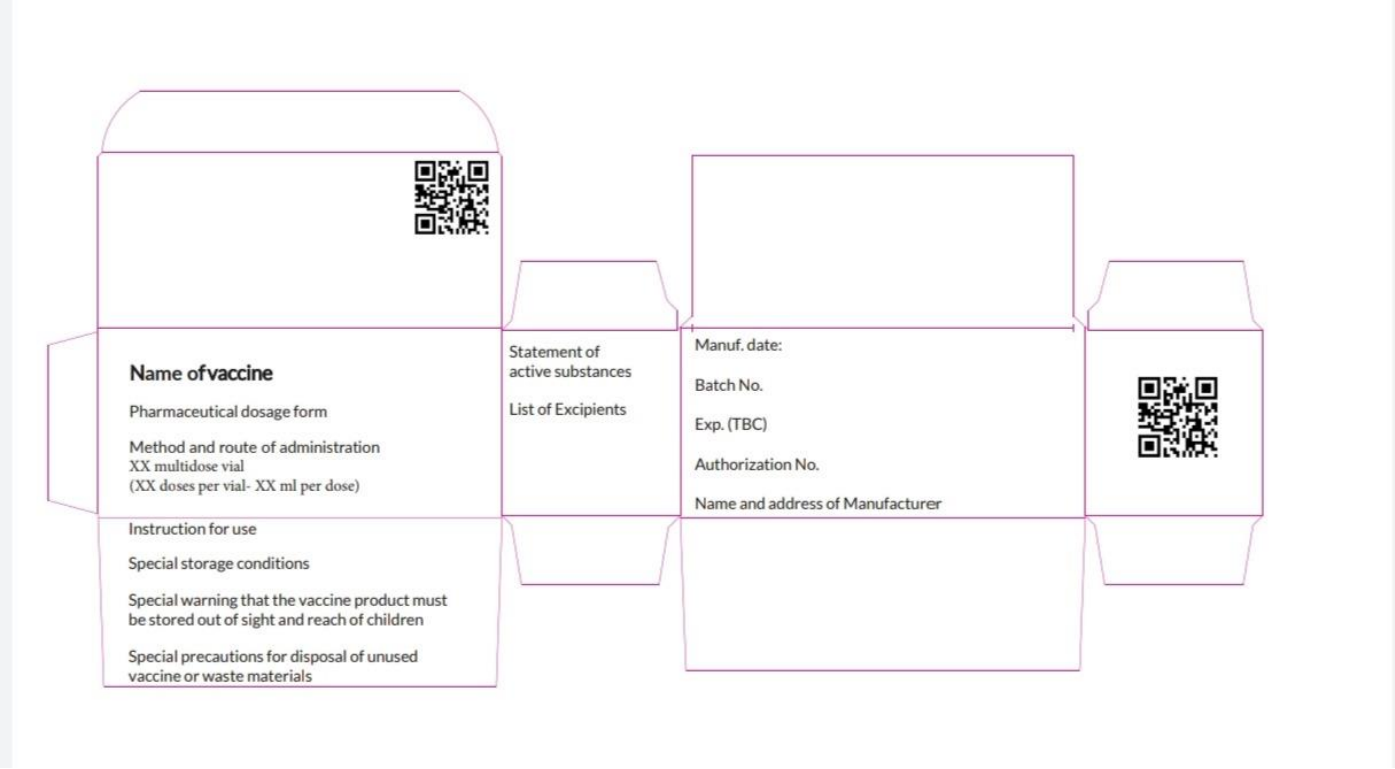
remotely monitoring and regulating the real-time status of perishable items across the cold chain, enabling the FEFO system.

Time-temperature indicators (TTI):

TTIs are low-cost, basic devices that display the time-temperature history of the objects they are used on. These indicators can be customised for your needs on user portals, gadgets, and cars. TTIs can be programmed to identify and correlate the safety and quality of a specific food product at any stage in the supply chain , thus providing an effective decision tool.

3.8 VACCINE PAKAGING AND LABELLING

Vaccine Carton Packaging



M odel labels for vials and packaging have historically been prepared by WHO for many vaccines to provide guidance to manufacturers on the advised format., WHO has developed a working position for vial and carton label requirements.

A vaccine carton contains the following details ;

1. Name of the vaccine

2.method and route of administration

3. Instruction for use

4. Special storage conditions

5.special warning that the vaccine product must be stored out of sight and reach of children

6.special precaution for disposal of unused vaccine or waste materials.

7. Statement of active substance

8. list of excipients

9. Manufacturing date

10. Batch No

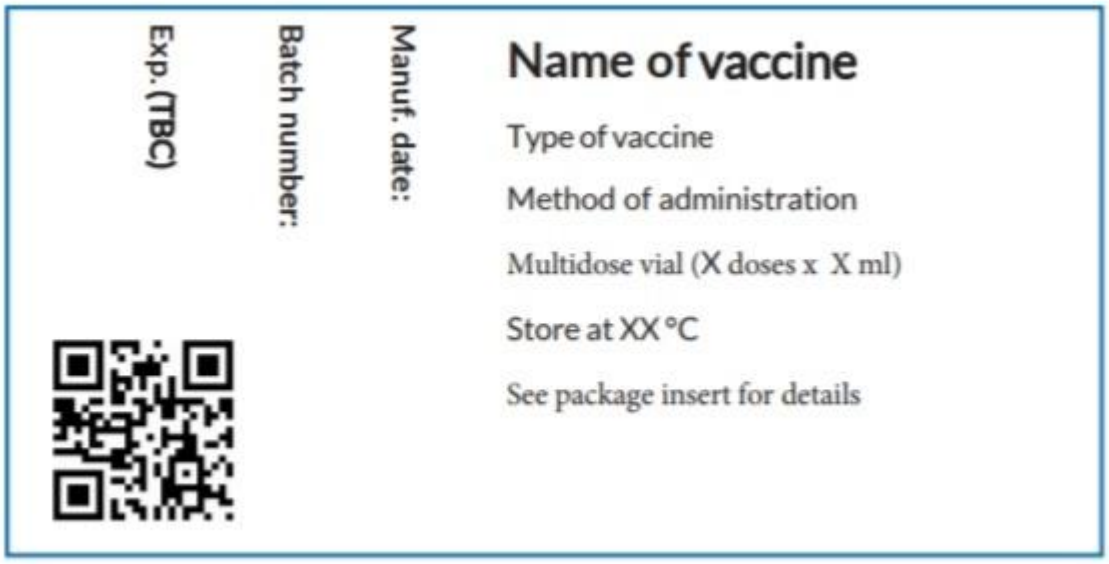
11.Expiry date

12.Authorization No.

13.Address of the manufacturer

14.Barcode on opposite sides**.**

VIAL LABELING



Apart from the marking on the carton , it is important to maintain labeling in the vials. Specially in the situation where the vaccine carrier contains more than one type of vaccine, a slight mistake could cause a life.

The vial label details include:

1.Name of the vaccine

2.Method of administration

3. Multidose Vial

4.Required storage temperature

5.Manufacturing date

6.Batch number

7.Expiry date and barcode.

CHAPTER-4

VACCINE COLD CHAIN IN INDIA

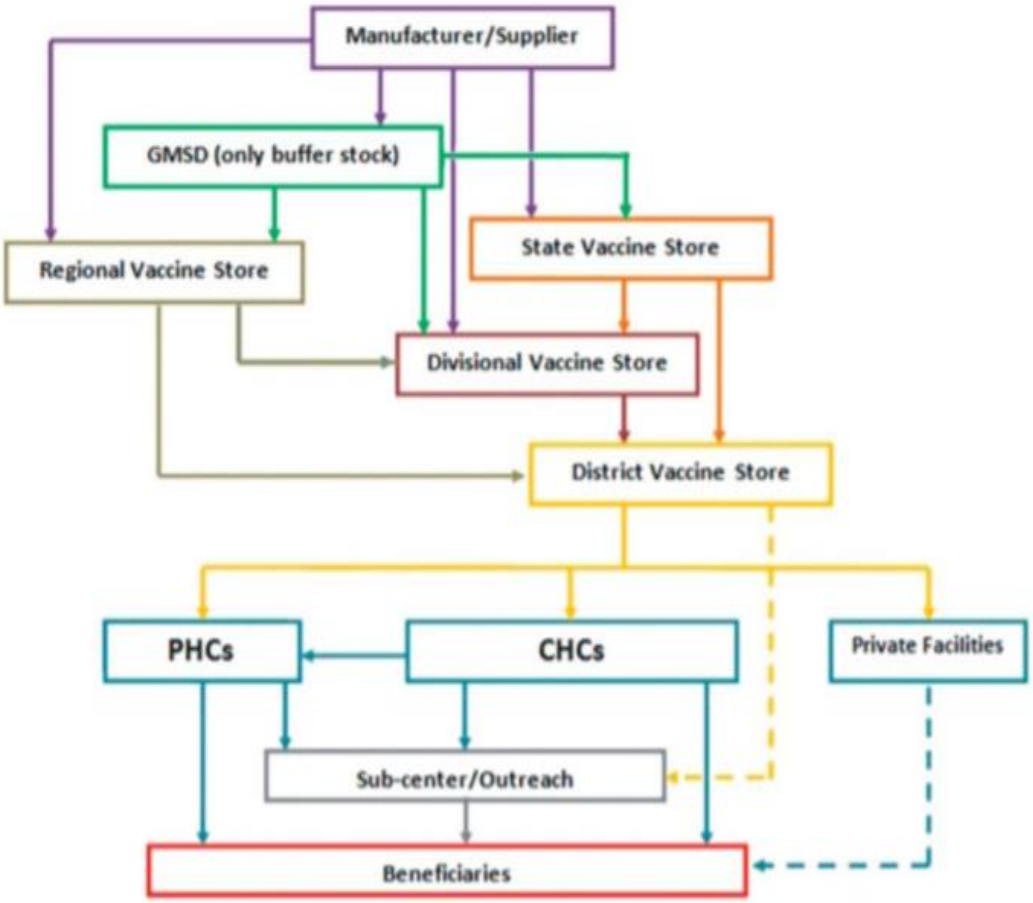
4.1 NEEDS FOR AWELL CONNECTED COLD CHAIN IN INDIA FOR COVID 19 VACCINE

The cold chain network and market in India is highly fragmented, About 50% of the entire cold chain network is concentrated in the state of Uttar pradesh and 80% of the total network is concentrated in 7 states across the country. The sector is populated with small players . And inadequate to meet current demand for mass immunization programme across the country .Thus the need for a well connected cold chain network across the country are of great importance . Since majority of the player currently working in cold chain sector mainly handles perishable food product , the neccessity of massive training program is required throughout the cold chain regarding the handling and storage of covid -19 vaccines . The scope of the usage of Pfizer vaccine from US A has been negated till date because of the current incapability of cold chain sector , which requires a cold chain storage of the temperature range of -70^{o} c or lower . Which not possible for the time being since most freezer currently available has a temperature range of $-20^{o\ c}$ to -40^{o}c .The process of the transfer of vaccine from the origin to the refrigerator and from refrigerator to the ice box must be strictly monitored ,as 70-80% 0f vaccine degradation happens during this time . When the vials are taken from the ice box for its use , the entire ice box is exposed to the ambient temperature , which causes the degradation of the vaccine .These issues can be mitigated with the use of technology , such with the usage of portable vaccine carrier, with rapid cooling technology that ensures strict temperature control during the last mile distribution and vial receiving stage , this technology helps to prevent degradation by 97% .The employment of additional infrastructure is also required for the establishment of a well connected cold chain network and management. The government currently in the phase of installing 29000 cold chain point , 240 walk in coolers , 70 walk in freezer , 45000 ice lined refrigerators , 41000 deep freezers and 300 solar refrigerators across the country .They also made guidelines for the estimation of electrical and non electrical cold chain equipment and their strengthening issue.

4.2 VACCINE COLD CHAIN IN INDIA AT A GLANCE

India being the largest manufacturers of vaccine in the world , with serum institute of india , holding a majority of shares in the production. Still lacks in effectively distributing the vaccines to its citizen . The one of the major factor that lead to this situation is the shortage of required infrastructure to support the largest immunization mission that ever takes place. Since more than 70% of the cold chain infrastructure are being concentrated in 4 states in the country , the task of distributing temperature sensitive vaccine on a pan india level becomes merely posssible. This unevenness in the distribution network results in shortage of vaccine supply in other parts of the country were cold chain network merely exist.

The vaccine cold chain network structure as issued by the union ministry of health is as follow**s**


Manufacturer/Supplier
GMSD (only buffer stock)
Regional Vaccine Store
State Vaccine Store
Divisional Vaccine Store
District Vaccine Store
PHCs
CHCs
Private Facilities
Sub-center/Outreach
Beneficiaries

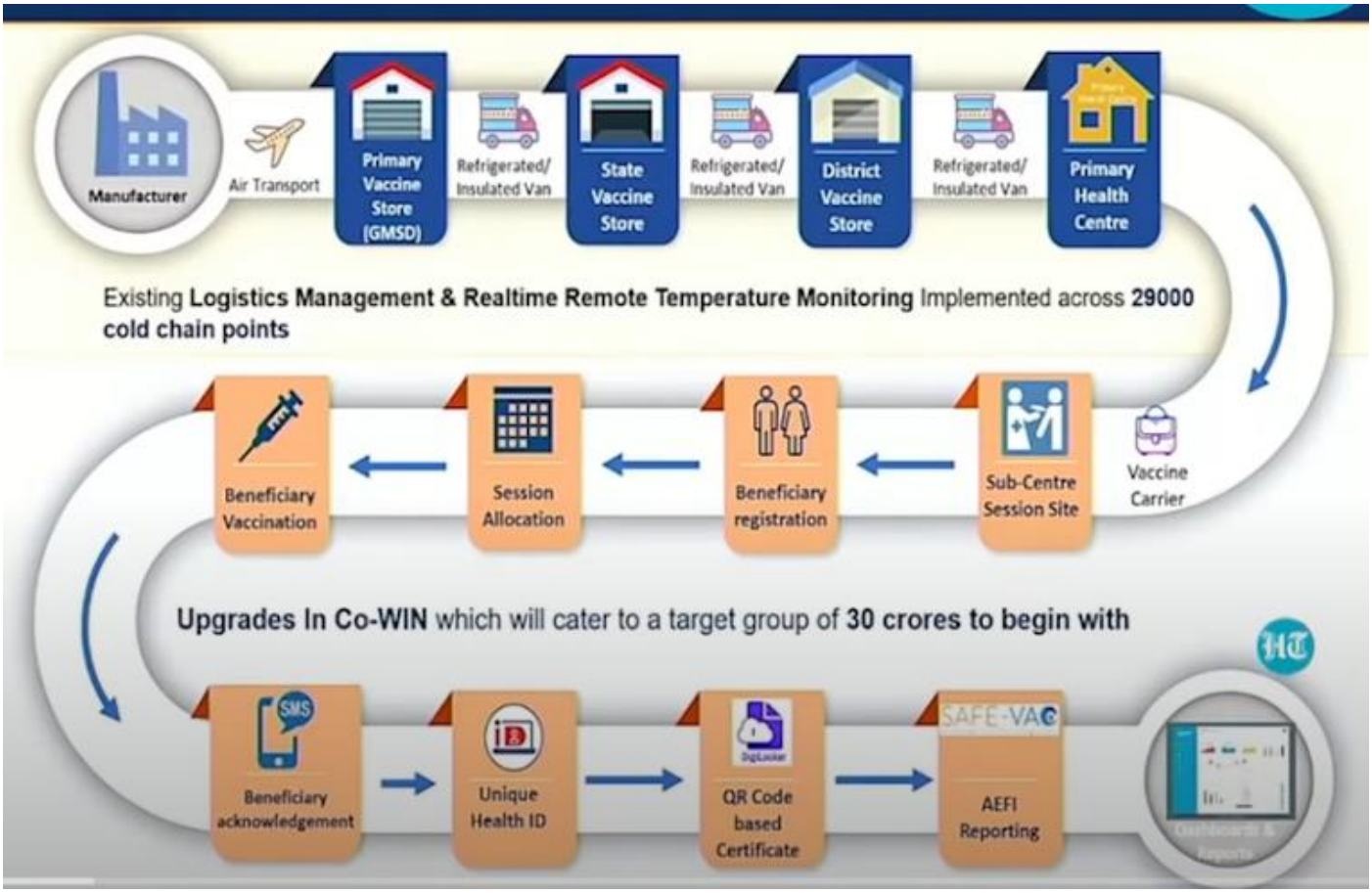
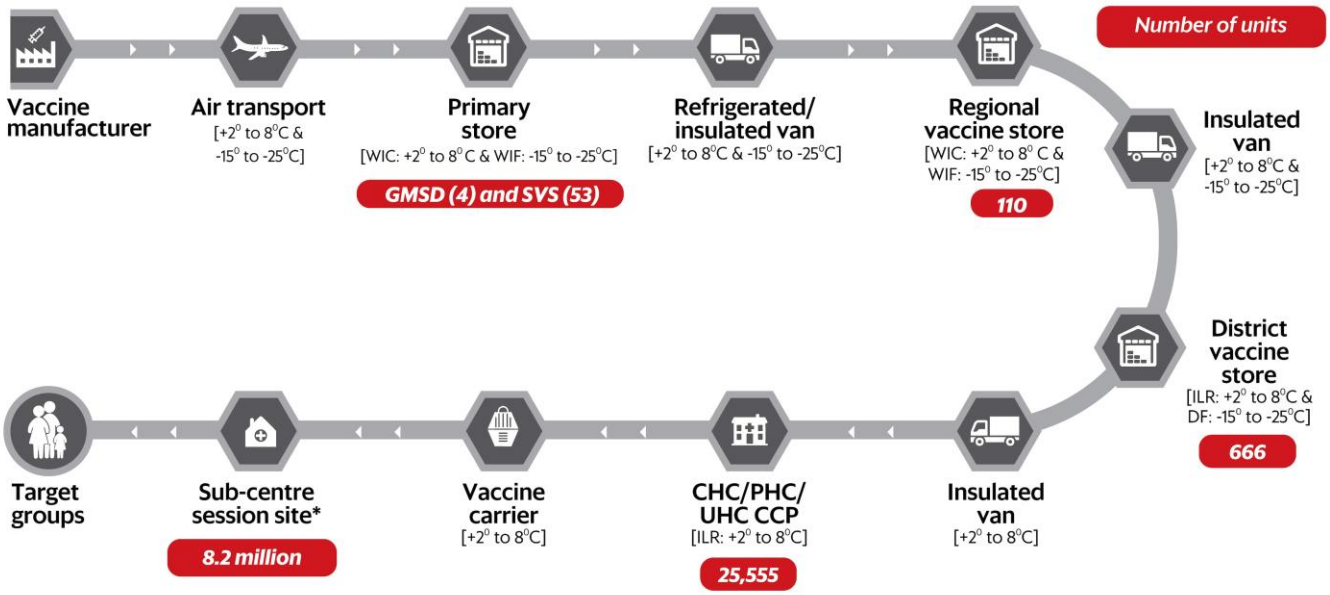


Chart 2

Vaccine cold chain distribution network in India



GMSD = Government medical store depot; SVS = State vaccine store; WIC = Walk-in cooler; WIF = Walk-in freezer; CHC = Community health centre; PHC = Primary health centre; UHC = Urban health centre; CCP = Cold chain point; ILR = Ice lined refrigerator; DF = Deep freezer; *in some of the states, selected sub-centres also function as CCP

Source: 'National EVM Assessment 2018' by NCCVMRC-NIHFW & UNICEF; 'Comprehensive Multi-Year Plan 2018-22: Universal Immunization Programme' by MoHFW

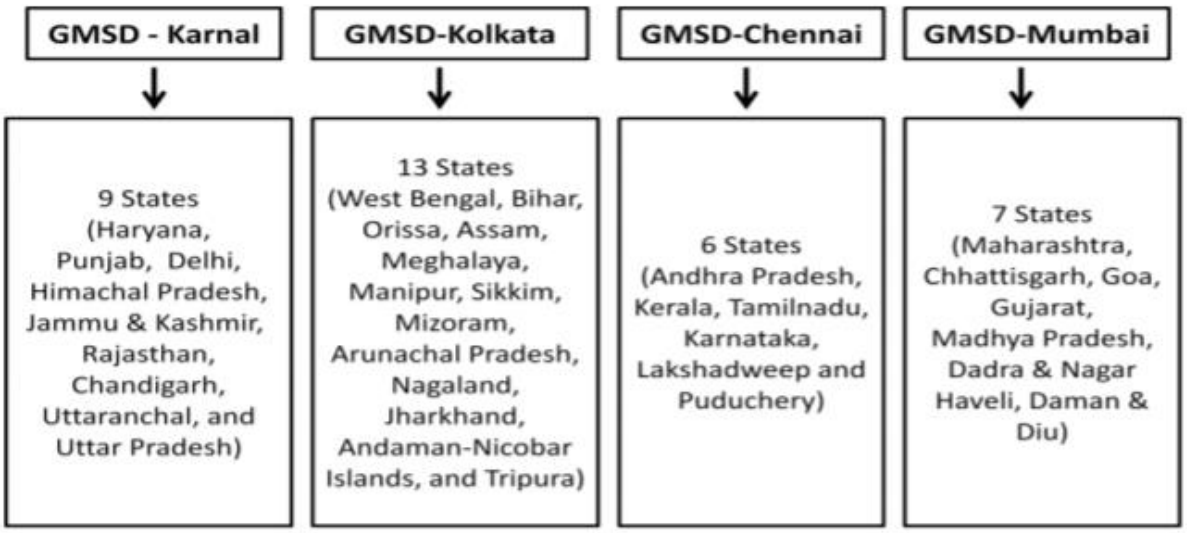
MANUFACTURER

The vaccine vials from the manufacturers premises is transported to four government medical store depot at four parts of the country through the air mode of transport. The transportation via road from manufacturer premise to the airport in refrigerated temperature controlled trucks . Logistics service provider like kool-Ex , specialised in integrated cold chain solutions have become logistics partner for SII for its distribution around the country .Balmer Lawrie is the logistics partner of Bharat Bio tech and are being continue to be part of aatmanirbhar bharat mission of the country .

PRIMARY VACCINE STORES -Government Medical Store Depot

There are 4 primary vaccine stores called Government Medical Store Department (GMSD) located in Karnal, Mumbai, Chennai and Kolkata and there are 53 vaccine stores in the country. They store vaccines in bulk and distribute further. Since these GMSD are located at north , west , south and eastern parts of the country, each depots will distribute the quantity they received to their corresponding state vaccine stores.At present the Medical Stores Organisation consist of 7 Government Medical Store Depots, located at Mumbai, Kolkata, Chennai, Hyderabad, Guwahati, Karnal and New Delhi. Chemical Testing Laboratories are attached to the depots in Mumbai, Kolkata, and Chennai to ensure the quality of the pharmaceuticals purchased from the companies. The primary vaccine stores make use of walk in coolers and walk in freezers. Which has the facility to storage at temperature ranging from -25^{o}c to 8^{o}c.

Figure.1.2: The vaccine supply network of GMSDs in India *



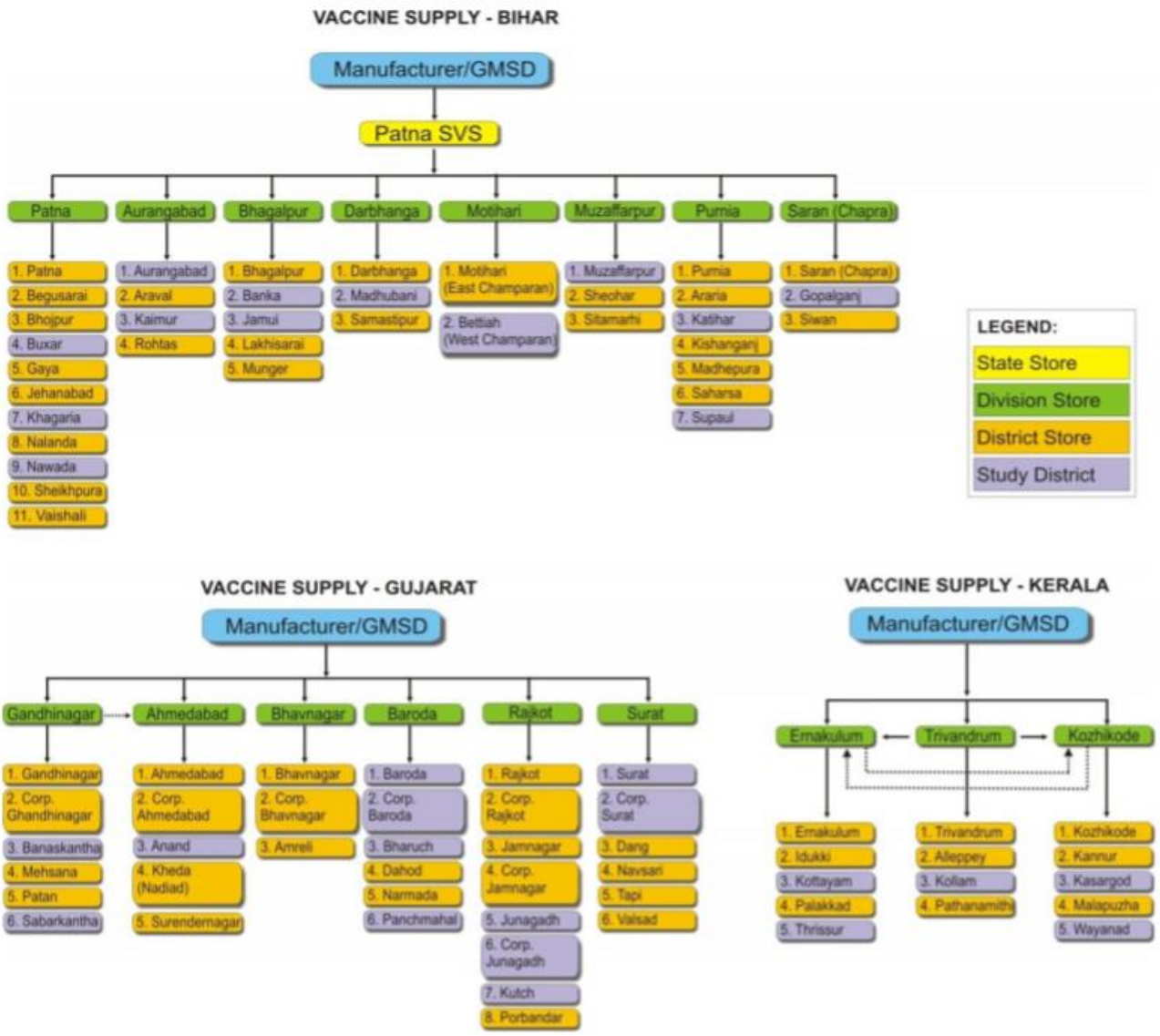
* *This identifies the regular supply practice. In real scenario, state receives from more than one GMSD.*

State vaccine stores

They are currently 53 state vaccine store as part of the mass immunization mission. The state vaccine store are allocated after considering varoius factors like the population of the region , its density , the number people infected by the corona virus ,the TRP rating of a particular region and the cold chain infrastructure available to support the distribution . These stores also makes use of walk in freezers and coolers, which has a range of -25^{o} c to -15^{o} c for walk in freezers and 2^{0}c to 8^{0} c for walk in coolers.

Kerala: In Kerala, three division vaccine stores had 4 functional and 2 non functional WICs.One WIC at Thiruvananthapuram was awaiting installation. Administrative data listed only 2WICs at two stores. The only WIF at Thiruvananthapuram was not functional at the time of the observation. The division stores in Kerala had a total of 16 ILRs (15 large ILRs and one small ILR) and23 large DFs, while the administrative record listed only about half of them (7 large ILRs and12 large DFs).A total of 439 ILRs (27 large ILRs and 412 small ILRs) and 395 DFs (14 large DFs and 381small DFs) were observed at the five districts (including the district and sub-district facilities). The administrative record indicated almost matching total number of ILRs (total421; large ILRs 14 and small ILRs 407) and DFs (total 393; large DFs 8 and small DFs 385),although the breakup numbers for ILRs differed a little 2 Electrical Cold chain equipment estimation , If the COVID-19 vaccine's recommended temperature range is +2o to +8oC, it should be kept in WICs at State/ Regional Vaccine Stores and ILRs at District Vaccine Stores and Last Cold Chain Points. COVID-19 vaccines that require storage at a temperature range of -15o to -25oC should be stored in WIFs at State/ Regional Vaccine Stores, Deep Freezers at District Vaccine Stores, and ILRs at Last Cold Chain Points.

Figure 5.1: Vaccine Supply Network in Bihar, Gujarat and Kerala



District vaccine stores

There are a total of 666 District vaccine stores around the country. The same parameter used in the selection of State vaccine stores , is also applicable to the district vaccine stores. The district vaccine store make use of deep freezers and Ice lined refrigerators.

Primary Health Centre

Currently there are 25,555 primary health centre , acting as part of the vaccination program .They pre dominantly depends on ice lined refrigerator for storage .All the above mentioned stores have active storage units for vaccine , that are highly depend on electricity ,and solar powered storage units.Rest of the part of the cold chain uses passive storage units for storage such as ice bags, portable storage units etc.

4.3 Equipment usage in cold chain network in India

S. No.	Equipment	Temperature range (°C)	Size	Level of Stores	Gross storage	Storage volume (L)	Vaccines stored
1	Cold rooms	+2 to +8	27 m^3	GMSDs and Nagpur DVS	27 m^3		BCG, Measles, TT, DPT, Hep B, Pentavalent, JE
			108 m^3		108 m^3		
2	Walk-in-Coolers (WIC)	+2 to +8	16 m^3	States and Regional/ Divisional Stores	16 m^3	5760	BCG, Measles, TT, DPT, Hep B, Pentavalent, JE
			20 m^3		20 m^3	7200	
			32 m^3		32 m^3	13440	
3	Walk-in-Freezers (WIF)	-15 to -25	16 m^3	States and Regional/ Divisional Stores	16 m^3	5760	OPV, Ice packs
			32 m^3		32 m^3	13440	
4	Ice Lined Refrigerator (ILR)- Large	+2 to +8	Large	District & Divisional Stores	198-218 L	90-108	Storage of all vaccines
5	Ice Lined Refrigerator (ILR)- Small	+2 to +8	Small	CHCs and PHCs	63.7-71 L	45	Storage of all vaccines
6	Deep Freezer (DF)- Large	-15 to -25	Large	District & Divisional Stores	281-298 L	200-213	OPV (district level and above only) and ice packs.
7	Deep Freezer (DF)- Small	-15 to -25	Small	CHCs and PHCs	105-121 L	72-92	Ice packs.

Ref: POS. World Health Organization

Walk in coolers

Walk in freezer

ICE LINED REFRIGERATOR

4.4 COLD CHAIN LOGISTICS COMPANIES IN INDIA

GATI KAUSAR INDIA LIMITED

Gati Kausar India Limited, a Gati Limited cold chain solutions division, provides temperature-controlled supply chain solutions. Gati Kausar's service offering is backed by a big refrigerated fleet, temperature-controlled facilities throughout India, and a well-trained team of cold chain professionals. Gati Kausar's goal is to give its customers a competitive advantage by providing an effective supply chain network that ensures that no orders are delayed or missed by its clients.

They have 34 years of experience in cold chain solutions and are well-versed in "best practises for handling cold chain items." Gati Kausar is well-known in the industry for handling delicate items like ice cream and medication

SNOWMAN LOGISTICS

Snowman is the country's top integrated temperature-controlled logistics service provider, focusing in warehousing, distribution, and other value-added services. They have integrated distribution solutions and state-of-the-art temperature-controlled warehouse facilities in prominent areas like Mumbai, Chennai, and Bengaluru, Which enables them to ensure the quality and temperature integrity of their customers' products from the point of origin to the point of consumption.. Their vision is " To Be Recognized As Trend Setter In Supply Chain Management By Setting Standards In Customer Satisfaction And Continuously Improving The Process. "

KOOL EX

KOOL EX is India's largest and most well-organized distribution and supply chain enterprise.
Their competitive market position is strengthened by their comprehensive offerings, which comprise surface logistics and warehousing infrastructure, a pan-India distribution network, and sophisticated technological systems. They serve a variety of industries and business divisions, including food service and pharmaceuticals. Vision of the Company Include ;To strive for excellence and innovation in everything we do.;To provide the best customer service in the business.;To establish a cost structure that ensures both our company and our customers' long-term financial viability.To strive for and maintain the greatest possible standard of quality.

For more than two decades, Kool-ex has been closely affiliated with the pharmaceutical industry. With the GDP regulations to become mandatory soon, the pharmaceutical industry's whole distribution network is undergoing a makeover. With 12 reefer vans and four cool rooms, they began our venture into the pharmaceutical cold chain in 2012. Kool-ex now has 300 reefer vans and a chain of 9 strategically situated

cool rooms, making it the industry leader in pharmaceutical shipping. Kool-ex offers services for specific temperatures: +2–8°C, 15–25°C, and -20–25°C. Kool-ex has reefer vans in the following sizes: 10', 14', 20', 24', and 32'. Dual cabinet temperature capability is available in 32FT vans.

4.5 CHALLENGES FOR VACCINE COLD CHAIN IN INDIA

Cold chain equipment replacement

To achieve goal vaccination coverage effectively and equitably, efficient and dependable cold chain equipment is essential. Some cold-chain equipment is antiquated, resulting in high operational costs as well as energy and environmental implications. Such equipment may lack temperature control capabilities, resulting in temperature swings, poor vaccination administration, and unnecessary waste..

Energy access and energy efficiency

Maintaining cold chains and keeping vaccines requires reliable energy supply. According to estimates, tens of thousands of health centres in low- and middle-income nations are not linked to the grid, and an equal number of hospitals have an inconsistent electricity supply. The energy cost of the vaccine cold chain is not taken into account in many nations' procurement processes. Inefficient systems are also added to the cold chain due to a lack of application-specific energy efficiency rules and policies. Countries' procurement guidelines should include energy efficiency as a key consideration to ensure that the cold chain's energy consumption is kept to a minimal.

Higher concentration of cold chain network in specific region

More than 70-80 percent of the cold chain network has been concentrated mainly in 4 states of the country. This dense concentration of cold chain activities itself poses a serious challenge to massive immunization mission of covid 19. The success of the mission heavily depends on the effectiveness of the cold chain network . There must be even distribution of infrastructure around country , in order to avail the vaccine vials to the people.

Absences of specially design infrastructure to vaccine distribution

Current cold chain infrastructure exist in the country , has been formed as a result universal immunization programme (UIP) , Which is meant to vaccinate newborns and the pregnant women in range of 2-3 crores. But when it comes vaccination of about 1.4 billion people , each requiring a necessary of 2 doses, means that the current infrastructure is’nt sufficient enough to support the ever rising demand. Most of the existing infrastructures has been redesign to cope with existing demand . The cold van used to transport perishable

goods such as fruits and vegetables has been altered according specification required for vaccine transportation.

Current inability to transport ultra cold vaccines

Vaccine such as pfizer , required to be stored at very low temperature of the range of -70^{o} c. But cold chain storage facilities currently available in india has a capacity of only -20^{0}c for massive distribution . Which stays a huge bottleneck for the immunization mission.

Special training requirement for vaccine handling personnel

Since the distribution of vaccine takes place at a pan india level , number of personnel available for service needs to be increase . Because of the complexity of the task involved , specific training must be given to the handling personnel , in order to ensure effective functioning of the cold chain and integrity of vaccine . The monitoring of the temperature inside the vaccine chamber, coordination of activities within supply chain require special training and becomes much more challenging when expand all over the country.

Huge level of investment for developing cold change infrastructure

At present condition , Indian logistics industry is well prepared to handle the requirements of vaccines under the range of-20^{o}c .but When it comes to ultra cold vaccines like pfizer , it was estimated that an investment of 3000 crores is required in terms of manufacturing freezers of that temperature both mobile and static as per speculation of Blue star refrigerant manufacturer.

High population

considering the size and population of the country , getting the vaccine to each individual place at distant location , while maintaining the integrity and monitoring the temperature of the vaccine required high level of coordination along the cold chain. A single mistake at any point could disrupt the flow of the entire supply chain.

Last mile delivery

Since the vaccine travel from the manufacturer premises to the end users place , the level expertise involve , will eventually diminishes.

Road express :Since vaccine distribution depends heavily on road express. The transportation of vaccine around the country , covering different states , having different infrastructure facilities from the worst to the higher level. Its the uniform effectiveness of the cold chain.

4.6 WAYS TO STRENGHTEN COLD CHAIN INDUSTRY IN INDIA

Tax incentives:

1.Section 80 of the Income Tax Act allows for deductions for profits from Cold Chain-related industrial operations. The deductions are 100 percent for the first five years, then 25 percent for the next five years.

2.A deduction of 150 percent is allowed under Section 35-AD of the Income-tax Act 1961 for capital investment in establishing a cold chain facility.

3. Under the project import advantages, a concessionary rate of customs tax of 10% is applied to imported equipment for cold chain facilities

4. Under the Income-tax Act of 1961, a deduction for investment expenditure is allowed provided the investment is made solely and exclusively for the purpose of one of the specified businesses listed below. This deduction, however, is only available for investments made in the preceding year and prior to the start of operations.

Cold chain system strengthening

Anticipating the flexible character of the COVID-19 vaccine supply in terms of mixed goods with varying storage temperature ranges, the Government of India has already put plans in place for the supply of additional cold chain equipment. . States will be critical in ensuring that these measures are completed in a timely and high-quality manner in order to ensure enough cold chain system capacity for the COVID-19 vaccine campaign. The following are the primary activities that must be ensured in order to effectively improve the cold chain network:

- Identifying places for WIC/WIF installation in accordance with the Government of India's distribution strategy.

- Ensuring that the specified sites are ready for the installation of WIC/WIF, as per standard site readiness checklists.

- Identifying locations for WIC/WIF installation in accordance with the distribution strategy of the Indian government.

• Ensuring that the designated sites, as per standard site preparation checklists, are ready for the installation of WIC/WIF.

Management during COVID-19 vaccination campaign

Sites where campaign sessions are held To avoid exposing the vaccine carrier, vaccine vials, or icepacks to direct sunlight, all precautions should be taken. Vaccines and diluents should be stored in the vaccine carrier with the lid closed until a beneficiary arrives at the vaccination centre. While the COVID-19 vaccine may not have a VVM or an expiration date on the label, this should not deter vaccinators from using the vaccine. If the COVID-19 vaccine is heat sensitive, the vaccinator should remove one ice pack from the vaccine cabinet and lay it on top of the COVID-19 vaccine, or keep it on the table (in case the vaccine is not very heat sensitive). The vaccine carrier, along with all icepacks and unopened vaccine vials, should be returned to the distributing cold chain point at the end of the session.

Intact sealed vials returned on the previous session day should be clearly identified and stored separately on the top layer of the ice lined refrigerator (ILR) so that they are the first to be utilised on the next session day.

At last cold chain points

Vaccine carriers must be clean and dry before being packed into a zipper pouch with four conditioned ice packs and vaccine vials. The VCCH should ensure that the AVDS volunteer/vaccine transporter receives the correct amount of vials, syringes, tally sheets, and hub cutter.

The Ministry of Health and Human Services will issue vaccine-specific instructions on the open vial policy. If the vaccine is not eligible for reuse open vials, dispose of the remaining vaccine and vaccination container according to the latest open vial policy instructions.

After all immunisation waste has been returned to the cold chain points at the end of the session, it should be disposed of according to the latest Government of India immunisation waste management recommendations.

On the session day itself, data input of the session day vaccination distribution should be documented in eVIN/standard stock records. The VCCH and MO I/C should monitor temperature records twice daily, either via the eVIN RTM or manually, to identify potential vaccine degradation caused by temperature excursions.. eVIN and/or regular stock registers should be used to record details of abandoned vaccines owing to any occurrence

. Weekly vaccine stock reviews will be conducted by the MO I/C and VCCH, with appropriate official notice to the supplier store in the event of any requirements for the following week's campaign activity.

. All VCCH should have the cold chain technician's contact information on hand in case there is a technical problem or a breakdown of cold chain equipment . The VCCH should undertake planned preventative maintenance of equipment in accordance with the VCCH module's guidelines.

At district level

Vaccinations must be transferred in insulated vaccine vans to sub-district stores, and all vaccines should be kept in refrigerated boxes with the required amount of condition ice packs. Vaccine stock records in eVIN and/or regular stock registers should be updated on the day of the transaction. The keeper of the district vaccine store (DVS) shall check the temperature of the DVS equipment twice a day using eVINRTM and/or manual temperature monitoring. During the campaign, the cold chain technician should follow the approved preventive maintenance schedule to cover all cold chain locations in the district once a quarter. The cold chain technician shall adhere to the recommended response time (less than 2 days following notification) and device downtime guidelines (maximum of 7 days in normal areas& 21 days in hilly areas). DIO should undertake weekly reviews of the district for the following:

• Vaccine stock situation and sufficiency for the following week at the DVS and all LCCPs in the district;

• monitoring of temperature of all district equipment, with follow-up action taken if a temperature anomaly is discovered;

• Breakdowns of cold chain equipment during the week, including required follow-up;

• Availability of VCCH at all LCCPs in the district with alternate plans for emergencies;

• Examination of vaccine stockpiles and cold chain inventory data

Using the standard GoI monitoring checklists on the SS mobile app, all district supervisors should conduct frequent, scheduled monitoring and supporting supervision of cold chain points and session locations for immunisation supply chain (ISC) management and quality.

At state level

Vaccinations should be transported to regional and district stores in insulated vaccine vans, with all vaccines kept in cool boxes with the appropriate amount of conditioned ice packs. Vaccine stock records in eVIN and/or regular stock registers should be updated on the day of the transaction. The temperature of the state

vaccine store (SVS)/ regional vaccine store (RVS) equipment should be monitored twice daily using eVIN RTM and/or manual temperature monitoring.

If a private or non-health public sector cold chain is used for vaccine storage, SEPIO and the state team should guarantee that vaccine storage is monitored on a regular basis to verify that necessary storage quality criteria are met.The SEPIO, in collaboration with the state team, should hold ISC review sessions on a weekly, bimonthly, or monthly basis, covering the following topics:

• A review of stock levels at the district level, with a focus on identifying specific replenishment needs;

• A review of temperature monitoring and equipment performance data, with a focus on required follow-up measures;

• Revision of supportive supervision data, as well as follow-up feedback and suggestions for district level activity;

• A financial evaluation of ISC expenditure for the campaign, with appropriate follow-up activities to ensure continued activity;

• A review of ISC HR status, with identification of important deficiencies and follow-up action.

Using the standard GoI monitoring checklists available on the SS mobile app, all state supervisors should conduct frequent, scheduled monitoring and supporting supervision of DVS for ISC management and quality.

Vaccine Safety and Security

The safety and security of each dosage of COVID-19 vaccine is critical, and states must take appropriate safety and security measures at the vaccine storage facility, throughout transportation, and at the session site. Vaccine security must be ensured by the state/district administration at the following locations:

1. respective vaccine cold chain points;

2. During transit of vaccine at all levels; and

3. At session site.

To prevent theft and pilferage, a strict surveillance mechanism must be in place. Any such activity should be reported promptly, and swift police action taken with clear accountability.

4.7 Operational management of COVID-19 vaccines under special circumstances (No VVM and Expiry Date on vaccine vials)

At session site

All vaccination teams should include an extra vaccine carrier with conditioned ice packs so that ice packs in the vaccine carrier with vaccine vials can be replenished quickly. A supervisor should oversee each session location, including reviewing and inspecting vaccination carrier temperature and data.

At the cold chain point

Any temperature change that lasts longer than 30 minutes should be met with alternate vaccine storage in the short term and prompt repair of the compromised cold chain equipment. During the campaign duration, the VCCH shall verify and record storage temperature at least twice daily from the eVIN RTM.

During vaccine distribution, proper ice pack conditioning should be assured, and every vaccine distribution should be monitored during campaign days. Depending on the type of vaccination provided, the open vial policy may or may not apply to the COVID-19 vaccine. The GoI will convey the specifics of the open vial policy's applicability..

In terms of the WMF, vaccine doses should be issued in accordance with the registered list of beneficiaries (rounded off to the nearest higher whole number of vials), with no adjustments made for vaccine wastage, and vaccine vials with earlier manufacturing dates should be prioritised for issue first.

At district vaccine stores

To eliminate any additional danger of temperature excursions during delivery of greater vaccine quantities, vaccine distribution should be arranged in modest quantities (e.g. on a weekly basis to all cold chain locations). A 30 DTR should be included in all refrigerated boxes used to transport COVID-19 vaccine. If there is evidence of a temperature excursion during transit, the receiving store should store the vaccine according to standard protocols in the equipment and notify the DIO as soon as possible. With cooperation from the SEPIO, CCO, and other development partners, further decisions on the use of these vaccines will be made on a case-by-case basis based on current facts.

In accordance with the WMF, vaccination doses supplied should be equal to the number of registered beneficiaries for each cold chain point (rounded up to the nearest greater number of vaccine vials). The issue amount will be determined by the supply frequency (e.g., a weekly estimate of registered beneficiaries at district cold chain sites), and vaccine batches with earlier manufacture dates should be selected for issue first.

All COVID-19 vaccines should always be stored in different ILRs/DFs from other RI vaccines (as per the vaccine's specified temperature range), and the lid should only be opened when necessary. .Continuous temperature monitoring should be ensured with the eVIN RTM with recording of half hourly temperatures for review. DIO shall conduct daily temperature checks on COVID-19 vaccination equipment and keep track of every vaccine delivery event. Any temperature change of more than 30 minutes should be met with alternate vaccine storage and emergency repair of affected equipment as soon as possible.

At State/ regional vaccine stores

All WIC/WIF should have a working autostart system with enough fuel to ensure uninterrupted power during power outages. Only during vaccine packing and distribution should WIC/WIF doors be opened and staff entry permitted. Vaccine distribution strategies should guarantee that vaccines arrive at district stores in a reasonable amount of time, and vaccine vials with earlier manufacturing dates should be issued first.

A 30 DTR should be included in all refrigerated boxes used to transport COVID-19 vaccine. If there is evidence of a temperature excursion during transportation, the receiving store should store the vaccine according to standard protocols in the equipment and notify the SEPIO immediately. Subsequent decisions on the use of these vaccines will be made on a case-by-case basis, based on available data, with the help of a national workgroup. SEPIO and CCO must check portable alarms on a daily basis, and all vaccine storage equipment must have a working eVIN RTM. Appropriate vaccine storage facilities should be established in advance of vaccine arrival, as well as all contractual arrangements and site inspections (both private and non-health public sector). Every vaccine arrival and distribution event should be overseen by state-level monitors to ensure a quality procedure in vaccine receiving and deployment.

CHAPTER-5

DATA ANALYTICS

5.1 TABLE -1 COLD CHAIN POINTS IN INDIA STATE WISE LIST

S NO	STATE/UNION TERRITORY	COLD CHAIN POINT
1	ANDAMAN & INCOBAR ISLANDS	40
2	ANDHRA PRADESH	1650
3	ARUNACHAL PRADESH	193
4	ASSAM	792
5	BIHAR	678
6	CHANDIGARH	51
7	CHHATTISGARH	630
8	DADRA & NAGAR HAVELI	19
9	DAMAN & DIU	2
10	DELHI	629
11	GOA	41
12	GUJARAT	2291
13	HARYANA	682
14	HIMACHAL PRADESH	416
15	JAMMU AND KASHMIR	681
16	JHARKHAND	275
17	KARNATAKA	2870
18	KERALA	1251
19	LAKSHADWEEP	5
20	MADHYA PRADESH	1214
21	MAHARASHTRA	3257

22	**MANIPUR**	**123**
23	**MEGHALAYA**	**189**
24	**MIZORAM**	**85**
25	**NAGALAND**	**120**
26	**ODISHA**	**1224**
27	**PUDUCHEERY**	**56**
28	**PUNJAB**	**750**
29	**RAJASTAN**	**2405**
30	**SIKKIM**	**34**
31	**TAMIL NADU**	**2599**
32	**TELANGANA**	**897**
33	**TRIPURA**	**160**
34	**UTTAR PRADESH**	**1308**
35	**UTTARAKHAND**	**373**
36	**WEST BENGAL**	**942**
TOTAL	**INDIA**	**28932**

As per the data given by NCCMIS ,Accessed on 6 th December 2020.

INTERPRETATION ;

Out of the 28 states and 8 union territories , the region with the largest number of cold chain points are in the state of Maharashtra with a total of 3257 cold chain points , followed by Karnataka with 2870 cold chain points. The cold chain points in six states constitute more than 50 % of the entire cold chain points in the state. 6 states contribute to a total of 15072 cold chain points out of the 28932 cold chain points in the country . We could also see that the number of cold chain mostly depends on the size and population of the region .

5.2 TABLE-2 COLD CHAIN EQUIPMENTS IN INDIA STATE WISE DETAILS

S NO	STATE/UNION TERRITORY	WALK IN COOLER	WALK IN FREEZER	ICE LINED REFRIGERATOR	DEEP FREEZER	SOLAR UNITS
1	ANDAMAN & INCOBAR ISLANDS	1	0	53	56	6
2	ANDHRA PRADESH	9	6	2307	2109	0
3	ARUNACHAL PRADESH	2	0	282	249	49
4	ASSAM	5	2	1186	1033	26
5	BIHAR	19	4	1655	931	
6	CHANDIGARH	1	0	69	58	
7	CHHATTISGARH	5	2	908	1017	18
8	DADRA & NAGAR HAVELI	0	0	30	33	0
9	DAMAN & DIU	0	0	26	16	0
10	DELHI	1	0	817	478	0
11	GOA	1	0	77	61	0
12	GUJARAT	9	2	2597	2467	1
13	HARYANA	8	2	1089	887	0
14	HIMACHAL PRADESH	5	1	565	579	4
15	JAMMU AND KASHMIR	5	1	1032	831	16

16	**JHARKHAND**	**5**	**3**	**686**	**699**	**5**
17	**KARNATAKA**	**9**	**5**	**3776**	**3495**	**0**
18	**KERALA**	**6**	**1**	**2106**	**1832**	**0**
19	**LAKSHADWEEP**	**0**	**0**	**26**	**15**	**14**
20	**MADHYA PRADESH**	**11**	**5**	**2311**	**2164**	**12**
21	**MAHARASHTRA**	**18**	**6**	**4408**	**4199**	**27**
22	**MANIPUR**	**2**	**0**	**109**	**99**	**15**
23	**MEGHALAYA**	**3**	**0**	**207**	**230**	**1**
24	**MIZORAM**	**1**	**0**	**131**	**111**	**20**
25	**NAGALAND**	**1**	**0**	**122**	**124**	**18**
26	**ODISHA**	**13**	**2**	**1793**	**1712**	**0**
27	**PUDUCHEERY**	**0**	**0**	**77**	**76**	**0**
28	**PUNJAB**	**6**	**3**	**1149**	**1042**	**18**
29	**RAJASTAN**	**14**	**3**	**3522**	**3472**	**6**
30	**SIKKIM**	**0**	**0**	**107**	**88**	**0**
31	**TAMIL NADU**	**18**	**3**	**2785**	**2677**	**0**
32	**TELANGANA**	**7**	**3**	**1201**	**1139**	**0**
33	**TRIPURA**	**2**	**1**	**191**	**217**	**17**
34	**UTTAR PRADESH**	**30**	**10**	**3574**	**4060**	**16**
35	**UTTARAKHAND**	**5**	**1**	**698**	**609**	**0**
36	**WEST BENGAL**	**18**	**4**	**2554**	**1927**	**294**
TOTAL	**INDIA**	**240**	**70**	**44226**	**40792**	**294**

As per the data given by NCCMIS ,Accessed on 6 th December 2020.

INTERPRETATION ;

Out of the 28 states and 8 union territories , Maharashtra has the highest number of cold chain equipment , with a total of 8643 equipment including walk in coolers , freezers, Ice lined refrigerator and deep freezer . Karnakata follows Maharashtra with a total of 7285 cold chain equipment .. The states following karnataka

are Tamil nadu , Rajasthan , Gujarat and Andrapradesh .

We could conclude that 6 states out of the 28 states and 8 bunion territory , has 52 % of the entire cold chain point and 39% of the entire cold chain equipment distribution .

5.3 TABLE-3 VACCINE DOSES ADMINISTERED IN INDIA STATE WISE DETAILS

S NO	STATE/UNION TERRITORY	DOSE ADMINISTERED
1	ANDAMAN & INCOBAR ISLANDS	149307
2	ANDHRA PRADESH	14396221
3	ARUNACHAL PRADESH	528810
4	ASSAM	6514097
5	BIHAR	15243684
6	CHANDIGARH	482322
7	CHHATTISGARH	7001970
8	DADRA & NAGAR HAVELI	341044
9	LADAKH	203984
10	DELHI	6965663
11	GOA	818072
12	GUJARAT	23964259
13	HARYANA	8167261
14	HIMACHAL PRADESH	3223244
15	JAMMU AND KASHMIR	4165831
16	JHARKHAND	6247351
17	KARNATAKA	20910937
18	KERALA	13059710
19	LAKSHADWEEP	53061
20	MADHYA PRADESH	18726397
21	MAHARASHTRA	29778681
22	MANIPUR	587845

23	**MEGHALAYA**	**641571**
24	**MIZORAM**	**518475**
25	**NAGALAND**	**440501**
26	**ODISHA**	**11037457**
27	**PUDUCHEERY**	**462474**
28	**PUNJAB**	**5839784**
29	**RAJASTAN**	**22705491**
30	**SIKKIM**	**409951**
31	**TAMIL NADU**	**14004257**
32	**TELANGANA**	**9862996**
33	**TRIPURA**	**2394983**
34	**UTTAR PRADESH**	**28906255**
35	**UTTARAKHAND**	**4023380**
36	**WEST BENGAL**	**20346448**
TOTAL	**INDIA**	**303126774**

As per the data given by Geographic insights , Dare 24-06-2021

INTERPRETATION;

Out of the 28 states and 8 union territory , Maharashtra has vaccinated the largest number of people , amoung other states , in the country ,followed by uttar Pradesh with 28906255.. A total of 303126774 Doses has been Administered in the country , which include both first and second doses of vaccine available currently , which includes Covid shield , Covaxin and sputnik .

INTERFERENCE ;

The amount of doses administered by each state of the country , has a close relation with Cold chain logistics available in each state . Maharashtra with largest number of cold chain points and equipment stands first , with the largest number of doses being administered in the country , followed by Uttar Pradesh, Gujarat and Karnataka. All these state are well advanced in terms of cold chain infrastructure , compare to other states in the list.

CHAPTER-6

FINDINGS, SUGGESTIONS&CONCLUSION

6.1 Findings

1.Indian cold chain network currently have a capacity of 374.25 lakh MT , predominantly focused in the perishable food products. For the massive immunization mission , its requires a considerable re - modeling and investment in the infrastructure capacity and capability.

2.Most of the cold chain networks in the country is concentrated in four states , which accounts for more than 70% of the total cold chain infrastructure.

3.In order to provide vaccine to 1.5 billion people across the country , the government could rely on single logistics provider and a hand full of manufacturers. The high level demand for the vaccine in the market should be balanced with an equal amount of supply , which means the vproduction capacity should be augmented .

4.The number of cold chain points and vaccine administering points should be increased in order to reach further beneficiaries.

5.The use of technology in monitoring the vaccine temperature helps to determine vaccine integrity and the counter measure to take , in case of serious faults in the cold chain system .

6. The government have devised a concrete plan for the effective flow of vaccine along the cold chain network. The use active and passive storage units , depending on the availability of resources , has been one of the criteria for the determination of the cold chain points along the national , state and district level

7.The storage of ultra cold vaccine , in the last mile delivery has been a major concern for its employment in the Indian scenario . Manufactures such as voltus , blue star came up with the idea of the use of dry ice , to substain the temperature upto level -70^0c. For a duration of 24 to 48 hrs in the vaccine carrier.

8. In the initial stage of the introduction of the vaccine to the indian market was provided with high level of security and protection , because of the issue of pilferages and theft .The logistics provider were given protection from the central and state armed forces throughout flow across the cold chain.

9.Strict instruction were provided by the logistics providers to the driver , regarding the movement, any deviation from the proposed plan could detected by the provider , with geographical positioning system(GPS).

10. The government also provide support to the logistics industry, by provide incentives , guidelines and training to the personnels handling vaccine for the first time.

11.Currently India deals with three types of vaccine , all the three are producing within the country , which means the vaccine transportation will be predominantly based on road express. Cold chain logistics provider such as TCI, Snowman, kool-ex , all other provider ,targets utilise this oppurtunity to the maximum extent.

12.There exist a trends in existence of cold chain infrastructure towards richer parts of the country , while leaving behind the poor region with minimal facilities.

6.2 Suggestions

1. In the initial phase of vaccine distribution , the country experience its shortage , mainly because of the miscalculation in the amount of the required quantity . Expanding the production capacity is one of the ways to mitigate this problem . Currently Serum institute expands its production level to 90-100 million doses , in the month june 2021.

2.The training of the personnel in the cold chain networks , helps to avoid wastage of vaccine due to mishandling and other technical glitches.

3.Proper coordination of the cold chain is required for the smooth functioning of the network.The use of evin helps to determine the stock and monitor temperature level at the state, district amd regional level.

4.The vaccine storage facility must develop and maintain clearly written, detailed, and up-to-date storage and handling standard operating procedures (SOPs) . . Standard operating procedures (SOPs) will keep your facility structured, operate as a reference and training tool, and ensure correct vaccine administration. SOPs assist in ensuring that proper procedures are followed and that issues are detected, reported, and corrected. SOPs should also include instructions for dealing with emergencies such as equipment breakdowns, power outages, or natural disasters.

5.when it comes to vaccine storage in large quantity Use purpose-built or pharmaceutical-grade units designed to either refrigerate or freeze. These units might be small, under-the-counter, or enormous in size.

6. Storage unit doors that is not sealed properly or left open unnecessarily not only affects the temperature in a unit, it also exposes vaccines to light, which can reduce potency of some vaccines. Consider installing self-closing door hinges, door alarms, or door locks to assure that the unit's doors stay sealed.

7. Use a digital data recorder to have the most comprehensive storage unit temperature data, along with how long a unit has been operating outside of the recommended temperature range (known as a "temperature excursion"). A DDL offers extensive information on all temperatures recorded at predefined intervals, unlike a conventional minimum/maximum thermometer, which only indicates the coldest and warmest temperatures measured in a unit.

8. The first step in vaccine inventory management is to keep the cold chain intact. When vaccine delivery come, staff members who may accept them should be instructed to quickly alert the vaccination coordinator or substitute coordinator. Vaccines must always be checked and stored properly as soon as they arrive.

9. Vaccine makers should also offer information on how to properly dispose of their products, including any vaccines that are no longer in use. Unused vaccines may be returned to the manufacturer in some cases. Empty vaccination vials aren't normally considered hazardous or pharmaceutical waste, thus they don't need to be thrown away in a biomedical waste receptacle.. Check and comply with the regulations for disposal within the specified jurisdiction.

10. COVID-19 vaccination programmes should be planned all the way down to the final mile. To preserve the efficacy of the COVID-19 vaccine, the main issue will be to ensure that each immunisation station is equipped with enough fixed and outreach cooling equipment based on local needs (such as target population, road conditions, and electrical access) It's also crucial to consider population densities, travel times, and distance to vaccination sites, all of which can be aided by geographic information systems (GIS) data. Vaccines are provided through fixed facilities (health centres), outreach sessions, and, in certain situations, mobile activities in many countries' routine immunisation programmes., In rural and isolated locations where there is no direct access to health centres, outreach tactics are commonly utilised to raise immunisation rates. Over 44 percent of the world's population lives in rural areas (for example 63 percent in Bangladesh, 65 percent in India and 83 percent in Rwanda) .

11. Getting vaccines to far-flung locations necessitates significant investments and technological ingenuity. International development aid alone will not be sufficient to meet the demand; coordination between the private sector and governmental resources, as well as locally mobilised private finance, will be required. Even if the vaccine requires a temperature range of 2–8°C, current government-controlled vaccine cold chains utilised in routine immunisation programmes will not be able to meet demand, especially in developing nations The cold chain capacity must be improved in terms of storage, transportation, and having in place a skilled workforce for monitoring, maintenance, and support to ensure the continuous availability of quality COVID-19 vaccines from the manufacturer to every community, village, and settlement in a country. Furthermore, cold chains should be outfitted with sophisticated temperature and humidity control systems, as well as waste management and recycling infrastructure.

6.3 CONCLUSION

The India cold chain network is currently adequate to support the massive immunization mission initiated by the government of India. The government lay down a systematic plan for the distribution of vaccine throughout the country with the help of third party logistics provider .The public private partnership in the covid 19 vaccine distribution proves to be fruitful .The incentives provide by the government to the private entities helps to them to invest heavily in the distribution of new sophisticated infrastructure to respond to the ever change requirements in the market and to become highly resilient in their way of working . The manufacturers of vaccines were given a financial assistance around 3000 crores in the vaccine programme. The development and efficient use of technology also helps to strictly monitor the flow of vaccine through the cold chain and takes preventive measures , as and when required. The use of internet of things (IOT) and AI , helps to make things much more automated . Helps finds deficiencies in the cold chain and rectify those errors .Despite the concentration of cold chain activities in few regions in rthe country The logistics providers coupled with government support were able to overcome this issue.

Despite the negative aspect of the covid 19 virus . Vaccination programmes also helps in the development of cold chain infrastructure in the country . The instalments of cold chain infrastructures like walk in freezers, refrigerator ,Reefer van , large cold storage structures are examples of such development .With production reaching 10 crores of doses per month and completely digitalised and technical supported cold chain infrastructure , we could estimate that the pandemic could be ended by the end 2022 . Proper coordination and monitoring in the cold chain network is required to achieve this goal .

6.4 Direction for future Researcher

Indian cold chain network is current on the path of development . The covid 19 crisis provides opportunity for investment in the cold chain infrastructure development mainly in the number of cold chain storage and technology used in the industry .With increase in number of participants in the Indian cold chain industry , mainly due to boom produced the necessity temperature sensitive covid vaccine ,threat of theft and pilferages are on the higher side . The data of each cold chain logistics company are highly confidential pertaining to a particular customer . Therefore the future emphasis in cold chain should be towards the development of technology , both conservation of goods onboard and to avoid data leakage with the installation of block chain technology and Internet of things.

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