Study of Supply Chain Management in Cold Chain Logistics in Vaccines of Pharmaceutical Industry (Central Drug Store)

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Abstract: This Paper studies the Supply chain management in Cold chain logistics of pharmaceutical industry, in this that the Vaccines cold supply chain process generally starts after the completion of manufacturing of vaccine at the industry. It is transported to the various countries according to the requirement of temperatures. The vaccine is transported from industry to SVS (State Vaccine store), RVS (Regional Vaccine Store), DVS (District Vaccine Store), PHC (Paramedical Health Centers), Sub-centers & Vaccination places. Throughout this transport the vaccine is maintained at the required temperatures without losing their quality. The WIC (Walk in coolers) and WIF (Walk in freezers) are used for the storage of huge number of vaccines with in the required temperatures and from PHCs to the vaccination point the vaccine will be transported in Non electrical equipment like Vaccine carriers which contain icepacks to maintain the required temperature for about 6 hours. The ILR (Ice Lined Refrigerator), DF (Deep Freezers) are used for storage of vaccines according to the required temperature. The ILR temperature is between $+2^{\circ}$ to $+8^{\circ}$ C. The DF temperature is between -15° to -25° C. It should be very close and cautious monitoring of temperatures, so that the vaccine condition will not get altered from starting to ending of the process and for this there will be thermometers kept inside and special personnel equipment will also be allotted for the monitoring.

Index Terms - Cold chain logistics, Pharmaceutical Vaccines, Temperatures.

I. INTRODUCTION

Vaccine Immunization is one of the best ways to prevent infections. All citizens of the nation are protected under the UIP (Universal Immunization Program) from Tuberculosis, Polio, Hepatitis B, Diphtheria, Pertussis, Tetanus, Hemophilus influenzae (type b), Meningitis, Pneumonia, and other invading illnesses are all fatal vaccine-preventable illnesses (VPDs). Rotavirus diarrhea and the influenza. Since that UIP's inception, a huge network of refrigerated chain retailers has been established, including State, District, and Sub District Vaccine Stores as well as Government Medical Stores Depots (GMSD).

Immunization, the executives have a goal to keep up with the health and intensity of vaccination while shipment and capability. The immunizations lost their power on the off chance that they are not put away or shipped at the suggested temperature and condition.

On the off chance that antibodies are not put away securely (inside suggested temp.), it might prompt Unfriendly Occasion Following Inoculation (AEFI). Consequently, all endeavors ought to be made to hold the security of the antibody, and keeping up with the suggested temperature.

Refrigerated system in the nation has been the spine to guarantee the conveyance of immunization, The coordinated factors has been overseen through a pattern of putting away and moving immunizations in a pre-characterized connections. In India, there are 5 degrees of immunization stores:

- 1. Primary Vaccination Stores
- 2. State Vaccination Stores
- 3. District Vaccination Stores
- 4. Primary Health Centre (PHC)
- 5. Subcenters or session sites

The cooler network is essential to maintaining vaccine environmental consistency because it ensures the efficiency, security, and purity of the vaccine, which in turn gives patients enough immunity against a variety of contagious illnesses. A biotechnology item, vaccines must be distributed with great care. The cold-chain approach is a method of transmission in which vaccinations are kept at a specific temperatures beginning with dispatching from the manufacturing facility and continuing through transport, storing, and use. Although polio vaccinations are temperature-controlled at -20°C, vaccines against OPV (ORAL-POLIO-VACCINE), RVV (ROTA-VIRUS-VACCINE), BCG ((BACILLE-CALMETTE-GUERIN), and diseases are maintained between 2 and 8°C.

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III. Cold Chain comprises a progression of capacity and transport interfaces, which are all intended to keep the immunization at the required temperature from the place of production until it arrives at the objective recipient.

To give powerful and workable immunization to the recipients, a huge We need a refrigeration network, which needs to have an organization of Immunization Stores alongside essential -walk in-freezers (WIF), walk-in-coolers (WIC) (WIF), Deep Freezers (DF), Ice Lined Refrigerators (ILR), At the basic level to the regions up to the initiative conferences, chilled vans, secured immunization vans, cold boxes, vaccine transports, and ice packs are available.

This is a representation of the nation's cool supply network and vaccination supply.:



Cold Chain System

A collection of equipment known as "cold chain system" helps keep vaccines at a specific temperature when transporting from the place of manufacturing and storing to the calculated recipients, protecting their purity. The UIP's technology is organized into the following categories.

• <u>Vaccine transport from the place of manufacture to the place of vaccination and the</u> <u>management of Temperature during the transport</u>

AFTER VACCINE - MANUFACTURE, COLD CHAIN OF VACCINES FROM AIR-TRANSPORT TO PRIMARY VACCINE STORE

In the wake of finishing the production of vaccines, they need to be put away at specific required temperatures i.e., $(+2 \circ C \text{ to } +8 \circ C)$ and $(-15 \circ C \text{ to } -25 \circ C)$ in air-transport cargo,



via air guiding airliners and In order to maintain the low temperatures within - 8° C and - 70° C necessary for its transportation, airline authority must ensure the vaccinations are packaged in dried ice and chilled material. The Standard Aeronautical Director General will issue the regulations to all planned administrators who have been right now approved to obtain vaccines like Measles, OPV (Oral Polio Vaccine), RVV (Rota Viral vaccine), BCG (Bacilli Calmette-Guerin), J.E(Japanese Encephalitis), The Vaccines were loaded in dry ice, meeting the administrative requirements, and it was the beginning phase of the cold chain. According to the rules, Vaccines loaded in dry ice need to ideally be moved in the bottom decks of an aircraft's cargo hold but on the off chance that the administrators want to carry vaccines in the passenger cabin area, the administrators should guarantee that the citizens on board are restricted to the flight group while different passengers need not be permitted. The administrator needs to do whatever it takes to guarantee that the flight team isn't damaged by carbon dioxide weakening or intoxication. Flight groups need to be appropriately prepared for the dangers and dangers of dry shipping ice and the methods connected with the activity. Some other citizens on board need to possibly be permitted whenever expected under exhibited alarming functional necessities (e.g., extra flight group for the return flight or extra people required for the cargo taking care of). Inhabitants, those who are not considered as flight team, need to be safeguarded against a potential CO2 intoxication by the method for approaching during all periods of the travel an authorized supplementary oxygenation apparatus fit to be utilized, having been appropriately prepared on the utilization of oxygen hardware," it added. It stated that there needed to be enough CO2 sensors available in the cabins. In the event that more vaccinations are transported in ice cubes than allowed by the job manuals or other pertinent manufacturer records for the aircraft, the administrator needs to perform a special risk evaluation. The risk evaluation needs to guarantee that all significant specialized and functional views have been considered, it noted. For airplane dispatch, the cooling, air supply, and distribution/ventilation framework need to utilize designs suggested by the producer, DGCA (Director General of Common Aeronautics) expressed. "In the event that the

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ventilator partially fails during plane, the situation must be thoroughly examined in order to determine whether the plane can proceed to its destination. The OEM (Original Equipment Manufacturers) recommendations should take into accounts an one subsequent major failures to allow the aircraft to continue, although the respiratory system as a whole would be a huge disaster in flight needs to start a quick redirection to the closest reasonable airport," it added. The flying service had coordinated all aircraft to start arrangements and had educated air terminal administrators, including the state-run Airport Authority of India (AAI), ground dealing with specialist organizations and aircraft to set up standard operating procedures (SOPs) for the shipment of vaccinations with the authorized funding, transport of vaccinations from the vaccine assembly facilities to the site of organization acquires huge significance, particularly in the radiance of the elevated requirements of the government(s), medical care faculty and the overall population. It is clear that air travel is the highest efficient option available amongst various modes of transportation. Thus, air coordinated operations genuinely should give an obvious strategy that satisfies the worldwide security guidelines and prerequisites in view of nearby circumstances," the DGCA (Director General of Common Flying) noted. The Operators need to guarantee that the shipments containing antibodies pressed in dry ice will be acknowledged and taken care of by suitably prepared staff as it were. Operators arranged a 'Dos and Don'ts' direction and course among those dealing with staff regarding the particular conditions that might be suitable for dealing with shipments containing vaccines The document stated that "satisfactory safety measures should be gone towards the end of a plane, as containers or a Cargo Handset involving ice cubes will usually have a rising density of CO2 and moreover the area rapidly outdoor, the door encounters high grouping of CO2 for a few minutes." Operators must also make sure that each package of vaccinations packed in dry ice is prominently marked with the words "Dry ice or Carbon Dioxide Strong." Technicians must also communicate the quantity of dry ice packed, indicating storage regions, to the Pilot-in-Charge in writing, and after the appearance of vaccines to state vaccination store or regional vaccine store.

- **Walk-in-Freezers** (**WIF**) The walk-in-freezers are a specially constructed freezer rooms with two equal refrigerators and a backup generator set that is shielded by a polyurethane froth (PUF) panels to supply give continuous power. The Generator set begins naturally when the power cuts off.



Walk-in-Freezers (**WIF**) The walk-in-Freezers a pre-manufactured particular Two sets refrigerator units are housed in a cold store covered by polymeric frothy (PUF) panels, and a system operating is built up to provide continual electricity. The Generating device begins naturally when the power cuts off.



The vaccines need to be kept in WIF (Walk In-Coolers), WIC ((Walk In-Coolers) as the (Walk in-Coolers and (Walk In-Coolers are pre-manufactured Two equal refrigerated units are placed in a module polyurethane foam (PUF) covered boards collection cold room, and a system operating is installed up to provide continuous electricity. They keep a temperature of $+2^{\circ}$ C to $+8^{\circ}$ C(WIC) and -15° C to -25° C (WIF). In India, under UIP ordinarily, WIC with limits of 16.5, 32, and 40 Cubic meters are being used. The devices are utilized generally in cold and cooler rooms where mass vaccines are put away and, in this transportation, for temperature checking, there is temperature Monitoring systems, multi-log sensors, data loggers, and indicators. which were alert alarms, auto-dialers, changing boundaries like logging intervals, estimating units (° C or ° F) to the site area, and information document area. Telematic information abilities are like that of compartment systems. It requires programming for designing and downloading the information to the computer, which is vital for vaccine security until it arrives at the following cold chain process vaccination store.

COLD CHAIN OF VACCINES FROM PRIMARY TO STATE VACCINE STORE THROUGH REFRIGERATED VAN

For over distribution, a variety of transporting refrigerator products in a few capacities are available from primary to state vaccination stores through refrigerated vans.



Examples of refrigerated systems for vehicle and trailers transportation. Trucking solutions are often categorized as those used with box lengths in the 3.5 to 9.5 m range. Solutions for trucks are used to more significant 12 to 16-m box sizes. Refrigerated items for roadway transportation utilize onboard power generators for independent activity. Diesel motors that have independent fueling supplies from the primary movers supply either straight energy to the cooling unit or energy from auxiliary generators. Fans in straight circuits will be able to bypass belts or use a small generators, and a blowers connected to the engines will be included. All refrigerated components in purely electric installations are powered by generators that are connected to the engines, or alternator. The ability to use standby modules energy while not in transportation makes purely electric trailers solutions and straight solutions with a standby motor useful for on-location capability. They are suitable for all situations with the exception of extremely low vaccination temperatures because their normal temperatures regulation ranges from - 30°C to 30°C in environments up to 50°C. Units are upstream, with returned air coming from the base and adaptive air conducted out of the greatest position of the units.

A few applications use air chutes or different methods for guiding wind stream to the rear of the compartment to further develop temperature circulation, and power upon the item stacking setup. Furthermore, after the appearance of immunizations to state vaccination stores, Vaccines need to be kept in WIF (Walk In-Coolers), and WIC (Walk In-Coolers) on the grounds that the Walk in-Cooler is a pre-created particular Polyurethane Foam (PUF) protected board gathered Two identical refrigerated units are placed in a deep freezer, and a system operating is set up to provide continual electricity.

Furthermore, the Walk in-Cooler is a pre-manufactured measured Polyurethane (PUF) protected board collected two similar refrigerators in a deep freezer. They monitor the temperatures of $+2^{\circ}$ C to $+8^{\circ}$ C and -15° C to -25° C. Under UIP as a rule in India, WIC with limits of 16.5, 32, and 40 Cubic meters are being used. The gadgets are generally utilized in cold and cooler rooms where mass vaccines are put away and, in this transportation, for temperature checking, there is focal temperature Observing systems, multi-log sensors, information lumberjacks, and markers, which were caution alarms, auto-dialers, changing boundaries like logging stretches, estimating units ($^{\circ}$ C or $^{\circ}$ F) to site area, and information documents area. Telematic information abilities are like that on holder systems. It requires programming for designing and downloading the information to the personal computer, which is critical for vaccine security until it arrives at the following cold chain process vaccination store.

COLD CHAIN OF VACCINES FROM STATE TO DISTRICT VACCINE STORE THROUGH INSULATED VAN

Insulated vans are small delivery vehicles, commonly utilized for local short-distance delivery from state to districts, with various configurations accessible. In this vehicle, the systems use a blower powered from the main truck, coupled to the refrigerated unit by refrigerant hoses. Others employ a generator that is powered by the car, with the refrigerated unit receiving electrical energy. Moreover, warm capability is utilised in some situations. Climate control ranges from - 29° C to 30° C degrees Celsius in environments up to 50° C degrees Celsius, making them suitable for various vaccine storing settings. The figure shows an illustration of a little refrigerated delivery vehicle.



For local supply and capacity, mobile transporting containers lifters with temperatures controls are available. Examples of mobile refrigeration containers are shown in the figure. A working refrigerated systems with an integrated compressors and evaporators for refreshing, melting, and warmth are present in these kinds of vessels. Such chambers are designed to be arranged inside a transport truck, where they can operate separately using synchronized, additional battery power or by drawing power from an assistance port on the truck. These receptacles can be used to store the item at desired conditions once they have reached their destination using regular wall electricity. Quantities for applications in the pharma industry range from 140 L to 720 L. Temperature control for the most part goes from -21 to 30° C, with a portion of the larger compartments able to do -30° C set-focuses in up to

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 50° C surrounding. Little, cooler-sized (32 L to 82 L) items are additionally accessible for more limited-size circulation. Cooling ability ranges by size, from - 24°C down to - 31°C.

Furthermore, after the appearance of vaccines in the state vaccination stores, the vaccine at the Primary Health Centre will be put away at the optimum temperature in ILRs (Ice Lined refrigerators), which is the main connection in ILR is the cold link. This technology uses a vapour compression technique, much like any other standard cooler that runs on a 220 volt, AC mains source. In any case, the ILR has a top entrance covering to stop cold air from escaping when the door is opened. Cabinets temperatures are must be maintained among +2°C to + 8°C and - 15°C to - 25°C, and DFs (Deep Freezers)), The Deeper Freezing is a piece of machinery that runs on the same vapour compression systems as any typical refrigerators that is powered by a 220 volt AC mains supply. However, the DF features a top opening top to stop the loss of cold air when the door is opened. DFs were made available as part of the vaccination programme for the capacity of vaccine immunizations at suitable levels and planning of Icepacks, according to their necessity of capacity temperature. There will be separate ILRS and DFs for every immunization at District Vaccination Store. The gadgets are utilized generally in cold and cooler rooms where mass vaccines are put away and, in this transportation, for temperature checking, there is focal temperature Observing systems, multi-log sensors, information lumberjacks, and indicators. which were alarm warning cautions, auto-diallers, changing boundaries like logging intervals, estimating units (° C or ° F) to the webpage area and information records area, Administrators arranged a 'Do's and Don'ts' direction and flow among those dealing with staff the particular necessities that might be relevant for taking care of shipments containing vaccines. Telematic information abilities are like that of container systems. It requires programming for designing and downloading the information to the computer and is urgent for vaccine immunization security until it arrives at the following cold chain process vaccination store. COLD CHAIN OF VACCINES FROM DISTRICT TO PRIMARY HEALTH CENTRE THROUGH **INSULATED VAN**

Vaccines will be transported from districts vaccine station from the statewide vaccine shop and from theregarding the local vaccine shop and then to the PHCs in insulated vehicles.

In addition to heat exchanges for chilling, freezing, and warming, these kinds of vessels have an active refrigeration unit with an integrated compressors. These containers are made to be placed inside a transport truck, where they can use the vehicle's accessory port for energy or run independently on an optional inbuilt battery. These canisters can be used to keep the goods at appropriate conditions once they have reached their destinations using regular wall electricity. Quantities for applications in the pharma industry ranged from 140 L to 720 L. The typical temperatures regulation spans from -21 to 30°C, with some of the bigger containers being able to maintain limit values of -30°C in temperatures as high as 50°C external. For smaller-scale delivery, shorter, cooler-sized (32 L to 82 L) items are also offered. Size-dependent refrigeration varies from -24°C to -31°C., which will maintain the required temperature of vaccine storage throughout the transportation. The transport vehicle size from the DVS (district vaccine store) to PHCs will be relatively lesser as the quantity is less. And after the arrival of vaccines to state vaccination store, the vaccine at Primary Health Centre will be stored in the optimum temperature in ILRs (Ice Lined refrigerators), The ILR is the cold chain's most crucial link. This device uses a vapour compressing process that is identical to that of any typical refrigerators that runs on a 220 volt, AC mains source. ILR, however, has an upper lid to stop the loss of cooler air when the door opens. ILRs are required to keep a cabinets temperatures of within +2°C and +8°C, while DFs (Deep Freezers) are equipments that use a vapour compressing process to work on a 220 volt A.C. mains source, much like any other common form of refrigerators. To counteract the loss of cooler air during doorway, the DF incorporates a top opening lid. DFs have been provided as part of the immunisation campaign for vaccine storing at the proper level for ice packing manufacturing, as per their requirement of storage temperature. There will be separate ILRS and DFs for each vaccine at DVS. And there will be one DF and 1 ILR at PHC levels. The devices are used mostly in cold and freezer rooms where bulk vaccines are stored and, in this transportation, for temperature monitoring there are



central temperature Monitoring systems, multi-log sensors, data loggers, indicators. which were alarm-alerts, auto-dialers, adjusting parameters such as logging intervals, measuring units (° C or ° F) to site location and data file's location, Operators prepared a 'Do's & Don't give instructions or make the precise specifications for managing packages carrying vaccinations known to the processing workers. The possibilities of telematics data are comparable to those of containment networks. It requires software for configuring and downloading the data to the computer, is crucial for vaccine security until to reach the next cold chain process vaccination store.

• <u>ILR(Ice Lined Refrigerator)</u>

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ILRs (Ice Lined refrigerators) is ILR is the critical link in the refrigeration. This device uses a vapour compressing mechanism that is identical to that of any typical refrigerators that runs on a 220 volt, AC mains source. ILR, however, has an upper lid to stop the loss of cooler air when the door opens. ILRs are required to keep the cabinets at a temperatures of within $+2^{\circ}C$ and $+8^{\circ}C$.



• **DF(DEEP FREEZER)**

DFs (Deep Freezers)), The Deeper Freezing is a piece of machinery that runs on a vapour compressing mechanism, much like a regular refrigerators that is powered by a 220 volt, 50 hertz mains source. To counteract the loss of cooler air during doorway, the DF incorporates a top opening lid. DFs have been provided as part of the immunization campaign for vaccine storing at the proper levels for ice packet manufacturing, as per their requirement of storage temperature.



COLD CHAIN OF VACCINES FROM PRIMARY HEALTH CENTRE TO SUBCENTRES AND FINALLY TO PATIENTS THROUGH VACCINE CARRIERS

The vaccine immunization on the vaccination days will be shipped from the PHC to the sub-centers or the spot any place the vaccination happens, through vaccine carriers.



When fitted with coolant packs, VACCINE Shippers are shielded holders that keep diluents and vaccinations cold during travel. Vaccine transporters are smaller and easier to carry while walking than refrigerated boxes. The volume of vaccine immunisation carriers is more manageable for use by health workers during immunisation campaigns and outreach at administrators. Since these are passive devices, coolant packs are used as extras for cold containers and vaccine vehicles to provide temporary cooling. On a primitive level, the items are simple. Generally speaking, little talent is required to use them. According to the instructions provided for the item (drawings inside the front of the packages or carriers), coolant packs are put into the containers that have been filled with vaccine vials. The maximum amount of vaccine that can be stored in vaccination carriers ranges from 0.8 to 3.4 litres. One bunch of cooling packs are included with every cold box and vaccination carrier as standard.

Vaccine bearers can be divided into two groups, as follows:

- 1. Limited reach: At 43°C external temperatures, the minimal cold life is 15 hours.
- 2. Extended range: With a minimal freezing life of 30 hours at 43°C external temperatures.



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COLD BOXES are enclosed receptacles with cooling packets mounted to them that are used for both short-term storing and transporting of vaccinations and diluents. Cold boxes are used to collect and transport vaccination materials from one vaccination store to the next as well as from vaccination stores to medical offices. When the refrigerators is broken, full, or melting down, these items are also utilised to permanently hold vaccines. The maximum amount of vaccines that can be stored in cold boxes is between 5 and 25 litres. Cold boxes go into one of two categories: 1. Short reach: A 48-hour minimum period of cold exposure at 43 °C. 2. Long reach: A least 96-hour cold survival at 43°C ambient temperatures

These vaccine carriers contain ice packs that will keep the optimum temperature for vaccines for 6 hours. These ice packs are loaded up with water and kept in deep freezers to make them cool and helpful for keeping up with temperature during the local transport of vaccine immunization.



VACCINE CARRIER INSIDE



ICE PACKS INSIDE THE COLD BOX

ICE PACKS Preparation and Usage:

- > Up to the marking, add water to the cold packs.
- > Fill the sealant bung, then firmly screws on the lid.
- > Compress each cold pack while holding it upside-down to prevent leaks.
- > Put the cold pack in the refrigerator that is deep.
- > It's not necessary to refill cold pack after each use. Water may be reused over and over.
- Saline water should not be used for loading.

> STATISTICAL ANALSYS

S.NO	VACCINATION STORES (WITH REQUIRED EQUIPMENT)	VACCINES	TEMPERATURES IN CENTIGRADE
1	PRIMARY, STATE VACCINATION STORE (WALK IN FREEZER(WIF))	OPV (ORAL- POLIO VACCINE)	-23.5 °C
2	PRIMARY, STATE VACCINATION STORE (WALK IN COOLERS(WIC))	RVV (ROTA- VIRUS VACCINE)	-18.6 °C
3	DISTRICT VACCINE STORE, PRIMARY HEALTH CENTRE (ICE-LINED REFRIGERATOR(ILR))	BCG (BACILLE CALMETTE- GUERIN)	4.2 °C
4	DISTRICT, PRIMARYHEALTH CENTRE (DEEP FREEZER(DF), VACCINE CARRIERS)	MEASLES	6.1 °C



Note: When research packets are housed together in storing rooms or transported in cold chain machinery during the refrigeration operation, temperature records from each study packet varies somewhat. The location of the research packets and the cold air flow were both impacted by thermodynamic, which is mostly to blame.

RESULTS AND CONCLUSION

The research included different vaccines in the cold chain equipment in the references I plot a pie-chart between temperatures in centigrade and for vaccines in different equipment and in my overall observation I found that different temperatures have been recorded between the range of (-15 °C to -25 °C) and (+2 °C to +8 °C) within the specific time to maintain and reach the final stage., among 60 health organization centers, just 46(76.7%) had walk-in-coolers/walk-in-freezers. 21 (35%) had a function generator for support administration and 28(46.6%) had an airliner/refrigerated-van/insulated-van/motorbike for transportation of vaccine immunizations if there should be an occurrence of refrigerator/power disappointment. Twenty-nine (48.3%) had known the right vaccine storage temperature (2 °C - 8° C) in the Ice Lined Refrigerators (ILR)/Deep Freezers and the results of this study found that just 23(38.3%) of respondents had good knowledge about vaccine immunization cold chain management by temperature monitoring devices.

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