Advancement in Cold Chain Logistics

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IPA INNOVATION. QUALITY. GLOBAL REACH.

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"Certain information set forth in this presentation contains forward-looking information.

“Our mission is to improve life expectancy and the quality of life. This requires good science. For science to be good, it has to result in affordable medicine.”

Dr. K. Anji Reddy
Founder, Dr. Reddy’s
(1941-2013)

One Purpose

We accelerate access to affordable and innovative medicines

because

Good Health Can't Wait.

Billion plus patients served

40+ countries

400+ products

We are present in all major regions of the world

Commercial Presence in

42

Countries

- ALGERIA
- AUSTRALIA
- BANGLADESH
- BARBADOS
- BELARUS
- BRAZIL
- CANADA
- CHILE
- CHINA
- COLOMBIA
- FRANCE
- GERMANY
- GHANA
- GUATEMALA
- INDIA
- INDONESIA
- ITALY
- JAMAICA
- KAZAKHSTAN
- MALAYSIA
- MALDIVES
- MEXICO
- MOROCCO
- MYANMAR
- NEPAL
- NEW ZEALAND
- PERU
- ROMANIA
- RUSSIA
- SINGAPORE
- SOUTH AFRICA
- SPAIN
- SRI LANKA
- THAILAND
- TRINIDAD
- TURKEY
- UK
- UKRAINE
- US
- UZBEKISTAN
- VENEZUELA
- VIETNAM

9

API Manufacturing Facilities

13

Formulations Manufacturing Facilities

5

Global R&D Centres

2.3

USD 2.3 Bn turnover in FY 20

Agenda

Evolution

Quality Standards for the Elements of Cold Chain

Template for the End to End Cold Chain for Pharma

Cold Chain Public Infrastructure in India

Elements for setting up a Cold Chain Network

Last mile distribution for Vaccines

Quality System for Cold Chain

Summary - Key Considerations for Cold Chain

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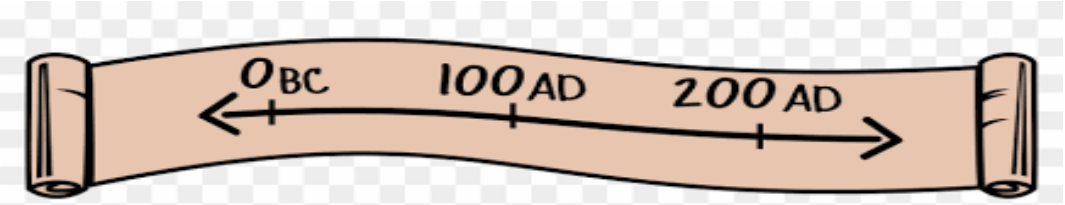
Evolution



1. Cold chain logistics started with moving the perishables like fish using ice .
2. In 1930, Frederick Jones designed and patented a portable air-cooling unit for trucks carrying perishable food. By the late 1930s, refrigerated rail cars and trucks were carrying medical supplies, perishable foods for long distance.
3. Ice Block Expedition of 1959 where the insulation material producer Glassvatt decided to equip a truck to bring a three-ton block of ice from Mo i Rana by the Arctic Circle, to Libreville by the Equator.
4. Present times ISO 6346 certified reefer containers being used for intermodal freight transport

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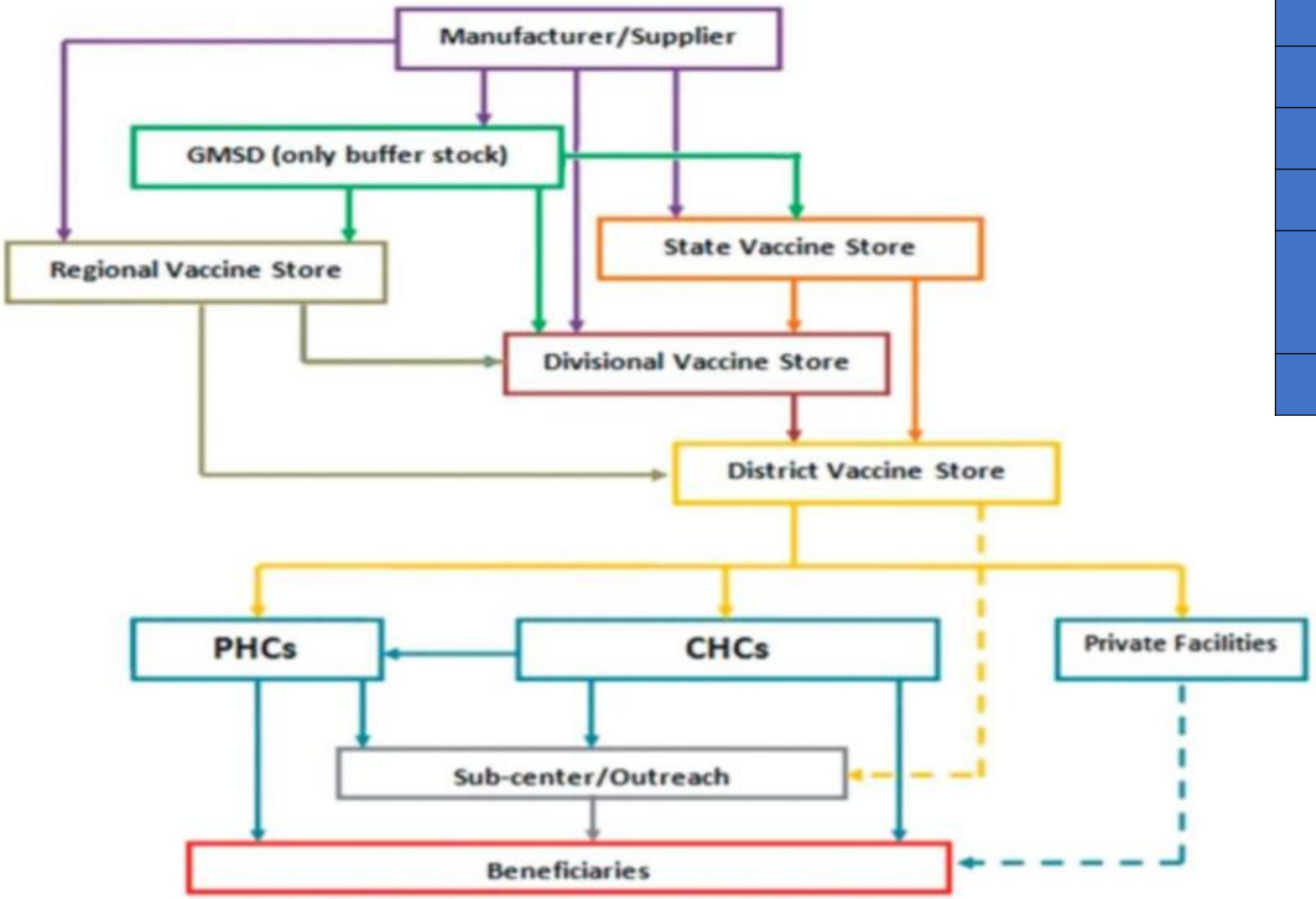
Quality Standards for the Elements of Cold Chain

- Warehouse Storage
  - WHO Technical Report series 908 – Annex 9;
  - WHO Technical Report series 961 – Supplement 2
- Road Transport
  - ISO 23412:2020 Indirect, temperature-controlled refrigerated delivery services **Land transport of parcels** with intermediate transfer
- Air Transport
  - IATA Guidance for Vaccine and Pharmaceutical Logistics & Distribution
  - IATA Temperature Control Regulations
- Sea Transport
  - ISO 6346 is an international standard covering the coding, identification and marking of intermodal (shipping) containers used within containerized intermodal freight transport.
- European Union Good Distribution Practices
- World Health Organization Annex 5
- US Pharmacopeia Chapter 1079, 1083
- Standards for Freezers
  - New European Medical Device Regulation (EU) 2017/745 and Medical Device Directive 93/42/EEC or
  - Certified as per medical devices Class I acc. to FDA regulation 21 CFR part 862.2050

Template for the End-to-End Cold Chain for Pharma

Imagine the complexity if the entire chain is to be setup to maintain a temperature of -20℃

Cold Chain Public Infrastructure in India for Vaccine Distribution



Public Cold Chain Infrastructure	
Cold Chain Points	28932
Walk in Coolers	240
Walk in Freezers	70
Ice Lined Refrigerator	44226
Deep Freezers	40792

Reference - in-depth analysis of cold chain, vaccine supply and logistics management for routine immunization in three Indian states: an INCLEN program evaluation network study - INCLEN trust & MOH Report

Elements for setting up a Cold Chain Network

1. Storage – Cold Storage facilities such as temperature-controlled warehouses
2. Packaging – Provision to ensure safety of the product during transit
3. Transport – Temperature controlled transport
4. Monitoring – Monitoring the temperature of the product throughout the supply chain using tools like data loggers
5. Quality Systems – The process of quality control to manage quality failures

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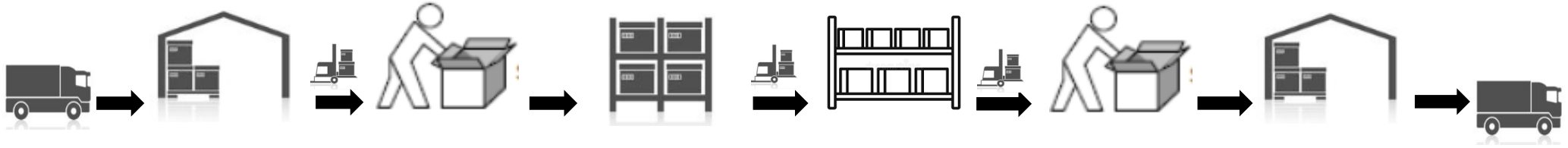
Warehousing Facility Setup for Cold Chain

State of the Art Warehouse

- High rise racks for pallet storage
- Operating temperature range in line with product requirement
- Separation ante-rooms with temperature control for material entry & exit

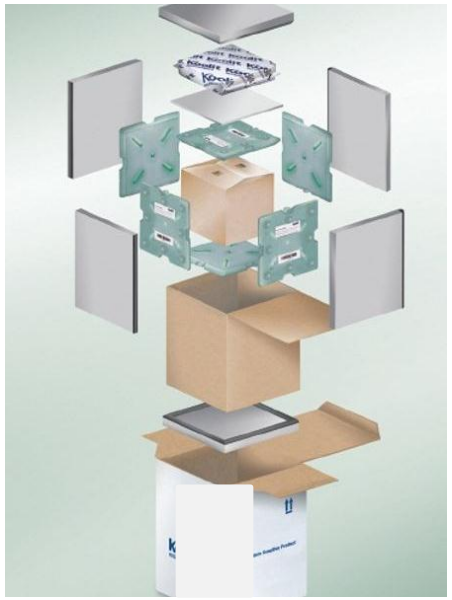
Process Flow for Storage & Dispatch of Vaccine from Warehouse



- **Trained Manpower**
- **24X7 temp monitoring with alarm system**
- **WHO GDP Certifications**
- **Detailed activity logs maintained**

Cold Chain Packaging

Insulated Box



Insulated Box Components

- Insulation Layer
- Payload box
- Gel packs

Freezers for Gel Pack Conditioning

Walk in Freezer Chambers

Chest Freezers

Plate Freezers

Blast Freezers

Cold Chain Transport – Long-haul

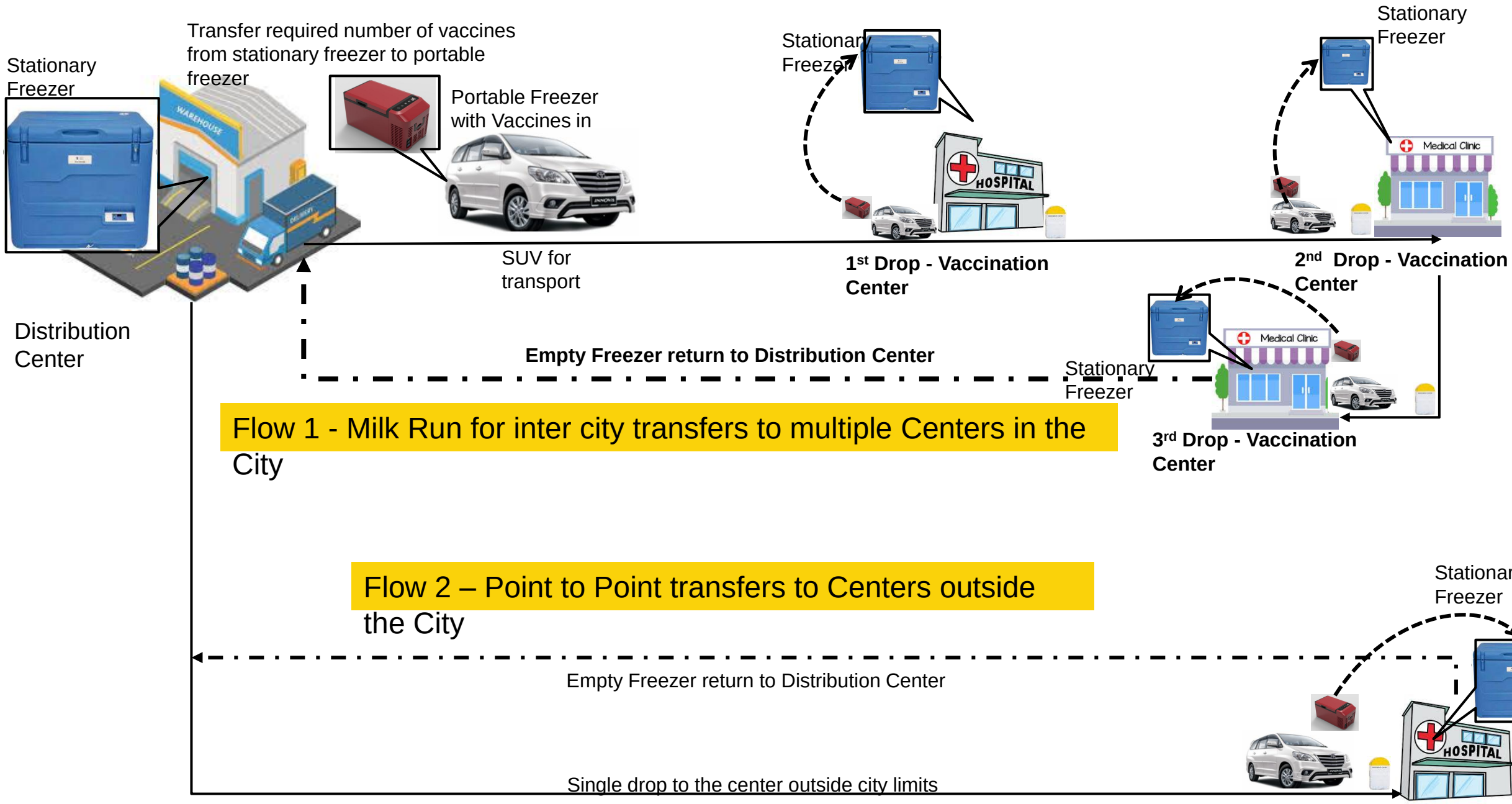
32ft Trucks for Long Haulage

Small Reefer Vehicles for last mile deliveries

Controls:

- Temperature Tracking using data loggers for live temperature dashboards & reports
- Cold Storage System failure Alerts
- Location Tracking by GPS
- Quality Agreement in place with Service Providers

Last Mile Distribution for Vaccines



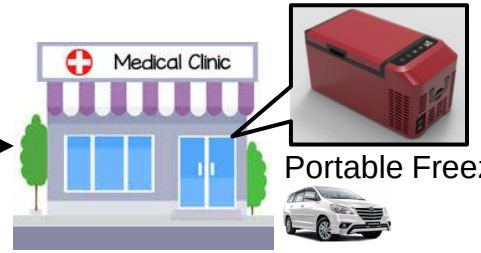
Outreach Programs for Vaccines Managed from Hospitals

Stationary Freezer

Distribution Center

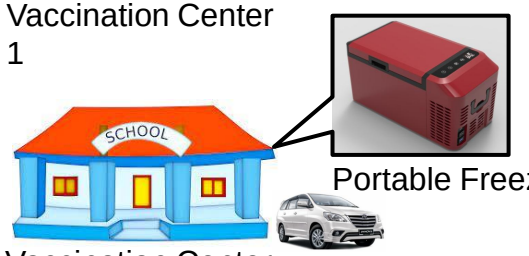
Portable Freezer with Vaccines in

SUV for transport



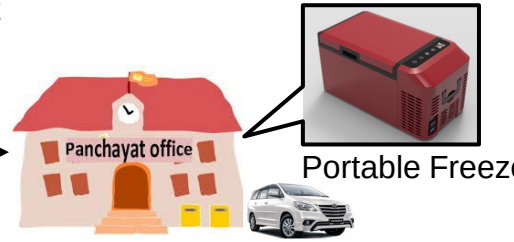
Portable Freezer

Vaccination Center 1



Portable Freezer

Vaccination Center 2



Portable Freezer

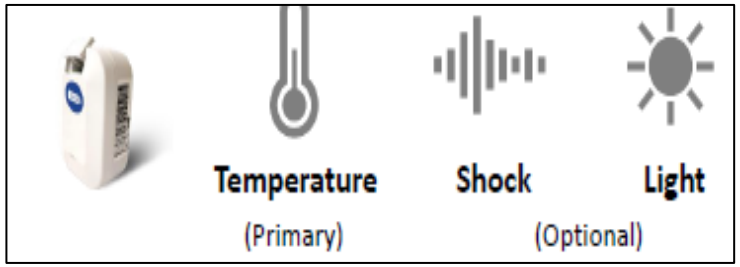
Vaccination Center 3

Empty Freezer return to Distribution Center

- Enlarged View of a portable -20C freezer

Separate Freezer not required at Vaccination Center

System for Cold Chain Monitoring



Sensors | **Barcodes/ QR Codes** | **Gateways** | **Cloud**

- **Small size sensors:** No bigger than a matchbox.
- **No wires:** Based on Bluetooth Low Energy (BLE). Easy to deploy.
- **Big battery life:**2 years+ battery life even in -40C temperature.
- **Large memory:** On-device storage of 16K readings (3 months at **5 minute data rate**)
- **Multi Sensing:** Monitor vaccine temperature, mishandling (shock) and pilferage (light)
- **Barcodes and QR codes** help in uniquely identifying vaccine samples, packaging boxes and sensors

- **Sync and Send**: Read multiple sensors and transmit to cloud via cellular or Wi-Fi
- Real-time temperature data from truck sensor and truck location (from phone GPS) transmitted to control tower
- If there is temperature excursion in truck, alarm is raised to control tower and SMS will be sent to driver's phone
- **Locate Anywhere**: Capture real-time GPS location
- **Real time** alerts to relevant stakeholders

Quality System for Cold Chain

- Detailed SOP to be prepared for the activities
- Ensure training of the personnel and review effectiveness of training
- Validation of the different components – Boxes, freezers, storage
- Lane assessment with transit temperature study
- Risk assessment to be performed and mitigation measures to be identified
- Temperature monitoring to be setup and validated
- Alarm system for reporting of excursions
- Documentation for the dispatch execution to be ensured
- Review of the documentation and monitoring dashboard

Summary - Key Considerations of a Cold Chain

1. Design a warehousing and distribution network with minimum touch points
2. Temperature controlled warehouses for primary warehousing
3. Insulated cold chain boxes validated for 72 hrs to 96 hrs of transit
4. Active transportation solutions such as Refrigerated Vans
5. Temperature controlled solutions conducive for air freight
6. Medical grade freezers for storage of vaccines at primary health centres & clinics
7. Continuous temperature monitoring solutions for storage and transit
8. Geofencing and in-transit tracking of shipment
9. Standard Operating procedures and training of all personnel at all nodes
10. Digital platform for end to end visibility

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Thank you for your attention

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