

- **Temperature Monitoring:** Continuous and accurate temperature monitoring is critical in cold chain management. This involves using temperature sensors, data loggers, or IoT (Internet of Things) devices to track temperature variations at various stages, such as storage, transportation, and handling. Real-time monitoring allows for proactive intervention in case of temperature excursions, helping to prevent product spoilage or degradation.
- **Proper Packaging:** Packaging plays a vital role in preserving product quality during transportation and storage. It involves using specialized packaging materials, such as insulated containers, thermal blankets, or refrigerated trucks, to maintain the desired temperature range. The packaging should provide adequate insulation and protection from external environmental factors and minimize temperature fluctuations.
- **Cold Storage and Warehousing:** Temperature-controlled storage facilities are essential for maintaining product quality and integrity. These facilities, including refrigerated warehouses or cold rooms, are designed to regulate and maintain specific temperature conditions. Proper airflow, temperature distribution, and segregation of different products help ensure consistent temperature control and minimize the risk of cross-contamination.
- **Transportation:** Cold chain transportation involves using vehicles and logistics systems that maintain the required temperature conditions throughout transit. Specialized refrigerated trucks, containers, or cold chain logistics providers are employed to protect the products from temperature excursions during transportation. Proper loading and unloading procedures and adherence to temperature control protocols are critical during transportation.
- **Training and Standard Operating Procedures (SOPs):** Adequate training of personnel involved in cold chain management is crucial. Staff members should be knowledgeable about cold chain requirements, including proper handling, storage, and transportation practices. Developing and implementing standardized operating procedures ensures consistency, minimizes errors, and enhances compliance with cold chain protocols.
- **Regulatory Compliance:** Cold chain management is subject to regulatory guidelines and industry standards to ensure product safety and efficacy. Compliance with regulations, such as Good Distribution Practices (GDP), Good Manufacturing Practices (GMP), or Hazard Analysis and Critical Control Points (HACCP), is essential. Adhering to these standards helps ensure product quality, patient safety, and regulatory compliance throughout the cold chain.
- **Documentation and Traceability:** Maintaining accurate and comprehensive documentation is vital for traceability and accountability. This includes recording temperature data, handling procedures, product information, and any deviations or incidents that occur during the cold chain process. Documentation helps track the product's journey, identify potential issues, and demonstrate compliance with regulatory requirements.
- **Risk Management:** Cold chain management involves assessing and managing risks associated with temperature-sensitive products. This includes identifying potential risks, implementing risk mitigation strategies, and establishing contingency plans to address unforeseen events. Risk management ensures that potential disruptions to the cold chain are minimized and the integrity of the products is maintained.

**What is the temperature range maintained by an ILR?**

An ILR maintains the temperature between +2°C and +8°C.

**At what level of health care delivery are the vaccines stored in an ILR?**

An ILR is used to store all Universal Immunization Program vaccines at the Primary Health Centre (PHC) level.

**Why is an ILR used at PHC for storage of vaccines?**

This is because the power supply at PHC may be unreliable. An ILR can maintain a temperature from +2°C to +8°C with as little as 8 hours of power supply in 24 hours.

If the electricity supply fails, then the ice lining maintains the inside temperature of the refrigerator at a safe level for vaccines.

Also an ILR has a top-opening lid which prevents loss of cold air during door opening.

Therefore the temperature is maintained in ILR for much longer duration than in deep freezers and ILRs can keep vaccine safe.

ILRs are available in two sizes – large (for districts) and small (for PHCs).

**Which is the coldest portion of an ILR?**

The bottom of the ILR is its coldest part.

**How are the vaccines stored in an ILR?**

Vaccines are stored in baskets hanging into the ILR cabinet.

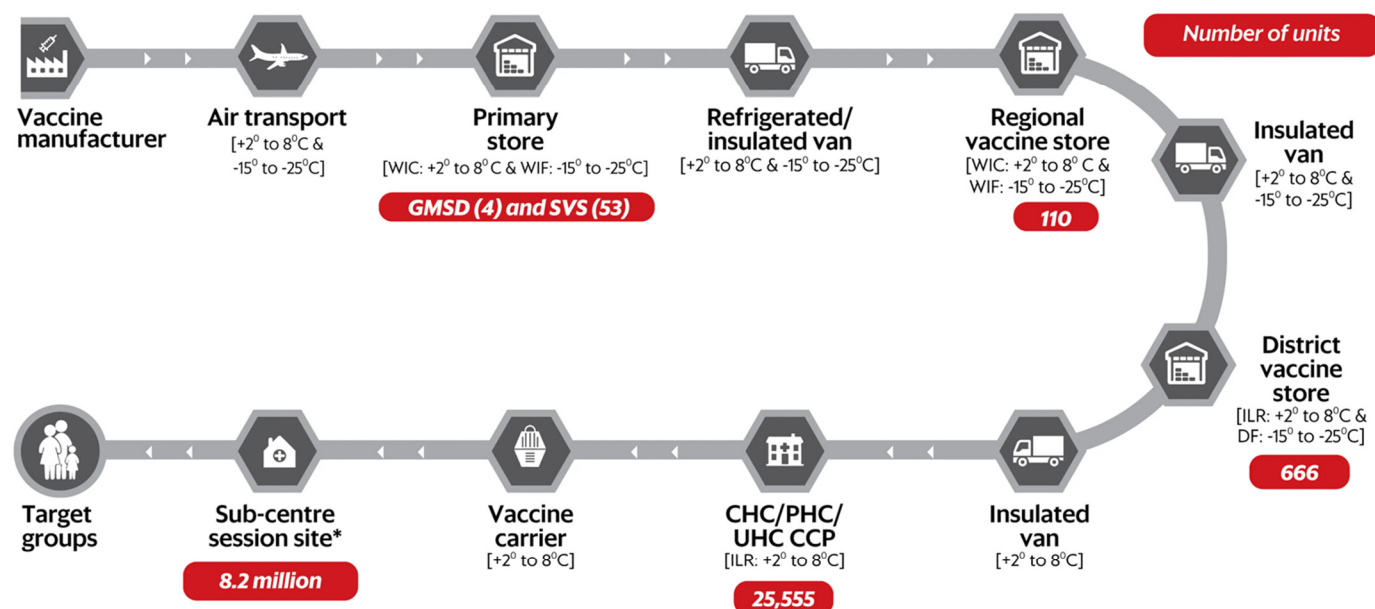
The vaccines are arranged according to their freeze sensitivity; the least freeze-sensitive vaccines are placed at the bottom of the basket and the most freeze-sensitive vaccines are placed at the top.

Also the vaccines should be arranged as per their expiry dates. (Early expiry should be kept above the later expiry ones).

Reconstitution means that the lyophilized (freeze-dried) vaccine powder or water in one vial must be mixed with the diluent (liquid) in another. **Only use the diluent provided by the manufacturer for that vaccine as indicated on the chart.** ALWAYS check the expiration date on the diluent and vaccine.

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-NIHF & UNICEF; 'Comprehensive Multi-Year Plan 2018-22: Universal Immunization Programme' by MoHFW