

**IN-DEPTH ANALYSIS OF COLD CHAIN, VACCINE SUPPLY AND  
LOGISTICS MANAGEMENT FOR ROUTINE IMMUNIZATION IN  
THREE INDIAN STATES:  
AN INCLen PROGRAM EVALUATION NETWORK STUDY**

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## Abbreviations

|      |   |
|------|---|
| CFC  | Chloro Fluoro Carbon (refrigerant)              |
| CHC  | Community Health Center                         |
| DF   | Deep Freezer                                    |
| DLHS | District Level Health Survey                    |
| DPT  | Diphtheria Pertussis and Tetanus Toxoid vaccine |
| EVM  | Effective Vaccine Management                    |
| ESIC | Employee's State Insurance Corporation          |
| GMSD | Government Medical Supply Depot                 |
| HBV  | Hepatitis B Virus                               |
| HF   | Health Facility                                 |
| ILR  | Ice Lined Refrigerator                          |
| IPV  | Inactivated Polio Vaccine                       |
| JE   | Japanese B Encephalitis                         |
| OPV  | Oral Polio Vaccine                              |
| PHC  | Primary Health Center                           |
| PCV  | Pneumococcal Conjugate Vaccine                  |
| TT   | Tetanus Toxoid vaccine                          |
| UIP  | Universal Immunization Programme                |
| VMAT | Vaccine Management Assessment Tool              |
| VVM  | Vaccine Vial Monitor                            |
| WIC  | Walk-in Cooler                                  |
| WIF  | Walk-in Freezer                                 |

## 1. Background and rationale

### 1.1 The Current UIP

Immunization has been demonstrated to be one of the most cost-effective public health interventions. The Expanded Program for Immunization (EPI) in India was launched in 1978 with six childhood vaccines namely BCG, TT, DPT, DT, Polio, and Typhoid. The ambit of EPI was increased with the inclusion of measles vaccine (and discontinuation of typhoid vaccine) in 1985 and it was renamed as the Universal Immunization Program (UIP). The aim of UIP was to cover all districts in the country by 1990, in a phased manner and target all infants with the primary immunization and all pregnant women with TT immunization. The stated objectives of UIP were to rapidly increase immunization coverage, improve the quality of services, establish a reliable cold chain system to the health facility level, introduce a district-wise system for monitoring of performance, and achieve self-sufficiency in vaccine production. The objective of UIP was to cover at least 85% of all infants against the six vaccine-preventable diseases by 1990 and to achieve self-sufficiency in vaccine production and the manufacture of cold-chain equipments. The target in UIP districts is to achieve universal coverage within one year (1986) and maintain the same in the subsequent years. This scheme has been introduced in every district of the country, and the target now is to achieve 100% immunization coverage although technically 85% coverage levels would ensure herd immunity.

The UIP in India is one of the largest immunization programs in the world, in terms of quantities of vaccine used, number of beneficiaries (The UIP in India targets 26.4 million infants and 30 million pregnant women every year), number of immunization sessions organized, and the geographical spread and diversity of areas covered. For almost 2 decades, UIP did not add any additional vaccine. However, since 2006, vaccines namely Hepatitis B, second dose of measles and Japanese Encephalitis (JE) vaccine have been introduced. In 2011, *Haemophilus influenzae* type b (Hib) vaccine as pentavalent vaccine (DPT+ HepB+ Hib) was introduced in two states of India and later expanded to additional 6 states. The pentavalent vaccine is expected to be universalized in the country by year 2015.

**Table 1.1: National Immunization Schedule for Infants, Children and Pregnant Women**

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

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

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

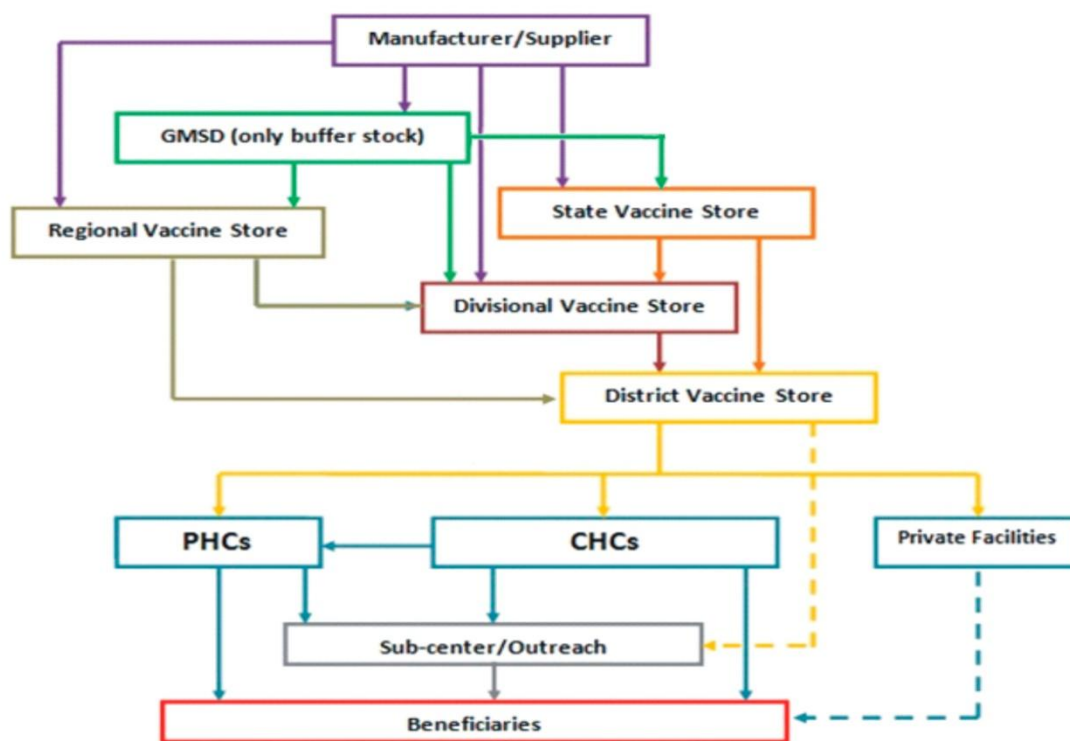
\*\*\*\* The 2nd to 9th doses of Vitamin A can be administered to children 1-5 years old during biannual rounds, in collaboration with ICDS.

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

## 1.2 Current Cold Chain System in India and States

Under the UIP, a wide network of cold chain stores have been created at different levels consisting of Government Medical Supply Depots (GMSD), State/ Regional/ Divisional Vaccine stores, District and CHC/ PHC vaccine storage points. In addition, in some states, there are municipalities as separate health administrative system at district level, which have cold chain system similar to the district level. Cold chain network in the country has been the backbone to ensure storage at different stores and supply of vaccine between the nodes of storage and to the outreach sites at the recommended temperature for administration to the target population. The vaccine logistics has been managed through the cycle of storing and transportation through the wide pre-defined cold chain network. Vaccines through the state, divisional and district vaccine stores, reach the last storage point of CHC or PHC. From there, the vaccines are supplied to the outreach session sites for vaccination. In India the cold chain network is organized as per 6 levels as shown in the figure below.

**Figure 1.1: Vaccine supply and cold chain network in India**



The vaccine cold chain network in India included 4 GMSDs, 39 state vaccine stores, 123 divisional vaccine stores, 644 district stores and 22674 CHC/PHC stores.

## 1.3 Vaccine and Immunization Logistics Chain

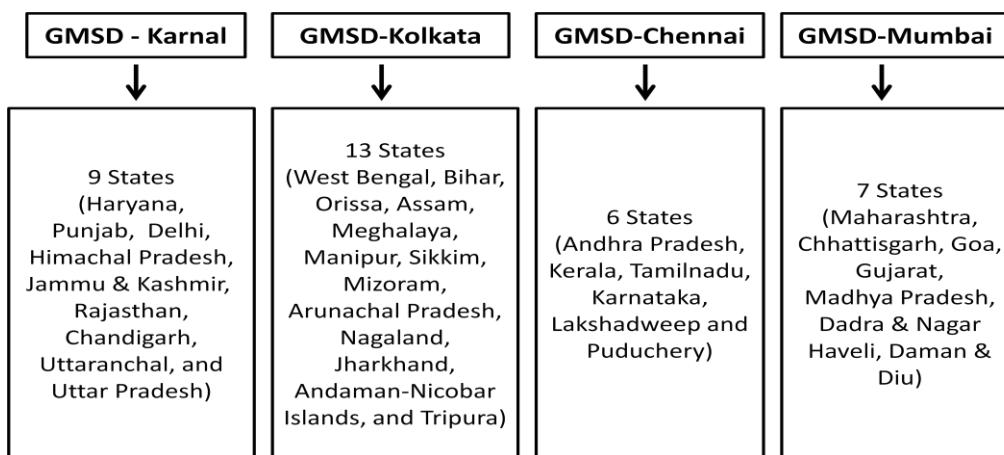
The largest share of required vaccine from manufacturer or supplier usually arrives directly at state and division stores (depending on the airport availability). A proportion (about 20%) of the



annual need is supplied to the Government Medical Store Depots (GMSDs) where stock is maintained for maximum of 3 months. There are 4 GMSDs in the country (Karnal, Chennai, Mumbai and Kolkata), who supply to different states and union territories in India. Usually, 80% of the annual vaccine need is supplied directly to the state and/or divisional/regional vaccine stores in the states by the manufacturer/ supplier directly. The rest 20% is supplied to the GMSDs. Depending on the need; the vaccines from the GMSD are supplied to the state/ regional/ division stores. The vaccine supply network is shown in Figure 2.1. In some states the vaccines are also supplied to the private facilities for administration to the beneficiaries.

The supply network of the GMSDs is shown in figure 2.2.

**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.

Across the vaccine supply chain network, the stores at different levels store the vaccines at the specific temperature for a specified period of time. Based on this, the procurement and supply logistics of vaccine and the related dry supplies are planned.

**Figure 1.3: Vaccine storage and supply network with storage timeline**

| Months                       |   |   |                      |   |   |                         |   |                         |    |         |              |
|------------------------------|---|---|----------------------|---|---|-------------------------|---|-------------------------|----|---------|--------------|
| 1                            | 2 | 3 | 4                    | 5 | 6 | 7                       | 8 | 9                       | 10 | 11      | 12           |
| 3 months                     |   |   | 3 months             |   |   | 2 months                |   | 2 months                |    | 1 month | Immunization |
| GMSDs<br>(Only Buffer stock) |   |   | State Vaccine Stores |   |   | Division Vaccine Stores |   | District Vaccine Stores |    | CHC/PHC |              |

\* Findings - State vaccine stores actually receive vaccines for less than 3 months.

## 1.4 Type of Equipments/ Devices

According to the storage norms (temperature, quantity and duration) of vaccines at different levels of stores, various types of cold chain devices are used. Most of the cold chain devices in India are electrically powered. In some states, solar driven cold chain devices are also in use. The types of cold chain devices in use in India are as follows.

**Table 1.2: Electrical cold chain storage equipments 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 <sup>3</sup>  | GMSDs and Nagpur DVS                   | 27 m <sup>3</sup>  |                    | BCG, Measles, TT, DPT, Hep B, Pentavalent, JE      |
|        |                                     |                        | 108 m <sup>3</sup> |  | 108 m <sup>3</sup> |                    |  |
| 2      | Walk-in-Coolers (WIC)               | +2 to +8               | 16 m <sup>3</sup>  | States and Regional/ Divisional Stores | 16 m <sup>3</sup>  | 5760               | BCG, Measles, TT, DPT, Hep B, Pentavalent, JE      |
|        |                                     |                        | 20 m <sup>3</sup>  |  | 20 m <sup>3</sup>  | 7200               |  |
|        |                                     |                        | 32 m <sup>3</sup>  |  | 32 m <sup>3</sup>  | 13440              |  |
| 3      | Walk-in-Freezers (WIF)              | -15 to -25             | 16 m <sup>3</sup>  | States and Regional/ Divisional Stores | 16 m <sup>3</sup>  | 5760               | OPV, Ice packs                                     |
|        |                                     |                        | 32 m <sup>3</sup>  |  | 32 m <sup>3</sup>  | 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: PQS, World Health Organization

**Table 1.3: Non-electrical (passive) cold chain devices used in India**

| S. No. | Equipment       | Temperature range (°C) | Size (L)     | Level of Stores                        | Hold over time                                     |
|--------|-----------------|------------------------|--------------|--|--|
| 1.     | Cold Box-Large  | +2 to +8               | 20 & 22      | State, Divisional, and District stores | 6 days at +43 <sup>0</sup> C ambient temperature   |
| 2      | Cold Box-Small  | +2 to +8               | 5 & 8        | District, CHCs and PHCs                | 90 hours at +43 <sup>0</sup> C ambient temperature |
| 3      | Vaccine Carrier | +2 to +8               | 1.7 (approx) | District, CHC and PHC Stores           | 12 hours   |

*Ref: Cold chain handler for vaccine management, MOHFW, New Delhi*

**Table 1.4: Summary of Cold Chain Equipments used under UIP**

| Equipment             | Temperature (°C) | Storage capacity   | Holdover time  |
|-----------------------|------------------|--|--|
| <b>Electrical</b>     |                  |  |  |
| DF (Large)            | -15 to - 25      | 200 ice packs or 120,000 doses of OPV  | 43 <sup>0</sup> C for 18 hours<br>32 <sup>0</sup> C for 22 hours |
| ILR (Large)           | +2 to +8         | BCG, DPT, DT, TT, Measles, hepatitis B vaccine stock (60,000 doses) of mixed antigen | 43 <sup>0</sup> C for 62 hours<br>32 <sup>0</sup> C for 78 hours |
| <b>Non-electrical</b> |                  |  |  |
| Cold Box (Large)      | +2 to +8         | All vaccines stored for transport or in case of power failure (6,000 doses)          | 43 <sup>0</sup> C for 6.5 days<br>31 <sup>0</sup> C for 10 hours |
| Vaccine Carrier       | +2 to +8         | 4 ice packs and 16-20 vials  | 43 <sup>0</sup> C for 34 days<br>32 <sup>0</sup> C for 51 hours  |

## 1.5 Cold Chain Manpower and Training System

The functionaries engaged at different levels of facilities for discharging various activities related to cold chain are given specific orientation/ training. The following training programs are undertaken at state and district level related to the cold chain.

**Table 1.5: Trainings Specific to Cold Chain Handling and Routine Immunization**

| <b>Functionaries</b>   | <b>Training</b>             | <b>Duration</b> | <b>Training manual/guideline</b>                |
|------------------------|-----------------------------|-----------------|---|
| Cold chain handlers    | At district and block level | 2 days          | Handbook for Vaccine & Cold Chain Handlers      |
| Medical Officers       | At district and block level | 3 days          | Immunization handbook for Medical Officers      |
| ANMs and LHVs          | At block and PHC            | 2 days          | Immunization handbook for health workers        |
| Block Program Managers | At district level           | 3 days          | Immunization Guide for Block Programme Managers |

Additionally, the National Cold Chain Training Center at Pune undertakes specific training for the cold chain technicians from states. The training courses offered by the center are as follows.

**Table 1.6: Trainings Specific to Cold Chain Devices and Support Equipments**

| <b>Course</b>   | <b>Duration</b> |
|---|-----------------|
| ILR and DF maintenance and repair   | 7 days          |
| WIC and WIF maintenance and repair  | 9 days          |
| Voltage stabilizer maintenance and repair   | 7 days          |
| Generator maintenance and repair  | 7 days          |
| Refrigeration   | 7 days          |
| Refresher course for Refrigeration equipments, Voltage stabilizers and generators (after 2 years of induction training) | 10 days         |

## **1.6 The Indenting and Storage Norms**

For each level an estimate of vaccine requirement based on the target population, beneficiaries and previous stock balance is prepared annually. An indent to the respective higher level is sent at regular interval requesting for supply of vaccines. The system of forecast, indent and supply is shown in table below.

**Table 1.7: The recommended norms for vaccine logistics for different levels**

| Level   | Forecast | Storage period       | Indent frequency | Supply                     |
|---|----------|----------------------|------------------|----------------------------|
| State vaccine store   | Annual   | 3 months             | Annual           | Periodic from manufacturer |
| Division vaccine store  | Annual   | 2 months (+2 weeks)  | Quarterly**      | Quarterly**                |
| District vaccine store  | Annual   | 2 months (+2 weeks)* | Quarterly**      | Quarterly**                |
| CHC store   | Annual   | 1 month (+ 1 week)   | Monthly          | Monthly                    |
| PHC store   | Annual   | 1 month (+ 1 week)   | Monthly          | Monthly                    |
| <p>* Although it is recommended for indenting at 3 months interval, in practice a monthly indenting process is followed at many places</p> <p>** Although it is recommended for indenting at quarterly interval, in practice a monthly indenting process is followed at many places. Corresponding to the indent at monthly interval, the supply is also received at monthly interval at many places.</p> |          |                      |                  |                            |

While making estimation of annual need based on the population and number of beneficiaries, inclusion of a buffer stock (25% for vaccine and syringes) and wastage 25% in the case of vaccines and 10% in the case of AD and disposable syringes are added. For national immunization days/mass vaccination campaigns, wastage rate of 10 % is estimated. The buffer stock serves as a cushion as buffer against emergencies, major fluctuations in demand or unexpected transport delay.

## 1.7 Prospects for New Vaccine Introduction

In India, after Kerala and Tamilnadu, pentavalent (DPT-Hib-HBV) vaccine has been expanded to 6 more states. It is expected in coming years the pentavalent vaccine shall cover whole India. JE vaccine is in pipeline for expansion to more endemic districts in several states. Recently the successful completion of efficacy train with Indian indigenous rotavirus vaccine (Rotavac) has raised hope for possible introduction of the vaccine in coming years. As part of the global polio eradication program, with no WPV case for last 3 years, India is planning for introduction of IPV. As a step towards this, an additional dose of IPV along with DPT-3 is being planned for introduction into the UIP. This is expected to be followed by total switch of OPV to IPV in next 5 years. Rubella vaccine inform of Measles-Rubella combination (MR) is also under consideration for introduction in UIP at 16-24 months of age. There is increasing advocacy based on eh emerging evidences for introduction of pneumococcal vaccine as part of the UIP.

All these new developments are likely to increase the cold chain space need for India to ensure the momentum of RI coverage gain in recent years.

## 1.8 Vaccine Specific Cold Chain Requirements

According to the prescribed norm, all Vaccines requires a storage temperature in the range of +2<sup>0</sup>C to +8<sup>0</sup>C, except for Oral Polio Vaccine which need to be stored in frozen state (-25<sup>0</sup>C to -15<sup>0</sup>C) at all stores except PHC/ CHC/Health post. The new vaccine ROTAVAC (116E rotavirus) by Bharat Biotech is being recommended to be stored at (-15 to -25<sup>0</sup>C) till the intermediate stores and to be stored in the range of +2<sup>0</sup>C to +8<sup>0</sup>C at the last storage points like PHC/ CHC/Health posts.

**Table 1.8: The recommended norm for storing vaccines**

| WHO Norm   | Vaccine                          | Primary                                    | Intermediate |          |          | Health Centers (CHC/PHC/UHC)           |
|--|----------------------------------|--|--------------|----------|----------|--|
|  |                                  | GMSD                                       | State        | Division | District |  |
| UIP Vaccines   | OPV                              | (-15 <sup>0</sup> C to -25 <sup>0</sup> C) |              |          |          | +2 <sup>0</sup> C to +8 <sup>0</sup> C |
|  | BCG                              | +2 <sup>0</sup> C to +8 <sup>0</sup> C     |              |          |          |  |
|  | JE                               |  |              |          |          |  |
|  | HepB                             |  |              |          |          |  |
|  | DPT                              |  |              |          |          |  |
|  | DPT-Hib-HBV (Pentavalent Liquid) |  |              |          |          |  |
|  | TT                               |  |              |          |          |  |
|  | Measles                          |  |              |          |          |  |
| Additional Vaccines  | MMR                              | +2 <sup>0</sup> C to +8 <sup>0</sup> C     |              |          |          |  |
|  | MR                               |  |              |          |          |  |
|  | IPV                              |  |              |          |          |  |
|  | PCV                              |  |              |          |          |  |
|  | Rotateq (RV-5)                   |  |              |          |          |  |
|  | Rotarix (RV-1)                   | (-15 <sup>0</sup> C to -25 <sup>0</sup> C) |              |          |          |  |
|  | ROTAVAC (116E)                   |  |              |          |          |  |
| <p><i>Diluents vials must NEVER be frozen. If the manufacturer supplies a freeze-dried vaccine packed with its diluents, ALWAYS store the product at between +2<sup>0</sup>C to +8<sup>0</sup>C. If space permits, diluents supplied separately from vaccines may safely be stored in the cold chain between +2<sup>0</sup>C to +8<sup>0</sup>C.</i></p> |                                  |  |              |          |          |  |

Source: - Temperature Sensitivity of Vaccine, WHO/IVB/06.10

**Table 1.9: Summary of vaccine sensitivity to heat and cold**

| Vaccine                                  | Exposure to heat or light                      | Exposure to cold              | Recommended storage temperature        |
|--|--|-------------------------------|--|
| <b>Heat and light sensitive vaccines</b> |  |                               |  |
| BCG                                      | Relatively heat stable, but sensitive to light | Not damaged by freezing       | +2 <sup>0</sup> C to +8 <sup>0</sup> C |
| OPV                                      | Heat sensitive                                 | Not damaged by freezing       | +2 <sup>0</sup> C to +8 <sup>0</sup> C |
| Measles                                  | Sensitive to heat and light                    | Not damaged by freezing       | +2 <sup>0</sup> C to +8 <sup>0</sup> C |
| <b>Freeze sensitive vaccines</b>         |  |                               |  |
| DPT                                      | Relatively heat stable                         | Freeze at -3 <sup>0</sup> C   | +2 <sup>0</sup> C to +8 <sup>0</sup> C |
| HepB                                     | Relatively heat stable                         | Freeze at -0.5 <sup>0</sup> C | +2 <sup>0</sup> C to +8 <sup>0</sup> C |
| DT                                       | Relatively heat stable                         | Freeze at -3 <sup>0</sup> C   | +2 <sup>0</sup> C to +8 <sup>0</sup> C |
| TT                                       | Relatively heat stable                         | Freeze at -0.5 <sup>0</sup> C | +2 <sup>0</sup> C to +8 <sup>0</sup> C |

**Table 1.10: Shelf life of the vaccines**

| Vaccine                    | Doses per Vial | Manufacturer                                     | Shelf Life (Months)     |                    |
|----------------------------|----------------|--|-------------------------|--------------------|
|                            |                |  | +2 to +8 <sup>0</sup> C | -20 <sup>0</sup> C |
| <b>UIP Vaccines</b>        |                |  |                         |                    |
| OPV                        | 20             | Serum Institute of India Ltd                     | 6                       | 24                 |
| BCG                        | 10             | Serum Institute of India Ltd                     | 24                      |                    |
| Measles                    | 5              | Serum Institute of India Ltd                     | 24                      |                    |
| DPT                        | 10             | Serum Institute of India Ltd                     | 24                      |                    |
| Hep B                      | 10             | Serum Institute of India Ltd                     | 36                      |                    |
| TT                         | 10             | Serum Institute of India Ltd                     | 36                      |                    |
| Pentavalent                | 10             | Serum Institute of India Ltd                     | 24                      |                    |
| JE                         | 5              | Chengdu Institute of Biological Products Co. Ltd | 18                      |                    |
| <b>Additional Vaccines</b> |                |  |                         |                    |
| IPV                        | 10             | Sanofi Pasteur                                   | 36                      |                    |
| Rotarix                    | 1              | GlaxoSmithKline, Belgium                         | 36                      |                    |
| Rotateq                    | 1              | Merck Sharp and Dohme Corp, USA                  | 24                      |                    |
| Rotavac                    | 1              | Bharat Biotech                                   | 6                       | 24                 |
| MMR                        | 10             | Serum Institute of India Ltd                     | 24                      |                    |
| MR                         | 10             | Serum Institute of India Ltd                     | 24                      |                    |
| Typhoid                    | 20             | Sanofi Pasteur                                   | 36                      |                    |
| Pneumococcal               | 1              | Wyeth, USA                                       | 24                      |                    |

Source: - Immunization standard, WHO

## 1.9 Storage and Transport Volume per Dose

The national UIP targets for 100% coverage of infant population in the country. The annual birth cohort of India is about 26.4 million (@ CBR of 21.8; 2012).

The storage volume for each fully immunized child (FIC) in the states with UIP schedule is 69 cm<sup>3</sup> for district level and above, and 78 cm<sup>3</sup> for CHC/PHC level, and the storage volume for each fully immunized child in the states with pentavalent schedule is 54 cm<sup>3</sup> for district level and above, and 63 cm<sup>3</sup> for CHC/PHC level.

For the states/districts with JE vaccine as part of the UIP schedule, an additional volume of 7.98 cm<sup>3</sup> at bulk storage and district vaccine stores and 9.3 cm<sup>3</sup> (with the diluents) at PHC/ CHC level to accommodate the JE vaccine.

**Table 1.11: Cold chain space need for each FIC as per UIP schedule**

| Vaccine   | Number of Doses per vial | Storage volume per dose (cm <sup>3</sup> ) | Wastage rate | Net Storage volume per dose | Number of doses per target | Storage volume required per target(cm <sup>3</sup> ) |
|---|--------------------------|--|--------------|-----------------------------|----------------------------|--|
| <i>Vaccine to be stored at +2<sup>0</sup>C to +8<sup>0</sup>C at intermediate stores</i>  |                          |  |              |                             |                            |  |
| BCG   | 10                       | 1.2  | 25%          | 1.6                         | 1                          | 1.6  |
| DPT   | 10                       | 3  | 25%          | 4.0                         | 5                          | 20.0   |
| TT  | 10                       | 3  | 25%          | 4.0                         | 3.5*                       | 14.0   |
| Measles   | 5                        | 5  | 25%          | 6.7                         | 2                          | 13.3   |
| Hep B   | 10                       | 3.8  | 25%          | 5.1                         | 4                          | 20.2   |
| Total Cold chain Volume required  |                          |  |              |                             |                            | <b>69.0</b>  |
| <i>Vaccine to be stored at (-25<sup>0</sup>C to -15<sup>0</sup>C) at intermediate stores</i>  |                          |  |              |                             |                            |  |
| OPV   | 20                       | 1  | 25%          | 1.33                        | 5                          | 6.65   |
| <i>Diluents to be stored at +2<sup>0</sup>C to +8<sup>0</sup>C at Primary Health Centers</i>  |                          |  |              |                             |                            |  |
| BCG   | 10                       | 0.7  | 25%          | 0.93                        | 1                          | 0.93   |
| Measles   | 5                        | 4  | 25%          | 5.33                        | 2                          | 10.66  |
| Net storage volume required for +2 <sup>0</sup> C to +8 <sup>0</sup> C at State, Regional and District Vaccine Stores per every child to be fully immunized |                          |  |              |                             |                            | <b>69.0</b>  |
| Net storage volume required for (-25 <sup>0</sup> C to -15 <sup>0</sup> C) at State, Regional and District Vaccine Stores                                   |                          |  |              |                             |                            | <b>6.65</b>  |
| Net Storage volume required for +2 <sup>0</sup> C to +8 <sup>0</sup> C at Primary Health Centers without Diluents   |                          |  |              |                             |                            | <b>75.68</b>   |
| Net Storage volume required for +2 <sup>0</sup> C to +8 <sup>0</sup> C at Primary Health Centers with Diluents per every child to be fully immunized        |                          |  |              |                             |                            | <b>77.99</b>   |
| * Government of India procures and supplies 3.5 doses of TT per target pregnant women (1.5 doses) & child (2 doses)   |                          |  |              |                             |                            |  |



**Table 1.12: Cold chain space need for each FIC as per UIP schedule with pentavalent vaccine**

| Vaccine   | Number of Doses per vial | Storage volume per dose (cm <sup>3</sup> ) | Wastage rate | Net Storage volume per dose | Number of doses per target | Storage volume required per target(cm <sup>3</sup> ) |
|---|--------------------------|--|--------------|-----------------------------|----------------------------|--|
| <b><i>Vaccine to be stored at +2<sup>0</sup>C to +8<sup>0</sup>C at intermediate stores</i></b>   |                          |  |              |                             |                            |  |
| BCG   | 10                       | 1.2  | 25%          | 1.6                         | 1                          | 1.6  |
| DPT   | 10                       | 3  | 25%          | 4.0                         | 2                          | 8.0  |
| TT  | 10                       | 3  | 25%          | 4.0                         | 3.5*                       | 14.0   |
| Measles   | 5                        | 5  | 25%          | 6.7                         | 2                          | 13.3   |
| Hep B   | 10                       | 3.8  | 25%          | 5.1                         | 1                          | 5.1  |
| Penta   | 10                       | 3  | 25%          | 4.0                         | 3                          | 12.0   |
| Total Cold chain Volume required  |                          |  |              |                             |                            | <b>53.9</b>  |
| <b><i>Vaccine to be stored at (-25<sup>0</sup>C to -15<sup>0</sup>C) at intermediate stores</i></b>   |                          |  |              |                             |                            |  |
| OPV   | 20                       | 1  | 25%          | 1.33                        | 5                          | <b>6.65</b>  |
| <b><i>Diluents to be stored at +2<sup>0</sup>C to +8<sup>0</sup>C at Primary Health Centers</i></b>   |                          |  |              |                             |                            |  |
| BCG   | 10                       | 0.7  | 25%          | 0.93                        | 1                          | 0.93   |
| Measles   | 5                        | 4  | 25%          | 5.33                        | 2                          | 10.64  |
| Net storage volume required for +2 <sup>0</sup> C to +8 <sup>0</sup> C at State, Regional and District Vaccine Stores per every child to be fully immunized |                          |  |              |                             |                            | <b>53.9</b>  |
| Net storage volume required for (-25 <sup>0</sup> C to -15 <sup>0</sup> C) at State, Regional and District Vaccine Stores                                   |                          |  |              |                             |                            | <b>6.65</b>  |
| Net Storage volume required for +2 <sup>0</sup> C to +8 <sup>0</sup> C at Primary Health Centers without Diluents   |                          |  |              |                             |                            | <b>60.52</b>   |
| Net Storage volume required for +2 <sup>0</sup> C to +8 <sup>0</sup> C at Primary Health Centers with Diluents per every child to be fully immunized        |                          |  |              |                             |                            | <b>62.83</b>   |
| * Government of India procures and supplies 3.5 doses of TT per target pregnant women (1.5 doses) & child (2 doses)   |                          |  |              |                             |                            |  |

The pipeline vaccines, MR, IPV and PCV are to be stored at +2<sup>0</sup>C to +8<sup>0</sup>C at both the intermediate and last cold chain points. The recently licensed Indian rotavirus vaccine, ROTAVAC (116E) is to be stored at -25<sup>0</sup>C to -15<sup>0</sup>C at intermediate stores and at +2<sup>0</sup>C to +8<sup>0</sup>C at last cold chain stores and once removed from -25<sup>0</sup>C to -15<sup>0</sup>C storage cannot be returned to the same. The other rotavirus vaccines (Rotateq and Rotarix) can be stored at +2<sup>0</sup>C to +8<sup>0</sup>C at all levels. For the current scenario of cold chain space projection, we have considered the following vaccines.

**Table 1.13: The specification of pipeline vaccines**

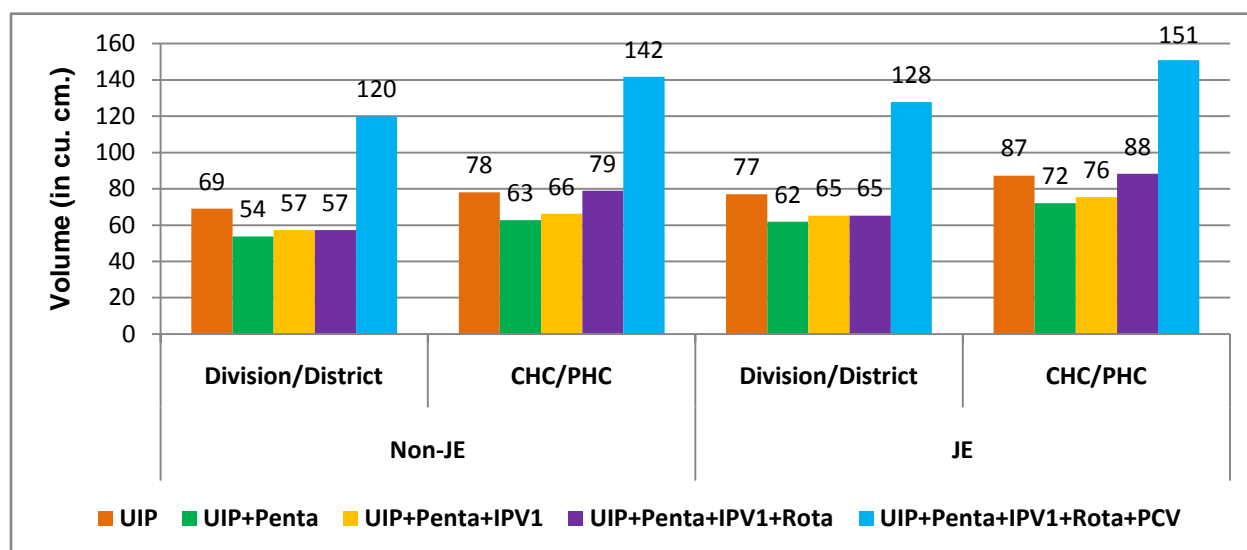
| Vaccine | Number of Doses per vial | Storage volume per dose (cm <sup>3</sup> ) | Wastage rate | Net Storage volume per dose | Number of doses per target | Storage volume per target (cm <sup>3</sup> ) |
|---------|--------------------------|--|--------------|-----------------------------|----------------------------|--|
| IPV     | 10                       | 2.5  | 25%          | 3.3                         | 1                          | 3.3  |
| PCV*    | 5                        | 15.7                                       | 25%          | 20.9                        | 3                          | 62.6   |
| Rotavac | 10                       | 3.2  | 25%          | 4.3                         | 3                          | 12.8   |

\* PCV projected for 5 dose vial.

## 1.10 Volume per Each Fully Immunized Child

The cold space volume for each fully immunized child (FIC) as per different schedule (with or without JE vaccine) is represented in the figure below. Traditionally, fully immunized child (FIC) is defined as a child aged 12-23 months who has received one dose of BCG, 3 doses of DPT and OPV, and 1 dose of measles vaccine.

**Figure 1.4: The cold chain volume (in cm<sup>3</sup>) required for each fully immunized child (FIC)**



## 1.11 Open Vial Policy

Recently Government of India has adopted open vial policy for the liquid vaccines other than OPV (Pentavalent, DPT, TT and HBV) to reduce their wastage. As per the policy, the aforementioned vaccines opened at a session can be used for next immunization sessions up to 4 weeks provided ALL of the following conditions are fulfilled:

- VVM is usable.
- Expiry date has not passed.

- Vaccine is stored in appropriate cold chain conditions: both during transport & storage.
- All doses are withdrawn using aseptic technique.
- Vaccine septum has not been contaminated or submerged in water.
- Date and time is marked on the vial when opened for the first use.

The vaccine vial is to be discarded if any of the above mentioned conditions is not satisfied. Open vial policy is not applicable for BCG, Measles and JE vaccines.

For Live attenuated vaccines, the Government of India has allowed 1 vial per session. GOI has allowed estimation and use of one vial of BCG and Measles per session.

### **1.12 National Cold Chain Management Information System**

The National Cold Chain Management Information System (NCCMIS) developed by National Cold Chain Training Center, SHTO Pune with support from Unicef aims at capturing the cold chain equipment inventory and status on a dynamic manner. The data for most of the districts (504) has been uploaded on the website. The National Centers for Cold Chain & Vaccine Management Resource Center (NCCVMRC) is being established at National Institute of Health and Family Welfare, New Delhi with inclusion of National Cold Chain Training Center (NCCTC), SHTO, Pune as part of the NCCVMRC to streamline the cold chain capacity building.

## 2. The Current Assessment

### 2.1.Rationale

In order to deliver current vaccines at high quality and prepare the routine immunization system to accommodate newly available vaccines, a strong cold chain system is critical. Currently, India lacks systematic analysis on the requirements for expanding its cold chain for future adoption of vaccines. The last cold chain assessment (in 2008, by UNICEF) was important, but primarily a desk review based on the system level information. There is lack of primary data to inform the policy makers and program managers for appropriate strategy to address these challenges and also project the actual needs of the space and system to improve the immunization coverage. Review of literature reflected the following evidence gaps:

- Lack of primary data in cold chain status in India based on which the projection for vaccine storage space and dry space can be developed
- Lack of primary data on quality of temperature maintenance at the cold chain points
- Lack of primary data on the determinants, barriers related to immunization logistics and opportunities for improving the system

### 2.2.Goal and Objectives of the Study

INCLIN in collaboration with PATH undertook this in-depth analysis of cold chain, vaccine supply and logistics management in three states.

#### **Goal of the Study**

*To understand the cold chain upgradation requirements for inclusion of new vaccines into India's Universal Immunization Program and develop the analysis framework necessary to inform GOI policy and program decisions.*

#### **Objectives of the Study**

- a. Quantify cold chain volume expansion requirements for inclusion of priority new vaccines into the UIP (pentavalent, rotavirus, IPV and pneumococcus, etc.) through conducting an inventory of cold chain equipment and calculating volume requirements
- b. Assess the cold chain temperature quality and integrity at different levels through use of a temperature logging device at cold chain points, and vaccine vial monitor (VVM) assessment at outreach sessions
- c. Identify and prioritize challenges and opportunities related to cold chain supply and logistics management.

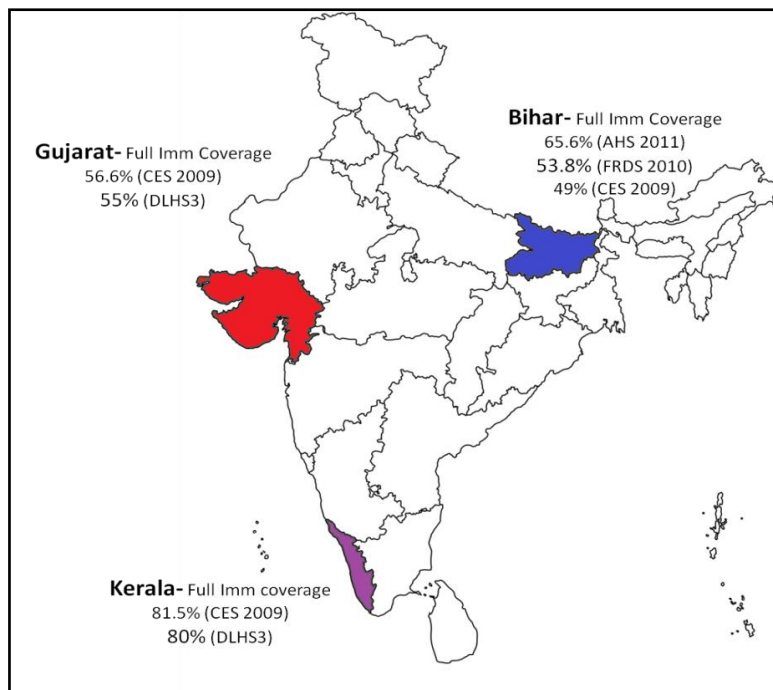
### 3. Study Methodology

#### 3.1. Study Design

This was a cross sectional study covering the vaccine storage facilities at state, division, district, block and PHC level in three selected states.

#### 3.2 Study area

**Figure 2.1: The Study States**



The states included in the study were Bihar, Gujarat and Kerala which represented the status of immunization coverage from worst, moderate and best in India and also represented three different governance zones.

In each state, one third of the districts, all division vaccine stores and state vaccine store were covered under the study.

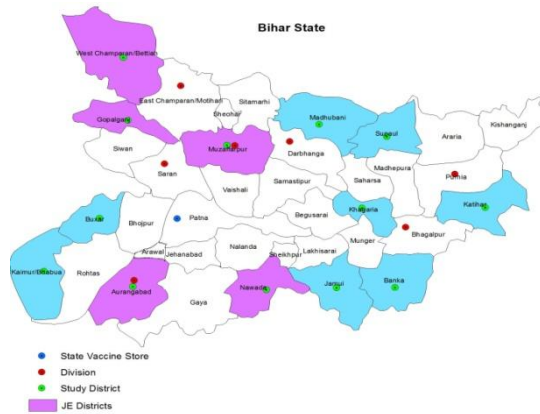
In Bihar, out of the 38 districts, 13 districts included in the study were, Aurangabad, Banka, Buxar, Gopalganj, Jamui, Kaimur, Katihar, Khagaria, Madhubani, Muzzafarpur, Nawada, Supaul and W.Champaran. Among these districts, five districts had JE as part of the UIP vaccination schedule. Apart from these districts, the seven division vaccine stores at Aurangabad, E. Champaran, Darbhanga, Muzaffarpur, Saran, Purnia and Bhagalpur and the state vaccine store at Patna were also studied.

In Gujarat, out of the 26 districts, the 9 districts included in the study were Anand, Banaskanta, Vadodhara/Baroda, Bharuch, Junagadh, Kutch, Panchmahal, Sabarkanta and Surat. In three districts, Vadodhara/Baroda, Junagadh, and Surat, which had also the municipality corporation in the district, were also studied. The six division stores, Gandhinagar, Ahmedabad, Surat, Bhavnagar, Rajkot and Vadodhara/Baroda were also studied. There was no dedicated state vaccine store in Gujarat.

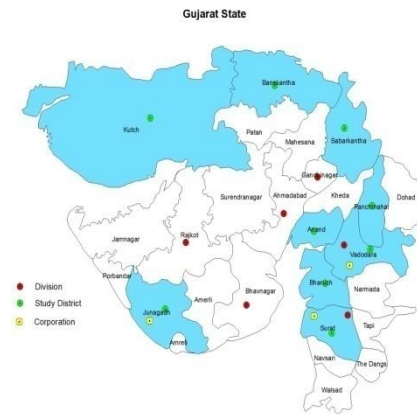
In Kerala out of the 14 districts, five study districts Kasargod, Kollam, Kottayam, Thrissur and Wayanad and three division stores at Thiruvananthapuram, Ernakulum and Kozhikode were studied. There was no dedicated state vaccine store in Kerala. The study districts and the division stores in the three states are shown in the map.

**Figure 3.1: The study districts in three states**

**Figure 3.1.1: Bihar**



**Figure 3.1.2: Gujarat**



**Figure 3.1.3: Kerala**



### 3.3 Study Implementation

#### 3.3.1 Central Coordinating Team & Central Coordinating Office

The Central Coordinating Team (CCT) was the think tank for the project. It comprised of experienced technical experts in cold chain, immunization, child health, public health, social science, biostatistics, supply chain and logistics management, refrigeration engineering and program managers. This team assisted in the study tool development, training, quality assurance, data analysis and report writing and dissemination.

Program Management Team at INCLIN included the Investigators and technical staff (program officer and social scientist) for coordinating the activities. This team The data quality check and management team undertook the data entry and database management. Research Associates and Research Assistants assisted the technical team in accomplishing the project activities.

Central Coordinating Office (CCO) of the study was located at INCLIN Office, New Delhi. The CCO provided the technical and quality assurance support for the study, managed the network activities, was responsible for coordinating with all the partner medical colleges, monitoring the progress of the network, screening the data to ensure quality, processing and analyzing the data.

### 3.3.2 State Coordinating Center & Partner Medical Colleges

In each of the 3 states, the state investigator coordinated the project activities in the state and one medical college was functioning as the coordinating center. This center coordinated identification of research teams, training of the research team members, data collection and quality assurance activities in the study districts.

In three states, there were 16 partner medical colleges (PMCs) involved in the study. Each PMC formed 2-3 survey teams. From each partner medical colleges several faculty members from Community Medicine and/or Pediatrics were involved as investigators in the study, who visited the field and supervised the research team members for high quality data collection. Table 3.1 shows the partner medical colleges in each of the states. From these institutes 37 teams with (three members in each team), about 120 members were engaged in the field activity.

**Table 3.1: List of Partner Medical Colleges**

| State   | Partner Medical College   |
|---------|---|
| Bihar   | Patna Medical College, Patna<br>(Coordinating Center)                   |
|         | SK Medical College, Muzaffarpur   |
|         | Darbhanga Medical College, Darbhanga                                    |
|         | Katihar Medical College, Katihar  |
| Gujarat | MP Shah Medical College and GG Hospital, Jamnagar (Coordinating Center) |
|         | BJ Medical College, Ahmedabad   |
|         | PS Medical College, Karamsad  |
|         | Govt. Medical College, Baroda   |
|         | Govt. Medical College, Surat  |
| Kerala  | Govt. Medical College, Trivandrum (Coordinating Center)                 |
|         | Govt. TD Medical College, Alappuzha                                     |
|         | Govt. Medical College, Kozhikode  |
|         | Govt. Medical College, Thrissur   |
|         | Govt. Medical College, Kottayam   |
|         | Academy of Medical Sciences, Pariyaram                                  |
|         | Amala Institute of Medical Sciences, Thrissur                           |

### 3.3.3 Study Tool Development and Finalization

A team of investigators at the central coordinating office including experts in the field of cold chain and refrigeration, immunization program, community medicine and public health, pediatrics, supply and logistics management and program evaluation along with social scientists, epidemiologists, biostatisticians, and anthropologists conducted several rounds of discussions and developed draft study tools keeping in mind the key objectives of the study, points of interest for policy makers, program managers, and implementers.

The cold chain assessment tool was developed in reference to the types of equipments and accessories at the vaccine stores at different levels. National guidelines, cold chain handbooks, multi-year immunization plan, EVM, VMAT, CCEM and HERMES tools were referred to while preparing the quantitative study tools.

The qualitative (in-depth interview) study tools were prepared by investigators with sound experience of qualitative research to capture the perceptions, beliefs, opinions and practices of key stakeholders to supplement the quantitative observations.

Draft study tools were piloted in all states for validity, question framing, relevance, and sequencing before finalizing. Study tool specific and general comments obtained during the pilot phase were also incorporated. The final versions of study tools were prepared with inputs from the state investigators and investigators from PMCs. The study tools were then translated into local languages (Hindi, Gujarati and Malayalam for Bihar, Gujarat and Kerala respectively).

### 3.3.4 Training of the Research Teams

Training of the state research team members was done in three phases:

- a) National Protocol Finalization Workshop
- b) State Training Workshop and
- c) On the job field training.

**National Protocol Finalization Workshop:** At national level, a workshop was organized during July 20-22, 2012 at New Delhi involving all the CCT Members and all the investigators from the partner medical colleges of the three states. This workshop discussed the methodology, study tools and details of data collection and analysis plan and arrived at a consensus. Participation of the state investigators allowed common understanding of the study tools and methodology among all the key investigators. These investigators from state were the trainers for the research team members at the state level along with the CCT members.

**State Training Workshop:** Three state level training workshops were organized in the three states involving all the state co-investigators and research team members identified. Two CCT members from INCLLEN were also present to ensure training of the research team members in uniform and standardized manner for high quality data collection. The training involved field and facility level assessment practicum for comprehensive understanding. The schedules of state workshops were:

- State Workshop, Kerala at Kochi during August 20-23, 2012
- State Workshop, Gujarat at Jamnagar during September 11-14, 2012
- State Workshop, Bihar at Patna during September 17-20, 2012

**On the job field training:** The research team members were supported by the state level investigators and the CCT members for additional training on specific issues as they emerged



over time. The research team members were reached on field for verification and hands-on training and also contacted over phone for additional training and guidance.

### 3.3.5 Data Collection

The study used a combination of methods; direct observation and quantitative methodology, qualitative methodology (in-depth interview with key categories of stakeholders) and desk review of available reports and documents.

In the study districts, all cold chain points housing the cold chain device and storing vaccines were visited and studied using the study tools. The equipment and ancillary items were observed and recorded by the study teams. For additional information, study teams interacted with the concerned health functionary. At each facility interaction with at least 2 health functionaries was done to complete the study tools. For temperature quality assessment, a logtag device was used programmed to record temperature every 15 minutes was used. The logtag device was kept in the cold chain equipment on the top of the vaccine for a period of at least one weekend and Sunday. For vaccine transfer temperature recording, the logtag was placed on the vaccines inside the vaccine carrier just before the closure of the lid at the facility. The logtag device data was downloaded using the docking device and software at CCO, INCLEN.

The data collection was done by these teams over 3 months in Kerala, 4 months in Gujarat and 5 months in Bihar. Many of the facilities required more than one visit for complete data collection and temperature data logger placement and collection.

Administrative data was collected at the time of visit to the facility from the officials and website data was accessed for cold chain equipment inventory on Aug 5 2013 (<http://www.nccvmtc.org>).

This approach allowed to synthesize multiple sources of information to draw a comprehensive picture of vaccine store and vaccine supply and logistics management issues related to routine immunization.

### 3.3.6 Quality Assurance

Quality assurance measures were incorporated into the study implementation design at several levels.

**Level 1: Central Coordinating Team (CCT):** The Central Coordinating Team (CCT) was the multidisciplinary think tank for the project and all the decisions on the study methodology, study tools, quality assurance, analysis and interpretation were arrived through consensus. The CCT monitored the field level activities at periodic intervals.

**Level 2: National Protocol Finalization Workshop:** A three-day workshop was held for all the investigators including CCT members, technical experts and state level investigators from the partner medical colleges, donor agency and other stakeholders. Objectives of the national

workshop were to finalize the study protocol including the study tools by consensus. Modalities of data collection, transmission and quality assurance measures were also finalized.

***Level 3: State Training Workshops:*** State level training workshops were conducted in each state for training the research teams from partner institutions for the data collection. The research team members and senior field investigators were trained on the study objectives, study tools and data collection techniques in detail during these workshops. Participation of CCT members ensured that there are no distortions or dilutions in communicating the study protocol to the research teams across the network. All participants were given hands on experience to undertake the cold chain facility assessment, temperature monitoring and conduct interviews under the close supervision of state coordinator and CCT members.

***Level 4: Quality Check at Field Level:*** Every day at the end of the data collection, the Senior Field Investigators scrutinized the schedules filled by MOs and RAs for completeness. If satisfied, they signed the completed study tool or else the research team members were asked to complete the study tool after collecting the desired information or repeat the data collection/interview.

***Level 5: Quality Check at State Level:*** On receipt of the filled study tools at the state level, the state coordinator checked 10% of the filled tools for completeness. If incomplete or any mistakes were observed, the study tool was returned to the research team and appropriate action was taken to complete the data.

***Level 6: Field Visit by State Coordinator/State Investigators during Data Collection:*** In every state, the State Coordinator and/or the Investigators from PMCs visited the districts during the field data collection to check and ensure quality and consistency of the data collected. The investigators cross checked the quality and correctness of the data that was collected and observed the interviews being conducted by the researchers. The investigators also provided the feedback about overall field activities, interview techniques, quality (correctness and completeness) of data collected, and quality of transcription of data by the team members to CCO.

***Level 7: Field Visit by the CCT Members during Data Collection:*** The CCT members also visited each state and selected districts during the data collection phase to check and ensure the quality and consistency of data collection. The objective of these visits was to identify problems of methodology and logistics in the field and find solutions in consultation with State Coordinators and CCO. The CCT members cross checked the authenticity of the data that was actually collected and quality of interviews being conducted by the researchers through direct observation. The CCT members also provided the feedback to CCO.

***Level 8: Quality Check at CCO:*** At the CCO, the data was reviewed for completeness and consistency. Strict quality assurance processes were followed for screening the data. All the hard copies of the filled study tools were checked for completeness, correctness and translation. It was only after verification, the information in the study tools was summarized into ICR sheets by the

Research Assistants. Then the ICR sheets were scanned and read using the ABBY software followed by export into the excel database. For any problem in reading by the software, the data entry operators again cross checked with the ICR and hard copy.

For the qualitative tools, all the study tool hard copies were cross checked with the audio tape/CD for correct transcription and translation. The qualitative data was then entered onto the database using INCLLEN Qualitative Data Analysis Software. After quality checks, the validated data was posted to a master database.

All databases were backed-up on a daily basis for security. Data security measures were also put in place to ensure data safety and avoid data loss or tampering.

### **3.3.7 Assumptions and Context for Analysis of the Data**

During survey we observed several types of cold chain devices. For many of the older devices the details about year of purchase, installation, and space were not available. For some of the devices, the National Cold Chain Training Center, Pune had given information about the net capacity and other information (<http://www.nccvmtc.org>). We have referred and used these figures for cold chain space estimation for these devices.

For the logtag temperature recorded at 15 minute interval, we considered three consecutive readings out of range ( $<2^{\circ}\text{C}$  or  $>8^{\circ}\text{C}$ ) as significant episode of excursion, as any deviation due to transient opening of the device should return to the normal range in next 15-30 minutes.

## Findings

### 4. Magnitude of data collected

In the three states and 27 districts visited, a total of 1336 cold chain stores at different levels were studied, as given in table below.

**Table 4.2: Summary of Facilities Visited**

| State   | State | Division | District                   | CHC/PHC/UHC | Others (Med Col/ ESIC) | Private | Total |
|---------|-------|----------|----------------------------|-------------|------------------------|---------|-------|
| Bihar   | 1     | 8*       | 11 <sup>#</sup>            | 160         | 1                      | 0       | 180   |
| Gujarat |       | 6        | 9                          | 645         | 2                      | 1       | 726   |
|         |       |          | 3<br>Municipal corporation | 60          |                        |         |       |
| Kerala  |       | 3        | 5                          | 347         | 5                      | 70      | 430   |
| Total   | 1     | 17*      | 28                         | 1212        | 8                      | 71      | 1336  |

\* including Patna division store  
<sup>#</sup> the division stores at Aurangabad and Muzaffarpur also house the respective district stores, therefore these 2 district stores are not counted here

The logtag device for recording temperature of the vaccine storage devices were installed at a total of 195 facilities and 223 devices. Temperature inside 46 cold boxes used for vaccine transfer instances between different vaccine stores in the states was documented. In three states the study teams observed 136 outreach sessions including 62 in Bihar, 43 in Gujarat and 31 in Kerala to document the vaccine vial status (VVM and freezing) and vaccine handling practices. Additionally, temperature inside the vaccine carrier was also documented for 60 outreach sessions.

Additionally, in-depth interviews with 336 key functionaries were done.

### 5. Vaccine supply network organization in the study states

In Bihar, the vaccines from manufacturers and GMSDs were received by Patna state store only. The division and the district stores were using vaccine van or private vehicle to collect vaccines from the state store.

In Gujarat there was no clearly designated state store and the division stores directly received vaccines from the manufacturers and GMSDs. The district stores were collecting the vaccines from the division stores. The CHCs and PHCs in the district were collecting the vaccines from the district store. In several districts, there were municipal corporation health facilities. The corporation medical store was receiving the vaccines and supplying to the

health facilities in the municipality area. We encountered three municipality systems in Vadodara (Baroda), Surat and Junagarh districts. There were instances of vaccine sharing between the division stores like Ahmedabad and Gandhinagar.

In Kerala, there was no designated state vaccine store and the three division stores were receiving the vaccines from suppliers and GMSDs. The division stores then were supplying vaccines to their respective districts. There were instances of vaccine sharing between the division stores like Thiruvananthapuram and Kozhikode.

It was apparent that the three states had variable vaccine supply network and system of vaccine logistics.

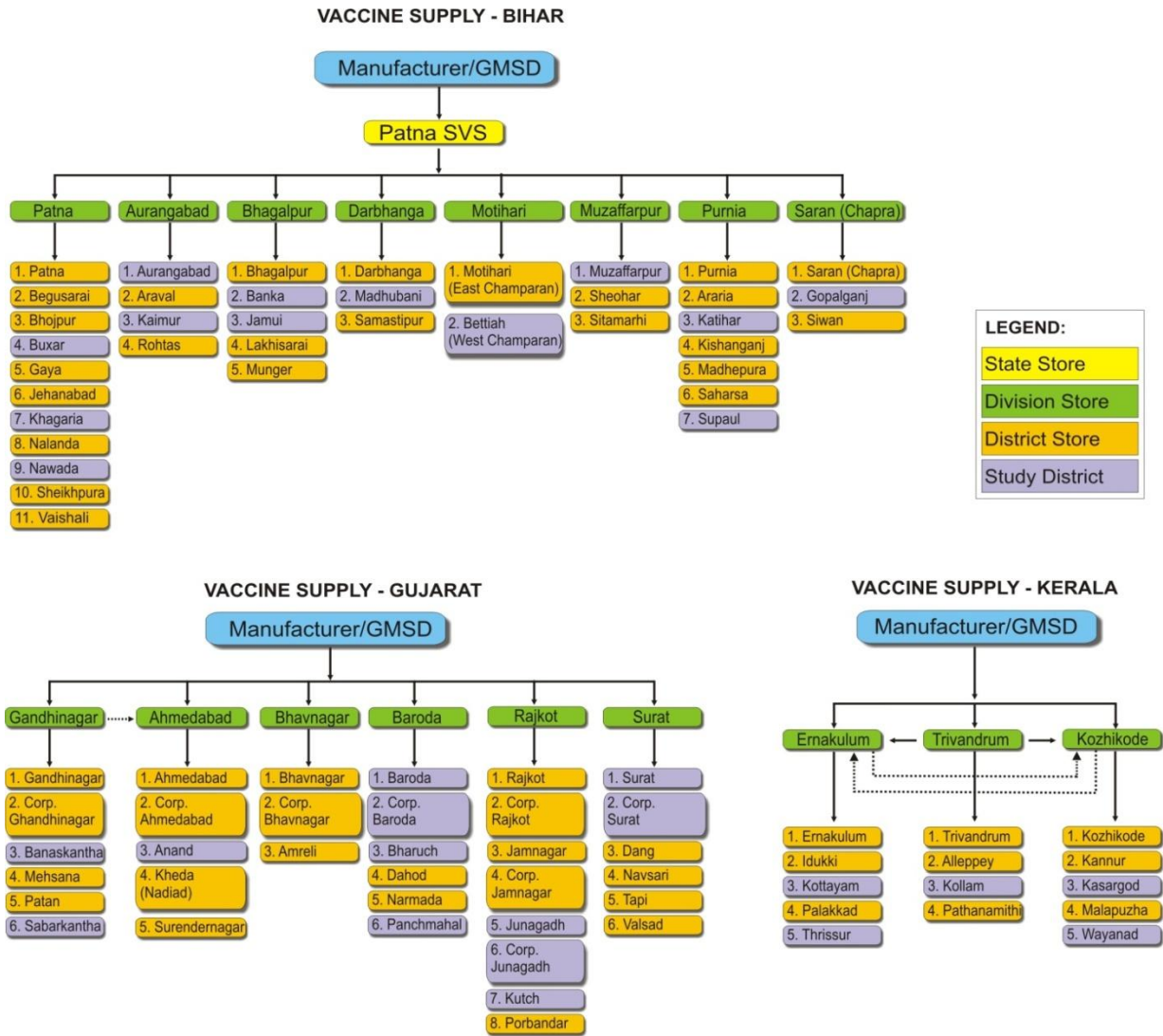
**Table 5.1: Population served by the vaccine stores at different level in the three states**

| State   |                       | No of facilities | Population  |            |            |            |
|---------|-----------------------|------------------|-------------|------------|------------|------------|
|         |                       |                  | Total       | Mean       | Minimum    | Maximum    |
| Bihar   | Division              | 8                | 136,120,566 | 17,015,071 | 10,311,542 | 35,308,283 |
|         | District              | 11               | 27,449,147  | 2,495,377  | 1,666,886  | 4,587,945  |
|         | CHC/PHCs              | 160              | 32,040,865  | 201,515    | 21,000     | 462,414    |
| Gujarat | Division              | 6                | 60,383,628  | 10,063,938 | 4,391,575  | 13,353,283 |
|         | District              | 9                | 33,114,003  | 3,679,334  | 1,550,822  | 10,543,324 |
|         | CHC/PHCs              | 645              | 35,493,314  | 55,028     | 3,664      | 1,214,032  |
|         | Municipal Corporation | 3                | 6,448,955   | 2,149,652  | 320,250    | 4,462,002  |
|         | Municipal HF          | 60               | 6,829,028   | 113,817    | 13,042     | 588,773    |
| Kerala  | Division              | 3                | 43,064,364  | 14,354,788 | 12,561,751 | 15,567,776 |
|         | District              | 5                | 9,932,429   | 1,986,486  | 817,420    | 3,121,200  |
|         | CHC/PHCs              | 347              | 15,260,549  | 43,979     | 3,325      | 430,688    |

The vaccine storage and supply network is different in the three states. Compared to the other two states, in Bihar, there is relatively fewer lower level cold chain points, which are based at block PHCs (equivalent to CHCs in other states) and cater to a relatively larger population compared to the other states. Based on the cold chain point census and population, it was apparent that per 100,000 populations, Kerala had more cold chain points (3.6 points) followed by Gujarat (2.7) compared to Bihar (0.5) in the study districts visited.

The vaccine supply network in the three states is represented below.

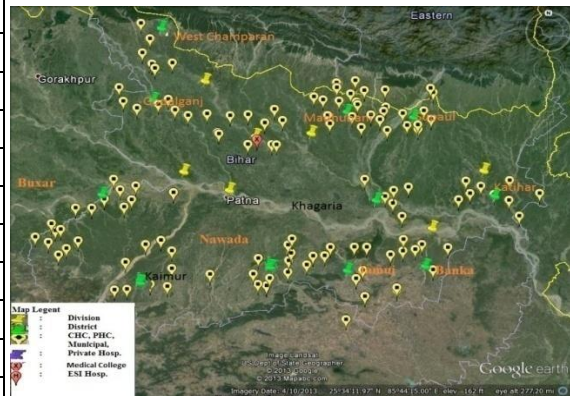
**Figure 5.1: Vaccine Supply Network in Bihar, Gujarat and Kerala**



**Table 5.1: Cold chain points visited in Bihar**

| BIHAR  | Level of vaccine store |     |            | Total      |
|--|------------------------|-----|------------|------------|
|  | District               | CHC | PHC        |            |
| Aurangabad   | 1                      |     | 11         | 12         |
| Banka  | 1                      |     | 10         | 11         |
| Buxar  | 1                      |     | 10         | 11         |
| Gopalganj  | 1                      |     | 14         | 15         |
| Jamui  | 1                      |     | 10         | 11         |
| Kaimur   | 1                      |     | 11         | 12         |
| Katihar  | 1                      |     | 13         | 14         |
| Khagaria   | 1                      |     | 7          | 8          |
| Madhubani  | 1                      |     | 18         | 19         |
| Muzaffarpur  | 1                      |     | 15         | 17         |
| Nawada   | 1                      |     | 14         | 15         |
| Supaul   | 1                      |     | 12         | 13         |
| W<br>Champaran   | 1                      |     | 15         | 16         |
| <b>TOTAL</b>   | <b>13</b>              |     | <b>160</b> | <b>174</b> |
| <i>Also visited: 1 Medical College in Muzaffarpur District</i> |                        |     |            |            |

**Figure 2.1: The Cold Chain Points in Bihar Visited under the Study**



**Table 5.2: Cold chain points visited in Gujarat**

| GUJARAT  | Level of vaccine store |            |            |                      | Total      |
|--|------------------------|------------|------------|----------------------|------------|
|  | Distri<br>ct           | CH<br>C    | PH<br>C    | Muni<br>cipalit<br>y |            |
| Anand  | 1                      | 15         | 47         |                      | 64         |
| Banaskanta   | 1                      | 1          | 78         |                      | 80         |
| Baroda   | 2                      | 16         | 77         | 21                   | 118        |
| Bharuch  | 1                      | 9          | 40         |                      | 50         |
| Junagadh   | 2                      | 18         | 55         | 6                    | 81         |
| Kutch  | 1                      | 14         | 42         |                      | 57         |
| Panchmahal   | 1                      | 16         | 73         |                      | 90         |
| Sabarkanta   | 1                      | 20         | 67         |                      | 88         |
| Surat  | 2                      | 10         | 47         | 33                   | 92         |
| <b>TOTAL</b>   | <b>12</b>              | <b>119</b> | <b>526</b> | <b>60</b>            | <b>720</b> |
| <i>Also visited: 1 Private Facility in Anand and 2 Medical Colleges in Baroda District</i> |                        |            |            |                      |            |

**Figure 2.1: The Cold chain Points in Gujarati visited under the Study**

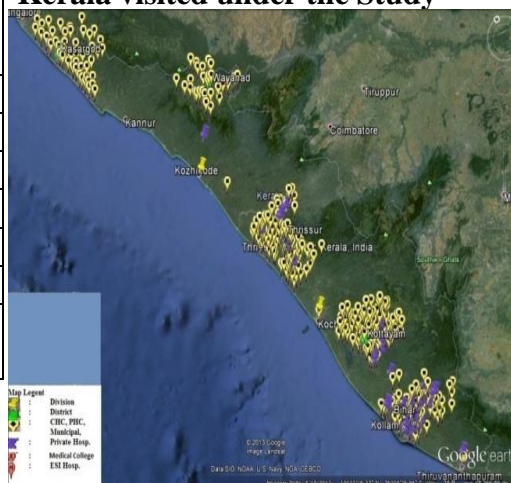


**Table 5.3: Cold chain points visited in Kerala**

| KERALA       | Level of vaccine store |           |            |           | Total      |
|--------------|------------------------|-----------|------------|-----------|------------|
|              | Distri ct              | CH C      | PH C       | Privat e  |            |
| Kasargod     | 1                      | 11        | 38         | 5         | 55         |
| Kollam       | 1                      | 20        | 60         | 41        | 123        |
| Kottayam     | 1                      | 19        | 60         | 9         | 91         |
| Thrissur     | 1                      | 24        | 83         | 15        | 125        |
| Wayanad      | 1                      | 7         | 25         |           | 33         |
| <b>TOTAL</b> | <b>5</b>               | <b>81</b> | <b>266</b> | <b>70</b> | <b>427</b> |

*Also visited: 1 ESI Hospital in Kollam, 2 Medical Colleges in Kottayam and 2 in Thrissur District*

**Figure 2.1: The Cold chain Points in Kerala visited under the Study**



## 6. Cold chain inventory

### 6.1. Inventory of electrically powered cold chain equipments

**Bihar:** In Bihar, there were 14 WIC across the state vaccine store (Patna) and 7 other division vaccine stores. Out of these, 3 WICs at three stores were out of order at the time of observation. The administrative data was shorter by one WIC and functionality status was not indicated. Out of the 4 WIFs in Bihar (at Patna and two other division stores), one WIF was not functional. The administrative data listed only 3 WIFs in the state.

At the division stores, a total of 35 ILRs (18 large ILRs and 17 small ILRs) were observed. While the number of small ILRs observed matched with the administrative record, higher number of large ILRs were observed compared to record. Across the division stores, a total of 27 DFs (24 large ones and 3 small ones) were observed and 2 divisions did not have any DF (had WIFs). Although the administrative record had near matching total DF number, the number of large and small DFs individually had significant mismatch (total 24 DFs; 11 large DFs and 13 small DFs).

A total of 446 ILRs (87 large ILRs and 359 small ILRs) were observed in study districts (2 district stores were accounted as division stores). The administrative data listed fewer devices with total tally of 389 devices (47 large ILRs and 342 small ILRs). Across the study districts 332 DFs (124 large DFs and 208 small DFs) were observed. The administrative data comprised of 320 DFs (65 large DFs and 255 small DFs), a lesser number of large DFs and larger number of small DFs.

**Gujarat:** In Gujarat, 12 WICs were observed at 6 division vaccine stores with two in nonfunctional state. While the total number of WICs matched with administrative record, the figures at two stores did not match. The only WIF at Vadodara (Baroda) was functional at the time of the observation.

At the division vaccine stores 25 large ILRs were observed, which were higher (by about 25%) than the administrative record. At district stores, the gap between number of DFs observed and administrative record was small (39 versus 33 respectively). But higher number



of larger DFs was observed compared to the administrative record (36 versus 29 respectively) and marginally lower number for the small DFs (3 versus 4 respectively).

A total of 756 ILRs (97 large ILRs and 659 small ILRs) were observed in 9 districts (including district and subdistrict facilities). The administrative data for 6 districts was available at the time of survey listed 70 large ILRs and 454 small ILRs. Compared to the observed figure, administrative data was comparable for large ILRs, but lower for small ILRs.

In 9 districts, a total of 727 DFs (104 large DFs and 623 small DFs) were observed, which were higher than the administrative record available (total DFs 559; large DFs 65 and small DFs 494).

**Kerala:** In Kerala, three division vaccine stores had 4 functional and 2 nonfunctional WICs. One WIC at Thiruvananthapuram was awaiting installation. Administrative data listed only 2 WICs 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) and 23 large DFs, while the administrative record listed only about half of them (7 large ILRs and 12 large DFs).

A total of 439 ILRs (27 large ILRs and 412 small ILRs) and 395 DFs (14 large DFs and 381 small DFs) were observed at the five districts (including the district and sub-district facilities). The administrative record indicated almost matching total number of ILRs (total 421; 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.

**Table 6.1: Census of Ice Lined Refrigerators in Study Districts and Divisions (Observed vs Administrative vs Website Data)**

| State   | Level    | Cold Chain Points | Observed |             |       | Admin Record |             |       | Website Record |             |       |
|---------|----------|-------------------|----------|-------------|-------|--------------|-------------|-------|----------------|-------------|-------|
|         |          |                   | Working  | Not Working | Total | Working      | Not Working | Total | Working        | Not Working | Total |
| Bihar   | Division | 8                 | 31       | 3           | 35    | 19           | 6           | 25    | 8              | 3           | 11    |
|         | District | 171               | 279      | 170         | 449   | 279          | 114         | 393   | 238            | 68          | 306   |
| Gujarat | Division | 6                 | 25       | 0           | 25    | 19           | 0           | 19    | 25             | 0           | 25    |
|         | District | 717               | 689      | 67          | 756   | 457          | 67          | 524   | 388            | 15          | 403   |
| Kerala  | Division | 3                 | 13       | 3           | 16    | 7            | 1           | 8     | 0              | 0           | 0     |
|         | District | 352               | 380      | 59          | 439   | 370          | 51          | 421   | 159            | 28          | 187   |

**Table 6.2: Census of Deep Freezers in Study Districts and Divisions (Observed vs Administrative vs Website Data)**

| State   |          | Cold Chain Points | Observed |             |       | Admin Record |             |       | Website Record |             |       |
|---------|----------|-------------------|----------|-------------|-------|--------------|-------------|-------|----------------|-------------|-------|
|         |          |                   | Working  | Not Working | Total | Working      | Not Working | Total | Working        | Not Working | Total |
| Bihar   | Division | 8                 | 20       | 7           | 27    | 18           | 2           | 24    | 11             | 1           | 12    |
|         | District | 171               | 234      | 107         | 341   | 194          | 135         | 329   | 143            | 53          | 196   |
| Gujarat | Division | 6                 | 38       | 0           | 38    | 33           | 0           | 33    | 39             | 0           | 39    |
|         | District | 717               | 653      | 74          | 727   | 473          | 86          | 559   | 236            | 9           | 245   |
| Kerala  | Division | 3                 | 19       | 4           | 23    | 11           | 1           | 12    | 0              | 0           | 0     |
|         | District | 352               | 359      | 36          | 395   | 367          | 26          | 393   | 96             | 4           | 100   |

## 6.2. Age of the electrically powered cold chain devices

**Bihar:** Out of the 14 WICs observed in Bihar (at division and state stores), 3 WICs were younger than 5 years, while 4 WICs were aged >6-10 years and 6 were > 10 years. Age of one nonfunctional WIC at Patna store was not known. Out of the 4 WIFs observed, 2 were younger than 5 years and one each were aged 6-10 years and > 10 years. One younger WIF was not functional at the time of visit.

As shown in Figure 2, district and sub-district level facilities had about 60% of ILRs and DFs aged < 5 years.

**Gujarat:** Out of the 12 WICs at division stores of Gujarat, 5 devices were younger than 5 years, 7 devices were >10 years. Two of the older devices were not functional at the time of visit. Only one WIF in Gujarat was aged < 5 years.

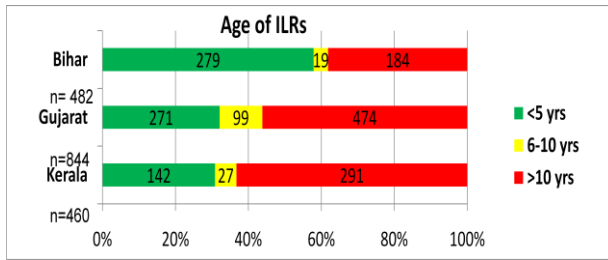
As reflected in Figure 2, district and sub-district level facilities had more than half of ILRs (54%) and DFs (56%) aged > 10 years.

**Kerala:** In Kerala, out of the 6 WICs, two devices were aged < 5 years and three devices were aged > 10 years. Age of one device was not known. One of the younger devices was waiting installation at Thiruvananthapuram. The only WIF in Kerala was an aged < 5 years.

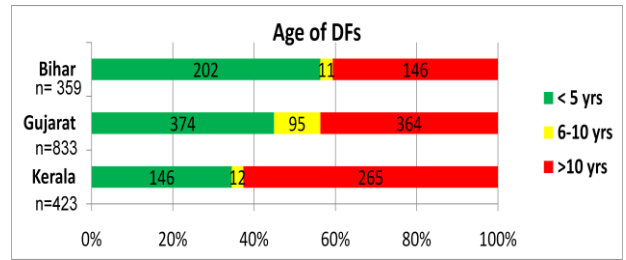
At district and sub-district level facilities, share of older equipments aged >10 years was >60% for the both type of devices (ILRs and DFs), as reflected in Figure 2.

**Figure 6.1: Age-wise breakup of devices in the districts**

**Figure 6.1.1: ILRs (combined)**



**Figure 6.1.2: DFs (combined)**

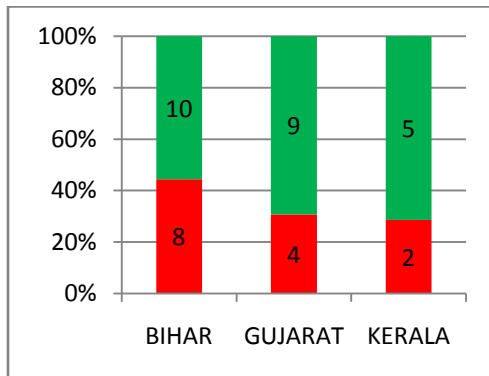


### 6.3. Coolant types of the cold chain devices

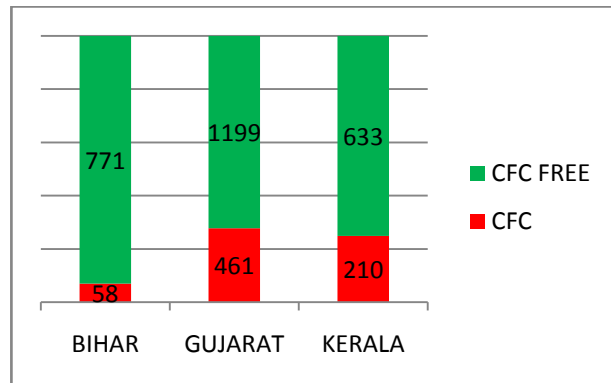
In Bihar, 7 out of the 14 WICs and 3 out of the 4 WIFs was CFC free. In Gujarat, 8 of the 12 WICs and single WIF was CFC free. In Kerala, 4 of the 6 WICs and the single WIF was CFC free.

**Figure 6.2: Coolant status of the cold chain devices in the three states**

**Figure 6.2.1: WICs and WIFs**



**Figure 6.2.2: ILRS and DFs**



While 87% of the ILRs and 98% of DFs in Bihar were CFC free, 59% of ILRs and 84% of DFs in Gujarat and 59% of ILRs and 86% of DFs in Kerala were CFC free. The CFC status of about 1.5% of ILRs and DFs in Bihar, 0.5%-1.5% of ILRs and DFs in Gujarat were not clear.

## 6.4 Devices to be boarded Off

According to the norm the CFC devices are to be taken off the system immediately. Government of India has taken a stand for not to repair the CFC devices if they stop functioning. Additionally the average life of a cold chain device is considered to be 10 years, after which the investment in repair is not economical compared to the replacement. So, replacement plan for the older devices (aged >10 years) are to be also planned. We have considered the CFC devices to be boarded off as soon as possible.

On review, 7 WICs and 1 WIF in Bihar, 5 WICs in Gujarat and 2 WICs in Kerala need to be replaced with CFC-free ones. It was evident that 162 ILRs (140 small ILRS and 22 large ILRs) in Bihar, 380 ILRs in Gujarat (375 small ILRS and 5 large ILRs) and 229 ILRs in Kerala (219 small ILRS and 10 larger ILRs) need to be boarded off at the earliest. Similarly, 83 DFs (66 small DFs and 17 large DFs) in Bihar, 179 DFs in Gujarat (165 small DFs and 14 large DFs) and 82 DFs in Kerala (76 small DFs and 6 large DFs) need to be boarded off immediately or as soon as possible. It appears that a significant proportion of the devices in Gujarat and Kerala need replacement as soon as possible. This is not additional need, but to ensure the current status of cold chain space is available.

### Summary:

- The inventory of equipments and functional status was not updated in administrative record and not readily available at many of the districts visited.
- Bihar cold chain system had a large proportion of younger and CFC free cold chain devices including ILRs and DFs at district and sub-district level facilities.
- Compared to Bihar, Gujarat and Kerala district and sub-district facilities had higher proportion of older devices with CFC coolant.
- About half of the WICs and WIFs in Bihar had CFC free coolant compared to one third of these in Gujarat and Kerala.
- An early replacement plan for a sizable proportion of cold chain devices in Gujarat and Kerala is to be developed to replace the devices > 10 years old and with CFC coolant.

## 7 Equipment Maintenance

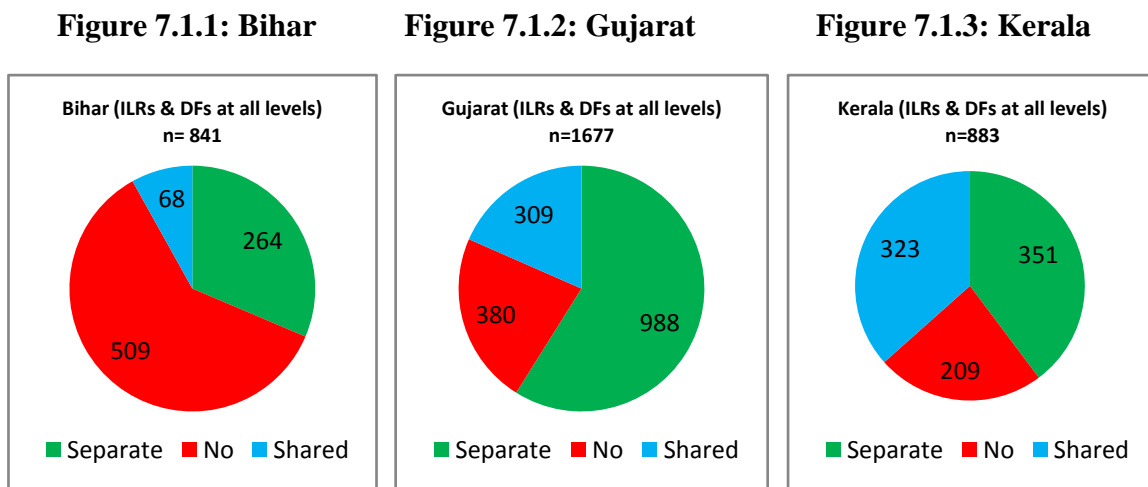
### 7.1 Voltage Stabilizers

Out of the 13 functional WICs in division stores of Bihar, 7 WICs had external and separate voltage stabilizers and 1 WIC was reported to have in-built voltage stabilizer. In Gujarat, out of 12 WICs, only 1 WIC had external and separate voltage stabilizer and 6 were reported to have in-built stabilizers. In division stores of Kerala, out of the 6 WICs, 4 functional WICs were connected to external and separate stabilizers. In Bihar (2 WIFs) and Kerala (1 WIF), all the WIFs were connected to external and separate voltage stabilizers. The only WIF in Gujarat was not connected to voltage stabilizer.

In Bihar, more than half of the electrically driven cold chain devices were not connected to voltage stabilizer in Bihar. In Gujarat and Kerala, about 20% of the devices were not connected to a separate voltage stabilizer. The proportion of devices with separate voltage stabilizer increased progressively from Bihar (31%) to Kerala (40%) and Gujarat (59%). The proportion of devices sharing voltage stabilizer with other devices were 8% in Bihar (8%), 18% in Gujarat and 32% in Kerala. The usage of voltage stabilizer was similar across all levels of vaccine stores in all three states. While only 56% of the available voltage stabilizers in Bihar were functional and in use, 84% of these in Gujarat and 93% of these in Kerala were in use.

Facility for display of input and output voltage was observed in only 30% of voltage stabilizers in Bihar, while the same was observed in 47% and 72% of the voltage stabilizers in Kerala and Gujarat respectively.

**Figure 7.1: Availability of voltage stabilizers for the cold chain devices (ILRs and DFs)**



## 7.2 Sickness Rate

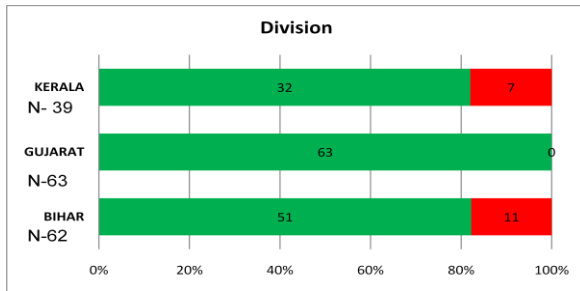
In Bihar, out of the 14 WICs, 3 were out of order at the time of observation. In Gujarat, two out of 12 WICs were nonfunctional at the time of visit. In Kerala, while only three out of 6 WICs were functional, one new WIC at Thiruvananthapuram was awaiting installation. Out of the 4 WIFs at division stores in Bihar, one was not functional. In Gujarat, the only one WIF at Vadodara was functional. In Kerala, the lone WIF at Thiruvananthapuram was not functional at the time of the observation.

As indicated in the figure 5, one-third (34%) of the devices (ILRs and DFs) in Bihar were sick compared to 9% in Gujarat, 12% Kerala at the time of survey. Sickness rate proportion increased with age of the devices.

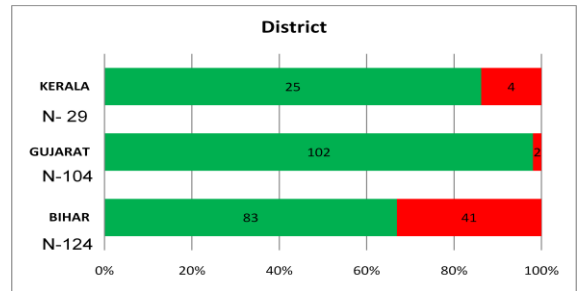
On further analysis, the sickness rate of devices in Bihar was higher compared to that in Gujarat and Kerala, irrespective of age of the device.

**Figure 7.2: Sickness rate of cold chain devices (ILRs and DFs) at different level stores**

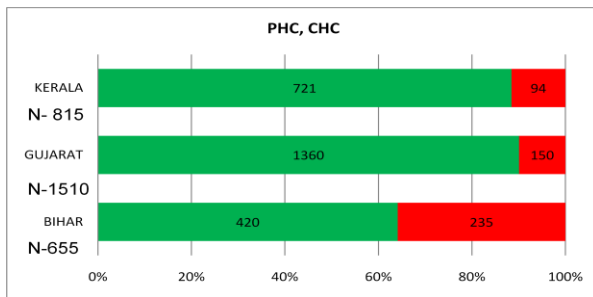
**Figure 7.2.1: Division vaccine stores**



**Figure 7.2.2: District vaccine stores**



**Figure 7.2.3: Sub-district vaccine stores**

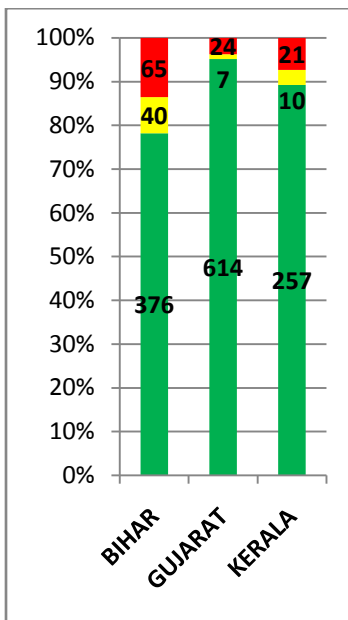


**Figure 7.2.4: All stores in state combined**

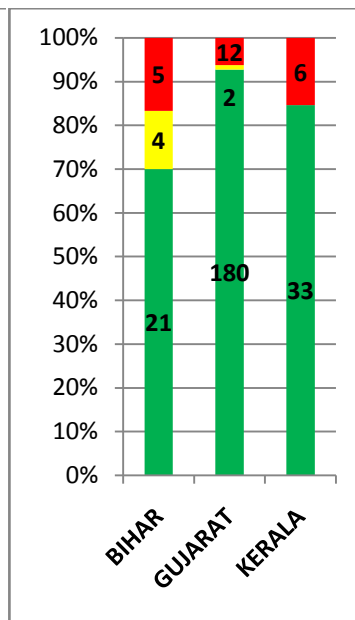


**Figure 7.3: Age of the devices and sickness rate**

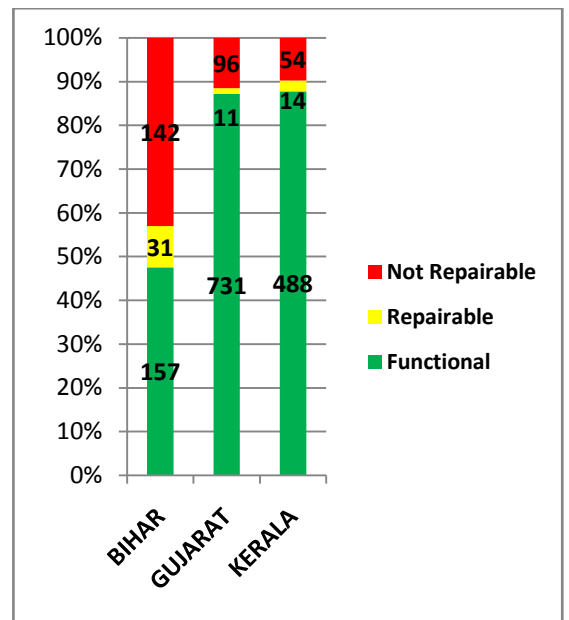
**Figure 7.3.1: Devices aged < 5 yrs**



**Figure 7.3.2: Devices aged 5-10 yrs**



**Figure 7.3.3: Devices aged > 10 yrs**



### 7.3 Breakdown maintenance practices and sickness rates

Only 11% of facilities had an arrangement for breakdown maintenance of devices in Bihar. In contrast, about 80% of the facilities in Gujarat and 58% facilities in Kerala had an arrangement for breakdown maintenance. The repair was being done primarily by the designated staffs in Kerala. In Gujarat, along with repairing by designated staff (56% of facilities), engagement of private agency for repair work (30% of facilities) was reported. In Bihar there was limited availability of the designated cold chain technicians and no formal engagement of private agency for repair and maintenance work of the cold chain devices.

For the recent breakdown instances, the reported response time for breakdowns of devices in Gujarat and Kerala were <7 days to a large extent compared to the Bihar. The reported down time for the devices were less than a week for about half of the breakdown instances in Gujarat and Kerala. These observations were correlated well with the availability of cold chain technicians and engagement of any agency.

### 7.4 Preventive maintenance practices

Out of the facilities visited in the study districts, 12% of facilities Bihar, 13% facilities in Gujarat and 20% facilities in Kerala had written plan for preventive maintenance of equipments. Very few facilities (10% in Kerala, 12% in Gujarat and 6% in Bihar) had any log book for recording preventive maintenance of cold chain equipments. A record of maintenance of equipments in last one month was observed in 3%, 4%, and 8% of facilities Bihar, Gujarat and Kerala respectively.

The status of preventive maintenance of equipments observed is summarized below. It appears that the practice of routine preventive maintenance needs significant improvement poor in all three states.

**Table 7.1: Preventive maintenance status of the cold chain devices**

| State   | Facilities (n) | Devices (ILR+DF) (n) | Gasket damaged/ not fitting (%) | ILR with >5mm ice on wall (%) | Device at uneven level (%) |
|---------|----------------|----------------------|---------------------------------|-------------------------------|----------------------------|
| Bihar   | 180            | 434                  | 20                              | 7                             | 24                         |
| Gujarat | 726            | 1495                 | 11                              | 7                             | 38                         |
| Kerala  | 430            | 736                  | 39                              | 13                            | 20                         |

### Summary:

- More than half of the cold chain devices in Bihar and about one-third of the devices in Gujarat and Kerala were not connected to separate voltage stabilizer.
- Practice of connecting more than one device to one voltage stabilizer was highest in Kerala followed by Gujarat and Bihar.
- Running cold chain devices without voltage stabilizer or using two devices with one voltage stabilizer puts the devices at risk for damage due to voltage fluctuation.
- High equipment sickness rate was documented in Bihar, with about 1/3<sup>rd</sup> of the devices non functional compared to about 10% in Gujarat and Kerala.
- The equipment sickness rate in Bihar was higher irrespective of the age of the devices compared to other two states.
- A significant proportion of devices were reported to be repairable and awaiting repair in all states.
- Preventive maintenance plan was available at limited proportion of facilities.

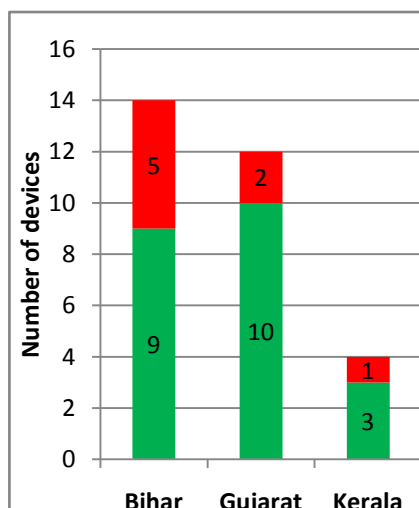
## 8 Vaccine safety and temperature integrity

### 8.1 Temperature Monitoring Practice

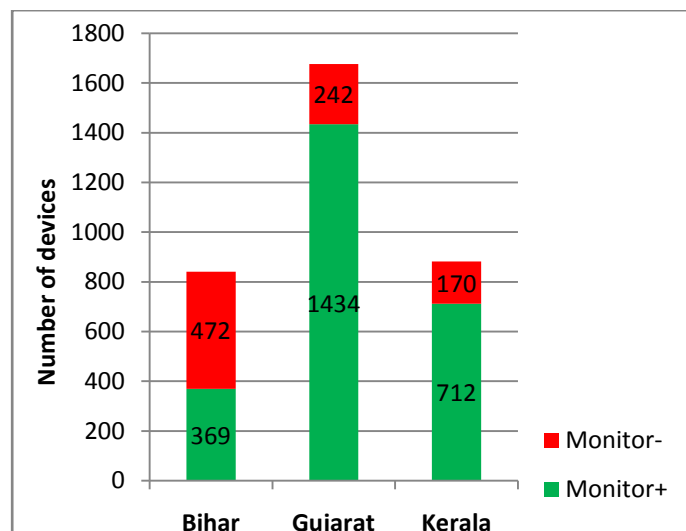
As reflected in Figure 8.1, continuous temperature monitoring system was not available at several WICs and WIFs at division stores in Bihar and few stores in Gujarat and Kerala. A several stores, although the digital temperature monitor was available and functional with the WICs and WIFs, no written/ printed record of the temperature was maintained. For the ILRs and DFs, functional temperature monitors were available for less than half (43%) of the devices in Bihar, 85% of the devices in Gujarat and 80% of the devices in Kerala.

**Figure 8.1: Availability of temperature monitors for cold chain devices**

**Figure 8.1.1: WICs and WIFs**



**Figure 8.1.2: ILRs and DFs**





In Bihar, for 34% of the ILRs and DFs twice a day temperature record was observed. In Gujarat, 77% of ILRs and 75% of DFs were monitored twice for temperature. In Kerala, 74% of ILRs and 78% of DFs had temperature monitoring twice a day. The temperature records were reviewed and signed by the officer in-charge in only 7%, 29% and 22% of facilities in Bihar, Gujarat and Kerala respectively. While 37% of facilities in Kerala and 29% of facilities in Gujarat were visited by a supervisor within one month of observation, only 18% of facilities were supervised. There was no or limited variation in the temperature documented in the registers/ monitoring sheets.

## 8.2 Vaccine storage practices

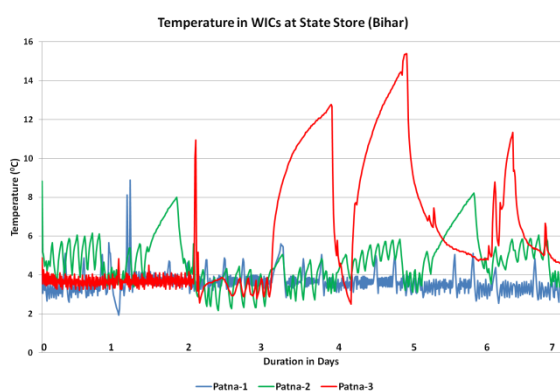
The practice of storing vaccines in baskets or in separate containers was observed in 88% of ILRs in Kerala followed by 79% in Gujarat and 32% in Bihar. The practice of storing T-series vaccines on top level was observed in 90% -94% of the ILRs in three states. Vaccine vials without label and damaged top was observed in 7% of ILRs of Gujarat and in 2-3% of ILRs in Kerala and Bihar.

## 8.3 Temperature records by the LogTag devices

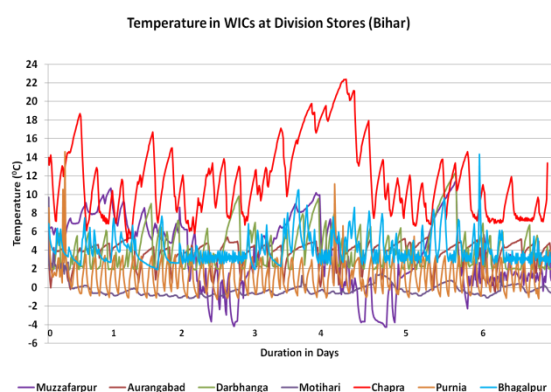
Temperature recording by the logtags at the WICs at state vaccine store and division vaccine stores of Bihar indicated widely fluctuating temperature inside WICs as indicated in Figure 8.1. The temperature inside all WICs in Kerala and all except one WIC in Gujarat were in acceptable range.

**Figure 8.1: Temperature recording in WICs at state and division vaccine stores in the three states**

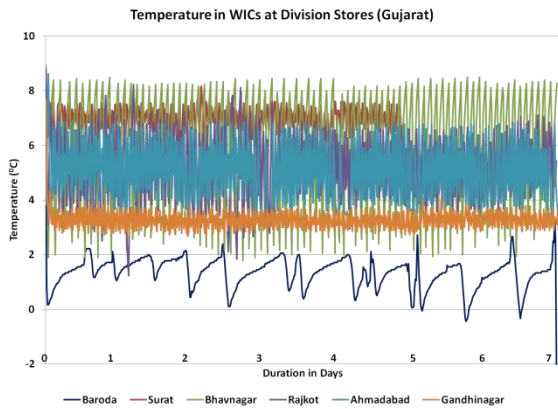
**Figure 8.1.1: WICs at state vaccine store in Bihar**



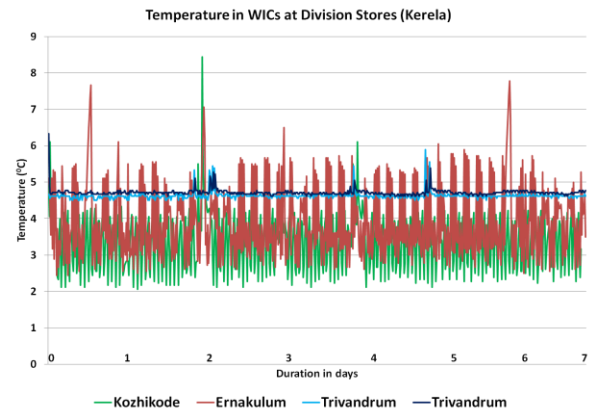
**Figure 8.1.2: WICs at division vaccine stores in Bihar**



**Figure 8.1.3: WICs at division vaccine stores in Gujarat**



**Figure 8.1.4: WICs at division vaccine stores in Kerala**



## 8.4 Temperature Monitoring by LogTag Devices

The data logger devices (logtags) for recording temperature of the vaccine storage equipments were installed at a total of 196 facilities and 223 devices. The table representing the levels of different facilities across the states and the types of devices where logtags were installed is given in Table 8.1 and Table 8.2 below. The temperature was recorded at 15 minutes interval continuously for at least 7 days including at least one weekend. Regarding temperature excursion, any excursions below 2°C and above 8°C at least once and for consecutively 3 readings (minimum of 45 minutes) were isolated. We considered three consecutive readings out of range as significant episode of excursion, as any deviation due to transient opening of the device should return to the normal range in next 15-30 minutes. Additionally, temperature excursions during day and night and during week days and weekends were also analyzed.

**Table 8.1: Summary of the facilities where logtag was installed**

| State   | Division store | District store | CHC/PHC/UHC | Total |
|---------|----------------|----------------|-------------|-------|
| Bihar   | 8              | 11             | 73          | 92    |
| Gujarat | 6              | 8              | 49          | 63    |
| Kerala  | 3              | 5              | 33          | 41    |
| Total   | 17             | 24             | 155         | 196   |

**Table 8.2: Summary of the devices where logtag was installed**

| State   | WIC | ILR | DF | Domestic Refrigerator | Cold box | Total |
|---------|-----|-----|----|-----------------------|----------|-------|
| Bihar   | 10  | 90  | 3  | 1                     | 3        | 107   |
| Gujarat | 6   | 61  | 3  |                       |          | 70    |
| Kerala  | 4   | 38  | 4  |                       |          | 46    |
| Total   | 20  | 189 | 10 | 1                     | 3        | 223   |

The data recorded by logtag devices for WICs and ILRs storing vaccines only were taken for analysis (191 facilities and 213 devices). The data for deep freezers and cold boxes were not considered for analysis.

**Table 8.3: Summary of Quality of Temperature Maintained in the ILRs and WICs**

| State/ Level         | No of Facilities | No of Devices | Total Hours  | % of Reading |           |           |           | Temperature Reached |           |              |
|----------------------|------------------|---------------|--------------|--------------|-----------|-----------|-----------|---------------------|-----------|--------------|
|                      |                  |               |              | <0           | 0 to <2   | 2 to 8    | >8        | Min (°C)            | Max (°C)  | Average (°C) |
| <b>Bihar</b>         |                  |               |              |              |           |           |           |                     |           |              |
| Div Total            | 8                | 13            | 4108         | 16           | 14        | 60        | 10        | -16                 | 26        | 3            |
| Dist Total           | 9                | 14            | 5002         | 21           | 17        | 48        | 14        | -23                 | 24        | 3            |
| PHC Total            | 72               | 77            | 23810        | 21           | 17        | 53        | 9         | -33                 | 35        | 2            |
| <b>Bihar Total</b>   | <b>89</b>        | <b>104</b>    | <b>32920</b> | <b>20</b>    | <b>17</b> | <b>53</b> | <b>10</b> | <b>-33</b>          | <b>35</b> | <b>2</b>     |
| <b>Gujarat</b>       |                  |               |              |              |           |           |           |                     |           |              |
| Div Total            | 6                | 8             | 1340         | 0.4          | 11        | 86        | 2         | -7                  | 20        | 5            |
| Dist Total           | 8                | 10            | 2365         | 0            | 3         | 96        | 0.3       | 1                   | 25        | 5            |
| PHC Total            | 49               | 49            | 12956        | 17           | 25        | 56        | 2         | -14                 | 33        | 2            |
| <b>Gujarat Total</b> | <b>63</b>        | <b>67</b>     | <b>16661</b> | <b>13</b>    | <b>20</b> | <b>66</b> | <b>2</b>  | <b>-14</b>          | <b>33</b> | <b>3</b>     |
| <b>Kerala</b>        |                  |               |              |              |           |           |           |                     |           |              |
| Div Total            | 3                | 5             | 861          | 0            | 0         | 100       | 0.4       | 2                   | 33        | 5            |
| Dist Total           | 5                | 6             | 1915         | 2            | 2         | 96        | 0         | -1                  | 13        | 4            |
| PHC Total            | 31               | 31            | 6336         | 5            | 37        | 55        | 3         | -3                  | 35        | 3            |
| <b>Kerala Total</b>  | <b>39</b>        | <b>42</b>     | <b>9111</b>  | <b>4</b>     | <b>27</b> | <b>66</b> | <b>2</b>  | <b>-3</b>           | <b>35</b> | <b>3</b>     |
| <b>Grand Total</b>   | <b>191</b>       | <b>213</b>    | <b>58691</b> | <b>15</b>    | <b>20</b> | <b>60</b> | <b>6</b>  | <b>-33</b>          | <b>35</b> | <b>3</b>     |

It was apparent that about 60% of temperature recordings in the devices at division stores in Bihar were in the desired range compared to 86% in Gujarat and 100% in Kerala. Similarly at district level stores, for about half of the recording time the temperature was in the desired range compared to 96% of the devices in Gujarat and Kerala. Little more than half of the recording time at lower level facilities, PHCs, CHC and municipality health facilities the temperature was in the desired range. A significant proportion of recordings (20%) in Bihar, across all levels had temperature in the sub-zero range. The temperature excursion in sub-zero range was observed in 13% of the recording time in Gujarat, mostly at CHC/PHC/ municipality facilities level. The temperature excursion below 0°C was about 4% of the recording time. Similarly the temperature excursion above 8°C was also observed to be highest in Bihar (10%) compared to the Gujarat and Kerala (20% each).

On further analysis, it was observed that most of these subzero recordings were contributed by continuous spells (the spells with at least 3 consecutive readings by a data logger at an interval of 15 minutes), 98% in Bihar, 97% in Gujarat and Kerala. Similarly the above 8°C excursion was

also contributed mainly by the continuous spells (the spells with at least 3 consecutive readings by a data logger at an interval of 15 minutes). The continuous spells contributed to 98%, 86% and 93% of the readings above 8°C in Bihar, Gujarat and Kerala respectively. The details of the temperature excursion to <0°C and >8°C are summarized in the tables below.

**Table 8.4: Spells of continuous exposure of vaccines to temperature of <0°C**

| State          | Level        | Total Duration of observation (hrs) | Exposure to temperature <0°C |                               |                  |                  |                    |           |            |
|----------------|--------------|-------------------------------------|------------------------------|-------------------------------|------------------|------------------|--------------------|-----------|------------|
|                |              |                                     | Total duration (hrs)         | Continu ous for >45 min (hrs) | Number of spells |                  |                    |           | Total      |
|                |              |                                     |                              |                               | 45 mins          | >45 min to 2 hrs | >2 hrs to ≤ 10 hrs | >10 hrs   |            |
| <b>Bihar</b>   |              |                                     |                              |                               |                  |                  |                    |           |            |
|                | Division     | 4107                                | 540                          | 501                           | 19               | 47               | 30                 | 9         | 105        |
|                | District     | 5002                                | 666                          | 661                           | 1                | 6                | 8                  | 9         | 24         |
|                | CHC/ PHC     | 23809                               | 4663                         | 4618                          | 5                | 39               | 50                 | 67        | 161        |
|                | <b>Total</b> | <b>32919</b>                        | <b>5870</b>                  | <b>5781</b>                   | <b>25</b>        | <b>92</b>        | <b>88</b>          | <b>85</b> | <b>290</b> |
| <b>Gujarat</b> |              |                                     |                              |                               |                  |                  |                    |           |            |
|                | Division     | 1339                                | 5                            | 5                             | 0                | 2                | 1                  | 0         | 3          |
|                | District     | 2364                                | 0                            | 0                             | 0                | 0                | 0                  | 0         | 0          |
|                | CHC/ PHC     | 12956                               | 2406                         | 2332                          | 19               | 116              | 36                 | 29        | 200        |
|                | <b>Total</b> | <b>16660</b>                        | <b>2411</b>                  | <b>2337</b>                   | <b>19</b>        | <b>118</b>       | <b>37</b>          | <b>29</b> | <b>203</b> |
| <b>Kerala</b>  |              |                                     |                              |                               |                  |                  |                    |           |            |
|                | Division     | 860                                 | 0                            | 0                             | 0                | 0                | 0                  | 0         | 0          |
|                | District     | 1914                                | 19                           | 18                            | 0                | 0                | 4                  | 0         | 4          |
|                | CHC/ PHC     | 6335                                | 421                          | 407                           | 1                | 40               | 9                  | 7         | 57         |
|                | <b>Total</b> | <b>9110</b>                         | <b>440</b>                   | <b>426</b>                    | <b>1</b>         | <b>40</b>        | <b>13</b>          | <b>7</b>  | <b>61</b>  |

**Table 8.5: Spells of continuous exposure of vaccines to temperature of >8°C**

| State          | Level        | Total Duration of observation (hrs) | Exposure to temperature >8°C |                             |                  |                  |                    |           |            |
|----------------|--------------|-------------------------------------|------------------------------|-----------------------------|------------------|------------------|--------------------|-----------|------------|
|                |              |                                     | Total duration (hrs)         | Continuus for >45 min (hrs) | Number of spells |                  |                    |           | Total      |
|                |              |                                     |                              |                             | 45 mins to 2 hrs | >45 min to 2 hrs | >2 hrs to ≤ 10 hrs | >10 hrs   |            |
| <b>Bihar</b>   |              |                                     |                              |                             |                  |                  |                    |           |            |
|                | Division     | 4107                                | 302                          | 283                         | 5                | 15               | 25                 | 6         | 51         |
|                | District     | 5002                                | 1196                         | 1192                        | 1                | 0                | 3                  | 4         | 8          |
|                | CHC/P HC     | 23809                               | 1931                         | 1884                        | 6                | 19               | 26                 | 38        | 89         |
|                | <b>Total</b> | <b>32919</b>                        | <b>3430</b>                  | <b>3360</b>                 | <b>12</b>        | <b>34</b>        | <b>54</b>          | <b>48</b> | <b>148</b> |
| <b>Gujarat</b> |              |                                     |                              |                             |                  |                  |                    |           |            |
|                | Division     | 1339                                | 26                           | 0                           | 0                | 0                | 0                  | 0         | 0          |
|                | District     | 2364                                | 14                           | 92                          | 0                | 0                | 0                  | 2         | 2          |
|                | CHC/P HC     | 12956                               | 186                          | 170                         | 2                | 4                | 5                  | 5         | 16         |
|                | <b>Total</b> | <b>16660</b>                        | <b>262</b>                   | <b>226</b>                  | <b>2</b>         | <b>4</b>         | <b>5</b>           | <b>7</b>  | <b>18</b>  |
| <b>Kerala</b>  |              |                                     |                              |                             |                  |                  |                    |           |            |
|                | Division     | 860                                 | 3                            | 3                           | 0                | 0                | 1                  | 0         | 1          |
|                | District     | 1914                                | 36                           | 26                          | 0                | 0                | 1                  | 3         | 4          |
|                | CHC/P HC     | 6335                                | 184                          | 178                         | 0                | 1                | 0                  | 9         | 10         |
|                | <b>Total</b> | <b>9110</b>                         | <b>223</b>                   | <b>207</b>                  | <b>0</b>         | <b>1</b>         | <b>2</b>           | <b>12</b> | <b>15</b>  |

## 8.5 VVM and freezing status of vials at outreach sites

At the outreach sessions observed, 3 out of the 160 OPV vials, none out of 197 Measles vaccines and 1 out of 122 Hepatitis B vials. Three out of these vials with unusable VVM were in Kerala.

At these outreach sessions, 3 out of 223 DPT vials, 4 out of the 163 TT vials and 4 out of the 122 Hepatitis B vials were observed to be frozen. Seven frozen vials were observed in Bihar, 3 vials in Gujarat and 1 vial in Kerala.

Frozen T series vaccines were observed in 5% of PHCs in Bihar (at 12 PHCs across 5 districts), 1% of Facilities in Gujarat (at 7 PHCs across 3 districts) and 2% of CHCs/PHCs in Kerala (1 CHC and 5 PHCs across 4 districts). Additionally, at 3 of the 70 private health facilities observed in Kerala had frozen T series vaccine vials.

## 8.6 Temperature maintenance during vaccine transfer between facilities

During transfer of vaccines from higher facility to lower facility, logtag was installed in the cold box for recording the temperature. The logtag was installed in the cold box on completion of the vaccine before closure of the lid and removed at the facility just before transfer of the vaccines

into the ILRs. The logtags were installed for 20 transfers in Bihar, 13 transfers each in Gujarat and Kerala, as per the breakup given in Table below.

**Table 8.6: Summary of the vaccine transfers where logtag was installed**

| State          | Vaccines transferred from |                      |                     |            | Total |
|----------------|---------------------------|----------------------|---------------------|------------|-------|
|                | State to Division         | Division to District | District to CHC/PHC | CHC to PHC |       |
| <b>Bihar</b>   | 2                         | 5                    | 13                  |            | 20    |
| <b>Gujarat</b> |                           | 2                    | 4                   | 7          | 13    |
| <b>Kerala</b>  |                           | 2                    | 7                   | 4          | 13    |
| <b>Total</b>   | 2                         | 9                    | 24                  | 11         | 46    |

Temperature of total 46 vaccine transfers in three states was observed for 6060 minutes. Overall, the exposures to temperatures  $<0^{\circ}\text{C}$  were observed for 22% of the time whereas temperature went above  $8^{\circ}\text{C}$  for 26% of time. Overall, temperature was observed to be in 2 to  $8^{\circ}\text{C}$  for only 33% of the time.

In Bihar, about half of the time the readings during vaccine transfer from state and division stores (to other divisions or districts) were in the desired range. While the temperature was in sub-zero range for 10% of times, 19% times it was above  $8^{\circ}\text{C}$ . In Gujarat, the temperature was in desired range for 31% of time and for one transfer the temperature was throughout in sub-zero range. In Kerala, the temperature was in desired range for 23% of time and for 50% of the times the temperature was in sub-zero range.

All the intra-districts vaccine transfers from district stores in Bihar, the temperatures gone above  $8^{\circ}\text{C}$  (overall 50% of times). In two transfers, the temperature reached sub zero also. For the intra-district vaccine transfers in Gujarat and Kerala, the temperature excursion beyond  $8^{\circ}\text{C}$  were less compared to Bihar and were limited to the transfers from CHCs to PHCs. But exposure of the vaccines to sub-zero temperature was observed.

## 8.7 Temperature maintenance during vaccine transfer to outreach sessions

In total for 60 episodes of vaccine carrier transfer to outreach sessions were documented in three states (9 in Bihar, 26 in Gujarat and 25 in Kerala). The average time taken for onward transfer of vaccine carrier was 54 min (15 min- 120 min), 27 min (5 min- 120 min) and 19 min (10 min – 70 min) in Bihar, Gujarat and Kerala respectively.

For transfers in Bihar, the temperature was recorded to be in desired range in only 15% of instances, while 61% of recordings were above  $8^{\circ}\text{C}$  and 8% recordings were in sub-zero range. In Gujarat, while 33% of the readings were in the desired range, 34% were above  $8^{\circ}\text{C}$  and 19% recordings were in sub-zero range. In Kerala, while 46% of the readings were in the desired range, 36% were above  $8^{\circ}\text{C}$  and 8% recordings were in sub-zero range

The recordings indicated exposure of the vaccines to wide temperature excursion during transfer and especially to the sub-zero temperature with risk of freezing.

**Summary:**

- More than half of the facilities in Bihar had no separate thermometer to record the temperature of cold chain devices.
- Practice of twice a day temperature recording on temperature chart was observed at most of the facilities in all three states. But, there was no or limited variation in temperature.
- Temperature recording by logtag devices indicated widely fluctuating temperature at WICs at division stores of Bihar with exposure to both sub-zero and  $>8^{\circ}\text{C}$  temperatures.
- In Bihar, vaccines were exposed to both sub-zero and  $>8^{\circ}\text{C}$  temperatures for relatively higher proportion of time than that at the district or sub-district facilities.
- Poor practice of storage of vaccines in ILRs was observed at many facilities in Bihar and Gujarat and few in Kerala.
- Although less than 2% of the vaccine vials observed had unusable VVM, 2.1% at the T series and Hep B vaccine vials were frozen at outreach session level.
- Up to 5% of the facilities had frozen T series vaccine vials in the ILRs.
- The vaccines are exposed to wide temperature excursion during vaccine transfer from division stores and are at risk of freezing.

## 9 Infrastructure

### 9.1 Building of the facilities

One third of the facilities in Bihar, one fourth of facilities in Gujarat and about one fifth of the facilities had dedicated room for the cold chain devices. Overall the room housing cold chain devices required major repair in 14%, 7% and 5% of facilities in Bihar, Gujarat and Kerala. Minor repair for the room housing cold chain devices was needed for 39%, 27% and 22% of facilities in Bihar, Gujarat and Kerala respectively.

In Bihar, 62% of the facilities require improvement in electrical wiring and closed systems compared to 14% in Gujarat and 10% in Kerala.

### 9.2 Dry supply storage

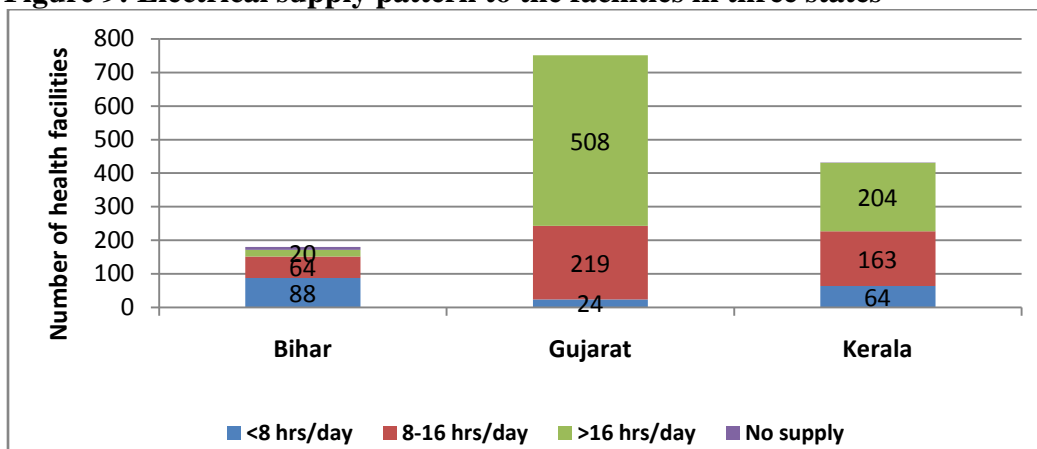
Dedicated space for dry supply storage was available in 56%, 52% and 56% of facilities in Bihar, Gujarat and Kerala. Dry supplies were properly stacked and stored in 26%, 36% and 65% of the facilities.

### 9.3 Electricity supply

The electricity supply status of the facilities visited in the three states is shown in the figure below. As evident from the figure, a significant proportion of facilities in Bihar had either supply less than 8 hours/day or unpredictable. Even half of the he division and district level facilities did

not have uninterrupted electricity supply. Compared to Bihar, Gujarat and Kerala had better electricity supply status.

**Figure 9: Electrical supply pattern to the facilities in three states**



#### 9.4 Manpower availability

**Vaccine handler:** In 21% of the facilities in Bihar, there was a dedicated vaccine handler was reported to be available. In 60% facilities there was a part-time vaccine handler available. In Gujarat, 10% facilities had a dedicated vaccine handler, while at 69% facilities there was a part-time vaccine handler. In Kerala while 35% of facilities had a dedicated vaccine handler, 37% had a part-time person handling vaccines.

**Store keeper:** While 51% of the facilities in Bihar reported to have a dedicated store keeper, 35% had a part-time person. In Gujarat, 50% facilities had a dedicated store keeper and 26% facilities had a part-time person. In Kerala while 12% of facilities had a dedicated store keeper, 60% had a part-time person.

**Cold chain technician:** Two division stores in Bihar visited reported to have a cold chain technician. In Gujarat, three division stores reported to have a cold chain technician and one division store in Kerala had a cold chain technician. At district level, four facilities in Gujarat reported to have cold chain technician, while none of the district stores in Kerala had technician.



**Summary:**

- Less than 1/3<sup>rd</sup> of the facilities had dedicated room for the cold chain devices.
- About 1/3<sup>rd</sup> of the room/ space housing the cold chain devices needed repair.
- About half of the facilities in Bihar did not have uninterrupted 8 hours of electricity supply daily.
- About half of the facilities had a dedicated area for dry storage and proper organization of dry storage needs attention in all states.
- Very few cold chain technicians were in position in the states and facilities studied to tackle the cold chain device breakdown and maintenance.
- Many of the facilities were managing with part-time vaccine handlers and store keepers in all three states.

## 10 Vaccine supply and logistics

### 10.1 Vaccine supply network and practices

In Bihar, the state vaccine store received vaccines from manufacturer/supplier. The division stores and district stores used to collect the vaccines from the state vaccine store. The PHCs also collected the vaccines and dry supplies from the district store. In Gujarat, all except one division store used to receive the vaccines directly from the supplier/ manufacture. The district stores collected vaccines from the division stores. Within the districts, a mixed pattern of supply was observed; some CHCs/PHCs collected their vaccines while some were delivered the vaccines. In Kerala, the three division stores directly received the vaccines from supplier/ manufacture. Some districts were delivered the vaccines by division stores while some collected their vaccines. Within the districts, a mixed pattern of supply was observed; some CHCs/PHCs collected their vaccines while some were delivered the vaccines.

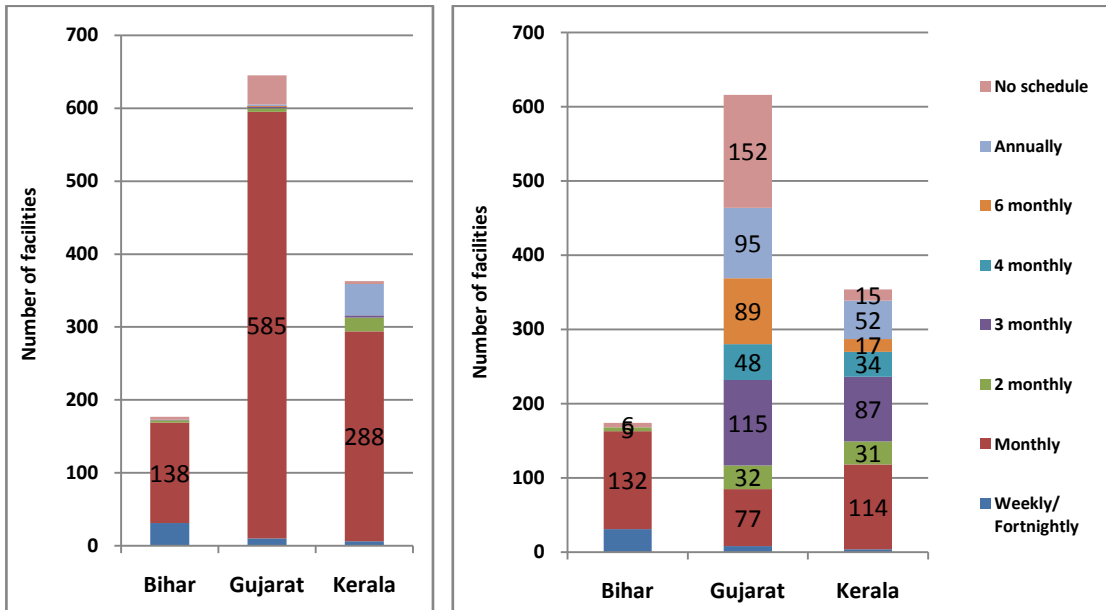
### 10.2 Forecasting, indenting and supply of vaccines

Majority of the facilities were sending vaccine indent request on monthly schedule. As indicated in Figure 10, most of the facilities in the states received vaccine at monthly interval. In Bihar, several (15%) of the facilities were making more than one visit in a month to collect vaccines. In Bihar, the schedule of supply for dry supplies matched with the vaccines. The schedule of dry supplies delivery/ collection was mixed and varied widely from more than once in a month to annually in Gujarat and Kerala.

**Figure 10.1: Frequency of vaccine and dry supply in the states**

**Figure 10.1.1: Vaccines**

**Figure 10.1.2: Dry supplies**



### 10.3 Stock record keeping

Stock registers/records related to vaccine and dry supplies were available for review during the visit/ survey in 90% of facilities in Bihar and Gujarat and 80% of the facilities in Kerala. Several of these facilities were also using computer for stock recording. Stock register/ record for all 12 months during 2011-12 was found in 58%, 49% and 65% of the facilities in Bihar, Gujarat and Kerala respectively. In these states, facilities were using one to four registers for recording the vaccine and dry supply stock. Several facilities were also maintaining antigen wise stock record/register. Several of the facilities had no mention of the VVM and expiry date of the vaccines in stock register/ record.

### 10.4 Stock out of vaccines

According to the stock registers at facilities during 2011-12, most of the facilities in Bihar (92%) and Gujarat (88%) and majority (68%) of facilities in Kerala had stock out of one or more vaccine for once or more than once. Most of the division and district stores also experienced stock outs.

**Table 10.1: The stock out status of antigens during 2011-12**

| State   | No of facilities |                                 | % of facilities with stock out |                                |                           |
|---------|------------------|---------------------------------|--------------------------------|--------------------------------|---------------------------|
|         | Total            | With stock record available (n) | Any vaccine at least once (%)  | Any vaccine more than once (%) | More than one vaccine (%) |
| Bihar   | 180              | 129                             | 92                             | 80                             | 77                        |
| Gujarat | 726              | 571                             | 88                             | 74                             | 73                        |
| Kerala  | 430              | 340                             | 68                             | 37                             | 48                        |

Apart from stock outs, as evident from Table 10.2, during 2011-12, majority of the health facilities in the study districts across Bihar, Gujarat and Kerala experienced wide fluctuation in vaccine stock levels. Many of these facilities experienced more than one fluctuation and for more than one vaccine during the period. The periods of stock levels reaching below minimum threshold level and reaching above maximum threshold level ranged between 1-5 months and the stock fluctuation was observed for all the UIP vaccines. OPV, DPT and HepB were the vaccines which reached to lowest stock level at maximum number of facilities. Similarly the surplus level was observed commonly for BCG and TT.

**Table 10.2: The stock status compared to above or below threshold level of antigens**

|   | No of facilities |                              | BCG       |           | OPV       |           | DPT       |           | TT        |           | HepB      |           | Measles   |           | Pentavalent |           |
|---|------------------|------------------------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-------------|-----------|
|   | Total (n)        | Stock record for >3 mons (n) | Above (%) | Below (%) | Above (%) | Below (%) | Above (%) | Below (%) | Above (%) | Below (%) | Above (%) | Below (%) | Above (%) | Below (%) | Above (%)   | Below (%) |
| Bihar   | 180              | 129                          | 92        | 65        | 40        | 95        | 23        | 98        | 60        | 72        | 16        | 74        | 57        | 90        | -           | -         |
| Gujarat   | 726              | 571                          | 82        | 79        | 60        | 92        | 58        | 73        | 79        | 55        | 68        | 81        | 75        | 64        | -           | -         |
| Kerala  | 430              | 340                          | 85        | 60        | 82        | 84        | 56        | 82        | 90        | 64        | 63        | 79        | 76        | 76        | 46          | 69        |
| <i>Note: Below: Below minimum threshold level at least once in the year<br/> Above: Above maximum threshold level at least once in the year</i> |                  |                              |           |           |           |           |           |           |           |           |           |           |           |           |             |           |

**Summary:**

- Bihar had a single receiving point of vaccines at state vaccine store Patna, compared to multiple division stores in Gujarat and Kerala receiving vaccines and dry supplies directly.
- While in Bihar, PHCs collected their supply from district store, a mixture of supply and collection pattern was observed in Gujarat and Kerala.
- Although most of the facilities projected their forecast annually, a monthly indent and supply system was observed. The dry supply frequency was widely variable across the states.
- Stock registers were available in about half to 2/3<sup>rd</sup> of the facilities and several facilities had no mention of VVM and expiry date in the register.
- Most of the facilities in Bihar and Gujarat and majority in Kerala experienced stock out of one or more vaccines.
- In addition to stock out, many of the facilities also experienced fluctuation in stock status (above or below the maximum and minimum threshold levels).

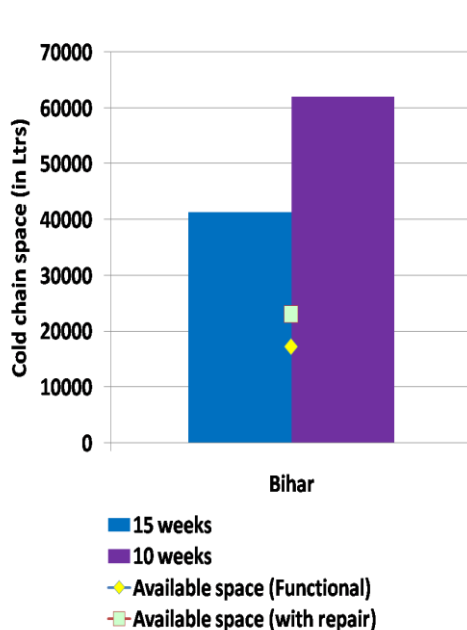
## 11 Cold chain space

### 11.1 Currently available +2<sup>0</sup>C to + 8<sup>0</sup>C space and projection for new vaccine addition

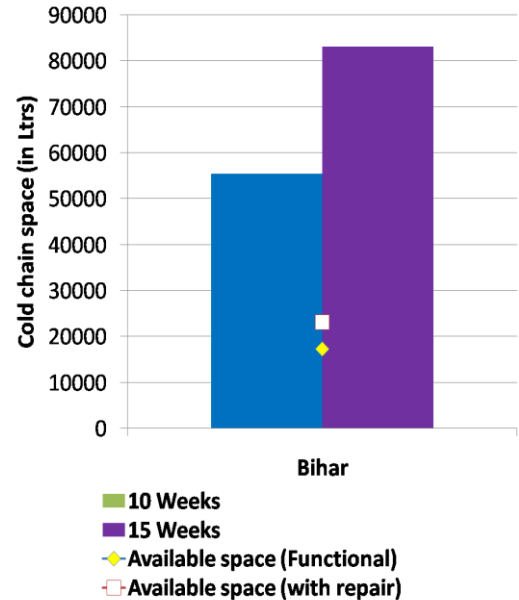
**State store:** The estimation is based on assumption that the state vaccine store (only in Bihar for the study states) is storing vaccines for a period of 3 months and 3 weeks buffer (a total of 15 weeks). The Patna state vaccine store is also functioning as division vaccine store. Considering the Patna vaccine store as state vaccine store only, there is deficit of 38985 litres for the current UIP schedule. When the store is considered as combined state and division store the space deficit increased to 60258 litres for the current UIP schedule.

**Figure 11.1: Available vs required +2 to +8<sup>0</sup>C chain space at state and division stores in Bihar**

**Fig 11.1.1: Patna store- projection for state vaccine store only**

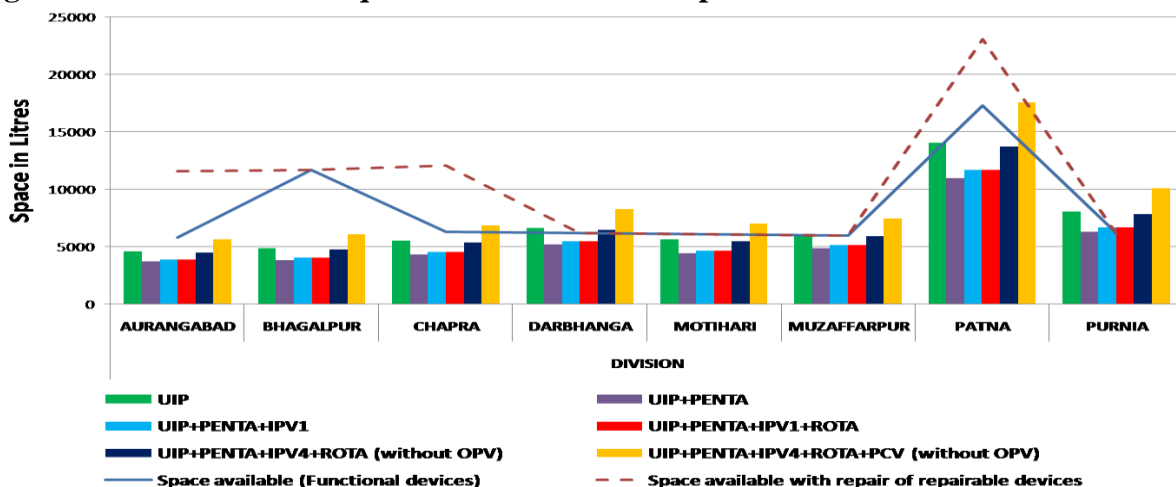


**Fig 11.1.1: Patna store - projection for state vaccine store and division store combined**

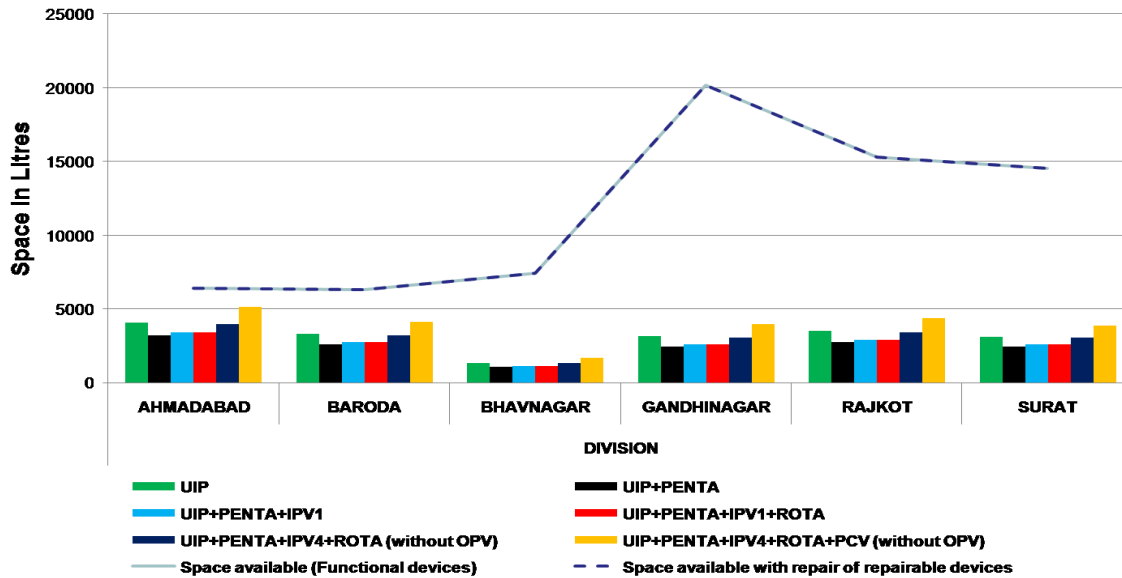


**Division stores:** The estimation is based on assumption that the division vaccine stores are storing vaccines for a period of 2 months and 2 weeks buffer (a total of 10 weeks). Based on the current cold chain space in +2 to +8<sup>0</sup> C four of the division stores in Bihar are constrained for cold chain space as per the current UIP schedule. None of the division vaccine stores in are constrained for space for the current immunization schedule. With addition of new vaccines (PCV along with others) only one division vaccine store shall have space deficit. Figures 11.2 to 11.4 represent the space projections for division stores in the three states separately.

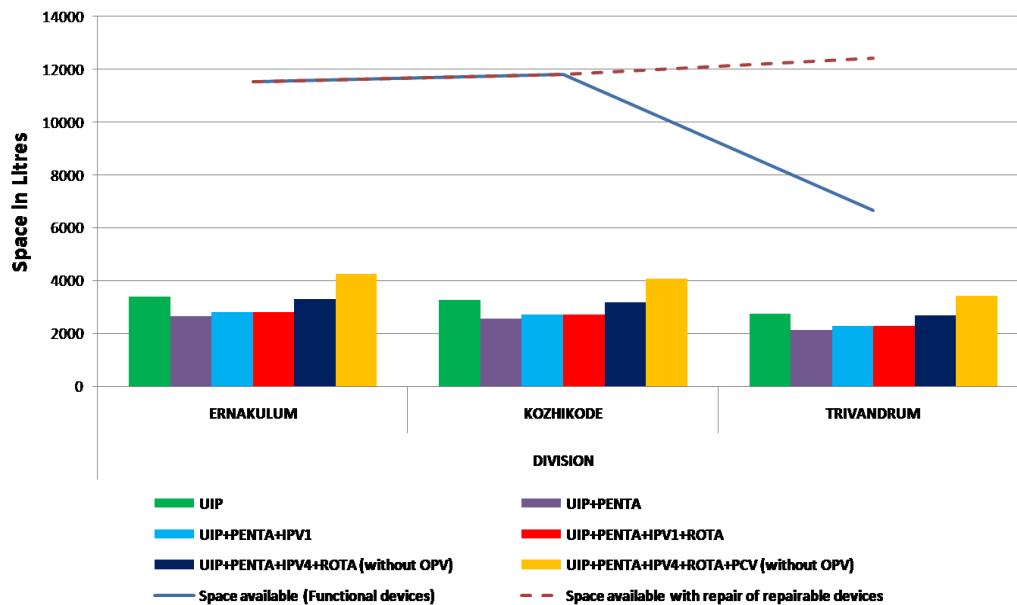
**Figure 11.2: Available vs required +2 to +8<sup>0</sup>C chain space at division stores in Bihar**



**Figure 11.3: Available vs required +2 to +8°C chain space at division stores in Gujarat**



**Figure 11.4: Available vs required +2 to +8°C chain space at division stores in Kerala**



**District store:** The estimation is based on assumption that the division vaccine stores are storing vaccines for a period of 2 months and 2 weeks buffer (a total of 10 weeks). None of the district vaccine stores in Bihar have adequate space for storing the current UIP schedule vaccines. Four district vaccine stores in Gujarat and three district vaccine stores in Kerala have deficit for the current UIP schedule demand. The cold chain space demand is expected to go further with addition of new vaccines in future. Figure 11.5 to 11.7 represent the space projection for district stores in the three states separately.

Figure 11.5: Available vs required +2 to +8°C chain space at district stores in Bihar

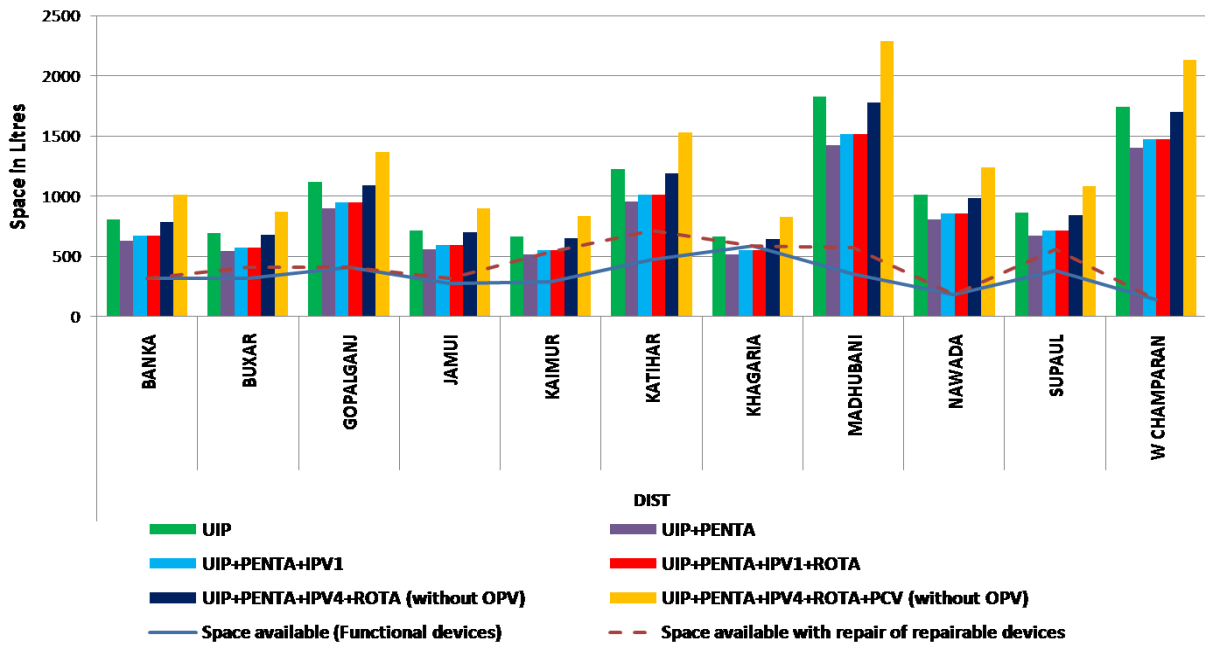
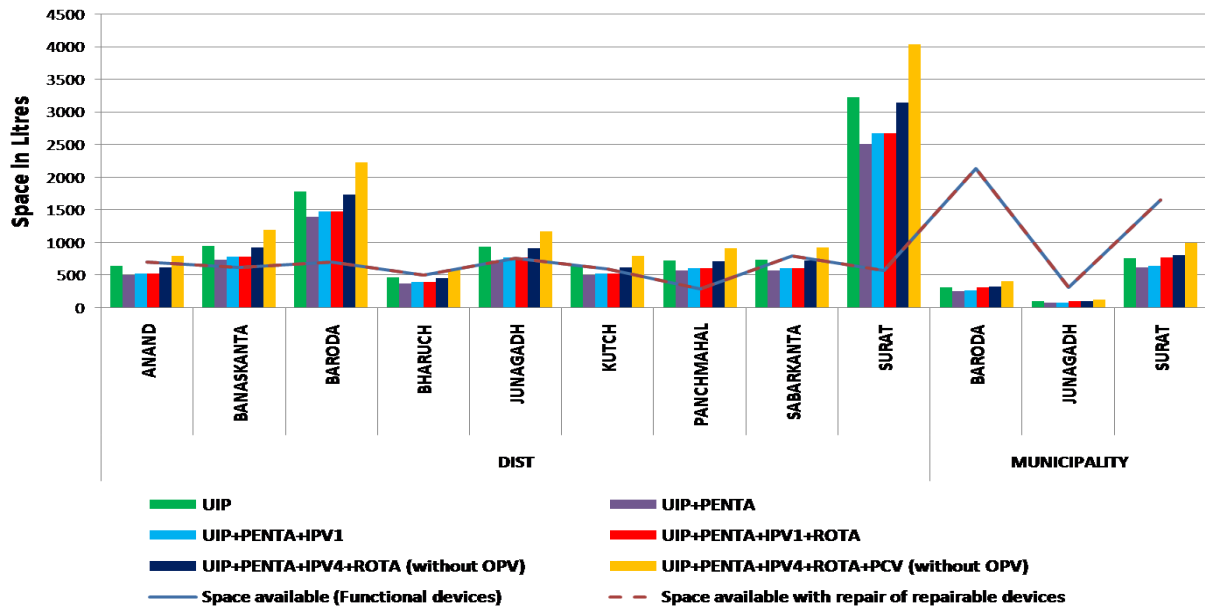
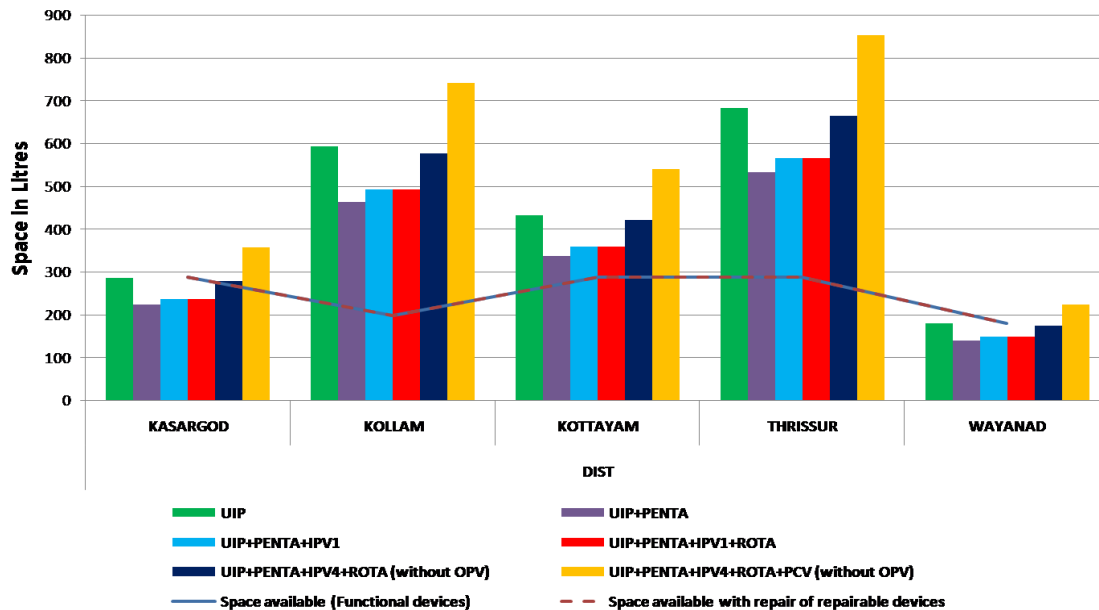


Figure 11.6: Available vs required +2 to +8°C chain space at district stores in Gujarat



**Figure 11.7: Available vs required +2 to +8°C chain space at district stores in Kerala**



**CHCs and PHCs:** The estimation is based on assumption that the CHCs and PHCs are storing vaccines for a period of 1 month and 1 week buffer (a total of 5 weeks). Overall most of the districts in three states (except two districts in Bihar) have adequate space for the current cold chain space demand as per current UIP schedule. With addition of new vaccines under consideration, the CHCs and PHCs in districts of Gujarat and Kerala shall be able to accommodate the new vaccines. In Bihar, CHCs (or block PHCs) of 2 districts are likely to have space constraint with addition of IPV, Rotavac and PCV vaccine. Figure 11.8 to 11.10 represent the space projection for sub-district stores in the three states.

**Figure 11.8: Available vs required +2 to +8°C chain space at PHCs in Bihar**

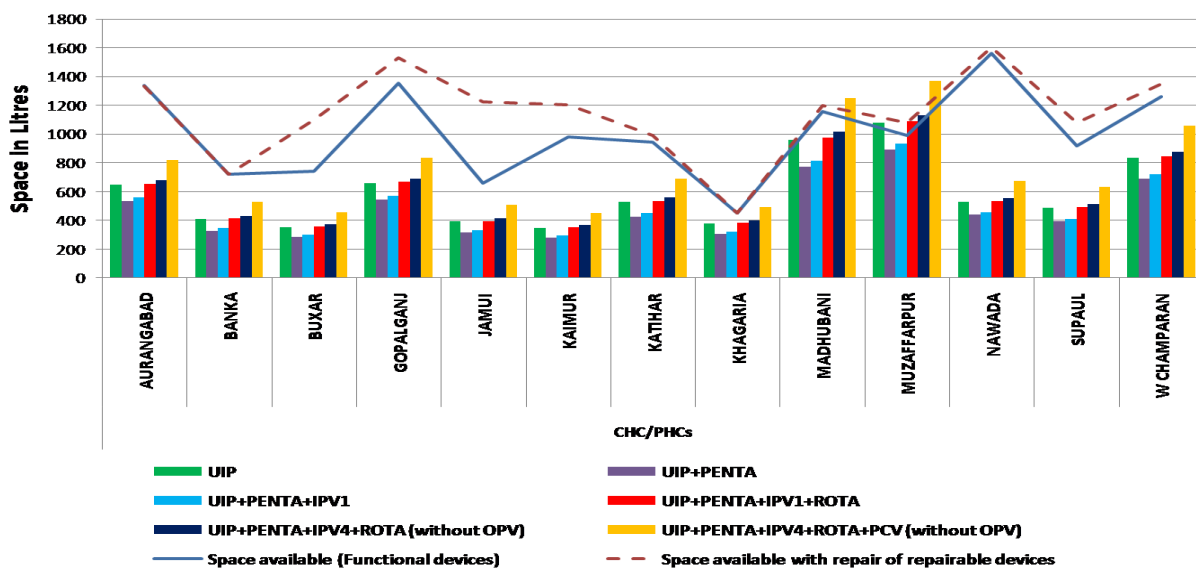




Figure 11.9: Available vs required +2 to +8°C chain space at CHCs and PHCs in Gujarat

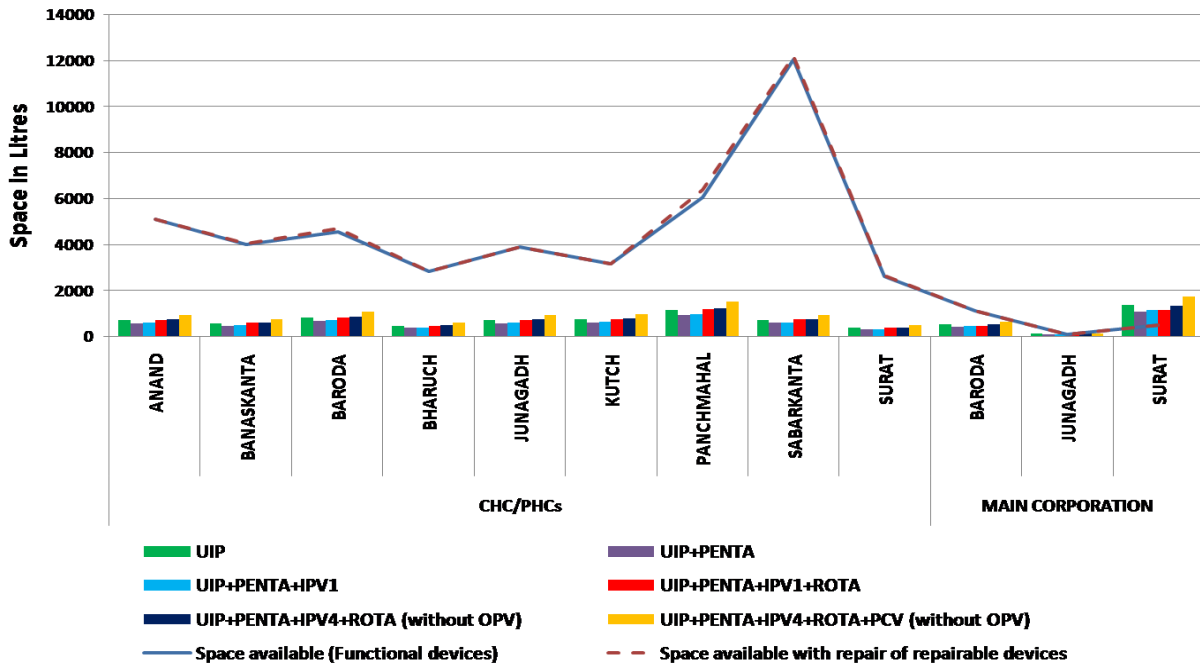
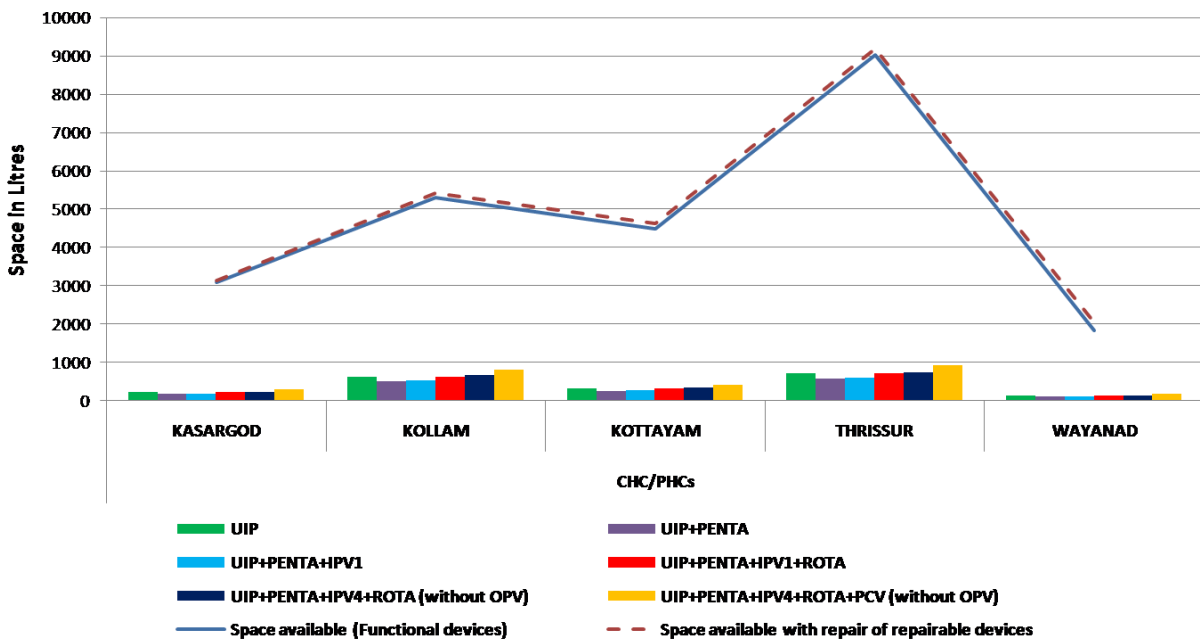


Figure 11.10: Available vs required +2 to +8°C chain space at CHCs and PHCs in Kerala



## 11.2 Currently available -15°C to -25°C space and projection for new vaccine addition

## 4.2 Currently available cold chain space at different level of facilities (-20°C) and additional requirements

The freezer cold chain space (-20°C) requirement was estimated in reference to the icepack making at CHCs and PHCs for the outreach services and storage of OPV at division and district stores. It was apparent that the freezer space was reasonably adequate for most of the facilities in three states. In the future vaccine introduction, only rotavirus vaccine (ROTAVAC) may have implication for the freezing space (-20°C) requirement at the bulk stores (state and division stores). For addition of rotavirus vaccine (ROTAVAC), the current freezing cold chain space is adequate at most of the facilities across the three states.

### **Summary:**

#### **Cold chain space in +2°C to +8°C for the current UIP schedule**

- As per the current demand and UIP schedule, Bihar state vaccines store have major space deficit.
- Most of the division stores in Gujarat and Kerala have adequate space for the current UIP schedule. Some of the division stores in Bihar are constrained in space for current UIP schedule.
- Most of the district vaccine stores in all three states have cold chain space deficiency to cater the current UIP schedule demand.
- Most of the sub-district vaccine stores (CHCs and PHCs) have adequate space for the current schedule.

#### **Cold chain space in +2°C to +8°C for the new vaccines under consideration**

- In Bihar, the state vaccine store and 4 division stores will not be able to accommodate all the new vaccines under consideration.
- In Gujarat and Kerala, all the division stores will be able to accommodate all the new vaccines under consideration.
- None of the district vaccine stores in three states (except two districts in Gujarat) will be able to accommodate all the new vaccines under consideration.
- PHCs in three districts of Bihar and the health facilities under three municipal corporations of Gujarat will not be able to accommodate all the new vaccines under consideration.

#### **Cold chain space in -20°C for the current UIP schedule**

- As per the current demand and UIP schedule, most of the vaccines stores have adequate space.

#### **Cold chain space in -20°C for the new vaccines under consideration**

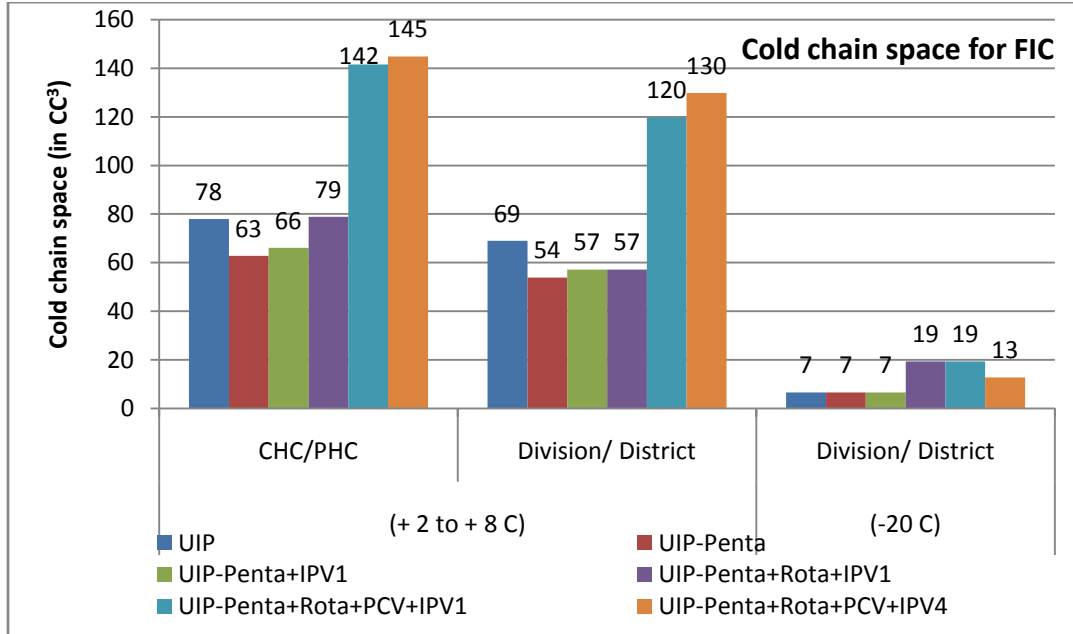
- For the new vaccines under consideration, most of the vaccines stores will be able to accommodate these vaccines.

## 12 Recommendations

- There is urgent need to complete the cold chain inventory at all levels and their functional status. The inventory updating is to be done at regular interval (initially quarterly and then monthly).
- Review and reconciliation of the cold chain devices must be done for validation and realistic projection of cold chain space need at different levels.
- Plan for replacement of the old and CFC coolant cold chain device is to be done, especially for Gujarat and Kerala.
- Appropriate technician manpower positioning to be done along with enabling of spare parts and mobility support to ensure timely repair and maintenance of the equipments to reduce sickness rate and down time.
- Repair and maintenance of the cold chain devices in Bihar needs special attention.
- Appropriate attention to equipment safety is needed including use of separate voltage stabilizer.
- All cold chain equipments must have separate stem/ digital thermometer for temperature monitoring to ensure vaccine safety. In areas with unsecured power supply careful monitoring of temperature in the ILRs to be done to ensure vaccine safety.
- Continuous temperature monitoring with functional alarm system is to be ensured at bulk vaccine stores.
- Calibration of thermometers on annual basis should be done as part of the protocol.
- Freezing of vaccines (T series and Hepatitis B vaccines) must also be checked and cared for along with VVM and expiry date at both facility and outreach level.
- Care is needed for transferring the vaccines in vaccine carrier to outreach sessions to ensure temperature maintenance and also avoid freezing of vaccines.
- Attention to appropriate storage of vaccines in ILRs at facilities is needed.
- Appropriate space for both cold chain equipments and dry storage is needed at most of the facilities to avoid damage and wastage.
- There is need for reorganization of the vaccine and dry supply logistics and supply system in all states along with stringent monitoring to avoid fluctuations in stock status and frequent stock out, which is likely to affect vaccine coverage.
- Orientation and reinforcement of stock keeping practice including maximum and minimum stock level is needed at all levels.
- Preferably real time vaccine and dry supply logistics management system is needed along with transportation organization is to be adopted.
- Refrigerated vaccine vans must be considered for positioning at least at the division level stores for supply of the vaccines.
- The current cold chain space (+2 to +8<sup>0</sup> C) at state vaccine store, division vaccine store and most of the district vaccine stores in the three states is deficient for the current UIP schedule.
- Most of the sub-district facilities have adequate cold chain space (+2 to +8<sup>0</sup> C) to accommodate the monthly vaccine need for the current UIP schedule.
- The cold chain space (+2 to +8<sup>0</sup> C) at state, division and district level needs to be expanded significantly to enable required vaccine availability for the current UIP schedule and also to accommodate the additional vaccines in pipeline.
- It appears that most of the sub-district level facilities shall be able to handle the additional cold chain space demand with addition of additional vaccines in pipeline. But in Bihar, expansion of the cold chain network at sub-district level may help in expanding the reach of UIP and ease the UIP logistics system.

## Annexure

### Annexure A.1: Cold chain space for fully immunized child (FIC) for different vaccine schedules



**Note:**

*UIP: the routine UIP without liquid pentavalent vaccine*

*UIP + Penta: the routine UIP with liquid pentavalent vaccine (penta)*

*IPV-1: One additional dose of IPV along with OPV in the UIP (10 doses/vial)*

*Rota: Rotavirus vaccine- Rotavac equivalent 3 doses (10 doses /vial)*

*IPV-4: UIP with full IPV (4 doses) instead of OPV (10 doses/vial)*

*PCV: pneumococcal conjugate vaccine 4 doses, PCV-10 equivalent (5 dose dose/vial)*

*The space estimated includes storage of diluents (for 1 week) at 2-8<sup>0</sup>C*

## Annexure A.2: National immunization schedule for infants, children and pregnant women

| Vaccine   | When to give   | Dose                             | Route |
|---|--|----------------------------------|-------|
| <b>For Pregnant Women</b>                                   |  |                                  |       |
| TT-1  | Early in pregnancy   | 0.5 ml                           | IM    |
| TT-2  | 4 weeks after TT-1*  | 0.5 ml                           | IM    |
| TT- Booster   | If received 2 TT doses in a pregnancy within the last 3 yrs*                             | 0.5 ml                           | IM    |
| <b>For Infants</b>  |  |                                  |       |
| BCG   | At birth or as early as possible till 1 year of age                                      | 0.1ml (0.05ml until 1 month age) | ID    |
| Hepatitis B-0   | At birth or within 24 hours  | 0.5 ml                           | IM    |
| OPV-0   | At birth or as early as possible within the first 15 days                                | 2 drops                          | Oral  |
| OPV- 1,2 & 3  | At 6 weeks, 10 weeks & 14 weeks  | 2 drops                          | Oral  |
| DPT- 1,2 & 3 / Pentavalent vaccine (DTP-Hib_HepB) 1,2 & 3** | At 6 weeks, 10 weeks & 14 weeks  | 0.5 ml                           | IM    |
| Hepatitis B 1, 2 & 3**                                      | At 6 weeks, 10 weeks & 14 weeks  | 0.5 ml                           | IM    |
| Measles- 1  | 9 completed months-12 months   | 0.5 ml                           | SC    |
| Vitamin A (1stdose)   | At 9 months with measles   | 1 ml (1 lakh IU)                 | Oral  |
| <b>For Children</b>   |  |                                  |       |
| DPT booster   | 16-24 months   | 0.5 ml                           | IM    |
| OPV Booster   | 16-24 months   | 2 drops                          | Oral  |
| Measles – 2***  | 16-24 months   | 0.5 ml                           | SC    |
| Japanese Encephalitis#                                      | 16-24 months   | 0.5 ml                           | SC    |
| Vitamin A## (2 <sup>nd</sup> to 9 <sup>th</sup> dose)       | 16-18 months with DPT/OPV booster then, one dose every 6 months up to the age of 5 years | 2 ml (2 lakh IU)                 | Oral  |
| DPT Booster   | 5-6 years  | 0.5 ml.                          | IM    |
| TT  | 10 years & 16 years  | 0.5 ml                           | IM    |

### Note

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

\*\* Pentavalent in select states.

DPT vaccine primary doses at 6, 10, 14 weeks replaced with DPT-HepB-Hib (pentavalent) vaccine in select states along with omission of separate HepB vaccine doses at 6, 10, 14 weeks

\*\*\* MR is being offered in select states (and union territories) in place of Measles 2<sup>nd</sup> dose at 16-24 months (Dose: 0.5 ml; Route: Sub-cutaneous; Site: Right Upper Arm)

# SA 14-14-2 Vaccine, in select endemic districts after the campaign.

## The 2<sup>nd</sup> to 9<sup>th</sup> doses of Vitamin A administered to children 1-5 years old during biannual rounds, in collaboration with ICDS.

Vaccination schedule may get modified with introduction of new vaccines in future under Universal Immunization Programme.

**Annexure A.3: The recommended norms for vaccine logistics for different levels of vaccine stores**

| Level   | Forecast | Recommended storage period | Indent frequency | Supply   |
|---|----------|----------------------------|------------------|--|
| State vaccine store   | Annual   | 3 months                   | Annual           | Periodic from manufacturer<br>Need based from GMSD |
| Divisional vaccine store  | Annual   | 2 months (+2 weeks)        | Quarterly*       | Quarterly*   |
| District vaccine store  | Annual   | 2 months (+2 weeks)*       | Quarterly*       | Quarterly*   |
| CHC store   | Annual   | 1month (+ 1 week)          | Monthly          | Monthly  |
| PHC store   | Annual   | 1month (+ 1 week)          | Monthly          | Monthly  |
| * Although it is recommended interval, in practice a monthly indenting process is followed at many places. Corresponding to the indent at monthly interval, the supply is also received at monthly interval at many places. |          |                            |                  |  |

While making estimation of annual need based on the population and number of beneficiaries, inclusion of a buffer stock (25% for vaccine and syringes) and wastage 25% in the case of vaccines and 10% in the case of AD and disposable syringes are added. The buffer stock serves as a cushion as buffer against emergencies, major fluctuations in demand or unexpected transport delay.

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