A Report on

Effective Vaccine Management in Gujarat

16 August to 3 September 2011

UNICEF
India Country Office, Delhi

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ABBREVIATION AND GLOSSARY

°C	Degree Celsius
AD	Auto-disable (syringe)
AEFI	Adverse Event Following Immunization
ANM	Auxiliary Nurse Midwife
BCG	Bacilli Calmette-Guérin (tuberculosis vaccine)
CC	Cold Chain
CC&VLM	Cold Chain and Vaccine Logistics Management
CDHO	Chief District Health Officer
CES	Coverage Evaluation Survey
CFC	Chlorofluorocarbon (ozone depleting substance)
CHC	Community Health Centre
CI	Critical Indicator (in EVM)
CPCB	Central pollution control board
DF	Deep Freezer
DLHS	District Level Household and Facility Survey
DPC	District Programme Coordinator (NRHM)
DTP	Diphtheria, Tetanus and Pertussis vaccine
DVS	District Vaccine Store
EEFO	Earliest Expiry First Out
EPI	Expanded Programme on Immunization
EVM	Effective Vaccine Management
EVSM	(WHO-UNICEF) Effective Vaccine Store Management initiative
FIC	Fully Immunized Child
GAVI	Global Alliance for Vaccines and Immunisation
GMSD	Government Medical Supply Depot
GoI	Government of India
GTN	Global Training Network
HepB	Hepatitis B vaccine
ILR	Ice-lined refrigerator
LD	Lowest delivery level store
MDVP	Multi Dose Vial Policy (not adopted in India)

MO	Medical Officer
MOHFW	Ministry of Health & Family Welfare of Govt. of India
MQP	Model Quality Plan (module 2 of EVSM)
OPV	Oral Polio Vaccine
PHC	Primary Health Centre
PIP	Project implementation Plan
PR	Primary store
PWD	Public Works Department
RCHO	Reproductive and Child Health Officer
RM or RT	Refrigeration Mechanic / Refrigeration Technician
RVS	Regional vaccine store
SC	Sub-Centre
SN	Sub-national store (zone, divisional or Regional store-RVS)
SEPIO	State EPI Officer
SOP	Standard Operating Procedure
SP	Service point (health facility)
SRS	Sample Registration System
SVS	State Vaccine Store
UNICEF	United Nation's Children Fund
VAR	Vaccine Arrival Report
VM	Vaccine Management
VMAT	Vaccine Management Assessment Tool
VVM	Vaccine Vial Monitor
WHO	World Health Organization
WIC	Walk-in-Cooler (Cold room)
WIF	Walk-in-Freezer (Freezer room)

Effective Vaccine Management Assessment in Gujarat

16 August to 3 September 2011

EXECUTIVE SUMMARY

BACKGROUND

The total population of Gujarat, according to the recent census this year, is 60,383,628 with a sex ratio of 918 females to 1000 males; 42% of which live in urban areas. The total Immunization target group (infants less than 1 year) of the state is estimated to 13,64,670 with a birth rate of 22.6 per 1000 population as per the Sample Registration System (2009) for Gujarat.

The state is administratively divided into 6 regions and further into 26 districts. In addition there are 7 municipal corporations. For immunization, the districts cover a target group of 10,31,944 infants while the municipal corporation caters to a target population of 332,726 infants corresponding to 24% of infants. .

According to the DLHS-3 (2007-08) the immunization coverage of fully immunized children was 54.8% and 6.7 % children had not received any vaccination. The BCG coverage was 87.7 % and the Measles coverage was 72.6 %. The recent CES 2009 shows some improvement with coverage of fully immunized children increased to 56.6% (as compared to average of 61% for entire India), and Measles coverage of 78%. The reported drop-out rate (between BCG to DTP3) is 18.1%.

The current mission for assessment of cold chain and vaccine logistics management was initiated by the Ministry of Health & Family Welfare (MoHFW) of Govt. of Gujarat and supported by UNICEF - Gujarat. The present exercise is meant to contribute towards the vision and efforts of MoHFW to build the basic infrastructure and further strengthen the quality of its immunization programme in the state. It was also undertaken keeping in mind that the measles campaign is already underway in the state.

OBJECTIVE

The objective of such an assessment is to identify the following aspects of Cold chain and vaccine management:

- Strengths & good practices
- Major knowledge gaps
3. Major performance gaps
4. Resource & Training needs

Thereby, prepare a road map for strengthening Cold chain and vaccine management

THE TOOL

WHO-UNICEF have designed the Global Effective Vaccine Management (EVM) initiative to help countries to improve the quality of their vaccine and cold chain management from the time the vaccine arrives in their country down to the service delivery point. Assessment of the vaccine and cold chain management is mandatory for any country applying for GAVI support for introduction of new vaccines. It is based on nine basic *indicators listed below.*

1. Vaccine arrival procedures
2. Vaccine storage temperatures
3. Cold storage capacity
4. Buildings, cold chain equipment and transport
5. Maintenance of cold chain equipment and transport
6. Stock management
7. Effective vaccine delivery
8. Vaccine Management practices
9. SOPs and Supportive Management Systems

It consists of a series of focussed questions, which are numerically scored based on the observed practices and records of the past 12 months, against recommended standards.

The performance scores are depicted graphically on a radar graph to reflect the strengths and weaknesses of a vaccine supply chain system. Based on these, the assessors can define the nature of support required for improving the performance of each indicator.

The questions under the 9 indicators can be divided into 7 management implementation categories: **Building, Storage Capacity, Equipment, Management issues, Repair and Maintenance, Training and Vehicles**. The radar graphs are also obtained under these categories. Based on the detailed score of the indicators, targeted actions can be defined under the respective category for improving the performance of the different programmatic areas associated with the supply chain.

METHODOLOGY AND IMPLEMENTATION

The methodology used is based on the principles of adult learning and the philosophy of the Global Learning Opportunities of WHO: "Learning by Doing".

Several additional complementary activities, many in form of capacity building, are integrated into the assessment mission.

It aims also to develop internal capacity of the system to conduct similar self-assessment periodically in order to further strengthen and ensure a more reliable cold chain and vaccine logistic system in a self-sustainable manner.

A total of 27 participants were inducted in the use of EVM tool through a 5 day capacity building programme from 16 to 20 August 2011, consisting of theoretical sessions in the morning followed by practical exercise of assessment in the nearby vaccine stores in the afternoons. It also included hands-on support during the assessments.

This was followed by a 6 days field assessment from 23 to29 August. The assessment sites were identified using the "Site-Selection Tool" based on 85% confidence level and 15% precision. Besides all the 6 Regional vaccine stores (RVS) total of 12 District vaccine stores (DVS) were selected which included 3 of 6 districts selected for upcoming Measles SIA, and 2 of the 5 districts where the SIA has been completed. It also included 4 of the 8 UNICEF focus districts, and 3 of the 6 NRHM focus district. In addition, 24 health facilities (PHCs) were selected under these Districts using the sampling tool.

Note that the Corporation stores and Urban centres were not part of this assessment exercise.

The assessment was conducted by 6 teams comprising of two medical offices (RCHO and RCSO), one vaccine store pharmacist and one technician. Each team assessed 1 RVS, 2 DVS and 4 PHCs selected within it. The visits also included carrying out of necessary corrective actions that were feasible during the visits.

The facilitation team members travelled separately and joined different teams at different times to provide on site hand-holding in assessment, verification of collected data and also to carry out their own observations.

Following the assessment, the data was verified, validated, and consolidated. The result of the State Vaccine Store (SVS) at Gandhinagar has been provided separately, as it was assessed during the training. However, its role is not very clear. The SVS works partially as a state store to receive Hep B vaccine and campaign vaccines for the entire state, while most of the other vaccines are sent directly to the regional stores. Hence it is not discussed in details.

One district vaccine store and 2 PHCS assessed during the training week are also included in the consolidation.

These were then analysed with the help of selected team members. The team members then developed their own practicable recommendations through consensus to address the weaknesses with the guidance from the facilitation team.

Thus, the methodology enables to obtain the following outputs:

- Learning about the good practices of Cold Chain and Vaccine logistics Management (CC&VLM)
- In-state capacity building of health staff in use of EVM
- Assessment of the selected vaccine storage points
- Developing skills in hand-holding
- Provide on spot hand-holding of correct practices in CC &VLM
- Analysing the data collected from the field using the EVM tool
- Developing capacity to identify weaknesses and define recommendations to address them
- Learn to summarise the observations and make its presentation
- Computer skills (Excel) – mandatory for data collection and using the EVM tool

Thus, the EVM Mission is a multi-faceted capacity building activity, which is targeted at strengthening the vaccine management system in order to make the system more efficient with zero stock-out.

RESULTS

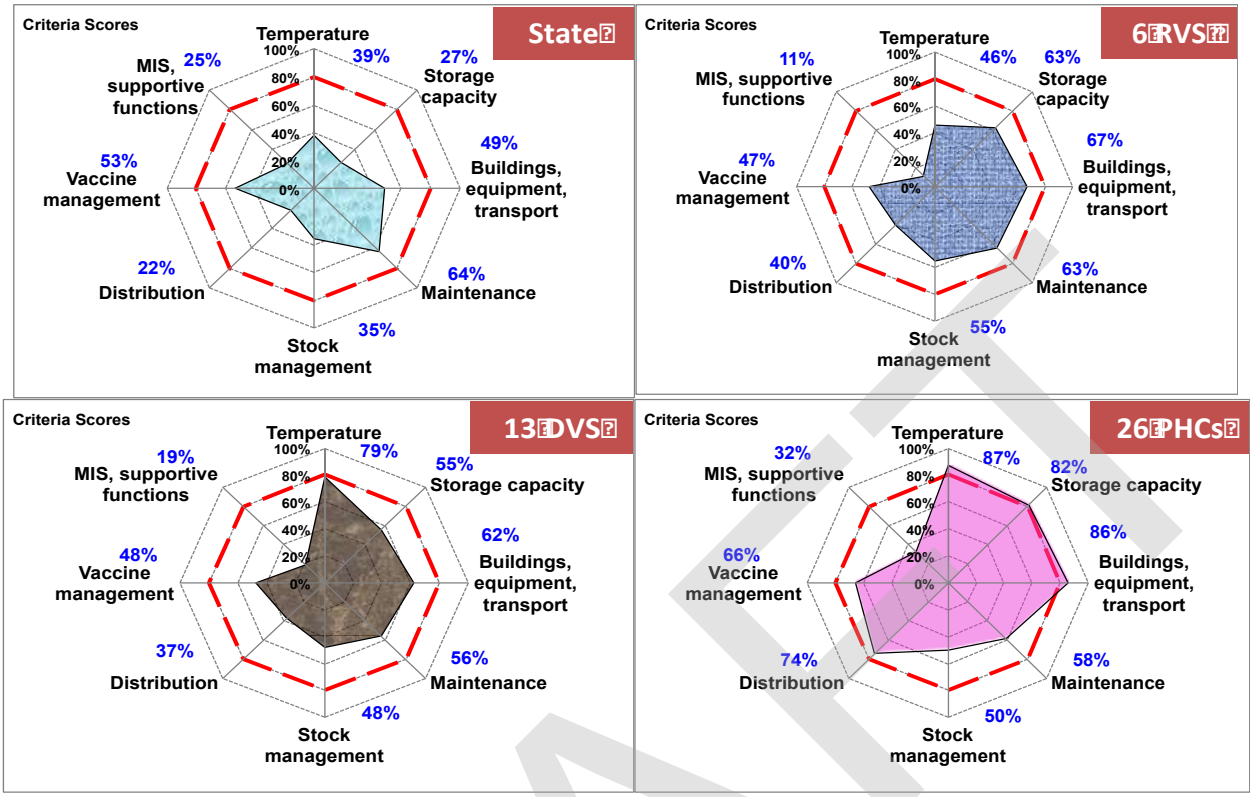
The summary of the consolidated results is given in the table below. WHO recommends a minimum of 80% of performance for each criterion. Hence, scores ***less than or equal to 70% are marked in red*** to underscore the need for attention. The scores between 70% and 90% are left in the normal black font to indicate that they are in the acceptable range. Scores **above 90% are marked in green** to indicate that these are in a very comfortable range.

Table 1: Summary of consolidated EVM indicator score for Gujarat

#	Indicator		Consolidated scores			
		1 SVS	6 RVS	13 DVS	26 PHCs	Average
1	Vaccine Arrival Process	44%	NA	NA	NA	NA
2	Vaccine Storage Temperature	39%	46%	79%	87%	71%
3	Storage Capacity	27%	63%	55%	82%	67%
4	Building, Cold Chain Equipment & Transport	49%	67%	62%	86%	72%
5	Maintenance of Building, Cold Chain & Transport	64%	63%	56%	58%	59%
6	Stock Management	35%	55%	48%	50%	51%
7	Distribution	22%	40%	37%	74%	50%
8	Vaccine Management Practices	53%	47%	48%	66%	54%
9	MIS & Supportive Functions	25%	11%	19%	32%	21%

SVS: Vaccine Store; **RVS**: Regional Vaccine Store; **DVS**: District Vaccine Store; **PHC**: Primary Health Centre.

The resulting Radar graphs for the different levels are given below.



The areas covered by the polygons in the graphs indicate the achievements in the areas of the respective indicators.

Looking at the score table above, one can observe that none of the scores are above 90%. There are only five scores in black. The rest are all in ***red,*** with many of them being less than 50% reflecting predominance of need for improvements in the system. The average score of the RVS, DVS and PHCs levels is indicated in the right most columns are also all less than 70% for 6 of the indicators.

The associated strengths that can be enumerated are:

In terms of human resource and supportive management

1. State has one State Immunization Officer.
2. Each Region has one Regional Child Survival Officer (RCSO), and most districts have one Reproductive Child Health Officer (RCHO).
3. Qualified and trained pharmacists are posted from Regional level right down to PHCs. (except RVS Vadodara & Few PHCs).
4. 19 out of 26 districts have designated refrigeration technician.
5. Comprehensive work plan and budget form the PIP part 3 of NRHM.
6. Training on cold chain and vaccine handling, and immunization have been conducted and manuals for reference are available for all staff workers.
7. So are specific templates for keeping different records and checklists for supportive supervision.

In the area of cold chain and vaccine management:

1. Most Pharmacists know the good practices and are implementing the same with a some exception in the area of shake test, stock register maintenance and safe storage temperature.

2. Manual Temperature monitoring is done on 6/7 days at most District vaccine stores and PHCs (but not at all the Regional vaccine stores).
3. Storage capacity is sufficient at most regional vaccines stores (except Ahmedabad, and Vadodara) and all PHCs.
4. There is sufficient OPV storage capacity at all levels (except RVS-Gandhinagar) as well as IP freezing capacity at most vaccine stores.
5. PHCs have good physical space.
6. Most staff know the good practices in handling vaccines and they use Vaccine Vial Monitor (VVM) and practice Early-Expiry-First-Out (EEFO).
7. Except for some broken diluents, all supplies have been carried out in good condition.
8. Amreli has a well-planned distribution system from Districts to its 52 PHCs, which can be adopted as a model.
9. The practices of correct use of freeze-dried vaccines with corresponding cooled diluent, and discard of reconstituted vials after 4 hours is well implemented.
10. At most facilities the bio-medical waste is collected by contracted agency or buries in a local pit.

Key areas that need improvement are:

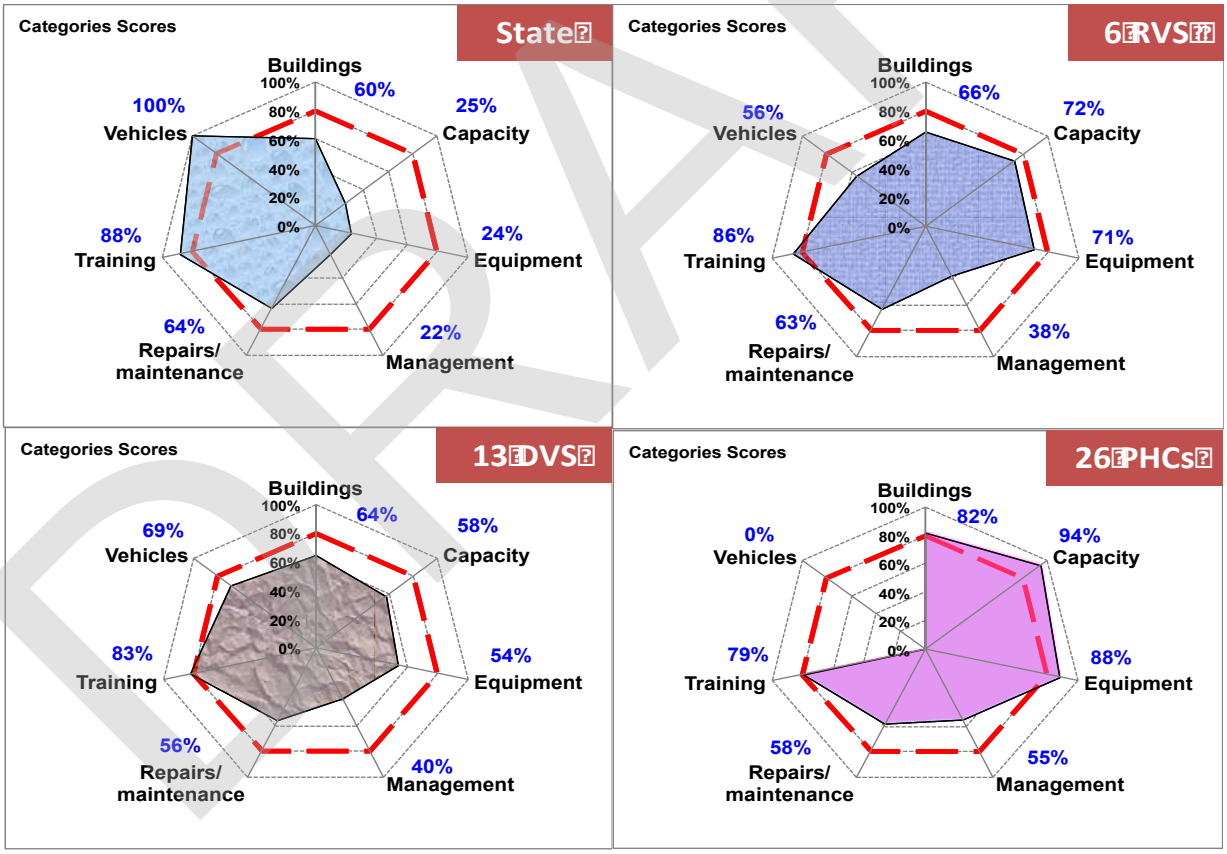
1. The post of cold chain officer is vacant since 2 years, as a result the state lacks a cold chain manager with an engineering background to manage the cold chain technicians, ensure proper periodic preventive maintenance and keep the equipment and its inventory up to date.
2. There is no supervision of vaccine Management and immunization program at regional level. Regional vaccine stores not supervised by regional level officers. However, there is a post of Asst. Dir. (PH) at every region who can be given responsibility of RVS and vaccine management system. The position of Asst. Dir. Public Health (ADPH) r is vacant at most of the regions.
3. Likewise the supportive supervision by RCHO of cold chain and vaccine management is also weak.
4. Refrigeration technicians are not posted at district head quarters for better movement within district. They do not have adequate means of transport to be effective.
5. Regional and District vaccine stores do not have any semi-skilled helpers to support the pharmacists who are over loaded.
6. Continuous temperature recorders and the acoustic alarms are not functioning at any regional stores, putting at risk large stocks of vaccines.
7. Large volumes of Anti-Rabies vaccines are occupying 20- 30% of the space, specially at the regional level, thereby limiting effective storage volumes for the RI-Vaccines (specially at Vadodara).
8. 3 out of 6 Regional (RVS) and 10 out of 13 District vaccine stores (DVS) visited have inadequate building space or the condition of building is poorly maintained. At DVS there is no space to add more equipment for enhancing its vaccine storage capacity, which is currently insufficient. There is lack of space to conduct equipment repair at the DVS.
9. Standardized formats exist for stock recording, temperature monitoring, vaccine indenting forms, and supply vouchers – but the same are neither available everywhere, nor used systematically.
10. Vaccine supply is not based on standard procedure and there have been instances of stock-outs due to absence of buffer stocks.

The 9 indicators of EVM contain questions that can be divided into 7 management implementation categories to define the achievements and derive actions required. The table below provides the corresponding consolidated scores for these categories for the different levels along with the average of the RVSs, DVSs and PHCs in the right most column.

The font styles used in the earlier table has also been used here to **highlight the strengths (in green bold)** or the **need for rapid intervention (red bold).**

#	Category	Consolidated scores				
		1 SVS	6 RVS	13 DVS	26 PHCs	Average
1	Building	60%	66%	64%	82%	71%
2	Capacity	24%	72%	58%	94%	75%
3	Equipment	24%	71%	54%	88%	71%
4	Management	22%	38%	40%	55%	44%
5	Repair & Maintenance	64%	63%	56%	58%	59%
6	Training	88%	86%	86%	79%	84%
7	Vehicles	100%	56%	69%	NA	63%

These scores are represented in the graphs below for the respective levels.



The scores at the different level indicate that training is a good strength at all levels – reflecting the achievement from the efforts of the last 2 years by the MoHFW. Building, equipment and storage capacity at PHCs are in good condition.

On the other hand the table and graphs above show that management aspects of different activities, including supportive supervision in all areas covered under the 9 indicators, is a rather weak component at all levels. This leads to the loss of performance in different indicators mentioned earlier. Maintenance and repair is another weak component across the levels.

Building, equipment and transport vehicles are areas that require attention at upper levels. At district level there is a need for intervention in most of the categories.

In the following section specific recommendations to improve the performance of the indicators are provided.

RECOMMENDATIONS

Based on the indicators requiring intervention the recommendations are provided according to the implementation categories.
The priorities are indicated as follows:

1: Immediate - Urgent, as soon as possible, but no later than 1 month

2. Intermediate - Within the next 3 to 6 months

3: Long term – within the next 12 months

4: Future – within the next 2 to 3 years

Category	Priority	Level	Action required
Human Resource	1	Commissionerate	All cold chain technicians designated to districts must be stationed at respective district head quarters.
	2	Commissionerate	Fill the post of Cold Chain Officer at state level. Fill the vacant position of Assistant Director (PH) at every region. Appointed AD(PH) at regional level should be given responsibility of supervision of Regional vaccine store.
	3	Commissionerate	Appoint one state vaccine logistic manager who will coordinate with regional level / district level to ensure efficient vaccine supply with zero stock-outs.
	2	RDD RCHO	Outsource service to provide semi-skilled helpers round the clock at all RVSs. Outsource service to provide one semi-skilled helper according to the need at each DVS.
Building	2	Commissionerate	Define the need for a state vaccine store and if required segregate Gandhinagar State vaccine store from the regional vaccine store in terms of space, equipment and staff.
	2 2 4	RCHO / RDD / Commissionerate	Evaluate condition of building and sufficiency of space at all Regional and district vaccine stores for equipment required for vaccine storage space, dry space, repair workshop and office space for the pharmacist. Ensure availability of the same through management of space – specially disposal of unwanted materials. If required plan for a new building, with adequate space to ensure sufficiency of storage space for vaccines, diluents, syringes, repair workshop and office area.
Capacity	2	RDDs	At all regional stores: Plan adequate segregation of non-RI vaccines from RI vaccines, so as to ensure sufficient storage capacity for vaccine storage at –20 deg C & +2 to +8 deg C. This may require expansion of the vaccine store. Also ensure availability of sufficient dry storage for syringes, diluents, and cold boxes along with proper office space for the pharmacist and a repair workshop.
Capacity	2	RCHOs	At all district stores: Plan adequate space for placing equipment to ensure storage capacity of 3 months of working stocks of the vaccines along with 25% buffer stocks. Also ensure availability of sufficient dry storage for syringes,

			diluents, and cold boxes along with proper office space for the pharmacist and a repair workshop.
Equipment	1	CCO/RDD/ADPHO	Equip all walk-in-coolers and walk-in-freezers with continuous temperature recorders and acoustic alarms.
	3	Commissionerate	Equip the state level and regional level vaccine stores with a computerised vaccine logistic software to better manage the vaccine supply. Extend the facility to district level with time.
Management	2	RDD / RCHO	Define bound vaccine passbooks to monitor movement of vaccines at every vaccine store. Ensure availability of all standard documents and formats for proper record keeping at all levels, without alternation of formats.
	2	Commissionerate / RDD / RCHO	Strengthen supportive supervision and ensure that all aspects of cold chain and vaccine management are implemented correctly (eg. All aspects of planning, implementation and record keeping are followed and non-standard practices (eg. use of wrong icepacks, foam boxes etc.) are not continued. Develop and distribute job aids for quick reference of salient activities.
	2 2	Commissionerate / RDD / RCHO RCHO / MO	Request GoI to provide vaccine supply plan well in advance, and ensure preparation of a supply plans at the RVS, DVS and PHC. At district level, ensure timely collection of vaccines from the regional store and distribution to PHCs is carried out according to a plan.
Repair & Maintenance	2	CCO / CCT	Equip the cold chain technicians with suitable tools and mode of transport for timely interventions. Plan and ensure implementation of periodic preventive maintenance of equipment by the technicians. A logbook for each equipment should be adequately maintained.
Training	1 2	Commissionerate / RCHO	Train all untrained staff in cold chain and vaccine handling Ensure that all new or rotated staff is adequately trained before deputation. ➢ Specific areas to focus: are: Shake test, ice pack conditioning and proper indenting of vaccines. Ensure that all staff are provided with required SOPs and are using them.
Vehicles	3	Commissionerate	Ensure that all vehicles have up to date logbook with information on regular servicing and repair.

1 INTRODUCTION

The total population of Gujarat, according to the recent census this year, is 60,383,628 with a sex ratio of 918 females to 1000 males; 42% of which live in urban areas. The total area of Gujarat measures 1,96,000 Sq.km, resulting in a population density of 308 person per sq. Km. The total immunization target group (infants less than 1 year) of the state is estimated to 13,64,670 with a birth rate of 22.6 per 1000 population as per the Sample Registration System (2009) for Gujarat.

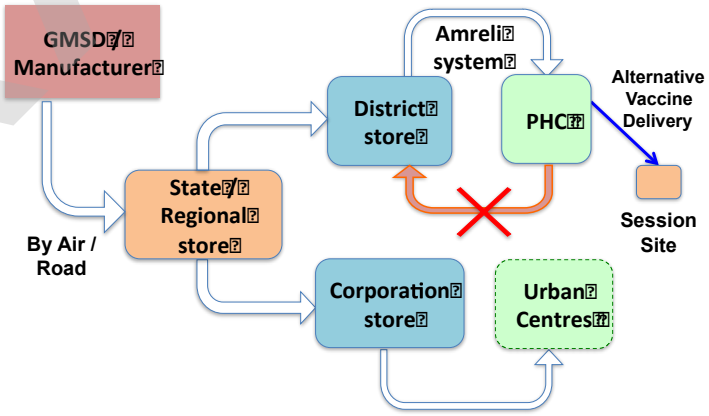
According to the DLHS-3 (2007-08) the immunization coverage of fully immunized children was 54.8% and 6.7 % children had not received any vaccination. The BCG coverage was 87.7 % and the Measles coverage was 72.6 %. The recent CES 2009 shows improvement in coverage of fully immunized children increased to 56.6% (as compared to average of 61% for entire India), and Measles coverage of 78%. The reported drop-out rate (between BCG to DTP3) is 18.1%.

WHO-UNICEF have designed the Global Effective Vaccine Management (EVM) initiative to help countries to improve the quality of their vaccine and cold chain management from the time the vaccine arrives in their country down to the service delivery point. This tool is used to assess the quality and sufficiency of the salient components of an effective vaccine supply chain. Assessment of the vaccine and cold chain management is mandatory for any country applying for GAVI support for introduction of new vaccines.

The current mission for assessment of cold chain and vaccine logistics management was initiated by the Ministry of Health & Family Welfare (MoHFW) of Govt. of Gujarat and supported by UNICEF - Gujarat. The present exercise is meant to contribute towards the vision and efforts of MoHFW to build the basic infrastructure and further strengthen the quality of its immunization programme in the state. It was also undertaken keeping in mind that the measles campaign is already underway in the state.

ORGANIZATION OF IMMUNIZATION SERVICES

The state is administratively divided into 6 regions and further into 26 districts. In addition there are 7 municipal corporations. For immunization, the districts cover a target group of 10,31,944 infants, while the municipal corporation caters to a target population of 332,726 infants corresponding to 24% of infants.



Typical vaccine supply chain organigramme

Most of the domestically manufactured vaccines are supplied to the 6 regional vaccine stores directly by the manufacturers, except to Bhavnagar, which is supplied through Gandhinagar store. The latter, operates as a State vaccine store (SVS) as well as the Regional vaccine store (RVS) of Gandhinagar. Some imported vaccines (eg. Campaign vaccines) are first supplied to this store, from where it is distributed to all the Regional stores. However, its function as a dedicated SVS is unclear.

The 6 regional stores supply the vaccines to the districts within their respective zones. The districts in turn supply them to the PHCs and the latter manage the immunization programmes at its site as well as at the outreach session.

The regional stores also distribute the vaccines to the 7 Corporation stores which supply to the same to the urban health centres – catering to a total population of 14,722,363 (Immunization

target group of 332,726 infants less than 1 year).

The syringes and needle cutters are not handled by the Regional stored. These are supplied directly to the districts stores and Municipal corporation stores who distribute them to the service points.

Six new Walk-in Coolers have been installed recently to enhance the regionals vaccine storage capacity in the State.

2 Objective of Effective Vaccine Management Assessment

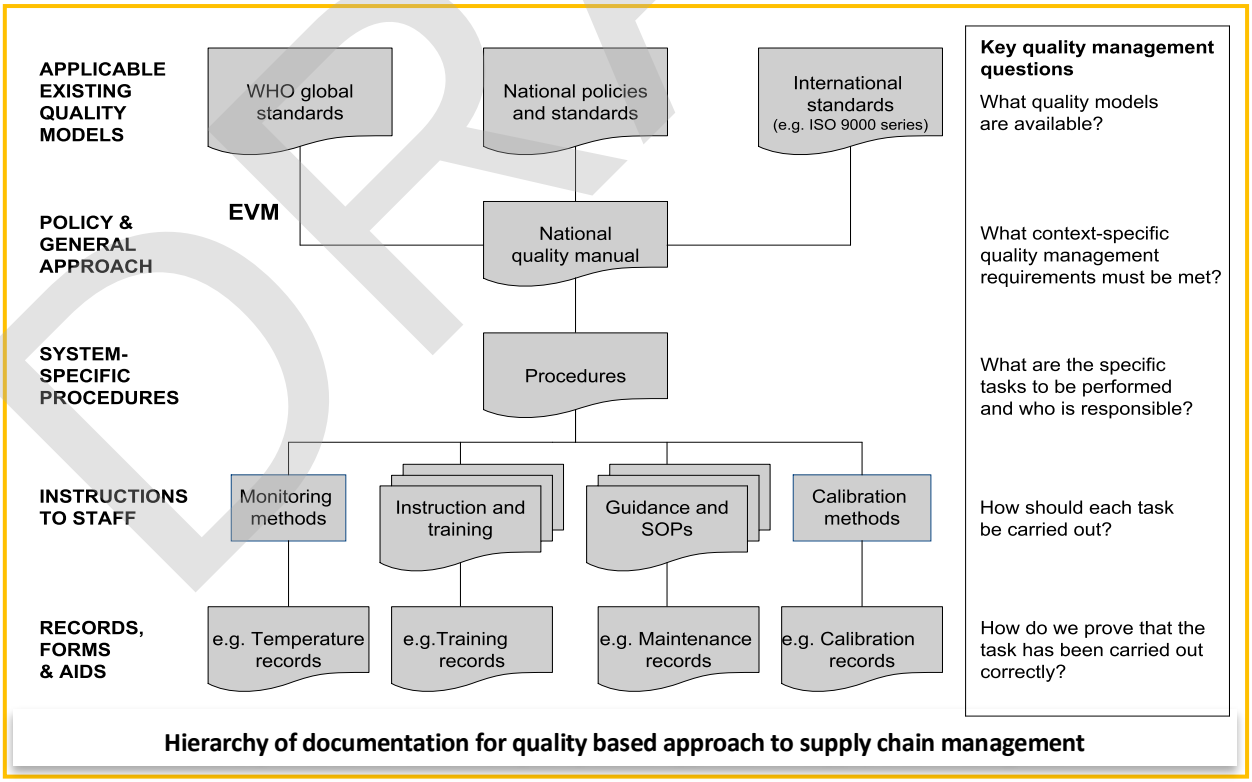
The objective of such an assessment is to identify the following aspects of Cold chain and vaccine management:

- Strengths & good practices
- Major knowledge gaps
- 3. Major performance gaps
- 4. Resource & Training needs

Thereby, prepare a road map for strengthening cold chain and vaccine management

3 The Tool

WHO-UNICEF have designed the Global Effective Vaccine Management (EVM) initiative integrates the learning from the former Effective Vaccine Store Management (EVSM) initiative and the Vaccine Management Assessment (VMA) tool which have been used till date for such assessments. EVM follows the well-established principles of quality management used throughout the industrialised world – for example the ISO 9000 series of quality standards.



Hierarchy of documentation for quality based approach to supply chain management

EVM is designed to help countries to develop strength-in-depth by building a culture of quality based on a structured approach to supply chain management, monitoring and record keeping. The figure above illustrates the hierarchy of documentation needed to support this approach.

EVM covers the grey shaded area of the diagram.

Assessment of the vaccine and cold chain management is mandatory for any country applying for GAVI support for introduction of new vaccines.

It is based on nine basic *indicators listed below.*

1. Vaccine arrival procedures
2. Vaccine storage temperatures
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The EVM package has been designed so that it can also be used both as an assessment tool for the systematic analysis of strengths and weaknesses across the supply chain but also as a supervisory aid to monitor and support the long-term progress of individual facilities.

It is used to assess the quality and sufficiency of the seven management categories that form the salient components of an effective supply chain: buildings; storage and transport capacity; cold chain equipment; vehicles; repairs and maintenance; training and the management systems needed for the effective operation and control of the system.

An EVM assessment uses a structured questionnaire; this questionnaire is designed to allow evaluation of four distinctly different levels in the supply chain, as follows:

1. The primary (PR - generally national) level store where vaccine is received directly from the vaccine manufacturer or from an international supplier such as UNICEF Supply Division. Typically vaccine is stored in large cold rooms and freezer rooms.
   In the context of India this would correspond to the 4 GMSDs and the State Vaccine Stores (SVS).
2. The sub-national (SN) level where vaccine is received from the primary store, stored for an agreed period, and then distributed to lower levels stores or to health facilities. These stores may have a cold room and/or a number of vaccine refrigerators and freezers. There can be more than 1 level of sub-national stores.

   In the context of any state in India this would correspond to the Divisional / Zonal / Regional Vaccine Store (RVS) that receive vaccines from the MSDS or SVS and distribute vaccines to several districts below it. These are equipped with Walk-in-Cooler (WICs).

3. The lowest level of delivery level (LLD) store where vaccine is received, either from the primary store or from a sub-national store. From this point it is distributed directly to service delivery points. The LD does not provide any immunization service.

   In the Indian context, this would best correspond to the District Vaccine Store (DVS), which distribute the vaccines to CHCs and PHCs or to the CHCs/Block when the latter distribute the vaccines to their respective PHCs. The DVS are equipped with ILRs and DFs only.

4. Service delivery points (SD) such as health centres, health posts, CHCs and PHCs, where vaccine is stored for a short time before delivery to the target population – usually in a single refrigerator, but also, on a very short-term basis, in vaccine cold boxes or vaccine carriers.

   In the Indian context, the SD point consists of the CHCs and PHCs. They are referred to as Health Facilities (HF) in the present context. They also distribute vaccines for outreach immunization posts.

Note that indicator 1 in applicable only at national and state level vaccine store (SVS). Indicator 8 is mostly specific for the assessment of the periphery (SD or HF) level, while indicator 9 is again applicable essentially to the national and state level.

The 9 indicators are divided into a number of *requirements* and *sub-requirements;* together these characterize the fundamental qualities of a good vaccine supply chain.

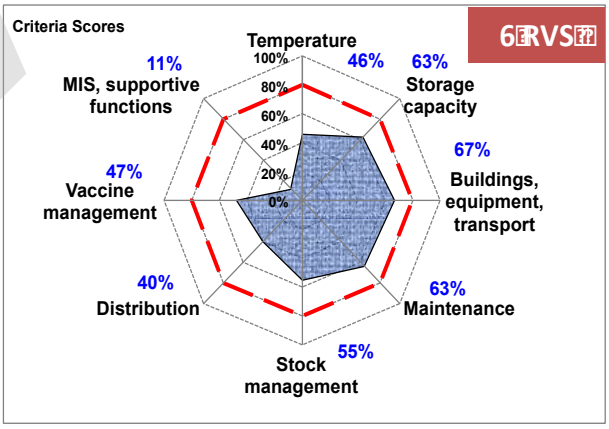
Compliance with the fundamental qualities of a good vaccine supply chain is tested using a series of tightly focussed questions, which are numerically scored. It bases itself on the data and practices over the last 12 months.

A single common list of requirements, sub-requirements and questions is used for the entire supply chain. The EVM tool automatically filters this common list to create questionnaires that are specifically directed at each of the four levels described above. These level-specific questionnaires can be further filtered to pick out only the most critical indicators depending on whether one wants to carry out a full EVM assessment at a specific facility or a rapid review assessment respectively.

Full assessments will typically be used by national staff to carry out long-term monitoring of individual facilities to achieve specific, targeted improvements. Review assessments are intended to be used to gain an overall assessment of a carefully selected sample of the supply chain. Generally speaking this type of assessment will be carried out by national or international teams, over a short period of time.

The resulting scores are used to depict graphically on a radar graph the strengths and weaknesses of a country's vaccine management systems. The score helps assessors to identify and document the areas of strengths and good practices as well as the major knowledge and performance gaps in a consistent format. Based on these, the assessor can define targeted support and training needs to address the weaknesses in each indicator.

The adjacent graph shows the consolidated result of the assessment of 6 Regional vaccine stores (RVSs). A minimum of 80% score is recommended for each criterion as shown by the red polygon. One can see that the performance of all the criteria are less than 80%. These are cause for concern and are the areas that need to be addressed.



Typical EVM consolidated radar graph

The questions under the 9 indicators can be divided into 7 management implementation categories: **Building, Storage Capacity, Equipment, Management issues, Repair and Maintenance, Training and Vehicles**. The radar graphs are also obtained under these categories. Based on the detailed score of the indicators, and the emerging recommendations, the action can be taken under the respective categories for improving the performance of the different programmatic areas associated with the supply chain.

EVM version 1. 0. 5. 0. was used for this mission.

4 METHODOLOGY

The methodology used is based on the principles of adult learning and the philosophy of the Global Learning Opportunities of WHO: "Learning by Doing".

Several additional complementary activities, many in form of capacity building, are integrated into the assessment mission.

It aims also to develop internal capacity of the system to conduct similar self-assessment periodically in order to further strengthen and ensure a more reliable and self-sustainable vaccine supply chain.

4.1 INTRODUCTION

The EVM mission has several stages, the first being mission preparation through the following steps:

1. Discussion with key state level officials regarding the objective and methodology of the mission,
2. Selection and invitation of key participants for the mission who will implement the knowledge and skill of EVM in future in the state
3. Collection of background information consisting of:
    a. Demographic details,
    b. Immunization coverage,
    c. Vaccine supply chain system (organogram with site names),
    d. Equipment inventory,
    e. Human resource,
4. Sampling of assessment sites using the standard EVM tool,
5. Preparation for the training and assessment logistics.

4.2 TIME FRAME

The table below gives the time frame for the implementation of the different aspects of the EVM mission.

Steps	Activity	Time line	work days	State Officials (SEPIO & CCO)	Team Leaders	Other Participants	Consultant Team
1	Preparation for the EVM mission and sampling	1week	5	3	0	0	4
2	EVM Training (Concept, principles of Cold chain and Vaccine management with actual field practice)	5 days	5	5	5	5	5
3	Field Assessment and data collection by teams	7 days	7	7	7	7	7
4	DATA compilation by the team	2 days	2	0	2	0	2
5	Data validation & consolidation (Teams + Lead assessor + State Officer + Partners)	2 days	2	1	2	0	2

Steps	Activity	Time line	work days	State Officials (SEPIO & CCO)	Team Leaders	Other Participants	Consultant Team
6	Analysis of results and development of recommendations (Teams + Lead assessor + State Officer + Partners)	3 days	3	3	3	0	3
7	Review of recommendations and preparation for debriefing (presentation)	3 days	3	1	0	0	3
8	Preparation of Final report	5 days	5	0	0	0	5
9	Detailed work plan preparation (Director FW, NRHM and Partners,) for implementation of recommendations	1 day Imme-diate	1	1	1	0	0
	Total work days		33	21	20	12	31
10	Implementation of work plan gradually	1year		Ongoing			

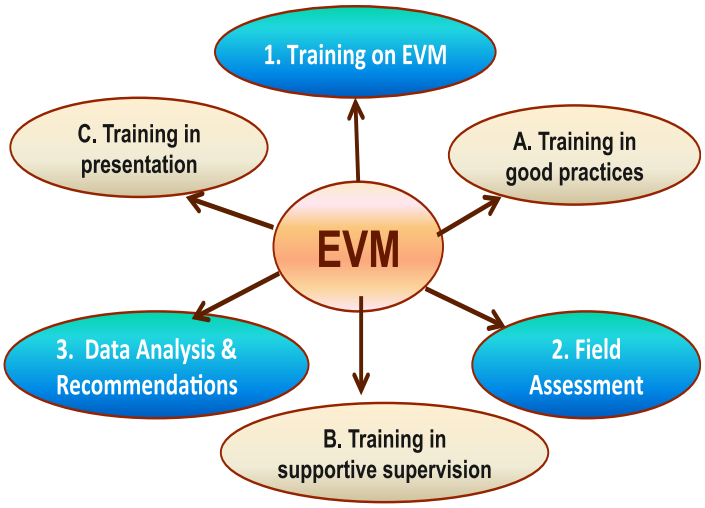
A follow-up EVM assessment should be carried out again after 1-2 years.

The salient aspect of the methodology of the EVM mission is illustrated in the figure given below. Steps 1, 2 and 3 describe the three phases of the EVM mission. Steps A, B and C mark the principle value addition during the mission.

4.3 The Mission steps

The adjacent schematic illustrates the different steps of the mission.

The **first phase (1-Training in EVM) consists of training** of selected health department staff (DIOs / Logistic managers / Storekeepers / vaccine handlers and cold chain technicians) in the use of the Effective Vaccine Management Assessment (EVM) tool. The assumption is that the selected participants have been working in the immunization programme since several years and are well familiar with the good practices.



EVM Mission steps

The reality is surprisingly quite different. In spite of being on the job as a storekeeper or logistic manager or even RCHO / DIO, the concerned staff is not knowledgeable about several aspects (e.g. correct manner of estimation of vaccine requirement, evaluation of cold chain capacity requirement and availability, ice-pack conditioning or correct manner of packing a cold box, etc.). Therefore, it becomes necessary to spend significant time to correct the existing mis-information and practices as well as provide additional updating of information, This is indicates as step **A- Training in good**

Practices.

Hence, the training on EVM is 50% consisting of familiarising the participants to the questionnaires within each of the criteria of EVM, sharing actual related field situations and discussions. The other 50% is based on practical assessment of selected vaccine stores in teams using the tool and then analysing and discussing the results. This "learning by doing" approach helps the participants to get a better grasp at the tool and be more confident in its use. They would then be able to use it periodically to their system in future for supervision or self-assessment.

The second phase (**2-Field Assessment**) consists of **the actual assessment of the selected vaccine stores through a sample size.** The required numbers of teams are formed involving all the participants. The participants are usually sent to assess places other than their duty stations in order to ensure impartiality.

The sample size is decided based on the total number of DVS. The sample size and selection of the sites to be assessed is defined with the help of the **"Site Selection Tool"** described in more detail below.

During the field assessment, whenever the assessment teams identify incorrect practices, they try to improve the situation through hands-on corrective actions. The participants learn through this exercise to become better observers and to provide the necessary support where required. Thus through this exercise, they also learn to provide supportive hands-on (**Step B**).

The assessment exercise opens their eyes to the real issues present in their own system, which stimulates them to take ownership to address them. It is worth comparing this against an expert conducting a 2 week assessment, and submitting a report which is most likely to gather dust in a shelf.

The third phase (**3-Data Analysis and Recommendation**) consists of data verification, entry into the computer, validation and analysis. This entire exercise is conducted with selected team members. At first, the correctness of the collected data is verified. Following this, the data is imported inside the tool and consolidated. Then the results are analysed in order to identify the strengths and weaknesses in the system based on the different scores of the criteria. Detailed discussions are held to then define, in consensus, the best ways to address the weaknesses. As a result, the recommendation are largely through the active participation and contributions of the participants, enhancing their taking of ownership.

As an additional outcome of such an approach, depending on the calibre of the participants, it is possible to have the team leaders and members to make a short write up on observations made at the sites they visited and the nature of support provided. Such a record can then be used to a) define specific action in that region, b) define common issues of priority across the state and last but not least c) help each of the participants to define an action plan for himself.

A further benefit that can be attempted is to involve the participants during the formal debriefing, where each team can present their findings, recommendations, supportive actions provided by them and finally their own action plan to all the others (**Step C – Training in Presentation Skills**). This can be a stimulating exercise, which gives recognition to their efforts.

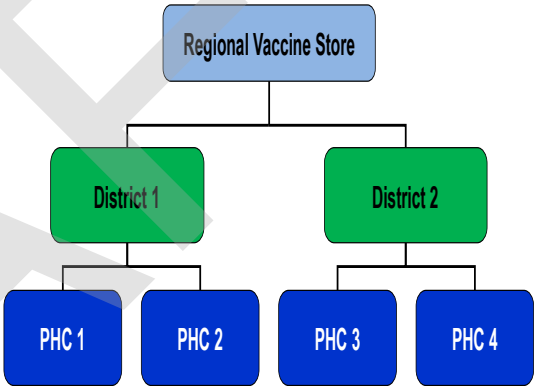
Thus, the methodology enables to obtain the following outputs:

- Learning about the good practices of Cold Chain and Vaccine logistics Management (CC&VLM)
- In-state capacity building of health staff in use of EVM
- Assessment of the selected vaccine storage points
- Developing skills in hand-holding
- Provide on spot hand-holding of correct practices in CC &VLM
- Analysing the data collected from the field using the EVM tool
- Developing capacity to identify weaknesses and define recommendations to address them
- Learn to summarise the observations and make its presentation
- Computer skills (Excel) – mandatory for data collection and using the EVM tool

Thus, the EVM Mission is a multi-faceted capacity building activity, which is targeted at strengthening the vaccine management system in order to make the system more efficient with zero stock-out.

4.4 Assessment Strategy and Sampling Tool

In the context of India, for any given state, the sample size should be such that any reasonable assessment should include at least the state store (SVS) (all the SVS in case there are more than one), most of the sub-national stores (RVSs) which are supplied by the SVS or MSDS and one or more DVS supplied by each RVS. Further, it should include two health facilities within each DVS. This is illustrated in the adjacent diagram.



The EVM package provides a Site-Selection Tool which is based on the Bio-Statistics. It is used for random selection of the assessment sites. For this, the DVS level is considered as the last level of distribution (LLD), as it is the last level beyond which delivery of immunization service is provided.

A precision of 85% and an accuracy of 15%, leads to the identification of 12 DVS from a total of 26 DVSs in Gujarat. The next step is to identify at least 2 health facilities under each of the selected DVS. The actual results of the selection are discussed in the next section.

5 IMPLEMENTATION

5.1 INDUCTION PROGRAMME

A total of 27 participants were inducted in the use of EVM tool through a 5 day capacity building programme from 16 to 20 August 2011. The facilitation team consisted of 6 facilitators. In addition the SEPIO from West Bengal state and one Unicef consultant were present. Dr. Srihari Dutta, Immunization Specialist from UNICEF-ICO supported the mission as facilitator cum observer. Annexure A gives the list of the participants that were selected by the MoHFW of the GoG.

Annexure B gives the schedule of the induction programme. The programme began with a pre-course questionnaire (Annexure C1) to evaluate the knowledge level of the group. Four questions which were considered not applicable were not considered in the total scoring. The results are depicted in the performance matrix given in Annexure C2. The performance of most indicators is relatively good and reflects a good level of knowledge. **The average comes up to be 63 %.**

The induction programme consisted of theoretical sessions on 2 indicators each day in the morning followed by practical exercise of assessment in the nearby vaccine stores in the afternoons. It also included hands-on support during the assessments.

The practical field training was carried out by dividing the entire group into 4 teams. Each team visited one of the 4 vaccine stores (the State Vaccine Store, District Vaccine Store, and 2 CHC/PHCs) each day and carried out the assessment using the criteria discussed in the morning.

Thus, over 4 afternoons, each team got a chance to visit a different store and assess it with a different set of criteria. Annexure D gives the details of the practical exercise plan along with the respective teams.

The following aspects were stressed during this phase:

1. Familiarising the participant with the tool,
2. Training the health staff to use the tool to assess specific facilities, (State, District and HF level),
3. Collect data from the different facilities visited,
4. Guide the participants in better data collection,
5. Draw major conclusions on the preliminary data.

The participants were also briefed on the following aspects:

1. To take the store managers into confidence,
2. To try and verify all information as much as possible using documented records,
3. To report factual information based on what is seen or recroded. This is important to avoid misinterpretation of results.
4. To provide sufficient comments to support the score given to a question – especially if it is zero,
5. Not to disturb or correct any existing practice unless one is knowledgeable about the good practice,
6. Not to tamper with any equipment (e. g. thermostats) unless one is an authorised technician,.

Each day, after the field visits, the collected assessment data is consolidated. The experience of the participants is discussed and the data analysed.

During the 5 day programme, significant time was devoted to some of the related critical areas

that were found to be weak in the understanding of the participants.

a. Correct manner of estimation of vaccine requirement,
b. Evaluation of cold chain capacity requirement and availability,
c. Proper ice-pack conditioning
d. Correct manner of packing a cold box.
e. Salient aspects in defining contingency plans.

Towards the end of the induction programme, half day was spent to prepare the team leaders on proper handling of the software files to do proper data recording in the assessment tool. Many of the data managers' needed significant support in working with the EVM tool which is in form of excel workbooks.

All the participants worked very enthusiastically over the 5 days and participated actively both in the interactive sessions and in the field exercises. This contributed significantly to enhance their understanding of the good practices and their confidence in the use of the EVM tool.

At the end of the first phase, the consultant circulated an evaluation form for the participants to assess the training programme. It included three aspects: training delivery of the facilitators, the relevance of the training programme to their work and last but not least the confidence of the participants in use of the EVM tool. Annexure E summarises the result of the feedback for the 2 latter parts.

5.2 Field Assessment

This was followed by a 6 days field assessment from 23 to 28 August. The assessment sites were identified as described earlier. The selection included 3 of 6 districts selected for upcoming Measles SIA, and 2 of the 5 districts where the SIA has been completed. It also included 4 of the 8 UNICEF focus districts, and 3 of the 6 NRHM focus district. In addition, 24 health facilities (PHCs) were selected under these Districts using the sampling tool.

Note that the Corporation stores and Urban centres were not part of this assessment exercise.

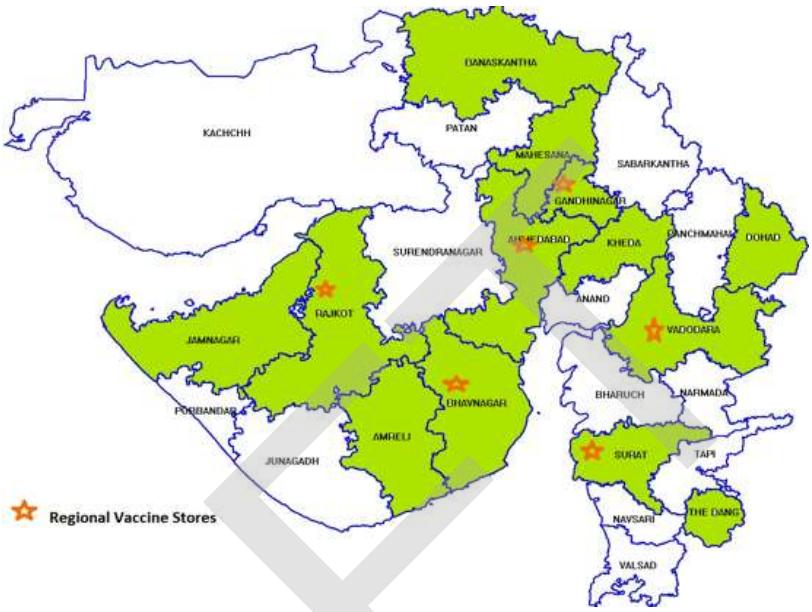
The assessment was conducted by 6 teams comprising of two medical offices (RCHO and RCSO), one vaccine store pharmacist and one technician. Each team assessed 1 RVS, 2 DVS and 4 PHCs

selected within it. The visits also included carrying out of necessary corrective actions that were feasible during the visits. Details of the teams and locations they visited are given in Annexure F.

The adjacent map of Gujarat depicts the locations of the 6 RVS (Stars) and the 13 DVSs (green) selected for the assessment.

The facilitation team members travelled separately and joined different teams at different times. This permitted to achieve the following objectives:

a. Make independent observations of the vaccine stores visited,
b. Verify the data collection carried out by the teams,
c. Guide the teams to improve the quality of assessment
d. Visit some vaccines stores that are on their itinerary for a rapid appraisal.



Map showing the Regional stores and districts visited during the assessment

This way, couple of PHCs in Junagadh district, its district store, and the municipal corporation of Rajkot and Bhavnagar were also visited.

5.3 Data Validation and Analysis

Following the assessment, in the third phase of the mission, the facilitation team conducted a 5 day workshop for data verification, consolidation, validation and analysis.

The RCSOs who had entered the data in their laptops were invited to this workshop from each team. The exercise was directed to ensure reliability and consistency of data between the teams for similar observations, and clarification of the comments accompanying the scores. This is critical to ensure a balanced assessment, since the facilitation team could not visit all the locations.

The result of the State Vaccine Store (SVS) at Gandhinagar has been considered separately. However, its role is not very clear. The SVS works partially as a state store to receive Hep B vaccine and campaign vaccines for the entire state, while most of the other vaccines are sent directly to the regional stores. Hence it is not discussed in much details.

One district vaccine store and 2 PHCS assessed during the training week are also included in the consolidation.

Thereafter, details discussions were conducted to analyse the result and walking through the essential conclusions and identification of strengths and weaknesses. In order to overcome the weaknesses, the team derived the essential practicable recommendations through consensus.

The consolidated table with detailed scores is given in Annexure I along with the averages resulting at each level.

The summary of the consolidated results is given in the table below. WHO recommends a minimum of 80% of performance for each criterion. Hence, scores ***less than or equal to 70% are***

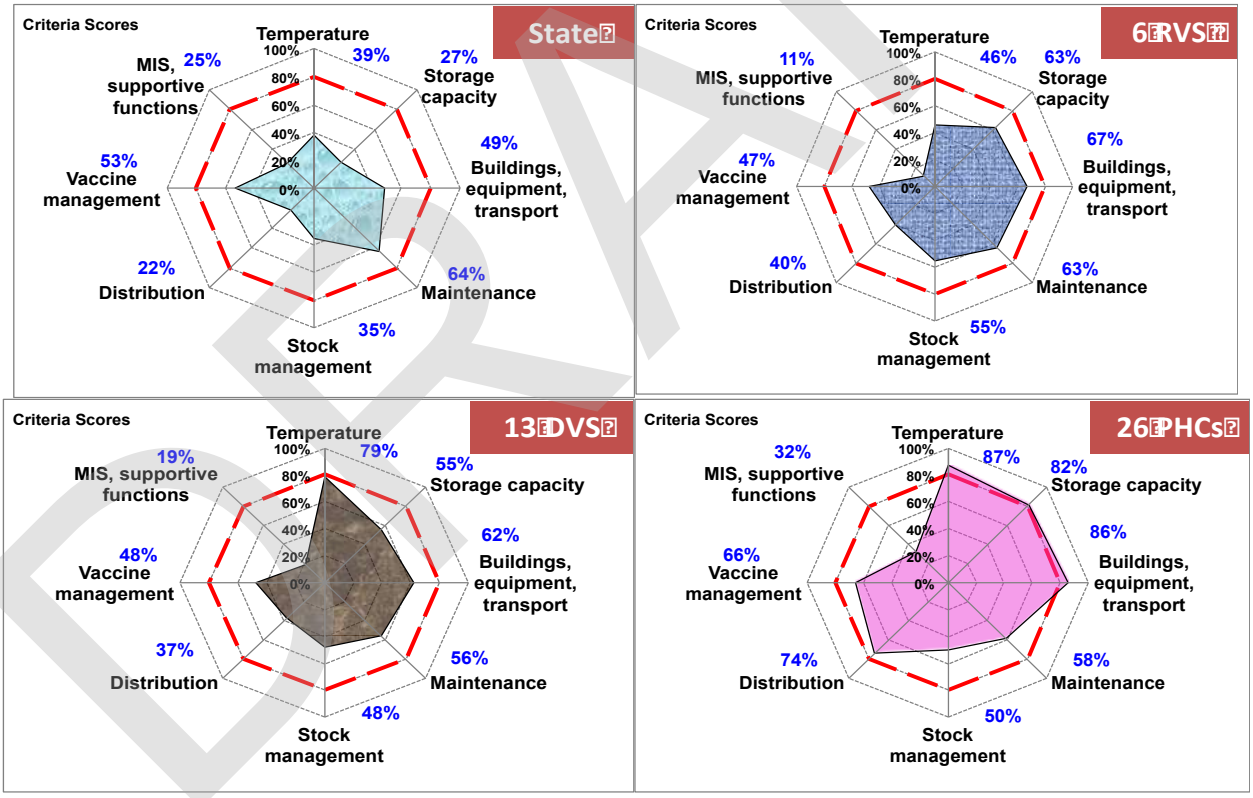
marked in red to underscore the need for attention. The scores between 70% and 90% are left in the normal black font to indicate that they are in the acceptable range. Scores **above 90% are marked in green** to indicate that these are in a very comfortable range.

Table 1: Summary of consolidated EVM indicator score for Gujarat

#	Indicator	Consolidated scores				
		1 SVS	6 RVS	13 DVS	26 PHCs	Average
1	Vaccine Arrival Process	44%	NA	NA	NA	NA
2	Vaccine Storage Temperature	39%	46%	79%	87%	71%
3	Storage Capacity	27%	63%	55%	82%	67%
4	Building, Cold Chain Equipment & Transport	49%	67%	62%	86%	72%
5	Maintenance of Building, Cold Chain & Transport	64%	63%	56%	58%	59%
6	Stock Management	35%	55%	48%	50%	51%
7	Distribution	22%	40%	37%	74%	50%
8	Vaccine Management Practices	53%	47%	48%	66%	54%
9	MIS & Supportive Functions	25%	11%	19%	32%	21%

SVS: Vaccine Store; **RVS**: Regional Vaccine Store; **DVS**: District Vaccine Store; **PHC**: Primary Health Centre.

The resulting Radar graphs for the different levels are given below.



The areas covered by the polygons in the graphs indicate the achievements in the areas of the respective indicators.

Looking at the score table above, one can observe that none of the scores are above 90%. There are only five scores in black. The rest are all in ***red,*** with many of them being less than 50% reflecting predominance of need for improvements in the system. The average score of the RVS, DVS and PHCs levels is indicated in the right most columns are also all less than 70% for 6 of the indicators.

The findings of the analysis are given in the next section. The resulting graphic representation for

each of the SVS / RVS, consolidated result of the two districts and their respective four CHC / PHC is given in Annexure G for respective zones.

5.4 DEBRIEFING

The debriefing of the findings was conducted on the 9th of September to all the RDDs and RCHOs. The meeting was chaired by the Commissioner of Health- Mr. Taneja (IAS). Other dignitaries present were Dr. B. K. Patel (Dy Director…..), Dr. N. Dholakia (SEPIO), Dr. Henri van der Hombergh (Chief – Health section at UNICEF-ICO) and Dr. P. Gurnani (UNICEF-Chief).

Dr. N. Gaonkar presented the introduction to the EVM mission. This was followed by the findings by Dr. Kshem Prasad (Principle consultant) and Good Practices in Cold Chain by Mr. Anshu Kumar (Cold Chain Specialist) both from APT Progress Consultancy, agency that was mandated to undertake the mission. Then Dr. van der Hombergh presented a brief overview on the multi-state assessment. Following the presentations, the Principle consultant along with the help of UNICEF consultant – Dr. Tapasvi Puwar conducted a short exercise on how to prepare the action plan based on a predefined template.

5.5 ADDITIONAL TASKS

The following additional tasks were undertaken by the teams during the mission, the reports and presentations of which are also shared.

Reports

- EVM Gujarat - Special observations and Corrective Action taken during visits by the teams. Doc
- Note on new WIC installations in Gujarat.Doc

Team Presentations

The team members were requested to prepare short presentation for the debriefing. These have been also included in the final debriefing package.

- T1-Gandhinagar Team Presentation. ppt
- T2-Bhavanagar-Team presentation. ppt
- T3-Ahmedabad Team Presentation. ppt
- T4-Rajkot Team Presentation. ppt
- T5-Vadodara-Team presentation. ppt
- T6-Surat Team Presentation. ppt

6 FINDINGS

In this section, the findings for each global indicator is presented in detail.

First, a general introduction on what that criterion is about is given in a framed coloured box. Then the performance score obtained from EVM for different levels is given. The performance is then discussed in terms of strengths and weaknesses. In certain cases, examples of specific names of sites where a particular problem has been observed is also listed. The objective is not to point any finger, but simply to define some examples of a typical case for any required verification.

It should be noted that the role of State Vaccine Store (SVS) at Gandhinagar is not very clear. It functions partially as a state store to receive Hep B vaccine and campaign vaccines for the entire state, and in many cases the stocks destined for RVS-Bhavnagar. Out of 31 consignments received by RVS-Bhavnagar during the past 12 months period – 21 were collected from Gandhinagar Vaccine Stores. On the other hand, most of the other vaccines are sent directly to the other 5 regional stores, bypassing the SVS at Gandhinagar. Due to this, the results of this store, assessed during the week of the training, is not discussed in detail. Its performance is similar to that of the Regional store of Gandhinagar which is merged with it, and in certain cases (eg. storage capacity) has some severe limitations.

The recommendations emerging from the analysis of the findings are consolidated in the next section and categorised as described there.

First, some of the general aspect worth noting in terms of **Human resource are :**

- State has one State Immunization Officer.
- Most districts has one Reproductive Child Health Officer (RCHO)
- Each Region has one Regional Child Survival Officer (RCSO).
- Qualified and trained pharmacists are posted from Regional level right down to most PHCs, (except Vadodara & Few PHCs).
- 19 out of 26 districts have designated refrigeration technician – though they are not posted at the district head quarters.

6.1 PRE-SHIPMENT AND ARRIVAL PROCEDURES

This indicator assesses the process of vaccine arrival from the manufacturer to the primary store. It verifies the following aspects:

- The standard process of reporting of arrivals is followed
- A Lot Release Certificate is received for every lot of vaccines
- The clearing of the vaccine through the customs is reliable
- Measures for safekeeping of the vaccine during delays in clearing is ensured
- The process of receiving, clearing and checking of consumables is effective.

This criterion is applicable only to national primary stores.

In the case of India, the criterion is applicable to the GMSDs and partially to the State Vaccine Stores, which receive vaccines from the GMSDs and sometimes directly from some of the domestic manufacturers.

This criterion is applicable only partially to the State Vaccine Store (SVS) at Gandhinagar.

The SVS does not clear any vaccines through the customs, however its score is consider as full

since the option of "Not Applicable" is not available in the tool. The MoHFW and GMSDs receive the Lot Release Certificates for each lot of vaccines. Hence, this scoring for these aspects is assumed in order.

This criterion is not applicable to the other levels of vaccine stores.

Findings

Vaccine Store	State	Region	District	PHCs
Performance Score	***44%***	NA	NA	NA

The 44% of score is resulting from the points mentioned above and that all 39 vaccine lots supplied from GMSD Mumbai and domestic manufacturers have arrived in good condition.

The Vaccine Arrival Reports (VAR) have been filled only for those lots (usually Campaign vaccines) which had a blank form included along with it.

Hence, to improve the performance, there is a need to systematically record all the salient information related to the vaccine shipments, as noted in sections I to VII of the VAR form (e. g. pre-notification, actual arrival, condition of the shipment, status of temperature monitors, and other salient aspects of the shipment) for each and every vaccine lot that arrives at the SVS. The pharmacist should keep extra copies of VAR and fill it for each and every vaccine lot that is received.

6.2 Temperature Monitoring

All vaccines are sensitive biological substances. The higher the temperature to which the vaccine is exposed, the quicker is the loss of potency. Some vaccines are also sensitive to freezing, and this can cause irreversible damage.

In this criterion the following aspects are assessed to ensure that vaccines are stored at the recommended temperatures:

- Knowledge of the storekeeper with regard to the storing temperature for the different vaccines and their sensitivity to freezing
- The quality of cold chain is systematically monitored
- Continuous temperature records of the cold rooms and freezers rooms and refrigerated vehicles exist
- Twice daily manual temperature recording for all equipment storing vaccines is maintained
- The temperature records are regularly inspected and retained for auditing purposes.

Findings

Vaccine Store	Region	District	PHCs
Performance Score	**46%**	79%	87%

The benefit of deputing trained pharmacists at all levels is reflected through the performance achieved here. Most of the staff (with few exception of new deputations) have received training based on the cold chain and vaccine handler's handbook. All pharmacists at RVS (except RVS-Vadodara) and DVS and most pharmacist in PHCs know the safe storage temperature and the freeze sensitivity of the vaccines. The vaccines are therefore stored at the recommended temperatures.

At RVS, all DVS (except DVS-Kheda) and most PHCs the manual records are maintained at least 6 days out of 7, and most of them also have these records endorsed by the supervisor. In several

places the standard format provided in form of temperature recording booklet is correctly implemented. These records are also kept safely for 3 years.

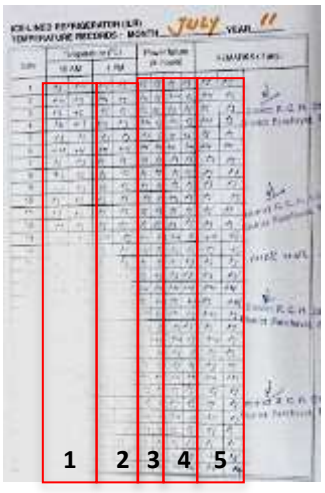
The areas that need improvement are :

- None of the old or new walk-in-cooler (WICs) and Walk-in Freezers (WIF) at Gandhinagar have a working continuous temperature recording unit; not even the newly installed WICs at the 5 regional stores.

  Large stocks of vaccines are stored at these levels and failure to track the storage temperature continuously may lead to damage to these stocks in case system malfunction. Hence this is a critical parameter and it influences the performance score at RVS (& SVS).
- The pharmacist of Vadodara RVS is deputed recently from a CHC and is not confident regarding the safe storage temperature of vaccines. The knowledge of the pharmacist at Surat RVS is shaky regarding the freeze sensitivity of vaccines. Handling of vaccines by untrained staff, specially at RVS or DVS level puts a serious threat to the safety and potency of the large stocks of vaccines.
- None of the WICs have been mapped for temperature profiling. In fact the cold chain technicians are not knowledgeable of its usefulness and how to do it.
- The manual temperature records are maintained only at two RVS (Vadodara and Surat). There are gaps during holidays in most of manual temperature records.
- Safe storage of vaccines requires correct operation and monitoring of equipment. Thermometers need to be precise and reliable for this purpose. For this the thermometers should be calibrated at least once a year. The cold chain technicians are not knowledgeable about how to calibrate the thermometers.
- At several vaccines stores (eg. DVS-Rajkot, DVS-Kheda) the temperature of several ILRs is recorded on a single page of the standard format. This results in lack of space to mark additional information such as defrosting or power cuts. Extra copies of temperature recording booklet were not available.
- Equipment temperatures is not monitored at all at Sinhuj and Varsola PHCs.
- At several places the temperature records are not monitored by the supervisor (eg. DVS-Dharan, DVS-Mehsana).

This results in the low sat the RVS and moderate ones at DVS and PHCs as mentioned above. Recommendations for improvements are listed in next section.

Correct use of temperature monitoring form



Temperature monitoring form used for several units

6.3 Capacity of Cold and Dry Storage and Transport

Capacity should be adequate for storage and transport of routine as well as campaign vaccines and the required consumable. Hence the following issues are assessed:

- Storage capacity is sufficient to accommodate maximum stock requirements for the routine immunization and its consumables, and for supplementary immunization if the same are also kept in the store
- Storage capacity is sufficient to accommodate maximum stock requirements of vaccines and consumables for all supplementary immunization at the temporary facilities if these are used for this purpose
- Transport capacity is able to meet the maximum demand
- There is sufficient number of passive containers and there is capacity to produce the required quantity of coolant as required
- Contingency plans are in place to protect the vaccines in case of any emergency.

Findings

Vaccine Store	Region	District	PHCs
Performance Score	63%	55%	82%

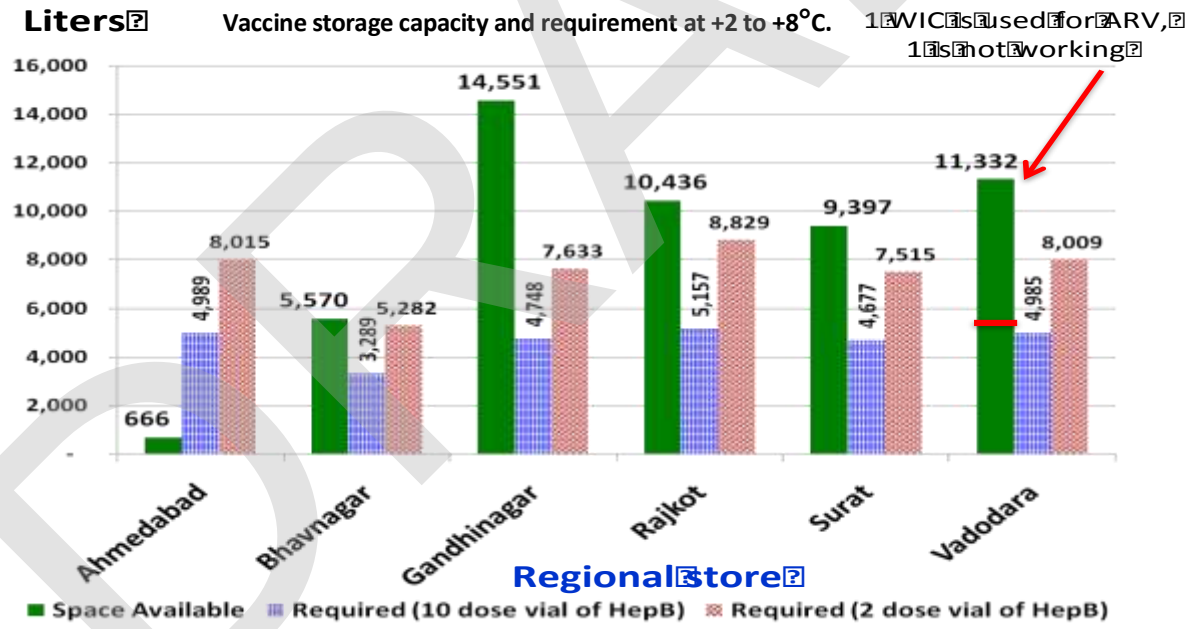
The performance at the RVSs and DVSs is weak.. At the DVS, the basic reason being lack of adequate storage capacity as per the required GoI guidelines.

There is sufficient storage capacity at -15 to -25 ^{o}C for OPVat all levels. There is also sufficient ice pack freezing capacity at all levels. PHCs have sufficient vaccine storage capacity for its requirements.

SVS & RVS

The state store has 3 WICs (2 old and one newly installed) with a total capacity of 14,551 Litres. The same store with these WICs also forms the Regional store for Gandhinagar. Thus the store is expected to keep as a state store 3.75 months (3 months of working stock and 25% of buffer stocks) for Gandhinagar and Bhavnagar region, and in addition as a regional store keep 3.75 months of stocks for the Gandhinagar region. This results in insufficiency of storage space at 2 to 8°C for all the vaccines (except OPV), although if considered either as the State store or only a regional store, there is sufficiency of storage space.

Looking at the situation of the RVS, the graph below illustrates the total storage capacity available and required.



The graph shows in green the total capacity available along with what would be required to store 3.75 months (+10% buffer space) of stocks of vaccines for the respective regions. The computation of the space requirement considers two scenarios: a) HepB is used in 10 dose presentation having a volume of 3 Cucm/dose and b) 2 dose presentation with a volume of 13 Cucm/dose. One can see that there is sufficient storage space at most regional stores (except Ahmedabad) even with the 2 dose presentation of HepB.

However, one needs to also consider that in the case of Gandhinagar, as explained above the same WICs are used in the form of state store. Hence in reality there is a space limitation here.

At Vadodara, there are three cold rooms and one freezer room. Out of the 3 WICs, one is out of order since three months due to major repairing, the 2nd one is being used for keeping Anti-

Rabies Vaccine (ARV) and 3rd newly installed WIC is used for routine UIP vaccine. Thus, currently the actual usable space is about 50% of that which can be available, which may just be sufficient. This is indicated by the red horizontal line.

At Ahmedabad, the newly installed WIC is in non-functional, as one of the condensing unit of the refrigeration unit is unserviceable due to theft of certain components as a result of lack of canopy on the installation of the condensing unit close to the open window. As a result, capacity available is that obtained using the ILRs.

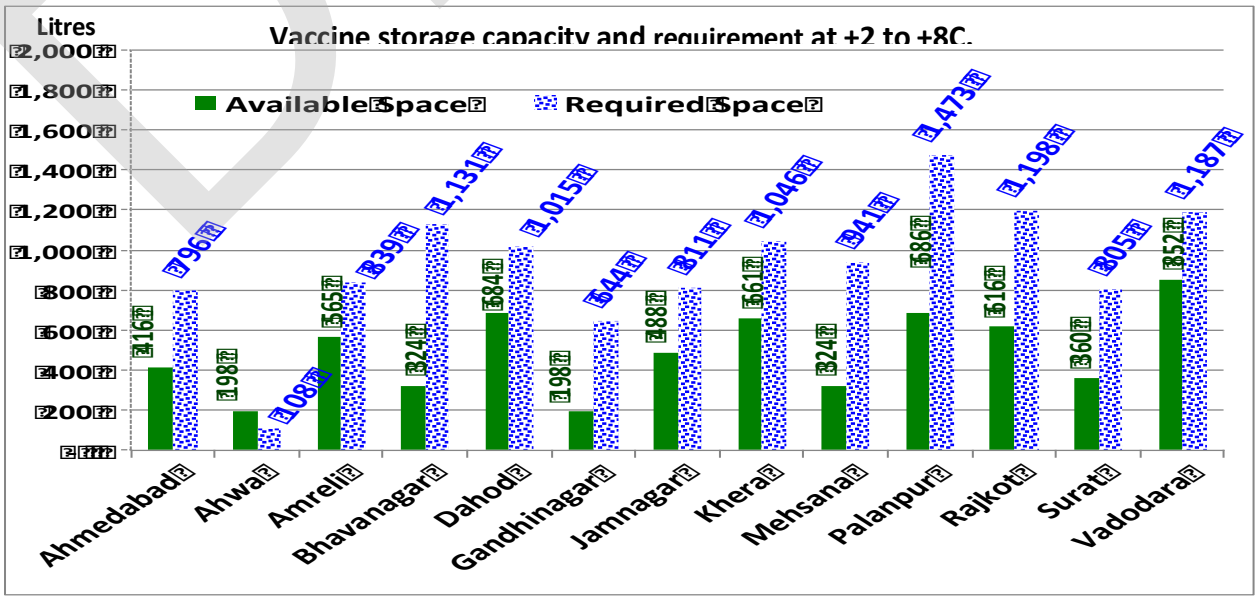
Note that, at most regional vaccine stores, significant cold chain space is occupied by Anti-Rabies vaccines. At the regional level this amounts to almost 20-30%, while at DVS they have been segregated and stored in a separate ILR.

Overloaded cold room (left) with ARV stocks (right)

In summary, there is potential to store 3.75 months of vaccines at all stores except Ahmedabad and Gandhinagar if equipment are functioning and the non-RI vaccines are accommodated separately.

DVS

The graph below illustrates the similar study in the case of the 13 DVS visited. The available storage space is depicted in green and required space for storage of 3 months of working stock and 25% of buffer stock is represented in blue, (considering 10 dose presentation of HepB).



One can see that in this case, none of the DVSs have sufficient storage capacity. Currently, at many DVS, the cold chain is clogged with 2 dose HepB, as large stocks have been pushed down the supply chain recently.

The current practice is to store only one month of vaccine stock at the DVS without considering buffer stocks. The DVS is supplied by the RVS once every month based on its indent, which is basically based on the target group and adapted according to stocks available.

In order to increase the total cold chain space, one could consider enhancing the storage capacity by adding new ILRs, from the reserve stock. However, there is serious limitation of space in the building and rooms allotted for DVS.

The non-RI vaccines (ARV) stored in separate ILRs, which take up physical space in an already limited space.

PHCs

At service level, current practice is to keep a maximum of 1 month of working stock only. Even if one would add to this a buffer (safety) stock of 2 weeks, there would be no shortage of storage space at the service level. At times, depending on the stocks of Hep B (2 dose presentation), there are constraints to keep all the diluents in the ILR.

There is one DF available at all PHCS, thus ensuring sufficient capacity to produce and store ice packs.

Non-RI vaccines and drugs are kept in a separate domestic refrigerator purchased locally.

Miscellaneous

Vaccine vans are available at all RVS except Ahmedabad and most DVS.

There is sufficiency of cold boxes and vaccine carriers. However, staff tend to use the thermocol boxes in which vaccines have been supplied by the manufacturers, as the same are lighter and less cumbersome to use. However, this is a wrong practice as these boxes do not guaranty the required hold overtime.

Due to shortage of space at RVS and DVS, there is no dedicated space for diluents. These are stacked in the little space available (eg. Window sill at DVS -Rajkot) .

There are no written contingency plans at any level to handle emergencies. Most staff have limited knowledge on how to handle emergencies arising from equipment breakdown or excess stock in hand. They have never had any exercise in form of mock drill. Emergency numbers are not always visibly displayed.

Addressing these issues will contribute to increasing the performance scores.

6.4 Status of Building, Equipment and Transport

The good operating conditions of the building housing the vaccine store, the equipment storing the vaccines and the vehicles that are used for transport are important aspects to ensure safety of the vaccines. The following aspects are assessed here:

- The location of the store building, the quality of construction and accessibility are satisfactory
- The building provides space for all the activities to be carried out there
- The condition of all the equipment used is satisfactory
- WIC and WIF, ILR and DF, and generator
- The condition of transport vehicles and containers are satisfactory.

Findings

Vaccine Store	Region	District	PHCs
Performance Score	67%	62%	86%

The scores indicate the status of the building, equipment and transport at different levels. It reflects serious concerns at the RVS and DVS level but at PHC level it is within recommended range.

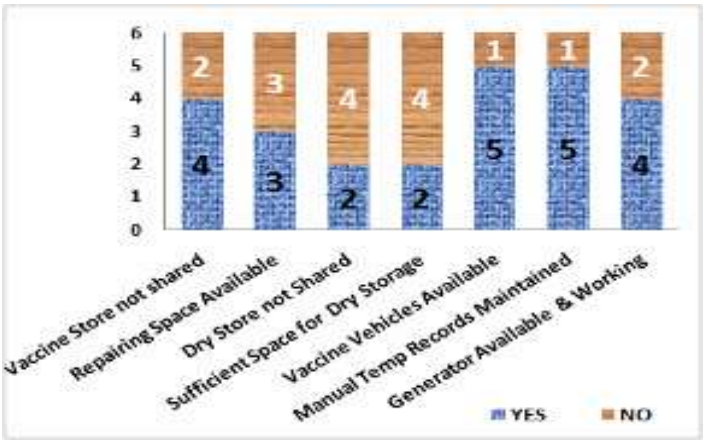
At the same time the assessment identified several complementary limitations that are not directly scored in the tool, but which are important to be addressed as well. These are also discussed as part of the findings in this section.

RVS

The table below summarises the status at the RVS. The result are dipicted in the graph below.

Summary of Status of the 6 RVSs

	Category	Aspects	Gandhinagar	Bhavnagar	Ahmedabad	Rajkot	Vadodara	Surat	Positive results
1	Cold storage	Vaccine Store is Shared	Y	Y	N	N	N	N	4
3		Repairing Space Available	N	N	Y	Y	Y	N	3
4	Dry Storage	Dry Store Shared	N	Y	Y	Y	Y	N	2
5		Sufficient Dry Space	N	N	N	N	Y	Y	2
6	Transport	Vaccine Vehicles Available	Y	Y	N	Y	Y	Y	5
7	Temperature Records	Manual Temp Records Maintained	N	Y	Y	Y	Y	Y	5
8	Other Resources	Generator Working	Y	Y	Y	Y	N	N	4
9	Human Resource	ADPH is posted	N	N	N	N	N	Y	1
11		Is there Vaccine Store keeper ?	Y	Y	Y	Y	Y	Y	6
12		Refrigerator Mechanic posted	Y	Y	Y	Y	Y	Y	6



Summary Graph of Status at Six Regional Vaccine stores and the Vacccine store at DVS-Gandhinangar

The concerns are summarized below:

- Different limitations in terms of shared space, dry storage space, repairing workshop space etc. exist at different stores.
- RVS Vadodara and Rajkot are also in good conditions, but the space is less.
- RVS – Vadodara the building is in good condition except that it is on the first floor, where the transport management is difficult.
- Approach by vehcle is difficult at RVS Ahmedabad and Gandhinagar.
- Ahmedabad Regional store is good in terms of space and status of the building, but building is going to be demolished very soon and the store needs to be relocated.
- RVS Gandhinagar - building is not up to the mark. The vaccine store is shared and the installations of the new WIC in done in the garage. Window panes are broken in this premise.
- All Regional Vaccine Stores have vehicles for transport of vaccines all vehicles are working in good condition (except at Ahmedabad).

Overall, 3 out of 6 Regional stores are in rather poor condition (Bhavnagar, Surat, Gandhinagar) and others need certain amount of revitalization.

New WIC a garage at in SVS/RVS Gandhinagar

Broken windowpanes at the SVS Gandhinagar

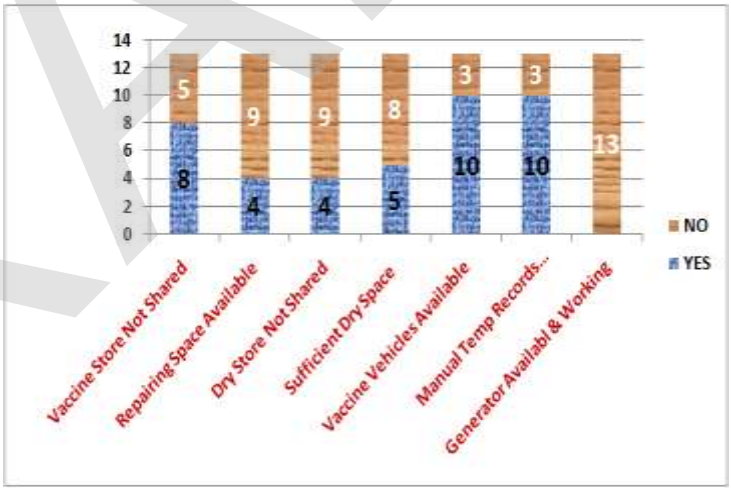
DVS

The tble and grpah below summarise the status of the 13 DVS that were visited.

Summary of Status of the 13 DVSs

Parameter	Aspects	Gandhunagar	Mehasana	Palanpur	Bhavnagar	Amreli	Ahmedabad	Khera	Rajkot	Jamnagar	Vadodara	Dahod	Surat	Dangs	Positive results
Cold storage	Vaccine Store Shared	N	N	N	Y	N	Y	Y	N	N	N	N	Y	Y	8
	Vacccine Store Status Good	N	Y	Y	N	Y	N	N	N	Y	Y	N	N	N	5
	Repairing Space Available	N	Y	Y	N	Y	N	N	N	N	Y	N	N	N	4
Dry Storage	Dry Store Shared	N	Y	Y	Y	N	Y	Y	N	N	Y	Y	Y	Y	4
	Sufficient Dry Space	N	Y	Y	N	Y	N	Y	N	N	Y	N	N	N	5
Transport	Vaccine Vehicles Available	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Y	Y	10
Temperature Records	Manual Temp Records Maintained	Y	N	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	10
Other Resources	Generator Working	N	N	N	N	N	N	N	N	N	N	N	N	N	0
Human Resource	Is RCHO Posted?	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	9
	Infra Structure Support to RCHO	N	N	N	Y	Y	N	N	N	Y	Y	Y	Y	Y	7
	Is there Vaccine Store keeper ?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	13
	Refrigerator Mechanic deputed but not posted	Y	Y	Y	Y	Y	Y	Y	N	N	N	N	Y	N	8

Graph of Summary of Status of the 13 DVSs



- Likewise, the Graph above illustrates the summary of status at the 13 DVS visited during the assessment. As a summary 10 out of 13 District stores are in poor condition or have space limitations.
- At Jamnagar, Palanpur, Vadodara overall building status is good.
- At DVS Surat, painting is required. The new installations have been put in the condemned building, no cross ventilation has been seen in the storage & installation space. Window panes are also in broken condition.
- At Bhavagnagar the cross ventilation is very poor and very small size for storage.
- At Ahmedabad and Kheda level of store is below the ground,
- Sughad - Dahod drainage system is in very bad condition. Even both the stores have no vaccine stores are available.
- Most of the District Vaccine Stores (except Surat and Ahmedabad) are approachable.
- **Space Management**
- DVS Surat, Bhavnagar, Amerili dry storage space is insufficient whereas Mehasana, Ammedabad and Dahod are sharing the stores.
- DVS Gandhinagar, Rajkot, Bhavagnagar all are running shortage of space.
- Gandhinagar, Rajkot, Bhavagnagar, Dharan and Surat space is too less. Few of them have dumped unwanted goods.
- DVS are not equipped with any generator.

In summary 10 out of 13 DVS require upgrading.

PHCs

- As for space PHCs are concerned no serious issue at any health facilities.
- At PHC level, particularly Dhan the building has a large unwanted material dumped and needs attention immediately. While at PHC Jamnagar, Lamba, Gohanta lot of doors & window panes are broken. On wall there are lot of cracks as well as on roof, dampness is in all the PHCs. Jamnagar - Lamba, Gohanta poor doors and lot of cracks on roof. PHC Lamba and Dhan have no drainage system.
    - Almost all the PHCs are approachable.

New WIC at Gandhinagar
Inner Wall with water droplets

Equipment:

New WIC / WIF installation

6 WICs and WIF have been supplied by the GoI for the SVS and RVSs. The facilitation team have encountered many of these and observed serious lacuna in the quality of installation. A separate report has been submitted to this effect as the observations and learning pertain to all 91 units being installed by Blue Star across India.

As an example - at the SVS/RVS Gandhinagar, the condensing unit of the outdoor condensing units were without canopy. Stabilizer was not working and Generator was also not checked

Condensing Units without canopy (before) and after intervention of the Consultant Team with Blue Star.

during installation. The roof and the walls of the WIC were leaking with condensate water due to poor filling of silicon material in gaps. The WIC was running without any stabilizer support with a certain risk of failure.

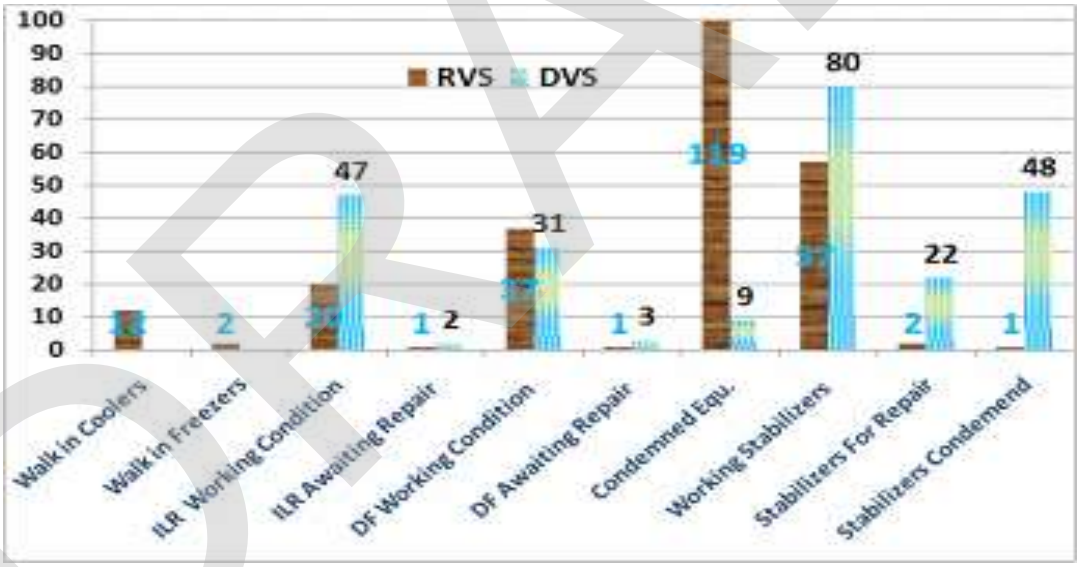
The condensing unit of the RVS-Ahmedabad was installed indoor close to a window without a canopy. This has led to a theft of some components, from the condensing unit, through the window. Blue Star has asked for Rs. 48,000/- approximately for conducting the repair. Since the theft took place due to the open condensing unit, responsibility for the same should be assumed by Blue Star. Here too, the stabilizer was not working and the generator was not checked during installation.

Damaged condensing unit at Ahmedabad

All the WIC/WIF in the state are running without an acoustic alarm system, except the RVS Gandhinagar. New installations are also without acoustic alarm. This adds to the risk of damage to vaccines in case of system failure and increase in temperature which may go unnoticed.

Summary of status of ILRs and DFs at RVSs and DVSs

The equipment status at the 6 RVS (in brown) and 13 DVS (in sky blue) is illustrated in the graph below.



The graph here illustrates the status of the equipment across the Gujarat Vaccine cold chain.

- A total of 119 condemned equipments at RVS and 9 condemned equipments need to be replaced from cold chain as occupying the space at Regional & Divisional vaccine store. Total of 7
- units are awaiting repair (3 ILRs and 4 DFs) at the DVS and RVS. The same are lying since several months, cluttering the corridors of the old building where it is located.
- Likewise, only 137 stabilizers are in working condition and in some places stabilizers are missing or being shared between two equipments. 24 Stabilizers (2 at RVS and 22 at DVS) are awaiting repair and another 49 need to be disposed of.
- In many CHC and PHCs the stabilizers are shared. Several stabilizers are no-functional.

Equipments running on CFC

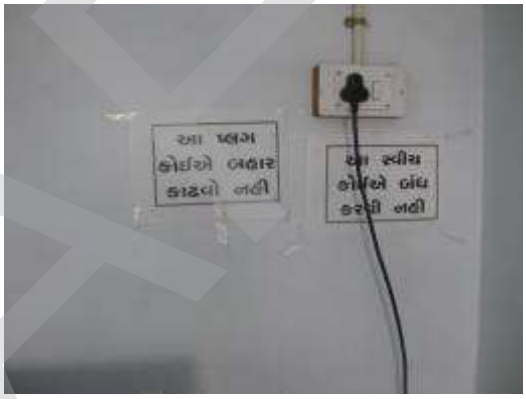
Due to the Ozone Depletion by certain refrigerants & chemicals, Government of India became party of the Montreal Protocol in 1992 and agreed to phase-out of the CFCs by 1 January, 2010. As a result of subsequent amendments CFCs have now been phased-out of India as of 1st August 2008, seventeen months ahead of the original deadline.

As of today, 10 WIC refrigeration units and about 29 ILRS / DF are operating on CFC. The ILRs and DF are distributed a according to : Surat 5, Vadodara 3, Bhavanagar 4, Rajkot 10, Gandhinagar 4 and Ahmedabad.

These should be replace these units at the next major failure, and if possible recover and reclaim the CFC refrigerant to avoid further damage to the Ozone layer. In case of damage to the compressor, equivalent compressor data can be used to make the equipment set right by relacing with new alternate technology refrigerants.

Miscellaneous

- 



❖ Electrical system throughout the SVS, RVS, DVS and PHCs is commendable (eg. RVS Rajkot, Ahmedabad) except few places like RVS Surat and DVS Dharan.


- At RVS Surat Naked wires without plug, at DVS -Dhan loose connections.


- Electrical system at RVS Rajkot, Ahmedabad and Gandhinagar has No problem

Fire Extinguishers

- None of the RVS is having fire extinguishers.
- In DVSs fire extinguishers are absent except Dharan. In Dharan fire extinguishers are in working condition and the team did a mock drill also.
- All PHCs are lacking in providing the fire extinguisher

Transport

- 6 DVS have vehicles in poor condition.

7.5 Maintenance of Building, Equipment and Transport

For ensuring a sustainable safety of the vaccines, the building, equipment and transport vehicles need to be maintained and upgraded periodically. Hence it is important to ensure that:

- A periodic preventive maintenance plan for building, equipment and vehicles is in place and being implemented,
- An arrangement is in place to carry out prompt repairs of equipment and vehicles in case of any failures.

Findings

Vaccine Store	Division/Region	District	PHCs
Performance Score	63%	56%	58%

The performance score results from **the following strengths**:

- Funds are available for periodic preventive maintenance (though these are not used effectively).
- Vaccines have never been damaged due to failure of equipment. In case of equipment failure and if the problem is major, the non-functioning equipment is promptly replaced with a new one.
- The state benefits of the regular replacement plan prepared by the GOI based on plans submitted to it and the new equipment are supplied accordingly. Large stocks of new equipment exist at the regional level.

The areas that need improvements are:

- There are no preventive maintenance plans for the buildings. Several RVS and DVS buildings require significant maintenance work to be carried out (eg. RVS-Gandhinagar, Bhavnagar & Surat, DVS-Bhavnagar, Ahmedabad & Kheda).
- Refrigeration technicians, though deputed, are not posted at district head-quarters for easier movement and rapid intervention within the district. They do not have adequate means of transport to be effective. This has resulted in delay for repairing equipment which resulted in the weakness of the cold chain equipment maintenance.
- There is lack of systematic preventive maintenance for equipment. Visits are based on calls for repair, and there are very few records of maintenance or repair.
- The regional repair workshop (HER) appears to be non-operating at Bhavnagar.
- Defective equipment are replaced with new one, as large stocks exist, before the failed ones have served its expected life. This is reflected wrongly with a very low sickness rates.
- Equipment maintenance and repair works are not supervised.
- Vadodara and Surat RVS have disposed off the condemned equipment. Large stocks were seen in Rajkot RVS and some at Bhavnagar RVS. According to the reports available for some equipment,

all those have been condemned due to internal leaks. The status of most condemned equipment is not very clear. There reports as well as equipment need to be verified by technical supervisors.

- No service records for maintenance of vehicles.

6.6 Stock Management System & Procedures

In order to maintain the quality of vaccines and consumables throughout the cold chain, it is essential to keep complete and accurate records of all stocks and their transactions. A stock control system comprises of several steps, each of which must be performed regularly, accurately and completely. The various steps are checking and recording details of the consignments or stocks:

1) When they arrive, 2) During their storage and 3) When they are leave the storage point for distribution and finally 4) In case any vaccine is damaged or expired.

Here the following issues are assessed:

- A standardised recording and reporting system, preferably computerized at the primary level is in place and is being followed
- All lots of vaccines, diluents and consumable have been recorded at the time of arrival, distribution and dispatch along with all their salient parameters
- Stocks of vaccines and diluents are maintained between maximum and safety (buffer) stock levels
- Periodic physical inventories is conducted
- Proper requisition and receipt forms are in place
- Good warehouse practices are followed
- Deliveries are made following Early Expiry First Out (EEFO)
- Storekeepers know when to over ride EEFO based on VVM status
- Standard recording system is in place to safely dispose of damaged or expired stock

Findings

Vaccine Store	Region	District	PHC
Performance Score	55%	48%	50%

The performance achieved is attributed to :

- Gujarat has introduced the recommended format of vaccine stock recoding in form of registers. Some of the stores use them effectively with stocks updated within 24 hours.
- Likewise there are standard indent forms, a copy of which can be kept at the requesting store, while the other is sent to the supplying store. Supply vouchers in 3 copies have been defined and supplied to the vaccine stores.
- Most staff being trained pharmacists, are practicing the Early Expiry-First-Out (EEFO). They also know how to ove-ride EEFO due to advance stage of VVM.
- Waste disposal of vaccine is carried out in accordance with the WHO / GOI guidelines (except e.g. Surat & Amreli DVS). In most PHCs, an outsourced agency (IMA) is contracted for its collection and disposal. Some of the other PHCs use some form of local pits, which are used.
- The stock of vaccines and diluents and dry storage are safe at most stores (except DVS Dharan, DVS Surat- due to shortage of space).
- Surat-RVS has taken the lead to introduce Freeze indicators, though these are yet to be formally introduced and distributed in India

The areas that need further attention are:

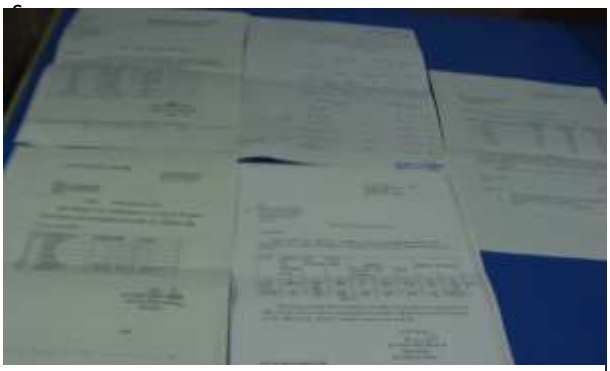
- The standardized stock registers are not available at all vaccine stores. In many vaccine stores normal account ledgers or rules registers are used after formatting the same for some but not all of the vaccine parameters.
- As a result vaccine records are incomplete in terms of all salient parameters presentation such as VVM status etc.
- Diluents are seldom recorded in the registers at any level – despite training.
- Standard indent forms are yet to be implemented across the state. Requesting stores often use any other alternative form of indent, and do not keep a copy for future reference.
- The supply form have seldom returned back to the supplying store from the receiving store after due filling and signing. The supply form does not contain information on the status of the VVM of the vaccines upon receipt.
- The practice of defining and implementing maximum, minimum and buffer stock is not carried out anywhere. The DVSs collect vaccines once a month instead of the recommended practice.
- One of the hurdles in implementing practice recommended by the MoHFW is that the Regional vaccine stores are not receiving requested quantities of vaccines at stipulated intervals from the suppliers. Information of supply plan from the manufacturers or GOI is not available in order to prepare downstream distribution plan.

  This makes it difficult to maintain the recommended stock at lower distribution levels as stock at RVS is insufficient.
- In most cases, vaccines to PHCs are issued on the basis of the consumption during previous month. Though the staff are knowledgeable on the standard method of vaccine forecast, the same is not implemented.
- Stock-outs have occurred in several PHCs including at Subir, Lavate etc (at least one PHC in each region). The table below provides details on the stock-out situation gathered during the assessment.

Vaccine Store	Vaccine	From	To	Period
RVS Rajkot and below	TT	5 May 2011	25 May 11	3 weeks
Several places	BCG OPV	1 August	till date	More than one month

- Vaccine damage records are not available at any of the stores. Breakages of diluents that have occurred during transport (e.g. DVS Mehasana and Palanpur), have not been recorded.
- Internal reviews on vaccine wastage management are not conducted. Standard guidelines available for management of damaged vaccines including recording, storage and disposal are lacking.
- Periodic inventory of vaccine stocks is not carried out at most of the stores, and registers are not corrected in accordance.
- Vaccine indent forms exist but each DVS or PHC use different formats as per their convenience.

  e.g. within the Gandhinagar region, five different indent forms were recorded by the assessors.



Five different Indent Forms been within Gandhinagar Region

Broken Diluents Vials at DVS-Palanpur

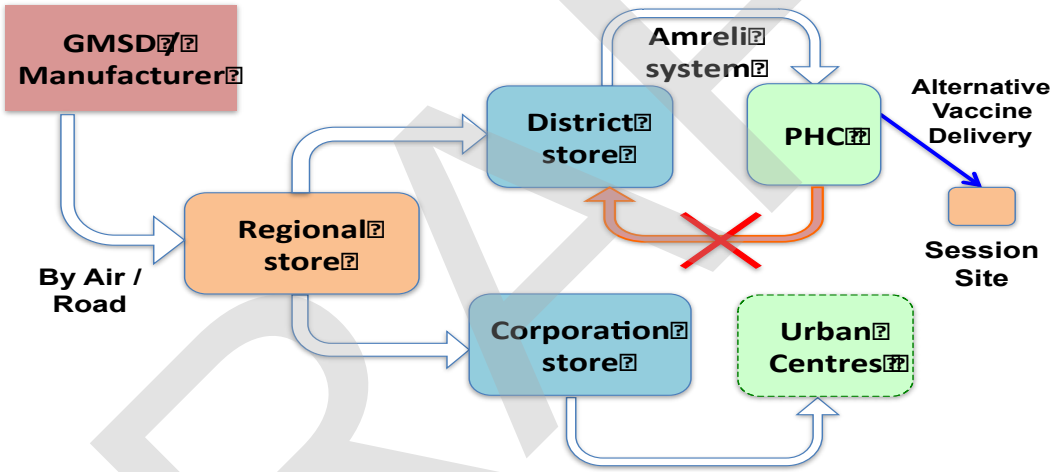
6.7 Effective Distribution

For an effective immunization programme, timely deliveries of the required quantities of vaccines are important. The parameters assessed here ensure the effectiveness of the vaccine distribution between each level of the supply chain. These are:

- The vaccine distribution programme is planned and implemented in timely fashion,
- A system to manage short shipment is in place,
- Vaccines are correctly packed during transport,
- Freeze indicators are used correctly to monitor the quality of the transport,
- In case of damage to the vaccine during transport, a system is in place to take corrective action effectivelv.

Findings

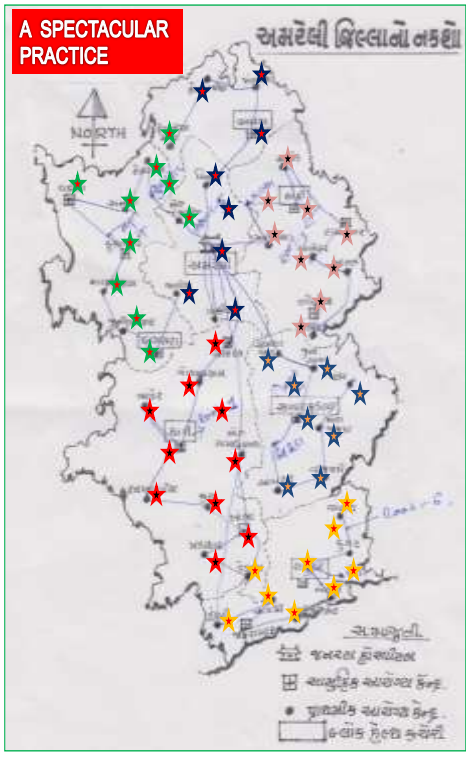
Vaccine Store	Region	District	PHC
Performance Score	40%	37%	74%



Typical Vaccine supply chain in Gujarat

The limited achievements at RVS and DVS, and the score at PHCs are due to the following strengths:

- Staffs at all RVS are knowledgeable about the correct ice pack conditioning and vaccine packing during transport (except RVS -Vadodara)
- Transport system and contingency plan during transport emergency is well established. As an example, during one of the distribution of vaccines from Bhavnagar, there was a failure of vehicles. The driver call at Amreli DVS and requested to receive it and thereby save the vaccines.
- Amreli has a very efficient Vaccine



Distribution System: It has made a plan to distribute vaccines once a month to all its 52 PHCs upon receipt of the vaccines. This is illustrated in the adjacent distribution route map. Each day vaccines are distributed by the DVS to a number of PHCs. Thus, over 8 days all the 52 PHCs are supplied efficiently.

Store keeper of Amreli accompanies vehicle during distribution which ensures safety of vaccines.

The areas of concern are:

- The DVSs do not follow the recommended practice of distributing the vaccines to their PHCs. Most have their PHCs coming to collect vaccines from them, though they have the funds and vehicle to do it.
- In advance, well defined plans for supply of vaccines (except Amreli) is missing across the state.

  One of the hurdles is the absence of information from the central level for supply to the RVS as mentioned before.

  The supply pre-notification (usually by mobile) is communicated just before delivery.
- The vaccine distribution is carried out based on the receipt of the vaccines supplied from GOI.
- There is no system to take care of short supplies or situation of stock outs.
- With the exception of RVS-Surat, freeze indicators are not implemented to monitor status of freeze sensitive vaccines during storage and transport. India is yet to implement use of freeze indicators across the states
- Planning of Vaccine receipt and distribution is based on demand. The written plans for vaccine receipt and distribution are missing at all levels. DVS level the distribution is done regularly on monthly frequency based on advocacy
- Finally at most of the stores, supply vouchers are not returned to the issuing stores with VVM status (except Amreli).
- Staff at DVS are also not fully knowledgeable about correct way of packing cold boxes. Some tend to make use of the non-standard ice packs (containing gel or blue coloured ones).

Non-standard icepack

- Staff at most of the PHCs including Pharmacists and Female Social Healthcare worker does not know proper ice pack conditioning. In most places hard frozen IPs are sent along with T series vaccines, with the rick of causing freeze damage to the vaccines by the time it arrives to its destination.

  The current practice puts serious threat of freezing of the liquid vaccines during long transport.

Significant improvements are needed in this sector in order to streamline the distribution system.

6.8 VACCINE MANAGEMENT AND HANDLING

This criterion is essentially applied to the service delivery level. Only 6 out of 16 questions are applied at the SVS, RVS and DVS.

For the proper Vaccine Management and handling several parameters are assessed:

- Knowledge and proper use of VVM and shake test by the staff,
- The freeze dried vaccines and their corresponding diluents are correctly ordered, received, stored and distributed,
- The vaccines are always used with their corresponding diluents,
- Diluents are maintained at +2 to +8°C, same as the vaccine before reconstitution,
- The reconstituted vaccines are discarded within 6 hours of reconstitution (4 hours in case of India) or at the end of each immunization session, which ever comes first.
- The MDVP is implemented correctly. (MDVP is currently not implemented in India)
- A vaccine wastage monitoring system should be in place:
- Reporting forms are used to monitor vaccine wastage,
- Wastage data can be used to make necessary corrections when re-ordering vaccines. The information can be used to reduce wastage in future,
- Is regular supportive supervision exist,
- There must be an effective system for disposal of used sharps and vials.

Findings

Vaccine Store	Region	District	PHC
Performance Score	47%	48%	66%

The consolidated scores indicate weak performance of this criteria at all levels.

The strengths that contribute to the performance indicated above are:

- The Regional Vaccine stores staff have good knowledgeable of shake test (except RVS-Vadodara), although there is no instance when it has been implemented.
- Most of the staff at all levels, are familiar with VVM and make use of its status as a management tool to override EEFO.
- The freeze dried vaccines and their corresponding diluents are correctly ordered, received, stored and distributed.
- The vaccines are always distributed / used with their corresponding diluents at most levels
- Diluents are maintained at 2-8°C, same as the vaccines before reconstitution as per the SoP.
- Needle cutters are in used at each PHC level and are in proper working condition. They are also used at the outreach session.
- Reconstituted vials are discarded within four hours of its use or at the end of the session whatever is earlier as per the GoI guideline (exception PHC-Kadva).
- The wastage due to expiry or due to heat damage (VVM stage 3) seems to be low. As such there are no records for such wastage. However, there are some exceptions (as mentioned earlier): At Surat DVS the vaccine wastage recording system is implemented , however wastage rate for any vaccine is not recorded nor used for improving the vaccine forecast, not even at SuraT.
- At most PHCS biomedical waste is collected by contracted agencies (e .g. Bhavnagar- by IMA) or discarded in a local waste disposal pit e.g. Versola, Sinhuj .

The weaknesses that need to be addressed are:

- Saline or distilled is in some places as couple of instances were recorded where the diluents supplied by a different manufacturer than that of the vaccine manufacturer.
- Knowledge on implementation of Shake test was poor at DVS level. In particular, the staff at DVS - Bhavnagar, Rajkot, Palanpur, Surat, Gandhinagar don't know when to conduct the shake test. Suspected DTP vaccines at Palanpur were tested by RCHO using shake test before six month and the test was negative.
- At some PHCs (eg. Chorda and Vejpur) staff had poor knowledge of VVM. Job-aids on VVM were missing.
- There is short Supply of the VVM poster at most of the stores and PHCs.
- One of the key area of concern is the rather poor supervision at most levels:
    - At the Regional level, the post of Asst Director Public Health (ADPH) is vacant and designated supervisors are not knowledgeable on aspects of supervision in detail. This leads to poor performance of practices at regional level.
    - Particularly at District vaccine stores (e.g. DVS kheda, Dharan, Rajkot, Bhavnagar, Amreli) and health facilities.
- There is no documentary evidences of any supportive supervision at any level.
- Only limited number of staff understand wastage properly. A vaccine wastage monitoring system is not in place at present.
- A formal system to record the wastage is lacking at most stores, the available information at some store is insufficient to make necessary corrections when reordering the vaccines
- Store managers are lacking with the tools, formats and data to assess wastage and integrate improvement in the system to reduce wastage in future.
- Opened or damaged vials are not disposed as per the CPCB (Central pollution control board immunization waste control guidelines) in 10 out of 31 health facilities visited during the assessment. At Vasai and Madanaghad, pits do not exit and the waste is thrown in the open.

Multi Dose Vial Policy

As the govt. of India has not adopted this policy, this issue is scored as non-applicable, this criteria is not assessed during assessment.

Vaccine wastage control

- Its observed that, proper disinfection of used syringes before disposal is practiced at most PHCs .

6.9 MIS AND SUPPORTIVE MANAGEMENT FUNCTIONS

This criterion is essentially applicable at the Primary (National or State) level. Only 4 out of 18 questions apply at the RVS and DVS level. It is not applicable and therefore not scored for the health facility level, although it is marked as 0 in the spider graph.

The aspects evaluated here are:

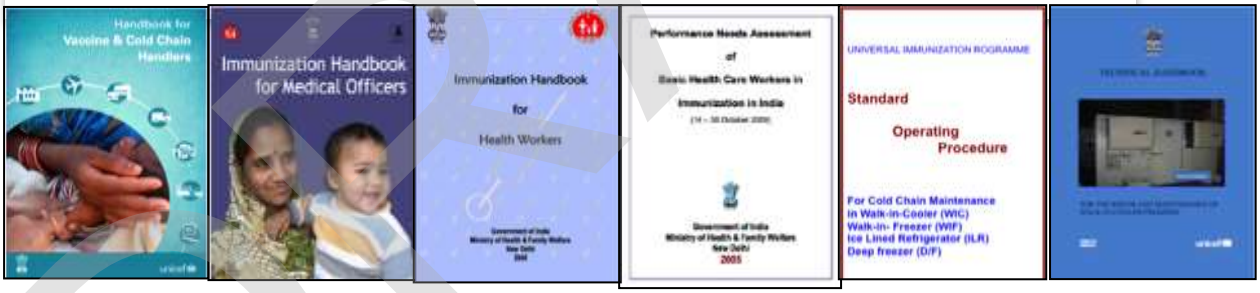
- Standard Operating Procedures are in place,
- Field data is collected and the same are used for programme management purpose,
- An annual work plan is in place,
- Out-sourced services are fully funded and resourced.

Findings

Vaccine Store	Region	District	PHC
Performance Score	**11%**	**19%**	**32%**

The MoH&FW of GoI has developed several manuals, which form part of the teaching aids, guidelines and Standard Operating Procedures. These are supplied to the states for further distribution and use at respective levels. Some of the important documents directly related to or covering the Vaccine and Cold Chain Management are:

1. Handbook of Cold chain and vaccine handlers.
2. Immunization Handbook for Medical Officers and Health Workers and
3. Several other technical manuals.



These are updated, reprinted and distributed as and when the need is identified by the GoI, and all the states benefit by this.

The MoHFW has also initiated the National Rural Health Mission (NRHM) in 2005. Every year the State Govt. prepares a work plan and budget in Part C of the Programme Implementation Plan (PIP) for the implementation of the upcoming year's immunization programme. The plan contains the line items that cover all the salient aspects of the programme

Certain number of guidelines and checklists are also available for supportive supervision.

Gujarat has translated the new "Handbook for Vaccine and Cold Chain Handlers" in Gujarati. It has also conducted the training on cold chain and vaccine handling, and immunization. Related manuals for reference are provided to all staff workers.

The state does not outsource any of the services to external parties.

The forecast of vaccine at the state level is based on the total and target population obtained from the recent census and using the standard method. However, the wastage rate is not evidence based and coverage is assumed 100% for all antigens. The same process is used at

Regional and District level, though in many cases the new census results are yet to replace the old extrapolated figures.

A few other areas that require improvements are :

- Many of the vaccine stores do not have a copy of the important documented material for quick reference.
- Staff do not make adequate use of SoPs
- Supportive supervision is not carried out as it should.
- The senior staffs do not make use of the supervisory checklists.
- As wastage records do not exist, the annual vaccine forecast is made based on estimated values.
- The inventory of the cold chain equipment is available only for some regions. The complete inventory lists only the total number of ILRs and DF without details of make or model making analysis of capacity difficult.

7 RECOMMENDATIONS

The 9 indicators of EVM contain questions that can be divided into 7 management implementation categories to define the achievements and derive actions required. The table below provides the corresponding consolidated scores for these categories for the different levels along with the average of the RVSs, DVSs and PHCs in the right most column.

The font styles used in the earlier table has also been used here to **highlight the strengths (in green bold)** or the **need for rapid intervention (red bold).**

#	Category		Consolidated scores			
		1 SVS	6 RVS	13 DVS	26 PHCs	Average
1	Building	60%	66%	64%	82%	71%
2	Capacity	24%	72%	58%	94%	75%
3	Equipment	24%	71%	54%	88%	71%
4	Management	22%	38%	40%	55%	44%
5	Repair & Maintenance	64%	63%	56%	58%	59%
6	Training	88%	86%	86%	79%	84%
7	Vehicles	100%	56%	69%	NA	63%

These scores are represented in the graphs below for the respective levels.

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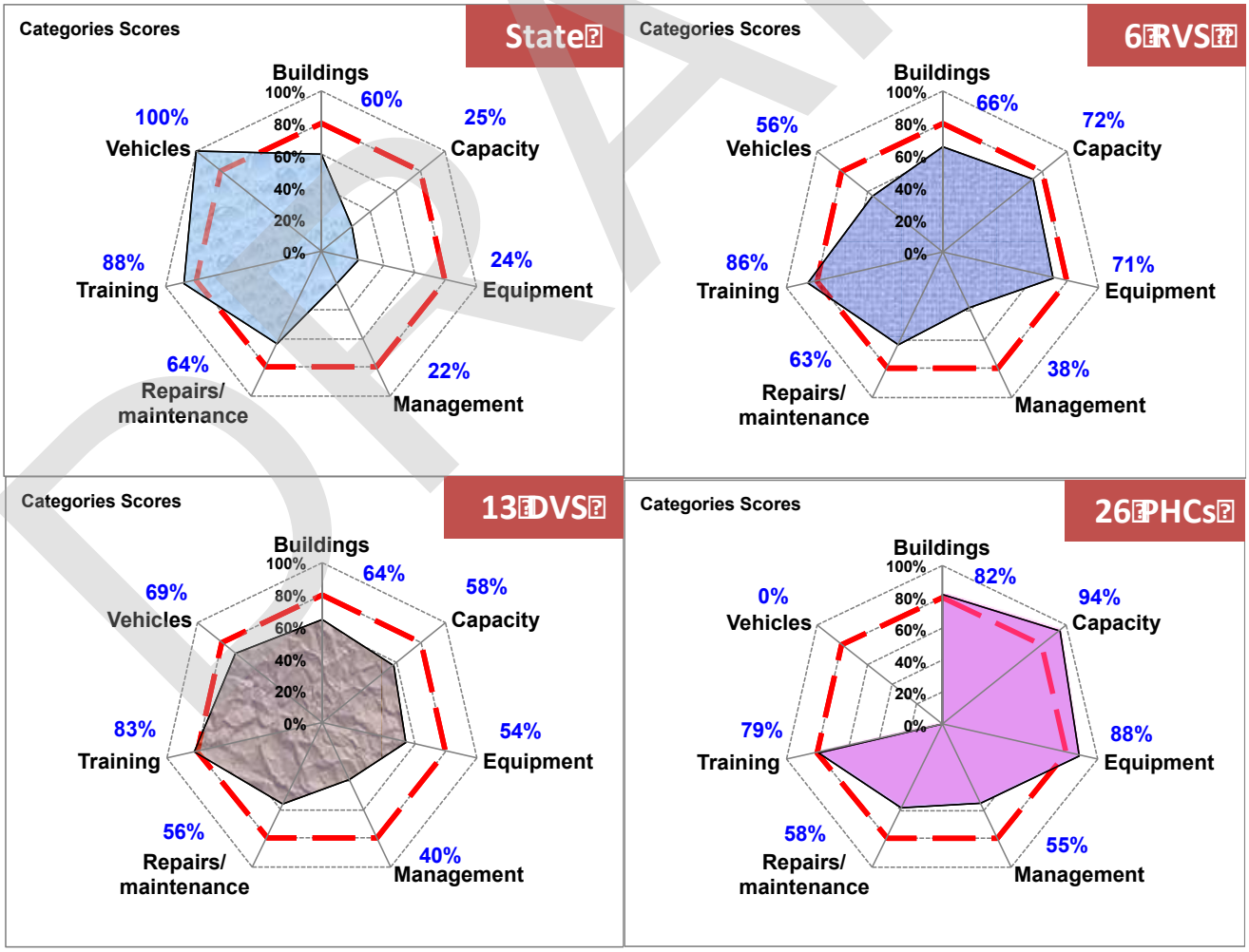

The scores at the different level indicates that training is a good strength at all levels – reflecting

the achievement from the efforts of the last 2 years by the MoHFW in conducting several training programmes in cold chain and vaccine handling and immunization.

The scores at the different level indicate that training is a good strength at all levels – reflecting the achievement from the efforts of the last 2 years by the MoHFW. Building, equipment and storage capacity at PHCs are in good condition.

On the other hand the table above and the graphs show that management aspects of different activities, including supportive supervision in all aspects covered under the 9 indicators, is a rather weak component at all levels. This leads to the loss of performance in different aspects of the indicators mentioned earlier. Maintenance and repair is another weak component across the levels. Building, equipment and transport vehicles are areas that require attention at upper levels. At district level there is a need for intervention in most of the categories.

In the following section specific recommendations to improve the performance of the indicators are provided.

Based on the indicators requiring intervention the recommendations are provided according to the implementation categories. The priorities are indicated as follows:

1. Immediate - Urgent, as soon as possible, but no later than 1 month
2. Intermediate - Within the next 3 to 6 months
3. Long term – within the next 12 months
4. Future – within the next 2 to 3 years

It is hoped that these categorised recommendations will be helpful to draw up an action plan and a road map by the respective authorities to rapidly implement the corrective actions.

Category	Priority	Level	Action required
Human Resource	1	Commissionerate	All cold chain technicians designated to districts must be stationed at respective district head quarters.
	2	Commissionerate	Fill the post of Cold Chain Officer at state level to manage the cold chain inventory and the cold chain technicians. Preferably, select a manager with an engineering profile, having experience in refrigeration. Fill the vacant position of Assistant Director (PH) at every region. Appointed AD(PH) at regional level should be given responsibility of supervision of Regional vaccine store.
	3	Commissionerate	Appoint one state vaccine logistic manager who will coordinate with regional level / district level to ensure efficient vaccine supply with zero stock-outs.
	2	RDD RCHO	Outsource service to provide semi-skilled helpers round the clock at all RVSs, so as to ensure the safety of the vaccine and to help the pharmacist in his different duties. Outsource service to provide one semi-skilled helper according to the need at each DVS to support the pharmacist there.
Building	2	Commissionerate	Define the need for a state vaccine store and if required segregate Gandhinagar State vaccine store from the regional vaccine store in terms of space, equipment and staff.
	2 2 4	RCHO / RDD / Commissionerate	Evaluate condition of building and sufficiency of space at all Regional and district vaccine stores for equipment required for vaccine storage space, dry space, repair workshop and office space for the pharmacist. Ensure availability of the same through management of space – especially disposal of unwanted materials. If required plan for a new building, with adequate space to ensure sufficiency of storage space for vaccines, diluents, syringes, repair workshop and office area. Define need based on population to be served. Use the IPHS guidelines and prototype of Orissa for designing the store.
	2	RCHO / MO	Ensure proper waste disposal through its collection by a contracted agency or build a waste disposal pit according to recommendation at every PHC.
Capacity	2	RDDs	At all regional stores: Plan adequate segregation of non-RI vaccines (ARV, ASV, Swine Flue) from RI vaccines, so as to ensure sufficient storage capacity for vaccine storage at –20 deg C & +2 to +8 deg C. This may require expansion of the vaccine store. Also ensure availability of sufficient dry storage for syringes, diluents, and cold boxes along with proper office space for the pharmacist and a repair workshop.

Category	Priority	Level	Action required
Capacity	2	RCHOs	At all district stores: Plan adequate space for placing equipment to ensure storage capacity of 3 months of working stocks of the vaccines along with 25% buffer stocks. Also ensure availability of sufficient dry storage for syringes, diluents, and cold boxes along with proper office space for the pharmacist and a repair workshop.
Equipment	1	CCO/RDD/ADPHO	Equip all walk-in-coolers and walk-in-freezers with continuous temperature recorders and acoustic alarms.
	2	Commissionerate	Contact GoI for rapid implementation of freeze indicators during storage and transport of freeze sensitive vaccines across the state.
	3	Commissionerate	Equip the state level and regional level vaccine stores with a computerised vaccine logistic management software (VLMS) to better manage the vaccine supply. Extend this facility to DVSs and then PHCs with time.
	3	Commissionerate	Procure and install a computerised temperature monitoring system for all WICs and WIFs with option of remote monitoring through internet.
Management	1	Commissionerate RDD / RCHO / MO	Request vaccine supply plan from MoHFW / GoI to enable preparation of vaccine distribution plan. Prepare vaccine distribution schedule in a systematic manner for each level.
	2	RDD / RCHO	Define bound vaccine registers in form of passbooks to record and monitor movement of vaccines at every vaccine store, in lieu of supply vouchers, as these get lost. Ensure availability of all standard documents and formats for proper record keeping at all levels. This includes temperature monitoring booklet with equipment maintenance log sheets, indenting and stock registers. Ensure contingency plans are defined for each store and staff is competent to implement them.
	2	RDD / RCHO	Ensure that Stock management is meticulously carried out. In particular: ➢ All salient aspects of vaccines and diluents are recorded. ➢ Maximum and minimum stocks are respected to ensure zero stock-out. ➢ Vaccines are packed correctly for transport using correctly conditioned ice-packs.
	2	Commissionerate / RDD / RCHO	Strengthen supportive supervision and ensure that all aspects of cold chain and vaccine management are implemented correctly ➢ All aspects of planning, implementation and record keeping are followed and non-standard practices (eg. use

Category	Priority	Level	Action required
Management			of non-conforming icepacks, foam boxes etc.) are not continued. ➢ Temperature records, stock records, indent registers, and passbooks are monitored to ensure compliance with SOP. Develop and distribute job aids for quick reference of important activities (eg. VVM, Shake test, handling of freeze sensitive vaccines, arranging vaccines in ILR).
	2 2	Commissionerate / RDD / RCHO RCHO / MO	Request GoI to provide vaccine supply plan well in advance, and ensure preparation of a supply plans at the RVS, DVS and PHC. At district level, ensure timely collection of vaccines from the regional store and distribution to PHCs is carried out according to a plan.
Repair & Maintenance	2	CCO / CCT	Equip the cold chain technicians with suitable tools and mode of transport for timely interventions. Plan and ensure implementation of periodic preventive maintenance of equipment by the technicians. A logbook for each equipment should be adequately maintained.
Training	1 2	Commissionerate / RCHO	Train all untrained staff in cold chain and vaccine handling Ensure that all new or rotated staff are always adequately trained before deputation to their new post. Preferably train 2 staff at every PHC. ➢ Specific areas to focus: are: Shake test, ice pack conditioning and proper indenting of vaccines. ➢ Train staffs on how to manage their resources effectively Ensure that all staff are provided with required SOPs and are using them.
	1	Commissionerate / RCHO	Use the skills of the trained RCHOs and RCSOs to orient all RCHOs and MO in good practices and supportive supervision.
	2	Commissionerate / CCO	Provide hands-on training to all cold chain technicians with specific emphasis on: ➢ Temperature profiling ➢ Temperature sensor calibration ➢ Trouble shooting and Good service practices for HFC units.
Vehicles	3	Commissionerate	Ensure that all vehicles have up to date logbook with information on regular servicing and repair.