Assessment of Effective Vaccine Management in Maharashtra

13 October to 3 November 2011

UNICEF, Delhi

TABLE OF CONTENT

Abbreviation and Glossary

°C	Degree Celsius
AD	Auto-disable (syringe)
AEFI	Adverse Event Following Immunization
ANM	Auxiliary Nurse Midwife
BCG	BacilliCalmette-Guérin (tuberculosis vaccine)
CC	Cold Chain
CC&VLM	Cold Chain and Vaccine Logistics Management
CES	
CFC	Chloro-fluoro-carbon (ozone depleting substance)
CHC	Community Health Centre
CI	Critical Indicator (in EVM)
CPCB	Central pollution control board
DF	Deep Freezer
DLHS	District Level House to House Survey
DPC	District Programme Coordinator (NRHM)
DRCHO	District Reproductive & Child Health Officer
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
GMSD	Government Medical Supply Depot
GoI	Government of India
GTN	Global Training Network (Now known as Global Learning Opportunities- GLO)
HepB	Hepatitis B vaccine
ILR	Ice-lined refrigerator
LD	Lowest delivery level store
MDVP	Multi Dose Vial Policy (currently partially 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
RM or RT	Refrigeration Mechanic / Refrigeration Technician
RVS	Regional vaccine store
SN	Sub-national store (zone, divisional or Regional store-RVS)
SEPIO	State EPI Officer
SOP	Standard Operating Procedure
SP	Service point (health facility)
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 Maharashtra

EXECUTIVE SUMMARY

BACKGROUND

The total population of Maharashtra, according to the recent census this year, is 11,23,72,972 with a sex ratio of 925 females to 1,000 males; 45.23% of which live in urban areas. The total area of Maharashtra measures 1,96,000 Sq. km, resulting in a population density of 365 person per sq. Km. The total immunization target group (infants less than 1 year) of the state is estimated to 19,81,346 with a birth rate of 17.6% per 1,000 population as per the Sample Registration System (2009) for Maharashtra.

According to the DLHS-3 (2007-08) the immunization coverage of fully immunized children was 69.1% and 2.5 % children had not received any vaccination. The BCG coverage was 95.7 % and the Measles coverage was 84.2%. The recent CES 2009 shows improvement in coverage of fully immunized children increased to 78.6% (as compared to average of 61% for entire India), and Measles coverage of 91.2%. The reported drop-out rate between BCG to DTP3 is 9.4%. (whereas India is 18%).

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 Maharashtra and supported by UNICEF - Maharashtra. 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 keeping in mind that the measles campaign is already implemented in the state.

ORGANIZATION OF IMMUNIZATION SERVICES

The state is administratively divided into 8 regions and further into 33 districts. In addition there are 23 municipal corporation (MC) For immunization, the districts cover a target group of 13,25,410 infants, while the municipal corporation caters to a target population of 6,55,936 infants corresponding to 24% of infants.

Most of the domestically manufactured vaccines are supplied to the Govt. Medical Store Depot (GMSD) from where it is supplied to 1 State Vaccine Store, 8 regional vaccine stores & to Bruhan Mumbai MC Vaccine Store which is covering a total population 140,98,743 (2,38,269 less than 1 year infants). During NIDs Polio Vaccine is directly supplied by Manufacturer to 5 Regional Stores viz Aurangabad, Pune, Nagpur, Thane & Mumbai.

The 8 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 23 Corporation stores which supply to the same to the urban health centres – catering to a total population of 3,83,23,758 (Immunization target group of 6,55,936 infants less than 1 year).

The syringes and needle cutters are not handled by the Regional stores. These are supplied

directly to the districts stores and Municipal corporation stores who distribute them to the service points.

Six new Walk-in Coolers & 2 Walk-in Freezers have been installed recently to enhance the regional vaccine storage capacity 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**
- **Major performance gaps**
- **Resource and Training needs**

Based on these findings, provide recommendations to prepare a road map for strengthening Cold chain and vaccine management, through addressing the different management aspects.

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 focused 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

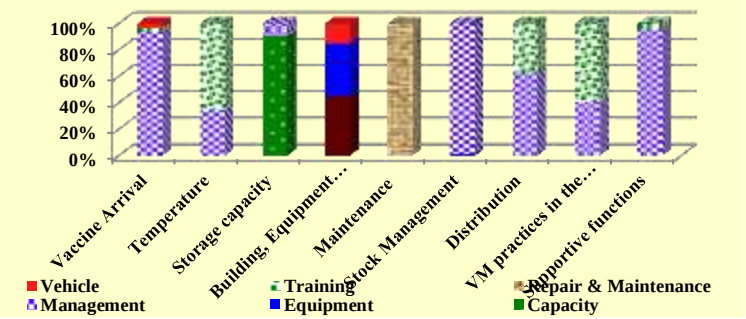
The questions under the 9 indicators can be divided into 7 management implementation categories: **Building, Storage Capacity, Equipment, Management issues, Repair and Maintenance, Training and Vehicles**. The radar graphs are also obtained under these categories.

The adjacent table below show the relation between criteria and categories.

The graph below reflects this in bar charts.

One can observe that most indicators

Category / Indicator / Criteria	Building	Capacity	Equipment	Management	Repair & Maintenance	Training	Vehicle
Vaccine Arrival				93%		3%	3%
Temperature				34%		66%	
Storage capacity		90%		10%			
Building, Equip. & Transport	45%		40%				15%
Maintenance					100%		
Stock Management			1%	99%			
Distribution				63%		38%	
VM practices				41%		59%	
Supportive functions				96%		4%	



contain components of management and training.

Based on the detailed score of the indicators and categories, targeted actions can be 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**".

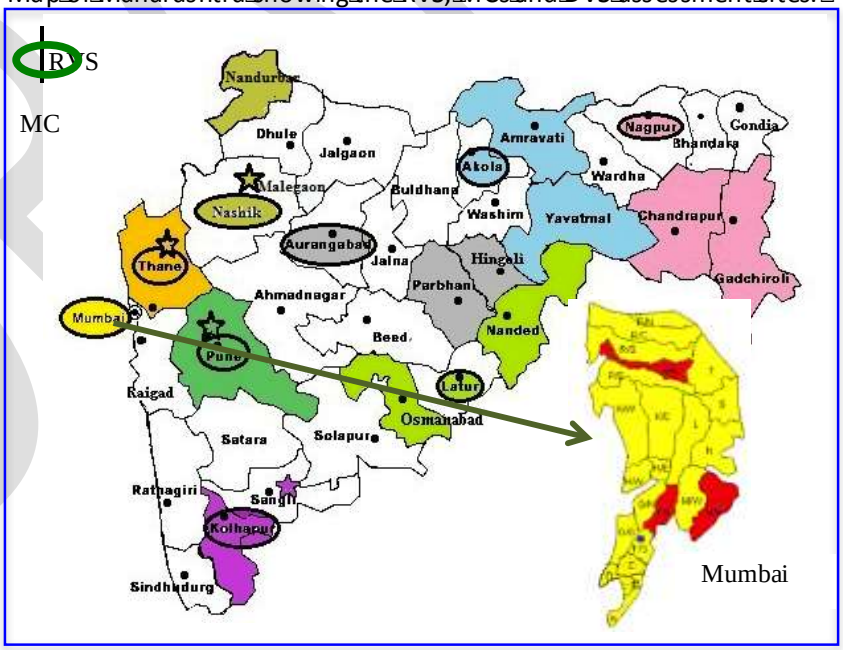
Several additional complementary activities, many in form of capacity building, are integrated into the assessment mission.

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 28 participants were inducted in the use of EVM tool through a 5 day capacity building programme from 13 to 17 October 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 7 days field assessment from 18 to 24 October. The assessment sites were identified using the random Site-Selection Tool using 85% confidence level and 15% precision. A total of 8 Regional vaccine stores (RVS) belonging to the 8 circles and 12 District vaccine stores (DVS)were selected. The selection of the districts include 3 of the 5 UNICEF focus districts, and 4 of the 6 NRHM focus district. In addition, 25 health facilities (PHCs) were selected under these 12 Districts using the sampling tool. The state store at Pune was also included in the assessment.

Map of Maharashtra showing the RVS, MCs and DVS assessment sites.



Note that the selection also included 4 Municipal Corporation (MC) stores in 4 circles and the MC of Br. Mumbai. A total of 12Urbanhealth posts, 4 of which are under the Br. Mumbai MC were also selected using the tool.

The assessment was conducted by 9 teams comprising of one medical officer (DRCHO or UNICEF consultant), one vaccine store pharmacist (belonging to the circle's vaccine store) and one technician. Each team covered one circle, and assessed the circle RVS, 2 DVS or 1 DVS and 1 MC and 4 PHCs or 2 PHCs and 2 UC respectively, as selected within the circle. 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 hands-on in assessment, verification of collected data and also to carry out their

own observations.

Following the assessment, the data was verified, validated, and consolidated. These were then analysed with the help of selected team members. The team members then developed their own practicable recommendations, based on the national guidelines, 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.

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

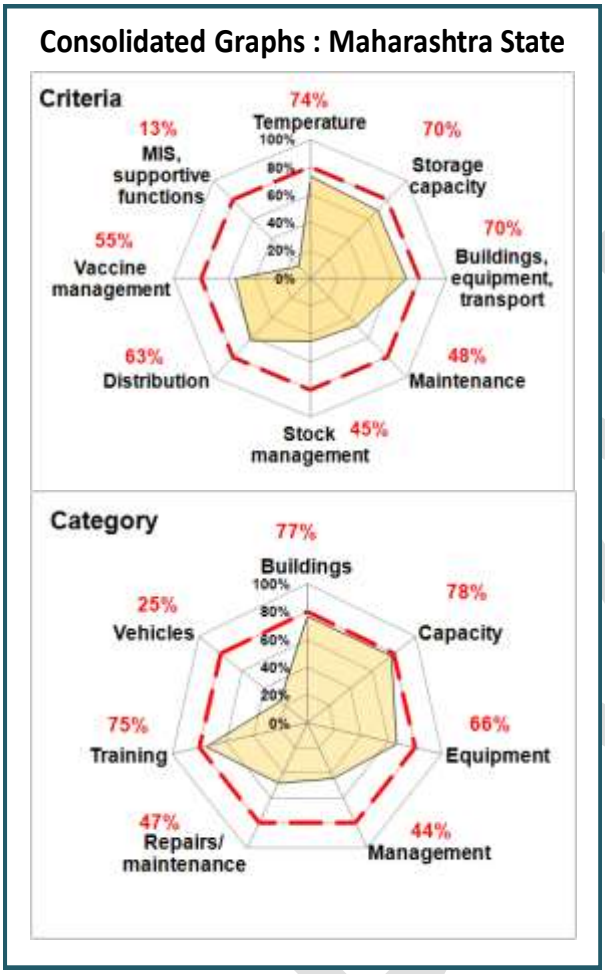
Summary of consolidated EVM indicator score

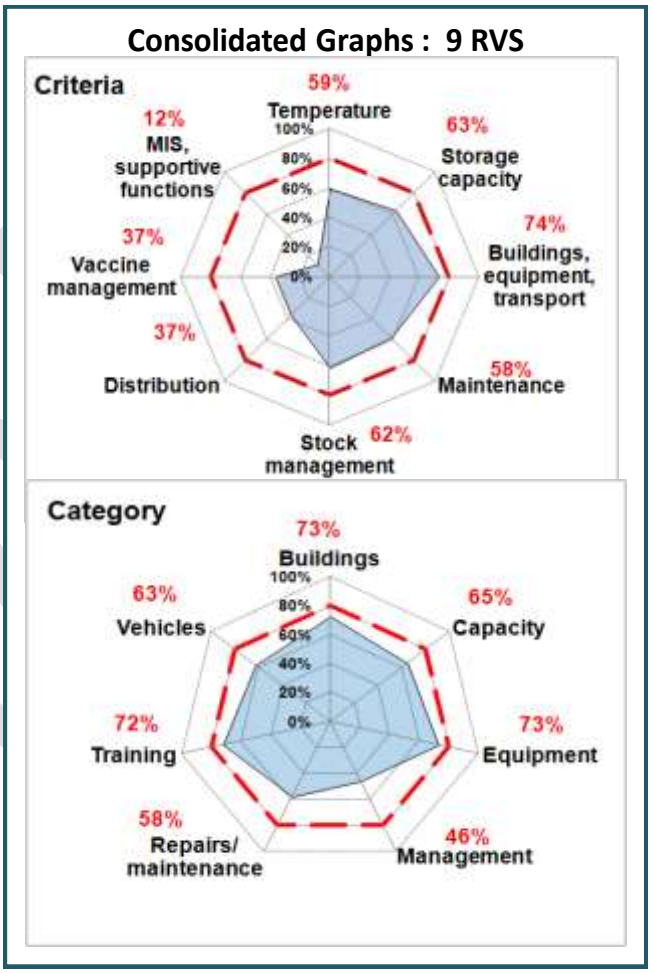
#	Indicator / Criteria	Consolidated Scores				
		State	1 SVS	9 RVS	12 DVS+ 4 MC+3 Wds	25 PHCs + 12 UHPs
1	Vaccine Arrival Process	19%	19%	NA	NA	NA
2	Vaccine Storage Temperature	74%	44%	59%	77%	76%
3	Storage Capacity	70%	78%	63%	54%	79%
4	Building, Cold Chain Equipment & Transport	71%	87%	74%	63%	73%
5	Maintenance of Building, Cold Chain & Transport	48%	45%	58%	56%	41%
6	Stock Management	46%	39%	62%	43%	42%
7	Distribution	63%	39%	37%	53%	74%
8	Vaccine Management Practices	56%	50%	37%	43%	66%
9	MIS & Supportive Functions	13%	38%	12%	19%	9%

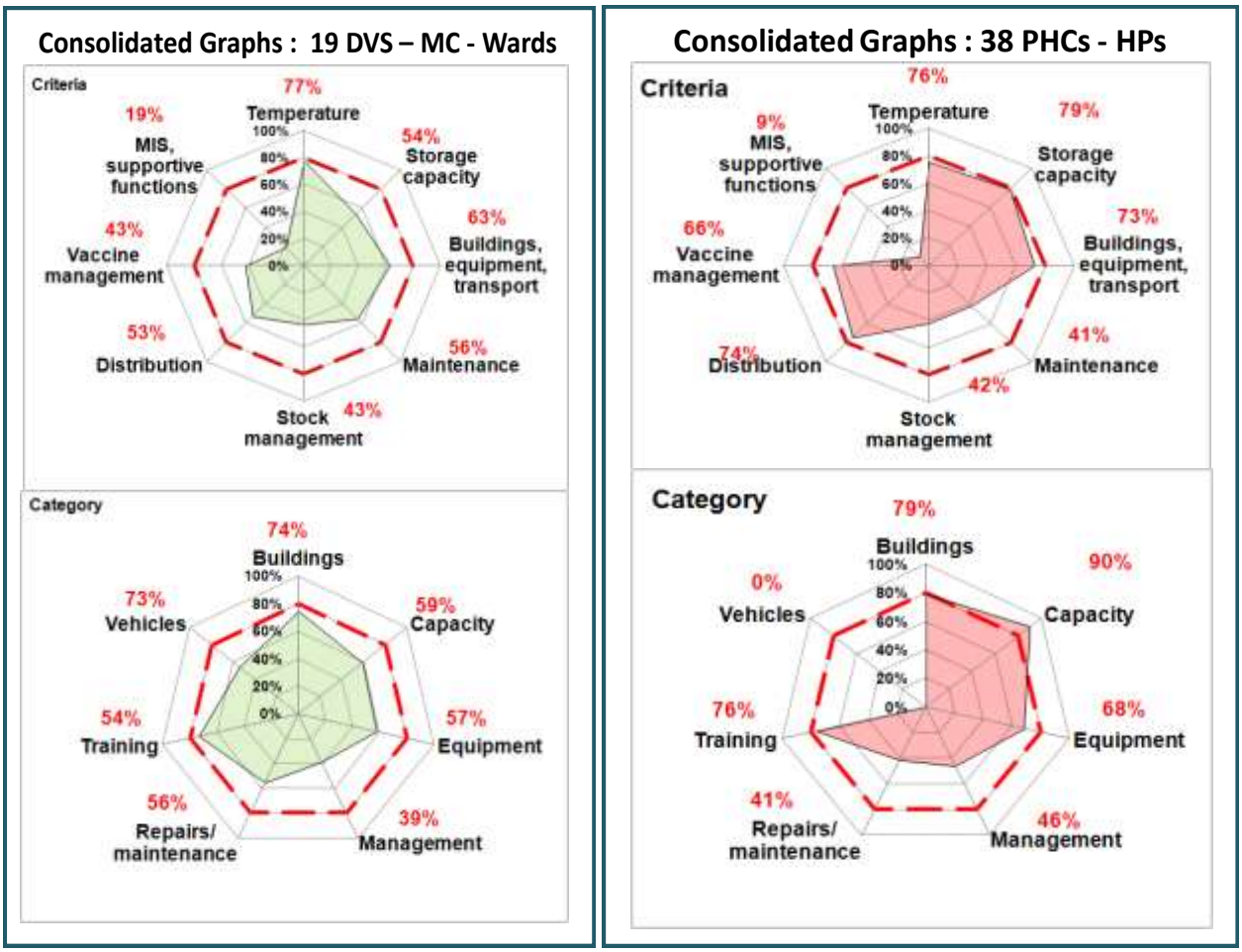
Summary of consolidated EVM category score

#	Indicator	Consolidated Scores			
		State	9 RVS	12 DVS+ 4 MC+3 Wds	25 PHCs + 13 UHPs
1	Building	78%	73%	74%	79%
2	Capacity	78%	65%	59%	90%
3	Equipment	67%	73%	57%	68%
4	Management	44%	46%	39%	46%
5	Repair & Maintenance	48%	58%	56%	41%
6	Training	75%	72%	73%	76%
7	Vehicles	25%	63%	54%	0%

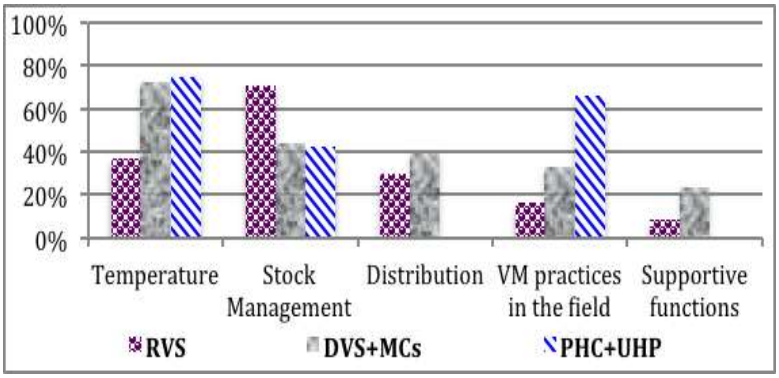
Spider charts of criteria and categories corresponding to the tables above.







The category graphs of all levels indicate that management scores are weakest at all levels. The adjacent bar graph depicts the performance of management components that are integrated in the different indicators for the three levels. The results show that management of different activities, including supportive supervision in all aspects, is a rather weak component at all levels, particularly at distribution and supportive functions. This leads to the loss of performance in indicators mentioned earlier.



Graph of performance of management components in the different indicators at different levels.

Maintenance and repair is another weak component across all the levels. Building, equipment and transport vehicles are areas that require attention at all levels.

In the spider graphs above, the areas covered by the polygons result form the achievements and strengths in the areas of the respective indicators.

Looking at the score table above, one can observe that only one score is above 90%. Some of the scores are 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 of the state also has only 3 of 9 indicators having scores above 70%, the rest are in the red zone. The salient strengths that help achieve the scores are listed below flowed by the areas of concern that require attention.

The associated strengths and good practices that can be enumerated are:

In terms of human resource and supportive management

1. The State has one Dy. Dir. Immun.
2. There is a post for State EPI Officer (currently in-charge).
3. There is one Cold Chain Officer.
4. Comprehensive work plan and budget are form the PIP part C.
5. State has conducted Cold Chain and Vaccine Handlers training.
6. Directives have been provided through letter dated 18 Sept. 09. (ref no 212/40973-113/09)

In the area of cold chain and vaccine management:

1. All store keepers at RVS are Pharmacists
2. All RVS staff have good knowledge about storage temperature and freeze sensitiveness of vaccines.
3. Manual temperature recording are available at all RVS and at MC of Br. Mumbai. At Mc-Br. Mumbai, it is recorded every hour by 3 staff in rotation., 24 hors on 24.
4. At RVS Latur and Br. Mumbai there is good continuous temperature recording and manual temp records are matching with them.
5. All RVS except Latur have a vaccine van.
6. PHC Para has good performance due to supportive supervision
7. Latur WIC is working well.
8. Excellent monthly preventive maintenance and log book of the outsources service for WIC at MC-Br. Mumbai
9. Nagpur has model stock register.
10. RVS Kolaphur, Thane and Nagpur stock records of vaccines and diluents are updated within 24 hrs.
11. Diluents recorded on arrival at most stores
12. Physical count of vaccines stock match with stock records at RVS Latur, Pune, Nagpur, Kolaphur, Aurangabad. Same also at several DVS (Parbhani, Hingoli,Thane, Kolphur, Gadchiroli, Nanded).
13. Diluent stocks match with Measles vaccines at all RVS and DVS-Thane Kolhapur, Gadchiroli and Nanded.
14. Good warehouse practice at most RVS, DVS and PHCs.
15. Supply vouchers in form of registers with 3 copies are available and used by many RVS and DVS.
16. Most staff are aware of EEFO and use of VVM to override EEFO.
17. Nanded DVS has a very effective distribution plan which is implemented. RVS Akola and DV, Hingoli, and Pune also have distribution plans.
18. All RVS staff know proper ice pack conditioning.
19. Freeze indicators are implemented at DVS Nanded but staff need induction on its proper usage.
20. At Br. Mumbai health posts, the master register also has vaccine labels stuck to it at the end of the day .
21. SOPs exist and most places have the Vaccine handlers hand book and RI training Modules.
22. 200 PHCs in tribal areas are equipped with solar or inverter/ Battery backup, some power one fan and one light in each room.

Key areas that need improvements are:

In terms of human resource and supportive management

1. Several post of medical officers responsible for immunization are vacant:
    a. Asst. Dir. HS posts are not all filled
    b. 13 posted of DRCHOs are vacant
    c. 2 DHO posts are vacant
    d. 19 out of 21 posts of ADHO are vacant , There is no medical authority in Vashim District
2. Every district does not have designated refrigeration technician.
3. Pharmacists are not posted at all DVS for vaccine handling .
4. No helpers are provided to vaccine store keepers at RVS and DVS.
5. Staff carry out required communication using personal resources.
6. Funds for emergency repair of vehicle have been missing.
7. CPCB Guidelines for proper disposal of bio-medical waste available are circulated on 6th December 2004 .

Several of these issues were addressed in the directives given in the letter dated 18 Sept. 09. (ref no 212/40973-113/09)

In the area of cold chain and vaccine management:

1. There has not been any temperature profiling of any WICs and technical staff do are not knowledgeable of thermometer calibration process.
2. Most RVS (7 in all) do not have continuous temperature recording.
3. Manual temperature recording at state level is totally absent.
4. Manual recording at many DVS and PHCs are not carried out using standard record booklet, and there is no recording on holidays and Sundays.
5. Supervision of records is carried out without much attention to what is noted.
6. Vaccine storage space is limited at most DVS, MC and Wards for 2 to 8C, and at -20°C at two

regional stores (Thane, Aurangabad).
7. Large stocks of ARV stored alongside RI vaccines
8. Several stores lack sufficient cold boxes and Ice pack.
9. Emergency Contingency plans not existing anywhere.
10. Staff have limited knowledge on how to handle emergency
11. Several MC vaccine stores are on upper floors with inadequate and insufficient working space (MC -Br. Mumbai, Wards, MC-Pune).
12. Lack of any maintenance of buildings at several stores.
13. New installation of WIC and WIF are sub-standard, the units are not into fully in operation for the benefit of the programme, though installation has been completed several months ago.
14. There are no records of maintenance of equipment (except at MC - Br. Mumbai).
15. Supervision and management of cold chain technicians is unclear between CCO and HEMR / SHTO – resulting in weak maintenance in the whole state.
16. Breakdown of vehicle at Akola delayed vaccine distribution by 15 days - leading to stock-outs at several levels in the circle.
17. Several condemned equipment awaiting disposal (Br. Mumbai). Some beyond repair equipment are awaiting condemnation as well (Stabilizers at Pune).
18. There is rampant use of non-standard thermocol boxes for vaccine transport.
19. There are no records of diluents or status of VVM in stock registers. The format lacks rows for these in the stock register or issue vouchers.
20. Stock books are missing at Nandurbar, Gadchorli DVS and very poor at several PHCS (eg. Nimgaon, Shembal pimpiri).
21. Stock books at most vaccines stores are not updated on time. At upper stores (SVS, RVS, DVS) this leads to short supply due to lack of complete stock information during deliveries.
22. Practice of maximum stock and buffer stock level is not practiced by most of the staff almost at all levels.
23. Mismatch of vaccine and its diluents (measles at RVS-Nasik, BCG at DVS Osmanadabad)
24. Supplies are not as per indenting: there is a tendency to demand more, and short shipment is a general tendency.
25. There is no standard Vaccine Indenting format.
26. Supply schedule is missing at most RVS and DVS. The practice of upper store distributing to lower stores is not followed.
27. Supply details are at times provided on a blank sheet instead of using a standard format Receipt vouchers are not returned to the supply store for several months
28. Non RI drugs (insulin) and returned open vials observed in cold chain at PHC level.
29. Staff handling vaccines at most PHCs do not know proper IP conditioning.
30. Staff at most stores have poor knowledge of shake test.
31. Poor Management of waste disposal at several locations (except at MC Pune and PHC Jiwati).
32. Syringe disposal pits constructed at many PHCs are not as per the CPCB guidelines and are not used by the staff
33. There is no recording system for damaged or wasted vaccine.
34. Supportive supervision is poor at all levels and stores with very few exceptions.
35. MC- Malegaon is in a rather poor condition:
    1. Condemned items cluttering usable space
    2. Vaccine not stored in cold chain
    3. No temperature records
    4. Stock records not maintained.

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

SUMMARY OF KEY RECOMMENDATIONS

The key recommendations are provided according to the implementation categories to improve the performance of the indicators. Stress is needed in the area of management aspects as evident from the above discussion. The priorities are indicated as follows:

1: Immediate- Urgent, as soon as possible (within 1month)

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

In additional recommendations for human resource is also included, as this a key component of an efficient supply chain. The suggestion is that supervision of the activity be carrier out by the staff as given in the table below for the respective level. More over the staff will reprot to the officer responsible for the full RI. And each officer responsible for the full RI will reprot to the one having this responsibility at the upper level.

List of supervising staff at different levels and activities			
Level	Full RI Responsibility	Vaccine Management	Cold Chain
State	State EPI Officer	State Vaccine Logistic Manager	SCCO
Regional	ADHS	CC & VM Coordinator	
District	DRCHO / DIO		
Health Facility	MO		

List of key recommendations classified in terms of implementation categories and priority

Category	Priority	To be implemented by at respective levels	Action required
Human Resource and Policy	1	ACS / Directorate	➢ Ensure that the state has a dynamic and proactive State Immunization Officer
	1	ACS / Directorate	➢ Ensure that the state has a competent State Cold Chain Officer ➢ The State Cold Chain Officer should have a profile of a manager who also understands certain technical aspects of refrigeration. He should manage the cold chain inventory and the cold chain technicians' operations with the help of divisional level cold chain coordinators / HEMR technicians.
	2	ACS / Directorate	➢ Appointment of one State Vaccine Logistic Manager who will report to the State Immunization Officer. He will oversee and manage the vaccine stocks at all levels to ensure that stock-outs incidents are reduced to nil. He will coordinate at regional level with the regional level cold chain coordinators or store managers for this.
	2	ACS / Directorate	➢ Appoint one cold chain and vaccine logistic coordinator at the regional level who will ensure proper supply to and from the regional stores and supervise the repair

Category	Priority	To be implemented by at respective levels	Action required
			and maintenance by the cold chain technicians. He will report to the state vaccine logistic manager on vaccine issues and to the cold chain officer for cold chain and technician related issued. ➢ Alternatively, the task of supervising the district cold chain technicians can be given to the senior cold chain technicians of the HEMR unit stationed at each circle
	2	ACS / Directorate	➢ Appoint a dedicated person to oversee the Cold Chain and Vaccine Management at RVS level (eg. Asst. Dir. of HS - Public Health). He should also supervise the Regional cold chain and vaccine logistic coordinator.
	2	ACS / Directorate/ SEPIO ACS / Directorate / RDD / DRCHO	➢ At the State and Regional vaccine store it is important to have round the clock monitoring as in Br. Mumbai. Vaccines worth more than 2 crore Rs. may be present in SVS and more than 40 Lacs at each SVS. Adequate number of semi skilled helpers or funds to engage them on contract are required at SVS and RVS (round the clock) and ➢ Ensure one helper at each DVSs (Vaccine worth 3 to 10 lacs are handled at the DVS).
	2	ACS/Directorate /ADHS	➢ Support revamping and upgrading of MC-Malegaon to make it a model MC-vaccine store
	2	ACS / Directorate/ SEPIO / ADHS / DRCHOs	➢ Ensure that all staff handling vaccines at SVS, RVS and DVS are pharmacists, and have been trained in vaccine logistic management.
	3	ACS / Directorate	➢ Strengthen staffing by ensuring that all vacant posts at all levels are filled by staff with the right profile (DRCHOs, Pharmacist, Cold chain technicians etc).
Building	2	MOs/ DRCHOs	➢ Make immunization disposal pit as per guidelines wherever not appropriate or non-existent.
	3	ACS / Directorate/ MCs	➢ Move all MC vaccine stores that are on upper floors to ground floor or in the last resort to the 1st floor. Same applies to other stores if located on upper floors ➢ Every vaccine store MUST have dedicated room with adequately ventilated space for equipment, dry space, staff office, working space, and repair space (at DVS and MC).
	3	DRCHOs / ADHS	➢ Evaluate condition of building and sufficiency of space at all District vaccine stores according to the recommended norms for equipment required for vaccine storage space, dry space, repair workshop and office space for the pharmacist. ➢ Explore availability of the same through management of space – especially by disposal of unwanted materials. a. If the space required in insufficient then plan for a new building, with adequate space to ensure sufficiency of storage space for vaccines (placing of required equipment), diluents, syringes, repair workshop and office area. Define the need based on population to be served.

Category	Priority	To be implemented by at respective levels	Action required
			➢ Develop and adopt state specific model for RVS and DVS based on IPHS recommendations and prototype from Orissa for designing the store.
Equipment	1	ACS / Directorate/ SCCO / HEMR	➢ Ensure completion of installation of all newly installed WICs and WIFs as per standard. Ensure the same are handed over with submission of completion and commissioning report. ➢ It is advisable, considering the poor quality of installation, that a third party verifies the commissioning reports and installations.
	2	ACS / Directorate	➢ A real time computerized Vaccine Logistic Supply Management system (VLSM) should be implemented in the state at all levels. Orissa has a working programme.
	2	SCCO / ADHS	➢ Ensure that all WIC and WIF have continuous temperature recorders and recording is carried out in a continuous manner.
	2	SCCO / ADHS	➢ Ensure that all WICs / WIFs are equipped with working hooters.
Capacity	1	SCCO / ADHS	➢ Ensure sufficiency of freezing space at all RVS by providing additional DFs.
	1	SCCO / DRCHO	➢ Strengthen storage capacity at all DVS by providing required additional cold chain equipment. Important to take into account net storage space based on 3 months of vaccines requirement as per GoI guidelines. Ensure that adequate and suitable floor space is made available for the same.
Management	1	ACS / Directorate / SEPIO	➢ Implement directives of 18 Sept 2009 letter.
	1	SEPIO / ADHS / DRCHO	➢ All transport of vaccines MUST be carried out using standard containers and according to the SOP. a. Thermocol boxes must not be used b. Non-standard ice packs and gel packs must not be used ➢ Proper ice pack condition is carried out .
	1	SEPIO / ADHS / DRCHO	➢ Segregate the non-RI drugs from RI vaccines at all levels.
	1	SEPIO / ADHS / DRCHO / MO	➢ Provide sufficient attention to safety issues (recharged fire extinguishers,
	1	ADHS / DRCHO	➢ Contingency funds MUST be available to ensure timely repair of all vehicles Ensure staff know how to handle different types of emergencies
	2	SEPIO / ADHS / DRCHO	➢ Prepare contingency plans required for each store and ensure that staff is competent to implement them.
	2	ACS / Directorate/ RDD / RCHO	➢ Strengthen supportive supervision and ensure that all aspects of cold chain and vaccine management are implemented correctly a. All aspects of planning, implementation and record keeping are followed and non-standard practices (eg. use of non-conforming icepacks, foam boxes etc.) are not

Category	Priority	To be implemented by at respective levels	Action required
			continued. b. Temperature records, stock records, indent registers, and passbooks are monitored to ensure compliance with SOP. ➢ Ensure that stock management is carried out correctly b. a. All salient aspects of vaccines and diluents are recorded. c. Maximum and minimum stocks are respected to ensure zero stock-out. d. Indents are based on peak stock calculations and balance in hand, e. Timely indents are made on reaching minimum stock and emergency indent is made on breaching buffer stocks. ➢ 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	SEPIO / ADHS / DRCHO / MO	➢ Improve proper stock management and distribution of vaccines with its diluents. Diluents details should be recorded in the same manner as vaccines.
	2	ADHS / DRCHO	➢ Fund allocation for van drivers for telecommunication during transport of vaccines
Training	2	ACS / Directorate	➢ Supervising staff requires orientation in CC & VLM and its supportive supervision. Conduct required capacity building workshops with hands on practical exercises.
Vehicle	3	SCCO / ADHS / DRCHO	➢ Vaccine vans required at RVS-Latur and 8 DVS for distribution of vaccines

1 INTRODUCTION

BACKGROUND

The total population of Maharashtra, according to the recent census this year, is 11,23,72,972 with a sex ratio of 925 females to 1,000 males; 45.23% of which live in urban areas. The total area of Maharashtra measures 1,96,000 Sq. km, resulting in a population density of 365 person per sq. Km. The total immunization target group (infants less than 1 year) of the state is estimated to 19,81,346 with a birth rate of 17.6% per 1,000 population as per the Sample Registration System (2009) for Maharashtra.

According to the DLHS-3 (2007-08) the immunization coverage of fully immunized children was 59.1 % and 2.5 % children had not received any vaccination. The BCG coverage was 95.7 % and the Measles coverage was 84.5 %. The recent CES 2009 shows improvement in coverage of fully immunized children increased to 61 % (with matches the average for entire India), and Measles coverage of 74.1 %. The reported dropout rate (between BCG to DTP3) is 18 %.

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 Maharashtra and supported by UNICEF - Maharashtra. 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. The measles campaign is already implemented in the state.

ORGANIZATION OF IMMUNIZATION SERVICES

The state is administratively divided into 8 regions and further into 33 districts. In addition, there are 23 municipal corporations (MCs). For immunization, the districts cover a target group of 13,25,410 infants, while the municipal corporation caters to a target population of 6,55,936 infants corresponding to 24% of infants.

Most of the domestically manufactured vaccines are supplied to the Govt. Medical Store Depot (GMSD) from where it is supplied to 1 State Vaccine Store, 8 regional vaccine stores & to Bruhan Mumbai MC Vaccine Store which is covering a total population 140,98,743 (2,38,269 less than 1 year infants). During NIDs Polio Vaccine is directly supplied by Manufacturer to 5 Regional Stores viz Aurangabad, Pune, Nagpur, Thane & Mumbai.

The 8 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 23 Corporation stores which supply the same to the urban health centres – catering to a total population of 3,83,23,758 (Immunization target group of 6,55,936 infants less than 1 year).

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

Six new Walk-in Coolers (WICs) & 2 Walk-in Freezers (WIFs) have been installed during 2011 to

enhance the regional 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
- 3. Major performance gaps
- Major knowledge gaps
- 4. Resource & Training needs

Thereby, prepare a road map for strengthening cold chain and vaccine management and define management aspects that need strengthening

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.

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.

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

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: 1. buildings; 2. storage and transport capacity; 3. cold chain equipment; 4. vehicles; 5. repairs and maintenance; 6. training and 7. 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 Govt. Medical Supply Depots (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.

   This would correspond to the Divisional / Zonal / Regional Vaccine Store (RVS) of a state 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.

   The LLD would correspond to the District Vaccine Stores (DVSs), 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 points correspond to 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 is 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 largely applicable 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.

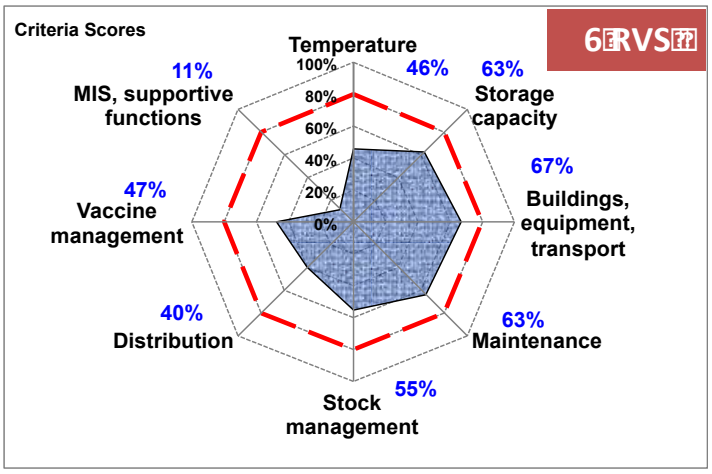
Compliance with the fundamental qualities of a good vaccine supply chain is tested using a series of tightly focused questions, which are numerically scored. It bases itself on the data and practices over the last 12 months.

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

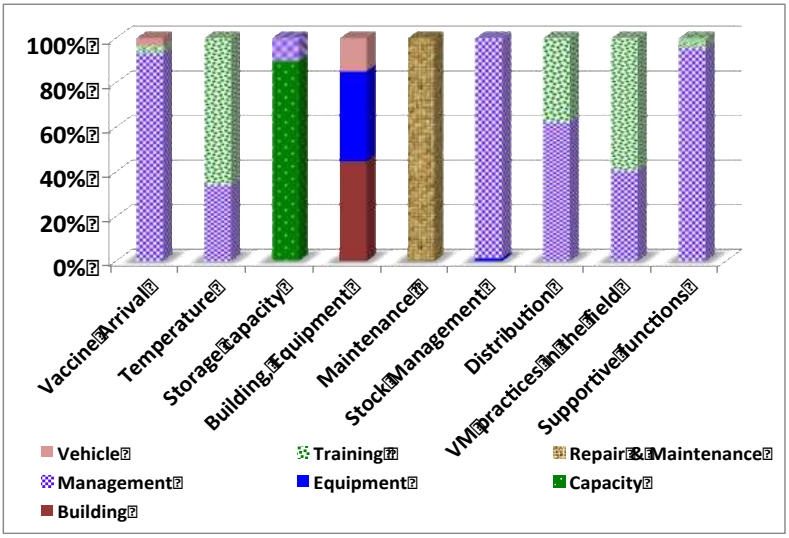
The questions under the 9 indicators can be divided into 7 management implementation categories: Building, Storage Capacity, Equipment, Management issues, Repair and Maintenance, Training and Vehicles.

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.

The adjacent table shows the relation between criteria and categories.

Category / Indicator / Criteria	Building	Capacity	Equipment	Management	Repair & Maintenance	Training	Vehicle
Vaccine Arrival				93%		3%	3%
Temperature				34%		66%	
Storage capacity		90%		10%			
Building, Equip. & Transport	45%		40%				15%
Maintenance					100%		
Stock Management			1%	99%			
Distribution				63%		38%	
VM practices				41%		59%	
Supportive functions				96%		4%	



The accompanying graph reflects this in bar charts.

One can observe that most indicators contain components of management and training.

Based on the detailed score of the indicators and categories, targeted actions can be 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 MISSION PLAN AND TIME FRAME

There are essentially 3 main phases in the EVM mission. The table below gives the time frame for the implementation of the different aspects of the EVM mission along with the involvement required by the different staff. .

Steps	Activity	work days	State Officials (SEPIO & CCO)	Team Leaders	Other Participants	Consultant Team
			Days	Days	Days	Days
1	Preparation for the EVM mission and sampling	5	3	0	0	4
2	**Phase 1** - EVM Training (Concept, principles of Cold chain and Vaccine management with actual field practice)	5	5	5	5	5
3	**Phase 2** - Field Assessment and data collection by teams	7	7	7	7	7
4	DATA compilation by the team	2	0	2	0	2

Steps	Activity	work days	State Officials (SEPIO & CCO)	Team Leaders	Other Participants	Consultant Team
			Days	Days	Days	Days
5	**Phase 3a** - Data validation & consolidation (Teams + Lead assessor + State Officer + Partners)	2	1	2	0	2
6	**Phase 3b** - Analysis of results and development of recommendations (Teams + Lead assessor + State Officer + Partners)	3	3	3	0	3
7	Review of recommendations and preparation for debriefing (presentation)	3	1	0	0	3
8	Preparation of Final report	5	0	0	0	5
9	Detailed work plan preparation(Director FW, NRHM and Partners,) for implementation of recommendations	1	1	1	0	0
	Total work days	**33**	**21**	**20**	**12**	**31**
10	Implementation of work plan gradually		On-going			

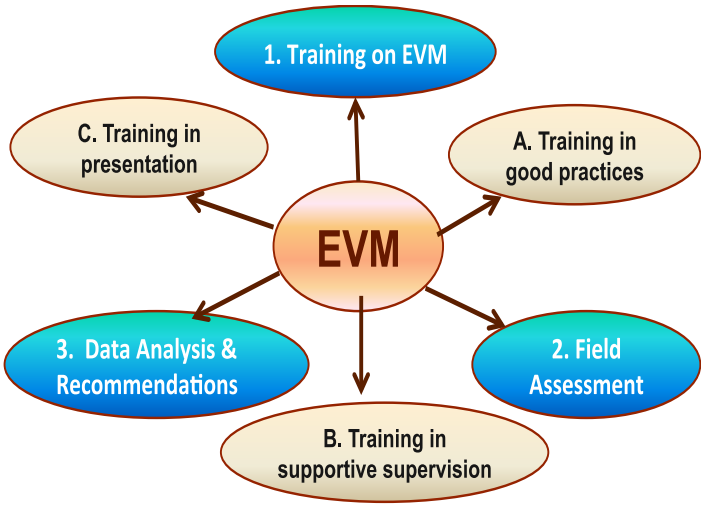
A follow-up EVM assessment should be carried out again after 1-2 years to define the effective progress.

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.

0The **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 DRCHO / DIO, the concerned staff is not knowledgeable about several aspects of

VM (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 misinformation and practices as well as provide additional updating of information, This is indicates as step **A- Training in good Practices.**

Hence, the phase A, consisting of 50 % 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 weeks assessment, and submitting a report, which is unlikely to receive any follow up.

The third phase (**3-Data Analysis and Recommendations**) 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 recommendations 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 finally c) help each of the participants to define an action plan for himself.

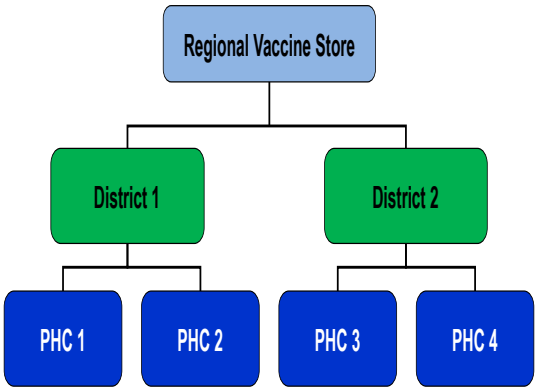
A further benefit that can be attempted is to involve the participants during the formal debriefing, where each team can present their findings, recommendations, supportive actions provided by them and finally their own action plan to all the others (**Step C – Training in Presentation Skills**). This 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), all 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 and 5 MCs from a total of 33 DVSs and 23 MCs in Maharashtra. The next step is to identify at least 2 health facilities under each of the selected DVS or MC. The actual results of the selection are discussed in the next section.

The team of participants and facilitators

5 IMPLEMENTATION

The proposed EVM mission plan is provided in Annexure A. It provides chronologically the different phases.

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 13 to 17 October 2011. The facilitation team consisted of 4 facilitators. In addition, the Sr. CMO from GMSD Kolkata joined for 2 days. Dr. Srihari Dutta, Immunization Specialist from UNICEF-ICO supported the mission as facilitator cum observer for couple of days. Annexure B gives the list of the participants that were selected by the MoHFW of the GoMH.

Annexure C gives a sample of the schedule of the induction programme for the first 2 days. A five-day schedule has a similar pattern. The programme began with a pre-course questionnaire to evaluate the knowledge level of the group. Three questions, which were considered not applicable, as the topics were not implemented in Maharashtra, were not considered in the total scoring. The results are depicted in the performance matrix given in Annexure D (First plot). The performance is rather varied. For some questions it is very good, while for some it is rather low. **The average score is 60 %.**

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 5 teams. Each team visited one of the 5 vaccine stores in rotation (the State Vaccine Store, Pune-District Vaccine Store, 1 of its PHC, the Pune MC and 1 of its health post) 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 E 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 recorded. 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 “No” or “0”,
5. Not to disturb or correct any existing practice unless one is confident 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 days of training 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.
f. Calibration of thermometers.

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.

All the participants were very actively involved during the week and this contributed to greatly to their learning and understanding of the good practices, their confidence in the use of the EVM tool, and gathering of useful data.

At the end of the first phase, the consultant circulated an evaluation form for the participants to assess the training programme. It included four aspects: the training course arrangement, the training material and methodology, training delivery of the facilitators and the confidence of the participants in use of the EVM tool. Annexure F summarises the result of the feedback.

5.2 FIELD ASSESSMENT

This was followed by a 7 days field assessment from 18 to 24 October. The assessment sites were identified as described earlier using the details of the districts and total population as given by the MoHFW (Annexure G). A total of 8 Regional vaccine stores (RVS) belonging to the 8 circles and 12 District Vaccine Stores (DVS) were selected. The selection of the districts includes 3 of the 5 UNICEF focus districts, and 4 of the 6 NRHM focus district. In addition, 25 health facilities (PHCs) were selected under these 12 Districts using the sampling tool. The state store at Pune was also included in the assessment.

Note that the selection also included 4 Municipal Corporation (MC) stores in 4 circles and the MC of Br. Mumbai. A total of 12 Urban health posts, 4 of which are under the Br. Mumbai MC were also selected using the tool.

The assessment was conducted by 9 teams comprising of one medical officer (DRCHO or UNICEF consultant), one vaccine store pharmacist (belonging to the circle's vaccine store) and one technician. Each team covered one circle, and assessed the circle RVS, 2 DVS or 1 DVS and 1 MC and 4 PHCs or 2 PHCs and 2 UC respectively, as selected within the circle. 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 H.

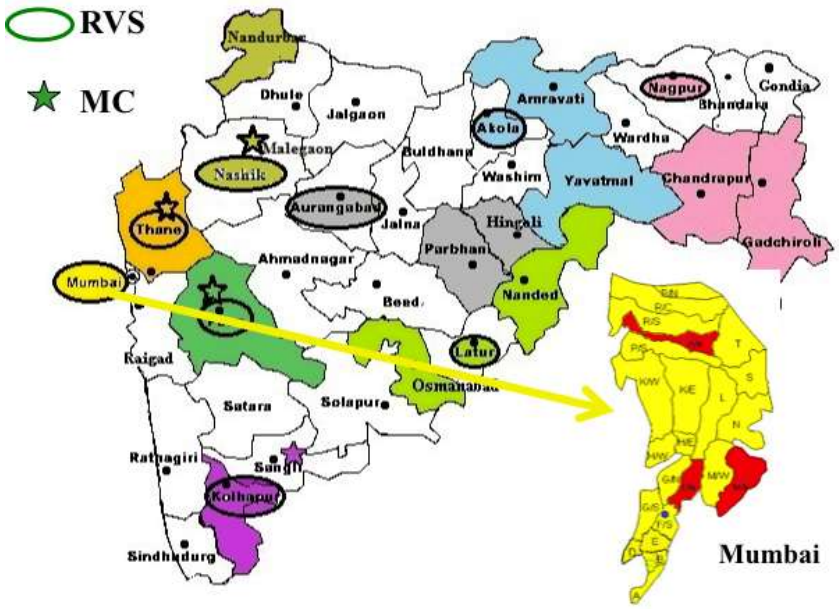
The map of Maharashtra given below depicts the locations of the 8 RVS (circles), the 12 DVSs and 4 MCs (stars) selected for the assessment

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.

5.3 DATA VALIDATION AND ANALYSIS

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

The DRCHOs and the UNICEF consultants 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.

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 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.

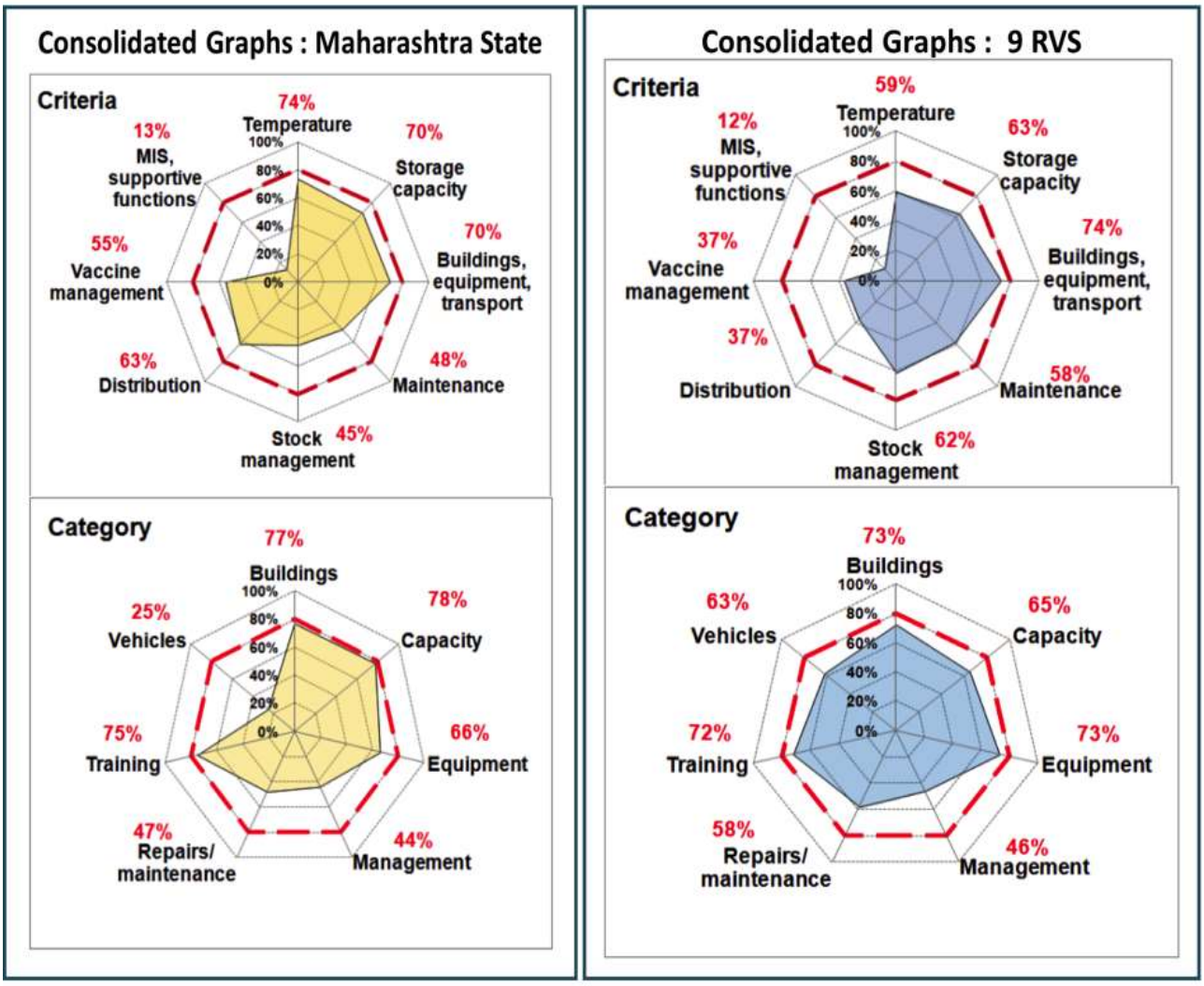
Summary of consolidated EVM indicator score

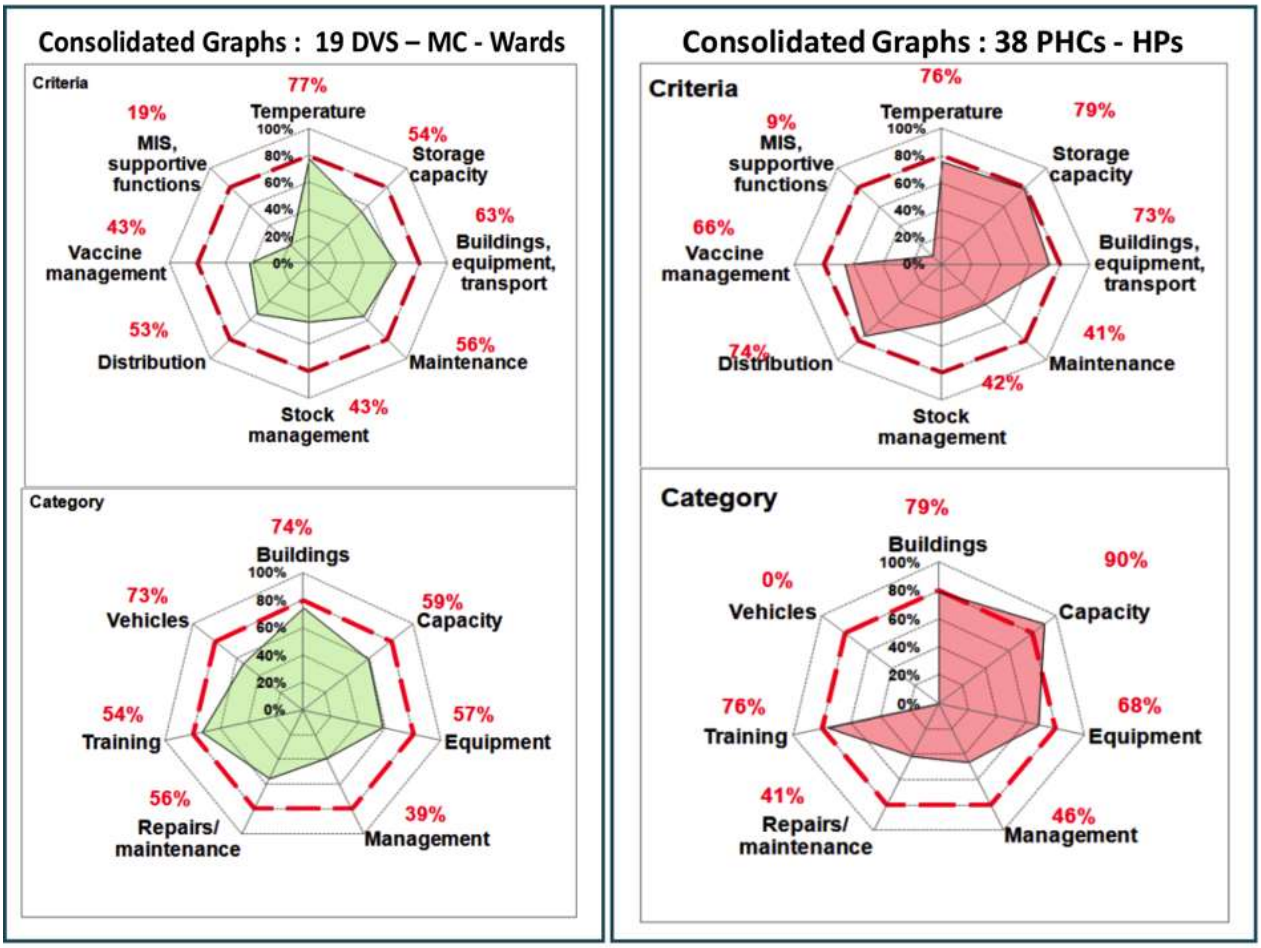
#	Indicator / Criteria	Consolidated Scores				
		State	1 SVS	9 RVS	12 DVS+ 4 MC+3 Wds	25 PHCs + 12 UHPs
1	Vaccine Arrival Process	19%	19%	NA	NA	NA
2	Vaccine Storage Temperature	74%	44%	59%	77%	76%
3	Storage Capacity	70%	78%	63%	54%	79%
4	Building, Cold Chain Equipment & Transport	71%	87%	74%	63%	73%
5	Maintenance of Building, Cold Chain & Transport	48%	45%	58%	56%	41%
6	Stock Management	46%	39%	62%	43%	42%
7	Distribution	63%	39%	37%	53%	74%
8	Vaccine Management Practices	56%	50%	37%	43%	66%
9	MIS & Supportive Functions	13%	38%	12%	19%	9%

Summary of consolidated EVM category score

#	Indicator	Consolidated Scores			
		State	9 RVS	12 DVS+ 4 MC+3 Wds	25 PHCs + 13 UHPs
1	Building	78%	73%	74%	79%
2	Capacity	78%	65%	59%	90%
3	Equipment	67%	73%	57%	68%
4	Management	44%	46%	39%	46%
5	Repair & Maintenance	48%	58%	56%	41%
6	Training	75%	72%	73%	76%
7	Vehicles	25%	63%	54%	0%

Spider charts of criteria and categories corresponding to the tables above.





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 only none of the indicator scores are above 90 %. There are only eleven 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 scores of the RVS, DVS and PHCs levels is indicated in the left most column are also all less than 70% for 6 of the indicators.

During analysis week at Pune, UNICEF officers organised a visit to the BMW incineration plant on request of the consultant. The visit was vey helpful to the participants in terms of understanding the basic methodology of incineration carried out for safe disposal of the biomedical waste.

The findings of the analysis are given in the next section. The resulting graphic representation for each of the RVS, consolidated result of the two districts and their respective four CHC / PHC is given in Annexure I1-I9 for respective circles/zones. The detailed score for each vaccine store is given in Annexure J.

5.4 DEBRIEFING

The debriefing meeting was held on the 9th November and was chaired by Shri J. Banthia (ACS). The Mission Director (NRHM) Mr.Vikas Kharage and the Addl. Director of Family planning were also part of the dignitaries. All the RDDs, DRCHOs and the MOs from MCs.

All presentations were conducted by APT Progress team members.

Ms. Meghna Udgire presented the introduction to the EVM mission. This was followed by the consolidated findings by Dr. Kshem Prasad (Principle Consultant). Thereafter, Mr. Anshu Kumar presented two sessions: first one on Good Practices in Cold Chain and the second one on conversion of CFC based WICs to non-CFC. The latter is of interest since MH has several old units still working on CFC, while the newly installed WICs have been sub-standard.

Then Dr. Kshem Prasad (Principle Consultant) presented a brief overview on the multi-state assessment. This was followed by an example of how to prepare an action plan using a predefined template containing a list of recommendations.

6 FINDINGS

GENERAL

In this section, the findings for each global indicator are 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 in a tabulated manner as given below:

Vaccine Store	State vaccine store	Regional vaccine store	District vaccine store	PHCs	Municipal Corp.	Health posts	Br. Mumbai MC	Br. Mumbai Ward.	Br. Mumbai Health Post
Abbre-viated as	State	Region	District	PHCs	MC	HP	M.MC	M.W.	HP

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.

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 positive aspect worth noting in terms of **Human resource are :**

Strengths of human resource and supportive management

- The State has one Dy. Dir. Immunization.
- There is a post for State EPI Officer (currently in-charge).
- There is one Cold Chain Officer.
- Comprehensive work plan and budget are form the PIP part C.
- State has conducted Cold Chain and Vaccine Handlers training.
- Directives have been provided through letter dated 18 Sept. 09 (ref no 212/40973-113/09).

The weaknesses in terms of human resource and supportive management

- Several post of medical officers responsible for immunization are vacant:
  a. Asst. Dir. HS posts are not all filled
  b. 13 posted of DRCHOs are vacant
  c. 2 DHO posts are vacant
  d. 19 out of 21 posts of ADHO are vacant , There is no medical authority in Vashim District
- Every district does not have designated refrigeration technician.
- Br. Mumbai covering 11 % of total MH population and having 606 cold chain equipment have only 1 cold chain technician.
- Pharmacists are not posted at all DVS for vaccine handling.
- No helpers are provided to vaccine storekeepers at RVS and DVS.
- Staff carries out required communication using personal resources.
- Funds for emergency repair of vehicle have been missing.
- CPCB Guidelines for proper disposal of bio-medical waste available are circulated on 6thDecember 2004.

Several of these issues were addressed in the directives given in the letter dated 18 Sept. 09. (ref no 212 / 40973-113/09).

VACCINE COST

The table below gives the cost of the individual vaccines used in the UIP.

Sr. No	Age group	Vaccine	No of doses	Cost per dose Rs.	Total cost Rs.
1	At Birth	BCG	1	2.8	2.8
2		OPV	1	3.9	3.9
		Hepatitis B	1	3.34	3.34
3	6, 10 and 14 weeks	OPV	3	3.9	11.7
4		DPT	3	2.12	6.36
5		Hepatitis B	3	3.34	10.02
6	9 to 12 months	Measles	1	10	10
Sub total for less than 1 year					**48.12**
7	15 to 24 months	DPT Booster 1	1	2.12	2.12
8		OPV Booster 1	1	3.9	3.9
9		Measles 2	1	10	10
10	5 years	DPT Booster 2	1	2.12	2.12
11		OPV Booster 2	1	3.9	3.9
12	10 years	TT	1	1.56	1.56
13	16 years	TT	1	1.56	1.56
14	Pregnant women	TT	2	1.06	2.12
15	**TOTAL**				**75.4**

The approximate cost of immunizing an infant less than 1 year old is about Rs. 50.- Taking this value, the total target population (children below 1 year old) to be fully immunized, the c the cost of vaccines stored at the different levels. The minimum cost of fully immunized child is estimated at Rs. 50.- based on the individual cost of vaccines (BCG, DTP, Hep B, Measles and OPV). The table below shows the cost of one month of stocks (current practice) for fully immunizing the children below 1 year, and for 3months of stocks (as recommended by GoI).

Parameter	Target group (0-1 Year)	1 Month Stock (Rs.)	3 Months Stock (Recommended) (Rs.)
State level vaccine store (SVS)	19,81,348	82.5 Lacs	2.5 Cr.
Aurangabad (small Circle) ***Nasik (Large Circle)***	1,50,000 ***3,40,000***	6 Lacs ***14*** lacs	20 Lacs ***42*** Lacs
Garchiroli (small District): **Nasik (large District)**	20,000 **75,217**	85,000 ***3*** Lacs	2.5 L.acs ***9.4*** Lacs
Small MC – Kohlapur MC	10,000	40,000	1.3 Lacs

One can appreciate that the total cost of vaccines at any facility is not insignificant. It is therefore of great importance to ensure that the vaccines are stored correctly, including proper monitoring of storage temperature.

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 Pune. It is not applicable at other levels. Hence in the spider

While the SVS does not clear any vaccines through the customs, there is no proper MoU between the GoI and the customs. This affects the performance score.

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	8 RVS	12 DVS	25 PHCs	3 MC	9 UHP	M.MC	M.W.	4 HP
Score	19%	NA	NA	NA	NA	NA	NA	NA	NA

The score obtained of 19 % is attributed to the reasons stated above and that no vaccine lot was received in a damaged state.

The aspects that contributed to the loss of score are :

- VAR are filled only during the receipt of the campaign vaccines, as these contain the blank VAR form. For other vaccines arrivals, out of 25 vaccines lots, 5 had VAR forms, but none had been filled completely.

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	State	8 RVS	12 DVS	25 PHCs	3 MC	9 UHP	M.MC	M.W.	4 HP
Score	44%	57%	81%	73%	76%	75%	77%	81%	93%

The scores achieved in this indicator are attributed for the following reasons:

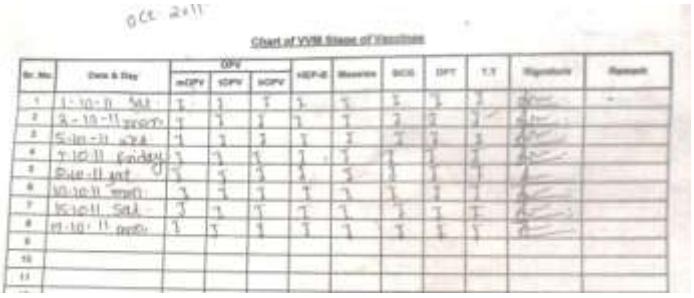
- Most staffs know very well the storage temperature and freezing risks of the vaccines.
- All RVS have good manual temperature records.
- The MC of Br. Mumbai has an old walk in cold room which is cooled using 2 CFC based old open type 10 Ton compressors. The store is manned by semi-skilled helpers round the clock.
- There is a commendable practice to record the manual temperature every hour instead of twice a day. Besides the temperature, the salient parameters of the open type refrigeration system is also recorded.

- There is also a continuous temperature graph recorder which provides a weekly record in a graph paper. Past records of the same are neatly packed and kept safely at the store. The records also routinely verified and countersigned by the supervisor.

There is a good match between the manual and continuous temperature records – though the temperature sensors have never been calibrated.

- At Wards there are large and small ILRS and DFs, while at the health posts, there are small size equipment. The temperature recording is manual, and carried out in a printed monitoring book. At the wards, which are mostly on an upper floor, there is no manual recording carried out during public holidays and weekends – as the equipment are within administration premises.

Hence to circumvent this limitation, Br. Mumbai has adopted an excellent practice to record the status of VVM before the weekend/ holiday and upon arrival on the next working day. The format of the temperature monitoring provides a table to record this opposite the temperature-recording page.



The areas that require improvements are :

- 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.
- Only 2 out of 4 WIC and WIF at SVS have continuous temperature records.
- There are no manual temperature records at SVS.
- Several RVS do not have any working continuous temperature records (Eg. SVS, RVS, Thane, Nasik Kohlapur, Aurangabad). Even the recorders of the newly installed WIC/ WIF are not operational.

Large stocks of vaccines are stored at SVS and RVS levels, costing a significant amount as shown above. A 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 lowers the score at RVS (& SVS) dramatically.

- 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.
- Standard booklet not used in many places and thee is no recording on public holidays and Sundays.
- Supervision tend to sign the records without proper verification.

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

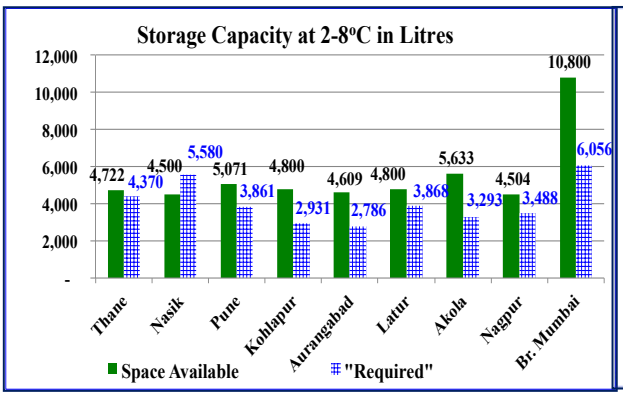
Vaccine Store	State	8 RVS	12 DVS	25 PHCs	3 MC	9 UHP	M.MC	M.W.	4 HP
Score	78%	59%	50%	80%	71%	80%	60%	51%	91%

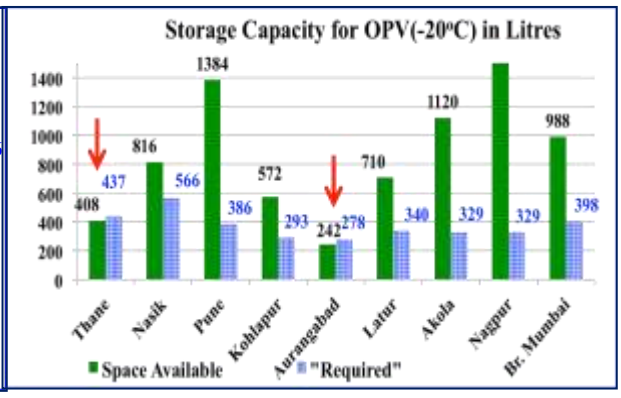
The factors contributing to the scores are :

- There is sufficient storage capacity at -15 to -25 ^{o}C for OPV at all levels. There is also sufficient ice pack freezing capacity at all levels
- PHCs have sufficient vaccine storage capacity for its requirements.
- Some places emergency numbers pasted in right places
- All RVS except Latur have proper transport facility using a vaccine van.
- 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.
- There is one DF available at all PHCS, thus ensuring sufficient capacity to produce and store ice packs.

Factors that contribute to the poor scores are given below.

The graphs above indicate the storage capacity available (green) and required (blue) at the RVS. The calculation considers that the 6 newly installed WICs and 2 WIFs are operational.





- Several of the new WICs are still not commissioned and handed over for use. This causes the score of RVS to fall due to the actual shortage of space at 2-8 °C.
- In couple of places large stocks of Anti Rabies Vaccines (ARV) are occupying significant space of the WIC (eg. MC-Br. Mumbai and RVS-Nasik) (see adjacent photo)
- Freezing space limitation at Thane and Aurangabad
- Dry storage is severely insufficient at RVS Latur
- Most stores lack sufficient cold boxes and Ice pack (eg. RVS-Latur, Nasik).

ARV vaccines filling space

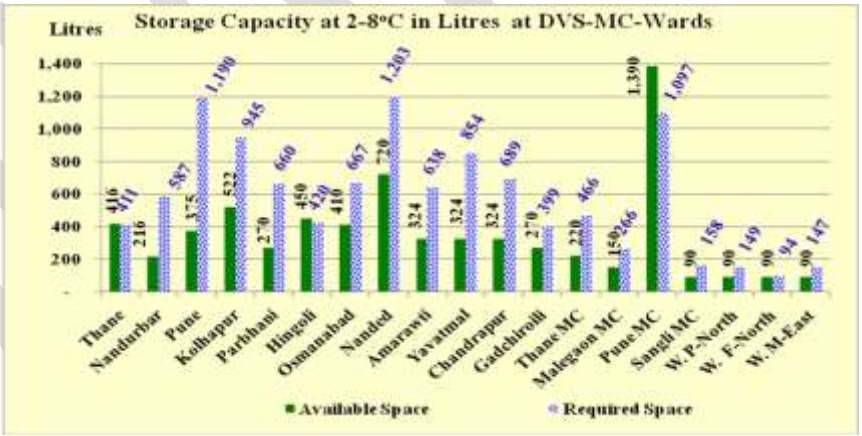
- There is rampant use of non-standard themocol boxes- which is not recommended.
- Emergency Contingency plans not existing anywhere, and emergency numbers are not readily available.
- Staff have limited knowledge on how to handle emergency. The understanding is to push vaccine to lower facilities.

Note that for the temporary store of State store at Kondwa while the vaccines are stored along with potatoes (see adjacent photo) the rental is Rs. 19 / carton / month. Typical State expenditure amounts to Rs. 2 Lacs / Annum. This can be saved with proper use of state store and vaccine supply frequency.

DVS

The graph below illustrates the similar study in the case of the 19 DVS visited.

- At most DVSs (except Thane and MC Pune) , there is lack of adequate storage capacity as per the required GoI guidelines (see adjacent graph).
- non-RI vaccines (ARV) stored in separate ILRs, which take up physical space in an already limited space.



Vaccine storage capacity (+2 to 8°C) available and required at the 13

MC – Br. Mumbai

The old WIC has a gross capacity of 31,320 Litres considering a usable height of 2.80 m. The effective net volume is 10,800 Litres. This is more than the requirement for 3 months of stock, however, a significant part of the store (one side entire shelves) is filled with 980 doses of ARV occupying 450 Litres of space. When new stocks of ARV arrive, up to 25,000 doses occupying 1,250 Litres of space are kept in the WIC. GoI recommends segregating all non-RI vaccines and drugs from the RI ones.

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

Findings

Vaccine Store	State	8 RVS	12 DVS	25 PHCs	3 MC	9 UHP	M.MC	M.W.	4 HP
Score	87%	72%	57%	74%	70%	63%	83%	88%	89%

The scores indicate the status of the building, equipment and transport at different levels. It reflects serious concerns at the DVS and Urban health posts level .

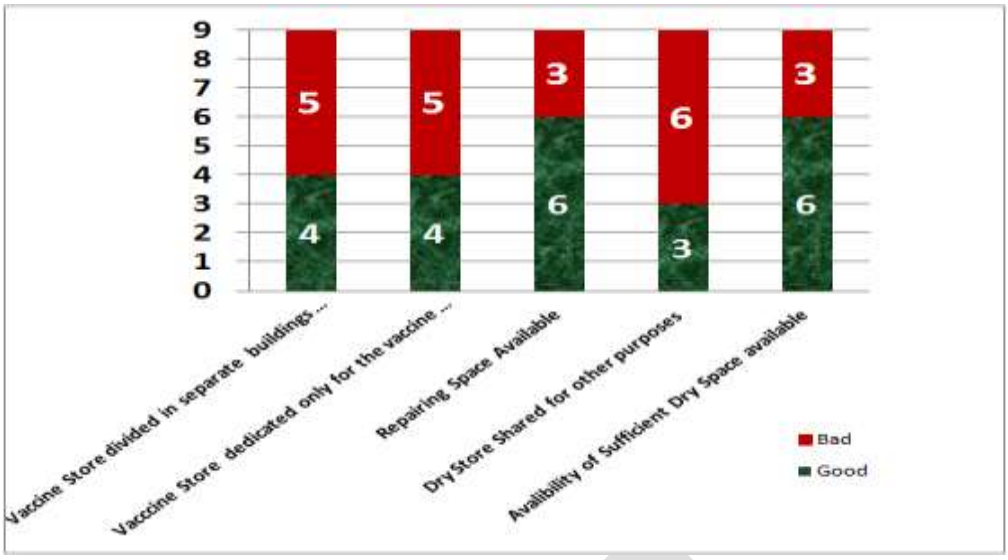
During the assessment information on several complementary aspects were also collected. These aspects were not directly scored by the tool, but which are important to be addressed . These are also discussed as part of the findings in this section.

RVS

The table below summarizes the status at the RVS. The results are depicted in the graph below.

Summary of Status of the 9 RVSs

Para-meter	Aspects	1	2	3	4	5	6	7	8	9		
		Thane	Nashik	Pune	Kolhapur	Aurangabad	Latur	Akola	Nagpur	MC-Mumbai	Good	Bad
Cold storage	Is Vaccine Store divided in separate buildings or floors?	Y	Y	N	N	Y	Y	N	N	Y	4	5
	Is Vacccine Store dedicated only for the vaccine storage?	Y	Y	N	Y	N	N	N	Y	N	4	5
	Is Repairing Space Available	Y	Y	Y	N	y	N	Y	Y	N	6	3
Dry Storage	Dry Store Shared for other purposes (eg. Other drugs etc.)	Y	Y	N	N	Y	Y	Y	N	Y	3	6
	Availability of Sufficient Dry Space available	Y	Y	Y	N	Y	N	Y	Y	N	6	3



STORGAE CONDITIONS : RVS SUMMARY

The scores are attributed at RVS level for Building as

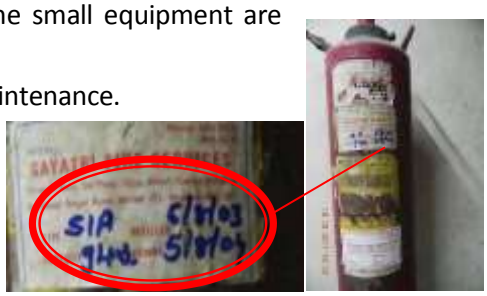
At most of the stores (six out of nine) as indicated in the RVS summary graph sufficient repairing space and dry storage space available

The concerns are summarized below:

- Several MC and wards vaccine stores are on an upper floor. This makes operations more difficult for the staff.

  At Pune for example it is on 2nd floor while there is space available at the ground floor.
- The MC and wards are sharing storage space with other services (eg. birth and death registration at Br. Mumbai) . Often the office space is congested with little space for moving and working.
- Most RVS WICs and WIFs do not have functioning continuous temperature recorders
- Acoustic alarms are not functioning in most places
- At many MCs and DVS small ILRS are in operation. The small equipment are more suited for the PHCs and UHPs.
- Several buildings are in poor conditions with want of maintenance.
- Fire extinguisher available at 3 RVS (Akola, Br. Mumbai and Pune) not available at 6 RVS

  If present, they are not always recharged and maintained up to date.



- At several RVS, there are different types of limitations: eg. Shared space, dry storage spa ce, repair workshop space etc.
- At Aurangabad RVS, electrical wiring was in bad condition.
- As indicated in graph above the vaccine store is divided at four out of nine RVS (Aurangabad, Thane, Nashik, and Latur)
- Out of nine regional vaccine stores in the state five stores (Pune, Aurangabad, Latur, Akola and MC-Mumbai) share the space for other purpose apart from storing vaccines. dispensary etc
- Out of nine regional vaccine stores in the state six stores (Thane, Nashik, Aurangabad, Latur, Akola and MC-Mumbai) share the dry storage space with the other stores e.g. drugs vitamins etc.

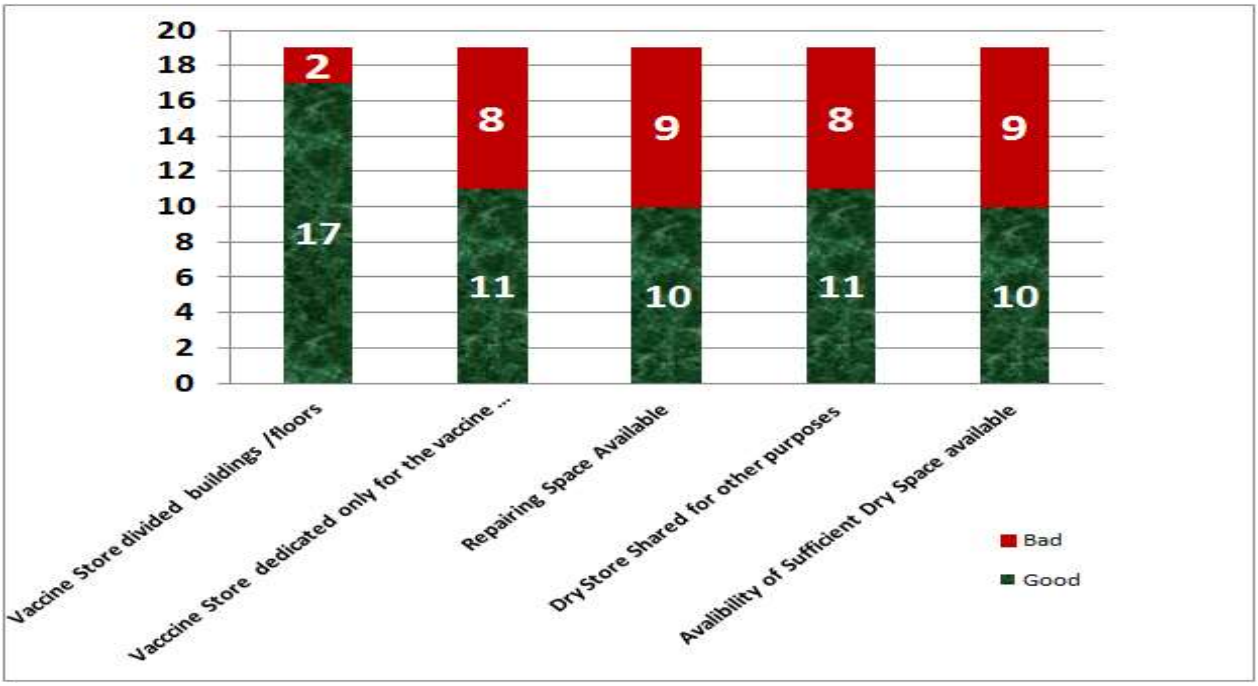
- The normal practice at all RVS/DVS/PHCs is that they run two cold chain equipment with a single stabilizer or at times even without a stabilizer.

DVS

The table below summarizes the status of the 13 DVS that were visited.

Summary of DVS Status

Parameter	Aspects	1	2	3	4	#	6	7	8	9	10	##	12	13	14	15	##	17	18	19		
		Thane	Thane-MC	Nandurbar	Malegaon	PUNE	PUNE-MC	Kolhapur-Sangli	Hingoli	Parbhani	Osmanabad	Nanded	Amravati	Yavatmal	Chandrapur	Gadchiroli	P-North	F-North	M-East	Good	Bad
Cold storage	Is Vaccine Store divided in separate buildings or	N	N	N	Y	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	17	2
	Is Vacccine Store dedicated only for the vaccine storage?	Y	N	N	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N	N	N	N	N	11	8
	Is Repairing Space Available	N	N	N	Y	N	Y	Y	Y	Y	Y	N	Y	N	Y	N	N	N	Y	Y	10	9
Dry Storage	Dry Store Shared for other purposes (eg. Other drugs	N	Y	Y	N	N	N	N	Y	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	8	11
	Is Sufficient Dry Space available?	N	N	N	Y	N	Y	Y	Y	Y	Y	N	N	Y	Y	Y	N	N	Y	N	10	9



STORAGE CONDITIONS: RVS SUMMARY

The poor score at the DVS level for this indicator clearly indicated in the graph illustrated above as

- Out of nineteen vaccine stores only two are divided in separate buildings or floors (eg. Kohlapur and Malegaon.
- Total of eight stores(Thane-MC, Nandurbar,Hingoli, Chandrapur, Gadchorali, P-North, F-North and M-East) the vaccine store is share for other activities
- Repairing space is available only at ten stores
- Although the sufficient dry storage space is available at ten out of nineteen stores,

almost eight stores it is shared with the other stock of drugs and other supplements etc.

PHCs

The good score at PHC level contributed as

- ❖ All PHCs are having enough space for health facilities, and most of the PHCs are approachable by vaccine van.
- ❖ PHC Para the building can be a model for rest of the state which is a result of the proper supportive supervision
- ❖ The wiring at PHC Jiwati needs immediate attention.

PHC - Jiwati

PHC Para

MC-Br. Mumbai

The MC vaccine store, and also the Wards vaccine stores in Br. Mumbai are all placed on an upper floor making transport of vaccines from the vehicle difficult. The total space of the vaccine store is small. Two large DF are installed in the passage to the WIC and there is not sufficient place to carry out the packing.

There are couple of more equipment (2 small DF and 1 small ILR) are placed in an adjacent office, along with some administrators table.

The old WIC has a working continuous temperature recorder and a functioning alarm. In fact it has also a separate alarm that can be activated from inside the WIC in case anyone is trapped inside.

General limitations at several Municipal corporations:

- ➢ The stores are often placed on an upper floor instead of ground floor
- ➢ Lack of direct and easy access to vehicles
- ➢ Lift service is not always available.
- ➢ Staff tend to avoid use of cold boxes which are bulky and heavy - instead use of thermocol boxes is preferred.

EQUIPMENT

Equipment 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 of1st August 2008, seventeen months ahead of the original deadline.

Summary of CFC Equipment in the state

	RVS level	DVS & PHC			MC / UHP	
Circles	**WIC**	**WIC**	**DVS-ILR**	**DVS-DF**	**MC-ILR**	**MC-DF**
Thane	**2**		**2**	**1**	**2**	**1**
Nasik	**2**				**1**	
Pune			**2**		**11**	**5**
Kohlapur				**1**		
Aurangabad	**2**	**2**	**4**			
Latur			**2**	**2**		
Akola	**2**		**5**	**3**		
Nagpur	**2**	**2**	**2**	**3**		
Br. Mumbai	**2**				**0**	**0**
Total	**12**	**4**	**17**	**10**	**14**	**6**

As of today, in total 14 WIC refrigeration units and about 47 ILRS / DF are operating on CFC. The ILRs and DF are distributed the different RVS, DVS and PHCs, MC and UHPs.

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 replacing with new alternate technology refrigerants.

Equipment running on CFC at RVS and DVS and suggestions by APT

Four old WICs are running at Thane (1), Akola (1) and Mumbai (2) (Mumbai has only 1 old WIC working on open type compressor) with CFC refrigerant. As CFC as been phased out, the maintenance and disposal of CFC based equipment required appropriate attention. .

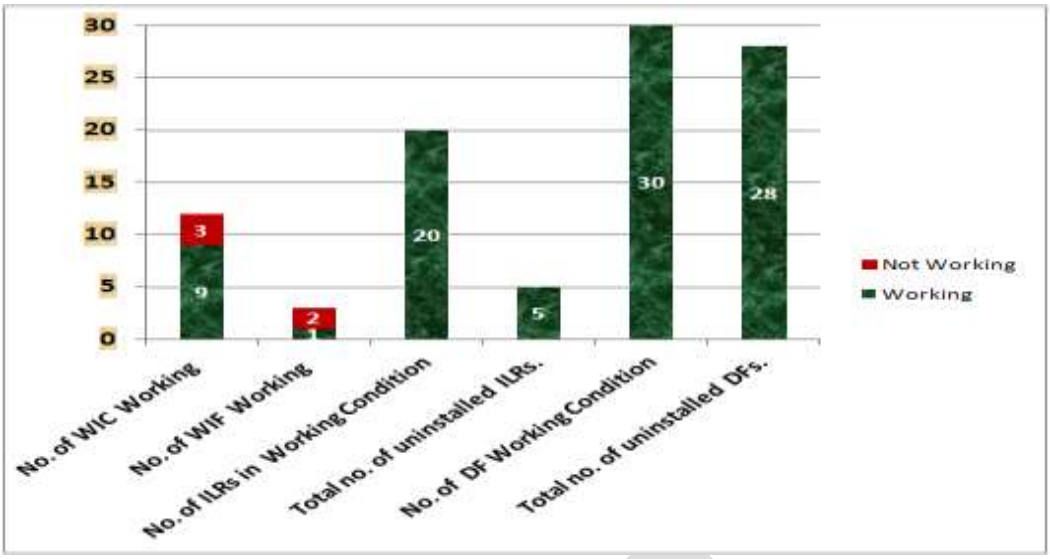
The WIC installed at DVS Parbhani its CFC based refrigeration units may be ready to be discarded at any stage. The State should get replacement of the condensing units based on R-134a or R-404 ozone friendly refrigerants. The basic body of the WIC is good enough to last for another 20 years.

Apparently, the consultant came to know that the process of condemnation is going to take place soon. Note that at the SVS, the two CFC based refrigeration units of one of the old WIC have been successfully replaced with alternate refrigerant technology and are working well. So there is no need to replace the complete WIC but to replace only the condensing units. This will save the exchequer for huge amount. The same policy can be adopted throughout Maharashtra. A technical committee can be formed to evaluate and take the final decision on such old units.

In RVS Aurangabad one old CFC based WIC have been dismantled. The walls, the flooring & rest items have been kept intact at the Regional W/shop & Lab. It is suggested that the same can be assembled & new units of R-134a or R404 can be installed for better life with ozone friendly refrigerant.

Status of the working condition of the equipment

The Graph below illustrates the equipment in working condition (working in green vs not working in red) in the state. Out of 12 WIC at RVS 3 are not working (Akola, Aurangabad and Kohlapur) Out of three WIF two WIF (Thane and Aurangabad) are not in a working condition. At all RVS the total no of 20 ILRs are in working conditions (and 5 ILRs are in stock-unpacked). Total of 30 DFs are in working condition at RVS level (and 28 are in stock-unpacked).



Summary of equipment at RVS Level

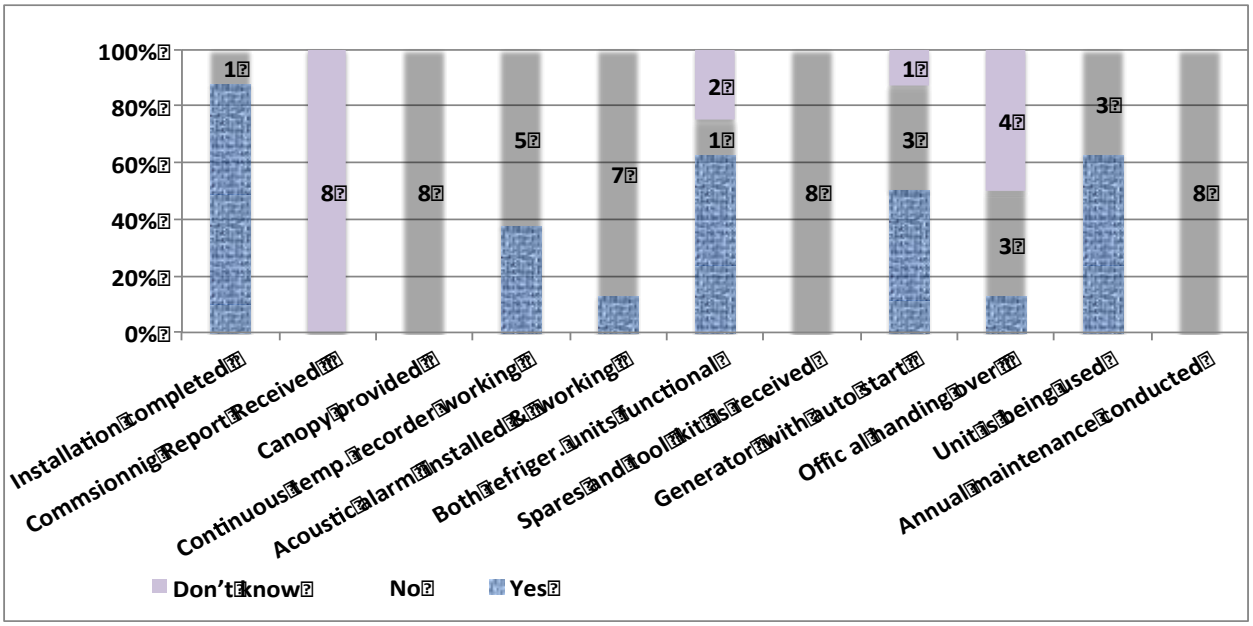
New WICs in Maharashtra

Six new WICs and two 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. The graph above reflects some of the lacunas. The table below summarises the status of the new WICs / WIFs installed since June 2010 in Maharashtra.

Summary status of New WIC and WIF at SVS and RVSs.

Aspects	SVS	Thane	Nasik	Kohla-pur	Auran-gabad	Akola	Nagpur
Installation is completed	Y	Y	Y	N	Y	Y	Y
Canopy provided on the condensing units	N	N	N	N	N	N	N
Paper record of continuous monitoring available.	N	N	N	Y	Y	N	N
Continuous temperature recorder is working	Y	N	N	N	N	N	Y
Acoustic alarm is installed and working	N	N	Y	N	N	N	N
Both refrigeration units are functioning well	Y	N	Y	?	?	Y	Y
Spares and tool kit is received?	N	N	N	N	N	N	N
Generator with auto start is working?	Y	N	N	N	Y	?	Y
Official handover is completed? / date	?	N	N	N	Y	?	?
Is the unit being used	Y	N	Y	N	N	Y	Y
Is annual maintenance being carried out	N	N	N	N	N	N	N

As can be seen from the table and graph, several tasks are pending in order to complete the

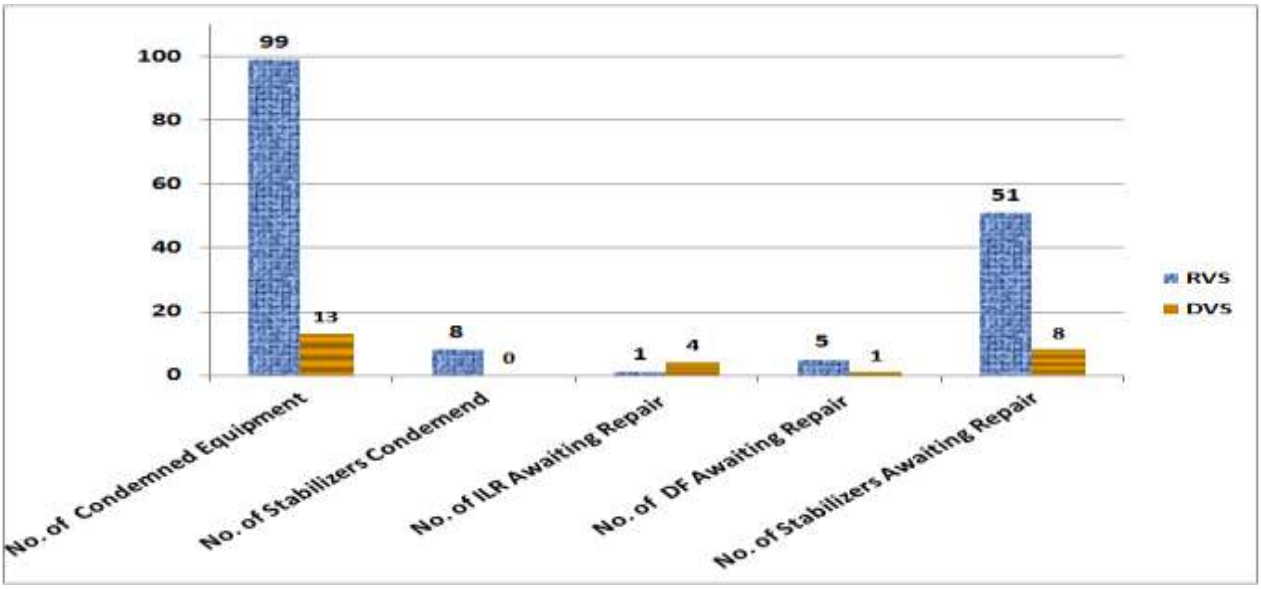


formal handing over after the installations. Unless this is followed up scrupulously with the company that was awarded the contract, while the systems are under the warrantee period, it is likely to result into chronic issues for years to come.

Examples of serious problems have been already reported to GoI – At Jaipur one condensing unit caught fire, at Ahmedabad there was vandalism through a window grill due to lack of canopy. The same thing has happened at RVS-Kohlapur.

Summary of status of condemned equipment at RVSs and DVSs

The equipment status at the 9 RVS (in mauve) and 19 DVS and MC (in blue) is illustrated in the graph below.



Total Number of condemned equipment are more at RVS (total 99 : Br-Mumbai 97 and Latur-2) as compare to the DVS level (Total13: Pune MC-8, Yavatmal-2 , Chandrapur-1, M-East-2) Total number of stabilizers condemned are eight at RVS Pune vaccine store only. Total number of ILR s awaiting repairs are five four at DVS level and one at RVS level similarly total number of deep freezers awaiting repair are six and total Stabilizers awaiting repair at RVS level id quite high fifty one(only at MC –Mumbai vaccine store)

Fire Extinguishers

- Fire extinguisher available at 3 RVS (Akola, Br. Mumbai and Pune) not available at 6 RVS
- In DVSs fire extinguishers are available and working at (Kolaphur, Hingoli , Pune- MC, and Mumbai P-North, F North, M-East out of 19 DVS/MC stores assessed
- Most of the PHCs are lacking in providing the fire extinguisher.

Transport

- All RVS except Latur has vaccine van
- 8 DVS and one MC do not have vehicles for transport.
- At Osmanadabad DVS from Oct '10 to Sept ' 11 , there were five times supply cancellation was occurred due to the unavailability of Vaccine transport Vehicle

According to state cold chain technician, 45 vehicles are procured by the state and soon the problem will resolve for transport at each level

6.5 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	State	8 RVS	12 DVS	25 PHCs	3 MC	9 UHP	M.MC	M.W.	4 HP
Score	45%	57%	55%	43%	55%	35%	67%	62%	48%

The performance is poor at all levels. The resulting score is due to **the following strengths**:

- 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 (where- give example?).
- MC-Br. Mumbai has an excellent periodic preventive maintenance plan that is working well. There is a complete monthly service / repair report for the visits by maintenance engineer by outsourced agency Voltas (adjacent photo).

Periodic maintenance report

The areas that affect the score adversely and need improvements are:

- There are no preventive maintenance plans for the buildings. Several RVS, DVS and PHC buildings require significant maintenance work to be carried out (eg. DVS-Nandurbar, PHC-Babulgaon) Painting is required at RVS- Thane, DVS-Yavatmal, PHC–Shembal-Pimpiri, where different concerns exist. (Some of these are indicated through photographs below.)

DVS Nandurbar

RVS Thane

PHC-Babulgaon

- 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 Cold chain technicians belong to the SHTO / HEMR, and are supposed to be supervised by the division. In reality supervision of equipment maintenance and repair works appear to be wanting.
- There are no equipment maintenance records except at MC - Br. Mumbai.

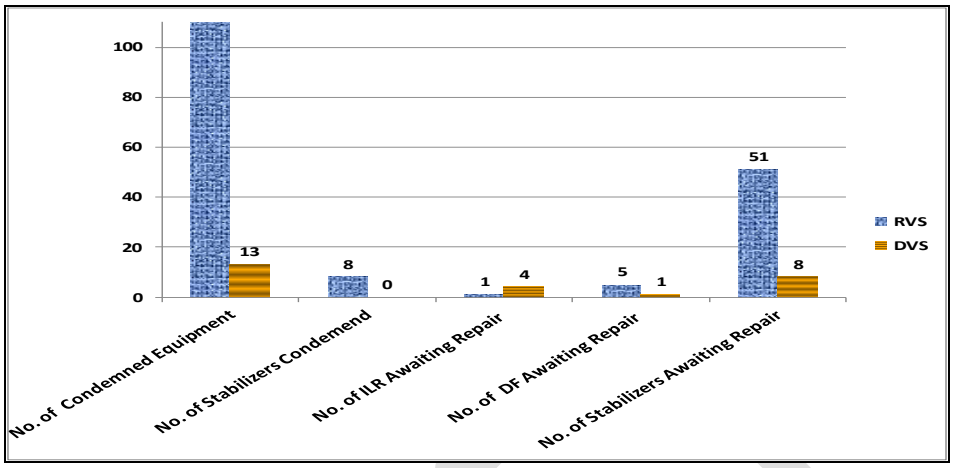
The graph below summarises the status of equipment

- At Br. Mumbai, significant amount of usable space is occupied with the condemned equipment (total 97) and several equipment are awaiting repair as well. Total number of condemned equipment in state are 116 at RVS stores.

There are some equipment awaiting condemnation at the RVS and DVS as well (17 at RVS Nagpur, 2 at

RVS Latur, 8 at Pune MC, 2 at Yavatmal, and 1 at Chandrapur).

- Number of stabilizers awaiting repair are 51 at MC-Br. Mumbai and 8 at DVS (1- Pune, 6-Hingoli and 1-Thane). Another 8 are awaiting condemnation at RVS Pune only.
- A small number of ILRs are awaiting repair (1 at MC-Br. Mumbai and 4 each at DVS Kolaphur, Thane, Nandurbar, Pune and Thane districts). The number of DFs awaiting repair are 5 at RVS (4-MC-Br. Mumbai and 1- Latur) while only one DF awaiting repair at Pune MC.



Status of condemned and awaiting repair equipment in the state

- Except DVS Nanded, preventive maintenance plan for vehicle, does not exist anywhere across the state.
- Contingency funds are not available for vehicle repair during transport of vaccine. At present at Akola RVS vehicle broken down during last transport of vaccines, is awaiting repair since 15 days due to absence of repair funds. This has led to the stock-outs from RVS to DVS to PHC level for 20 days. Most of the stores from this region reported stock-outs during assessment period.
- There are no written contingency plans at any level to handle emergencies. Most staffs 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.

Case Study of maintenance of a WIC

As an example of importance of carrying out regular service APT team undertook servicing of the condensing unit of one of the refrigeration unit of the WIC at SVS, Pune. The unit was not serviced from last four years as per records & conversation with State Vaccine Store Keeper. T

The exercise shows how the exchequer can be benefitted after servicing of the equipment.

The photograph below shows the condition of the condensing unit before (on left) and after the cleaning (on right).

The condition of WIC Condenser before (left) and after (right) servicing at SVS, Pune

The following calculations can be made regarding the total saving due to the reduction in the

consumption of the clean condensing unit.

The current before cleaning was 6.2 Amperes and it decreased to 4.6 Amperes. The computation given below indicates a total reduction of 1.6 Amperes leading to 1.1 KW / Hr. This translates into a financial saving of Rs. 22.5 lac per year.

The above parameters have been taken on 24 hours run time at a power factor of 0.9. If we take into the consideration 50% run time even though the state is going to save Rs. 11.2 Lacs /- per annum.

Therefore periodic cleaning and maintenance of all the condensers and cooling coils of WIC / WIFs will lead to a significant saving for the state.

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 standardized 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
- All Stocks and records are safe.

Findings

Vaccine Store	State	8 RVS	12 DVS	25 PHCs	3 MC	9 UHP	M.MC	M.W.	4 HP
Score	39%	62%	46%	39%	62%	52%	56%	27%	36%

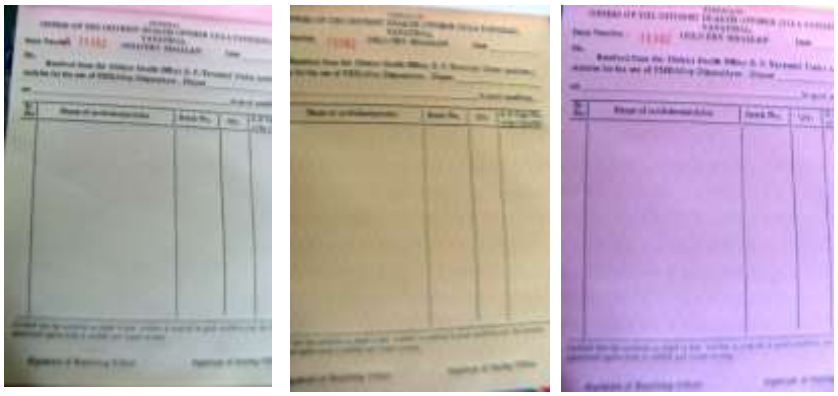
The performance is poor at all levels. Several reasons are responsible for this. The scores achieved are mainly attributed to :

- Maharashtra state has introduced the recommended format of vaccine stock recoding in form of registers, which includes a separate column for diluents and status of VVM of the vaccines. This format is implemented only at Regional store at Nagpur RVS. It was not even found at any of the DVS under Nagpur.

Stock Register used at RVS Nagpur

- Updating of Stock Register was good and the stock records matched with the Physical count of vaccines (inclusive of the stock of diluents) at most of the regional stores (Eg. Latur, Pune, Nagpur, Kolaphur and Aurangabad).
- Most of the DVS (Parbhani, Hingoli,Thane, Kolphur, Gadchiroli, Nanded) stock maintenance records match with the physical count of vaccines stock also contributed in the scores for stock management.
- For dry storage management the good practice was observed at most of the RVS, DVS and PHCs (except at RVS Aurangabad where it is stored in an old building and DVS Hingoli was where it also not maintained neatly).

- A standard format for Issue vouchers in 3 copies have been defined and supplied to the vaccine stores. Most of the RVS and DVS are having these Supply vouchers format book which are implemented during the transport of the vaccines



Issue Vouchers in three copies

- Most staff at RVS, DVS and MC being trained pharmacists are practicing the Early Expiry-First-Out (EEFO). They also know how to over-ride EEFO due to advance stage of VVM, except at DVS Nandurbar, where staff need training on how to read VVM.
- Freeze indicators are implemented at DVS Nanded, though these are yet to be formally introduced and distributed in India and staff needs induction on its proper usage.

The areas that need further attention are:

- Several poor practices regarding vaccines stock management were observed:

a. There is a general tendency to order in excess and the supply is in general less than the indent, even when there are sufficient stocks.

Store	Vaccine	Date	Doses required for 1 month	Requested	Received	Stock available at SVS on date of distribution
SVS	Hep B	24-Sep-10	**880,599**	20,00,000	465,490	
		13-Nov-10		10,00,000	436,030	
		20-Jun-11		10,00,000	100,000	
	Measles	20-Jan-11	**220,150**		125,000	
		12-May-11		5,00,000	100,000	
		25-Jul-11		5,00,000	91,575	
RVS Latur	Hep B	20-Apr-11	**82,000**	100,000	24,000	69,500
		01-Jun-11		140,000	-	Nil
		02-Jul-11		160,000	-	34,000
		09-Aug-11		160,000	-	NIL
		24-Aug-11		200,000	48,000	51,780
	Measles	01-Jun-11	**20,700**	60,000	5,000	Nil

b. Practice of maximum stock and buffer stock level is neither respected nor practiced by the staff at any level. This leads to several events of stock-outs.

c. Stock outs were recorded at several stores. Below are a few examples:

Vaccine Store	Vaccine	From	To	Days
SVS	Hep B	15-Feb-11	15-Mar-11	**28**
		16-May-11	20-Jun-11	**35**
		08-Jul-11	22-Jul-11	**14**
Br. Mumbai	DPT	5 Sept 2011	9 Sept 2011	5
	MMR	Since Aug 11	Till date of assessment	**> 75**
	Hep B	11-Mar-11	16-Mar-11	**5**
		27-May-11	20-Jun-11	**24**
		22 July 2011	25 July 11	**4 days**
Thane	Hep B	27 May 2011	26 June 2011	30
	BCG	27 May 2011	31 May 2011	5
RVS-Latur	BCG	02-Jun-11	02-Jul-11	**30**
		20-Jul-11	09-Aug-11	**20**

Vaccine Store	Vaccine	From	To	Days
	Hep B	20-Oct-10	10-Nov-10	**21**
		07-Jan-11	05-Feb-11	**29**
RVS-Nasik	Measles	28-May-11	05-Jul-11	**38**
	Hep B	27-Apr-11	15-May-11	**18**
	OPV	22-Sep-11	Till date of assessment	**> 39**

d. There is poor follow up for short shipment from state level.

- Diluents Stock for did not match with the measles at Nasik RVS, and for BCG Vaccines at DVS Osmanadabad.
- At some DVS physical verification was not possible due to the missing or poor up-dation of the stock (e.g Yavatmal, Chandrapur etc.) and most of the PHCs (Jiwati, Shankarpur, Runzaetc). Stock were not at all recorded at PHC Babhugaon and Rakaswade.
- No standard indent forms exist in the state. Most stores generate their store-defined copies each month for Vaccine indenting, at times using a black paper.
- Although the issue vouchers format is available and implemented by issuing stores, one copy is not returned to the issuing stores after receipt of the vaccines.
- Supply Voucher lack column for VVM status (and Freeze Indicator for future implementation).
- Dry storage is not maintained at DVS Nandubar (see photo).
- Records of damaged and wasted vaccine is not available at any PHCs (Except PHC Jiwati). Diluents stock have also not been recorded.
- Records of damaged and wasted vaccine and damaged diluents is not available at any PHCs. Waste disposal of vaccine due to heat exposure are not maintained at any store in the state (except at MC Pune and PHC Jiwati).

Dry store at Nandurbar

- At PHC practice is to pour damaged and unused vaccines without proper disinfection (eg. PHC Shankarpur) was observed. Staff is not aware of the proper disposal guidelines (Chemical treatment with 10% Sodium Hypochlorite) for the return the vials and broken syringes before their disposal in the sharp pit.
- Poor recording of campaign vaccine was observed at PHC Para.

6.7 EFFECTIVE DISTRIBUTION

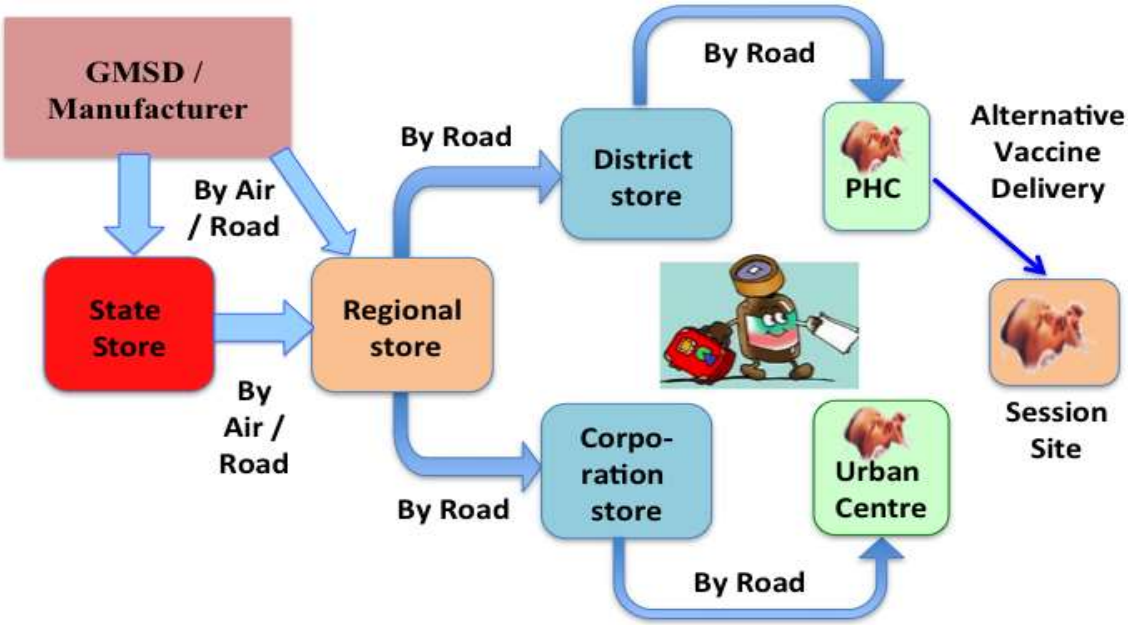
For an effective immunization programme, timely deliveries of the required quantities of vaccines are important. The parameters assessed here ensure the effectiveness of the vaccine distribution between each level of the supply chain. These are:

- 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

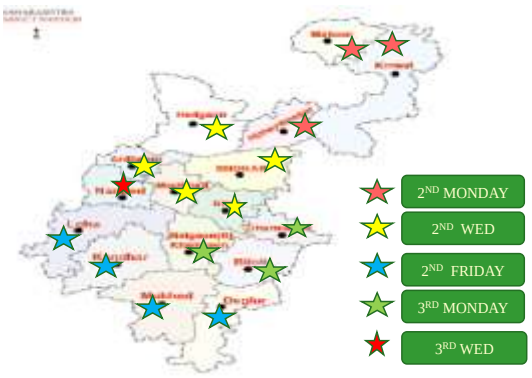
Vaccine Store	State	8 RVS	12 DVS	25 PHCs	3 MC	9 UHP	M.MC	M.W.	4 HP
Score	39%	37%	52%	69%	76%	78%	39%	42%	100%

Diagramme of the recommended distribution process



The limited achievements of the score are due to the following strengths:

- A very appreciable practice was notices at the urban health posts of Br. Mumbai. They stick the labels of the used vials on the distribution register at the end of the day, as a record of which vaccines were used during the day (photo on the left below).
- Distribution plan was available at only RVS Akola and DVSs Nanded , Hingoli, and Pune.
- DVS Nanded has a very efficient Vaccine distribution system, which is being implemented regularly and efficiently (right side photo below).
- Staffs at all RVS are knowledgeable about the correct ice pack conditioning and vaccine packing during transport.



The areas of concern that cause the scores to be limited are:

- Distribution schedule is missing at all RVS.
- Distribution plan is not available at SVS and DVS (Except Nandade, Hingoli and MC Pune). Most of the vaccine stores do not follow the recommended practice of distribution shown on top.

  The RVS do not distribute vaccines to the DVS, who have to come and collect. Likewise, the DVSs do not follow the recommended practice of distributing the vaccines to their PHCs. Most have their PHCs come to collect vaccines from them, though the DVS have the funds and vehicle to do it.
- At PHC level except (PHC Kategaon), vaccine demand, distribution and usage reporting register is not available.
- There are frequent instances of short shipment. The key reasons a are attributed to :
  a. low level stock at upper level
  b. Short shipment is a general tendency
  c. Tendency to demand more
- Staffs, including Pharmacists and Female Social Healthcare worker, at most of the PHCs do not know proper ice pack conditioning. In most places hard frozen IPs are sent along with freeze sensitive vaccines, with a serious risk of causing freeze damage to the vaccines by the time it arrives to its destination.
- There is no contingency plan for handling emergencies during transport.
- Vaccine vehicle repair/maintenance funds and as well as telecommunication funds are not allotted to the vaccine van drivers during transport.

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^{o}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, whichever 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	State	8 RVS	12 DVS	25 PHCs	3 MC	9 UHP	M.MC	M.W.	4 HP
Score	50%	35%	46%	68%	46%	56%	52%	30%	74%

The consolidated scores of the practices indicate weak performance of this criteria at all levels except the UHP of Br. Mumbai.

The strengths and concerns that contribute to the performance indicated above are:

- VVM Posters are available at many stores including RVS – Latur, DVS - Para, Chandrapur, Hospital Pune, MC Pune, Malegaon, and PHC-Vairagad, Shankarpur.
- Guidelines dated 18 September 2009 (ref no 212/40973-113/09) for proper vaccine storage and distribution is available and circulated to all vaccine stores at all levels.
- These guideline also includes that trained DPHN/HA should be appointed as vaccine handler to maintain the stock and stock records at district HOSPITAL/PHC/CHC. However in practice, the FSA and FHA (Female health assistant) all handles vaccine.
- CPCB Guidelines are available and have been circulated across state stores on 6th December 2004 for implementation of disposal of Biomedical waste generated during immunization program; However the same are not followed systematically.

The important concerns that need to be addressed to improve performance are:

- These Guidelines dated 18 September 2009 have not been implemented or followed by most of the staffs and supervisors in particular at any level.
- The Regional Vaccine stores staff is not having good knowledge of shake test (except RVS-Nagpur, Akola). There is no instance when it has been implemented. The same prevails at some PHCs (PHC Rajawad, Satargaon).
- Vaccine Wastage rate is not calculated in spite of the data being available in the regular MIS at any level in the state.

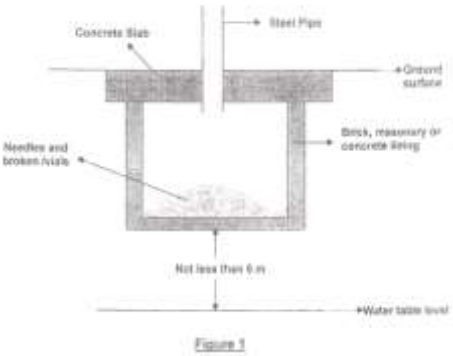
- There is a short supply of Vaccine Vial Monitor (VVM) posters mostly at RVS, PHCs.
- There are instances of distribution and use of mismatched vaccine and diluents (eg. Measles vaccines at PHC Babulgaon); the diluent was from a different manufacturer than the vaccine. The supply of diluent was traced up to DVS level.
- At PHC –Para HIV kit was kept in the cold chain along with the vaccines. While at PHC Shembal-Pimpiri transport Media and Insulin Injection was kept in the ILR dedicated for vaccine storage.


- **Transport Media and Insulin Injection in vaccine cold chain at PHC –Shembal-Pimpiri**

- Open return vaccine vials were observed at
  - TT at PHC-Vedha
  - DPT and TT at PHC -Runza


Open return vials at PHC Runza

- Opened or damaged vials are not disposed as per the CPCB (Central pollution control board immunization waste control guidelines). Staff is not aware of the need and method of disinfection of biological waste before disposal (eg PHC Shankarpur, Jiwati etc).
- Syringe disposal pits are constructed at most of the PHCs but not as per the guidelines. They are not used by the staff at PHCs in a methodical manner.




Disposal Pit PHC Shankarpur not in use

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.

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:

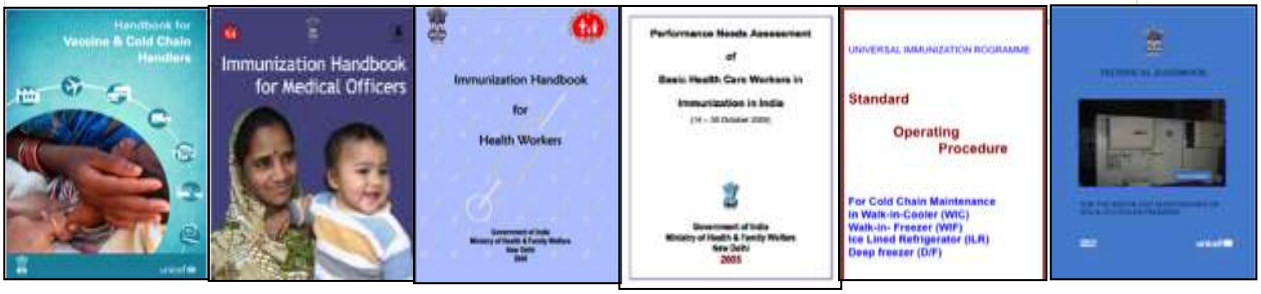
- Standard Operating Procedures are in place,
- Field data is collected and the same are used for programme management purpose,
- An annual work plan is in place,
- Out-sourced services are fully funded and resourced.

Findings

Vaccine Store	State	8 RVS	12 DVS	25 PHCs	3 MC	9 UHP	M.MC	M.W.	4 HP
Score	38%	10%	17%	9%	45%	9%	23%	6%	9%

The MoHFW 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.



Error! Reference source not found.

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. An important letter providing several directives for improvement the cold chain and vaccine management was issued on 18 Sept. 2009 by the Addl. Director.

Maharashtra has translated the new "Handbook for Vaccine and Cold Chain Handlers" in Marathi. 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, except the renting of cold room space at Konduwa for the SVS.

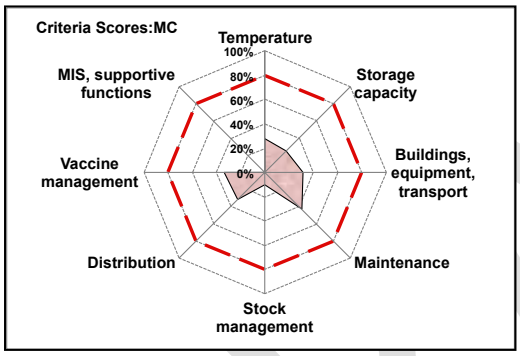
The forecast of vaccine at the state level is based on the total and target population obtained from the extrapolation of an old census, and using the standard method. However, the wastage rate is not evidence based and coverage is assumed 100% for all antigens.

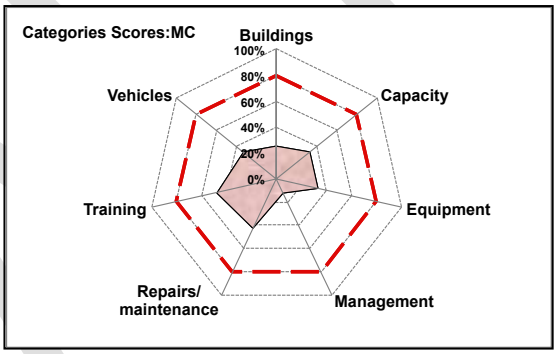
At lower levels, the standard method is not systematically used (eg. RVS Aurangabad, Kohlapur, Thane MC) as staff are not well familiar with the method.

A few other areas that require improvements are:

- Staff are not referring to the Vaccine Handler's handbook for doing their task correctly
- 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 cold chain inventory does not contain details of the equipment making evaluation of capacity available difficult.

MC- MALEGAON





The graphs above present the performance of Malegaon MC. The scores for all the indicators are rather poor with the scores being close to 0 for Stock management and Supportive functions among the indicators and for Management in the categories.

The key issues at this vaccine store are:

- The MC store been operations as a virtual store since quite some time. Vaccine is distributed for use as soon as it arrives.
- Though it has cold chain equipment, Vaccine is not stored at all in the cold chain.
- Hence temperature records are not maintained.
- Stock records are not maintained
- Condemned items cluttering usable space at MC – Malegaon

This store requires special attention to get revived and revitalized in all respects.

7. RECOMMENDATIONS

The key recommendations are provided according to the implementation categories to improve the performance of the indicators. Stress is needed in the area of management aspects as evident from the above discussion. The priorities are indicated as follows:

1: Immediate- Urgent, as soon as possible (within 1month)

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 and prioritized recommendations will be helpful to draw up an action plan and a road map by the respective authorities to rapidly implement the corrective actions. The resulting action plan will, it is hoped, be helpful to prepare the future PIP part C for the districts and the state.

In additional recommendations for human resource is also included, as this is a key component of an effective supply chain. The suggestion is that supervision of the activity be carrier out by the staff as given in the table below for the respective levels. The staff will then report to the officer responsible for the full RI at that level. Each officer responsible for the full RI will report in turn to the one having this responsibility at the upper level.

List of supervising staff at different levels and activities			
Level	**Full RI Responsibility**	**Vaccine Management**	**Cold Chain**
State	State EPI Officer	State Vaccine Logistic Manager	SCCO
Regional	ADHS	CC & VM Coordinator	
District	DRCHO / DIO		
Health Facility	MO		

List of Recommendations classified in terms of implementation categories and priority

Category	Priority	To be implemented by at respective levels	Action required
Human Resource and Policy	1	ACS / Directorate	✓ Ensure that the state has a dynamic and proactive State Immunization Officer
	1	ACS / Directorate	✓ Ensure that the state has a competent State Cold Chain Officer ✓ The State Cold Chain Officer should have a profile of a manager who also understands certain technical aspects of refrigeration. He should manage the cold chain inventory and the cold chain technicians' operations with the help of divisional level cold chain coordinators / HEMR technicians.
	2	ACS / Directorate	✓ Appointment of one State Vaccine Logistic Manager who will report to the State Immunization Officer. He will oversee and manage the vaccine stocks at all levels to ensure that stock-outs incidents are reduced to nil. He will coordinate at regional level with the regional level cold chain coordinators or store managers for this.

Category	Priority	To be implemented by at respective levels	Action required
	2	ACS / Directorate	✓ Appoint one cold chain and vaccine logistic coordinator at the regional level who will ensure proper supply to and from the regional stores and supervise the repair and maintenance by the cold chain technicians. He will report to the state vaccine logistic manager on vaccine issues and to the cold chain officer for cold chain and technician related issued. ✓ Alternatively, the task of supervising the district cold chain technicians can be given to the senior cold chain technicians of the HEMR unit stationed at each circle
	2	ACS / Directorate	✓ Appoint a dedicated person to oversee the Cold Chain and Vaccine Management at RVS level (eg. Asst. Dir. of HS - Public Health). He should also supervise the Regional cold chain and vaccine logistic coordinator.
	2	ACS / Directorate/ SEPIO ACS / Directorate / RDD / DRCHO	✓ At the State and Regional vaccine store it is important to have round the clock monitoring as in Br. Mumbai. Vaccines worth more than 2 crore Rs. may be present in SVS and more than 40 Lacs at each SVS. Adequate number of semi skilled helpers or funds to engage them on contract are required at SVS and RVS (round the clock) and ✓ Ensure one helper at each DVSs (Vaccine worth 3 to 10 lacs are handled at the DVS).
	2	ACS/Directorate /ADHS	✓ Support revamping and upgrading of MC-Malegaon to make it a model MC-vaccine store
	2	ACS / Directorate/ SEPIO / ADHS / DRCHOs	✓ Ensure that all staff handling vaccines at SVS, RVS and DVS are pharmacists, and have been trained in vaccine logistic management.
	3	ACS / Directorate	✓ Strengthen staffing by ensuring that all vacant posts at all levels are filled by staff with the right profile (DRCHOs, Pharmacist, Cold chain technicians etc).
	3	ACS / Directorate	✓ On the long run procure and install a computerized temperature monitoring system for all WICs / WIFs
Building	1	ACS / Directorate	✓ Ensure that Latur RVS is provided with adequate space in the new building on the ground floor.
	2	MOs/ DRCHOs	✓ Make immunization disposal pit as per guidelines wherever not appropriate or non-existent.
	3	ACS / Directorate/ MCs	✓ Move all MC vaccine stores that are on upper floors to ground floor or in the last resort to the 1st floor. Same applies to other stores if located on upper floors ✓ Every vaccine store MUST have dedicated room with adequately ventilated space for equipment, dry space, staff office, working space, and repair space (at DVS and MC).

Category	Priority	To be implemented by at respective levels	Action required
	3	DRCHOs / ADHS	✓ Evaluate condition of building and sufficiency of space at all District vaccine stores according to the recommended norms for equipment required for vaccine storage space, dry space, repair workshop and office space for the pharmacist. ✓ Explore availability of the same through management of space – especially by disposal of unwanted materials. ✓ If the space required in insufficient then plan for a new building, with adequate space to ensure sufficiency of storage space for vaccines (placing of required equipment), diluents, syringes, repair workshop and office area. Define the need based on population to be served. ✓ Develop and adopt state specific model for RVS and DVS based on IPHS recommendations and prototype from Orissa for designing the store.
	1	ACS / Directorate/ SCCO / HEMR	✓ Ensure completion of installation of all newly installed WICs and WIFs as per standard. Ensure the same are handed over with submission of completion and commissioning report. ✓ It is advisable, considering the poor quality of installation, that a third party verifies the commissioning reports and installations.
Equipment	2	ACS / Directorate	✓ A real time computerized Vaccine Logistic Supply Management system (VLSM) should be implemented in the state at all levels. Orissa has a working programme.
	2	SCCO / ADHS	✓ Ensure that all WIC and WIF have continuous temperature recorders and recording is carried out in a continuous manner.
	2	SCCO / ADHS	✓ Ensure that all WICs / WIFs are equipped with working hooters.
	2	SCCO / ADHS / DRCHO	✓ Ensure proper condemnation and disposal of non-repairable equipment
	2	SCCO	✓ Supply large size equipment at DVS, MC and Wards. Small ones should be reserved for PHCs and HPs.
	2	SEPIO / ACS / Directorate /	✓ Contact GoI for rapid implementation of freeze indicators during storage and transport of freeze sensitive vaccines across the state.
	2	DRCHO / MO / CCO	✓ Ensure that all PHCs which have a solar / inverter back up system is installed, the same is first serving the cold chain equipment.
Capacity	1	SCCO / ADHS	✓ Ensure sufficiency of freezing space at all RVS by providing additional DFs.

Category	Priority	To be implemented by at respective levels	Action required
	1	SCCO / DRCHO	✓ Strengthen storage capacity at all DVS by providing required additional cold chain equipment. Important to take into account net storage space based on 3 months of vaccines requirement as per GoI guidelines. Ensure that adequate and suitable floor space is made available for the same.
Management	1	ACS / Directorate / SEPIO	✓ Implement directives of 18 Sept 2009 letter.
	1	SEPIO / ADHS / DRCHO	✓ All transport of vaccines MUST be carried out using standard containers and according to the SOP. c. Thermocol boxes must not be used d. Non-standard ice packs and gel packs must not be used ✓ Proper ice pack condition is carried out .
	1	SEPIO / ADHS / DRCHO	✓ Segregate the non-RI drugs from RI vaccines at all levels.
	1	SEPIO / ADHS / DRCHO / MO	✓ Provide sufficient attention to safety issues (recharged fire extinguishers,
	1	ADHS / DRCHO	✓ Contingency funds MUST be available to ensure timely repair of all vehicles Ensure staff know how to handle different types of emergencies
	2	Directorate / SEPIO / ADHS / DRCHO	✓ Define, print and distribute standard formats of different records (temperature monitoring, all movement of vaccines: stock keeping, indent and supply etc) at all levels. ✓ Ensure availability of all for proper record keeping at all levels. ✓ Ensure that the vaccine receiving stores returns the issue vouchers to the issuing stores within 48 hrs
	2	SEPIO / ADHS / DRCHO	✓ Prepare contingency plans are required for each store and ensure that staff is competent to implement them.

Category	Priority	To be implemented by at respective levels	Action required
	2	ACS / Directorate/ RDD / RCHO	✓ Strengthen supportive supervision and ensure that all aspects of cold chain and vaccine management are implemented correctly c. All aspects of planning, implementation and record keeping are followed and non-standard practices (eg. use of non-conforming icepacks, foam boxes etc.) are not continued. d. Temperature records, stock records, indent registers, and passbooks are monitored to ensure compliance with SOP. ✓ Ensure that stock management is carried out correctly a. All salient aspects of vaccines and diluents are recorded. f. Maximum and minimum stocks are respected to ensure zero stock-out. g. Indents are based on peak stock calculations and balance in hand, h. Timely indents are made on reaching minimum stock and emergency indent is made on breaching buffer stocks. ✓ 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	ACS / Directorate/ ADHS / DRCHO	✓ Request GoI to provide vaccine supply plan well in advance, so that deliveries by the manufacturers can be planned directly to the RVS which are on the way.
	2	SEPIO / ADHS	✓ Ensure that at SVS and RVS periodic monitoring and recording of all salient parameters are carried out by the staff (round the clock).
	2	ADHS / DRCHO / MO	✓ Manual temperature monitoring should be twice daily, 365 days a year for each equipment containing vaccinesat every store .
	2	SEPIO / ADHS / DRCHO / MO	✓ Improve proper stock management and distribution of vaccines with its diluents. Diluents details should be recorded in the same manner as vaccines.
	2	ADHS / DRCHO	✓ Fund allocation for van drivers for tele-communication during transport of vaccines
	2	ADHS / DRCHO / MO	✓ System for bio-medical waste management is being correctly followed. ✓ Use CPCB guidelines circulated in 6th Dec 2004, for proper waste disposal of return vaccines , broken vials and syringes
	2	DRCHO / MO	✓ Disinfect the IPs used for stool samples before mixing with other ice packs in the cold chain.
	3	SEPIO / ADHS / DRCHO / MO	✓ Improve recording of wasted vaccine. ✓ Review vaccine wastage records.

Category	Priority	To be implemented by at respective levels	Action required
Repair & Maintenance	2	SCCO / HEMR / CCT	✓ Plan and ensure implementation of periodic preventive maintenance of equipment by the technicians. ✓ A logbook for each equipment should be adequately maintained (as in Br. Mumbai-MC).
	2	SEPIO / PWD	✓ Regular maintenance of the buildings should be carried out
	1 2	SCCO / HEMR	✓ Ensure that all the condensers and cooling coils of WIC/WIFs are cleansed without further delay. ✓ Ensure that this is done again periodically (every 6 months).
	2	ADHS / DRCHO	✓ Allocate the required funds for timely repairs maintenance of Vaccine vans.
Training	2	ACS / Directorate	✓ Supervising staff requires orientation in CC & VLM and its supportive supervision. Conduct required capacity building workshops with hands on practical exercises.
	2	SEPIO / ADHS / DRCHO / MO	✓ Store keepers and helper require retraining in ice pack conditioning
	2	SVLM / ADHS / DTCHO	✓ Staff need to be trained on correct forecasting based on actual needs and respecting maximum and buffer stocks.
	2	ADHS / DRCHO	✓ Ensure staff know how to handle different types of emergencies
	3	DRCHO / MO	✓ At service point (CHCs / PHCs / HPs) provide hands on training to at least 2 staff using vaccine handler's modules.
	3	ACS / Directorate / SCCO / HEMR	✓ 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.
	3	ADHS / DRCHO / MO	✓ Training of the staff on proper disinfection of the biomedical waste prior to its disposal, and correct disposal practices.
Vehicle	3	SCCO / ADHS / DRCHO	✓ Vaccine vans required at RVS-Latur and 8 DVS for distribution of vaccines