WHO-UNICEF

EFFECTIVE
VACCINE STORE
MANAGEMENT
INITIATIVE

EVSM Assessment ORISSA

September 2009

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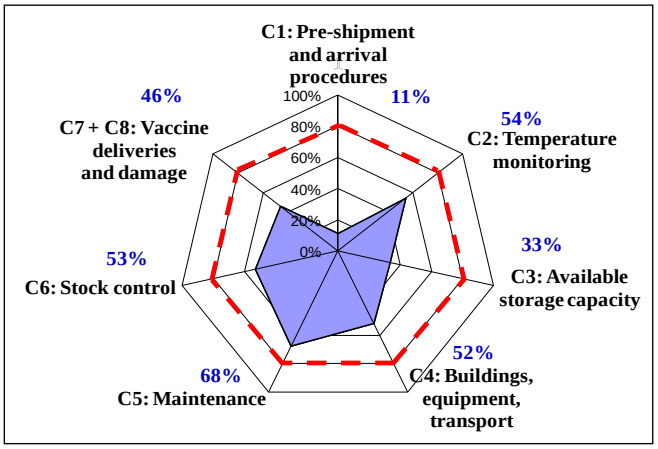
Executive Summary

The assessment of the state vaccine store of Orissa was conducted from 6 to 12 September 2009 using the WHO-Unicef Effective Vaccine Store Management Initiative modules number 3. The result of assessment in form of spider graph is shown alongside.



The graph and results indicate that while certain capacity and strengths have been built at the SVS, there are other areas that need to be addressed. The detailed recommendations are given in the respective section with discussion of the findings.

The key actions required to be taken have been grouped according to the nature of their implementation. These are :

Management - Policy

1. Two of the semi-skilled staff recruited recently do not fit the stipulated requirements. Review their caliber and replace them if necessary
2. There is only one foreman looking after all the WIC in the state. State also needs another foreman to look after the equipment of the 7 RVS.
3. One foreman must be dedicated for regular maintenance and service of the SVS.
4. The foreman responsible for repair and maintenance of WIC/WIF should be relieved of his duty of spares and equipment store. So that he can focus better to the SVS.
5. As the CCO is to retire in 1.5 years, the state should plan future recruitments with this in mind.
6. The MoH / FW should work out a MOU with the excise department, in view of ensuring rapid and trouble free passage through the state borders.
7. DFW should make a MOU with the owner of some private cold room to ensure safety of the vaccines in case of any emergency.
8. Plan adequate immediate expansion of the SVS.
9. On long term – build a new SVS based on future immunization needs of the state

Equipment related

1. Procure and install a computerized temperature monitoring system, to ensure continuous monitoring of storage temperature.
2. Repair all acoustic alarms on the WIC and WIF and ensure they are always in working condition.
3. Compute vaccine requirements on 2 monthly basis and request GoI to ensure timely supplies to the state.
4. Procure and introduce use of freeze indicators for each and every distribution of freeze sensitive vaccines.

Planning

1. Plan replacement of the State WIC which is working on CFC, rapidly.
2. Prepare a preventive maintenance plan for all equipment, and ensure that the foreman follows. it.

Improvement in Practices

1. Maintain a service log sheet for each equipment.
2. Define working stocks (2 months) and safety stocks (1 month) for each antigen

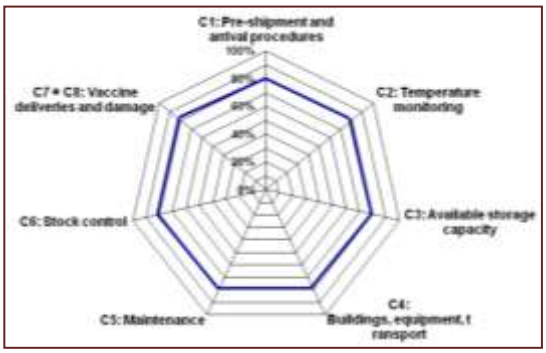
3. Implement recording of vaccine stocks on receipt at RVS
4. Always use standarised water/Ice Packs - do not use any Gel packs as its temperature is not well defined when conditioned.
5. The CCO needs to be more proactive in planning, management, and supervision of the activities of the staff at the Cell and the SVS.

1. Introduction to the Assessment Tool

The purpose of the WHO-UNICEF Effective Vaccine Store Management (EVSM) initiative is to encourage countries to procure and maintain equipment and to adopt management and training practices that fully protect vaccines in primary and intermediate vaccine stores. The initiative will provide countries with self-assessment tools, guidelines and model standards, focussed specifically on vaccine storage and distribution. Countries can use these tools and documents to assess weaknesses in equipment and operating procedures and to make the improvements necessary to meet the ten criteria set out in this document.

EVSM is based upon quality assurance principles. Vaccine quality can only be assured if the product is correctly stored and handled from point of manufacture to point of use. Managers and external assessors can only establish with certainty that quality has been maintained when detailed records are kept, and these records are reliable. If records are incomplete or inaccurate, the system cannot be properly assessed. Even if the vaccine is being stored and distributed correctly, a system that cannot be assessed is not "quality assured" and cannot be accepted as satisfactory under EVSM.

The results of the EVSM are represented on a spider web polygon. The spider web is composed of seven indicators (question 7&8 being merge d into one score) as illustrated here. The minimum score to be attained is 80% as indicated by the dark blue line running across the 80% level. Indicators 9 & 10 are only assessed qualitatively.



With the introduction of new more expensive vaccine it is critical that countries strengthen central and peripheral cold storage for vaccines. The Global Alliance for Vaccines and Immunization (GAVI Alliance) recommends in their Guidelines on country proposals for new and under-used vaccine support (NVS) that countries conduct regular assessments of their vaccine management using the WHO-UNICEF EVSM tools.

2. Objectives and Methodology of the Assessment

The last assessment of the state store Orissa was conducted in December 2007 using the VMAT. The current assessment has been undertaken to complement the new VMAT exercise and to assess the Orissa's readiness to introduce new vaccines.

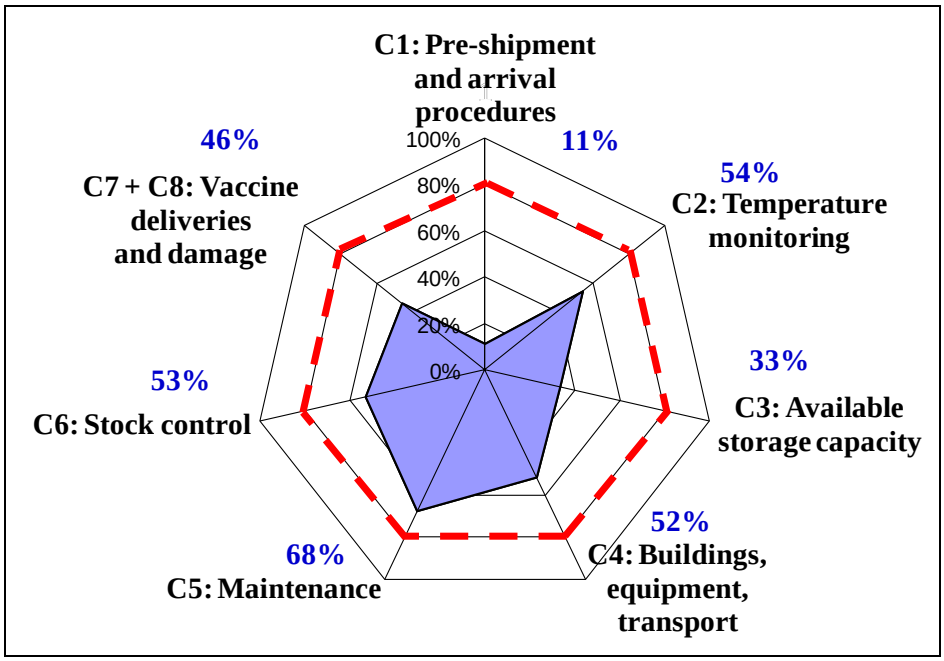
The objective of the assessment is to identify the weaknesses in the vaccine management and define measures needed to update institutional development plan with MFW to carry on with implementation of new procedures to fully achieve quality criteria for EVSM by 2011-12 in the state vaccine cold store and set an example for other states.

In the following section, the findings of the assessment are described in detail along with the resulting score for each criteria. Recommendations have been provided to address the weaknesses. They key recommendations have been classified in the executive summary and conclusion.

3. Findings and Recommendations

The spider graph below summarises the performance of the SVS. The achievements and compliance with quality plan result in the polygone within the spider chart. The thick dashed line indicate the 80%

minimum recommended score that needs to be achieved for WHO-UNICEF certification. The details for each of the indicators are discussed in the section below. Recommendations are provided to enhance the scores.



Pre-shipment and arrival procedures ***Implemented: 11%***

Over a period of 12 months, pre-shipment and arrival procedures have ensured that all shipments were in satisfactory condition when received in the primary stores.

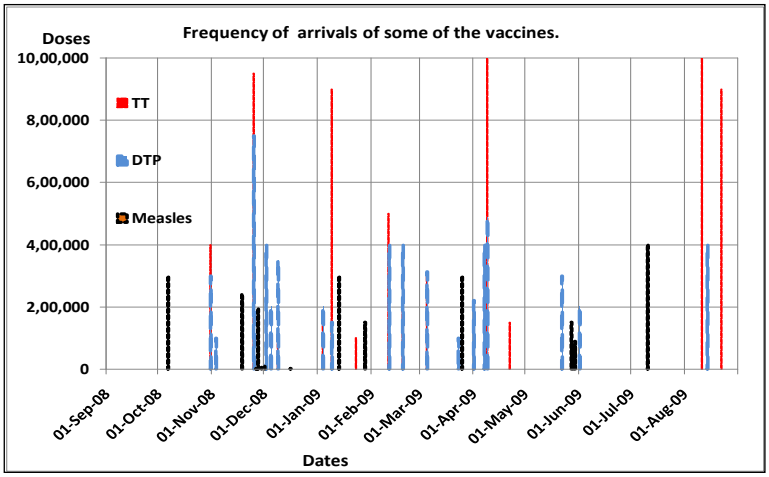
The arrival of vaccines in country, their temporary storage and clearance through customs and their subsequent transport to the central vaccine store is often the most critical stage in the cold chain. Unfortunately, experience shows that this is often the time when mistakes are made and delays occur. Such mistakes and delays may result in damage to the vaccine shipment.

The smooth arrival and handling of vaccine shipments depends on the manner in which each stage in the delivery process is performed. Many parties may be involved – for example the vaccine manufacturer, UNICEF Supply Division, the forwarding agent, the airline, the UNICEF field office, custom authorities, clearing agents and the ministry of health. Given the need to communicate accurate, time-sensitive information, and to act on this promptly, it is essential that strict guidelines are put in place to define the tasks involved, to assign responsibility for carrying out each task, and to monitor performance.

Ten Global Criteria for Effective Vaccine Store Management. WHO/IVB/04.16-20

This is the lowest performing indicator. Basically the VARs have not been adopted and the records of vaccine arrivals are not well complete and organised.

Vaccines are supplied by GoI either from the already procured stocks stored in the GMSD or ordered from and delivered by the Indian manufacturers. There have been 72 vaccine arrivals during the assessment period. Some of these



shipment have more than 1 antigens (TT & DTP have been shipped together).

The details are given in Annexure A. The summary is given in the table below. The adjoining chart illustrates the frequency for TT, DTP and measles. Clearly managing so many and frequent supplies is rather challenging.

Antigen	OPV	Hep B	Measles	BCG	TT	DT	DTP	Total
Arrivals	7	2	14	6	13	11	19	**72**
Dispatches	72	2	78	71	73	48	77	**421**

The dispatches of 421 lots have been carried out in 153 trips.

44 of these shipment had some of the key documents (e.g. advance intimation, invoice, lot release certificate and inspection report) which can be considered as next best set of documents to be stored. Only 2 arrivals had all these documents. 13 of these are having inspection notes more or less completed to a reasonable level. None of the incomplete documentation of the inspection were followed up

Of the 72 vaccine lots, only 15 had the lot release certificate from the country of origin.

There have been instances, when vaccines sent by Biologicals E limited, Hyderabad, have a different vaccine in the carton than what is mentioned on top : One TT cartons contained DTP (12,000 doses). One consignment of 4,00,540 doses of DPT from the same supplier, arrived during the assessment. The delivery note mentioned DTP while the accompanying document referred to TT. DTP was supplied.

There are no international shipment directly to Bhubaneswar, which require customs clearance. On the other hand, most shipment arrive by road using refrigerated or non-refrigerated vans. For example the GMSD –Kolkata sends vaccines in non -refrigerated vans and the drivers are not always trained in the proper handling of vaccines. Such deliveries are subjected to interstate border checks by the state excise staff. These are instances of potential delay as the excise personnel at the state border check points do not know the importance of vaccines. Depending on the nature of good and the level of documents, a certain fee is also required to be paid.

There is a need to develop a MOU with the excise department officials and obtain an authorization for a rapid transit through the border excise check points.

The HWf of the SVS is knowledgeable in vaccine handling. The 4 semi-skilled workers are new and are trained partially on the job. The entire process of receiving, unpacking and storing is currently functioning under her guidance and supervision.

Recommendations:

- 72 arrivals in a year is rather a large for a state store. Some of these arrivals contain more than 1 antigens. GoI should try to reduce the number of arrival by requesting manufacturers and GMSD to supply bulk quantities in one shipment.
- A separate file must be prepared for every lot of vaccine that arrives. The file should contain all the important documents and a copy of the VAR. A set of coloured files have already been given at the SVS, with initial guidance on how to prepare them for the old arrivals.
- The MoH / FW must work out a MOU with the excise department, in view of ensuring rapid and trouble free passage through the state borders.

Temperature Monitoring ***Implemented: 54%***

Over a period of 12 months, all vaccines have been stored within WHO recommended temperature ranges.

All vaccines are sensitive biological substances. Over a period of time, they lose their potency – that is, their ability to give protection against disease. 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 order to maintain their quality, all vaccines must be continuously stored at the appropriate temperature from the time they are manufactured until the moment when they are used. Once vaccine potency is lost, it cannot be regained or restored, and without proper care, any vaccine will eventually become ineffective. Once this occurs, the vaccine will no longer provide any protection against the target disease and the product is then useless. In some cases, loss of vaccine potency may also cause the vaccine to become more reactogenic.

The only way that it is possible to prove that vaccines have been stored at the correct temperature at all times is by using a continuous temperature recording device. This instrument should be regularly calibrated to ensure that it is accurate. Temperature records must be inspected regularly and retained for auditing purposes.

The recommended conditions for storing EPI vaccines are shown in the figure below. This diagram indicates the recommended storage temperatures and the maximum storage times at each level in the cold chain. At the higher levels of the cold chain, i.e., at primary, and regional intermediate stores oral polio vaccine (OPV) must be kept frozen between -15°C and -25°C). WHO no longer recommends that freeze-dried vaccines (measles, yellow fever, Hib and BCG) be shipped and stored at -20°C. Storing them at -20°C is not harmful but is unnecessary. Instead, these vaccines should be stored and transported at +2°C to +8°C. All other EPI vaccines should be stored at between +2°C and +8°C at all levels of the cold chain.

Diluents for vaccines are not sensitive to storage temperatures as the vaccines with which they are used. They are normally stored at ambient temperature, unless the diluent is packed with the vaccine. In this case they should be kept in the cold chain at between **+2°C to +8°C**. Diluent vials **must never be frozen.**

Ten Global Criteria for Effective Vaccine Store Management. WHO/IVB/04.16-20

Findings

The health worker- female (HWf) is knowledgeable of proper storage of vaccine. Some confusion existed regarding the storage of BCG at minus temperatures. The junior clerk is not knowledgeable about the proper storage temperatures. The 4 semi skilled staff are new and have been learning about the storage temperatures. They follow the instruction given by the HWf.

The HW has undergone earlier training of vaccine handlers, and has been actively involved during the 2 VMAT exercises. No formal training has been given to the semi skilled workers.

Continuous graphs are available for the WIF for the past 12 months. The continuous is lacking a working pen The WIC of SVS has not been equipped with the graph recorder, though it was already recommended during the 2007 assessment. 4 graph recorders have been in stock but these have not been used.

High temperature situations are marked with reason on trace charts of the WIF. However there are no written temperature review reports.

The HWf noted that there is a difference in temperature readings from plotter, digital temperature indicator and normal thermometer. The two foremen responsible of repair and maintenance of the cold rooms do not know how to calibrate the thermometers.

No vaccines have been wasted due to improper storage temperature at the SVS. Records of OPV and DTP were verified.

About 6,685 doses of Measles vaccine manufactured by HBI which were called back based on instruction from GoI are due to expire in Dec 09. The same have been kept in the 4th deep freezer as per instruction from HBI, and awaiting further instructions. However, no further communications have been received since the last letter dated 24 April 2008.

There are no written contingency plans. The HW has a good idea and has even identified and inquired with a private cold storage facility in case of emergency needs of vaccine transfer to alternate location. The cost of renting that facility is Rs. 80 per sq meter. However there is no MoU for such an arrangement. Contact numbers of this facility is included in emergency contacts pasted on wall.

Recommendations:

- State store must ensure continuous monitoring of temperature of all equipment used for storing the vaccines. The WIC must be ALWAYS equipped with a working continuous chart recorder.
  - On the long run, once the extension wing is ready, a 12 or 16 channel data logger must be fitted for monitoring the temperature in all the equipment at state level.
- All manual temperature records and charts must be properly filed and store for at least 3 years.
- Temperature sensors must be calibrated at least once every 6 months. The deviation should be marked visibly so that necessary correction can be carried out whenever required.
- DFW should make a MOU with the owner of some private cold room to ensure safety of the vaccines in case of any emergency.

Cold storage capacity ***Implemented: 33%***

Over a period of 12 months, the capacity of cold storage has been sufficient to meet the demand.

At all stores, but particularly at the primary level, new orders for vaccine must be placed early enough to ensure that a new shipment arrives before the safety stock level is reached. Supply intervals, working stock levels and safety stock levels should be selected to suit local circumstances, including available storage capacity and suppliers' lead times. Stores generally have longer supply intervals and larger safety stock levels the higher they are in the supply chain. For example, safety stock levels at the primary store are may be set at three month's normal consumption, whereas a health facility may only carry a two week safety stock.

When calculating the capacity of cold storage, programme managers must consider and balance a number of factors. These include financial considerations, vaccine expiry dates, supplementary immunization activities (national immunization days and campaigns), seasonal access, seasonal demand, and cold chain reliability.

Storage capacity should be enough to accommodate peak level stock requirements for the routine immunization schedule. In addition, satisfactory arrangements need to be made to ensure that vaccine supplied for national immunization days (NIDs) and campaigns can be temporarily accommodated in storage facilities that meet WHO standards.

Ten Global Criteria for Effective Vaccine Store Management. WHO/IVB/04.16-20

Findings

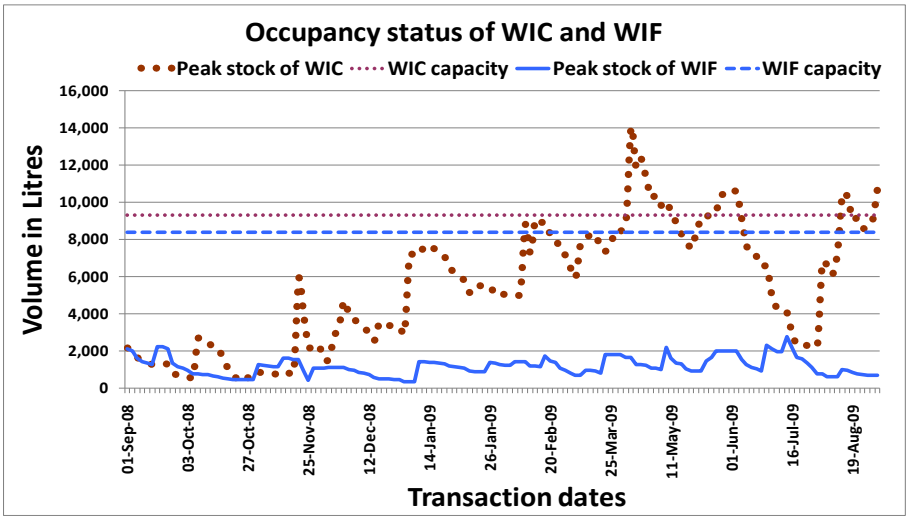
The SVS has one WIF having a gross capacity of 28 Cum (net 8,400 litres); one WIC having a gross capacity of 30.8 Cum (net 9,240 litres. The second WIC having a gross capacity of 16 CuM and net capacity of 4,800 litres is earmarked for the newly proposed RVS Bhubaneswar. However, its space is currently also used to store the SVS stocks.

The peak storage volume of stocks received in the past 12 months has been 15,359 litres for +2 to +8^{o}C and 1,733 litres for -15 to -25^{o}C. Due to shortage of storage space, the Measles has been stored in the WIF. Even considering the total space of the WIC earmarked for RVS-BBS, there would be a shortage of space for storage of all vaccines other than OPV for SVS and RVS.

The SVS staff and the vaccine logistic manager has not carried out any computation of the actual space requirement for vaccine storage.

According to WHO recommendation the state stores should keep 3 months of working stock and 1 month of safety stock. The table below provides the summary status of storage requirements under these assumptions for WIC and WIF. 2010 projected target population of less than 1 year (9,93,746) and pregnant women population of 10,93,120 is used for these calculations.

	Space at +2 to + 8C				Space at -15 to -15 deg C		
Immunization Plan	**Space Required**	**Total Space Available**	**Addl. Space Required**		**Required**	**total space Available**	**Surplus space available**
	Litres	**Litres**	**Litres**		**Litres**	**Litres**	**Litres**
Present Plan	14,045	9,240	**4,805**		3,533.3	8,400.0	**4,867**



While there is sufficient space for storing OPV, there is a serious shortage of space for storing the other vaccines.

In reality, due to inconsistent supply of vaccines from the manufacturers and GMSD, the actual quantities has never reached 3 + 1 month of stocks. The adjacent graph illustrates the actual supply of stocks during the past 12 months and the capacity of the storage. Due to the irregular and frequent supplies of vaccine, in reality the current space available was exceeded only on 4 instances.

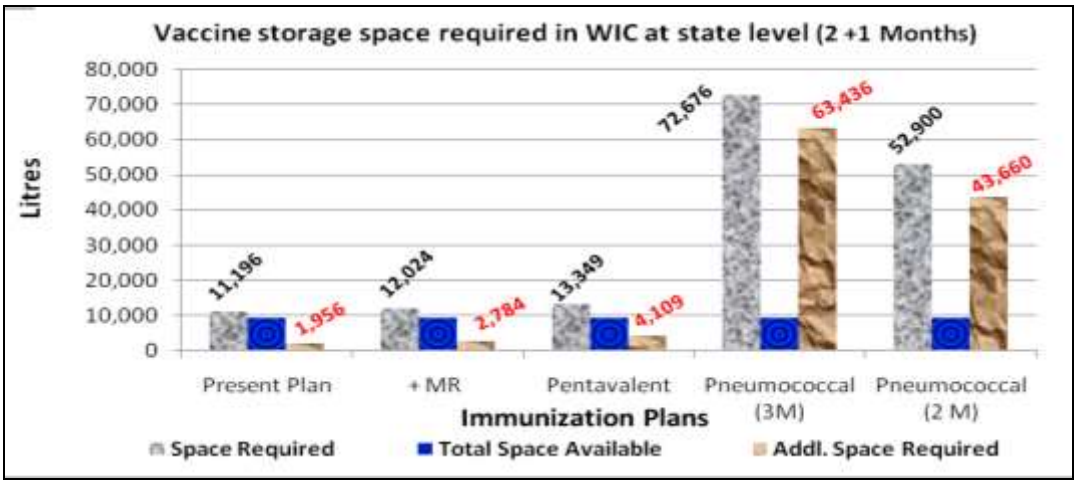
The total space required for OPV in all cases would be 2,650 Litres. There will remain an excess space of 5750 litres in the WIF. This may be used in case of emergency to store Measles (MR or BCG).

Considering that the GoI is requesting suppliers to supply vaccines at intervals of every 2 months, and the shortage of space, one may review the storage requirement based on 2 months of working stock and 1 month of safety stock. We can also estimate the requirements for the future plans: introduction of MR in 2010, thereafter the replacement of DTP and Hep B by introduction of Pentavalent, and in a few years the introduction of Pneumococcal. Annexure B gives the details of the storage space required upon addition of each respective antigen.

The large volumes of Pneumococcal (59.7 CuCm/dose) will demand a very large increase in the storage space. Besides, shipments corresponding to 2 months of requirements of Pneumoccoccal may not be possible as a single air cargo due to limitations of the aircrafts. Hence it is suggested to consider 1 month of working and 1 month of safety stock. This will reduce the demand on the total space needed in WICs by 30%.

	Space at +2 to + 8C		
Immunization Plan	**Space Required**	**Total Space Available**	**Addl. Space Required**
	Litres	**Litres**	**Litres**
Present Plan	11,196	9,240	**1,956**
With MR	12,024	9,240	**2,784**
With Pentavalent	13,349	9,240	**4,109**
+ Pneumococcal (2 +1 M)	72,676	9,240	**63,436**
Pneumococcal (1+1 M)	52,900	9,240	**43,660**

The adjacent table provides the summary for all the vaccines that need to be stored in the WIC. The graph below illustrates the volume of the vaccines, space available and additional space required.



Campaign vaccine (OPV) is normally dispatched the same day to the 7 RVS. If ever need arise it is stored in WIF which has excess capacity. Temporary facilities have not been used till date.

Recommendations:

- Staff responsible for the planning and storage of vaccines should evaluate the total space requirements and suitability. Methods explained during the VMAT training should be used for this purpose.
- Orissa needs immediately one WIC with a net capacity of at least 2,000 litres.
  - The WIC planned to be supplied by GoI is having a net storage capacity of 4,800 litres will be suitable to fill this current additional requirement.
- Another WIC with a net capacity of 10,000 litres is need to replace the current CFC cold room
- In view of the future possible introduction of pentavalent and pneumococcal, Orissa will need at least 45,000l Ltrs of additional net storage space at the state level. In the new master plan to make a totally new wing of the SVS for the future, the MoH should consider:
  - For every dose of Pneumococcal for the annual target group, Orissa will need to plan for an additional requirement of 17,300 litres of net storage space in a WIC in future.

Status of Building, Equipment and Transport ***Implemented: 52%***

Over a period of 12 months, the buildings, equipment and transport available to the programme have enabled the cold store to function effectively.

Vaccine stores should be housed in permanent buildings. These should be designed and constructed to a good standard to suit local climatic conditions. The building should have adequate spaces to accommodate the cold storage equipment: a store keeper's office; a temperature-controlled packing area; space for storing diluent, packaging materials and cold boxes, and space for freezing and storing icepacks. The store should have good access for vehicles and adequate telecommunications.

Wherever possible, refrigerators and freezers should be chosen from the WHO/UNICEF *Product Information Sheets*. Similarly, wherever possible, cold rooms and freezer rooms should comply with current WHO specifications. Adequate arrangements should be made to ensure continuous temperature monitoring and to ensure continuous refrigeration in the event of refrigeration equipment failure. Vaccine stores should have a reliable electricity supply, with an automatic standby power supply in the event of mains failure.

Reliable and suitable transport is essential for the delivery of vaccines and immunization supplies. Without access to an effective and reliable transport system, the operation of the cold store cannot be regarded as satisfactory.

Ten Global Criteria for Effective Vaccine Store Management. WHO/IVB/04.16-20

Findings

Building

The SVS is located in an old building as part of DHS. The corridor is cluttered with several ancillary items: AD syringes, cold boxes, diluents, Vaccine carriers, polythene bags, and even 2 condemned refrigerators. There are instances when there is hardly any space to move in the corridor due to arrival of new stocks.

Incidentally, there are 2 rooms, one of them within the wing of the SVS and one just adjacent to its entrance, which are locked. It was learnt from the CCO that the rooms contain some condemned items belonging to FW and the staff responsible has expired more than 5 years ago. The rooms have never been opened since then.

The technicians and foremen have their repair shop in the Govt. Health Equipment Repair (HER) unit, where the govt. vehicles are repaired. There is also one large room belonging to the SVS there, which is occupied by the Drugs management unit.

Equipment

There are two WICs and one WIF (Hurre – 28 CuM) for storage of vaccines. One WIC (Yorco : 16 CuM) is earmarked for the proposed RVS for Bhubaneswar which will distribute vaccines to 10 districts. Due to shortage of space it is also used to store the SVS stocks. The large WIC (Hurre – 31 CuM) meant for SVS is CFC based and will need rapid replacement. There does not seem to be any plans for its replacement. The new WIC to be supplied by GOI is 16.5 CuM (gross) sized for the use of RVSs (net capacity 4,800 litres).

Only the WIF is equipped with a working continuous chart recorder. The WIC does not have one. In spite of recommendation following the 2007 VMAT, no chart recorder has been fitted on it, though 4 units were available in the stock at SVS. 3 of these have now been sent to the other RVSs. Finally upon insistence, the 4th chart recorder was fitted on the 11 September 2009. It was not operational till the 16th.

One refrigeration unit of Hurre - WIF (non-CFC) is not operating properly since about a month due to leakage of refrigeration gas.

There are 4 large DFs (MF 304: gross capacity 296 Ltrs, Net about 250 Ltrs). 3 out of 4 large DF are used for freezing icepacks for the SVS. One DF is used to store the measles stock (6,685 doses) from Human Biological Institute which was stopped for use as per instruction from GoI. The instruction stated that the same would be returned to the manufacturer, but did not give any clear guidelines whether the vaccine should be removed from the cold chain

None of the units have a functioning alarm.

There are three generators – one for each of the WIC and WIF. The generators are not connected to the deep freezers. None of the generators have their auto-start in operating condition. There is no separate budget to procure the fuel to operate generator. Fuel is procured from transport budget.

The SVS can communicate with the CELL and other RVS on phone. E-mail links have been established are also available. Fax facility is not there.

Transport

There are 2 insulated vaccine vans. The bigger one (16 CuM: 49 CB) is just sufficient to send the total quantity of vaccines required for 1 month supply to the largest RVS (Sambalpur). The smaller one can only transport 16 CBs.

Recommendations

- There is an urgent need to have more space at the SVS for dry storage and seating of the vaccine logistic manager and cold chain consultant at the SVS.
    - Explore possibility of availing the 2 unused rooms currently occupied by the FW division which are adjacent to the SVS. This will provide a good relief while awaiting construction of the extension wing and the planned future construction at the state drugs management unit.
- Plans of the extension of the SVS must take into account the urgent need to have an additional capacity of about 1500- 2500 litres of WIC storage space, besides replacing the CFC based cold room.
- For future, Orissa should build a suitable building that can care to the management of the Vaccines to be introduced in future. Sufficient space to house the required cold rooms (total capacity 65,000 litres net), the present WIF with a net capacity of 8,400 litres, required number of Deep freezers, dry space and office space.
- Generator output should also ensure that the DF freezing ice packs or storing vaccines be operated in case of power failure.
- A separate DF needs to be earmarked for the RVS BBSR.
- CCO and CCC must ensure proper functioning of all equipment at the SVS and monitor the records periodically.

Maintenance of Building, Equipment and Transport ***Implemented: 68%***

Over a period of 12 months, all buildings, equipment and transport have been correctly maintained.

In order to prevent breakdowns affecting the performance of the immunization programme, all equipment, transport and buildings should be routinely maintained to a high standard using a programme of planned preventive maintenance. Emergency repairs should become the exception rather than the rule and there should be zero tolerance of breakdowns affecting key equipment.

In all cases there must be a reporting system which records breakdowns and the use and replacement of spare parts and which monitors the effectiveness of repair procedures.

Ten Global Criteria for Effective Vaccine Store Management. WHO/IVB/04.16-20

Findings

During the assessment period, no vaccine is reported to have been damaged due to lack of adequate service. No vehicles have also been put out of service.

2 cooling units still operate on CFC refrigerant. 2 units of WIF has been replaced with after it burnt out. However no replacement planned and executed for CFC based WIC cooling unit. Trace reorder is out of order and has not been replaced in spite of recommendation since December 2007.

The quality of electrical wiring in Poor electrical wiring. The earthing in the office of the HWf was repaired during the assessment, as even the computer was giving an electrical shock.

There are no preventive maintenance plans.

There is only one of the two foreman stationed at SVS knows how to repair and maintain the WICs and WIF. He has to hence, keep moving around the state to the 7 RVSs. He is also responsible for the spares and equipment stores and inventory. The WIC of Baleswar is handled by one mechanic who is knowledgeable also in the repairs.

The second foreman of Bhubaneswar supports the RVS to handle ILR and DF which the mechanics fail to handle.

Spares of servo stabilizers, not available locally, that need to be procured from New Delhi have not been procured. The foreman claims that he has had to address repair issues somehow, without the recommended spares. This is risky and can end up with a large expense if the refrigeration units get damaged.

Recommendations:

- The foreman responsible of servicing the SVS WIC and WIF should be relieved of his duty as store keeper, as that task can be handled by a non specialised mechanic. This will ensure proper attention to the WICs and WIF at the SVS (and the RVS-BBSR in future).
- The state should have at least one more foreman trained in repair of WIC and WIFs to reduce the travel load of the present forman to other RVS.
    - If possible the mechanic of Baleswar may be transferred to the west of Orissa so that he can assume the responsibility of more than one WIC.
- All equipment and rooms must have proper electrical wiring, particularly earthing cable.
- THE CCO and CCC must be more proactive in ordering and follow-ups for procurement of spares.

Stock Management ***Implemented: 53%***

Over a period of 12 months, stock management has been effective.

In order to maintain the quality of vaccines throughout the cold chain, it is essential to keep complete and accurate records of all stock transactions. A stock control system comprises three steps, each of which must be performed regularly, accurately and completely. The three steps are:

- Checking and recording details of vaccine consignments when they **arrive** at a storage point;
- Checking details and conditions of vaccine stocks **during** the time they are kept in storage;
- Checking and recording details of vaccines consignments when they **leave** the storage point for distribution to regions, provinces, districts and, eventually, the user.

In addition, good warehousing practices should be adopted and physical stock counts should be carried out on a regular basis to verify stock records.

Ten Global Criteria for Effective Vaccine Store Management. WHO/IVB/04.16-20

Findings

New stock registers have been introduced since January 2009. The register has been designed to mark all the receipts on the left side and all dispatches on the right side. Both sides provide dedicated columns for marking many of the salient parameters of the vaccines, including VVM. Manufacturers and vial size are not marked. Freeze tag information is not included as it is not yet implemented in Orissa.

Diluents are also marked for each freeze dried vaccines. The measles lot, which was recalled based on the notice form GoI and the manufacturer in April 2008, are marked and stored separately in one DF

as requested by the manufacturer. No follow up action has been taken since then, and the stock is still awaiting directives for disposal.

The HWf has been maintaining meticulous records of all vaccines stocks at arrival and dispatch. The record verification was simplified thanks to this. The physical stocks are found to match accurately with the stock records of the vaccines.

The Cell has prepared a software for the Orissa Vaccine Logistic Supply Management (OVLSM) to track all arrivals and supplies from the SVS. It is yet to be fully implemented.

The concept of safety stock and working stock is understood by the HWf and the VLM but it has not been possible to implement this as sufficient supplies are not received. There are also technical limitation to this implementations, as supplies from GoI are not regular to ensure that safety stock will not be breached, and the total capacity is not sufficient to keep 3 months of stocks (2 months of working stock and 1 months of safety stock).

Stock books are kept safely in a steel cupboard. The physical stocks are also safe in the building, though the locks of the WIC are not working.

Recommendations

- For all arrivals and dispatches the manufacturer's name should be marked. This is particularly critical while sending the freeze dried vaccines and if one is having such vaccines from more than one manufacturers.
- Free the Deep freezer space occupied by the Measles vaccines that were recalled, by following up with the manufacturer and GoI .

Vaccine distribution ***Implemented: 42%***

Over a period of 12 months, deliveries of vaccine to the next level have been timely, sufficient and correct.

An effective vaccine distribution system should provide sufficient supplies of vaccine to lower level stores. Deliveries should be made in a planned and timely fashion. Every shipment should be accurately documented by means of a vaccine delivery report.

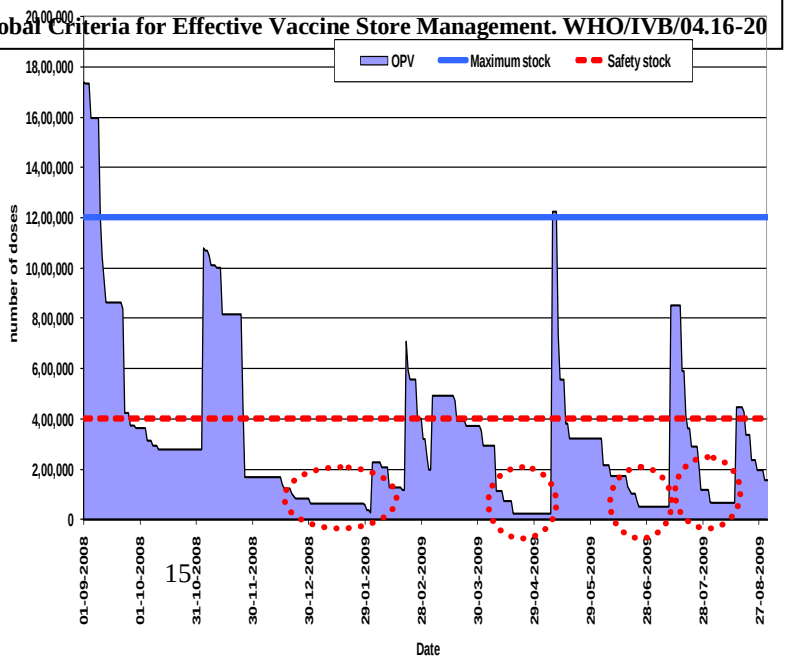
The earliest-expiry-first-out (EEFO) principle should generally be observed for deliveries. However, store keepers should be able to set aside the EEFO rule whenever vaccine vial monitor (VVM) status indicates heat exposure. Under such circumstances heat-exposed vaccines should be distributed first, regardless of expiry date.

A system should be adopted for managing short supplies.

Ten Global Criteria for Effective Vaccine Store Management. WHO/IVB/04.16-20

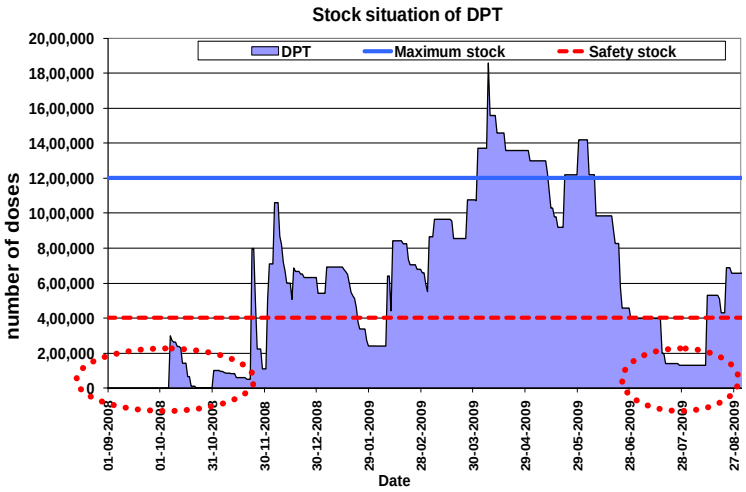
Findings:

There is a system of requisition having stock in hand at the RVSs. The information is utilized by the VLM to determine, using the OVLSM, the correctness of their orders. However, the main difficulties are the limited stocks of vaccine at the SVS due to which it is not possible to send the requisitioned quantities. 25% of the supplies received are kept in reserve at the SVS (as seen by



dotted lines in the adjacent graph for OPV). The rest is distributed in pro-rata. In case additional vaccines are received, the same are further distributed to fill the short shipment.

There are instance of stock-outs at SVS level and several times (see the red dotted oval), reaching rather low stock levels which have affected deliveries. This can be seen in the graph of DTP given below.



Though the reserve stock (25% of supply received) are held back to supply where the store runs out of stock, currently there is no effective system to inform the SVS in case of a stock out at DVS or BVS level.

The plot of OPV stocks (given above) illustrate that stocks have frequently reached rather low levels, and in case the requisitioned amounts were supplied, there would have been stock outs.

Advance intimation to the RVS staff is normally done through telephone only 1 day in advance. The SVS receives back one copy of the delivery note after receipt of vaccines. The status of VVM on receipt is not noted on delivery note. The OVLMS has option to enter the details of the receipts – this is still under implementation. The OVLMS also needs to be implemented down to DVS level.

The HWf knows how to implement EEFO and also make use of VVM status for better management of the distributions.

Recommendations

- Using the OVLMS and the support of the RVS and RI coordinators, define and implement a system to inform al the upper level stores – including SVS of any potential risk of stock outs. This should be followed up the adequate arrangement to ensure the required supply. A missed opportunity is difficult to capture on a later date.
- Implement a system to inform the SVS of any potential of stock-out so that the SVS can use its reserve supplies to avoid the same.
- Complete implementation of OVLMS at DVS levels.

Damage during Vaccine distribution ***Implemented: 50%***

Over a period of 12 months, minimal damage has occurred to the vaccine during distribution.

If correct practices are not followed during vaccine transport, vaccines may be damaged by exposure to excessive heat or to freezing temperatures. When vaccine is damaged in this way, this contributes to increased vaccine wastage and may result in short supplies.

New vaccines, such as hepatitis B freeze at close to 0°C. Recent evidence shows that vaccine freezing has now become the most serious consequence of poor distribution practice.

A monitoring and reporting system must be in place to ensure that vaccine damaged during transport is identified and replaced before it is distributed to the next level store. This can best be achieved by using electronic data loggers to record storage temperatures during transport. Data loggers should be used for all shipments from primary stores to the first level of intermediate stores, and elsewhere where possible.

Ten Global Criteria for Effective Vaccine Store Management. WHO/IVB/04.16-20

Findings

There has been one instance of 46,000 doses of BCG diluents which were damaged. The total supply made from SVS is much larger and the damage is less than 1%.

Freeze tags have not been adopted by GoI and GoO as yet and hence the monitoring of freezing is not implemented.

VVM status are noted in the registers on receipts. Implementation in OVLMS is pending at DVS levels for recording requisition and receipts.

Recommendations

- Procure and implement freeze indicators for storage and transport of freeze sensitive vaccines.
- Mark the status of VVM on every dispatch and receipt of vaccines in the OVLMS and delivery note.
- RVS coordinators should study the reports and identify / address if there have been change in VVM status.

Standard Operating Procedures (SOP)

Over a period of 12 months, the facility has followed standard operating procedures.

Standard operating procedures should be drawn up which are appropriate to each level in the distribution system. These procedures should be presented in a form which can be easily understood by the cadre of staff operating at each level.

Every cold store should be provided with a copy of these operating procedures, and staff should be trained to follow them and to keep appropriate records as evidence of compliance.

Standard procedures should cover the following topics:

- ordering/requisitioning vaccine;
- receiving a vaccine shipment:
- managing vaccine during storage, including temperature monitoring;
- distributing and transporting vaccines, including temperature monitoring.

Ten Global Criteria for Effective Vaccine Store Management. WHO/IVB/04.16-20

Findings and Recommendations

The GoI have issues, time to time several important directives related to immunization and vaccine handling. Recently, following the development and distribution of the new stock recording registers, Orissa State DFW has issued directives for use of the new stock registers.

The other useful and best reference material used by the health staff are the 'Health worker - immunization handbook' , 'Cold chain modules' and 'Medical officers modules'. The first two have been distributed at all levels. Though these are used during trainings and contain much of the material needed for good practices, they are not always referred to by the staff.

A formal form of Standard operating procedures do not exist. These have neither been initiated by the GoI or worked out by the GoO. Some parts of the immunization handbook are helpful to carry out some of the processes but are less comprehensive than a SOP.

The HWf, taking care of the state vaccine store is quite knowledgeable of the processes to be carried out. The other 4 semi-skilled support staff are not.

The EVSM assessment has identified several shortcomings in terms of practices. There is a need to prepare the SoPs first for each of the important processes at the state level and consolidated into a

book which can be referred by the staff as and when necessary. These SoPs should then be adapted for use at regional, district and block levels. A template for preparing SOP is given in Annexure D.

The SoPs should specifically stress on the following processes:

- Vaccine arrival - tasks to be carried out prior to arrival, on arrival and post arrival
- How to organise vaccines in cold chain equipment
- How to monitor and control temperature of WIF and WIC
- Reviewing and Maintaining temperature records
- Cold chain – contingency plan
- Preventive maintenance of cold chain equipment
- How to prepare freeze sensitive vaccine for transport
- Availing and using temporary storage facilities
- Recommended quality of infrastructure – building, equipment and transport vehicles
- Effective Maintenance of the infrastructure
- Effective Vaccine stock maintenance + use of forms
- Determining minimum required stock (safety stock)
- Delivery to intermediate stores
- Minimising wastage during storage, delivery and usage
- Implementing SOPs
- FAQs about VVM
- How to carry out shake test

The guidelines issued by GoI or GoO must be organised and kept at SVS and at an easy access of the concerned staff.

Human and Financial Resources

Over a period of 12 months, human and financial resources have been sufficient.

An effective vaccine distribution system must be properly resourced. Staff must be adequately trained, and motivated to perform their duties. Sufficient recurrent funding must be made available to purchase vaccine and essential consumables such as fuel and spare parts, to pay and to train staff, and to maintain equipment. In addition capital resources or donor funding must be available to sustain a rolling renewal programme to prevent the accumulation of increasingly unreliable and obsolete equipment.

Ten Global Criteria for Effective Vaccine Store Management. WHO/IVB/04.16-20

Findings

Planning :

Since the last VMAT assessment, the old WIC which was non functional since several years was repaired and put in operation, However, the chart recorders are not working on the 2 WICs

Funding was available for all items but graph recorders were insufficient and not procured since long and WICS were without graph recorder for 2 years. . The door locks have not been repaired, and the CFC refrigeration units of the WIC needs to be changed.

There is plan to increase cold chain capacity of SVS. A new building with one WIC is supposedly under implementation. The consltant has not seen any clear and definite plans.

New stock registered have been designed and introduced at all levels since 6 months. Training has been conducted to the RVS coordinators. Upscaling of training is planned for October onwards.

Funding

The Orissa State DFW receives support from several organizations : The NRHM plan (PIP part C), UNICEF , UNOPS, OHSP-Govt. of Orissa, and the Central Govt.

The OHSP funds have earmarked INR 4 Lacs for communications at all levels (including internet, fax etc); INR 12 Lacs for maintenance and repair of 38 vaccine vans; 30 lacs for purchase and operation of 23 Generators (7.5 KVA) for the 23 DVS. Each generator would cost about 50-60,000 Rs. 5 Lacs have been earmarked for 10 KVA servo stabilizers for the SVS and the 8 RVS.

The GoI covers directly the equipment requirement. Here there is a back log. The equipment needs of 2007-08 is supplied now, mostly in form of CFC replacement plan. No other new equipment is available to support proper segregation of the DVS from the RVS.

Rs. 2 L for transport of vaccines to RVS and generator operation.

The other sources cover the required maintenance funds, salaries of the staff.

Since 2008, UNICEF has funded and implemented the "Cell (expand full name)" for strengthening the immunization activities. These include employing and deploying 1 RVS coordinator for each region and 1 RI- coordinator in selected weak districts. At the state level the "Cell" is equipped with a team which includes 1 vaccine logistic manager and 1 cold chain consultant. After the first phase of 2 years, UNICEF has extended its commitment to the DFW for another 2 years - till end 2011.

Staffing :

Since the last VMAT evaluation, the CCO has taken on significant responsibilities and is working with an increased sense of responsibility and commitment.

The cold chain consultant is in place since December 2007. He is expected to coordinate the acticties and assess the performance of the 7 RVS-coordinators. Although he has been in post longer than all the RVS corordinators, holds an engineering degree, and has also been provided with constant support directed towards capacity building by the UNICEF project officer, he has not reached the level of performance and contribution which he should assure. In fact his knowledge and performance after 2 years is poorer than some of the RVS coordinators. Despite several requests and continuous reminders from the UNICEF officer, on necessary actions, there are serious delays, due to a rather passive and not committal attitude. Several of the technical weaknesses that need addressing would not have surfaced at all if the CCC would have performed according to his ToR. The current situation is also affecting the morals of the RVS coordinators.

The vaccine logistic manager is appointed since about 6 months. He is enthusiastic and committed and is putting in much hard work. However, much of the load of the Cell is falling in his hands due to non performance of the colleagues. Hence he is over burdened and this affects his productive contribution in duties he is expected to perform as per his ToR.

The post of the vaccine store keeper is vacant since several years. One junior clerk cum typist is supposed to manage the store. He is sitting 5 km away at the Directorate and is not active in providing the required support. The HWf has been deputed to the SVS since 7 years. She is only partly trained in vaccine management and stock keeping, and has learnt most on the job and has thereafter activity participated in the 2 VMAT exercises. She has been taking care meticulously the entire operation of receipt, handling, storage and supplies of vaccines for the entire state for the last 7 years.

Since the past 2 months she is also handling the proposed RVS of Bhubaneswar which has been defined by earmarking one of the WIC for this purpose. The operations are yet to be completely segregated from the SVS. The stock books have already been prepared and are up to date. Due to the shortage of storage capacity, the WIC earmarked for RVS is also used to store the SVS stocks. There is a need for additional staff to manage the RVS-BBSR.

The new extention plans of the state store needs to ensure adequate space so that the VL Manager and the cold chain consultant can sit at the SVS so as to coordinate and support all the operations for the state.

2 Technical staff are needed and 2 are appointed as foremen. They have been trained in Pune national training centre in all kinds of refrigeration units.These 2 foremen are also taking care of special emergencies in the state. The issue of the foremen is discussed in section on maintenance. Both are working hard, seem to motivated, however, lapses in good performance are perceived.

There are 4 positions of semi skilled workers. Recently these have been filled. However, the qualification required to fill these post was minimum metric pass with 3 years of experience. 2 of the 4 staff employed recently do not satisfy the prerequisites needed for this post. One support staff who had been working since the past 2 years has been reproved while employing the 4 new ones. .

Outsourced service are not used.

Recommendation

- For the improvement in the entire immunization programme, the CCO needs to clearly delegate the responsibilities between the team members of the Cell and ensure that each of them punctually delivers according to the defined quality.
- There is a need for a dynamic, pro-active and committed cold chain consultant. The performance of the present CCC is unsatisfactory and affecting the operations of the smooth operations of cold chain related aspects in the whole state.
- The health worker taking care of the SVS since the past 7 years has proved her capacity has made proof of her performance as a responsible state store manager. With her complete involvement in 2 rounds of VMAT and one EVSM assessment, she has enhanced her capacities further. It is therefore, in the interest of the DFW that her efforts be recognised and encouraged. In fact, there are good chances that things will no longer work as smoothly if another inexperienced staff replaces her.
- Roles and responsibility of the two foremen needs to be precised, to ensure constant presence and support of one of them at SVS.
- One additional experience technician is needed to strengthen the RVS-BBSR team.

4. Action initiated during the assessment

The following actions were initiated during the assessment :

1. At last after almost 2 years one continuous chart recorder was installed on the SVS – WIC.
2. The HWf of the SVS was shown how to file all the documents upon any vaccine shipment. A system of colour files was suggested.
3. Suggestions for improving the existing reports emerging from the OVLMS were given – including proper sorting of data.
4. Suggestion for additional useful reports which can be obtained from the OVLMS were also provided.
5. Introduction of a large board to include both SVS and RVS data was completed
6. Switching of refrigeration units once every 24 hours was recommended against the current practice of every 12 hours.
7. As there is a 24 hours duty at SVS, each of the staff should take one manual reading every 6 hours.
8. Suggestion that each of the semi skilled workers should mark his time of arrival and departure on duty.

5. Conclusion

The EVSM assessment results indicate that while Orissa has developed certain strengths, it also need to work towards addressing some of the weaknesses. The findings and recommendations are provided under the respective indicators.

In view of becoming the leader in the country to target and achieve an EVSM certification by 2011-12, Orissa should strive proactively to reach the standard proposed in the model quality plan. In order to do that it needs to first undertake the following tasks which are grouped in terms of the nature of their implementation:

Management - Policy

1. Two of the semi-skilled staff recruited recently do not fit the stipulated requirements. Review their caliber and replace them if necessary
2. There is only one foreman looking after all the WIC in the state. State also needs another foreman to look after the equipment of the 7 RVS.
3. One foreman must be dedicated for regular maintenance and service of the SVS.
4. The foreman responsible for repair and maintenance of WIC/WIF should be relieved of his duty of spares and equipment store. So that he can focus better to the SVS.
5. As the CCO is to retire in 1.5 years, the state should plan future recruitments with this in mind.
6. The MoH / FW should work out a MOU with the excise department, in view of ensuring rapid and trouble free passage through the state borders.
7. DFW should make a MOU with the owner of some private cold room to ensure safety of the vaccines in case of any emergency.
8. Plan adequate immediate expansion of the SVS.
9. On long term – build a new SVS based on future immunization needs of the state

Equipment related

10. Procure and install a computerized temperature monitoring system, to ensure continuous monitoring of storage temperature.
11. Repair all acoustic alarms on the WIC and WIF and ensure they are always in working condition.
12. Compute vaccine requirements on 2 monthly basis and request GoI to ensure timely supplies to the state.
13. Procure and introduce use of freeze indicators for each and every distribution of freeze sensitive vaccines.

Planning

14. Plan replacement of the State WIC which is working on CFC, rapidly.
15. Prepare a preventive maintenance plan for all equipment, and ensure that the foreman follows. it.

Improvement in Practices

16. Maintain a service log sheet for each equipment.
17. Define working stocks (2 months) and safety stocks (1 month) for each antigen

18. Implement recording of vaccine stocks on receipt at RVS
19. Always use standarised water/Ice Packs - do not use any Gel packs as its temperature is not well defined when conditioned.
20. The CCO needs to be more proactive in planning, management, and supervision of the activities of the staff at the Cell and the SVS.

Acknowledgement & Remark

The consultant is thankful to the Ranjit Dheeman who helped in data collection and preparation of some of the plots related to the stock situation.

The meticulous data records maintained by the Health worker at the SVS and her full collaboration is greatly appreciated. This helped immensely in completing the data collection in the given limited time.

The consultant is also thankful to the support of the state staff team in this mission.

In the opinion of the consultant the time frame for this mission was grossly underestimated. For doing proper justice to such a mission, with the importance it bears at least 15 days are needed. The present mission was compressed to 7 days, including 2 days for report writing. It is unfortunate that adequate time was not allotted to support the activity in a judicious manner. The present report has also demanded at least 3 full days of work.

Annexure A – Details of vaccine arrivals

Date	OPV	Hep B	MEASLES	BCG	TT	DT	DPT
19-Sep-08			300000				
06-Oct-08					4,00,000		3,00,000
31-Oct-08							1,00,000
03-Nov-08	8,00,000						
13-Nov-08			2,40,750				
18-Nov-08						50,000	
22-Nov-08					9,50,000		7,50,000
25-Nov-08			440				
26-Nov-08			1,95,000	1,00,000			
27-Nov-08			5,045				
29-Nov-08			9,250				
01-Dec-08							4,00,000
02-Dec-08							2,00,000
05-Dec-08					1,00,000		3,50,000
09-Dec-08			1,200				
16-Dec-08					1,50,000		2,00,000
04-Jan-09					9,00,000	3,62,110	1,50,000
09-Jan-09			3,00,000				
13-Jan-09				2,00,000	1,00,000		
23-Jan-09						1,87,890	
26-Jan-09			1,50,000				
28-Jan-09						1,00,000	
01-Feb-09	2,00,000						
08-Feb-09					5,00,000	3,50,000	4,00,000
11-Feb-09					2,00,000		4,00,000
19-Feb-09	6,00,000						
04-Mar-09					3,00,000		3,12,990
05-Mar-09	2,94,000	49,000					
07-Mar-09							1,00,000
23-Mar-09			3,00,000				
25-Mar-09						1,50,000	
26-Mar-09							2,21,000
01-Apr-09							4,00,000
07-Apr-09					10,00,000	2,00,000	4,87,010
09-Apr-09					1,50,000		
22-Apr-09						50,000	
08-May-09	12,00,000			2,00,000			
21-May-09							3,00,000
22-May-09						2,48,500	
26-May-09			1,50,000				
27-May-09			60,000	4,00,000			
28-May-09			90,000				
29-May-09						50,000	2,00,000
01-Jun-09				2,00,000			
20-Jun-09			4,00,000				
10-Jul-09	8,00,000						
30-Jul-09				14,00,000	10,00,000		
11-Aug-09							4,00,000
14-Aug-09	4,00,000				9,00,000	2,00,000	
22-Aug-09							4,57,600
02-Sep-09							1,42,400
03-Sep-09					6,00,000		
Total	42,94,000	99,000	22,01,685	25,00,000	72,50,000	19,48,500	62,71,000
No. of Arrivals	7	2	14	6	13	11	19

Annexure B – Forecast of current and future vaccine storage space.

Immunization Plan	Storage volume required at + 2 to +8 deg C (LTRs)										
	BCG	**Measles**	**MR**	**Penta**	**DTP**	**TT**	**TT**	**Peneumo-coccal**	**Total Required**	**Total Available**	**"-" Shortfall / "+" Extra**
	Under 1yr	Under 1yr	Under 1yr	Under 1yr	Under 1yr	CBA (Women)	at 10 & 16 yrs	Under 1yr			
	Ltrs	Ltrs	Ltrs	Ltrs	Ltrs	Ltrs	Ltrs	Ltrs	Ltrs	Ltrs	Ltrs
Present Plan	397	1,656	0	0	3,975	2,186	1,987	0	**11,196**	9,240	**-1,956**
+ MR	397	1,656	828	0	3,975	2,186	1,987	0	**12,024**	9,240	**-2,784**
+ Pentavalent	397	1,656	828	5,300	0	2,186	1,987	0	**13,349**	9,240	**-4,109**
Pneumoccocal (2+1M)	397	1,656	828	5,300	0	2,186	1,987	59,327	**72,676**	9,240	**-63,436**
Pneumoccocal (1+1M)	397	1,656	828	5,300	0	2,186	1,987	39,551	**52,900**	9,240	**-43,660**

Annexure C – Model of a Batch card

Vaccine / diluent Batch card (A new card to be sued for each batch / lot of vaccine)						**Vaccine Name :**	
Consignment Arrival Details		**Vaccine Details** (Vials)		**Diluent Details** (Vials)		**Max stock:**	
Delivery No. :		**Vial size :**		**Ampoule size :**		**Safety Stock:**	
Date of arrival :		**Batch No :**		**Batch No :**		**Status of Transport / monitors**	
		Expiry date :		**Expiry date :**		**Ice pack;**	
Manufacturer :		**Quantity :**		**Quantity :**		**Freeze Indicator:**	
		Storage location :		**Storage location :**		**Electronic Monitor**	
Remarks :							

Vaccine issued / Received *(Diluents if applicable is understood to be issued / received in same quantities as the vaccine)*

Date	**Issued to /** Received from	**Voucher no.**	**Quantity in Vials / diluents**			**VVM**				**Ramarks**	**Signature**
			Issued / Received	**Loss / Adjusted**	**Balance**	**1**	**2**	**3**	**4**		

Vaccine issued / Received (continued)						**Vaccine Name :**					
Date	**Issued to /** Received from	**Voucher no.**	**Quantity in Vials**			**VVM**				**Ramarks**	**Signature**
			Issued / Received	**Loss / Adjusted**	**Balance**	**1**	**2**	**3**	**4**		
Note: This documents should be stored safely for at least 3 years along with the vaccine stock records.											

Annexure D – Template for writing SOPs

SOP No. :	Date of issue:	Revision Date:
Version:	Effective date:	No. of Pages:
Title of the SOP		

1. Purpose

2. Scope

3. Responsibility

4. Documentation and material required

5. Procedure

Step	Action	Related SOP and remarks
1		
2		
3		
4		

6. Distribution

7. References