A study of the cold chain system in Andhra Pradesh

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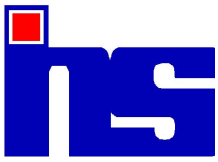

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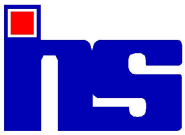

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Introduction:

Cold chain is a system of transporting and storing of vaccines at the recommended temperatures from the manufacturer to the actual point of use and is the life line of the immunization program (MOHFW, 1994). The cold chain system is essential because the vaccines are sensitive to temperature variations. When vaccines are exposed to excessive variation of temperature from the recommended level, they lose their potency. Potency once lost cannot be regained by any method.

Most of the studies and large scale surveys on immunization have focused on coverage against targets and dropout rates. However very few studies have looked into logistics and supply or cold chain management. This study focuses on cold chain management and logistics of vaccines for the Universal Immunization program. If the cold chain is not maintained, the potency will be lost. In such circumstances, even if the children were immunized they will not be protected, making the whole exercise redundant. A proper understanding of these issues would guide us towards achievement of effective immunization.

I. Objectives of the Study:

1. To understand the vaccine storage and distribution system in AP.
2. To gain an insight into the cold chain management at different levels.
3. To assess the knowledge, attitude and practices of field workers regarding cold chain maintenance procedures.
4. To identify weak links in the cold chain and recommend appropriate improvements.

This study traces the cold chain at all levels, starting with the State Cold Chain Unit to the vaccine administration points. Various aspects of cold chain were studied at each level. These are (a) pattern of arrival of the vaccines, (b)

the operation and maintenance of cold chain equipment at that level and (c) the pattern of distribution from one level to the, including the transportation from one level to another.

II. Materials & Methodology:

The cold chain system (CCS) consists of (a) storage points, (b) the final vaccination points, and (c) a system of transportation between these points. The storage points consist of the State Cold Chain Unit (SCU), Regional Cold Chain Unit (RCU) and the District Vaccine Stores (DVS). A sub sample of entities in each segment of the cold chain system in AP was taken up for detailed study. Field and data about the cold chain system were collected during November 2000 to January 2001.

Table-1: The cold chain segments in AP and number sampled for this Study

Segment Type	Segment	Total	Sample
Storage Point	State Cold Chain Unit	1	1
Storage Point	Regional cold chain facility	5	2
Storage Point	District vaccine stores	24	3
Vaccination Service Centers	PHCs	1386	9
Vaccination Service Centers	Area Hospital	49	2
Vaccination Point	Sub Centers, Hospitals Clinics	10568	15

Apart from the SCU, two out of the five RCUs (Warangal and Vishakapatnam) were selected for the study. Three districts (Mahbubnagar, Khammam & Nalgonda) were selected for the study. Selection of RCU and DVS was in view of resources constraints. Hence the primary criteria of selection was nearness to the State capital where the Institute of Health Systems is located. Mahbubnagar district was included as it was identified to be one of the low performing districts as far as immunization is concerned. Mahbubnagar reported large number of (209) measles cases inspite of a good coverage of immunization according to official records (Rajalakshmi & Rao, 1996). Khammam and Nalgonda were selected as they have been identified for implementation of district action plans under the European Commission

sponsored Reproductive Health Sector Reforms. The PHCs in each district were selected based on accessibility from the district headquarters.

To facilitate description of the study method, we distinguish between (a) Storage points, (b) Vaccination service centers and (c) Vaccination points. The following details were collected from each of these points:

A. Storage Points:

The vaccine storage equipment like the walk in cooler, walk in freezer etc. were identified. One of the authors, Swati Gayathri, familiarised with each of the identified equipment with help of the concerned maintenance staff. Equipment performance parameters certified for vaccine potency were identified. The following information was collected at each of the storage points:

1. Performance parameters of the cold chain equipment.
2. Data on vaccines flow in and out of the storage point was collected for a selected time period.
3. Personnel at each of the storage point were interviewed to understand the workload and staffing.
4. Since electricity is critical for the cold chain equipment, information about power supply situation and availability of backup power was collected by interviewing the respective staff incharge of the storage points.
5. Details about the adequacy of transportation facilities from the storage points to vaccination points were collected from the concerned staff at each point.
6. Knowledge of and practices by refrigerator mechanic was assessed using a questionnaire, shown in Annexure-1B.

B. PHC/ Vaccination Service Centers:

PHCs act as vaccine service centers. Vaccines are distributed from the PHC to the various vaccination points. Following information was collected from each of the 9 PHCs selected for the study.

1. Details about staffing, adequacy, vacant posts if any, availability of staff, were collected by interviewing the personnel incharge at these hospitals and PHCs
2. Details of arrivals and distributions for the past 2 years - calculation of the remaining life of the vaccine by the time it reaches the beneficiaries
3. Discussions were held with Medical Officers, Multi Purpose Health Exension Officers (MPHEOs), Multi Purpose Health Supervisors (MPHSs). Questionnaire used to assess knowledge of and practices by Pharmacists and MPHS is given in Annexure-1A.

4. Electricity details, alternative action during power failure and equipment breakdown were collected from the concerned staff.
5. Equipment maintenance personnel at each point were interviewed to understand the frequency and timeliness of maintenance of the equipment.

C. Vaccination Points:

These are the sub centers, hospital based immunisation clinics, etc. Information was collected about transportation of the vaccines to the place of immunization. Field observations were made on routine immunization days and house visits by the field workers - to observe the cold chain maintenance practices followed by the field workers. A Knowledge, awareness and practice survey was done among the field workers. The tools used are;

i. An interview to assess the Knowledge of and Practices by the field workers such as the Multi Purpose Health Assistants (MPHA). Questionnaire used for this purpose is given in Annexure-1A.
ii. Focus Group discussions with the ANMs using checklists to assess their knowledge levels, and
iii. Non participant observations of immunization sessions to understand the skills and practices of the field staff.

III. Results:

A. Stages in the Cold Chain:

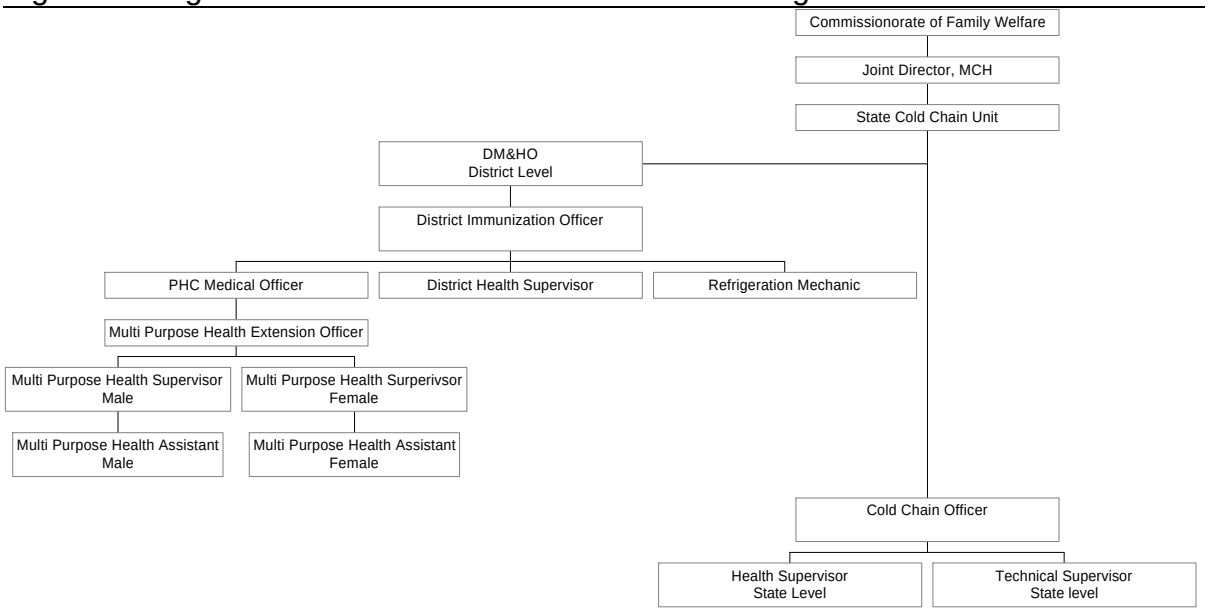
In the State, the first point of storage is the State Cold Chain Unit (SCU) which is located in the Directorate of Family Welfare. Here the vaccines arrive from all over the country. They are then distributed to the regional stores, from where they are sent to the district stores. From the district stores the vaccines are transported to the PHCs, and from the PHCs to the sub centers and finally administered to the beneficiaries by the MPHA - F, ie the ANM.

B. Organizational structure of the State Immunization Service:

The State immunization services are a part of the RCH program, under the Commissioner of Family Welfare. The program incharge for the entire State is the Joint Director, MCH. The State Cold Chain Unit (SCU) is supervised by the Cold Chain Officer (CCO). At the district level, the program is supervised by the District Medical & Health Officer (DM&HO), along with other programs. The DM&HO is also supported by the District Immunization Officer (DIO). Each district has a Statistical officer (SO) and a Refrigerator Mechanic (RM). The SO

or the Junior Assistant is responsible for vaccine issues and arrivals, etc. The RM is responsible for the maintenance of the cold chain equipment throughout the district. At the PHC level, the Medical Officer supervises the program, and the implementation of the program is the responsibility of the MPHSs and MPHAs.

Figure: 1 Organisation chart of the Cold chain management in the state



C. State Cold Chain Unit:

The State cold chain unit is the main storage point for all the vaccines used in the entire state. This is located in the Comissionorate of Family Welfare, Hyderabad. The State cold chain unit has a walk-in-cooler and a walk-in-freezer. The walk-in-cooler maintains temperatures between 2^0C to 8^0C and can store upto 15 lakh doses of vaccines. This is mainly used to store BCG, DPT, DT & TT vaccines. The walk-in-freezer maintains temperatures between -15^0C to -20^0C and can store up to 15 - 20 lakh doses of Polio and Measles vaccines. Oral Polio Vaccine (OPV) and measles vaccines are more sensitive to temperature. Hence these are stored in the freezer while the other vaccines are stored in the cooler. The vaccines are stored on an average for 6 months in the unit. Sometimes when the demand is high, vaccines are distributed as soon as they arrive.

The Cold chain officer is incharge of this unit, and is supported by one Health supervisor, one technical supervisor & one attendant who are on deputation from other units. The health supervisor checks the receipt of the vaccines and issues the vaccines. The technical supervisor is responsible for the storage and maintenance of vaccines and for the vaccine storage equipment.

1. Estimation and Allocation of Vaccine Requirement:

The estimation and allocation of vaccines for the State is done at Delhi. The estimation is done based on the number of beneficiaries in the State taking into account, allowance for wastage. This estimation is sent to the State Government for necessary approval. At the State, it is verified by the Statistical officer and the information is sent back to Delhi.

2. Procurement of Vaccines:

The Government of India places the orders for different vaccines. The vaccine samples from each batch are sent to the Central Drug Laboratories, at Kasauli, Himachal Pradesh, for testing their potency. After they are certified by the institute, they are sent to the respective States. Before dispatching the vaccines, the State unit is intimated by means of fax, telephone and a letter through the courier which provides information about the date of arrival of the vaccines, mode of transportation, quantity, batch number and the way bill number or delivery challan number. Based on this information, necessary arrangements are made for the receipt of vaccines at the state cold chain unit. If the vaccines are to arrive by air or train, the vaccine delivery van is sent to the airport or railway station. Delivery of vaccines by train is very rare. Vaccines which arrive by road, from other States arrive in refrigerated vans. Once the vaccines arrive, they are checked for quantity and stored in the freezer or the cooler. This is followed by entering details regarding the vaccines in the stock record maintained by the health supervisor. Sometimes vaccines are also sent directly to the regional stores at Vishakaptnam, bypassing the State cold chain unit. However details regarding the vaccines received are sent to the State unit, for record.

The following are some of the main sources from where vaccines are obtained :

1. Serum Institute of India, Pune - Measles vaccine
2. Haffkin Biopharma, Mumbai - OPV
3. Panacea Biotech Ltd., New Delhi - OPV
4. Biomed Pvt. Ltd., Ghaziabad - OPV
5. Bharath Immunological and Biological Corporation Ltd., Bulandsher - OPV
6. BCG Vaccine lab, Chennai - BCG
7. Pasteur Institute of India, Conoor - DPT, TT & DT
8. Biological Evans Ltd., Hyderabad - TT, DPT

Sometimes the vaccines also arrive from the Medical Stores Depots located in Mumbai and Chennai. Here the vaccines procured centrally are stored for any emergencies. There is a medical stores depot in Hyderabad also, but vaccines are usually not stored here, as there is a SCU.

In this study, information regarding the vaccines received from various manufacturers during the year 2000 has been collected. This will tell us about the procurement pattern that is being followed. By the time the vaccines are procured and received, four fifths of their life period should be remaining. However, this has not always been the case. It was observed that most of the vaccines arriving from the Medical stores depots either do not meet with this criteria or the batch numbers are not recorded. This is a significant gap because, around fifteen percent of the vaccines are procured from the MSDs. For example on 19th August, 2000, 1.216 lakh doses of DPT were procured from MSD, Chennai which had only 9 months life. By the time this batch was issued to the districts in September 2000, only 7-8 months life was remaining.

3. Storage of Vaccines:

The most critical factor in maintaining the potency of the vaccine is storage. The three important factors in storage of vaccines are (a) maintenance of temperature, (b) availability of power, and (c) quality assurance.

As already mentioned, the equipment for vaccine storage is maintained by the technical supervisor. The temperatures are maintained at 2^0C to 8^0C in the walk-in-cooler and between minus -15^0C to -20^0C in the walk-in-freezer.

There are monitors which show the temperature of the cooler or freezer, in addition to temperature recorders which graphically record every variation in the temperature. These units run 24 hours for all 365 days in a year. In case of any power failure there is an immediate backup provided by generators. The generators were found to be in working condition, and adequate funds were available for POL and maintenance at the State level. The technical supervisor maintains a generator log, where details regarding the quantity of diesel used and the time are recorded. This log has details from 1993 to date.

At the district stores and PHCs, the vaccines are stored in the Ice lined refrigerators (ILR) and freezers. ILR is a special kind of refrigerator, which has frozen ice packs around all the sides inside the cabinet. Because of this ice lining, ILR can maintain its temperature below 8^0C even up to 48 hours (holdover time), during continuous power cuts. ILR is used for the storage of DPT, DT, TT & BCG vaccines. Freezers maintain temperature between -15 to -20^0C and are used for storage of OPV, Measles and making of ice packs. Freezer can maintain the temperature below 8^0C for 12 hours in case of power failure.

Cold boxes are used for transporting large quantities of vaccines. (MOHFW, 1994). These are insulated boxes and maintain the temperature between 2^0 to 8^0C with adequate number of ice packs and hold the temperature upto 5 days. Vaccine carriers are insulated boxes of lesser capacity and are used for carrying small quantities of vaccines (15 - 20 vials) from PHCs to sub center villages. This requires 4 ice packs as lining and can maintain the temperature below 8^0C for 24 hours. Day carriers are smaller vaccine carriers and they require only 2 frozen ice packs to hold the temperature below 8^0C for 8 hours. They are used for carrying 8 - 10 vials of vaccines from PHCs to sub centers and villages. Ice packs are used for lining the walls of ILRs, cold boxes and vaccine carriers. They can be prepared by filling the packs with water upto the marked level, fixing the cap tightly and keeping them in the freezer at -20^0C for minimum of 24 hours. The ice packs

are provided with two holes for keeping the vaccine vials, during immunization session.

4. Equipment Maintenance:

Initially all equipment in the State were under annual maintenance contracts, provided first by Voltas and then by Blue Star and was funded by the Government of India and UNICEF. Then there was a contract with Allwyn, funded by the government of AP. Presently the equipment are all maintained by the Refrigeration mechanics (RM) in the districts and the technical supervisor at the State, who are also trained in maintenance. Installation of equipment is also being handled by the technical supervisor. Currently, for all the equipment purchased, the Blue Star provides maintenance service for the first one year. Subsequently the RMs maintain the equipment. However, when there is a breakdown (during the first year), the equipment has to be sent all the way to Hyderabad, to Blue Star office for repair. Usually by the time the equipment reaches the Blue Star office, the contract period expires. During this period repairs cannot be done locally by the RMs, as the spare parts are not available. Thus the equipment are kept unrepaired till the date of expiry of the contract only to be subsequently repaired by the RM. Hence, it is found to be easier to get the equipment repaired at the district level only as all the refrigerator mechanics are skilled enough.

At the State level, the responsibility for equipment maintenance is entirely with the Technical Supervisor. He is responsible for maintenance of the WIC and WIF at the SCU, monitoring the equipment at the districts and receiving reports regarding equipment status from each district.

Every month the districts are supposed to send the list of functioning equipment, repairable equipment, equipment requiring condemnation and requirement for spare parts, if any, to the technical supervisor at the SCU. The equipment for condemnation is proposed by the technical supervisor and has to be approved by the condemnation committee. The condemnation committee consists of the DM&HO, DIO, CCO and Administrative officer of that district. However, it was found that condemnation reports are not being sent

regularly by the district officials, to the State unit. Usually the major equipment replacements and installations are all done just before the Pulse Polio immunization (PPI) program every year. This is to accommodate the large quantities of vaccines used during the PPI.

5. Temperature Recording:

The cooler and freezer are provided with remote mini disc records (thermographs). These are direct action instruments that is designed to measure and record temperature on a circular paper chart. The chart is driven directly by the spindle of a clockwork. Recording takes place on a 125 radius mm paper disc. The receiver is fitted with an environmental temperature equalizer and is made up of a rolled-steel spiral tube located at the rear of the instrument. Recording during the nominal rated time occurs through a single pen that plots over a full disc revolution. The sensing element of a remote thermograph is stiff, 10 radius mm tubular stainless-steel sensor including a sensing bulb filled with high-pressure nitrogen and connected to the receiver in the housing through a copper or stainless steel capillary tube. The measurable variables are recorded through independent amplifying and plotting systems. These temperature graphs are filed with the technical supervisor. Any sudden fluctuations in the temperature are identified and the reasons for the variations are also noted. Usually the temperatures rise during loading or unloading of vaccines or due to failures like gas leak etc.

Figure 2: Temperature recording device

Source: http://www.who.int/vaccines-access/vaccines/Vaccine_Cold_Chain/temperature.htm

6. Quality Assurance:

As mentioned earlier, the quality assurance of the vaccines is undertaken at Central Drug Laboratories at Kasauli, before they are dispatched to the State units. No further quality assurance of the vaccines is undertaken at the SCU. However, samples of vaccines from selected district stores, PHCs and Urban Health Centers are collected and sent to the Institute of Preventive Medicine, Hyderabad, for testing their potency.

7. Distribution of Vaccines:

Based on the allocations to the State, district wise allocation of vaccines are made, taking into account the balance of vaccines in the districts. From the State cold chain unit, the vaccines are first sent to the regional stores at Guntur, Cuddapah, Kurnool, Warangal, Nizambad and Vishakapatnam, where there is a walk-in-cooler (Table 2). However, for the nearby district centers at Hyderabad, Rangareddy and Medak, vaccines are issued directly. At the Vishakapatnam regional stores, vaccines also arrive directly from the manufacturer, since there is an airport. Sometimes vaccines for the whole State are sent directly to Vishakapatnam, from where they are transported to the State cold chain unit.

Table 2: Regional Vaccine stores and districts covered by them

Regional Center	Districts Covered
Vishakapatnam	Srikakulam, Vijayanagaram, Vishakapatnam, East Godavari
Guntur	West Godavari, Prakasham, Krishna, Guntur
Cuddapah	Chittor, Nellore, Cuddapah
Nizambad	Adilabad, Nizambad
Kurnool	Mahbubnagar, Ananthapur, Kurnool

The first-in-first-out principle is generally followed for issue of vaccines. At times, issues are also made based on the date of expiry, that is, the vaccines with a closer expiry date are issued first. However, it was found that the average remaining life from the date of issue to date of expiry was 15 months and the minimum remaining life was 5 months.

The vaccine vials are securely packed in cardboard boxes. The vaccine packs containing the vials are kept in thermacool boxes along with ice packs, dry ice and sealed (airtight). These are then loaded in the insulated vaccine delivery van and transported to the regional centers. Incase of any breakdown, the vaccines are taken to the nearest PHC and stored in the ILRs till the van is repaired.

8. Data Recording:

The receipts and issues are recorded in a register at the State cold chain unit. A new register is maintained for each year, that is from April to March. This register records the (a) date of receipt or issue (b) place received from or issued to (c) quantity (d) batch numbers and expiry date. Data regarding receipts and issues at the SCU have been collected for the last two and half years. The following are some of the observations:

Most of the transactions (arrivals or issues) contained vaccines from multiple batches, wherein the batch identity was not maintained. This becomes a problem when a certain batch is not found to be meeting with the quality requirements and would have to be recalled. In this case, it would be difficult to trace the batch if the identity is not maintained. It would be more ideal if the dispatches and arrivals would all be of the same batch. Even if this cannot be done, and multiple batches have to be sent at a time, they should

be recorded separately (as separate entries on the same date). Presently the entries are recorded as follows:

Table: 3 Existing Format used to record arrival of vaccines

Date	Vaccine	Issued To	Quantity	Batch No	Exp. Date
20-Sep-00	Measles	Guntur	47,500	MVV - 943, 945, 1477	Jan-02, Feb-02

Instead if the same was recorded as follows it would be easier to maintain the batch identity.

Table: 4 Recommended format to record the vaccine arrivals

Date	Vaccine	Issued To	Batch No	Quantity	Exp. Date
20-Sep-00	Measles	Guntur	MVV - 943	12,500	Jan-02
			MVV - 945	15,000	Jan-02
			MVV - 1477	20,000	Feb-02

Some of the recordings were also not complete. In some cases batch numbers were missing or expiry date was missing or both were missing. This would be a problem while finding the remaining life of the vaccine which is very important.

9. Record Maintenance:

At the state cold chain unit, the reports are being maintained regularly but are not comprehensive. Out of the total recordings for the year 2000 at the SCU, nearly 53 percent of the recording were inadequate (Table-5). Shortcomings included no batch numbers and or no entry of expiry date, clubbing of multiple batches in one transaction. Of this about 9 percent was due to insufficient data ie., No batch number or expiry date and nearly 44 percent was transactions with multiple batches.

Table: 5 Recording errors in vaccine transactions at the State Cold Chain Unit, Hyderabad, Andhra Pradesh. Jan - Nov 2000.

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Total	
												#	%
Arrival													
Total arrivals	17	3	0	0	2	4	4	7	6	3	8	54	
No batch or exp. dt. record	4	0	0	0	2	1	0	2	1	2	4	16	30
Batch Id Lost	9	1	0	0	0	1	2	4	2	0	4	23	43
Issues													
Total issues	55	31	22	11	33	32	52	36	53	40	43	408	
No batch or exp. dt. record	13	0	0	3	3	3	0	0	2	1	0	25	6
Batch Id Lost	23	12	12	3	11	5	34	18	25	17	20	180	44
All transactions													
Total transactions	72	34	22	11	35	36	56	43	59	43	51	462	
No batch or exp. dt. record	17	0	0	3	5	4	0	2	3	3	4	41	9
Batch Id Lost	32	13	12	3	11	6	36	22	27	17	24	203	44

D. District Cold Chain Facility:

In each of the three districts selected for the study, the district vaccine stores, select PHCs and sub centers and civil hospitals were covered to understand the cold chain maintenance practices. Reports and registers for stock were being maintained manually at all levels. During the field visits it was observed that information management was critical input at all levels. However, it was found to be unsatisfactory. At the district and regional stores also, a similar problem was encountered.

Each district has a Refrigerator Mechanic, who is the point person for all the equipment in the district. He is responsible for catering to any complaints regarding equipment breakdowns in any of the health facilities in the district. All the reports regarding the equipment status in the district are sent by him every month to the SCU.

In the districts, the entire responsibility for equipment lies only with one person. With each district having around 50 - 80 facilities where vaccines are stored, it becomes impossible for the RM to visit all the places even once in two months. Moreover, in the absence of the RM there is a backlog of equipment repairs since there is no replacement for him. This problem is right

now being encountered in Mahbubnagar district where the RM is under suspension for the past one year.

Table: 6 Cold chain and vaccine supply logistics in three districts of AP

Cold chain component	Nalgonda	Khammam	Mahbubnagar
Equipment at District Store			
Ice lined refrigerator (ILR)	3	3	4
Freezer	3	2	4
Cold chain staff at the district hqrs.			
District Immunisation Officer (DIO)	+		1
Statistical Officer (SO)	1	1	1
Refrigeration Mechanic (RM)	1	1	
Vaccine delivery			
Vaccine delivery vans	*	1	1
Vaccine delivery routes	6	10	8
Vaccine service centres covered	78	80	88
Periodicity of vaccine delivery	Monthly	Bimonthly	Bimonthly
Immunization Coverage			
DPT	101.43%	104.84%	111.40%
Polio	101.43%	104.84%	115.07%
Measles	95.44%	73.99%	89.87%

+ District TB Officer is holding additional charge.

* The vaccine van is out of order. Vaccine is being delivered by ambulance or such other alternative vehicles

E. PHC/ Vaccination Service Centres:

At the PHC level, the stock registers were either not maintained regularly or did not include batch numbers and expiry dates. Temperature recording at PHCs was not satisfactory. There is confusion as to who is responsible for recording of temperature. There is no system to check whether the temperatures recorded is correct or not. Checking of temperature records, suggested that many a times false entries are made for entire period. Recording of temperature variations during power failure is very important to determine cold chain status. However temperatures are recorded only once every morning and evening. These recordings are not analysed by any one to determine any variations and the effect on cold chain management.

In PHCs there is no clarity as to who is incharge for equipment maintenance. The pharmacist, staff nurse and the head quarter ANM have been instructed to maintain the equipment and also vaccine stocks as some of them received technical training. However, due to the lack in clarity of roles,

most of the time the maintenance is not done. Some of the PHCs were maintaining stocks to last more than a month, mainly because the vaccines could not be supplied every month from the district stores.

Every PHC on an average had a minimum of 6 hours of load shedding every day. Since the stay over time of the ILR is 24 hours and that of the freezer is 8 hours, the vaccines were maintained in the equipment only. Many of the PHCs did not have stabilizers connected as they would automatically turn off the equipment during voltage fluctuations and in most PHCs the voltage is usually very low.

In Khammam district, two out of the three PHCs visited did not have any equipment. Their vaccines were stored in the nearby PHCs from where they are collected for immunization sessions. Details are given in Annexure 2.

F. Vaccination Points:

Immunization sessions were observed at selected PHCs, sub centers and villages. In most cases the vaccines were collected on the day of the immunization. However, in remote areas, where there is no transport facility, the vaccines were taken the previous evening in a vaccine carrier and stored in the ANMs residence. The requirement of vaccines for each session is calculated on the basis of expected number of beneficiaries.

At the time of collection of vaccines from the PHC, the ANMs usually check for the expiry date. Many of them do not check the Vaccine Vial Monitor (VVM). Even when they did, it was only at the time of receiving the vaccine, and not before administering the vaccine. The vaccine carriers were not closed tightly after opening each time which resulted in increase in temperatures in the carriers

The ANMs would not administer BCG vaccine unless there were a minimum of five children. To avoid wastage, they would administer BCG only once in a month when all the parents would be informed in advance. However, most of the times there was more than 50 percent wastage of BCG vaccine because of 20 dose vials. In about 90 percent of cases the ANMs were not

recording the batch numbers and expiry dates of the vaccine being administered, mainly because they were not aware of its importance. Opened but unused vaccine vials are to be returned to the PHC. This is, very rare since the ANM's usually have a good assessment of the quantity needed by them based on their assessment of the number of children to be immunised.

Fifteen ANMs were interviewed for their Knowledge, attitude and practices (KAP) regarding immunization and cold chain. Most of the ANMs were not very clear about the temperature sensitivity of the vaccines, which vaccines should be stored in ILR or freezer and about temperature recording. This was mainly because most of them were based at the sub centers, where there is no facility for storage of vaccines. However, all of them were aware of how the vaccines should be carried and where they should be placed during immunization.

Eight out of fifteen ANMs interviewed did not know the storage time of the vaccines in the vaccine carriers or the time within which the reconstituted vaccines should be used up. They thought that the reconstituted vaccines should be used up in that session. This holds good when the session lasts for less than 4 hours, as the reconstituted vaccines should be used within 4 hours. However, when the session lasts longer or when they cover the hamlets of the village on the same day, it becomes a problem. About 7 ANMs did not know what a Vaccine Vial Monitor (VVM) is. When asked, how they check for viability of vaccine before administering the Polio vaccine, they said they check for the color of the vaccine. Details are given in Annexure 3.

IV.Recommendations:

Based on the observations in the field, the study recommends the following changes at the different levels in the cold chain, to make the flow of vaccines smoother and ensure viability of the vaccines.

A. Vaccine Logistics Utilisation and Equipment (VALUE) Management System:

It was observed that the information at different levels was not comprehensive. Record keeping at all levels is manually done. Recording formats are not standardized. Maintenance of records and registers is a time consuming process. Moreover most of the details stored about vaccine arrivals or issues, is not easily available for any analyses. This made most of the information collected redundant. The information collected regarding vaccine flow, temperature maintenance, coverage etc. could prove useful if it were more organized and systematic. This could be achieved by having in place an effective Management Information System (MIS).

To start with, the SCU and RCUs should be linked through a wide area network, solution. Gradually district stores and vaccine service centres (PHCs) should be computerized. A vaccine logistics, utilisation and equipment (VALUE) management application should be developed and deployed over a wide area network linking the SCU, Regional units. The system should allow for receipts and issues of vaccines, recording of batch number etc. The solution should have bar code reader interface to minimise human errors in recording of batch numbers and expiry date. The solution should allow for recording of equipment status such as temperatures, power failure events, change over of operating personnel etc. Scope of interfacing the VALUE system with the cold chain equipment for automatic logging of equipment status and triggering of critical equipment failure-response mechanism should be explored. In Phase-2 the district stores should be brought in. Eventually the network and the software would extend to include the vaccine service centres and the vaccination points.

B. Equipment Design and Development:

Visits to PHCs revealed that though stabilizers are available, they are not connected to avoid frequent shutdown of the refrigerators. There is a mismatch between the operating voltage of the refrigerator and the voltage stabilizers. The refrigerators operate, may be under higher risk of damage to its parts, over a wider voltage range. The voltage stabilizers, when connected

would automatically shut off power if the incoming voltage is very low. Since voltage fluctuation is frequent in rural areas, and low voltage conditions are common, connecting the voltage stabiliser to the refrigerator would mean much frequent shut downs and the resultant need for closer supervision by the staff. One solution is to educate the staff and motivate them to increase supervision, but keep the voltage stabiliser connected to avoid equipment failure. Another alternative is to design a suitable voltage stabiliser, which may be little more expensive, but will work in this environment. We discuss below the design and development alternative.

Suitable stabilizer designs should be chosen so that they work in wide voltage fluctuation environment found in rural areas. Alternatively a combination of step up transformer plus a voltage stabiliser may be chosen. It should be possible to design a stabiliser that would sense incoming voltage, use an algorithm contained in an embedded chip to decide alternative processing such as (a) step up and stabilise (b) step down and stabilise and (c) in case of complete power failure display elapsed time since failure using a battery back up mechanism. Given the power conditions in India, such a stabiliser will have wider application. It is possible that such a stabiliser is already available. In that case, the appropriate course of action will be to have written specifications of such a voltage stabiliser, so that appropriate quality products are purchased. Testing facilities should be identified for acceptance testing of product sample. The Central Electronics Engineering Research Institute (CEERI)[1], Pilani, Rajasthan or any of its centres may be able to provide further guidance in this matter. The CEERI is a laboratory under the Council of Scientific and Industrial Research (CSIR), New Delhi. This laboratory should be able to give an opinion on the above design recommendation or direct to appropriate research institution in the country.

Solar refrigeration systems are now widely being used in many developing countries for maintaining the cold chain. In areas where there is no reliable conventional fuel supply, they may be the only option. In large-scale

[1] CEERI has its headquarter at Pilani, Rajasthan and regional centres are located in New Delhi and Chennai.

programs, however, it is recommended that a pre-feasibility survey be conducted. Organizations like WHO/EPI could be approached for assistance in this regard. In remote PHCs, where regular power supply is a problem, Solar refrigeration systems may be a good option. (WHO,2001)

C. Equipment Maintenance:

Equipment maintenance is a critical factor in the program, and hence there is a need for certain changes in this area to ensure better functioning of equipment at all levels.

It was observed that the Refrigerator mechanic is a key person in the district, being the only one with technical knowledge of cold chain equipment. It is not a good idea to depend only on one person for a critical function. A single RM is not able to cover the entire district even once a month. Hence technical staff requirement needs to be reviewed on the basis of work load, optimal productivity level, and additional positions created to meet short fall.

Pre and post commissions Training should be organised for the mechanics whenever, new and sophisticated equipment is introduced.

During the study it was also observed that preventive maintenance is not being done at the PHC level. The pharmacists at the PHCs therefore, should be trained on day to day maintenance of the equipment, defrosting and preventive maintenance, so that it is done regularly at this level. Additional personnel at the PHC should be trained to take charge of the cold chain equipment, when the pharmacist is not available.

D. Monitoring cold chain status and vaccine viability:

Regular monitoring and evaluation is very essential. At present however, the focus of monitoring is on coverage and achievement of immunisation target. Little attention is being paid to monitor, the vaccine flow, cold chain efficacy and viability of vaccines. The cold chain - a network of fridges, freezers and cold boxes - organized and maintained by teams of people - ensure that vaccines are kept at the right temperature to retain their potency, from the moment they leave from the manufacturer, until they are administered. The

recommended equipment for storage (cold rooms, refrigerators, freezers) and transport (cold boxes, vaccine carriers) has to comply with a set of performance standards. The WHO and UNICEF have defined many of these standards. Stock management procedures have been established so that vaccines are not stored longer than necessary at the central, regional and district levels of the cold chain. It is very essential to monitor that these standards are being followed, from time to time.

E. Continuing Education of health workers on vaccination procedures:

Results of the study show that the knowledge of the field workers regarding the immunization practices is not adequate. Therefore regular in service training for the Supervisors as well as the MPHAs becomes very important. Training for the ANMs should focus on (a) Importance of cold chain, (b) Sensitivity of different vaccines, (c) Practices to be followed during immunization sessions for maintaining cold chain, and (d) Recording - importance of maintaining complete records of vaccine details before administering them.

Pharmacists should be trained regarding equipment handling and maintenance. Training for all staff should focus on the importance of cold chain in the program. The Medical Officers need to be given training on management of services and logistic management and planing. So that they can efficiently supervise the program. Study tours and cross visits should be arranged for the field workers to different areas so that there is active learning.

F. Other Recommendations:

1. Wastage of BCG was observed to be as high as 50 percent. This a major concern in view of global shortage of the vaccine. It is therefore recommended number of doses per vials be reduced to 10 or 5.
2. The PHC level staff should be motivated for better maintenance of equipment by means of certain incentive schemes.
3. The vaccine arrivals and issues at the SCU, was observed to be a sporadic activity. For example large quantities are received and issued during January and February. The months of March, April are lean periods with no receipts of vaccines and very little issues. During 2000, nearly 40 lakh doses of DPT were received at the SCU, and then till August, DPT was not received again. This will increase the storage period of the vaccine at the different cold chain

facilities. Instead, the vaccines should be received and issued on a monthly or bimonthly basis at each facility.

V. Summary and Conclusion:

The cold chain system in AP was studied using a convenience sample of cold chain segments in the three districts. The state and regional cold chain units are being maintained reasonably well. There is however need for batch level accounting of vaccines and closer monitoring of the cold chain status. Computerisation of the state and regional cold chain units will help batch level accounting and better management of the cold chain system. At the district level the refrigerator mechanic is a critical link. At the current level of staffing a single refrigerator mechanic is not able to effectively service a large number of vaccine service centres i.e. the PHCs. District vaccine stores can also benefit from computerisation, as may suitable to batch level accounting of vaccine receipts and issues.

At the PHC level, unreliable and poor quality power supply is a major problem. Appropriate design changes in choice of voltage stabiliser is recommended to cope with the situation. There should be more clarity of job descriptions and alternates, so that there is always a person clearly identified to be responsible for the refrigerators and vaccine stock. These personnel should also receive continuing education at periodic intervals about vaccine storage and handling procedure. Knowledge about vaccine carrying, storage and usage procedures by the health workers was assessed using a structured questionnaire. Similarly practices were assessed by use of a structured questionnaire and direct observation. Many health workers are not aware of the usefulness of Vaccine Vial Monitor (VVM), and are not clear about vaccine life, once a vial is opened for use. Many gaps in vaccination related knowledge and practices exist. Hence continuing education of female health workers (MPH A-F) at regular intervals is recommended.

References:

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WHO,2001http://www.who.int/vaccines-access/vaccines/Vaccine_Cold_Chain/solarenergy.htm

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