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Assessment of cold chain and logistics management practices: a cross sectional study in Bundelkhand region of Madhya Pradesh

Ram K. Panika¹, Amarnath Gupta^{2*}

¹Assistant Professor, ²Associate Professor, Department of Community Medicine, Bundelkhand Medical College, Sagar, Madhya Pradesh, India

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***Correspondence:**

Dr. Amarnath Gupta,
E-mail: drangupta@yahoo.com

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ABSTRACT

Background: Immunization is one of the most effective disease prevention strategies. Potency of vaccine is dependent on effective management of cold chain system at all levels of vaccine handling. This study was carried out to assess the status of cold chain equipment and logistics management practices, Knowledge and practice of CCHs about cold chain equipment and logistics management.

Methods: Cross-sectional study was conducted in all functional cold chain points of Damoh district using structured questionnaires provided by UNICEF.

Results: Only 57.14% and 71% CCPs had dedicated space for dry storage and for conditioning of ice packs respectively. 50% CCPs had correct placement of ice-packs inside DFs. Functional thermometer inside every equipment was available in 86% CCPs. Twice daily temperature recording and temperature of ILRs was within normal range in 93% CCPs. Record of power failures and defrosting/cleaning in temperature log books was found in 57% and 43% CCPs. Temp log book was countersigned by facility in charge in 43% CCPs. UIP vaccines were stored within basket in 93%. Fractional IPV was stock out in 29% CCPs and in 07% CCPs OPV vials were found with not usable VVM. 86%, 72% and 64% of CCHs had knowledge on freeze/temperature sensitive vaccines, cold chain pray and, Shake test. In 79% CCPs expired/wasted vaccines were not documented in stock.

Conclusions: Most of the components of cold chain and logistics management practices were satisfactory while there is a gap in other components which needs to be improved.

Keywords: Cold chain, CCHs, CCPs, CCE, ILRs, DFs

INTRODUCTION

India has one of the largest immunization program in the world.¹ Immunization is one of the most effective methods of preventing childhood diseases.² In May 1974, WHO officially launched Expanded Program on Immunization (EPI) against six most common preventable childhood diseases. The Government of India launched EPI in 1978 with objective of reducing mortality and morbidity from vaccine preventable diseases of childhood.³ The program was revised and renamed as Universal Immunization Program (UIP) in

1985 focusing more on infants and pregnant mothers.⁴ Immunization is one of the safest and most effective methods of preventing childhood diseases. It is a key strategy to child survival which significantly lowers morbidity and mortality rates in children.⁵ despite the concerted efforts of the government and other health agencies, a large proportion of vulnerable infants and children in India remain unimmunized. India has the highest number (approximately 10 million) of such children in the world.⁶ According to NFHS-3 (2005-06), reports only 43.5% of children in India received all of their primary vaccines by 12 months of age.⁷ Vaccines

are the antigenic substances which when administered in an individual stimulate the production of specific antibodies and protect the individual against that particular disease.⁸ Success of national immunization program is highly dependent on supply chain system for delivery of vaccines and cold chain equipments.⁹ Immunization against a disease is achieved only if a potent vaccine is administered. The system of transporting, storing and distributing vaccines in a potent state at the recommended temperature from the point of manufacture to the point of use is the cold chain.¹⁰ Since most of the vaccines lose their potency within short time when exposed to room temperature, cold chain is an essential component for maintaining the quality of vaccine.¹¹ In order to realize the full benefits of immunization, coverage of vaccination has to be increased and more importantly potent vaccines should reach the beneficiaries for which cold chain maintenance is crucial.¹² So care must be taken to see that the vaccine do not lose their potency, before the date of expiry, by maintaining cold chain. All vaccines retain their potency at temperatures between +2° Celsius and +8° celsius. Polio vaccine (OPV) is the most sensitive and tetanus toxoid is the least sensitive to heat and light. With this background, this study was carried out to ascertain the status of cold chain equipment and logistics management and to assess awareness and practice of cold chain handlers about cold chain equipment and logistics management in Damoh district of Bundelkhand region of Madhya Pradesh.

METHODS

This cross sectional study was conducted during June 2016 to Sep. 2017 in Damoh district of Bundelkhand region of Madhya Pradesh. The study was a part of a project of strengthening Routine Immunization program in association with UNICEF Madhya Pradesh. The authors were monitors in this project. Damoh is a district in Bundelkhand region in Sagar Division of Madhya Pradesh with an area of 7306 square kilometers and population of 1264219 (2011 census). The district is served by a district hospital, seven community health centers and fifteen primary health centers. The study was carried out in all 14 functional cold chain points. Information was collected on a pre-designed and pre-tested questionnaire. Data was compiled and analyzed using percentages and proportions.

RESULTS

Among all cold chain points (CCPs) observed, all 14 (100%) CCPs had dedicated space/room for cold chain and only 08 (57.14%) CCPs had dedicated space for dry storage (syringes and diluents), dedicated table/Space for conditioning of ice packs was available in only 10 (71.42%) CCPs and Clean cloth for wiping of Icepacks after conditioning was found in only 11 (78.57%) CCPs. Only 07 (50.00%) CCPs had correct placement of ice-

packs inside DFs moreover in 12 (85.71%) CCPs ice packs were filled with water up to the mark (Table 1).

Table 1: Distribution of cold chain infrastructure.

Cold chain infrastructure	Yes (%)	No (%)
Dedicated room/space available for cold chain	14 (100)	00
Dedicated room/space available for syringes and diluents (dry storage).	8 (57.14)	06 (42.85)
Dedicated table/space available for conditioning of ice-packs	10 (71.42)	04 (28.57)
Clean cloth available for wiping of icepacks after conditioning.	11 (78.57)	03 (21.24)
Correct placement of icepacks inside deep freezer for freezing (criss-cross manner)	07 (50.00)	07 (50.00)
Icepacks kept for freezing filled up to the mark and capped.	12 (85.71)	02 (14.28)

It was observed that 12 (85.71%) CCPs had Separate functional thermometer inside every functional equipment however only in 9 (64.28%) CCPs functional thermometer were placed correctly in ILR and DFs. Temperature log books were maintained & temperature was being recorded twice daily in 13 (92.85%) whereas the temperature was being recorded on Sundays and holidays in 11 (78.57%) CCPs. Record of power failure and Records of defrosting/cleaning in temperature log book was maintained in 8 (57.14%) and 06 (42.85%) CCPs respectively. It was also observed that in only 06 (42.85%) CCPs temperature log book was countersigned by facility charge while it was countersigned by DIO in 12 (85.71%). Temperature of ILRs was within normal range in 13 (92.85%) and temperature of DFs was within normal range in 12 (85.71%) CCPs (Table 2).

It was found that in all CCPs, UIP vaccines and diluents were placed inside ILR within the basket in 13(92.85%) CCPs. However in 1(7.14%) CCP they were placed over 2 rows of empty ice packs within the ILRs. In 02(14.28%) CCPs The diluents were stored inside the ILRs from the time of receipt while in 12(85.71%) CCPs Diluents were stored inside ILR 24 hours before the session. It was also observed that opened vaccine vial were stored in separate box/zipper bag within ILRs in 10 (71.42%) CCPs. Date and time of opening was written on the vial in 9 (64.28%) CCPs and the opened vaccine vials were of <28 days duration in all of them (Table 3). It was observed that in all 14 CCPs vaccine vials had proper readable labels, all vaccines were found within expiry dates and vaccines were not found in frozen condition. However nil stock of fIPV vaccine was found in 04 (28.57%) CCPs and in 1 (7.14%) CCP vaccine vial of OPV was not usable (VVM stage III) (Table 4).

Table 2: Distribution of vaccine and diluents storage practices.

Vaccine and diluents storage practices	Yes (%)	No (%)
Separate functional thermometer inside every functional equipment	12 (85.71)	02 (14.28)
Separate functional thermometer placed correctly)	09 (64.28)	05 (35.71)
Each CCE is having separate temperature log book	13 (92.85)	01 (07.14)
Temperature is recorded twice daily	13 (92.85)	01 (07.14)
Temperature is recorded on Sundays and holidays	11 (78.57)	03 (21.24)
Record of power failure maintained in temp. log book	8 (57.14)	06 (42.85)
Records of defrosting / cleaning maintained in temp.log book	06 (42.85)	8 (57.14)
Temp. log book reviewed and countersigned by facility In charge	06 (42.85))	8 (57.14)
Temp. log book reviewed by DIO in last three months	12 (85.71)	02 (14.28)
Functional ILR within the temperature range (+2°C to +8°C)	13 (92.85)	01 (07.14)
Functional Deep freezer within the normal temperature range	12 (85.71)	02 (14.28)

Table 3: Distribution of vaccine and diluents storage Practices and Open vial Policy in the ILR.

Vaccine and diluents storage practice	Yes (%)	No (%)
Only UIP vaccines are placed inside ILR?	14 (100)	00 (00)
The diluents are stored inside the ILR from the time of receipt	02 (14.28)	12 (85.71)
Diluents are stored inside ILR 24 hours before the session	12 (85.71)	02 (14.28)
Diluents are never kept in the ILR till issue for session	00	00
Vaccines are stored in ILRs	Within basket	13 (92.85)
	Over 2 rows of empty ice packs	01 (07.14)
	Directly on the floor of ILR	00
T-series/Hep-B vaccines stored in the top of the ILR	14 (100)	00
Open vial policy		
Any opened vaccine vial is stored inside ILR	10 (71.42)	10 (71.42)
Opened vaccine vials are stored in separate box / zipper bag	10 (71.42)	10 (71.42)
Date and time of opening is written on the vial	09 (64.28)	05 (35.71)
All opened vaccine vials are of < 28 days duration, since opened?	09 (64.28)	05 (35.71)

Table: 4 Distribution of vaccine availability and vaccine condition.

Stock availability	Yes (%)	No (%)
Nil stock of any vaccine found during the visit.	04 (28.57)	10 (71.42)
All the vaccine vials have proper readable labels	14 (100)	00
All the vaccines found within expiry dates	14 (100)	00
All the vaccines with usable VVM	13 (92.85)	01 (07.14)
Any vaccine found in frozen condition	00	14 (100)

Table 5: Knowledge of cold chain handler (CCHs).

Knowledge of cold chain handler	Yes (%)	No (%)
Knowledge of CCH about all freeze sensitive vaccines	12 (85.71)	02 (14.28)
Knowledge of CCH about all temperature sensitive vaccines	12 (85.71)	02 (14.28)
Knowledge of CCH of Shake test	09 (64.28)	05 (35.71)
Knowledge of CCH of vaccine vial monitor	12 (85.71)	02 (14.28)
Knowledge of CCH of cold chain pray	10 (71.82)	04 (28.57)
Knowledge of CCH about time of use of reconstituted vaccine	12 (85.71)	02 (14.28)
Knowledge of CCH about timing of placement of diluents inside ILRs	12 (85.71)	02 (14.28)
Knowledge of CCH about vaccines requiring diluents	14 (100)	00 (00)
Knowledge of CCH about open vial policy	10 (71.82)	04 (28.57)
Knowledge of CCH of cabinet temperature range of ILRs and DFs	14 (100)	00 (00)
Knowledge of CCH about conditioning of ice packs	14 (100)	00 (00)

Table 6: Management information system, information education and communication and supporting management in CCPs.

Functions	Yes (%)	No (%)
The centre has got independent Internet connection	07 (50)	07 (50)
Is the internet connection working on the day of visit?	05 (35.71)	09 (64.28)
NCCMIS for this cold chain point is complete?	14 (100)	00
CCT visited this cold chain point for preventive maintenance in the last quarter?	10 (71.42)	04 (28.57)
Is stock register in use for vaccine and logistics as per norm?	13 (92.85)	01 (07.14)
All parameters for vaccines, logistics and diluents are recorded?	13 (92.85)	01 (07.14)
Returned vials from the field are entered in the stock register?	13 (92.85)	01 (07.14)
Is distribution register in use for vaccine and logistics as per norm?	13 (92.85)	01 (07.14)
Expired and wasted vaccines are documented in Stock register	03 (21.42)	11 (78.57)
Physical counting of vaccine stock is done at least once in last 3 months?	14 (100)	00
Physical stock of (BCG/measles) is matching the stock register for that day?	12 (85.71)	02 (14.28)
System in use for vaccine & logistics stock management	Paper 14 (100) Web 14 (100)	00(00) 00(00)
Vaccine & Logistics stock management updated till last transaction	12 (85.71)	02 (14.28)
Chart/SOP on ILR/DF/vaccine/ice pack arrangements available	13 (92.85)	01 (07.14)
Emergency/contingency plan visible	10 (71.42)	04 (28.57)

In present study in all the 14 (100%) CCPs, cold chain handlers had knowledge about vaccines requiring diluents, cabinet temperature range of ILRs and DFs, conditioning of ice packs. The cold chain handlers also had knowledge about all freeze sensitive vaccines, all temperature sensitive vaccines, time of use of reconstituted vaccine, timing of placement of diluents inside ILRs in 12(85.71%) CCPs, however in only 10(71.82%) CCPs cold chain handler had knowledge about cold chain prayer and Open vial policy. Cold chain handlers had complete knowledge of shake test in only 9 (64.28%) (Table 5).

Internet facility was available in 07(50%) CCPs, out of which, it was in working condition in 05 (35.71%) CCPs. Stock register and distribution register for vaccine and logistics were as per norms, returned vials from the field were entered in the stock register, all parameters for vaccines, logistics and diluents were recorded, charts / SOPs on ILR/DF/vaccine/ice pack arrangements were available in 13 (92.85%) CCPs. However cold chain technician visited only 10 (71.42%) CCPs for preventive maintenance in the last quarter. Expired and wasted vaccines were documented in stock register in only 03 (21.42%) CCPs, Physical stock of (BCG and measles) was matching with the stock register for that day and vaccine and logistics stock management updated till last transaction in 12 (85.71%) CCPs. It was also found that 10 (71.42 %) CCPs did not have visible emergency or contingency plan (Table 6).

DISCUSSION

Immunization is one of the most effective methods of preventing childhood diseases.² It is a key strategy to child survival which significantly lowers morbidity and mortality rates in children.⁵ In order to realize the full

benefits of immunization, coverage of vaccination has to be increased and more importantly potent vaccines should reach the beneficiaries for which cold chain maintenance is crucial.¹²

There should be a dedicated room for keeping the equipment and logistics, referred as cold chain room. The room should be protective enough to keep the vaccine, equipment and records safely. The room should be properly ventilated and illuminated. The room should be fitted with an exhaust fan for getting rid of the hot air (especially during the summer months).

Care should be taken so that the direct sunlight doesn't fall on the cold chain equipments. The room should be provided with racks and cupboard/almirah for storing vaccine logistics and records/registers/stationary.² In present study it was observed that all 14 (100%) CCPs had dedicated space/room for cold chain while only 08 (57.14%) CCPs had dedicated space for dry storage (syringes and diluents). In a similar study Sinha et al reported that among all CCPs visited only 40% had dedicated space/room and 75% had dedicated space for syringes and diluents.⁹ Ice packs are key components of cold chain, used for inside lining of cold boxes and vaccine carrier at facility and at field respectively for vaccine storage and transport. The water should be filled only up to the level of mark on the side and cork should be tight so that there is no leakage.⁹ Conditioning of ice packs is an important component to prevent freeze sensitive vaccines from freezing during immunization session or outreach session.² In present study we found that Dedicated table/Space for conditioning of ice packs was available in only 10 (71.42%) CCP, clean cloth for wiping of icepacks after conditioning was found in only 11 (78.57%) CCPs and only 07 (50.00) CCPs had correct placement of ice-packs inside DFs. Moreover in 12

(85.71%) CCPs ice packs were filled with water up to the mark over ice packs. Sinha et al in their study reported that 45% CCPs had dedicated table/space for conditioning and clean cloth was available at 55% CCPs.⁹ In a similar study Gupta et al observed the correct placement of ice packs inside DF (in crisscross manner) was found in only 66.66% CHCs.¹³ Ashish et al in their study found that Ice packs were stacked on the floor of the deep freezer horizontally in a crisscross manner in only one- third (35%) of the health centers.¹⁴

Temperature of ILR/DF used for storage of vaccines must be recorded twice daily. The ILR and DF each should have separate thermometer and temperature record book.⁹ In present study it was observed that 12 (85.71%) CCPs had separate functional thermometer inside every functional ILRs and DFs however only in 09 (64.28%) CCPs functional thermometer were placed correctly in ILRs and DFs. Gupta et al in their study observed that a functional thermometer was placed inside every ILR and DF of all the three (100%) CHCs.¹³ Biradar et al found that a functional thermometer was placed inside ILR and DF only in 76.1% health centers.¹¹ As per the UIP guidelines, the temperature is to be monitored and recorded twice daily on all days of the week, including Sundays and holidays². In this study we observed that temperature log book were maintained, temperature was being recorded twice daily in 13 (92.85%) and temperature was being recorded on Sundays and holidays in 11(78.57) CCPs. Biradar et al found that temperature log books were monitored twice daily in 95.6% health centers.¹¹ In their study Gupta et al reported that twice daily recording of temperature in temperature log book by cold chain handler was done in only two CHCs (66.66%).¹³ Mallik et al in a similar study observed that 55% of the organizations maintained temperature chart, 60% recorded temperature twice and 80% maintained temperature in optimal range.¹⁵ Rao et al in their study showed that well maintained temperature record was seen in 94.2% PHCs.¹⁰ In a study Sanghavi et al observed that temperature log book was not properly maintained in some PHCs.¹⁶

In a 24 hour period (day) the number of hours without electricity is to be documented. As per guidelines, defrosting and cleaning should be done if frost is >5 mm in thickness.² In the present study we found that record of power failure and records of defrosting/cleaning in temperature log book was maintained in 8(57.14%) and 06(42.85%) CCPs respectably. Rao et al in their study showed that the correct practices of defrosting and cleaning the ice lined refrigerator and steps in the event of power failure were seen in 61.8% and 73.7% of the medical officers.¹⁰ Sanghavi et al observed that record of defrosting was not available in 42.86% of PHCs.¹⁶ Sharma et al in their study showed that in 98% PHCs record of power failures were maintained and also verified by the facility in charge.¹⁷ Biradar et al found that record of power failures and defrosting of ILRs and DFs was maintained by only 65.2% health centers.¹¹ Gupta et

al in their study found that record of power failures/cuts (if any) and defrosting of ILRs and DFs was maintained in only 33.33% CHCs.¹³

Every day the vaccine and cold chain handler should fill the details as applicable and put his/her signature at the end of the day, the details entered/filled by the vaccine & cold chain handler should be verified and reviewed at least once in a week by the In charge of health facility or medical officer in charge.² In the present study it was observed that in only 06 (42.85%) CCPs temperature log book was countersigned by facility in charge while it was countersigned by District Immunization Officer in 12 (85.71%) CCPs. Gupta et al found that periodic checking of temperature log books by medical officers was done in all the three (100%) CHCs.¹³ Biradar et al found that periodic checking of temperature log books by medical officers was reported in 86.9% health centers.¹¹ We also observed that Temperature of ILRs was within normal range in 13 (92.85%) and temperature of DFs was within normal range in 12(85.71%) CCPs. Biradar et al reported that temperature of ILR was maintained in 93.5% health centers.¹¹ Gupta et al observed that in only 66.66% CHCs the cabinet temperature of ILR was maintained between +2⁰ C to +8⁰ C and the cabinet temperature of DFs was maintained between -15 to -25⁰ C in only two (66.66%) CHCs.¹³

As per the vaccine logistic management guidelines, all the vaccines must be kept in a basket and if basket not available, keep 2 layer of empty ice pack laid flat on the floor of ILR. OPV and measles are kept at the bottom of basket while BCG, pentavalent, DPT and TT vaccines are kept in upper part of the basket.⁹ In present study it was found that in all CCPs visited, UIP vaccines and diluents were placed inside ILR, however in 13 (92.85%) CCPs vaccines were stored within basket in ILRs and in 1 (7.14%) CCPs over 2 rows of empty ice packs in ILRs. Sharma et al observed that in 90% PHCs the vaccine arrangement was proper as T-series vaccine and Hep B vaccine was not found at the bottom of the ILR.¹⁷ As per the guidelines, diluents are to be stored in ILR. If there is space constraint, it can be stored outside the ILR but they need to be kept in ILR for at least 24 hours before vaccination because vaccines and diluents should be of similar temperature during reconstitution.⁹ In present study it was noticed that only in 2 (14.28%) CCPs the diluents were stored inside the ILR from the time of receipt while in 12(85.71%) CCPs diluents were stored inside ILR 24 hours before the session. It was also observed that opened vaccine vial were stored inside ILR in 10 (71.42%) CCPs, they were stored in a separate box/zipper bag; date and time of opening was written on the vial and opened vaccine vials were of <28 days duration in only 9 (64.28%) CCPs. Sinha et al observed that in 70% CCPs open vials were correctly (i.e. separate box/zipper bag) placed inside ILR with date and time mentioned on it.⁹ Sharma et al found that diluents were placed within 24 hours before session in ILR.¹⁷ Biradar et al reported that T-series or hepatitis B vaccine vials were

correctly placed in ILR in 84.8% health centers and in 95.6% health centers diluents were placed in ILR, at least 24 hours before distribution.¹¹ VVM, a time temperature indicator that accumulates information on the exposure of a given vaccine vial to heat and temperature, has allowed vaccinators to use vaccines.⁹ It was observed that in all 14 CCPs vaccine vials had proper readable labels and all vaccines were found within expiry dates, vaccine were not found in frozen condition in any CCPs, however nil stock of fIPV vaccine were found in 4 (28.57%) CCPs and in 01(07.14%) CCPs vaccine vial of OPV were not usable (VVM stage III).

In present study in all the 14 (100%) CCPs, cold chain handlers had knowledge about vaccines requiring diluents, cabinet temperature range of ILRs and DFs, conditioning of ice packs, however in 12 (85.71%) CCPs the cold chain handlers had knowledge about all freeze sensitive vaccines, all heat sensitive vaccines, time of use of reconstituted vaccine, timing of placement of diluents inside ILRs, in only 10 (71.82%) CCPs cold chain handler had knowledge about cold chain prayer and open vial policy. Only 09 (64.28%) cold chain handlers had complete knowledge of shake test. Gupta et al observed that in all the three (100%) cold chain handlers had knowledge about vaccine vial monitor, time of use of reconstituted vaccine and vaccine requiring diluents.¹³ Sinha et al observed that 73.48% cold chain handler had knowledge about all freeze sensitive vaccines and only 52.63% had complete knowledge about “shake test”.⁹

Using internet connectivity, the data gets uploaded from the mobile to the server and is available for real-time usage by the district and higher level authorities. This helps to view real time stock and temperature of vaccines, vaccine requirement, emergency management, consumption patterns, and stock reallocation. Out of all visited CCPs, only 07 (50%) had internet facility out of which in only 05 (35.71%) CCPs it was in working condition at the time of visit. 13 (92.85%) CCPs had stock register for vaccine and logistics as per norms, all parameters for vaccines, logistics and diluents were recorded, returned vials from the field were entered in the stock register, distribution register for vaccine and logistics was as per norms, and chart/SOP on ILR/DF/vaccine/ice pack arrangements were available. However only in 10 (71.42%) cold chain technician visited this CCPs for Preventive Maintenance in the last quarter. Expired and wasted vaccines are documented in Stock register in only 03(21.42%) CCPs, physical stock of (BCG/measles) was matching the stock register for that day and vaccine & logistics stock management updated till last transaction in 12 (85.71%) CCPs. In a similar study Sinha et al found that 90% of CCPs had stock register in place out of which only 66% centers had updated records of vaccine and the logistics. 80% CCPs was not documenting the records of expired and waste vaccine. Charts/SOPs for operating of ILR/DFs were available in 60% of centers.⁹ Sharma et al in their study showed that in 50% PHCs stock register tallied with issue

register for BCG/Measles vaccine and in 22% PHCs stock register tallied with issue register for BCG diluents /Measles diluents.¹⁷ Contingency plans for emergency situations specially electricity failure must be prepared in advance and appropriate sanctions taken so that no time is lost during an emergency. This will help to face such eventualities without any element of panic.² In present study it was also found that 04 (28.57%) CCPs did not have visible emergency or contingency plan. In a similar study Sinha et al found that Majority of the centers (80%) did not have visible emergency or contingency plan.⁹

CONCLUSION

Our study concludes that cold chain and logistics management practices were not satisfactory. There is inadequate infrastructure for storage of cold chain logistics. Maintenance of record as well as monitoring of record was not upto the mark, uninterrupted internet connectivity was also not present in most of the CCPs. The knowledge of CCHs regarding cold chain maintenance and handling practices was poor.

Recommendations

The gaps in cold chain and logistics management practices can be filled by adopting holistic approach which includes political commitment, uninterrupted supply of good quality cold chain equipments and vaccines, fixing accountability. There should be training and retraining of CCHs at regular interval with continuous supportive supervision.

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