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STUDY OF COLD CHAIN PRACTICES AT COMMUNITY HEALTH CENTERS OF DAMOH DISTRICT OF MADHYA PRADESH

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ABSTRACT

Introduction: Vaccination is one of the most effective disease prevention strategies and potency of vaccine is dependent on effective management of cold chain at all levels of vaccine handling. An effective cold chain maintenance system is the backbone of success of any immunization program. The study was done to assess the status of cold chain and vaccine storage practices in Damoh district of Madhya Pradesh.

Methodology: Cross-Sectional Study was done using a structured questionnaire.

Result: ILR and DF were found properly placed at all the three (100%) CHCs. ILR and DF were connected to functional Voltage Stabilizer in two (66.66%) CHCs. A functional thermometer was placed inside every ILR and DF of all the three (100%) CHCs. Twice daily recording of temperature was found only in two CHCs (66.66%). The cabinet temperature of ILR and DFs was maintained in correct range in only two (66.66%) CHCs.

Conclusion: The quality of immunization services can be improved by proper storage and management of vaccine in cold chain system. There is a need to improve methods of ILR and DF maintenance in terms of installation, temperature maintenance and regular defrosting with record keeping.

Key Words: Cold Chain, immunization Ice Lined Refrigerator, Deep Freezer vaccines

INTRODUCTION

In 1974, WHO 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.[1] In spite of Immunization Program operating in India since 1978, approximately 10 million infants and children remains unimmunized. This number is higher than any other country in the world.[2] Only 44% of infants receive full vaccination (all doses up to age of one year) and 5% of infants don't receive any vaccine in India.[3]Vaccine is an immune-biological substance designed to produce specific protection against a given disease. It stimulates production of specific antibodies and other immune mechanisms.[1] Vaccination is one of the most effective disease prevention strategies when implemented properly across all sections of the at risk population. 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. The cold chain remains a highly vulnerable point

for national immunization program.[4] This system of maintaining the cold life for vaccines is necessary because the vaccines are sensitive to heat and light, i.e. they lose their potency, when exposed to heat and light. Once the vaccine looses the potency, it cannot be restored and it becomes a waste. So care must be taken to see that the vaccine do not loose their potency, before the date of expiry, by maintaining cold chain. All vaccines retain their potency at temperatures between $+2^0$ Celsius and $+8^0$Celsius. Polio vaccine (OPV) is the most sensitive and tetanus toxoid is the least sensitive to heat and light.[5]

The quality of vaccines is one of important factor for success of immunization program which in turn depends on proper storage and handling of vaccines.[6] If vaccines are stored outside the recommended temperature for considerable time, its potency will be adversely effected thereby reducing protection from vaccine preventable diseases.[7]The vaccines should not be exposed to direct sunlight. The loss of potency depends upon the temperature and duration of exposure.[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.[8] A break in cold chain is indicated if the temperature goes above $+8^0$ Celsius or falls below $+2^0$ Celsius. The cold chain system consists of series of transportation links with equipments and the persons concerned from the manufacturer to the point of use. Longer the chain, greater is the risk of cold chain failure.[5] The cold chain equipments consists of following: Walk in cold rooms (WIC), Cold Boxes, deep freezers, Ice Lined Refrigerators, Conventional Refrigerator, Vaccine Carrier and Day-Carrier.[9]

With this back ground, this study was carried out with the objective of assessing the cold chain practices, with particular reference to assessing the availability of cold chain equipment, vaccine storage and handling practices, in Community health centers of Damoh district of Madhya Pradesh.

MATERIAL AND METHOD

This cross sectional study was conducted during Jan.2015 to Mar. 2015 in Damoh district of Madhya Pradesh. The study was a part of a project of strengthening Routine Immunization program run by Community Medicine Department of Bundelkhand Medical College Sagar in association with UNICEF Bhopal. 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 fourteen primary health centers. The study was done in three CHCs of the district viz. CHC Jabera, CHC Hindoria and CHC Patharia. Cold chain equipment and cold chain maintenance process was noted following direct observation by the investigator on uninformed visits. Information was collected on a pre-designed and pre-tested questionnaire regarding demographics, electrically powered vaccine storage instruments (e.g. ice lined refrigerators, deep freezers, voltage stabilizer); non electrical vaccine storage equipments (e.g. cold box, vaccine carriers); ice packs, power generator and temperature monitoring chart, set-up and maintenance record of electrical equipment. Data on repair and replacement of ILR and Deep Freezers was also acquired from the concerned Block Medical Officer. Data was compiled analyzed using percentages and proportions.

RESULT

It was observed that in all the three (100%) CHCs, ILR and DF were properly placed. ILR and DF were connected to functional Voltage Stabilizer in only two (66.66%) CHCs. A functional thermometer was placed inside every ILR and DF of all the three (100%) CHCs. (**Table-1**) There was no frost or frost less than 5mm on inside walls of ILR in only two (66.66%) CHCs. Twice daily recording of temperature in temperature log book by cold chain handler was done in only two CHCs (66.66%). Record of Power failures/cuts (if any) and Defrosting of ILRs & DFs was maintained by only one (33.33%) CHC. Periodic checking of temperature log books by medical officers was done in all the three (100%) CHCs. (**Table-1**)

It was observed that in only two (66.66%) CHCs the cabinet temperature of ILR was maintained between $+2^0$ C to $+8^0$ C. T-series or Hepatitis B vaccine vials were found correctly placed i.e. not placed in the bottom of ILR in only two (66.66%) CHCs. It was found that in only two (66.66%) CHCs, vaccine vials were correctly arranged inside labeled cartons. Diluents were placed in ILR, at least 24 hours before distribution in all the three (100%) CHCs. (**Table-1**) The Cabinet Temperature of DFs was maintained between -15 to -25◦C in only two (66.66%) CHCs. The Correct placement of ice packs inside DF (in crisscross manner) was found in only two (66.66%) CHCs. It was also found that in none of CHC had vaccines stored inside DFs. Functional generator was available in only two (66.66%) CHCs. The generator in the third CHC was found in non-functioning condition (**Table-1**).

Table-1: Vaccine storage and handling practices

Vaccine storage and handling practices	Yes (%)	No (%)
ILR and DF		
Placed on wooden blocks and at least 10 cm away from walls and surrounding equipment	3 (100)	0 (0)
Each equipment is connected through functional Voltage Stabilizer	2 (66.66)	1 (33.33)
Functional thermometer placed inside every ILR and DF	3 (100)	0 (0)
No frost OR frost less than 5mm on inside walls of every ILR	2 (66.66)	1 (33.33)
Temperature Log Book		
Twice daily monitoring of temperature in respective log books	2 (66.6)	1 (33.33)
Record of power failures/cuts (if any) and Record of Defrosting ILRs & DFs	1 (33.33)	2 (66.66)
Periodic checks of Temperature Log Books by Facility in-charge (evidence of signature)	3 (100)	0 (0)
Ice Lined Refrigerator (ILRS)		
Cabinet Temperature between +2 to +8◦C	2 (66.66)	1 (33.33)
All vaccine vials correctly arranged inside labeled cartons (expiry date, batch)	2 (66.66)	1 (33.33)
No T-series or Hepatitis B vaccine vials placed in the bottom of ILR	2 (66.66)	1 (33.33)
Diluents placed in ILR, at least 24 hours before distribution (observe)	3 (100)	0 (0)
Deep Freezers (DF)		
Cabinet temperature of DFs between -15 to -25◦C	2 (66.66)	1 (33.33)
Correct placement of ice packs inside DF (in crisscross manner, while freezing)	2 (66.66)	1 (33.33)
No RI vaccines stored inside DFs (including reconstituted vaccines)	3 (100)	0 (0)
Generator - Functional generator availability	2 (66.66)	1 (33.33)

Table-2: Correct knowledge of cold chain handlers about vaccines, cold chain equipment, storage and monitoring (N=3)

Parameter	Frequency (%)
Cold chain	3 (100)
Universal immunization program	3 (100)
Vaccine requiring diluents	3 (100)
Time of use of reconstituted vaccine	3 (100)
Vaccine Vial Monitor	3 (100)
Temperature monitoring	3 (100)
Shake Test	2 (66.66)
Steps to be taken in the event of power failure	3 (100)

As far as knowledge of cold chain handlers is concerned all the three (100%) had knowledge about cold chain, universal immunization program, vaccine vial monitor, time of use of reconstituted vaccine and vaccine requiring diluents (**Table-2**). Only two (66.66%) cold chain handlers had knowledge about the Shake test (**Table-2**).

DISCUSSION

The cold chain still remains a highly vulnerable element of any immunization program, both in developing and developed countries Careful attention to storage and handling is essential to ensure optimal potency of vaccines and to maximize the resulting efficacy of vaccination.[10]In the present study it was observed that in all the three (100%) CHCs, ILR and DF were properly placed on wooden blocks and at least 10 cm away from walls and surrounding equipment. ILR and DF were connected to functional Voltage Stabilizer in only two (66.66%) CHCs. A functional thermometer was placed inside every ILR and DF of all the three (100%) CHCs. There was no frost or frost less than 5mm on inside walls of ILR in only two (66.66%) CHCs. In a similar study Santosh M .Biradar et al at Bijapur Karnataka found that in only 76.1% health centers ILR and DF were properly placed, ILR and DF were connected to functional Voltage Stabilizer in 91.3% health centers. A functional thermometer was placed inside ILR and DF only in 76.1% health centers.[11]Goel NK et al in a similar study in Chandigarh observed that all (100%) the ILR and DF were correctly installed with functional thermometer.[12]The proper positioning of ILR/DF is important for correct functioning and improving durability of the equipments.

In the present study twice daily recording of temperature in temperature log book by cold chain handler was found in only two CHCs (66.66%). Record of Power failures/cuts (if any) and Defrosting of ILRs & DFs was maintained by only one (33.33%) CHC. Periodic checking of temperature log books by medical officers was found in all the three (100%) CHCs. Santosh M Biradar et al found that temperature log books were monitored twice daily in 95.6% health centers. Record of power failures and defrosting of ILRs & DFs was maintained by only 65.2% health centers and periodic checking of temperature log books by medical officers was reported in 86.9% health centers.[11] Goel NK et al found that temperature chart was updated in 97.5% and record of breakdown was noted in 80% of health centers and the temperature log book was countersigned by 95.3% Supervisor/Medical officers.[12]

It was also observed that in only two (66.66%) CHCs the cabinet temperature of ILR was maintained between $+2^0$ C to $+8^0$ C. T-series or Hepatitis B vaccine vials were found correctly placed i.e. not placed in the bottom of ILR in only two (66.66%) CHCs. In only two (66.66%) CHCs, vaccine vials were correctly arranged inside labeled cartons. Diluents were placed in ILR, at least 24 hours before distribution in all the three (100%) CHCs.

Keeping vaccines properly in labeled cartoons is important prevent mixing of different vaccines and avoid use of expired vaccines. T series vaccines are freeze sensitive hence they should not be kept at the bottom of ILR. Santosh M .Biradar et al reported that temperature of ILR was maintained in 93.5% health centers. 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] Tushar Patel et al in a similar study in rural areas of Gujarat reported that ILR temperature was maintained in 90.9% and vaccines were correctly stored in 93.2% health centers.[13]

Diluents need to be kept in ILR for at least 24 hours before vaccination because vaccine and diluents should be of similar temperature during reconstitution.

In the present study the Cabinet Temperature of DFs was maintained between -15 to -25◦C in only two (66.66%) CHCs. The Correct placement of ice packs inside DF (in crisscross manner) was found in only two (66.66%) CHCs. It was observed that in none of CHC had vaccines stored inside DFs. Santosh M .Biradar et al in their study found that the correct cabinet temperature of DFs was maintained in 91.3% health centers and the ice packs were correctly placed inside DF only in 73.9% health centers.[11] Goel NK et al in their study reported that all the icepacks were properly placed in Deep freezer.[12]

Good quality icepacks are requisite for field transportation of vaccine in vaccine carrier and these can be obtained from DF only if proper temperature is maintained with correct placement of ice packs (i.e. in crisscross manner). Functional generator was available in only two (66.66%) CHCs. The generator in the third CHC was found in nonfunctioning condition. Samant et al in a similar study found that only 45% health centers had power generator.[14] Rao S et al in a similar study in coastal south India reported that 94.2% health centers had generator facility.[4]

All the three (100%) cold chain handlers had knowledge about cold chain, universal immunization program, vaccine vial monitor, time of use of reconstituted vaccine and vaccine requiring diluents. Rao S et al in a similar study found that 100% had knowledge about cold chain, 97.4% had knowledge about universal immunization program, and 96.1% had knowledge about vaccine requiring diluents, 80.3% had knowledge about vaccine vial monitor.[4] Thakur et al in in a similar study at Chandigarh found that only 67% of the vaccinators were aware of the vaccine vial monitor.[15] A similar study done in Delhi showed that 82% of the vaccinators had knowledge about vaccine vial monitor.[16] In the present study only two (66.66%) cold chain handlers had knowledge about the Shake test. Rao S et al reported that only 22.4% knowledge about the Shake test. [4]

CONCLUSION

The availability of cold chain equipment was universal. Improper vaccine storage practices and poor knowledge in some fields of cold chain management may adversely affect the quality of administered vaccine. There is a need to improve methods of ILR and DF maintenance in terms of installation, temperature maintenance and regular defrosting with record keeping. The correct placement of vaccines in ILR and exclusive use of ILR for storage of vaccine is vital factor for successful immunization program. There should be training and retraining of health staff involved in handling the cold chain at regular interval with continuous supportive supervision. Strengthening immunization services will not only include the cold chain equipment availability but also the right attitude and practice of cold chain handling by the cold chain handlers.

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