

ORIGINAL RESEARCH

A Cross Sectional Study to Assess Knowledge of Vaccine Handlers and Vaccine Management in Cold Chain Point Facilities of District Gwalior, Madhya Pradesh

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ABSTRACT

Background: Vaccines are medical products with a short shelf life and are easily damaged by deviations in temperature from the recommended ranges. Vaccines lose their quality if the cold chain system is not properly managed. Cold chain management is still a major challenge in developing countries, including India. Thus, this study aimed to assess vaccine cold chain management and associated factors at public health facilities. **Methods:** A facility-based cross-sectional study design was applied. Data was collected using the observation check list and interviewer-administered pre-tested structured questionnaires. 54 cold chain handlers of 27 facilities of district Gwalior were interviewed. Multivariate analysis at a p -value <0.05 and OR with 95% CI was used to measure the degree of association between independent variables and the outcome variable. **Results:** The study indicates that 43 (79.6%) public health facilities had good/average cold chain management practice. Experience greater than 2 years (OR=5.1, 95% CI=1.2;22.0), cold chain guidelines (OR=7.59 (95% CI=1.4;39.6)), training on cold chain management (OR=8.40, 95% CI=1.4–9.8), and supportive supervision on cold chain management (4.50 (95% CI=1.0;19.4)) were statistically significantly associated with good cold chain management practice. **Conclusion:** The result of the study indicated that there was not satisfactory cold chain management practice in the study area. Strengthening the knowledge of healthcare workers and supportive supervision on cold chain management by giving training and monitoring their practice toward cold chain management may help to improve the cold chain management practice.

Keywords: Vaccine, Public health facility, Cold chain handlers, Cold chain management

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INTRODUCTION

Globally the high impact of vaccine-preventable diseases has been averted by introducing immunization, which saves two to three million lives per year and it was recognized as a powerful public health intervention.^{1,2} Globally 29% of under-five mortalities were due to poor vaccine cold chain management and poor immunization uptake in developing countries but, nowadays, many countries of the world enforce and achieve a high coverage of required vaccinations for every resident, making efforts to eliminate constraints to vaccination among vulnerable classes, but problems still remain in the vaccine storage and handling.³ 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 Vaccine preparation is delicate biological substance. Some vaccines are delicate to high temperatures, some too low temperature and others to sunlight. Vaccine ability to adequately protect the vaccinated person is called vaccine potency. Vaccine potency can be lost when exposed to non-recommended temperatures. The denatured vaccine cannot be renatured.⁵ Hence for the proper running of the Universal Immunization Programme (UIP) factors

like vaccine cold chain and vaccine management wants great focus and attention skills and knowledge of the vaccine cold chain handlers so for good implementation of UIP vaccine cold chain handlers are important.^{6,7}

Vaccines are the antigenic substances which when administered in an individual stimulate the production of specific antibodies and protects the individual against that particular disease.⁸ The Ministry of Health and Family Welfare, government of India launched Mission Indradhanush in December 2014 as a special drive to vaccinate all unvaccinated and partially vaccinated children under universal immunization program. 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. Vaccine potency once lost cannot be restored. The cold chain remains a highly vulnerable point for National Immunization Programs.¹⁰

Ministry of Health and Family Welfare, Government of India publishes vaccine and cold chain handlers handbook to guide cold chain handlers so that they can effectively manage the vaccines and vaccine cold chain system by providing them with the required technical and practical guidance.¹¹ Cold chain handler is the most crucial person at a cold chain point as his/her awareness and skills regarding vaccine cold chain practices, vaccine management, and handling are vital for the success of UIP. 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.¹² 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.¹³ Hence the present study was carried out with the objectives to assess the awareness and skills of the vaccine cold chain handlers regarding cold chain and vaccine management practices in district Gwalior and to identify any shortcomings and suggest recommendations for improvement

METHODOLOGY

STUDY DESIGN

This is a cross-sectional survey of all the Cold Chain Points in various health facilities in Gwalior district. All the twenty-seven Cold Chain points in Gwalior district were reviewed using questionnaire consisted of empirical observation of practices such as the presence of working ILR and DF, the presence of temperature charts and vaccines in the fridge. It also involved assessment of the cold chain facilities by physical inspection of the equipment at the health facilities, especially attention was paid to ILRs, Deep Freezers, Vaccine carriers and thermometers.

STUDY POPULATION

The study included All the 27 cold chain points (CCP) of Gwalior district having 54 Cold Chain Handlers (CCH), two at each CCP.

SAMPLE SIZE DETERMINATION

All the Cold Chain handlers that work in Cold Chain Points in the twenty-seven health facilities of Gwalior district were recruited for the study and were administered the questionnaire.

STUDY PERIOD

20 months from November 2020 to June 2022

DATA COLLECTION

All the 27 Cold Chain Points were visited and assessed using globally validated WHO-UNICEF standardized Effective Vaccine Management (EVM) assessment tool.¹⁴ Cold Chain Handlers at these Cold Chain Points were interviewed and cold chain system was observed. A structured questionnaire was used to gather information on the health workers knowledge regarding vaccine storage and handling, also to assess the knowledge of Cold Chain Handlers on vaccine storage temperature, VVM indicator, expiry dates and date of vaccine administration. The questions provided answers to in the form included availability of storage equipment, functioning or non-functioning of storage equipment, availability of regular electricity supply to storage equipment, presence or absence of temperature monitoring device, presence or absence of temperature chart, expiry dates of vaccines and conditions of the VVM indicator. The questionnaire included questions on background information of the respondents and more specific ones related to knowledge regarding management of the cold chain including the recommended storage temperature range, immunization schedules, use of diluents, storage in the deep freezers, measures to be taken in the event of power failure, the shake test and the effect of freezing of vaccines. At the same time observations were done simultaneously during interview. During observation, temperature monitoring charts, VVM states, ledger books for vaccine balance, and vaccine arrangement in the refrigerator were observed.

INCLUSION / EXCLUSION CRITERIA

The study included All the 27 cold chain points (CCP) of Gwalior district having 54 Cold Chain Handlers (CCH), two at each CCP avoiding any inclusion or exclusion criteria

DATA ANALYSIS

The completed questionnaires were sorted and entered into version 20 of statistical package for the social sciences (SPSS) and Microsoft 2019 Excel package for analysis. Descriptive statistics on the sample characteristics and questionnaire items were computed. Multivariable analysis at a P-value <0.05 and Odds Ratio (OR) with 95% CI was used to measure the degree of association between independent variables and the outcome variable.

ETHICAL CONSIDERATION

Ethical clearance for the study was obtained from the Institutional Ethical Committee of Gajra Raja Medical College, Gwalior (M.P.) before starting the study. This study did not need any intrusive or non-obstructive diagnostic strategy or holding of any prescribed medicine recommended by treating doctor or starting any new drug. Permission to include Health facilities for cold chain assessment was obtained from the Chief Medical Health Officer (CMHO) of Gwalior district, who is responsible for overseeing health centres in the study district. Cold chain equipment and cold chain maintenance process was noted following direct observation by the investigator on uninformed visits.

INFORMED CONSENT

The purpose of the study was explained to the participants and informed verbal consent was obtained from all participants.

RESULTS

The study was conducted from 27 facilities that incorporated all assigned health care workers in EPI service.

SOCIO-DEMOGRAPHIC CHARACTERISTICS

The dominant age interval of EPI focal person across 27 health facilities of Gwalior district is 26 to 35 years and the mean age of respondents were 29.3 years with a standard deviation of 6.4. More than half (35; 66.7%) of respondents were female. (23; (42.19%) of the respondents were health workers (HWs), and nurses were 19 (35.2%). The work experience background of the respondents indicated that majority 37 (77.8%) had more than 2 years. The socio-demographic characteristics of study participants are shown in Table 1.

Table1. Socio-Demographic Characteristics of EPI Focal Persons in Public Health Facilities

	Variable	Frequency	Percent
Age	≤25	13	24.1
	26–35	36	66.7
	>35	5	9.2
Sex	Female	35	64.8
	Male	19	35.1
Type of profession	Health worker	23	42.6
	Nurse	19	35.2
	Others (Midwifery, AWW, Medical Officer)	12	22.2
Work experience	<2 years	12	22.2
	≥2 years	37	77.8
In-service training	Yes	30	55.5
	No	24	44.4
Cold chain guidelines	Yes	29	53.7
	No	25	46.3
Supportive supervision	Yes	30	55.5
	No	24	44.5
Type of fridge	Top opening	49	90.7
	Front opening	5	9.2

From a total of 54 health care workers included in this study, thirty (55.5%) of EPI focal persons interviewed took EPI related in-service training and 25(46.3%) did not use vaccine cold chain management guidelines during cold chain management. Eighty-six (55.5%) health facilities who provided EPI services had taken EPI specific supportive supervision from their respective health department. Regarding the type of fridge, the majority (90.7%) of health facilities had top opening vaccine refrigerators for vaccine cold chain management.

INFRASTRUCTURE IN PUBLIC HEALTH FACILITIES

Almost all public health facilities (27; 100.0%) use electricity as the main power source for the vaccine refrigerator, whereas the none of them use other options as the main power source for the vaccine refrigerator. Among the health facilities that used

electricity as the main power source for vaccine refrigerators, 22 (81.5%) used an automatic voltage stabilizer for vaccine refrigerators, 9 (33.3%) had a functional backup generator in the facility to use at a time of electric power break, and 17 (62.9%) health facilities had a separate room for the vaccine refrigerator.

AVAILABILITY OF COLD CHAIN EQUIPMENT

The results of this study indicated that all 27 (100%) health facilities had functional vaccine refrigerators in the facilities, (85.2%) had ice packs and cold box, and 27 (100%) of them had vaccine carriers. 53.7% of the health facilities use a fridge tag and 55.5% use thermometer for temperature monitoring in the facility.

KNOWLEDGE OF HEALTH CARE WORKERS ON COLD CHAIN MANAGEMENT

The individual response was counted and calculated to classify respondents as having good knowledge and poor knowledge. Based on the knowledge score respondents were asked six questions and those who scored greater than or equal to 4 (75%) were

considered as “good knowledge” and those who scored in-between 3-4 (60% to75%) considered average and less than 3 considered as having “poor knowledge”. Accordingly, 43 (79.6%) respondents had good/Average knowledge, while others had poor knowledge. Knowledge of health care workers towards cold chain management is shown in Table 2.

Table 2 Knowledge Towards Cold Chain Management Among Health Care Workers in Public and district Health Facilities (N=54)

S. No	Variable	Frequency	Percent (%)	
1	Do you know vaccines are sensitivetoh heat?	Yes	33	61.1
		No	21	38.9
2	Do you know that vaccines are sensitive to light?	Yes	49	90.8
		No	5	9.2
3	Do you know that vaccines are sensitive to freezing?	Yes	48	88.8
		Yes	6	11.2
4	The recommended temperature for vaccines storage in vaccine refrigerator is in between?	2–8°C	47	87.1
		8–16°C	7	12.9
5	What should you do with a vaccine when the Vaccine vial monitor shows the inner square is the same color or darker than the outer circle?	Discard the vaccine	45	83.3
		Use the vaccine as soon as possible	9	16.7
6	When should a shake test be conducted on a vaccine vial?	Any time freeze	18	33.3
		Temperature negative	9	16.6
		Temperature exceeds 8°C	7	12.9
		Vaccine vial appears cloudy	20	37.1

ATTITUDE TOWARDS COLD CHAIN MANAGEMENT AMONG HEALTH CARE WORKERS IN PUBLIC HEALTH FACILITIES AND DISTRICT HEALTH OFFICE

The result of the attitude assessment among the respondents in public health facilities indicate that the majority (43; 79.6%) of the respondents had a positive attitude towards vaccine cold chain management practices.

COLD CHAIN MANAGEMENT AMONG HEALTH CARE WORKERS IN PUBLIC HEALTH FACILITIES AND DISTRICT HEALTH OFFICES

Twenty-one (77.7%) of the public health facilities had good cold chain management practice at a 95% CI (57.27, 90.62), whereas 11 (22.2%) of public health facilities had poor cold chain management.

GRADING OF ATTITUDE AND PRACTICES (PERFORMANCE)

A good proportion 79% (43 out of 54) are showing good/average performance on CCPs in terms of arrangements and storage of vaccines, EVIN, distribution criteria of vaccines (EEFO, FIFO, VVM), maintaining of stock register, indent register, AEFI register, log book, and contingency plan; and just 20% (11 out of 54) were showing poor performance (Table 3)

ASSOCIATED FACTORS OF COLD CHAIN MANAGEMENT

BIVARIATE ANALYSIS

Results of bivariate logistic regression analysis showed that experience, sex, type of profession, EPI training, presence of cold chain guideline, supportive supervision, presence of cold box, presence of fridge tag and thermometer, presence of separate room, attitude and knowledge of respondents were candidate variables for a multivariable logistic regression

MULTIVARIABLE ANALYSIS

The adjusted multivariable analysis at a *p*-value of less than or equal to 0.05 work experience of health professionals, presence of supportive supervision, EPI related training, and knowledge of health professionals were statistically significant. Facilities whose cold chain is managed by health workers with two or more years of work experience had 5.1-times higher odds of good cold chain management than facilities whose cold chain is managed by health workers with less than two years of work experience: OR=5.1 (95%CI=1.2;22.0, *p*=0.028) Health care workers who had a good cold chain management knowledge were 7.5-times more likely to practice cold chain management compared to health care workers with poor knowledge: OR 7.5 (95%CI=,1.4;39.6. *p*=0.016). Health care workers who had taken in-service training on cold chain management were 8.4-times more likely

to practice cold chain management than those who had not received in-service training: OR=8.40 (95%CI=1.4–9.8, p=0.002). Health care facilities with supportive supervision in their facilities were 4.5- times more likely to have good cold chain

management compared to those health care facilities without supportive supervision: OR =4.50 (95%CI=1.0;19.4,p=0.044)). Multivariable analysis for associated factors is shown in Table 3.

Table 3 Multivariable Analysis of Associated Factors for Cold Chain Management force practice

Variable	Categories	Level of Practice		OR (95% CI)	p-value
		Good/Average Practice(n=43)	Poor Practice (n=11)		
Experience	<2 years	6 (11.1%)	6 (11.1%)	1	0.028*
	≥2 years	37 (68.5%)	5(9.3%)	5.1 (1.2;22.0)	
Sex	Male	14 (25.9%)	5 (9.2%)	1	0.42
	Female	29 (53.7%)	6 (11.1%)	1.72 (0.4; 6.6)	
Type of profession	Health care workers	17 (31.5%)	6 (11.1%)	1	0.70
	Nurse	15 (27.7%)	4 (7.4%)	0.75 (0.17;3.1)	
	Others (Midwifery, AWW, Medical Officer)	11 (20.4%)	1 (1.8%)	0.25 (0.1 to 2.4)	
EPI Training	Yes	28 (51.8%)	2 (3.7%)	8.40 (1.4–9.8)	0.002*
	No	15(27.7%)	9(16.6%)	1	
Cold chain guide line	Yes	27 (50.0%)	2 (3.7%)	7.59 (1.4;39.6)	0.016*
	No	16 (29.6%)	9 (30.1%)	1	
Supportive supervision(n27)	Yes	13 (50.0%)	2 (5.5%)	4.50 (1.0;19.4)	0.044*
	No	8 (29.6%)	4 (14.8%)	1	
Cold box	Yes	28 (51.8%)	4 (7.4%)	3.26 (0.8;12.9)	0.092
	No	15 (27.7%)	7(12.9%)	1	

(Continued)

Variable	Categories	Level of Practice		AOR (95% CI)	p-value
		Good/Average Practice(n=43)	Poor Practice (n=11)		
Thermometer (n=27)	Yes	13 (48.1%)	2 (7.4%)	2.67 (0.7;10.5)	0.15
	No	8 (31.5%)	4 (12.9%)	1	
Fridge tag(n=27)	Yes	14 (46.3%)	2 (7.4%)	2.43 (0.6–9.5)	0.20
	No	9 (33.3%)	2 (12.9%)	1	
Separate room(n=27)	Yes	15 (55.5%)	2 (7.4%)	6.88 (1.5;30.4)	0.01*
	No	6 (22.2%)	4(14.8%)	1	
Attitude of CCH	Poor	3 (16.9%)	8 (17.6%)	1	0.01
	Average	26 (44.1%)	05 (21.3%)	13.8 (0.8;5.7)*	
	Good	12	0	41.2(1.8;92.7)*	
Knowledge of CCH	Poor	3 (21.3%)	9 (23.5%)	1	0.006*
	Average	27 (39.7%)	2 (15.4%)	40.5 (5.8;82.3) *	
	Good	13	0	53.3(3.3;90.2) *	

Notes: 1-Reference category. *Statistical significance at p<0.05.

DISCUSSION

Vaccine cold chain management is one of the most important challenges in public health facilities. 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.⁹

This study assessed vaccine cold chain management

and associated factors in public health facilities and revealed that 77.7% of public health facilities had a good to average cold chain management practice. This finding was consistent with studies conducted in South India (61.8%)¹⁵ and Oromia special zone Amhara region of Ethiopia (63%).¹⁶ This study finding was higher than reports from the Northwest region of Cameroon (24%).¹⁷ The higher or lower differences could be due to the time of study period, socio-demographic characteristics, economic and cultural

factors of the current study area and study settings and type of healthcare facilities. In addition, inadequacy and unavailability of the equipment and infrastructure used for cold chain management practice could be another possible reason for variation between the studies. In this study having work experience greater than two years had a positive association with good cold chain management practice. This finding was similar to the study conducted in Bahir Dar City, Ethiopia¹⁸, Etawah and Kanpur district of Uttar Pradesh India^{19,20}. This might be related with higher/longer work experience making them more familiar to cold chain management which helps them to acquire better essential information on cold chain management practice.

The current study revealed good knowledge of cold chain management had a positive association with cold chain management practice. This finding was similar with different study conducted in different regions of Ethiopia¹⁸ and India,^{19,6,12}. This could be associated with having in-service training regarding cold chain management which upgrades the knowledge and skill of health workers and benefits them to get updated information and then easily understand basic principles, standards of practice, and implement consistently on cold chain management. Biradar¹² et al reported that temperature of ILR was maintained in 93.5% health centers.

In our study the presence of supportive supervision in the facility had a positive association with good cold chain management practice. This study was similar to the study conducted in Southern Nigeria²¹ and by Choudhury et al²² in Chirang, Assam. The possible explanation for this finding could be associated with the benefits that health workers gain updated information and support from their supervisors to fill their gaps regarding cold chain management and practice.

The present study revealed that all CCHs had knowledge about VVM, open vial Policy, freeze sensitive vaccines, correct temperature range and diluents which is a quite commendable finding and was consistent with other studies of India^{9,19,22} and Ethiopia^{18,23}. Some of the health facilities reported that there was high staff turnover, especially in those taking EPI training, which could be seen as a limitation of the study.

CONCLUSION AND RECOMMENDATION

Quality of immunization program depends upon cold chain management specially at peripheral health institutions. The result of the study indicated that greater than 2 years work experience, presence of supportive supervision, good knowledge on cold chain management, and training on cold chain management were predictors of good cold chain management practices. There is need to improve the knowledge level of CCHs regarding cold chain maintenances and handling practices by regular training sessions and monitoring visits. Medical

officers of the health facility supported by district immunization officer should be actively involved in the monitoring and supervision of the CCHs on regular basis.

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