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'The Cold Chain and handling of vaccines in clinical practice.

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Abstract

Background: Many of the infectious diseases can be prevented by effective vaccines. Efficacy of vaccine can be compromised due to improper handling, not storing vaccine in recommended cold chain equipment and faulty transport that could be the possible reasons for break in cold chain. Change in temperature can alter the stability of vaccines. Smallpox-pox has been eradicated from the world and poliomyelitis is going to be eradicated. This proves that vaccination is the only way and best strategy in medical to control infectious diseases.

Methodology: A cross sectional study was conducted in urban area of Central India. Vaccine providers were interviewed about various immunization practices.

Results: Study population were private practitioners who were doing vaccination in private clinics and private hospital. The response rate was 91%.

Conclusion: This study found lacunae in vaccine dose reporting. Cold chain monitoring in private clinics was not effective as per WHO recommended guidelines.

Keywords: Vaccine, monitoring, WHO

INTRODUCTION

Most bacterial and viral diseases affecting children in the world can be prevented by vaccines. Vaccine is an immuno-biological substance designed to produce specific protection against a particular disease. Vaccination is accounting to save almost 2-3 million lives every year (1). So vaccine quality in terms of delivery and storage must not be compromised, otherwise it will have effect on efficacy of vaccine.

It is observed in many studies that most of the vaccines that are administered in private clinics are MMR, Typhoid vaccine, Varicella and HPV vaccines other than National immunization schedule provided in the public sector. In Catalonia, Spain, Dominguez A et al. found that 68.7% of children received vaccinations in public health centres compared to 31.3% in private offices. The private sector accounted for a larger proportion of non-EPI vaccines; 63.5% of children received varicella vaccine and 47.4% received pneumococcal vaccine, compared to 36.5% and 52.6% respectively at public health centres. (2) Vaccines are sensitive biological substance that are sensitive to higher temperature, but to light also. Vaccines like measles, mumps and rubella must always be protected from light. All vaccines must be stored and transported under WHO recommended temperature that is between 2 to 8 degree Celsius to assure successful storage and handling.(3)

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As we know that immunization is crucial to the human right to health and also help to prevent communicable diseases. It is important to follow checklist based surveillance and monitoring wherever vaccination is done. Insufficient monitoring is observed in vaccine storage and improper handling of vaccine in many countries. Among low- and middle-income countries in previous studies it was found that cold chain maintenance system was better in the government hospital, but vaccine administration practices were better in the private sectors. In urban Gujrat state [4] in India, private providers contribute a large share of immunization services (24%). In less urbanized, lower per-capita income states (Uttar Pradesh, Rajasthan, Madhya Pradesh, Orissa, Assam and Bihar) the private sector contribution is lower.

Maureen Mackintosh et al (2016) highlights the role of private sectors in provision of health care in countries like India and Nigeria with a dominant private sector display globally very high shares of out-of-pocket spending in total health expenditure, a private sector dominating activity in both primary and secondary care, and deteriorated public sectors, with varying reliance on fee payments. [5]

In a study by Santos et al. found that in Mexico, where the private sector plays a minimal role in immunization delivery, the government does not implement program monitoring mechanisms or post market surveillance for the private sector. Private providers are encouraged, but not obligated to report AEFIs and there are no clear penalties for failure to report. [6]

METHODS

A cross- sectional survey was conducted in urban area. Participants were chosen by selecting those who conduct vaccinations in their setup and had refrigerators to store vaccines in their clinics owned by themselves.

Interviewer visited the private clinics and hospitals and provided them questionnaire form. Questionnaire was administered for those responsible for vaccine administration. Vaccine refrigerator is observed for presence of minimax thermometer, food items and drink. Vaccine placement in various compartments were seen. Participants were asked to sign the informed consent form. There was no conflict of interest. Statistical analysis involves Chi-square test for qualitative variables. Statistical analysis done using SPSS version-20. Analysis done in the form of percentages, proportions and represented as tables and figures wherever necessary. Appropriate tests of significance applied.

RESULTS

Table 1 shows characteristics of private providers. Majority (68%) of the immunization service provider in study having experience of more or equal to 10 years with mean age of experience. This study shows that maximum participants were trained i.e.81% while only 19% were untrained. Immunization practices of private immunization providers are described in (Table 2 and 3). In this study higher percentage (79.01%) of trained practitioners were keeping the thermometer in the refrigerator as compared to 26.32% of untrained practitioners. Cold chain practices were better in trained participants. Table 3 shows that in almost all practices, vaccines were stored in domestic refrigerators (72.94%) and 79.31% of practitioners having < 10-year experience were storing vaccine in domestic refrigerator as compared to 69.64% having ≥ 10-year experience.

This study shows that 79 % child clinics had facility of vaccination. Only 27% of private providers were storing vaccines in WHO recommended refrigerator meant for storing vaccines as per guidelines. Visible temperature log was present in 82% of refrigerators and 69% of refrigerator had thermometer to record temperature, and 79% of practitioners were recording temperature two times daily. Participants with high level of experience that is more than ten years had better immunization practices.

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DISCUSSION

High knowledge among vaccine providers was contributed by their total working experience. Most of private immunization providers had experience of more than ten years. This means that participants had good knowledge of guidelines regarding cold chain operation, but few of them followed it. This finding was similar to earlier study that tells that only one sixth have ever attended training on cold chain, but majority 95.5% of GPs had knowledge on cold chain practices. This study is consistent with the study done by B. Ajaria. (7)

In this study,81% of private immunization providers had attended training on cold chain. Cold chain practices were better in those participants who were trained as compared to those who were not trained. This study is consistent with the study done by S Mallik et al in their study in assessing cold chain status in a metro city of India Kolkata observed significant improvement in correct placing of cold chain equipment, maintenance of stock security, orderly placing of ice packs, diluents and vaccines inside the equipment, temperature recording and maintenance after training of cold chain handlers. But awareness and skill of cold chain handlers regarding basics of cold chin maintenance was not satisfactory. [8]

In other study it was found that out of the 40 respondents, only 16 were aware of the appropriate storage conditions for the vaccines; Vaccines were exposed to temperatures that may reduce their potency. Safe storage of vaccines in the clinics cannot be ensured without adhering to the recommended guidelines. Provision of adequate equipment and training for staff in maintaining the "cold chain" and the use and care of equipment are important components of a successful immunisation programme. [9]

In current study most of the private immunization providers had correct knowledge of optimal temperature. Erika Woodyard et al (1995) found that in their study that of the 27 sites, only 2 had refrigerator temperature fell within acceptable range of 2 to 8 degree Celsius. Eight of the offices had a designated cold chain monitor but there was no correlation with appropriate monitoring and storage of vaccines. Nine of the offices had permanent thermometers, but no correlation could be found between these sites and appropriate storage temperatures. [10]

A study by D M Bishai et al found that vaccine storage errors occurred in in paediatric offices at an unacceptably high frequency. Only 16% of vaccine storage coordinators could site appropriate storage temperatures for vaccines and 18% were unaware that heat can harm certain vaccines. Refrigerators thermometers were checked at least weekly in only 20% of offices, and 22% of the refrigerators had inappropriately high temperatures. Vaccines were routinely stored outside of the refrigerator uninsulated during the practice day in 16% of the offices visited [11].

In another study on vaccine storage practices in primary care physician Offices: found that more than 89% of offices adhere to guidelines. 80% offices had thermometer; and 83% of temperature were appropriate. Adherence to guidelines improved after the quality improvement activity; the net change between pre- and post- intervention ranged from +1% to +19%.[12] This study highlights problems in vaccine storage and cold chain monitoring. The limitation of this study lies on selecting only private vaccination clinics that might not be representative of other private practices.

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Table 1: Characteristic of private immunization providers overall (All providers)(N=100)

Variables	Categories	N=100 (Percentage %)
Age (years)	**20 – 40 years**	**43 (43%)**
	41 – 60	**50 (50%)**
	61 -80	**7 (7.0%)**
Sex	**Male**	**75 (75%)**
	Female	**25 (25%)**
Religion	**Hindu**	**84 (84%)**
	N. Hindu	**16 (16%)**
Qualification	**Diploma in Paediatrics**	**29 (29%)**
	MD in Paediatrics	**71 (71%)**
Years of experience	**<10 years**	**32(32%)**
	≥10 years	**68(68%)**
Training status	**Trained**	**81 (81%)**
	Not trained	**19(19%)**
Type of clinic	**Child**	**82 (82%)**
	Mother and child	**10 (10%)**
	General	**8 (8.0%)**
Name of set up	**Children hospital**	**22 (22%)**
	Nursing home	**15 (15%)**
	Private paediatric clinic	**52 (52%)**
	Other	**11 (11%)**
Immunization clinic	**Registered**	**82 (82%)**
	Not registered	**18 (18%)**
Clinic is audited	**YES**	**51 (51%)**
	NO	**49 (49%)**

Table 2: Cold – chain practices by training status

Parameter		Trained n=81 (%)	Not trained n=19 (%)	Total N=100 (%)	p value
1.Cold chain equipment used	Domestic refrigerator	54(66.67%)	14(73.68%)	68(68%)	p=0.8097 χ^2 =0.422
	ILR	4(4.94%%)	1(5.26%)	5(5%)	
	Dedicated refrigerator	23(28.39%)	4(21.05%)	27(27%)	
	TOTAL	81(100%)	19(100%)	100(100%)	
2.Vaccine is transported to	Through vaccine carrier	81 (100%)	18(94.74%)	99(99%)	p=0.3797 χ^2 = 3.3062

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immunization clinic	In the plastic bag	0(0%)	0(0%)	0(0%)	
	Patients brings vaccine with them	0(0%)	1(5.26%)	1(01%)	
	Total	81(100%)	19(100%)	100(100%)	
3.visible temperature log present	YES	68(83.95%)	14(73.68%)	82(82%)	p=0.2944 χ^2 =1.099
	NO	13(16.05%)	5(26.32%)	18(18%)	
	TOTAL	81(100%)	19(100%)	100(100%)	
4. Vaccine refrigerator has a Thermometer	YES	64(79.01%)	5(26.32%)	69(69%)	**p=0.0001** **χ^2 =19.9799**
	NO	17(20.99%)	14(73.68%)	31(31%)	
	TOTAL	81(100%)	19(100%)	100(100%)	
5.Temperature is recorded	Once a day	5(6.17%)	2(10.53%)	7(07%)	p=0.6633 χ^2 =1.5824
	two times a day	66(81.48%)	13(68.42%)	79(79%)	
	many times, a day	5(6.17%)	2(10.53%)	7(07%)	
	No need to record	5(6.17%)	2(10.53%)	7(07%)	
	TOTAL	81(100%)	19(100%)	100(100%)	

Table 3: Cold – chain practices by level of experience

Parameters		**< 10 year n=32(%)**	**≥10 year n=68%**	**Total N=100(%)**	**p value**
1.Cold chain equipment used	Domestic refrigerator	26(79.31%)	42(69.64%)	68(72.94%)	**p=0.0009** **χ^2 =14.0134**
	ILR	4(13.79%)	1(1.79%)	5(5.88%)	
	Dedicated refrigerator	2(6.90%)	25(28.57%)	27(21.18%)	
	TOTAL	32(100%)	68(100%)	100(100%)	
2.Vaccine is transported to immunization clinic	Through vaccine carrier	32(100%)	67(98.21%)	99(98.82%)	p=0.4905 χ^2 = 0.4753
	In the plastic bag	0(0%)	0(0%)	0(0%)	

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	Patients brings vaccine with them	0(0%)	1(1.79%)	1(1.18%)	
	Total	32(100%)	68(100%)	100(100%)	
3.visible temperature log present	YES	29(89.66%)	53(76.79%)	82(81.18%)	p=0.0089 χ^2 =6.8334
	NO	3(10.34%)	15(23.21%)	18(18.82%)	
	TOTAL	32(100%)	68(100%)	100(100%)	
4. Vaccine refrigerator has a Thermometer	YES	21(62.07%)	38(66.07%)	69(64.70%)	p=0.9917 χ^2 =0.0001
	NO	11(37.93%)	20(33.93%)	31(35.30%)	
	TOTAL	32(100%)	68(100%)	100(100%)	
5.Temperature is recorded	Once a day	3(10.34%)	4(7.14%)	7(8.24%)	p=0.4627 χ^2 =2.5702
	two times a day	27(82.76%)	52(75%)	80(77.65%)	
	many times, a day	1(3.45%)	6(10.71%)	7(8.23%)	
	No need to record	1(3.45%)	6(7.14%)	7(5.88%)	
	TOTAL	32(100%)	68(100%)	100(100%)	

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