

Original article

COLD CHAIN MAINTENANCE AND VACCINE ADMINISTRATION PRACTICES IN HOSPITALS & CLINICS OF MANGALORE CITY - A HEALTH SYSTEM'S RESEARCH

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ABSTRACT

Background: Problems related to cold chain functioning & vaccine handling have been reported from developed & developing countries. Such studies help programme officers & policy makers. So this study was undertaken.**Objectives:** The study was conducted with an objective to know the Cold Chain Maintenance & vaccine administration practices in government, private hospitals & clinics of Mangalore city.**Material & Methods:** This health systems research was conducted in Mangalore City. List of government, private hospitals & private clinics were obtained from District Health Office and Indian Medical Association local chapter. A Pre-Tested semi-structured proforma was used to collect information to meet the objective. After obtaining consent from necessary authorities, these hospitals were visited and observations noted directly in the proforma. Photos were taken if permitted in the hospitals. The quality of vaccine administration practices were graded (1 to 5) and scored (from 20 to 100).**Results:** Comparison of government (n=8) & private hospitals (n=8) revealed that the cold chain maintenance system was better in the government hospitals. Vaccine administration practices were better in private hospitals. Various incorrect practices in cold chain maintenance and vaccine administration practices were noted in both government and private hospitals.**Conclusions:** Training in & periodic supervision of cold chain maintenance and vaccine administration practices are essential for achieving the benefits of vaccination.**Key Words:** Cold Chain Maintenance, Vaccination Administration Practices, Health Systems Research.

INTRODUCTION

Failure to maintain cold chain practices results in loss of vaccine potency.^{1,2} Problems related to cold chain functioning & handling both in government & private sector have been reported from developed & developing countries alike.³⁻¹³ There is one published report from India studying the cold chain maintenance practices but none for vaccine administration techniques.¹⁴ Such studies help in identifying problems, planning corrective measures & identify the training

needs for the personnel in-charge of cold chain maintenance & vaccine administration. This study was undertaken to know the Cold Chain Maintenance and Vaccine Administration Practices in government hospitals, private hospitals & clinics of Mangalore City.

MATERIALS & METHODS

Study Design: This health systems research describes the cold chain maintenance and vac-

cine administration practices in government, private hospitals & clinics of Mangalore City.

Study Setting: Mangalore city located in coastal Karnataka has got many Government, Private hospitals & clinics which provide vaccination services. These centers provide services not only to the local population but also for neighboring state of Kerala.

Study Period: This study was conducted over a period of two months ie, June to July 2009.

Study units: The unit of study was the government, private hospitals & clinics where vaccination services are being provided. Inclusion criterion: 1) Government Primary Health Centers (PHCs) & Urban Dispensaries (UDs) 2) Private Hospitals / Nursing homes / Polyclinics / Clinics which are providing vaccination services. 3) Private hospitals / Clinics which consented for the study. Exclusion criterion: 1) Due to feasibility reasons any hospital or Clinic outside Mangalore City. 2) Those which did not consent for the study.

Sample Size Calculation: Based on review of literature, rates of compliance with the storage guidelines range from 96% to 74% in hospitals.^{3,4,6} For feasibility reasons higher compliance rate was assumed (A pilot study done in neighboring city yielded high non-response rates from private hospitals). So, with 'P' equal to 96%, 'Q' will be 4. With $Z = 1.96$, for a precision of 10%, a sample of 16 hospitals was obtained using the formula for infinite population Z^2PQ/d^2 . Totally 16 hospitals providing vaccination services were included. To enable comparisons, equal number of government (8) and private hospitals (8) were included. As very little published information on compliance with vaccination practices in private clinics is available, sample size could not be determined for them. It was decided to include all those which meet inclusion criteria.

Sampling: List of PHCs & UD's were obtained from the District Health office (DHO). Totally 13 government hospitals met the inclusion criteria. Out of this 8 were selected by simple random sampling. List of private hospitals / clinics in Mangalore city was obtained from the local chapter of Indian Medical Association. The private hospitals were either called up by phone & or approached to know if they met the inclusion criteria for the study. Of the 17 hospitals, 11 consented for the study. Simple random sampling technique was used to get 8 hospitals out of 11. Private clinics, who met the inclusion, were

approached separately. Those who consented for the study were included.

Study Instrument: A semi-structured proforma was developed based on guidelines of Centers for Disease Control (CDC) USA.^{1,2} The semi-structured proforma has 2 parts. Part I of the proforma had 18 components related to Cold chain maintenance, Vaccine storage & handling practices. Each of the component had 'yes / no' option. Part II of the proforma had 20 components related to Vaccine administration covered under the following heads A. Parent Education, B. Vaccine Handling, C. Record Precautions, D. Administration. Each of 20 components of Vaccine administration technique were graded on a scale of 1 to 5 [1 = very good, 2 = good, 3 = just follows procedures, 4 = needs to improve & 5 = bad or unhygienic practice.^{1,2} So the total scores ranged from 20 to 100.

Pretesting: This semi-structured proforma was pretested on 1 government PHC and 1 nursing home & 4 private clinics situated in Udupi city (neighboring district) to study the feasibility and appropriateness of its use. Part I of the proforma had to be changed to suit our field circumstances so that it finally had only 13 components. Part II was appropriate for use in Government & Private hospitals. As private clinics did not have cold chain maintenance system, only 3 components of Part I & 7 components of part II were appropriate. So the necessary changes were made in the proforma to suit the private clinics.

Data Collection and Organization of Field Work: Permission was taken from the District Health Officer as well as Medical Superintendent / Medical Officer / Private practitioner of various private hospitals and/or clinics.

Each of these private hospitals was contacted by phone & the purpose explained. After obtaining consent, they were visited. All the components of activity in Part I & II noted down in the proforma. The person in-charge of storage and administration practices was sought for any clarification if needed. Vaccine administration technique was directly observed & each of the components was graded as mentioned above. If data collections could not be completed / all the components could not be observed on the same day then a revisit was made. Private practitioners were approached & data collected similarly. In case of refusal, the reasons for the same were noted.

Data Analysis: Data was entered in a SPSS version 10 and analyzed. Results are expressed as numbers, statements & photos. Vaccine administration technique was graded on a scale of 1 to 5 as mentioned above. So the total scores ranged from 20 to 100. Grades 1 to 3 were categorized as good and/or satisfactory practice and Grades 4 to 5 were categorized as bad practice. Total scores for each of these hospitals and Mean scores for each activity were computed. Students independent 't' test was used to know if the differences observed in mean scores between government and private hospitals were statistically significant. 'p' < 0.05 was considered significant. As only 7 components of vaccine administration activity (i.e., part II of the proforma) were observed from private clinics. So, total scores of the private clinics ranged from 7 to 35. Other specific observations are expressed as statements. Certain practices can be best appreciated with pictures taken at the time of visits, which are also included in the results.

RESULTS

Table 1: Comparisons of the individual components of Vaccine administration practices between government & private hospitals

Recommended Guidelines for Vaccine Administration (1* / 2**)	Government [n=8] (Mean) ^{§§}	Private [n=8] (Mean) ^{§§}	'p' Value ^{##}
Welcomes family (1)	8 (2)	8 (2.1)	0.68
Explains what vaccine will be given (1)	8 (2.3)	8 (2.4)	0.62
Accommodates language barrier (1)	8 (2.1)	8 (2.3)	0.53
Reviews comfort levels of child (1)	8 (2.4)	8 (2.3)	0.55
Checks vial expiration date (1)	8 (3)	8 (3) #	
Maintains aseptic technique (1/2)	1/7 (3.9) [§]	5/3 (3.3)	0.04 [§]
Select correct needle size (1)	8 (2.4) [§]	8 (1.9)	0.04 [§]
Shakes & inverts vaccine vial (1)	8 (2.5)	8 (2.4)	0.64
Demonstrates knowledge of proper vaccine handling (1)	8 (2.6)	8 (2.8)	0.62
Fully documents growth card (1)	8 (2)	8 (2)#	
Advice on follow up (1)	8 (2)	8 (2)#	
Washes hands & puts on disposable gloves (1/2)	2/6 (3.9)	3 / 5(3.6)	0.41
Demonstrates knowledge of appropriate route (1)	8 (2.4)	8 (2.3)	0.62
Positions patient & locates anatomic landmarks (1)	8 (2.4)	8 (2.4)#	
Prepares the site (1/2)	7/1 (3) [§]	8 (2.4)	0.03 [§]
Controls the limb & inserts needle at appropriate angle (1)	8 (2.5)	8 (2.5)#	
Injects using steady pressure & withdraws at angle of insertion (1)	8 (2.4)	8 (2.6)	0.45
Applies gentle pressure with cotton ball (1/2)	7/1 (2.5)	8 (2.6)	0.77
Properly disposes off sharps (1/2)	4/4 (3.5) [§]	2/6 (4.5)	0.00 [§]
Encourages comfort measures (1)	8 (2.3)	8 (2.3)#	

1* = Good &/satisfactory practice; 2** = Bad practice; § = These differences were statistically significant using Student's Independent 't' Test; # As the mean values are same, 't' test has not been computed; ^{§§}Mean Scores for that activity; ^{##} Student's Independent 't' Test

Other important general observations about Maintenance of Cold Chain & Vaccine handling are as follows: 1. There were non-functioning

Characteristics of the hospitals/health care facilities included for the study (N): Government District Hospital (1), Government PHC/UDs (7), Corporate Hospital (4), Polyclinics / Nursing Home (4). Location: Urban (13) & Rural (3). There were Government (8) & Private (8) Hospitals.

Maintenance of cold chain and vaccine handling in Hospitals

Comparison of observations about the Maintenance of Cold Chain & Vaccine handling between government & private hospitals is as follows {Government (n), Private (n)}: Thermometer is present in refrigerator (7, 2), Required temperature maintained in refrigerator (4, 1), Thermometer is present in freezer (7, 0), Required temperature maintained in freezer (7, 0), Ice packs well frozen (8, 3), Temperature log books maintained (8, 0), "Do Not Unplug" sign put near ILR (Ice Lined Refrigerator) / Refrigerator (0, 0), Had a designated person in-charge of handling and storage (8, 8), Vaccine Inventory Log maintained (8, 1), Vaccines inappropriately stored in ILR/ refrigerator (1, 4).

ILRs and broken thermometers which were not used & or repaired. 2. There were no voltage stabilizers in both government & private hospit-

als. 3. Even though icepacks were present, they were not used. 4. Most of the private hospitals did not have proper back up facilities in the event of power shortage. 5. A Vaccine Inventory Log did not have adequate information. 6. Vaccines were "stacked up" in refrigerators. & proper defrosting was not done in private hospitals. 7. Eatables were stored in the refrigerators and/or freezer.

Vaccine administration in Hospitals

Overall total scores of government hospitals (Range: 45 - 62, Mean: 51.9, SD: 5.6) compared with private hospitals (Range: 43 - 56, Mean: 50.2, SD: 4.9) were not statistically significant ($t=0.61$, $p=0.5$). Comparisons of the individual components of Vaccine administration techniques along with mean scores for each component are presented in Table 1.

Other important observations about Vaccine Administration Techniques are as follows: 1. Aseptic precautions were not maintained in government hospitals. 2. Hand washing was not practiced before vaccination. 3. Vaccine administration technique was incorrect & needle was bent while withdrawing vaccine from the vial. 4. Needle was touched or held with fingers before injecting. 5. No cotton swabs were used either before or after injecting vaccine. 6. There were no needle cutters & sharps were disposed off without decontamination along with other wastes.

Private Clinics

Totally 29 clinics met the inclusion criteria. Out of which only 13 consented for the study giving a response rate of 44.8%. The reasons for refusal were as follows (n): Practices are correct so no need of observation (6), Too busy so cannot spare time (6), No personal benefit (3) & No reason given (1). The private practitioners who consented for the study included (n): Pediatricians (4), general practitioners (7) & physicians (2). The vaccine storage practices are as follows (n): Refrigerators used for storing vaccine (6), Cold box used for vaccine storage (4) & vaccines kept on table without any storage practice (3). Total Scores obtained for Vaccine handling & administration practices were as follows {scores (number of clinicians)}: 28 - 35 (5), 21 - 27 (4) & 14 - 20 (3) & < 14 (1). Vaccine administration practices could be categorized as Good / Satisfactory in only 7 clinics ie, 53.8%. Other specific observations related to vaccine administration were as follows (n): Did not maintain aseptic precautions (4), incorrect injection technique (3), did not give

follow up advice (2), improper method of sharps disposal (8). Due to small numbers comparisons between groups (like pediatricians v/s general practitioners) was not possible.

Some sample pictures taken during the study highlight & reinforce the results.

DISCUSSION

Though most of the health care facilities (56.25%) had a thermometer in refrigerator, the temperature was not maintained in the required range (31.25%) increasing the risk of loss of potency of the vaccines. It also increases chances of Adverse Event Following Immunization (AEFI). One published study on cold chain maintenance practices from Gujarat has reported better practices when compared to our study.¹⁴ As the study from Gujarat included only Government PHC and no Private Hospitals were included, the results are not comparable. But the difference in results from the study from our study & the one reported from Gujarat bring out the reason for the difference. As the cold chain maintenance is supervised in Government Sector, it is better as compared to private sector hospitals. Government facilities fared better with respect to maintenance of temperature range in the refrigerator as compared to private sector. Bell et al⁵ have reported that lack of thermometer and failure to maintain temperature ranges in the refrigerator are a major risk factor for failure of potency of vaccines. Similar findings have been reported by Lewis et al⁴ from Australia. None of the private sector hospitals maintained a thermometer and required temperature ranges in the freezer. These findings are similar to those reported by Pai et al⁶ from China. This brings out the fact that in developing countries cold chain maintenance practices among the private practitioners/hospitals is not safe and the risk of failure of vaccine potency is high. The government sector fared better because of regular supervision of vaccination and cold chain maintenance activities. The private sector is not supervised and hence these differences. For similar reasons, temperature logbook was not maintained in any of the private hospitals. Our study findings are similar to those reported by Bell et al⁵, Lewis et al⁴ and Pai et al⁶. Poor maintenance of cold chain has also been reported by Thakker et al⁹ from United Kingdom. Similar results were obtained by Liddle et al⁸ and they recommended training and supervision of health personnel in private sector. As none of the health care

facilities put a “Do Not Unplug” sign, it reflects poor knowledge about the cold chain maintenance practices. So there is a need for training the primary care physicians (working in private hospitals/nursing homes), paramedical staff designated person for cold chain maintenance & vaccine administration in both government & private sectors. The importance of such training was highlighted by Liddle et al⁸ & Thakker et al⁹. Periodic supervision would ensure maintenance of correct practices.

In majority of the government health care facilities (87.5%), aseptic precautions were not followed at the time of vaccine administration, increasing chance of local complications like injection site abscess. Training in injection safety is important. Such training is effective.¹⁴ As the private health care facilities do not have any device for disposing the used needles, they are disposed along with other health care waste without decontamination. The efficacy of puncture proof container, needle cutter and the feasibility of their use have been demonstrated in Andhra Pradesh by Kaipilyawar.¹⁵

Ideally a study including all the hospitals would have given more valuable results. As these kind of studies are viewed as “sensitive” by the private hospitals, it is difficult to conduct one involving all hospitals. Even though conducted on small numbers, it does give an idea about the nature of problems and inputs for planning and training.

CONCLUSION

Cold chain Maintenance practices were better in Government hospitals as compared to private hospitals. Vaccine administration techniques were better in private hospitals. Lack of Hub cutter was a common problem in most hospitals.

Recommendations

Supervision of cold chain maintenance in the private hospitals reduces the chances of children getting impotent vaccines. Training of staff in both government & private hospitals in cold chain maintenance and vaccine administration practices would help in achieving the benefits of vaccination.

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