Assessment of Cold chain Status for Immunization in Central Ethiopia

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ABSTRACT

Background: In order to achieve immunization goals, two factors are necessary; the delivery of potent vaccines to children through properly maintained cold chain systems and achieving high vaccine coverage. Maintaining quality of vaccines has been one of the main challenges of immunization programs in Africa.

Objective: To assess the cold chain status and practices in 116 health facilities located in three CCRDA/CORE Group Ethiopia operational districts (woredas).

Methodology: An institution based cross-sectional study was conducted in December 2011 and January 2012 in three districts (woredas) of Oromiya, SNNP and Amhara Regions of Ethiopia, data was collected from 116 health facilities and from the same number of immunization service providers. Multiple logistic regression analysis was carried out to identify factors related to knowledge of cold chain management.

Result: Of 116 visited facilities, only 22 (19%) had functional refrigerators. The remaining facilities transported vaccines from nearby facilities having functional refrigerators. Complete temperature recording of the last month was observed in 13(59.1%) facilities. Of 22 functional fridges, the thermometer reading was found to be outside the recommended range in 6(27.3%) on the date of data collection. Vaccine storage in the refrigerator was not proper in 12(54.5%) facilities. Sixty-five (56%) health workers had satisfactory knowledge on cold chain management. Professional qualification and year of service in the immunization program showed a statistically significant association with knowledge of cold chain management ($P<0.05$).

Conclusion and Recommendations: Vaccines in some facilities were found to be at a high risk of losing their potency. There is an urgent need to improve knowledge and practice on cold chain management through improved supervision and training.

INTRODUCTION

The World Health Organization (WHO) launched the Expanded Program on Immunization (EPI) in 1974 with the goal of ensuring that every child would be protected against childhood Tuberculosis, Poliomyelitis, Diphtheria, Pertussis, Tetanus Toxoid and Measles. The goal was to achieve universal child immunization by 1990 (1).
In the last decade, most countries in the world achieved an immunization coverage of around 90% for DPT 3. The WHO African Region showed progress by attaining 83% coverage in the year 2010(2).

The Ethiopian Expanded Program on Immunization was launched in 1980 with six antigens; BCG, DPT, OPV and Measles with a target of 10% annual increment to achieve 100% coverage of all children under two years by 1990. However, in 1986, the coverage target was reviewed and observed to have reached 75%. The target age group was also changed to include all children under one year. In 1981, DPT 3 coverage that was 3%, increased to 49% in 1990. It increased from 13% in 1992 to 68% in 2004 and further increased to 86% in 2010 (2, 4).

In the past decade, all efforts had been focused towards the increment of vaccine coverage, considered as one of the indicators to measure the success of immunization programs. Inadequate attention was given to address the issue of quality of vaccination that greatly depended on two main factors; cold chain management that plays a great role for vaccine potency and the competence of health workers to manage the cold chain and administer safe vaccines for the targeted groups (5,6). Current global efforts such as the Polio Eradication initative cannot be successful without due attention to the effectiveness of the vaccines which are administered to the target population.

Since vaccines are sensitive to heat, freezing and exposure to any sort of contaminant, they must be kept within the recommended temperature range from the time of manufacturing up to the time of safe delivery. Preventing a break in the cold chain system during storage, transportation and delivery is critical to maintain vaccine

efficacy. Equally important is the competence of health workers to manage the cold chain system and administer safe vaccines (7,8).This study was conducted to assess the status of cold chain management in three districts (woredas) of Oromiya, Amhara and Southern Nations Nationalities and People's (SNNP) Regional States of Ethiopia, from December 2011 to January 2012. These districts of the three regions, despite their documentation of relatively good coevarage of Pentavalent-3, according to health reports, have experienced frequent measles outbreaks thereby forming the basis of this study. Furthermore similar studies have not been conducted on the status of cold chain in these study areas.

METHODS

Study Setting

The study was conducted in Bora, Soddo and Basona Worana Woredas in Oromiya, SNNPR and Amhara Regional States respectively. These woredas are located at a distance of approximately 130 kms from Addis Ababa to the south, south west and northern directions respectively. The common features uniting these various woredas are their agrarian nature and the fact that all are supported by the Consortium of Christian Relief and Development Association/CORE Group Ethiopia (CCRDA/CORE Group Ethiopia).

Study Design

An institution-based cross-sectional study was conducted in 116 out of 117 public health facilities in the selected woredas in December 2011 and January 2012. Data was not collected from one health center in Basona Worana Woreda since it did not provide immunization services.

Study Population

All public health facilities which had been rendering immunization services and all health workers who had been administering vaccination services in the same facilities during the data collection period were considered for the study.

One-hundred-and-three health posts and 13 health centers were included for direct observation of the cold chain status. All health workers in these health facilities who had been providing immunization services during data collection were interviewed to assess their knowledge on the cold chain system. The practical skills of these same health workers were also assessed

Data Collection Tools and Procedures

Structured questionnaires and observation checklists that were adapted from WHO (14, 17) were prepared in English, translated into Amharic and finally back-translated into English to maintain consistency and standardization of the instruments. Direct observation was done using a checklist on the cold chain status and health workers to assess their practice of cold chain management as they were providing immunization services. The same health workers were interviewed to assess their knowledge of cold chain management.

Experienced health officers and nurses were recruited to collect and coordinate data collection and trained for two days. The study tools were tested in facilities that were not part of the study area.

Data Entry and Analysis

Data entry and cleaning was handled by a data entry clerk and investigators using EpiInfo version 3.5. Thereafter, the data was exported to SPSS Version 16 for further univariate, bivariate and multivariate analysis.

The odds ratio was calculated to test the degree of association between knowledge (dependent) and professional qualification, years of experience in EPI and exposure to training on cold chain (independent) variables at 95% Confidence Interval (CI). As the outcome variable was categorical, logistic regression was used for controlling potential confounders.

Operational Definitions

Unsatisfactory knowledge: Immunization providers who scored less than or equal to 21 points (below the mean score).

Satisfactory knowledge: Providers who scored greater than 21 points (above the mean score).

Knowledge about cold chain: having an understanding about the existence of a network of refrigerators, cold boxes and vaccine carriers to keep vaccines at the right temperature range (2^0C – 8^0C) to safeguard their potency during transportation, storage and distribution to the point of delivery.

Practice on cold chain: Maintaining a network of refrigerators, cold boxes and vaccine carriers for keeping vaccines within the recommended temperature range (2^0C- 8^0C) to safeguard their potency during transportation, storage and delivery.

Good condition cold chain equipment: The cold chain equipments that are intact and clean to keep vaccines within the required temperature range (2 ^{0}C- 8^0C).

RESULTS

General Characteristics of Health Facilities

Among the 116 health facilities, 13 (11.2%) were health centers and 103(88.8%) were health posts. Ten (8.6%) health facilities were located in urban and 106(91.4%) in rural settings. Of the total, 31(26.7%) were located within 10 kms and the remaining 85(73.3%) were located 11 kms to 55 kms away from the woreda health office.

As shown in Table 1, 38(32.8%) facilities had refrigerators, and out of these only 22(57.9%) were functional. Seven (18.4%) had a functional generator for backup service and 12(31.6%) had a car/motorbike for transportation of vaccines in case of refrigerator/power failure. Fuel was available for only 4 (57.1%) generators, 8(66.7%) car/motorbikes and 9 (23.7%) refrigerators. From the 38 health facilities with refrigerators, 12 (31.6%) had trained personnel and 8(21.1%) had spare parts for minor maintenance. Twenty-four (63.2%) facilities permanently assigned personnel to follow

up the cold chain during working hours and only 14(36.8%) assigned personnel during holidays/weekends (Table 1).

General Characteristics of Vaccine Providers in the Study Facilities

Among the vaccine providers included in the study, 18 (15.5%) were nurses and 98 (84.5%) were Health Extension Workers. Among the nurses, 13 were providing immunization services in health centers, 5 in urban health posts and all Health Extension Workers in rural health posts. Thirty (25.9%) providers had served for a period of 2 years or less while 68 (58.6%) had worked for more than 2 years as EPI unit workers. The minimum and maximum years of service were 6 months and 13 years respectively. Out of the 73 (62.9%) trained respondents, 31 (42.5%) reported receiving training on Immunization in Practice (IIP) for six days, 17 (23.3%) on Injection Safety for three days and 44 (60.3%) had received other training related to minor refrigerator maintenance.

Table 1: Infrastructure and Cold Chain Equipment/Resource Availability in the Study Facilities (CORE Group Polio Project Implementation Districts in Amhara, Oromiya and SNNPR, Ethiopia), December 2011 – January 2012

Characteristics	Frequency	
	Yes (%)	No (%)
Availability of refrigerator in the health facility (n=116)	38(32.8)	78(67.2)
Functionality of the refrigerator in the facility (n=38)	22(57.9)	16(42.1)
Availability of functional generator in the facility (n=38)	7(18.4)	31(81.6)
Availability of functional car/motorbike in the facilities to use in case of refrigerator failur (n=38)	12(31.6)	26(68.4)
Availability of trained personnel for minor maintenance(n=38)	12(31.6)	26(68.4)
Availability of spare parts for minor maintenance(n=38)	8(21.1)	30(78.9)
Availability of permanently assigned personnel for cold chain follow up(n=38)	24(63.2)	14(36.8)
Availability of personnel assigned during holidays/weekend for cold chain follow-up(n=38)	14(36.8)	24(63.2)
Availability of kerosene for generator for at least 72 hours(n=7)	4(57.1)	3(42.9)
Availability of kerosene for refrigerator(n=38)	9(23.7)	29(76.3)

Availability and Adequacy of Vaccines and Logistics

With respect to cold chain equipment, 58 (50%) facilities had adequate ice packs and 104 (89.7%) had vaccine carriers in good condition. Only 65(56%) had foam pads. Of the 38 facilities that had refrigerators, 33 (86.8%) had functional cold boxes.

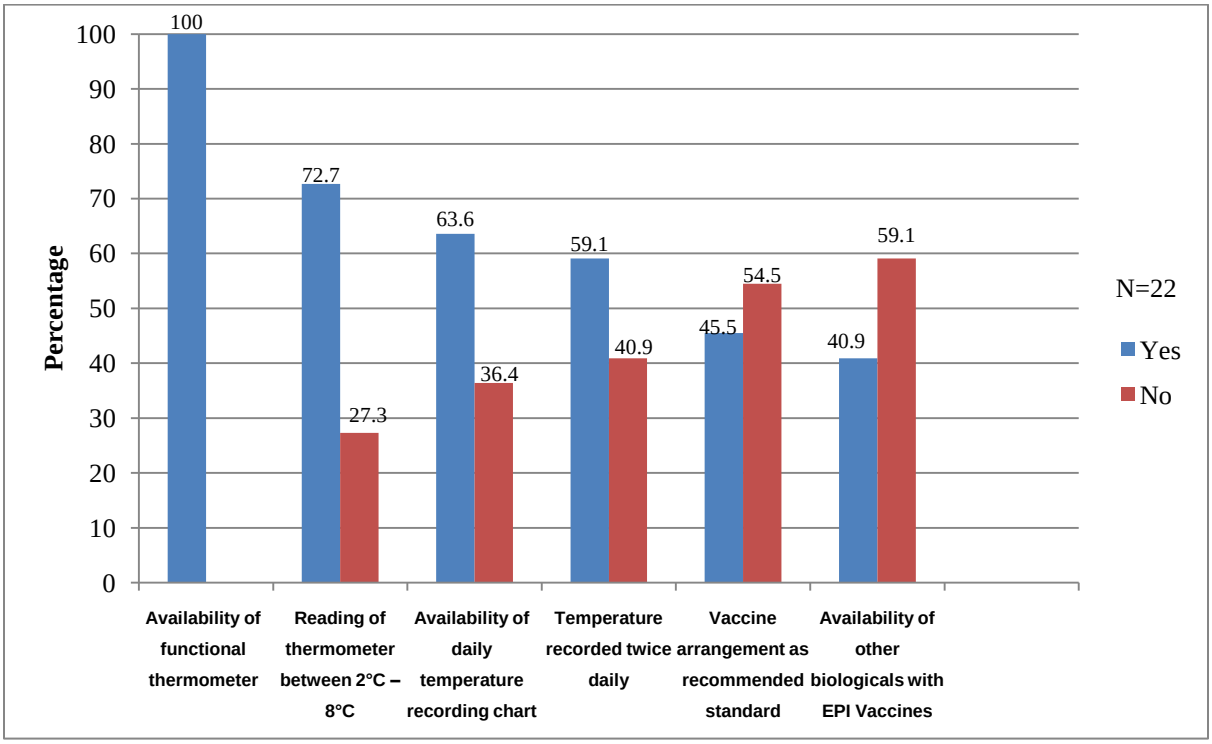
Status of Cold Chain

All 22 facilities having functional refrigerators had functional thermometers. On the day of the data collection, out of 22 functional fridges, 16(72.7%) showed temperature readings within the standard range ($2^{O}C$ - $8^{O}C$). Fourteen out of 22 (63.6%) functional fridges had a temperature monitoring chart, 13 (92.9%) updated their recordings twice daily. Proper vaccine arrangement was observed in 10 out of 22 (45.5%) facilities and foam pads for keeping vaccines cool during vaccination sessions were being properly used in only 10 out of 65(15.4%) facilities. During the data collection period, it was found that laboratory reagents, anti-rabies vaccines and maternity medicines were placed with EPI vaccines in 9 of the 22 (40.9%) health facilities (Figure 1).

Vaccine Providers' Knowledge on Cold Chain Management in the Study Facilities

Of 116 health workers questioned about the recommended range of temperature for vaccine storage, 91 (78.4%) responded correctly; also frequency of temperature recording was correctly described by 67 (57.8%). Proper compartment for placement of oral polio vaccine (OPV), tetanus toxoid (TT) and diphteria, pertussis, tetanus, hepatitis B and hemophilus influenza type B (Pentavalent vaccine) in vertical(upright) or chest type of refrigerators was correctly described by 83(71.6%), 58 (50%) and 30 (25.9%) respondents respectively. Only 15 (12.9%) of health workers knew the three vaccines that required a shake test. The purpose for application of the shake test was correctly mentioned by 42(36.2%) health workers. Types of vaccines that were most sensitive to heat, extreme cold and light were correctly identified by 52 (44.8%), 25 (21.6%) and 58 (50%) respondents respectively.

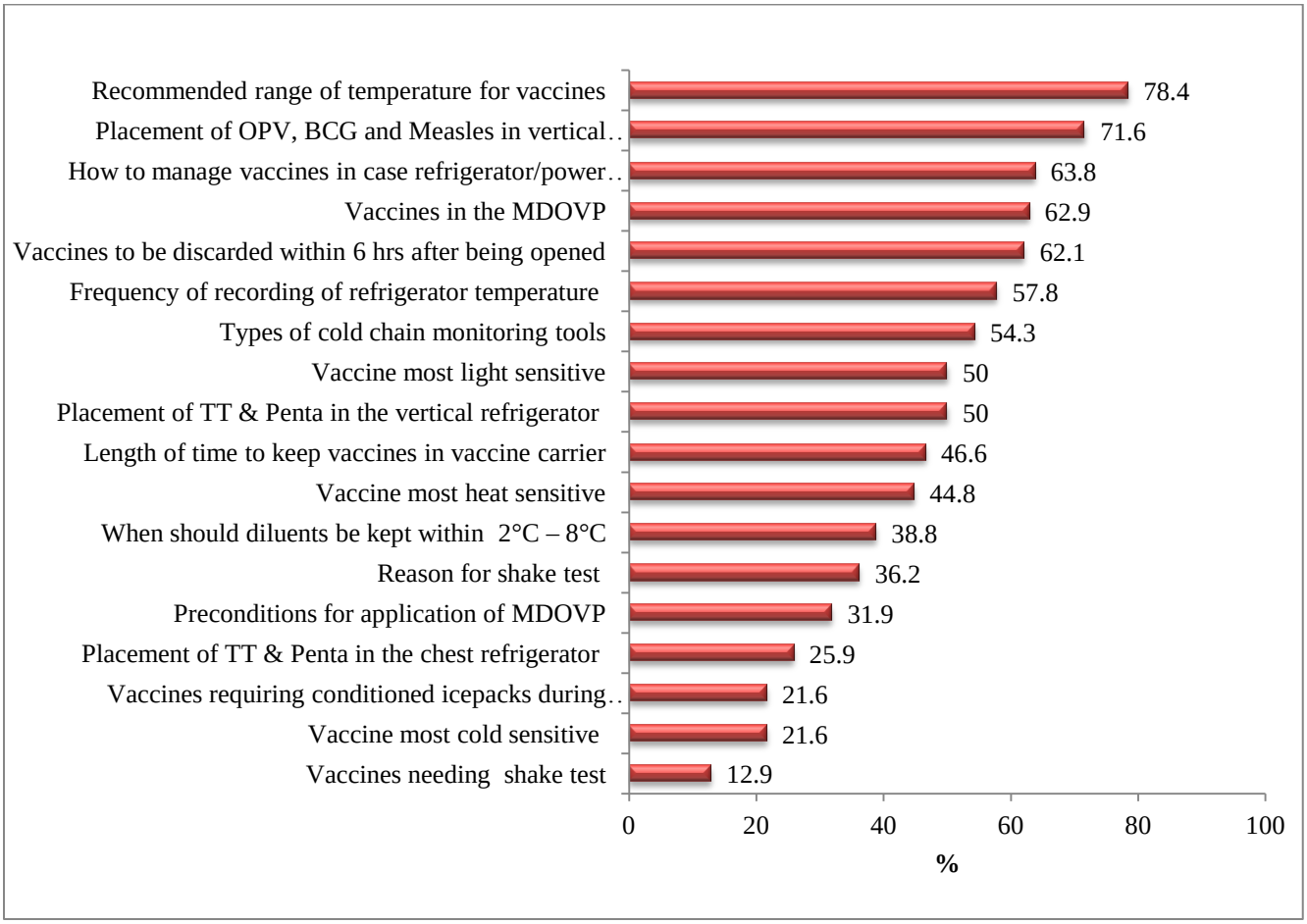
Figure 1: Key indicators for Cold Cahin Status Evaluation in the Studu Facilities (CORE Group Polio Project Implementation Districts in Amhara, Oromiya and SNNPR, Ethiopia), December 2011 –January 2012.



The number of health workers who knew how to use conditioned ice packs for all types of vaccines during transporation was 25 (21.6%). None of the providers were able to fully answer questions on how reconstituted vaccines should be handled; only 18 (15.5%) answered three out of five questions correctly while the rest provided correct responses to less than three questions. Seventy-three (62.9%) providers knew about two vaccines under Multi Dose Open Vial Policy (MDOVP) while 34 (29.3%) respondents did not know of either. All preconditions necessary to administer MDOVP were mentioned by 37 (31.9%) respondents and at least three preconditions were mentioned by 36 (31%). The length of time required to keep vaccines in the vaccine carriers after outreach sessions were responded to correctly by 54 (46.6%) providers (Figure 2).

In order to categorize the level of knowledge of vaccine providers as satisfactory and unsatisfactory, a mean score of 21(45%) was used. Considering the normal distribution of the data, a mean value was considered as an appropriate cut-off point to classify knowledge as satisfactory or unsatisfactory. Accordingly, respondents who scored less or equal to the mean were graded as having unsatisfactory knowledge and those scoring above 21 points, were graded as having satisfactory knowledge on cold chain management. Sixty-three (54.3%) were rated as having satisfactory knowledge while 53(45.7%) had unsatisfactory knowledge.

Figur 2: Knowledge of Health Workers on Cold Chain Management in Study Areas (CORE Group Polio Project Implementation Districts in Amhara, Oromiya and SNNPR, Ethiopia), December 2011 –January 2012.



Factors Associated with Knowledge of Vaccine Providers on Cold Chain Management

Professional qualification of the respondents, years of service working in EPI and having ever received in-service training were considered as factors and assessed for their effect on the knowledge of health workers on cold chain management. Among the factors, only professional qualification had a statistically significant association with the level of health workers' knowledge on cold chain management. Professional qualification, years of experience working in EPI were included in the regression model. The adjusted model indicated that nurses were about 9 times more likely to have satisfactory knowledge on cold chain management compared to Health Extension Workers (Adjusted OR = 8.83, 95% CI: 1.86 – 41.9). In addition, health workers who had served in routine immunization programs for more than 2 years were about 4 times more likely to have satisfactory knowledge on cold chain management as compared to those with less than two years of experience (Adjusted OR= 3.57, 95% CI: 1.57 – 12.41) (Table 2).

Table2: Bivariate and Multivariate Analysis of Providers' Knowledge on Cold Chain Management in the Study Areas, December 2011 – January 2012

Characteristics	Level of Knowledge		Crude OR (95% CI)	Adjusted OR (95% CI)
	Not Satisfactory	Satisfactory		
Qualification				
1. HEW*	50(49%)	48(51%)	1.0	1.0
2. Nurse	3(16.7%)	15(83.3)	**5.2 (1.4 -19.14)**	**8.83(1.86-41.9)**
Years of service in EPI				
1. Less than 1 year*	1(14.3%)	6(85.7%)	1.0	1.0
2. 1-2 years	14(60.9%)	9(39.1%)	0.21(0.024-1.82)	0.51(0.04-5.98)
3. >2 years	38(44.2%)	48(55.8%)	1.97(0.77-5.03)	**3.57(1.02-12.41)**
Ever received training on IIP/ Cold chain				
1. Yes	31(42.5%)	42(57.5%)	1.42(0.67-3.03)	1.45(0.60 – 3.50)
2. No*	22(51.2%)	21(48.8%)	1.0	1.0

*Health Extension Worker (HEW) Referrent category

DISCUSSION

In this assessment, out of 116 health facilities, only 38(32.8%) had refrigerators, of which only 22(57.9%) were functional. Health workers from the remaining 94(81.0%) facilities transported vaccines from facilities where there were functional refrigerators, which can be a cause for cold chain breakage that can adversely affect vaccine potency. In order to effectively maintain the cold chain system, there should be at least one refrigerator in every health facility since these facilities are expected to provide vaccination services for their communities on a daily basis. Of 16 functional refrigerators working with both electricity and kerosene, 7(43.8%) reported frequent kerosene shortage. Since electric supply is not available regularly, availability of reserve kerosene should be a prerequisite for maintenance of vaccine potency and sustainability of immunization service delivery. A study that was conducted to evaluate the cold chain status at immunization centers in Ethiopia in 2000 showed comparable findings; 9(42.9%) facilities reported shortage of kerosene for their refrigerators (3). In case of any emergency situation, interruption of power or kerosene supply, generators and vehicles are available in only 7(18.4%) and 12(31.6%) facilities respectively. Frequent cuts in power supply can have a direct impact on storage temperature and non-availability of standby generators will adversely affect vaccine potency at the vaccination centers (9). During our survey, trained personnel and spare parts for minor maintenance of refrigerator were available in 12(31.6%) and 6 (15.8%) health facilities respectively. As indicated above, vaccines are delicate biological products that need to be continuously maintained within a recommended narrow range of temperature (7). In this respect the availability of trained personnel and spare parts at the health facility level are mandatory for regular follow-up and timely maintenance (10).

One encouraging finding of this study was that all 22 (100%) functional refrigerators had thermometers that were fixed inside and outside the door. However, only 16(72.7%) had readings within the recommended temperature range. Vaccines in the remaining 6(27.3%) refrigerators were exposed to temperatures outside the recommended range ($+2^0$C - $+8^0$C). This could potentially lead to loss of costly vaccines

and accidental administration of compromised vaccines (11). In contrast to our finding, a study conducted in Kalasi, Thailand in 2011 showed a better result; only 13% of the refrigerators were outside the normal reading range of temperature (12).

In this study, of 22 facilities that had functional refrigerators, only 14(63.6%) had a temperature recording chart and among these, 13/14(92.9%) maintained the twice daily recording practice. WHO has recommended that the temperature range for vaccine storage should be 2^0C - 8^0C, to be read and recorded twice a day. This procedure helps for effective self monitoring to prevent breaking of the cold chain that can contribute for primary failure of immunization services (13, 14**).** A study conducted in Nyssa, Mozambique on Cold Chain Management in 2007 showed a better finding than this study in which 100% of the surveyed facilities had a thermometer log book that was updated twice per day (8).

One of the disturbing practices identified in this study was that the arrangement of vaccines in refrigerators was not correct in 12(54.5%) health facilities. This finding shows only a slight improvement from the findings of a study conducted in Benishangul Gumuz in 2009 in which 40(61.5%) facilities had improper and arrangement of vaccines (15).

The success of efforts by countries against vaccine preventable diseases is attributable in part to proper storage and handling of vaccines. By following a few simple steps and implementing standard storage practices, providers can ensure that eligible groups will get the full benefit of vaccines they received (11). This study also showed that vaccines were sharing space with laboratory reagents and other medicines in 9(40.9%) fridges. Ideally, the fridge containing vaccines should not be used to store other drugs in order to prevent two potential dangers: problem of not maintaining the recommended temperature range and wrongly administering drugs that have been packaged in similar color vials as the vaccine vials (14). The findings of studies that were done in Nyasa, Mozambique in 2007 and in Benishangul Gumuz, Ethiopia in 2009 showed that 4(30.8%) and 10(15.4%) facilities respectively shared space with other materials which was considered to be relatively better when compared to the findings from our study

(8, 10). It is evident from these findings that the cold chain system in these study areas raises serious concerns, indicating that immediate corrective action is warranted.

Of 116 health workers included in the survey, 91(78.4%) and 15(12.9%) knew the recommended range of temperature for vaccine storage and vaccines that need a shake test respectively. The poor knowledge about correct storage temperature range and shake test may be expected to adversely affect the quality of administered vaccines and consequently can give way for epidemic outbreaks of vaccine preventable diseases as is evidenced in many other parts of the country. The study conducted in Benishangul-Gumuz showed comparatively better results compared to our study; some 83.1% of respondents knew the recommended temperature range for storage of vaccines and 52.3% could correctly identify vaccines which needed a shake test (15). The findings of another study that was conducted in health facilities in Addis Ababa in 2009 likewise indicated better results; 93(87%) of respondents knew the recommended range of temperature for vaccine storage and 73.8% knew which vaccines needed a shake test (16).

This study also revealed that 52(44.8%), 25(21.6%) and 58(50%) respectively of health workers had knowledge about which vaccines were most sensitive to heat, extreme cold or light. By following a few simple steps, and implementing best storage and handling practices, providers can ensure that children and their mothers will get the full benefit of vaccines they received (11). Two studies done in health facilities in Addis Ababa in 2009 and Mozambique in 2007 have shown more encouraging findings than what is reported in our study. The study conducted in Addis Ababa in 2009 indicated 70(65.4%) of respondents knew which vaccines were cold-sensitive while in the study from Mozambique, 67% of respondents could identify the same (8, 16).

According to our findings, of 116 interviewed vaccine providers, 63(54%) had satisfactory knowledge on the cold chain management. The result of logistic regression analysis pointed out that nurses were nine times more likely to have satisfactory knowledge of cold chain management compared to Health Extension Workers which indicates that HEWs need more standardized in -service training that is supported with

practical demonstrations and well-designed supportive supervision in order to improve the quality of immunization services in rural Ethiopia, since both groups are equally assigned to deliver vaccination services. In addition, health workers who reported to have worked more than two years in the immunization program were about 4 times more likely to have satisfactory knowledge on cold chain management compared to those with less than two years of experience.

CONCLUSION AND RECOMMENDATIONS

This study found that there are gaps in knowledge and also in practice with respect to cold chain management. Since supervision and training as they are currently conducted do not appear to be making a difference, provision of standardized in–service training, supported with practical demonstrations and well-designed regular supportive supervision is recommended. In addition, distribution of at least one refrigerator per health facility, having an adequate amount of kerosene for regular and emergency uses and spare parts for minor maintenance should be considered as top priority for an effective and efficient immunization service.

Possible mechanism for transition of Kerosene/Electric refregrator with Solar Derived referigrators is required. Capacity assessment on the health workers and organizing periodic refresher training will help to fill gap related to immunization program. Further study should be done at district and facilities level and on client satisfaction using both qualitative and quantitative methods to identify gaps and recommend possible solutions.

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