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A. Koskei, BSc, MSc, MPH, E. Mibei, BSc, MSc, PhD, School of Science and Technology, University of Kabianga, S. Tabu, MBChB, MMed, P. K. Malalu, MBChB, MPH, MBA, School of Public Health, Moi University, I. Marete, MBChB, MMed, MPH and C. Tenge, MBChB, MMed, School of Medicine, Moi University, P.O.Box. 4606, Eldoret, Kenya.

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A. KOSKEI, E. MIBEI, S. TABU, P. K. MALALU, I. MARETE and C. TENGE

ABSTRACT

Background: Immunisation contributes significantly to the achievement of MDGs. It is one of the eight elements and success stories of primary health care. Proper utilisation of Immunisation services is associated with improved child health outcomes. The WHO targets Immunisation coverage of 90% for urban areas and 80% for rural areas.

Objectives: To assess the cold chain management practices that could affect potency of vaccines and its utilisation by under five year old children in Kacheliba Division.

Design: A cross-sectional descriptive study.

Setting: All health facilities in Kacheliba Division, Kenya.

Subjects: Parents/guardians of under-five year old children and all the health facility level within Kacheliba Division.

Results: Seven (87.5%) health facilities reported that they collect vaccines at intervals of more than one month. Four (50%) health institution were located 20 kilometers from the local vaccine store - Kacheliba District Hospital. Kacheliba District Hospital gets their vaccine stocks from Eldoret KEMSA depot, an estimated 90 kilometers away. Completely melted ice packs during transportation of vaccine were encountered only in one (12.5%) centre- Kacheliba mobile dispensary. Major source of power for the refrigerators was the gas (75%), and electricity (28.6%). During electricity power block out, the right temperature intervals were then generated using gas. It was found that all the eight health facilities did not have a stand by biomedical technician who maintains and repair refrigerators. Furthermore there was no budgetary allocation for the refrigerators maintenance and repair among all the health facilities. Problems related to cold chain were observed in all the eight facilities in Kacheliba Division. Inadequate air circulation was seen in seven (87.5%) facilities, water bottles were kept inside the cold boxes and fridges in three (37.5%) facilities, Food and drinks were kept in cold boxes and fridges in 4(50%) facilities and vaccines were not kept in proper compartment in three (37.5%) facilities.

Conclusion: The cold chain management practices among health facilities in Kacheliba Division of Pokot County were not upto the standards set by the Kenya Extended Programmeme on Immunisation (KEPI) Guidelines. Cold chain management should be improved through continuous medical educational programmemes and sufficient budgetary allocation.

INTRODUCTION

Immunisation is a life saving and cost-effective medical intervention which reduces childhood morbidity and mortality from diseases (1). Globally, there are 30 million children who are not routinely immunised every year and 1.5 million children under five years of age die each year from vaccine preventable diseases namely measles, whooping

cough (pertusis), Hemophilus influenza type B (HIB) and tetanus (2). In Kenya, the Immunisation coverage is still below the GAVI's 90% target by 2010 (3). According to KDHS 2007 report, national Immunisation coverage currently stood at 71% (4). Despite the Alma Ata declaration of universal access to health care, MDGs and primary health care policy, utilisation of Immunisation services in Kenya has not attained WHO's 90% and 80% Immunisation coverage in urban and rural areas respectively (5). The

maintenance of cold chain equipment still remains a major challenge in many developing countries.

The literature on cold chain studies in Kenya is limited but there are several studies done in Ethiopia, South Asia and South America. S. O. Ayaya *et al*, 2007 found low rate of Immunisation coverage and high drop out in Western Kenya (6). They also found that 25% of the staff had not been trained at supervisory level including on cold chain management and data management. The most commonly mentioned topic not covered on previous training was the maintenances of cold chain S.O. Ayaya *et al*. (6). On interviewing mid-level managers, Ayaya and Esamai study found weakness in KEPI programme which included poor maintenance of cold chain and inadequate number of staff. Berhane and Demissie, (7) found that in Ethiopia, out of the 67 centres visited, complete temperature records were observed in 57.8% centres, thermometers were not available in 6.3% of the total centres, and thermometer reading was found to be outside the optimal range in another 10.9% centres. The study also found that vaccine storage in the refrigerators was not proper in 73.4% centres. In addition, the study found that majority of the centres had neither trained personnel nor budget for maintenance of the cold chain. The main source of power was electricity (65.7%), kerosene (29.8%) and solar (3%). 32.8% of the health facilities/centres reported to collect vaccines at intervals longer than one month and completely melted ice packs during transportation of vaccines were observed in 4.5% of the total centres. The refrigerators were labeled as improperly stored with variety of reasons ranging from water bottles not kept (85.1%) to presence of food and drinks in refrigerators constituting 6.4% (7). A similar study in Thailand by SiriatTechathawat, *et al*, 2006 found that out of the 48 health facilities studied, 5 were found to have incomplete temperature records. WHO recommends using melting ice packs in cold boxes or vaccine carriers (8) but in Thailand it was found that insulating materials (such as plastic containers, paper wrapping, etc) were widely used to protect vials from direct exposure with frozen ice packs. Using ice instead of ice packs was also common (8). The recommended cold chain temperature for vaccine is +2°C to 8°C except OPV vaccine that have to be kept frozen (9).

Aggarwal *et al*, 1995 Indian study reported a number of short comings concerning cold chain such as power failure and improper and inadequate maintenance of cold chain equipment (10). A similar study done by Bachani *et al*, (11) found that shortage of temperature maintenance equipment in India with 58% of the health centres reported having the proper carriers to transport the vaccines (11). A recent study evaluating the vaccine vial monitor at different levels of storage in Northern India attributed the cold chain to the loss of vaccine potency (12). Vaccine

vial monitor is a crucial tool to monitor potential problems with potency of OPV in the field especially in developing countries with poor infrastructure and insufficient resources presents a big challenge maintaining the cold chain (13). Exposure to high temperatures is detrimental to OPV and vaccine loses its potency at a rate of 4% to 13% per day at 25°C, 11% at 31°C per day and 26%-34% per day at 37°C (14).

The vaccine vial monitor is a small patch of heat sensitive material placed on a vaccine vial to register cumulative heat exposure. A direct relationship exists between the rate at which the vaccine vial monitor changes colour and ambient temperature, the lower the temperature, the slower the colour change; the higher the temperature, the quicker the colour change (15). Some studies have reported knowledge deficit concerning vaccine vial monitor among health care workers. Thakur *et al*, 2000 found that 67% of the health workers are aware of the vaccine vial monitor in Chandigar, Northern India (16). Mukherjee *et al*, 2004 reported a relationship between changes in the vaccine vial monitor from stage 1 to 4 to failure to maintain an adequate cold chain (17).

Studies in Malaysia and Indonesia has demonstrated that while exposure to unduly high temperatures was fairly infrequent, most of their 2°C-8°C vaccine shipment were exposed to freezing temperatures at some stage of the cold chain (18,19). WHO studies showed that measles vaccines lose 50% of its potency after two to three days at 41°C (20). However, limited heat exposure may not cause vaccine damage as WHO estimate that measles vaccine kept at 22°C-25°C will remain potent for four weeks (20). A study in Bolivia showed that the monitoring of temperature in the vaccine cold chain fall shorts of WHO recommendation. In all the monitored shipment, vaccine was exposed to freezing temperatures at one or more points. In each of the shipment, temperature were below 0°C in 2- 50%. Seven of the 11 shipments were exposed to temperatures above 8°C (21). Similar findings in addition to lack of space for vaccine storage were also recorded in Indonesia (22).

MATERIALS AND METHODS

Study Setting: The study was carried out in Kacheliba Division, an administrative area of Pokot North district. Pokot North District covers a total area of about 9,064km² with an estimated population of 308,086 (2009 census) with Kacheliba's population of 48,644. Kacheliba Division has four locations namely Kodich, Kopulio, Lokichar and Suam. According to district records, the entire Pokot County has 53 points of health services delivery both MOH and private clinics with Kacheliba having only eight health facilities. There is one district hospital in Kacheliba Division- Kacheliba district Hospital. It is within

ASAL belt with periodic flooding, drought and rough mountainous terrains but also has dry vast plains. It borders Uganda to the east and is mainly inhabited by Pokot community.

Study population: Parents/guardians of under-five year old children and all the health facility level within Kacheliba Division.

Study design.: This was a cross sectional descriptive study conducted in July 2011 with the aim of assessing the influence of cold chain management factors on uptake of vaccines by under fives. A cross sectional health facility survey was conducted in all the eight health facilities in Kacheliba Division.

Sample size Determination: All the eight health facilities within Kacheliba Division were studied.

Sampling techniques: To assess and evaluate the status of cold chain management, a cross sectional survey of all the eight health facilities in Kacheliba Division was carried out. Data collection procedures: A pilot study was carried out in Kapenguria District to pre-test the questionnaire. This was done to enable the researcher to fine-tune the tools where necessary. The subjects were interviewed through an interviewer administered questionnaires. There were two research assistants each covering two location and its facilities. There was one supervisor who monitors the data collection and assists the two research assistants logistically. Training of research assistant was done to help them understand the questionnaire, sharpen their interview skills and clarify the ethical issues in research.

Data collection and management: The questionnaire consisted of both structured and semi-structured. The questionnaire was interviewer-administered. Filled questionnaire were checked for

completeness and coded by the researcher. Data was then entered in computerized MS access data base software and was later exported to Stata version 10 for analysis.

Ethical considerations: The proposal was reviewed and approved by Moi University's Institutional Research and Ethical Committee (IREC). A formal letter of permission from resident district Medical Officer of Health (MOH) was given before the research process starts. Confidentiality of information was maintained strictly by pass-warding its access and ethical conduct of research was strictly adhered to. Coding of questionnaire was done and its destructions may be done after the publications of research findings or after successfully defending the findings. The findings were also shared with the area Medical Officer of Health for the district health planning and with the entire Pokot County fraternity.

RESULTS

All the 8 health institutions in Kacheliba Division were studied and these include Kacheliba district Hospital, KiwawaACCK, Kasei, Konyao, Kodich and Amakuriate Mobile Dispensary, AIC Alale health centre and Kacheliba Mobile clinic. KiwawaACCK is the only one private facility providing Immunisation services. They provide Immunisation services daily except health centres and a mobile clinic which provide Immunisation services in 2-3 days per week, mainly Tuesday's and Wednesday's. Most facilities are managed by the Government in partnership with the local Non-Governmental Organizations. The human capacity is as shown in table 1.

Table 1

The health staff categories per facilities in Kacheliba Division

FACILITY	MOs	COs	LAB	PHN	Nurse of-ficers	CHWs	Immunisation Staff assigned
KachelibaD.Hospital	0	4	4	0	12	2	4
AIC Alale Health Centre	0	1	1	0	2	2	3
Konyao Dispensary	0	0	1	0	2	2	2
Kasei Dispensary	0	0	1	1	2	1	1
KiwawaACCKdisp	0	0	0	0	1	1	1
Kacheliba mobile clinic	0	1	0	0	2	3	2
Amakuriate mobile disp	0	0	1	0	3	2	3
TOTAL	0	6	8	1	24	13	16

Abbreviations: MO- Medical Officers, CO- Clinical Officers, LAB- Laboratory Technician, CHW- Community Health Workers

This study also found that only Kacheliba district hospital has one facility vehicle, a Land Rover, which is

shared among other public health facilities in Pokot North district. This was used in transporting vaccines, among other functions. The study therefore found that often missed opportunity for Immunisation could be partly due to shortage of personnel, among other reasons.

Upto seven (87.5%) health facilities reported that they collect vaccines at intervals of more than one month. 4 (50%) health facilities were located 20 kilometers from the local vaccine store - Kacheliba District Hospital. Kacheliba District Hospital gets their vaccine stocks from Eldoret KEMSA depot, an estimated 90 kilometers away. Completely melted ice packs during transportation of vaccine were encountered only in one (12.5%) Immunisation centre- Kacheliba mobile dispensary. Major source of power for the refrigerators was the gas (75%), and electricity (28.6%). During electricity power block out, the right temperature intervals were then generated using gas. It was found that all the eight (8) health facilities did not have a standby biomedical technician who maintains and repair refrigerators. Furthermore, there was no budgetary allocation for the refrigerators

maintenance and repair in all the health facilities. The results are summarized in table 2.

Problems related to cold chain were observed in all the eight facilities in Kacheliba Division. This is in reference to vaccine storage practices, record keeping and temperature regulation. There were also similar problems observed such as lack of budgetary allocation, standby biomedical technician for cold chain maintenance, inadequate personnel to operate the cold chain rooms and absence of specific designated rooms for cold chain storage. Other findings in the cold room and refrigerators which could partly affect negatively the potency of vaccines include Inadequate air circulation 7(87.5%), water bottles were kept inside the cold boxes and fridges 3 (37.5%), Food and drinks were kept in cold boxes and fridges 4(50%) and vaccines were not kept in proper compartment in 3(37.5%) facilities. All facilities had Immunisation charts well displayed in the MCH rooms but were not up to date. Files for Immunisation summaries were also present in all facilities.

Table 2
Characteristics of cold chain at vaccination

centres/ health facilities (n=8)		
Number of Centres		
Main source of power;		
Electricity	2	
Gas	6	
Kerosine	0	
Solar	0	
Refrigerator ever broken in last 12 months		
Yes	5	62.5%
No	2	25.0%
Not evaluated	1	12.5%
Time taken to fix the broken refrigerator		
One week	1	20.0%
Two weeks	1	20.0%
One month	1	20.0%
More than one month	2	40.0%
Person responsible for maintenance of the refrigerator/ icepacks at the facility;		
Yes	2	25.0%
No	5	62.5%
Not Applicable (Mobile facility)	1	
Budget available for refrigerator maintenance		
Yes	1	12.5%
No	6	75.0%
Not applicable (mobile clinic)	1	12.5%

Note: Amakuriate mobile clinic was left because of non functioning refrigerator and absent of vaccine outreach programme at the time of the survey.

There was a number of cases of missed Immunisation opportunity. A sample of 164 parents and guardians

were asked whether their under-five year old children has ever missed Immunisation after presenting themselves at the health facilities. Upto 65 (23.7%) respondents reported that they have at least once failed to get Immunisation services at various facilities in Kacheliba. The main reasons for missed Immunisation opportunity were lack of health personnel to attend them (29.2%), lack of drug supplies (33.9%), lack of vaccines (39%) and unknown reasons (9.2%). More

than a quarter (25%) of health facilities reported breakdown of refrigerators and that it took a period between two to three weeks before it was repaired. This study also found that in the health facilities, there was poor storage of vaccines against the standards set by KEPI. These include inadequate air circulation (n=7, 87.5%), water bottles not kept inside the cold boxes and fridges (n=3, 37.5%), Food and drinks were kept in cold boxes and fridges (n=4, 50%) and vaccines were not kept in proper compartment (n=3, 37.5%).

Table 3
Observed conditions of the cold chain equipment at health facilities
(n=8 centres)

Number of health facilities		%
Vaccine Records;		
Complete / updated	3	37.5%
Incomplete	5	62.5%
Daily temperature record / chart;		
Complete / updated	5	62.5%
Incomplete	3	37.5%
None	0	
Freezer working condition;		
Functional	5	62.5%
Not functional	2	25.0%
Not Available (mobile clinic)	1	12.5%
On spot Thermometer reading;		
Less than 0°C	0	
0°C to 8°C	7	87.5%
Greater than 8°C	0	
Not evaluated (mobile clinic)	1	12.5%
Thermometers' shake test routinely done;		
Yes	7	87.5%
No	0	
Not evaluated (mobile clinic)	1	12.5%
Vaccine storage in the refrigerator;		
Proper	4	50.0%
Not proper	3	37.5%
Not applicable (mobile clinic)	1	12.5%

DISCUSSION

This study revealed that there are many challenges facing the cold chain management in health facilities in Kacheliba ranging from human resources to cold chain equipments. On interviewing the household respondents, 65 (39.6%) household reported that they have at least once failed to get Immunisation services at various facilities in Kacheliba. When they asked why they could not get their children vaccinated, they were told that there were no personnel (29.2%), no Medical supplies (33.9%), no vaccines (39%) while others (9.2%) could not recalled reasons or could not know what happened. 25% of the facilities reported breakdown in fridges or refrigerators and it took some time, often two to three weeks, before it was repaired or fixed. These negatively affected the constant supply and availability of vaccines.

During this period, they would be compelled to store their vaccines in other nearest facility with cold chain facilities. These respondents were then referred to those facilities with cold chain services, which was often long distances away and hence could missed Immunisation opportunity. This contradicts KEPI standard rules that state that maintenance of refrigerators should be continuous process and any break up should be fixed immediately. This could have lead to increased missed Immunisation opportunities, poor vaccine storage and increased vaccine wastage. This, therefore, show that poor cold chain management may have affected potency of vaccines and utilisation of Immunisation services.

It was found that there was inadequate staffin the entire Division. The facilities are managed by clinical officers (COs) and community health nurses (CHNs). Nurses were assigned Immunisation clinics

and often rotate on regular basis including outreach Immunisation activities. This was consistent with the Ministry of Public Health and Sanitation report of 2008 and KNBS 2009 report which found doctor to patient ration very low and inadequate staff. Almost one third (29.2%) of the parents/guardians could not get vaccinations for their children because of absence or lack of personnel in these facilities. There was shortage of technician responsible for maintenance of refrigerators in many health facilities. These findings are similar to Aggarwal et al, 1995 study that found that cold chain system management in rural areas of India lack human and technological capacity. The characteristic of cold chain varies among the health facilities. The main source of power for maintaining vaccine potency was gas mainly used in health centres and dispensaries while electricity was used mainly in Kacheliba district hospital and Kodich dispensary. Kacheliba district hospital also uses gas when there is power block out. A key informant interview revealed that in June 2010, Kacheliba district hospital refrigerators were not working for a whole week and most of the vaccines were kept at Kapenguria District Hospital in West Pokot district during that period. This led to increased missed opportunities for vaccination as respondents were referred to other facilities with cold chain. These findings are similar to Berhane and Demissie cold chain study that found refrigerators used mainly gas and electricity power in visited health centres in Ethiopia.

The physical observations made on refrigerator include vaccine records, daily temperature records/charts, freezer working condition, thermometer reading and routine shake test. On vaccine records, few facilities had completed/up to date records. This was found to be similar to a study done by Sirirat et al. 2006 which found 10.4% of the health facilities in Thailand had incomplete temperature records (23). The daily temperature records were complete in most facilities with three facilities with incomplete temperature record chart. The KEPI standards of maintaining all records up to date were not met. The freezer working conditions were not up to the KVI standards with some facilities having problems with non functional freezers. The vaccine vial monitors were in stage I and II in all the facilities. No single facility was found to have thermometer reading outside the normal range or thermometers routinely not being shaken. These findings were similar to Berhane and Demissie cold chain study in Ethiopia and Carib et al, 2006 in Bolivia and contradicts Indonesian study commissioned by USAID/Delivery project of 2009.

A number of clinics were considered not to be labeling vaccines properly because of inadequate air circulation, water bottles not kept, food and drinks in refrigerators and vaccines not kept in its proper

compartment. This was also similar to the Berhane and Demissie, 2000 cold chain study in Ethiopia and Indonesian's USAID/Delivery project findings. All these could affect the potency of vaccines as well as could increase vaccine wastage hence low utilisation of Immunisation services by the under five year old children.

CONCLUSION AND RECOMMENDATIONS

The status of cold chain management was below the KEPI/GAVI recommendations and could have contributed to outbreaks of vaccine preventable diseases and poor utilisation of Immunisation services among under five year old children.

Cold chain management could be improved through continuous medical education and improving human resource for health.

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