Open Science Repository Medicine

doi: 10.7392/openaccess.23050475

KNOWLEDGE OF HEALTH WORKERS ON COLD CHAIN AND LOGISTICS' MANAGEMENT FOR EXPANDED PROGRAM ON IMMUNIZATION IN BUSIA AND NAMAYINGO DISTRICTS – EASTERN UGANDA

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EXECUTIVE SUMMARY

Appropriate knowledge of Expanded Program on Immunization (EPI) staff on cold chain and logistics' management (CCLM) ensures that vaccines are managed within optimum temperature range (between +2°C and +8°C) from the manufacturer up to use (Snow 2009). The objective of this study was to: assess EPI staff by cadre, on the knowledge and skills on cold chain and logistics management. This was a cross-sectional study that employed both qualitative and quantitative data collection methods. The study covered all the EPI service units (41). A total of 59 respondents (EPI staff) were interviewed.

Majority, 60% (33) of the respondents were knowledgeable about what vaccine vial monitor (VVM) measures (vaccine extreme/high temperatures) although all 100% (59) the respondents were not knowledgeable on whether VVM also measures vaccine potency. Majority (86% [12]) of the vaccinators was knowledgeable about what VVM measures - only 33% (9) of the qualified health workers (Nurses/Midwifes) were equally knowledgeable. None of the respondents was knowledgeable about freeze watch, vaccine shake test and multi-dose vaccine policy (MDVP). These results also show that 58% (34) of the respondents were knowledgeable about the use of first expiry first out (FEFO) and first in first out (FIFO) in vaccine storage and 73% (43) were knowledgeable about optimal temperature range for vaccines.

Key words: *Expanded Program on Immunization, vaccines, cold chain and logistics' management, EPI staff, optimum temperature range, ambient temperatures, refrigerators, vaccine vial monitor, multi-dose vaccine policy*

Introduction

Globally, all EPI staff and other health care professionals involved in the transportation, storage and administration of vaccines must understand the importance of the cold chain and ensure that it is maintained at all levels. According to the National Health Service (NHS) of Scotland (2010), the EPI staff, are primarily responsible for the success of EPI programs.

Monitoring of EPI service units with a focus on cold chain management practices was observed to have had a great impact on improving knowledge, attitude and practices of health workers in EPI (Bankole 2010). The Global Alliance for Vaccines and Immunization (GAVI) partners recognized technical support supervision as a priority and a critical management role in ensuring effective cold chain management. Supportive supervision therefore, forms one of the five key fundamentals of the Reaching Every District (RED) and Reaching Every Child (REC) - EPI strategies that are aimed at ensuring that all children in all the districts and families have access to quality and sustainable immunization (PATH 2003, Braka 2007).

In Uganda, the tasks of cold chain technicians (CCTs) have been shifted to cold chain assistants (CCAs) who are recruited from within the existing health workforce upon undergoing a two weeks training course coordinated by Uganda National Expanded Programme on Immunization (UNEPI) under the Ministry of Health. Such health workers retain their substantive appointments and they are assigned additional responsibilities under CCLM. They are provided with a set of tools to carry out minor operation and maintenance (O&M) of the refrigerators and assess the type of faults before ordering for spare parts from UNEPI. However as regards major faults, the refrigerators are normally sent to UNEPI headquarters (Ahmed 2007).

The staff in-charge of EPI service units at various levels in the district health system are supposed to be qualified health workers. Their primary duties include; to prepare orders and receive vaccines, maintain the equipment used, ensure appropriate handling of vaccines, monitor the vaccine refrigerator (temperatures) and adequately respond to a break in cold chain. They are also responsible for EPI inventory, logistics management information systems (LMIS), coordination of EPI activities, accountability for allocated resources and supervision of the entire EPI team under his/her management (Zaramba 2003 pp 7-8, MoH-Uganda 2005).

Although UNEPI was mandated to coordinate capacity building programs for CCLM at both national and district levels in Uganda, such programs were irregular mainly due to limited resources. Consequently UNEPI did not conduct any capacity building training during 2006/2007 financial year (Ahmed 2007). Monitoring of EPI service units with a focus on cold chain management practices was observed to have had a great impact on improving knowledge, attitude and practices of health workers in Nigeria (Bankole 2010).

Whereas immunization is a core function for the attainment of the Millennium Development Goals (MDGs) four and five, it is important to note that knowledge of health workers on CCLM is a cornerstone as regards the attainment of global immunization programs. Literature suggests that the overall goal of CCLM is to ensure safety of vaccines from the manufacturer up to the final recipient. CCLM also guarantees procurement of vaccines in right quantities, proper storage, and distribution so as to minimize waste, avoids stock-outs and maintain appropriate storage temperatures and prevent damage (WHO 2005,

Munck et al., 2008). A malfunctioning cold chain system can lead to vaccine wastage and missed opportunities due to lack of vaccines - beneficiaries may receive vaccines that do not protect them as intended or vaccines may actually make them sick. The objectives of good CCLM therefore include: giving assurance/confidence on potency of vaccines; ensuring maximum effective/clinical benefits from immunization; ensuring compliance with manufacturer's marketing authorization and minimizing financial loss from vaccine wastage (NHS of Scotland 2010 p. 3).

United Nations International Children's Educational Fund (UNICEF) hosted global immunization partners (Gates, JSI, PATH, Rota ADIP, Pneumo ADIP, UNICEF and WHO) for a meeting on November 1, 2007 to initiate a collaborative approach to strengthening national cold chain and logistics (CCL) systems globally. National immunization programs (NIPs) have increasing need for strong CCL systems due to new vaccines, new technologies and global health sector reforms (Magan et al. 2007, WHO 2009).

Monitoring of vaccine extreme temperatures

There are a number of technological advancements in monitoring vaccine temperatures. Some of the technologies include, vaccine vial monitors, freeze watch indicators and wireless temperature recording system. Policy reforms like multi-dose vaccine policy (MDVP) give further guidance in monitoring vaccine temperatures. Although cold chain management requires satisfactory cold chain infrastructure, compliance to standards and effective management, there is a high degree of noncompliance in both developed and low income countries (PATH 2012).

a) A vaccine vial monitor

A vaccine vial monitor (VVM) is a thermochromic sticker that is put on vaccine vials with an aim of giving visual warning of whether such a vaccine has been exposed to ambient temperatures that affect its potency. The combined effects of time and temperature-exposure cause the inner lighter square of the VVM to dim/darken, gradually and irreversibly. When the inner square matches or becomes darker than the outer circle the affected vaccine must be discarded (WHO 2002).

VVMs were primarily aimed at responding to the multiple challenges that affect cold chain within low income countries where denatured vaccines would be served to the unsuspecting clients. In 1979, Appropriate Technology in Health (PATH) in collaboration with World Health Organization (WHO), received financial support from United States Agency for International Development (USAID) and started developing VVMs - and by 1996 VVMs became commercially available for oral polio vaccine. Currently UNICEF and WHO have supported and promoted VVMs as an integral global requirement for all vaccines used under EPI (Melgaard et. al. 1999, PATH 2012).

b) Freezewatch Indicators

WHO emphasizes that freezewatch indicators should be constantly included in all vaccine shipments and vaccine refrigerators (WHO 2003). EPI stresses that vaccine stocks and temperatures must be monitored at all levels of storage, distribution and administration in order to avoid or reduce wastage (Munck et. al. 2008). Freeze Watch indicators consist of extremely sensitive indicating liquid inside a specially designed ampule that fractures upon exposure to freezing temperatures. The liquid permanently stains a paper behind the ampule, signifying that the product has been exposed to unacceptable freezing temperatures. Such vaccines require product quality testing performed before use (WHO 2003).

c) The vaccine shake test

The vaccine shake test is a method that was previously used as an indicator that a liquid vaccine had inappropriately frozen. A positive shake test generally refers to the formation of granular particles which show up upon shaking the vaccine after the vaccine was frozen and then thawed. The shake test is an unreliable technique of testing vaccine potency because a positive shake test may or may not occur or be seen by use of naked eyes after a liquid vaccine has been frozen (Gazmararian et.al.,2002, Kartoglu et. al.,2010). The most suitable gold standard for the shake test is the visual observation under a phase contrast microscope. Phase contrast microscopy is a confirmatory method of identifying freeze damaged vaccines. Under microscopy, damaged vaccines contain large conglomerates (massed precipitates with amorphous, crystalline solid and needle-like structures) while vaccines maintained within the optimal temperature range of 2^{o}c to 8°c will show a fine-grain structure (Kartoglu et. al. 2010).

d) Wireless temperature recording system

WHO and UNICEF developed a computer based vaccination supplies stock management (VSSM) version 4.0 and piloted it in Sudan before trying it in Egypt, Laos, Iran, Uzbekistan and now in Pakistan. VSSM produces a completely customizable dispatch voucher based on the countries local requirements. The system generates up-to-date information from both the national and local vaccine stores hence facilitating evidence based approach to managing EPI programs (Kone 2009).

In 2007, WHO provided financial and technical support for the installation of a wireless temperature recording system to monitor cold chain in the Sudanese national vaccine store. The vaccine store was certified to meet the minimum standards by WHO/UNICEF in 2008. The wireless has special sensors that measure both internal and external temperatures of the cold rooms - signals are sent through transmitters to the data capture computers. The system provides automated alarms whenever the temperatures record above 10^{o}C and below 0^{o}C. Once the alarm is triggered, a siren sounds, the networked telephone system sends short message service (SMS) text detailing the nature of the problem and the mobile phones on the network ring concurrently (WHO 2010, PATH 2010).

e) Expiry dates

The expiry date is the schedule within which the vaccines, diluents or other EPI products like syringes should be used under ideal conditions (when appropriately handled). All vaccines and diluents have expiry dates printed on both the vials and their package boxes. These expiry dates vary by type and lot of vaccines and diluents. Such vaccines and diluents should be used strictly within the expiry range including the actual date of expiry unless stated otherwise by the manufacture (product package insert). Whenever the dates of EPI products are marked with only a month and year, the vaccines or diluents may be used up to and including the last day of the month indicated on the vial (CDC, not dated).

During vaccine storage, stocks should be placed within the refrigerator so that stock with the shortest expiry is used first (first expiry first out). However, where vaccines of the same expiry date but received on different dates, they should be managed according to the principle of first in first out (NHS of Scotland 2010).

f) Multi-dose vaccine policy (MDVP)

According to WHO (2000 pp. 1-2), the previous EPI policy on use of opened multi-dose vials vaccines stated that all vaccine vials that had been opened for an immunization session had to be discarded at the

end of that session. Such vaccines were to be discarded regardless of the type of vaccine or the number of doses remaining in the vial. However the revised policy states that vaccines such as OPV, DPT-HepB + Hib, TT and liquid formulations of Hib vaccines may still be used only if they meet a certain criteria. The new MDVP states that opened multi-dose vials vaccines can be used within four weeks if; the vaccine had been opened at a static immunization clinic, the expiry date has not passed, the storage temperatures are appropriate and the vaccine vial septum has not been submerged in water. Other conditions to consider include, having used aseptic techniques to withdraw all doses and normal VVM colour of such vials. These categories of vaccine vials have bacteriostatic agents (stabilizers) that prevent the growth of bacteria unless vaccines become contaminated (Magan et.al. 2007, Parmar et. al. 2010). Single-dose vials (SDVs) are intended for one-time use only and once their protectives have been unsealed, they must be discarded since it may not be possible to establish if the rubber seals have been punctured through (Parmar et. al. 2010).

PATH currently offers technical support to the development of innovative vaccine preservatives and new multi-dose vaccine (MDV) products that will be critical to minimizing the challenges of new vaccines on CCLM (Magan at.el. 2007). MDV should always be marked by indicating the date when the first dose is withdrawn from the vial and must be returned to refrigerator as soon as possible. However once a MDV is opened it must be used within four weeks (unless otherwise indicated by the manufacturer's instructions) (WHO 2000, MoH Uganda 2005). The production and cold chain costs of MDV are spread over many doses as such; they tend to cost less per dose as compared to single-dose vials. However they are also associated with higher wastage rates (Parmar 2010).

Transportation

There are three main elements that are combined to ensure vaccine effectiveness. The three elements include proper vaccine transport, storage, and handling. Whereas transport is key in CCLM in Uganda, UNEPI lacked a well-functioning transport system. Three out of the eight trucks meant to transport supplies had been packed due to mechanical problems. UNEPI had only one supervisory vehicle to serve ten officers that were supposed to visit the districts (Ahmed 2007).

Recent studies in Great Britain, the United States, Canada, Pakistan, Malaysia, Hungary, Mongolia, and other countries found widespread freezing at many levels of the vaccine distribution system (WHO 2003). Transportation of vaccines requires optimum refrigeration temperatures ranging between +2°C and +8°C in addition to protection from light for some specific vaccines (BCG, Measles). However frozen vaccines may be transported at optimum temperatures of negative fifteen degrees and lower. The commercial sector has responded to the increasing high volumes of transporting vaccines by adapting use of a container system with specific carriers built with high-performance vacuum panels that are insulated and calibrated to maintain vaccines from 2°C to 8°C for up to nine days (WHO 2008).

Whenever vaccines are transported in cool boxes, such boxes must be validated for suitability to conform to EPI requirements. EPI recommends that cool boxes should provide enough space for the intended vaccines, easy to clean, good shock absorbent and be provided with good seal on the lid. Other requirements include, appropriate mark such as "EPI" and they should be easy to handle (NHS of Scotland 2010).

Methodology

The study was conducted in Busia and Namayingo districts respectively. The objective of this study was to: assess EPI staff by cadre on the knowledge and skills on cold chain and logistics management. This was a cross-sectional study that employed both qualitative and quantitative data collection methods. The study covered all the EPI service units (41) - a total of 59 respondents (EPI staff) were interviewed.

Busia and Namayingo districts were selected using purposive sampling technique. The two districts were chosen because of their location (rural districts in eastern Uganda), share common boundaries and have staffing levels of less than 40% (MoH Uganda 2011).

Results

Background and social-demographic characteristics of the respondents

A total of 41 EPI service units were visited and out of which majority 51% (21) were health centre IIs while 34% (12) were health centre IIIs as shown in table 1 below.

Table 1: Category of EPI service units by district

n = 41

Category of EPI service unit	District		Frequency	Percentage (%)
	Busia	Namayingo		
District vaccine stores	01	01	02	**05**
General hospitals	02	00	02	**05**
Health centre four (IVs)	01	01	02	**05**
Health centre three (IIIs)	08	06	14	**34**
Health centre two (IIs)	11	10	21	**51**
Total	**23**	**18**	**41**	**100**

A total of 59 respondents were interviewed (health workers working as EPI staff at EPI service units) out of whom 29% were males. Enrolled Midwifes were 36% (21), Nursing Assistants were 27% (16) - vaccinators were 24% (14) while enrolled Nurses were 5% (3) as reflected by table 2.

Table 2: Category of respondents from each of the districts by cadre

n = 59

Category of Respondents	District		Frequency	Percentage (%)
	Busia	Namayingo		
Nursing officer (nursing)	02	01	03	**05**
Cold chain assistant	01	01	02	**03**
Enrolled nurse	03	00	03	**05**
Enrolled midwife	17	04	21	**36**
Nursing assistant	04	12	16	**27**
Vaccinator	06	08	14	**24**
Total	**33**	**26**	**59**	**100**

Knowledge of EPI staff on cold chain and logistics management

Table 3 below shows that more than half (58% [33]) of the respondents had ever been trained for EPI (operational level training). Results also reflected that all respondents who ever been trained, all (100% [59]) had, had their training beyond three years from the date of the interview. It was also noted that majority of the EPI service unit in-charges (60% [23]) had never received EPI operational level training.

The results also show that 100% (14) of the vaccinators had ever been trained in EPI, while only 56% (15) and 25% (4) of the Midwifes/Nurses and Nursing assistants had a similar training respectively. The study established that less than a half (46% [27]) of the EPI staff were Nurses/Midwifes.

Table 3: Respondents trained in CCLM by category of health workers

	Category of health workers							
Training in EPI (operational level training).	**Nurse / midwife n=27**		**Nursing Asst n=16**		**Vaccinator n=14**		**Total trained n= 57**	
	Freq	%	Freq	%	Freq	%	Freq	%
Trained in EPI	15	56	04	25	14	100	33	58
Time when the last training was held								
- Within the last one year	00		00		00			
- Within the last three years	00		00		00			
- Beyond the last three years	15		04		14			
Duration of the last training								
- Less than two weeks	10		02		08			
- Two weeks	00		00		00			
- More than two weeks	00		00		00			
- Do not remember	05		02		06			

During the study it was also found out that none of the staff at the DVS had ever received EPI mid-level management training and that both district cold chain assistants (DCCA) had attended a cold chain assistants' course. None of the DCCA had had training within the last 3 years and the CCA for Namayingo district did not have a tool kit for O&M.

Table 4 shows that majority, 60% (33) of the respondents were knowledgeable about what VVM measures (vaccine extreme/high temperatures) although all 100% (59) of the respondents were not knowledgeable on whether it also measures vaccine potency.

Table 4: Levels of knowledge of EPI staff on VVM
n = 59

Vaccine vial monitor (VVM)	**Frequency**	**Percentage (%)**
Knowledge on what VVM measures		
Knowledgeable	33	60
Not knowledgeable	26	40
The lower the temperature, the slower the color changes		
Knowledgeable	39	66
Not knowledgeable	20	34
The higher the temperature, the faster the color change		
Knowledgeable	37	63
Not knowledgeable	22	37
VVM measure vaccine potency		
Knowledgeable	00	00
Not knowledgeable	59	100
Inner square is lighter than outer ring yet the expiry date has not been passed; use the vaccine.		
Knowledgeable	38	64
Not knowledgeable	21	36
Inner square matches the color of outer ring; use the vaccine		
Knowledgeable	20	34
Not knowledgeable	39	66
Inner square is darker than outer ring; Use the vaccine		
Knowledgeable	44	75
Not knowledgeable	24	41

Table 5 below reflects that although majority (86% [12]) of the vaccinators was knowledgeable about what VVM measures - only 33% (9) of the Nurses/Midwifes were equally knowledgeable. It was also established that all (100% [14]) of the vaccinators were knowledgeable that vaccines should never be used if the inner square was darker than outer ring. Some of the midwifes/nurses 33% (18) and Nursing assistants 25% (12) were not knowledgeable whether vaccines should never be used if the inner square was darker than outer ring (VVM).

Table 5: Variation of the knowledge of EPI staff on VVM by category of health workers

	Category of health workers					
Vaccine vial monitor (VVM)	**Nurse / midwife n=27**		**Nursing Asst n=16**		**Vaccinator n=14**	
About what VVM measures	Freq	%	Freq	%	Freq	%
- Knowledgeable	09	33	10	63	12	86
The lower the temperature, the slower the color changes						
- Knowledgeable	14	52	10	63	13	93
The higher the temperature, the faster the color change						
- Knowledgeable	14	52	09	56	12	86
VVM measure vaccine potency						
- Knowledgeable	00		00		00	
If the inner square is lighter than outer ring yet the expiry date has not been passed; USE the vaccine.						
- Knowledgeable	14	52	10	63	12	86
If the inner square matches the color of outer ring; Use the vaccine						
- Knowledgeable	02	07	06	38	12	86
If the inner square is darker than outer ring; Use the vaccine						
- Knowledgeable	18	67	12	75	14	100

Table 6 shows that none of the respondents was knowledgeable about freeze watch, vaccine shake test and MDVP. These results also show that 58% (34) of the respondents were knowledgeable about the use of FEFO and FIFO in vaccine storage and 73% (43) were knowledgeable about optimal temperature range for vaccines. The table further shows that 86% (51) and 73% (43) of the respondents were knowledgeable about the categories of waste generated at an immunization clinic and the risks associated to poor management of EPI waste respectively.

Table 6: Knowledge of EPI staff on other cold chain parameters (n = 59)

Cold chain parameter	**Frequency**	**Percentage (%)**
About what Freeze watch measures		
- Knowledgeable	00	00
About what vaccines shake test measures		
- Knowledgeable	00	00
About what MDVP means		
- Knowledgeable	00	00
About the use of FEFO in vaccine storage		
- Knowledgeable	34	58
About the use of FIFO in vaccine storage		
- Knowledgeable	34	58
About the optimal temperature range for vaccines		
- Knowledgeable	43	73
Naming at least one validated vaccine container		
- Knowledgeable	59	100
Mentioning at least one risk associated to using vaccine carriers		
- Knowledgeable	41	69
Naming categories of waste generated at an immunization clinic		
- Knowledgeable	51	86
- Fairly knowledgeable	08	16
Mentioning any risks associated to poor management of EPI waste		
- Knowledgeable	43	73
- Fairly knowledgeable	16	27

DISCUSSION

Knowledge of EPI staff on cold chain management

Although all vaccinators had had EPI training (operational level training), most midwives and nurses had never been trained yet majority also served as EPI staff in charges - yet all EPI staff in the two districts that had ever been trained had had such trainings conducted beyond the last three years from the date of data collection. The study findings further established that at the DVS in both districts, none of the EPI staff had ever had EPI mid-level management course. The DCCAs had ever received a two weeks training and the training had been conducted beyond three years from the date of data collection. These findings could imply that training in EPI was never prioritized either by the center (UNEPI and MoH) or the districts. This would intern compromise the quality of EPI services offered in both districts due to limited skills by the service providers. According to Ahmed (2007), UNEPI appreciated the importance of orienting EPI staff at district and health facility levels on vaccine management. UNEPI was also primarily responsible for planning and coordinating EPI management level and operational level trainings in Uganda. However in 2007 UNEPI did not conduct any such training due to lack of funds. Such a

challenge could have been one of the underlining causes of lack of training in the two districts of Busia and Namayingo.

Majority of the respondents were knowledgeable about the vaccine optimal temperature range and what VVM measures (vaccine extreme/high temperatures) although all the respondents were not knowledgeable on, whether VVM also measures vaccine potency. These results implied that although EPI staffs were relatively knowledgeable about VVM, none of them had comprehensive understanding of VVM in vaccine management – implying that they could not management decisions based on VVM.

It was also observed that vaccinators were more knowledgeable about VVM and its interpretation as compared to nursing assistants, midwifes and nurses yet they (vaccinators) were serving a volunteers. As discussed earlier - all vaccinators had ever been trained in EPI operational level management; that could have contributed to their level of knowledge as compared to the other categories of EPI staff. MoH outlawed the use of vaccinators in EPI activities (MoH Uganda 2005). Although these were outlawed, the results show that MoH had invested in them (trained) and they could still serve as a strong resource for the success of EPI particularly in the two study districts since their staffing levels were still low (at less than 40%) (MoH Uganda 2011).

Midwifes/Nurses were the least knowledgeable about VVM yet most of them were the staff in charges of EPI service units. The above findings may suggest that most EPI facility in charges did not have enough technical competencies to plan, coordinate and supervise EPI activities at those levels, which would compromise the quality of EPI services in the two districts. All respondents were not knowledgeable about freeze watch and vaccine shake test. This could imply that the vaccines were at risk of exposure to extreme cold temperatures without notice. Such exposure of vaccines could negatively affect vaccines that are contraindicated to extreme cold temperatures. The above findings were in line with studies in Uganda (Tumwine 2007 and Ahmed 2007) that revealed that majority of the health workers had limited knowledge on vaccine shake test. However, revitalization of EPI operational efficiency in Uganda requires that all EPI staff at both district and health facility levels receive appropriate training in vaccine management. They should have good skills on monitoring vaccine extreme temperatures (VVM, freeze watch and shake test) and application of MDVP.

Majority of the EPI staff were also generally knowledgeable about the categories of waste generated at an immunization clinic. All EPI staffs were knowledgeable about the risks associated to poor management of EPI wastes. These findings suggest that EPI staff could technically mitigate the risks associated to EPI wastes.

Conclusion

The findings herein generally suggest that the quality of EPI services in Busia and Namayingo districts was generally poor since EPI staff had limited knowledge on CCLM. This is shown by: inadequate training (in EPI) for qualified staff - none of the facility based EPI staff had ever had EPI mid-level management course, lack of comprehensive understanding of VVM in vaccine management and lack of knowledge about freeze watch and vaccine shake test. These were among some of the factors that justified limited knowledge of health workers in CCLM in the two districts hence negatively affecting the quality of EPI services.

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