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Adherence to Cold-Chain Management Guidelines and Influence on Stability of Live Attenuated Vaccines: Results from an Observational Study in Kisumu County, Kenya.

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Abstract

Purpose: Guidelines provide ethical frameworks to streamline processes for best outcomes. Live-attenuated vaccines in routine immunization programs in Kenya have challenges of instability despite the availability of guidelines. Diseases preventable by these vaccines are reported in Kisumu County more than others in the region. This observation is suspected to be associated with lapses in adherence to cold-chain management procedures. This study, hence purposed to assess whether there was any association between instability of vaccines and staff adherence level to the guidelines.

Method: Using analytical cross-sectional design with repeated observations, data was collected from 120 out of 170 public and non-governmental health facilities in the Kisumu County at three intervals, between October 2018 and March 2019. In each health facility, immunization manager on duty was

interviewed and observations made on compliance with cold-chain protocols using a checklist. Data was summarized descriptively and regression used to identify key points of adherence levels. Qualitative information was analyzed thematically to identify evolving themes.

Result: In 40% of the facilities, staff did not transfer vaccines when the need arose; 8.3% did not defrost fridges; while 45.8% did not dispense vaccines at VVM stage 2. Transferred vaccines accounted for improved stability of both OPV (95%C.I; 3.1 – 16.8, OR 7.2, p value< 0.001) and measles-rubella vaccines (95% C.I, 2.1 – 10.4, OR, 4.7, p=value <0.001). Dispensing vaccines at VVM stage 2 ahead of FEFO had better stability of OPV (95%C.I, 6.0 - 49, OR17.2, p=value <0.001) and measles-rubella vaccines (95%C.I 3.3-17.4; OR7.6, p=value <0.001) respectively. Defrosted fridge enhanced stability of OPV (95% C.I, 1.1 – 15.5; OR 4.17, p=value 0.033), measles-rubella (95% C.I, 1.3 – 12.3, OR 4, p-value 0.0017) and ROTA vaccine (95% C.I 1.9 – 21.5; OR 6.3, p= value 0.003).

Unique contribution to practice and policy: Lapses in transferring vaccines, defrosting of fridges and use of VVM to dispense vaccines significantly destabilized live attenuated vaccines worth linking to the outbreaks of Rota diarrhea and measles outbreaks in Kisumu. Due to inadequate staff adherence level to guidelines, new innovations meant to help improve stability of vaccines, inadequately improved the situation, so calls for strengthened capacity building to staff.

Key words: *Cold-chain system; adherence; guidelines; vaccine stability; routine immunization*;

BACKGROUND

Stable vaccines contribute significantly in the promotion of good health indicators among children below five years worldwide (MoH 2012; Angela *et al.*, 2014, WHO 2015a, Okomo *et al.*, 2019). Loss of vaccine stability due to any lapses has a considerable adverse impact on the success of immunization program. Vaccines stability refers to their ability to retain physical, chemical, biological, biopharmaceutical and microbiological properties within specified limits to assure clinical performance throughout shelf-life (Shen, *et al.*, 2014). This is detectable in clinical set ups through the use of Vaccine vial monitor (VVM) gadgets which are attached to each vaccine vial. Both adverse heat events (occurring when vaccines experience temperatures ≥8^{o}C for over 10 hours) and adverse cold events (occurring when vaccines experience temperatures ≤–5^{o}C for at least one hour) lead to degradation of vaccines immunological properties, consequently compromising their protective efficacy to the individuals receiving them. Adherence to cold-chain management guidelines is critical in improving time vaccines spend within the correct range thus sustaining their stability (WHO 2006, 2015a, 2015b). In Kenya, the national vaccines and immunization program manages the cold-chain system to ensure that all eligible children receive safe quality vaccines. The recent introduction of remote temperature monitoring technology besides fridge tag2 to monitor vaccine fridges provides an important additional tool to enable health managers to detect and address recurring lapses promptly hence, enhancing cold-chain management throughout the vaccine supply system (Lutukai, e*t al.*, 2019, Okomo *et al.*, 2019). However, recent evidence from facility national surveys indicates that maintaining cold-chain systems at the service delivery points remain a major challenge despite availability of cold-chain infrastructure and operational guidelines (MoH, 2012; Lutukai, 2019). In contrast, mass immunization campaigns, especially for Polio and Measles, gives relatively a better disease control results than routine immunization process due to higher efficiency and conscientious adherence to cold-chain management

guidelines (MoPHS 2013; Okomo *et al.*, 2019). This variance indicates potential lapses or less rigor in cold-chain management during routine immunization services.

To ensure quality of vaccines, immunization services staff providers are expected to perform the following procedures to sustain optimal vaccine quality. They are expected to: place diluents for use in fridges or carriers before use; place reserve icepacks in an alternative carrier during outreach; arrange vaccines in fridge based on their sensitivity levels to heat and cold. They are also expected to defrost fridges in time; chart temperature twice a day; transfer vaccines when a fridge is faulty; dispense any vaccine at VVM stage 2 ahead of FEFO sequence; accurately interpret VVM stages and observe FEFO sequence. Whereas guidelines and job aids are available per facility to guide practice by immunization providers and managers, their level of adherence remains unclear, despite regular support supervision.

In Kisumu County DHIS- Kenya 2014, 2015 and 2016 reports show progressive improved vaccination coverage from below 70% to 90% over the period, but with occasional upsurges of measles, Rota diarrhoea and tuberculosis, very inconsistent with the coverage levels. Fridge tag2 records of aberrant temperature excursions beyond the recommended temperature range of between 2^oC – 8^oC indicate lapses in cold-chain management system largely attributable to staff errors. The current study aimed to assess staff adherence levels to routine cold-chain management guidelines and determine potential influence of this on the stability of live attenuated vaccines at health facilities in Kisumu County. The findings are valuable to policy makers, service delivery managers and providers to enable them to develop targeted quality improvement interventions for respective contexts.

METHODOLOGY

Design and Sampling Procedure

The study was set and conducted in all sub-Counties of Kisumu, using an analytical cross-sectional design with repeated observations. The sample frame comprised of all health workers deployed to handle vaccines at 170 health facilities. These units were further categorized according to level of care (level 2 or 3 and above); and type of ownership (public or private). A sample of 120 facilities was calculated based on the Yamane (1967) simplified formula. Study facilities were identified per strata using simple random sampling as shown in Table1below. Data collection was done in three cycles of two Months interval using a pre-tested checklist adapted from WHO guidelines. A measure of reliability was performed on the three cycles of data as stated by Cronbach's alpha in (Gliem et.al. 2003). The second cycle reported the highest alpha of 0.8093, so was treated as most reliable, followed by first batch with an alpha of 0.7903 while third had an alpha of 0.7330. In each facility, immunization manager on duty on the day of study visit were identified as per the duty rosters. They were interviewed to ascertain their level of adherence to the guideline and influence on stability of live attenuated vaccines. Observation on their actual practice was also made. Reports of fridge tag two gadgets and those of VVMs' color code changes, guided the determination of the level of adherence to the guidelines and stability levels of vaccines in each facility.

Table 1: Sample size and sampling procedure

SUB COUNTY	# OF HEALTH FACILITIES AVAILABLE PER SUB-COUNTY / # SAMPLED	HEALTH FACILITY LEVEL ≥3		HEALTH FACILITY LEVEL 2		TOTALS:
		OWNERSHIP		OWNERSHIP		
		GOK	FB / PR	GOK	FB / PR	
KISUMU EAST	# H/FACILITIES	9	13	14	11	47
	# SAMPLED	6	9	10	8	33
KISUMU WEST	# H/FACILITIES	3	4	13	3	23
	#SAMPLED	2	3	9	2	16
MUHORONI	# H/FACILITIES	3	2	18	8	31
	#SAMPLED	2	1	13	6	22
SEME	# H/FACILITIES	3	0	21	1	25
	#SAMPLED	2	0	15	1	18
NYANDO	POPULATION	3	3	14		20
	SAMPLE	2	2	10	0	14
NYAKATCH	POPULATION	4	4	13	3	24
	SAMPLE	3	3	9	2	17
TOTAL	POPULATION	25	26	93	26	170
	SAMPLE	17	18	66	19	120

GOK (Government of Kenya) - Public Health facilities; FB _ Faith Based health facilities / PR- Private Health facilities

Data Analysis

Using SPSS version 20, data were summarized descriptively. Frequency distribution tables for both stability statuses of each vaccine and adherence levels of staff with the guidelines are reported. The levels of vaccine stability were clustered into "stable" and "unstable"; this allowed the use of generalized estimating equation algorithm customized for logistic regression with a binomial link. Chi-square inferential test was performed to detect the association between the two variables. Fisher's exact test was used whenever some cell values were either 0 or below 5. Bivariate and multivariate regression analyses were performed to identify factors that might be associated with instability of live-attenuated vaccines. Odds ratios and confidence intervals were then reported. Qualitative information was coded and analyzed thematically to identify evolving themes on staff practice and attitude.

Limitations

The method was limited to assessing how staff attitudes and adherence levels to cold-chain management's guidelines influence stability of live-attenuated vaccines at health facilities in the County, through the guidance of vaccine vial monitors and fridge tag2. Laboratory titter was not performed.

RESULTS

Variable characteristics of e study participants

The study comprised of 120 participants from the six sub-Counties, representing 70% of health facilities. The majority of service providers were nurses (98.3%; n=118) and 1.7% (n=2) public health officers. Of these, 73.3% (n =88) were females, whereas males were 26.7% (n=32). The majority of participants, 89.2% (n=107) had 2 years or more of experience. Most of the staff were aged between 36-60 years with a frequency of 63.3% (n=76) followed by 20-35 years, 31.7% (n=38) and finally those above 60 years were 5% (n=6). In terms of facility type and ownership, there were 66.7% (n=80) public facilities, 33.3% (n=40) private facilities including faith based. As for the level of operation, 70% (n=84) were level two while 30% (n=36) were level 3 and above. (See table 2)

Table 2: Summary Statistics of Personal Characteristics and Facility information

. Characteristic	Frequency (%)	Lower 95%CI	Upper 95%CI
Designation			
Nurse	98.33(n=118)	93.46	99.59
PHO	(1.67%(n=2)	4.09	6.54
Gender			
Male	26.7% (n=32)	15.11	30.06
Female	73.3% (n=88)	69.94	84.89
Experience			
Less than a year	3.3% (n=4)	0.41	6.59
1 to 2 years	7.5 % (n=9)	11.73	25.69
2 years and above	89.2% (n=107)	72.46	86.88
Age			
20-35	31.7% (n=38)	30.50	48.19
36-60	63.3% (n=76)	41.77	59.87
60+	5% (n=6)	5.82	17.18
Type of Facility			
Public	66.7%(n=80)	59.36	76.12
Private	33.3%(n=40)	23.88	40.63
Facility Level			
2 or Below	70%(n=84)	56.78	73.86
3 and Above	30% (n=36)	26.14	43.21

Staff Adherence level to Cold-Chain Management Guidelines and Influence on live attenuated Vaccines Stability

In 40% of the health facilities, staff did not transfer vaccines when the need arose; 8.3%did not defrost fridges; while facilities that did not dispense vaccines at VVM stage 2 but FEFO sequences were 45.8%. Transferred vaccines accounted for improved stability of both OPV (95%C.I; 3.1 – 16.8, OR 7.2, p value< 0.001) and stable measles-rubella vaccine (95% C.I, 2.1 – 10.4, OR, 4.7, p=value <0.001). In facilities that dispensed vaccines at VVM stage 2 ahead of FEFO sequences, OPV and measles-rubella vaccines were more stable (95%C.I, 6.0 - 49, OR17.2, p=value <0.001) and (95%C.I 3.325 -17.374; OR7.6, p=value <0.001) respectively. While defrosted fridges had enhanced stable

OPV (95% C.I, 1.1 – 15.5; OR 4.17, p=value 0.033), stable measles-rubella vaccines (95% C.I, 1.3 – 12.3, OR 4, p-value 0.0017) and stable ROTA vaccine (95% C.I 1.9 – 21.5; OR 6.3, p= value 0.003). Arrangement of vaccines in the fridge had significant influence on the stability of OPV (p-value 0.030) but did not predict any vaccine stability (*See table 3 and 4*) below. Food staff and non EPI drugs were occasionally observed in some fridges

Figure 1: Food stuff and non EPI drugs placed in the Fridge

Table 3: Cold-chain's guidelines adherence levels

POLICY FACTOR	YES	PERCENT (%)	NO	PERCENT (%)
Diluents In Fridge / Carrier	104	86.7%	16	13.3%
Extra Icepacks In Carrier	4	28.6%	10	71.4%
Vaccines Arrangement As Per Policy	81	67.5%	39	32.5%
Fridge Defrosted	110	91.7%	10	9.3%
Temperature Monitored Twice	75	62.5%	45	37.5%
Manual Temperature March Ft2	48	40%	72	60%
Vaccines Transferred As Per Need	74	61.7%	46	38.3%

VVM Stage 2 Issued Before FEFO	72	60%	55	40%
VVM Accurately Recorded	70	58.3%	50	41.7%

Table 4: Bivariate and multivariate analysis of providers' adherence levels to guidelines and stability of vaccines

	Bivariate Logistic Analysis of OPV			
Factor	**Odds Ratio**	**p-value**	**95% CI**	
FRIDGE DEFROST				
YES	4.17	0.033*	1.122	15.499
NO	Ref	Ref	Ref	Ref.
VACCINES ARRANGED PER POLICY				
YES	3.036	0.106*	0.791	11.65
NO	Ref	Ref	Ref	Ref.
VACCINES TRANSFERRED				
YES	7.216	<0.001*	3.091	16.846
NO	Ref	Ref	Ref	Ref.
VVM2 ISSUED BEFORE FIFO/FEFO				
YES	17.15	<0.001*	6.014	48.909
NO	Ref	Ref	Ref	Ref.
	Bivariate Logistic Analysis of M/R			
Factor	**Odds Ratio**	**p-value**	**95%CI**	
FRIDGE DEFROSTED				
YES	3.984	0.017*	1.286	12.342
NO	Ref	Ref	Ref	Ref.
VACCINES TRANSFERRED				
YES	4.741	<0.001*	2.163	10.392
NO	Ref	Ref	Ref	Ref.
VVM2 ISSUED BEFORE FIFO/FEFO				
YES	7.600	<0.001*	3.325	17.374
NO	Ref	Ref	Ref	Ref.
	Multivariate Logistic Analysis of M/R			
Factor	**Odds Ratio**	**p-value**	**95%CI**	
VVM2 ISSUED BEFORE FIFO/FEFO				
YES	4.419	0.002*	1.708	11.433
NO	Ref	Ref	Ref	Ref.
	Bivariate Logistic Analysis of ROTA			

Factor	Odds Ratio	p-value		95%CI
FRIDGE DEFROST				
YES	6.333	0.003*	1.867	21.481
NO	Ref	Ref	Ref	Ref.
VACCINES TRANSFERRED				
YES	4.469	0.015*	1.332	14.99
NO	Ref	Ref	Ref	Ref.

Multivariate Logistic Analysis of ROTA

Factor	Odds Ratio	p-value		95%CI
FRIDGE DEFROST				
YES	4.773	0.018*	1.307	17.438
NO	Ref	Ref	Ref	Ref.

Vaccines stability levels were classified into either stable or unstable. Findings revealed that 47% (n=56) of the fridges had some unstable oral polio vaccines; 30% (n=36) had some unstable measles-rubella vaccines, and 15.8% (n=19) had some unstable ROTA vaccines. (**See figure 1)**

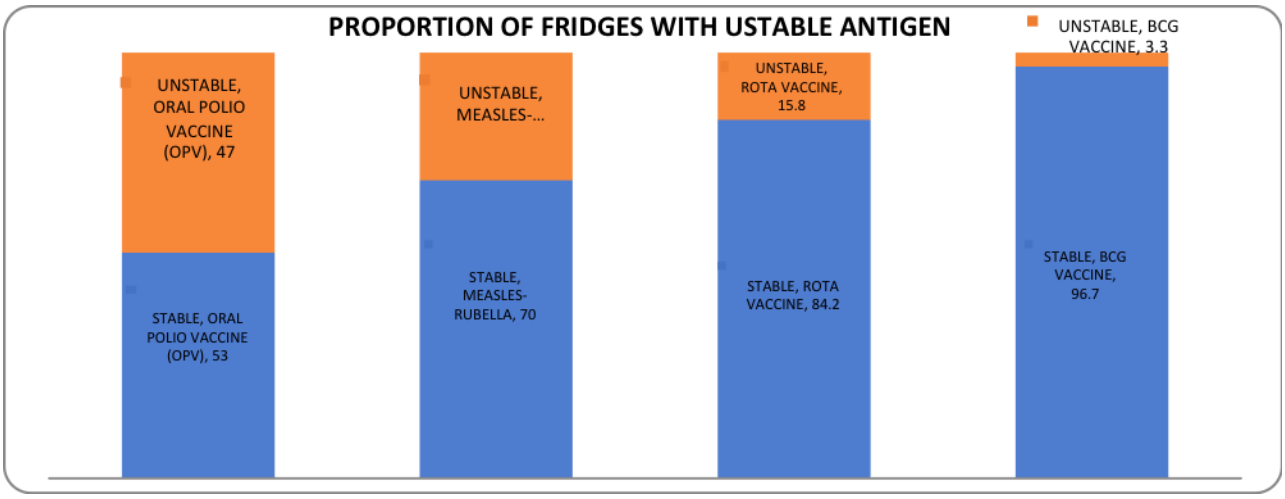

Fig. 2: Bar Graphs Showing Proportion Of Fridges versus Stability Status of Each Antigen

DISCUSSION

Though vaccines arrangements in the fridges were well observed in 67.5% of health facilities, OPV was still affected. It is possible that often, staff depict (stage-manage) ideal situations mainly during routine supervision to camouflage non-adherence. Evidence of food stuff and additional non-EPI drugs attests to non-adherence to guidelines. This might explain the observed OPV instability as frequent fridge opening precipitates internal temperature fluctuations. Similar lapses have been observed in other LMICs. Koskei *et al.*, (2017) observed 50% in a similar study in Kenya which compares closely

to a study by Rogie, *et al.*, (2013) who observed 45.5% adherence level to vaccines arrangement in Ethiopia. Both Rogie and Kosgei however, did not consider impact of these on the vaccine instability. Krishnappa *et al.*, (2014) established 36.4% adherence to vaccines arrangement order while they were evaluating cold-chain practices in urban health centers of a metro city in India.

Using VVM staging to dispense vaccines is a new technological approach of reducing vaccine wastage but seems to not be adequately observed by most staff. As shown in the study, 45.8% of facilities did not issue vaccines at VVM stage 2 instead they randomly dispensed, leading to a significant influence on all live-attenuated antigens in the study except BCG vaccine.

Based on VVM staging, it is worth appreciating that despite the fact that defrosting of fridges might have been a lesser concern in this County following the new supply of fridges, the 12.5% facilities which did not defrost had a significant adverse effect on the stability of all live attenuate vaccines except BCG. This implies vaccines spent more times outside the recommended range in freezing zones. It is possible that in this region uncertainties associated with erratic power supplies, lack of power back-up as well as wide climatic temperature ranges between 22^0C to 36^0C in a day precipitates poor fridge temperature regulation (Okomo *et al.*, 2019). While these challenges by themselves call for strict adherence to guidelines for the sake of sustaining vaccines' stability, the current study findings show considerable lapse in adherence with regard to vaccine arrangement, transfer vaccines and, defrosting fridges to ensure optimal temperature regulation. There is need to reconsider the current approach to conducting support supervision for immunization service providers at peripheral facilities. Remote temperature monitoring tool is an innovative digital technology that would help managers in prompting recurrent lapses to address them, for example through staff behavior change and competency based refresher cold chain management skills.

CONCLUSION

There are gaps in adherence to cold-chain system guidelines at health facility levels, such as failures to: transfer vaccines to safer fridges; defrosting of fridges and use of VVM staging to dispense vaccines a head of FEFO sequence. All had significant influence on the stability of ROTA, OPV and measles-rubella vaccines but not BCG. Placement of food stuff and non EPI drugs worsened the situation. It is justifiable to link these with the occasional resurgence of Rota diarrhea and measles diseases in Kisumu County.

Recommendations

- There is a need for a strengthened focused support, supervision to health facility staff by senior stakeholders in cold-chain management to improve adherence level to the guidelines
- There is a need for regular sensitization and updates to service providers on quality cold-chain management.
- Provision of additional fridges to every health facility that offers immunization is encouraged to cater for non EPI essential drugs which also require cold storage
- It is a rational idea to recommend fridges with ability freeze ice-packs for Kisumu County rather than the new non-freezing fridges in respect to warm climatic status in the region

Declarations

Ethics Approval

Ethical clearance was obtained from Maseno University Ethics Review Committee (Ref: MSU/DRPI/MUERC/00625/18). Consent and administrative approval was also obtained from the Kisumu County Director of heath. (Ref: CGK/DH/GN/133/VOLIII/ (232)/18; Medical officers in charge of each of the six Sub Counties and respective in charges / respondents in each health facility sampled.

Abbreviations

BCG: Bacilli Calmette-Guérin, EG: Electric Grid, EPI: Expanded Program on Immunization, FB: Faith Based, GOK: Government of Kenya, KEPI: Kenya Expanded Program on Immunization, MOH: Ministry of Health OPV; Oral Polio Vaccine, PR: Private, S/CHMT: Sub County Health Management Team, T.T: Tetanus Toxoid vaccine, VVM: Vaccine Vial Monitor, W.H.O: World Health Organization

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

MOOJ conceived, designed, coordinated and performed the study. MOOJ, DOA and BG analyzed the data. MOOJ and DOA drafted the manuscript. All authors read and approved the final manuscript.

Disclaimer

The findings and conclusions presented in this manuscript are those of the authors and do not necessarily reflect the official position of Maseno University

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Data Sharing

Requests for the data used for this analysis may be made to lead author, Moses Olunga Okomo John, jomokomo2010@yahoo.com, and can be shared

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