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This research was supported with a grant from the International Society for Infectious Diseases (ISID).

ISID Small Grant Report

Relationship between vaccine vial monitors and potency status of oral Polio virus vaccine among retrieved field samples in Kenya

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Background

The development and use of live attenuated oral poliovirus vaccine, has eliminated paralytic poliomyelitis as a public health concern in the industrialized world [1-3]. However, in the developing world, where an estimated 200,000 cases of paralytic poliomyelitis occur each year similar success has yet to be achieved [4,5]. Most of these cases reported from tropical and subtropical regions, are attributed to poor hygiene status, inadequate sanitation facilities among other factors facilitating the transmission of wild polioviruses and other enteric pathogens to the community [6].

In 1988 the World Health Organization (WHO) proposed mass immunization campaigns with the trivalent oral polio vaccine (TOPV) among children less than 5 years of age. TOPV, an effective vaccine against poliomyelitis, along with acute flaccid paralysis surveillance has restricted the incidence of polio to only a few countries. The Vaccine Vial Monitor (VVM) is a small patch of heat-sensitive material placed on the vaccine vial to register cumulative heat exposure. A direct relationship exists between the rate at which the VVM changes colour and ambient temperature. This in turn affects the potency of the oral polio vaccine. [7]

Objectives

To evaluate the status of the cold chain infrastructure in Kenya and to determine the total TOPV virus concentration of retrieved field samples.

Methods

Consent: This research did not involve human subjects and hence did not require the use of individual informed consent.

Sampling: A stratified multi-stage sampling strategy was used. Stage I involved sampling of facilities at each level. Stage II involved sampling temperature of equipment, power source and backup used to store the TOPV within each sampled facility in the stage I. Stage III involved sampling TOPV vials from equipment which was sampled for evaluation in Stage II. A sample of each batch contained in the facility was sampled. A total of 14 health centres were evaluated for this study.

Table 1: Sampled Health Centre

Kenyan terminology (WHO terminology)	Number sampled	Description
Medical Supply Agency store (WHO intermediate level-1)	2	This is a government funded national facility that supplies vaccine to all vaccinating facilities in the country.
Provincial Hospital (WHO intermediate level-2)	2	This is a state funded facility that acts as the highest vaccine distributer to the lower health facilities within a particular province. It may also have a vaccinating facility within it.
District Hospital (WHO health Centre)	4	This is a state funded facility that acts as vaccinating facility in a district within a province. It is an intermediate between provincial and sub-district facility.
Sub- district health centre (WHO health posts)	6	This is a state funded facility that acts as vaccinating facility.
Total	14	

A total of 23 TOPV vial samples were collected, separated into individual serotypes generating 69 samples for the potency test.

continued on next page

Vaccine potency test.
Potency of oral polio vaccine was assessed using L20 B cell line and tested using Karber's formula. Neutralization was first done on Vaccine samples to separate the viruses into individual serotypes. The samples were then subjected to titration to determine the individual titre of each virus contained in the vials. This was then compared to the Vaccine Vial Monitor stage of the vials

Results and Discussion

Equipment

a) Temperature

Fourteen cold chain storage facilities were evaluated for temperature.

Table 2: Cold Chain Evaluation.

Temperature	Number of Equipments	Percentage (%)
+2°c	1	7.1%
+3°c	2	14.3%
+4°c	5	35.8%
+6°c	2	14.3%
+7°c	1	7.1%
-18°c	1	7.1%
-22°c	2	14.3%
TOTALS	**14**	**100%**

All the facilities were monitoring temperatures and recording on a temperature recording charts.

b) Power Backup

Of the fourteen facilities eight (57.1%) had generators as power back up, four (28.6%) had gas as power backup and two (14.3%) facilities had no backup. Primary source of power for all the facilities was electricity. On average power blackouts were experienced twice a month in all health facilities.

Training on handling and discarding expired vaccine

A total of 14 facilities both distributing and vaccinating had their staff interviewed on handling expired vaccines.

Table 3: Staff Trained on Handling Expired Vaccine

	Number of facilities	Percentage (%)
	4 (Trained staff)	28.6%
	10 (No training)	71.4%
TOTALS	**14**	**100%**

Of the fourteen facilities only one (7.1%) had written guidelines on handling expired vaccines while the other 13 (92.9%) facilities had no guidelines.

Records on Vaccine Receipt and Deliveries

All 14 facilities (100%) that were distributing and vaccinating had records for vaccine receipt and deliveries.

Vaccine Vial Monitor (VVM) Stages

Twenty three oral poliovirus vaccine vials were evaluated for Vaccine Vial Monitor stages.

Table 4: VVM Score

Vaccine Vial Monitor Stage	Number of Vaccine vials.	Percentage (%)
VVM-I	15	65.3%
VVM-II	7	30.4%
VVM-III	0	0%
VVM-IV	1	4.3%
TOTAL	**23**	**100%**

Of the WHO recommended VVM stage for use in routine vaccination twenty two vials (95.7%) passed the VVM potency test. All the fourteen (100%) facilities had a displayed guide on scoring VVM.

continued on next page

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Vaccine Potency

This was done according to WHO potency testing standards.Vaccine contained in the trivalent poliovirus vaccine vials was neutralized using highly specific antisera to separate the serotypes to single serotypes (1, 2, & 3).this study included vaccines at VVM stages I and II as used in routine immunization. Our study showed that the average potency of polio vaccine serotype1, serotype 2 and serotype 3 were as follows;

Table 5.comparison between VVM1/VVM 2 and Serotype titres calculated

Polio 1 Standard (Mean Titre)	Polio 1 Test (Calculated Mean Titre)	Polio 2 Standard (Mean Titre)	Polio 2 test (Calculated Mean Titre)	Polio 3 Standard (Mean Titre)	Polio 3 test (Calculated Mean Titre)	VVM
10^6	$10^{6.05}$	10^5	$10^{4.98}$	$10^{5.5}$	$10^{5.73}$	1
10^6	$10^{6.83}$	10^5	$10^{5.88}$	$10^{5.5}$	$10^{5.35}$	2

**The mean titre was calculated using the Karber's formula [Log CCID50=L-d(S-0.5)]] with an allowance of + 0.5 log units*

Conclusion

Studies have shown that the thermo stability of poliovirus vaccine requires continuous monitoring of the cold chain. Exposure of poliovirus vaccine to higher temperatures causes rapid destruction making the vaccines unusable. [8] For successful Polio eradication it is necessary that storage and transport of OPV be ensured at all levels. The investigation noted that monitoring of storage conditions and potency of vaccines along with periodic training and reorientation of health personnel were required by the health facilities. More effort needs to be put in ensuring proper handling of vaccine vials and cold chain equipments.

Recommendations by the Expert Committee on Biologic Standardization, WHO are that each dose of Trivalent Oral Poliovirus Vaccine contain, at a minimum, 106 TCID50 of type 1, 105 of type 2, and 105.5 of type 3.[9] On average the vaccine vials used in the study were potent with satisfactory VVM and mean serotype titre. We found that some OPV vials had dissatisfactory VVM stage.Vaccine potency was seen to be directly proportional to VVM stage of vaccine vials. Vaccine vials kept at temperatures below -18°C had a better VVM leading to a better potency status. Some OPV Samples which had lower titre of serotype 2 were contributed to by the temperature of the equipment they were stored at.

A study needs to be done on the average difference between the satisfactory and dissatisfactory vials.

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This study was supported by a grant from the International Society for Infectious Diseases (ISID) under the Small Grants Program. We acknowledge the technical assistance provided by the staff of the Kenya Medical Research institute (KEMRI).