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Assessing the potency of oral polio vaccine kept outside of the cold chain during a national immunization campaign in Chad

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ABSTRACT

This study is the first systematic documentation of the potency of monovalent oral polio vaccine type 3 (mOPV3) kept at ambient temperatures during a polio immunization campaign in Chad. During the study test vials were exposed to temperatures of up to 47.1 °C, and kept outside of the 2–8 °C range for a maximum of 86.9 hours. Post-campaign laboratory testing confirmed that the test vials were still potent, and in conformity with the defined release specifications. Further, the Vaccine Vial Monitors performed as expected, giving an early warning indication of when cumulative exposure to heat reached levels that may have negatively affected the vaccine's potency. This study provides proof-of-concept evidence that certain types of OPV remain potent and thus can be kept, for limited periods of time, as well as administered at ambient temperatures.

1. Introduction

Oral polio vaccine (OPV) is the least stable of the vaccines commonly used in the Expanded Programme on Immunization (EPI) [1]. It is therefore recommended that OPV be kept in suitable cold chain conditions, ideally at −20 °C. However, if the vaccine cannot be kept at −20 °C, it can be kept between 2 and 8 °C for a maximum of 6 months, or for a period defined by the manufacturer based on real time stability data. Laboratory studies have demonstrated the correlation between exposure to heat and loss of vaccine potency [1].

Maintaining the cold chain under field conditions is frequently problematic, sometimes impossible and can be a major factor limiting the ability of immunization services to reach the entire population [2,3]. This is especially true during campaign activities, such as national or sub-national immunization days (NIDs or sNIDs). These NIDs, which aim to vaccinate all children under five, form a cornerstone of the global polio eradication strategy in both in endemic countries as well as for outbreak control in countries where the Polio virus can re-emerge [4]. Ideally, during campaign outreach activities, vaccinators should use vaccine carriers with frozen ice packs to prevent exposure to heat when transporting the vaccines. In Chad, as is the case in many other countries, polio immunization campaigns are faced with a limited availability of cold chain equipment and a limited ice and icepack production capacity. This makes maintaining OPV within the manufacturer recommended temperature range during campaign activities a challenge.

OPV vials, as with most other vaccines used in developing countries, are affixed with a vaccine vial monitor (VVM), in accordance with the joint WHO–UNICEF policy statement [5]. VVMs are small adhesive labels that gradually change colour as the vial's cumulative exposure to heat increases over time.

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When the vial has been exposed to cumulative heat levels at which the vaccine's potency can no longer be assured, the inner square on the VVM becomes darker than the outer reference ring. This allows health care workers to know whether the vaccine can safely be used even in situations where the cold chain cannot be guaranteed, or should unexpected cold chain breaks occur.

The vaccines that are part of the Expanded Programme on Immunization (EPI) have different sensitivities to heat. In order to account for this, there are several different types of VVMs. These are assigned to vaccines depending on the time (in days) that the potency of the vaccine remains above the WHO release specification at a temperature of 37 °C: VVM 2, 7, 14, and 30. OPV, which is the most heat sensitive of the EPI vaccines, is equipped with a VVM 2. This means the VVM of OPV reaches its endpoint after a cumulative exposure to 37 °C for two days [6] and/or 225 days when stored at +5 °C, with a 25% safety margin [7].

The rate at which the VVMs change colour has been proven in laboratory settings to be a reliable warning indicator of when heat exposure is likely to have negatively affected potency [8,9]. However, to-date these findings have not been systematically researched using vaccines exposed to field conditions.

2. Objectives

This study aims to investigate whether the potency of the OPV used during the campaign in Chad, and exposed to ambient temperatures while applying the WHO flexible cold chain management guidelines for OPV [10], is still within the acceptable potency range as measured in post-campaign laboratory testing. The study also aims to assess the relationships between the potency of the OPV, its assigned VVM and its exposure to heat.

3. Methodology

During a recent polio campaign in N'djamena, conducted as part of the Africa-wide Polio National Immunization Days (NID), 20 test vials were sent along with vaccinators while they conducted their regularly scheduled activities. These test vials were exposed to ambient temperatures while vaccination activities were conducted, but remained closed and unused throughout the study. The expiry dates of the vaccines were verified, and the temperatures to which these vials were exposed as well as their VVM status, were recorded at specified points throughout the day.

At the end of the campaign in N'djamena, the vials were transported to the Belgian National Control Laboratory in order to confirm that the correlations between VVMs and vaccine potency previously documented in laboratories hold true under field conditions.

For the purposes of this study, the same batch of vaccine that was used by Ministry of Health in Chad for its immunization campaign, monovalent oral poliomyelitis vaccine type 3 in 20 dose vials, was used. At the start of the study, 22 vials were selected at random: 20 'test vials' that would be exposed to ambient temperatures, and 2 'control vials' that would remain at the central cold store. All vials came from the same batch produced by a single manufacturer. These vials had travelled to Chad as part of the regular shipment for the NID, directly from the manufacturer to the central cold store in N'djamena. Once the vaccines were received at the central store by the Ministry of Health in Chad, they were kept in the central level freezer room, where temperatures were between −10 and −20 °C until the campaign.

3.1. Vial preparation

Prior to the start of the study, the 20 test vials were labelled T1 through T20, and a Libero PDF datalogger was attached to each. The Libero PDF datalogger, manufactured by ELPRO, is able to record 16,000 data points/device, and have proven reliable between −35 °C and +70 °C (accurate to ±0.5 °C). In addition, Liberos feature a visual temperature display, which allowed for periodic recording and verification of the temperatures during the study [11]. The two control vials, labelled C1 and C2 respectively were each assigned a digital LogTag temperature monitor, manufactured by LogTag Recorders Ltd., to continuously record their temperature exposure at all times [12].

In addition to continuous temperature monitoring, VVM status of the test and control vials were checked and recorded at the start of the study at the central store. The visual percentage-based colour intensity classification scale was used to conduct these readings, which had previously been used successfully in Mali [13] (Fig. 1). VVMs were deemed to have reached their discard point when the inner square reached the same colour as or was darker than the outer control ring, which, based on the scale used, is 100%. Both the ambient temperature and the VVM status were recorded on the tracking sheet that accompanied each vial.

3.2. Vial distribution

The 20 test vials were equally divided into two groups: one-day vials and two-day vials. One-day vials were, as indicated by their name, exposed to one day of campaign activities at ambient temperatures; two-day vials were exposed to a second day of campaign activities at ambient temperatures.

These vials were distributed amongst four health centres, selected purposively to represent a mix of urban, peri-urban and village settings. Attention was paid to ensuring each health centre received a mix of both types (one-day and two-day) of vials. These health centres were a mix of city centre (Polyclinic), outer city limits (Goudji) and those servicing small villages (Hele Houdjaj and Ardeptimane).

The test vials were stored and packed alongside the regular campaign vaccines at the central store and were transported to their respective health centres along with the regular campaign vaccines one to two days prior to the campaign. Upon arrival at the health centre, the VVM status and the temperature inside the vaccine carrier on arrival were recorded in each vial's record sheet. Once at the health centre, the test vaccines were kept alongside the regular campaign vaccines. This resulted in exposure to various storage conditions, as per the availability of cold chain space and equipment and the length of time until the start of the campaign activities. Vaccines were kept either in refrigerators (city centre Polyclinic) or in cold boxes with frozen icepacks (Goudji) or in a mix of both (Hele Houdjaj and Ardeptimane).

3.3. Vaccinator training and survey

On the day prior to the campaign, vaccinators were trained on conducting VVM visual reading using the percentage-based scale, given an overview of the Libero PDF datalogger and shown how to complete the study data collection form. A refresher session was conducted the morning the vaccination activities took place. A supervisor reviewed the first recording of the day to ensure there were no remaining questions. In addition, at the end of the days' activities, a supervisor validated the VVM and temperature readings upon return to the health centre. On return to the health centre, vaccinators were also asked to complete a quick survey on their views on the controlled temperature chain (CTC) practice.