Assessment of cold-chain maintenance in vaccine carriers during Pulse Polio National Immunization Day in a rural block of India

Abhijit P Pakhare, Surya Bali, Radhakishan B Pawar, Ganesh S Lokhande

ABSTRACT

India was certified polio free on 27 March 2014. Supplementary immunization activities, in the form of national immunization days, is one of the core strategies for eradication, where oral polio vaccine is administered to children aged under 5 years throughout the country. Oral polio vaccine is heat sensitive and requires maintenance of a stringent cold chain. Therefore, vaccine carriers with ice packs are used in the Pulse Polio Immunization (PPI) programme. This study assessed whether the cold chain is maintained during National Immunization Day in Beed district. A cross-sectional study was conducted at six randomly selected booths, one each from six primary health centres in Georai block of Beed district in Maharashtra. Electronic data loggers, configured to measure half-hourly temperatures, were kept in vaccine carriers throughout the day of PPI. The vaccine carrier temperature was below 8 °C at all six booths; minimum temperature recorded was –9.5 °C, while the maximum was 4.5 °C. The vaccine vial monitor did not reach discard point in any booth. A vaccine carrier with four ice packs very effectively maintains the cold chain required for oral polio vaccine.

Key words: Cold chain, data logger, national immunization day, oral polio vaccine, Pulse Polio, vaccine carrier

INTRODUCTION

India was certified polio free on 27 March 2014. The use of oral polio vaccine (OPV) on National Immunization Days (NIDs) throughout the country, followed by intensified house-to-house activity, mop-up rounds, surveillance for acute flaccid paralysis, and strengthening of the routine immunization programme, are core strategies adopted for polio eradication.

During NID, OPV is administered by trained vaccinators in booths located at places that are easily accessible to the community. Booth activity begins at 08:00 and is completed at 17:00. OPV is a heat-sensitive vaccine and needs to be stringently maintained in a cold chain at a temperature below 8 °C. Therefore, OPV is supplied at booths in a vaccine carrier from the respective primary health centre. Vaccine vials are usually wrapped in polythene and kept in a carrier with four ice packs, then transported to the booth site early in the morning. Supervisors designated for NID are expected to visit booths, check ice packs and replace them if melted. A vaccine vial monitor (VVM) is used to check whether the vaccine is in a usable condition or needs to be discarded.

Operational guidelines for the Pulse Polio Immunization (PPI) programme emphasize the necessity of using a vaccine carrier with four ice packs and monitoring with a VVM. The authors have been involved in NID implementation in Beed district. During discussion with health workers, we found that there are some operational difficulties perceived by health workers in preparing ice packs in the required quantity, and replacing them according to requirement during NID activity. In their opinion, it would be more convenient if immunizations could be done without ice packs.

Halm and colleagues reported on the feasibility of using OPV during NID in Mali without ice packs. They found that none of the VVMs reached discard point and that vaccinators preferred conducting NIDs without ice packs. However, Shrivastava and colleagues have reported that VVMs are not reliable when the environmental temperature is high and advised caution when using protocols outside the cold chain.

Assessment of the cold chain during PPI in rural India has been reported by various researchers. These studies involved assessment of the cold chain by monitoring the temperature of
ice-lined refrigerators and deep freezers at the primary health centres, while the cold chain at the booth sites was assessed with VVM readings. These readings are an indirect indicator of the temperature effect in cold-chain monitoring. Studies involving recording of the actual temperature in vaccine carriers at booth sites, which can be easily done with electronic portable devices such as data loggers, are lacking. This study was designed to use data loggers to assess whether the cold chain is maintained during NID in a vaccine carrier with the recommended four ice packs.

METHODS

This was a cross-sectional study, set in OPV immunization booths in a rural block of India on an NID of the PPI programme. The study was conducted on 15 April 2012 in Georai block of Beed district of India. Georai block comprises six primary health centres where data loggers were available. One booth from each primary health centre was randomly selected for the present study.

Data loggers are instruments that can record temperatures at scheduled intervals. This study used the EL-USB-1 (Lascar Electronics) temperature data logger. The EL-USB-1 is a USB temperature data logger with a measurement range of –35 °C to +80 °C (–31 °F to +176 °F). It can store up to 16 382 USB temperature data logger with a measurement range of orange LEDs. The status of EL-USB-1 is indicated by flashing red, green and one year (depending on the logging rate and temperature). The battery, allowing the unit to log data continually for at least

The unit was configured using the software provided with the data logger, to record temperature every 30

Data loggers were wrapped in polythene and kept in vaccine carriers at the time of loading the carriers with vaccine vials and ice packs. For NID, frozen ice packs are used according to guidelines. On NID, vaccine vials are transported early in the morning to the booth site. Therefore, data loggers were configured to record half-hourly temperature from 05:00, which is the time at which loading of ice packs and vaccine vials starts in the respective primary health centres, until 17:30, when the carriers are brought back. All data loggers were kept in the vaccine carriers before 05:00, except for one primary health centre where the data logger was placed at around 08:30. Vaccinators remove one vial at a time from the vaccine carrier and close the lid to avoid temperature fluctuation. It is opened only when the earlier vial is completely used up, or its VVM changes to the discard point.

Readings of each data logger were then transcribed using software in the form of a spreadsheet and a graphic output. Descriptive statistics measures were calculated using Microsoft Excel.

Permission for the study was obtained from the district health officer.

RESULTS

Data loggers were placed in all vaccine carriers at 05:00 except for PHC-5 where it was placed at 08:30. The temperature of all vaccine carriers was below 8 °C throughout period of immunization activity during NID. Table 1 shows, for each site, the average, minimum and maximum temperatures; number of beneficiaries given OPV; number of times ice packs were changed; number of vials whose VVMs reached discard point; and duration of freezing temperature. Figure 1 shows the temperature measured by data loggers for each booth. In PHC-4, the health workers replaced the ice packs in the afternoon.

DISCUSSION

This study found that the cold chain was maintained during NID in Beed district. It objectively confirms the utility of vaccine carriers with four ice packs in maintaining the cold chain required during NIDs.

In a recent study by Halm et al., reliance on VVMs is recommended for conducting NID without the use of ice packs. They also reported less wastage of vaccine and greater user preference for this strategy. However, Shrivastava et al. have reported that although a VVM can be relied on and gives an earlier indication of the discard point at ambient

Table 1: Booth-wise distribution of vaccine carrier temperature

<table>
<thead>
<tr>
<th>Site</th>
<th>Mean temperature, °C (standard deviation)</th>
<th>Temperature range, minimum to maximum, °C</th>
<th>Number of beneficiaries (number of vials of 20 dosages used/carrying at the booth)</th>
<th>Number of times ice packs were changed</th>
<th>Number of vials whose vaccine vial monitor reached discard point</th>
<th>Duration of freezing temperature, min</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHC-1</td>
<td>0.88 (1.23)</td>
<td>−2.50 to 2.50</td>
<td>190 (11/15)</td>
<td>0</td>
<td>0</td>
<td>90.00</td>
</tr>
<tr>
<td>PHC-2</td>
<td>1.48 (0.91)</td>
<td>−0.50 to 3.00</td>
<td>148 (8/10)</td>
<td>0</td>
<td>0</td>
<td>30.00</td>
</tr>
<tr>
<td>PHC-3</td>
<td>0.85 (0.83)</td>
<td>0.00 to 4.50</td>
<td>113 (7/9)</td>
<td>0</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>PHC-4</td>
<td>−0.35 (3.48)</td>
<td>−9.50 to 3.00</td>
<td>80 (4/5)</td>
<td>1</td>
<td>0</td>
<td>180.00</td>
</tr>
<tr>
<td>PHC-5</td>
<td>−1.47 (3.55)</td>
<td>−9.50 to 2.00</td>
<td>122 (7/9)</td>
<td>0</td>
<td>0</td>
<td>240.00</td>
</tr>
<tr>
<td>PHC-6</td>
<td>1.13 (1.38)</td>
<td>−1.00 to 5.50</td>
<td>294 (17/20)</td>
<td>0</td>
<td>0</td>
<td>90.00</td>
</tr>
</tbody>
</table>

PHC: primary health centre.
temperatures of 37 °C and 41 °C, at 45 °C it was not reliable, as the discard point was not reached in more than half of the vials even at the half-life point of the vaccine. In 2012, one of the NIDs was organized in the month of April when environmental temperatures in different states are high and a VVM alone cannot be relied upon. India’s PPI programme guidelines emphasize the importance of using a vaccine carrier with ice packs and, considering the effectiveness of vaccine carriers with ice packs in maintaining the cold chain, we recommend that their use be continued for NID.

From a programme perspective, future research might assess whether a lesser number of ice packs is able to maintain the required temperature as effectively. In addition, studies should specifically focus on investigating cold-chain maintenance in vaccine carriers during transportation (using data loggers) of vaccine from the last vaccine storage point to the routine immunization outreach sessions.

The study has some limitations. Although booths were selected randomly, health workers were aware of the presence of the data logger in the vaccine carrier, which gives scope for the possibility of frequent changes of ice packs. However, only one site reported a change of ice pack, on one occasion.

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**REFERENCES**


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