



Benefits of using vaccines out of the cold chain: Delivering Meningitis A vaccine in a controlled temperature chain during the mass immunization campaign in Benin[☆]



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ABSTRACT

Background: In October 2012, the Meningococcal A conjugate vaccine MenAfriVac was granted a label variation to allow for its use in a controlled temperature chain (CTC), at temperatures of up to 40 °C for not more than four days. This paper describes the first field use of MenAfriVac in a CTC during a campaign in Benin, December 2012, and assesses the feasibility and acceptability of the practice.

Methods: We implemented CTC in one selected district, Banikoara (target population of 147,207; 1–29 years of age), across 14 health facilities and 150 villages. We monitored the CTC practice using temperature indicators and daily monitoring sheets. At the end of the campaign we conducted a face-to-face survey to assess vaccinators' and supervisors' experience with CTC.

Findings: A mix of strategies were implemented in the field to maximize the benefits from CTC practice, depending on the distance from health centre to populations and the availability of a functioning refrigerator in the health centre. Coverage across Banikoara was 105.7%. Over the course of the campaign only nine out of approx. 15,000 vials were discarded due to surpassing the 4 day CTC limit and no vial was discarded because of exposure to a temperature higher than 40 °C or due to the Vaccine Vial Monitor (VVM) reaching its endpoint. Overall confidence and perceived usefulness of the CTC approach were very high among vaccinators and supervisors.

Interpretation: Vaccinators and supervisors see clear benefits from the CTC approach in low income settings, especially in hard-to-reach areas or where cold chain is weak. Taking advantage of the flexibility offered by CTC opens the door for the implementation of new immunization strategies to ensure all those at risk are protected.

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1. Introduction

Despite immunization being one of public health's most effective and cost-friendly interventions, over 20 million children worldwide are under vaccinated, and remain at risk of vaccine preventable diseases each year [1]. The need to continually keep vaccines in a 2–8 °C cold chain is a major constraining factor for achieving universal immunization coverage and impacts the choice

of vaccination strategies and activities, especially in the 'last mile', from health centre to vaccinee.

Many of the vaccines used today have some inherent stability in addition to what is currently reflected on their label [2–4]. Reflecting that stability on the product label would allow for limited use of the vaccine outside of the cold chain, without the constraints of needing to maintain 2–8 °C at all times.

The cold chain in the last mile is particularly labour intensive during immunization campaigns, such as those conducted across sub-saharan Africa against Meningitis A. Given the size of the target populations for MenAfriVac – up to 70% of the population, all those aged 29 years and under [5,6] – the logistical challenges in maintaining the cold chain, from faltering electricity, poorly functioning or absent equipment, to ice pack production capacity, are significant.

In October 2012, the Meningococcal A conjugate vaccine MenAfriVac was granted a label variation by the national regulatory

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authority in its country of manufacture and pre-qualified by WHO to allow for its use in a controlled temperature chain (CTC), at temperatures of up to 40 °C for not more than four days. This marks the first time a vaccine used in developing countries has been granted authorization to be used at ambient temperature. This paper evaluates the first use of the flexibility offered by MenAfriVac's new label during a mass vaccination campaign in Benin.

2. Objectives

The study aimed to capture the first field experience using MenAfriVac in a CTC, to evaluate whether the implementation of CTC – rather than a traditional 2–8 °C cold chain – during a mass campaign is feasible, acceptable to health care workers, and to identify the benefits and challenges of the approach.

3. Methods

3.1. Study site

The study took place in the district of Banikoara in Northern Benin as part of the sub-National Meningitis A vaccination campaign held from November 15–25, 2012. Banikoara is a rural area, made up of 150 villages and hamlets, divided into nine administrative zones. There is one rural hospital, one district health centre, nine smaller health centres and three dispensaries. The population is 210,296 (as of 2012), 70% of which are estimated to be 29 years of age or younger (target population = 147,207). Banikoara was selected as the site for this pilot study by the Ministry of Health in Benin, using criteria developed by WHO's Immunization Practices Advisory Committee as part of their guidance on the implementation of CTC campaigns for MenAfriVac [7]. During this campaign, Banikoara used a mixture of fixed site and mobile/outreach teams to vaccinate the population; all vaccination activities conducted in Banikoara were conducted using the CTC approach.

3.2. The vaccine

MenAfriVac is a Meningitis A polysaccharide conjugate vaccine designed for use across the sub-Saharan African meningitis belt. It comes in a 10-dose vial, with a separate diluent which contains an aluminium adjuvant, which is sensitive to freezing. As is standard for vaccines procured through UN agencies, the vaccine comes with a Vaccine Vial Monitor (VVM) on its label [8].

The original label for MenAfriVac stated that the vaccine should be kept between 2 and 8 °C at all times. As with all vaccines, these storage and use conditions on the vaccine's label were approved as part of the vaccine's licensure by the national regulatory authority in the country where the vaccine is manufactured, in this case India. In October 2012, based on scientific laboratory studies and analyses submitted by the vaccine manufacturer (Serum Institute of India), MenAfriVac's regulatory agency of record (India) and WHO both approved a revision to the label which states that MenAfriVac and its diluent can *"be stored at up to 40 °C for not more than four days immediately prior to administration, provided the vaccine has not reached its expiry date and the vaccine vial monitor is still valid, Unopened vials should be discarded at the end of the four days at up to 40 °C. Reconstituted vaccine should be used within six hours after reconstitution, otherwise discarded."*

3.3. Implementation of CTC

In order to ensure the vaccine is safe and effective at all times when used in a CTC, vaccination teams, comprised of one nurse and two volunteers relied on two indicators: the VVM, affixed to

the label of the vaccine, and a peak temperature threshold indicator – a small laminated card with a heat sensitive sticker that changed colour immediately upon being exposed to 40 °C, placed inside each vaccine carrier. Unlike the VVM, which gradually changes colour over time to reflect cumulative exposure to heat, the peak temperature threshold indicator is binary, and changes colour instantly if exposed to temperatures of 40 °C, without a gradual change. Teams were instructed to check this card at the start of their day, upon arrival at their vaccination site, and prior to opening each new vial throughout the day. If they found that either the VVM or the peak threshold indicator had changed colour, they were advised to stop using the vaccines and contact their supervisor immediately.

In addition to the standard pre-campaign training conducted in all campaign areas in Benin, training was provided in Banikoara on CTC prior to the campaign. This included explanations of what CTC is, how to use the threshold indicator, a review of all forms to complete and how to read the VVM, training on adverse events following immunization as well as 'scenario planning', on how to take advantage of the flexibility provided by CTC.

Teams were asked to complete a CTC monitoring form daily as follows: before departing the health centre, on arrival at the vaccination site, on administration of the last dose of vaccine and on return to the health centre. Teams recorded the time each of these activities took place, the number of vials they had with them at that point, and the status of the peak threshold indicator.

At the end of each day, when teams returned to the health centre, any vials that they had taken with them for the day but not used were marked with a line on the label, indicating one day of CTC exposure. All the marked vials from all teams were consolidated and stored at ambient temperature overnight, and were the first vials distributed to the teams for use the next day. Teams were instructed to use the marked vials first. From the second day of the campaign, teams indicated the number of marked and unmarked vials they took with them at the start of each day on their CTC monitoring form.

As this was the first use of CTC in a mass campaign, and in order to ensure the tools were being properly used, six additional supervisors were recruited to oversee campaign activities and provide support to vaccinators.

3.4. Data collection

The data on coverage, vaccine wastage and adverse events following immunization were collected using standard Ministry of Health issued forms.

Data on CTC specific vaccine wastage was collected through the specially designed CTC monitoring form, described above. At the end of the campaign a survey was conducted to evaluate the CTC practice among the vaccinators and supervisors in Banikoara. The survey was pre-tested with vaccinators prior to being administered. The survey included 20 multiple choice and short answer questions.

4. Results

Three different CTC scenarios were implemented in the campaign, based on the situation found in Banikoara.

The *first scenario* was the most standard option, used by all three dispensaries and seven of the health centres. It involved keeping the vaccines in the standard cold chain at the health centre. This meant the vaccine was transported from the district level to the health centre using the cold chain and placed into the fridge at district level. On the first morning of the campaign, vaccination teams arrived at the health centre and retrieved their vaccines. The vaccines were placed into a standard vaccine carrier, without icepacks, marking the beginning of the CTC practice.

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