

# **Use of MenAfriVac™ (meningitis A vaccine) in a controlled temperature chain (CTC) during campaigns**

## **Training module for organizing immunization sessions**

**Immunization, Vaccines and Biologicals**



**World Health  
Organization**

# **Use of MenAfriVac™ (meningitis A vaccine) in a controlled temperature chain (CTC) during campaigns**

**Guidance for immunization  
programme decision-makers  
and managers**

**Immunization, Vaccines and Biologicals**



**World Health  
Organization**

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**The Department of Immunization, Vaccines and Biologicals  
thanks the donors whose unspecified financial support  
has made the production of this document possible.**

This document was produced by the  
*Expanded Programme on Immunization (EPI)*  
of the Department of Immunization, Vaccines and Biologicals

This document forms part 2 of 3 parts of the training guide for  
the Use of MenAfriVac™ (meningitis A vaccine) in a  
controlled temperature chain (CTC) during campaigns

*Ordering code: WHO/IVB/13.05*  
*Printed: July 2013*

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**Printed by the WHO Document Production Services, Geneva, Switzerland**

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# Acknowledgements

This module has been prepared based on the following documents:

- Briefing to Immunization Practices Advisory Committee (IPAC) members July 2012. Proposed way forward: Use of threshold indicators for Meningitis A campaigns using CTC.
- Use of the Meningitis A vaccine MenAfriVac™ in a controlled temperature chain (CTC) during campaigns. Guidance for immunization programme decision-makers and managers.
- Immunization in Practice: A practical guide for health staff. Geneva, World Health Organization, 2004 (WHO/IVB/04/06).
- The initial draft of the training materials were completed by Karin Bergstrom.

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# Learning objectives of this module

By working through this module, you will learn how to integrate controlled temperature chain (CTC) into your regular immunization sessions during an immunization campaign with the Meningitis A vaccine. In particular, you will learn:

- the process for using the controlled temperature chain;
- how to plan for the immunization sessions during an immunization campaign with Meningitis A vaccine;
- how to prepare to transport vaccines using the controlled temperature chain;
- how to use the controlled temperature chain while transporting vaccines;
- how to use the controlled temperature chain during an immunization session.

As you read through the module you might find an unfamiliar word. If this is the case, ask one of your facilitators for assistance.

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# About meningitis

Meningococcal meningitis is an infection of the brain and spinal cord. It is caused by the bacterium *Neisseria meningitidis* (the meningococcus). The disease occurs throughout the world, but in sub-Saharan Africa meningitis epidemics occur every two to three years. Since the 1980s, the intervals between major epidemics have become shorter and more irregular. The disease is most common in young children, but it can also be found in children and young adults living in crowded conditions, such as institutions or barracks. In 2000, it is estimated that there were 300 000 cases and between 25 000 and 30 000 deaths from meningococcal meningitis.

Transmission of bacteria is from person-to-person through airborne droplets from the nose and throat of infected people. In children, if meningitis is not treated, mortality is 50%, but with early treatment mortality is reduced to between 5% and 10%. Even with treatment early in the disease, between 5% and 10% of children who are infected die. About 10%–15% of those surviving meningococcal meningitis will suffer from complications, including mental disorders, deafness, palsies and seizures. A less common, but more severe and often fatal form of meningococcal disease, is meningococcal septicaemia, which is characterized by rapid circulatory collapse and a haemorrhagic rash.

To protect as many persons as possible from the disease, immunization campaigns are organized. New technologies are being developed to facilitate the organization of these immunization campaigns. In this module, you will learn more about some of these technologies and how to use them during an immunization session.

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# 1. The cold chain

Vaccines are sensitive to heat and freezing and must be kept at the correct temperature from the time they are manufactured until they are used. The system used for keeping and distributing vaccines in good condition is called the **cold chain**. The cold chain consists of a series of storage and transport links, all designed to keep vaccines within an acceptable temperature range until they reach the user.

Maintenance of the cold chain requires vaccines and diluents to be:

- collected from the manufacturer, or an airport, as soon as they are available;
- transported between +2°C and +8°C from the airport and from one store to another;
- stored at the correct temperature in primary/central and intermediate vaccine stores and in health facilities;
- transported between +2°C and +8°C to outreach sites and during mobile sessions;
- kept between +2°C and +8°C range during immunization sessions;
- kept between +2°C and +8°C during return to health facilities from outreach sites.

You have been working with vaccines and organizing immunization sessions, so this module will not go into detail about the management of the cold chain. If you need more information about the cold chain you can refer to the training material from the World Health Organization called *Immunization in Practice: A practical guide for health staff*.



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## 2. The controlled temperature chain

Many vaccines used in immunization programmes today are actually more heat stable than is reflected in their current labelling. Keeping vaccines in a traditional +2°C to +8°C range cold chain is frequently extremely difficult, if not impossible, in settings with limited cold chain and ice pack production capacity. Therefore, many tests have been done to determine which vaccines can, for a limited period of time and under strict control, be kept outside the traditional +2°C to +8°C range cold chain. These tests have confirmed that it is possible to use MenAfriVac™ for a period of **up to four days at temperatures of up to 40°C**. In addition, the vaccine can be kept at temperatures of up to 40°C after reconstitution, for up to six hours. This system is called a **controlled temperature chain (CTC)**.

Thus, the CTC allows vaccines to be stored and transported:

- when on-label at temperatures outside the traditional +2°C to +8°C range cold chain for limited periods of time;
- under monitored and controlled conditions;
- as appropriate to the stability of the antigen;
- provided the vaccine is labelled with a vaccine vial monitor (VVM).

It is very important to remember that the CTC applies only to some vaccines.

### **CTC, the controlled temperature chain**

CTC, the controlled temperature chain, allows vaccines to be stored and transported at temperatures outside the traditional +2°C to +8°C range cold chain for limited periods of time, under monitored and controlled conditions, as appropriate to the stability of the antigen and provided the vaccine vial is labelled with a VVM.

The Ministry of Health in your country has decided that the Meningitis A vaccine, MenAfriVac™ can be used in a CTC during immunization campaigns. The manufacturer has revised the label.

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**The new, revised label for MenAfriVac™ states:**

The MenAfriVac™ vaccine can be stored under a controlled temperature chain (CTC), up to 40°C for not more than four days immediately prior to administration, provided that the vaccine has not reached its expiry date and the vaccine vial monitor is still valid. It can be kept at up to 40°C for up to six hours after reconstitution.



**STOP**

**Now do Exercise A — written exercise  
and group discussion**

When you reach this point, you are ready to do Exercise A. Turn to the section of the module that contains the exercises, located towards the back of the module, and find the exercise. Follow the instructions to prepare your answers. When everyone is ready, there will be a group discussion.

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## 3. Monitor the controlled temperature chain

To use the controlled temperature chain you must use two kinds of temperature monitors; the vaccine vial monitors (VVM) and the peak threshold temperature indicator. You are probably already familiar with the VVM. However, to facilitate the comparison, the VVM is briefly described below, followed by a description of the peak threshold temperature indicator.

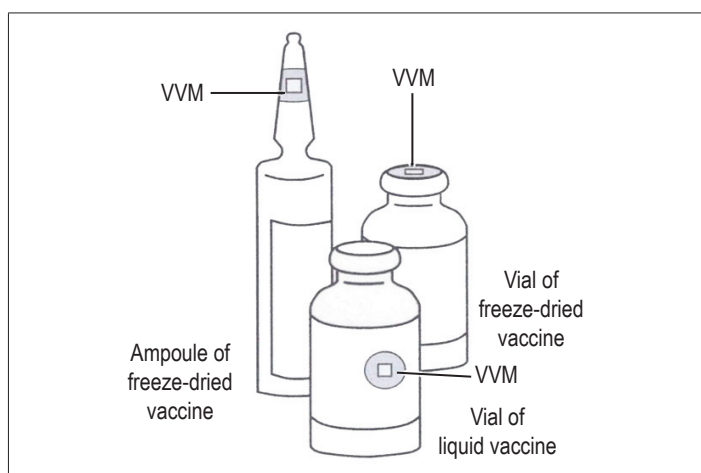
### 3.1 The vaccine vial monitor

A VVM is a label that changes colour when the vaccine vial has been exposed to heat over a period of time. Before opening a vial, you must check the status of the VVM to verify that the vaccine has not been damaged by heat. Manufacturers attach VVMs to vials of most vaccines.

The VVM is printed on the vial label or cap. It looks like a square inside a circle. If the vaccine vial is exposed to more heat, the square becomes darker. If the vaccine has been subjected to excessive heat that risks making it sub potent, the VVM shows this when the colour of the inner square is the same or darker than the outer circle.

You can use only vials with inner squares that are lighter in colour than the outside circle. Vials with VVMs in which the inner square has begun to darken, but is still lighter than the outer circle, should be used before the vials with a lighter inner square. Figure 1 shows how the VVM is placed on the vaccine vial.





**Figure 1: VVM on vial label or cap<sup>1</sup>**



In Figure 2 below you can see how to read and interpret the VVM.

<sup>1</sup> Source: Immunization in Practice. A practical guide for health staff. Module 3: The cold chain. Geneva, World Health Organization, 2004.

Figure 2: How to read a vaccine vial monitor (VVM)<sup>2</sup>

	✓	Inner square lighter than outer circle. <i>If the expiry date has not been passed, USE the vaccine.</i>
	✓	At a later time, inner square still lighter than outer circle. <i>If the expiry date has not been passed, USE the vaccine.</i>
	✗	<b>Discard point:</b> Inner square matches colour of outer circle, <i>DO NOT use the vaccine. Inform your supervisor.</i>
	✗	Beyond the discard point: Inner square darker than outer circle, <i>DO NOT use the vaccine. Inform your supervisor.</i>

### 3.2 The peak temperature threshold indicator

The peak temperature threshold indicators **do not replace** VVMs. The peak temperature threshold indicator measures **PEAK** exposure to heat, while the VVMs measure **CUMULATIVE** exposure to heat. Figure 3 below shows a peak temperature threshold indicator in actual, or real, size.

A peak temperature threshold indicator is a small, round sticker on a card. The sticker has the form of a black circle with a white circle in the middle. The sticker changes colour irreversibly when it is exposed to a peak temperature for a maximum period of time; the white colour in the middle turns black and thus the whole circle is black (see Figure 3 below). The indicator changes colour when the vaccine has been exposed to a **peak temperature** (i.e. a temperature over 40°C), which means the vaccine may no longer be effective and should not be used. You should immediately inform your supervisor if this happens.

You should not use the controlled temperature chain if you are not using the peak threshold temperature indicator. Without the peak temperature threshold indicator you cannot ensure that the vaccines have not been exposed to the peak upper limit of +40°C.

<sup>2</sup> Source: Immunization in Practice. A practical guide for health staff. Module 3: The cold chain. Geneva, World Health Organization, 2004.

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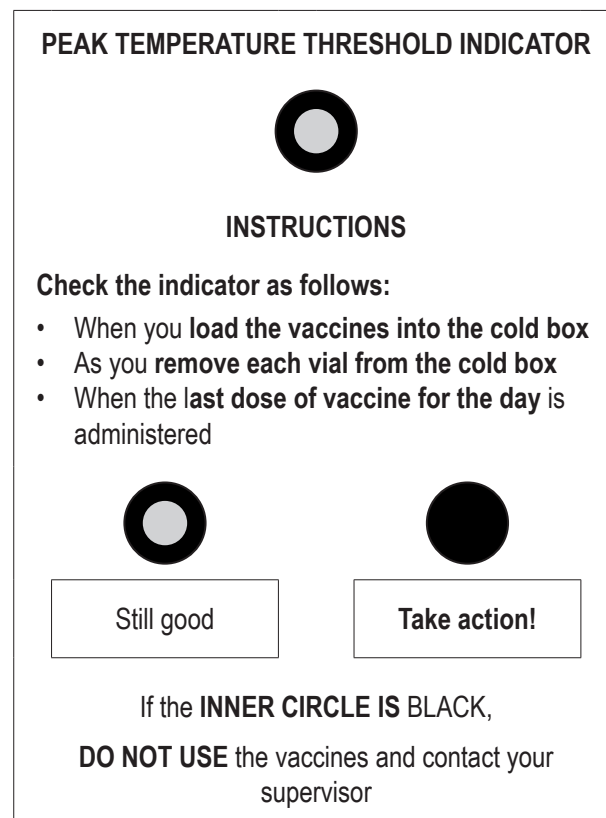
When using the CTC, the peak temperature threshold indicator should be used:

- **IMMEDIATELY** when you remove the vaccines from the traditional +2°C to +8°C range, a threshold indicator must be placed in the vaccine carrier/container with the vaccine.

Place the peak temperature threshold indicator inside the vaccine carrier for outreach immunization activities or transport. If you are transporting the vaccine in its original cardboard box packaging, place a peak temperature threshold indicator inside the box (one indicator per box of 3000 doses). The indicator should be kept in the vaccine carrier/container the whole time. There is no need to place a peak temperature threshold indicator in the diluent boxes.

It is important to note that the peak temperature threshold indicator should not be exposed to direct sunlight; it should be kept in the vaccine carrier at all times, or stored in a dark cool place in the health centre/district prior to use.

**Figure 3: The peak temperature threshold indicator**



### 3.3 Vaccine carriers

The standard vaccine carrier is still the preferred option for transporting vaccines in a CTC. The vaccine carrier has the advantage that it is associated with immunization activities, both by you and the community. You are also very familiar with its operation and use. However, when using the CTC, there is no need to insert and transport ice packs. This means that there will be much more space in the vaccine carrier. This does not mean, however, that you should put a lot more vaccine vials in the vaccine

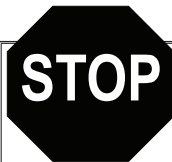
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carrier. You need to carefully calculate your vaccine needs, depending on your target population and your session plan, so that vaccines are not wasted. This is discussed more in chapter 5 below.

If you choose not to use vaccine carriers, it is important to ensure that you carry the vaccine in a carrier that:

- is well insulated
- protects the vaccines from direct sunlight
- keeps the vaccines and diluents safe from breakage.

The container used for transporting the vaccine should be sturdy (no loose bags), be dedicated specifically for vaccine transportation and not carry other equipment or supplies.



**Now do Exercise B — demonstration,  
written exercise and group discussion**

When you reach this point, you are ready to do Exercise B. Turn to the section of the module that contains the exercises, located towards the back of the module, and find the exercise. Follow the instructions to prepare your answers.  
When everyone is ready, there will be a group discussion.

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## 4. Transport vaccines using the controlled temperature chain

Before deciding to transport vaccines in a CTC, you must plan the CTC timeline. The CTC timeline is the time counted from when you take the vaccines out of the traditional +2°C to +8°C range cold chain until any remaining vaccines are placed back in the traditional cold chain. This period of time can be a **maximum of four days**. Once the vaccine is removed from the cold chain, its CTC use has started.

You should put one peak temperature threshold indicator in each vaccine carrier or cold box, or in the cardboard carton (one peak temperature threshold indicator per box of 300 vials, or 3000 doses). The peak threshold temperature indicator must be placed in the carton as soon as you remove the vaccines from the traditional +2°C to +8°C range cold chain. Before placing the peak temperature threshold indicator with the vaccines, verify that it is not damaged or that the inner circle of the indicator is already black.

You do not need ice packs. However, to the extent possible, you should transport the vaccines in a cold box to provide additional insulation if there is concern of peak ambient temperatures during transport that may exceed +40°C. When parking the car in which the vaccines are transported, or your motorcycle, try to avoid parking it or leaving the vaccine carrier in direct sunlight for any period of time, as this can raise the temperatures inside the vehicle to be even higher than outdoor ambient temperatures and have an impact on the temperature inside the cold box.

The same procedure for the use of the CTC to transport vaccines applies in all the following situations.

- If you are collecting vaccines at the district store and transport the vaccines back to your health facility.
- If you are collecting vaccines at the district store and transport them directly to the first outreach immunization site.
- If you take the vaccines out of the traditional +2°C to +8°C range cold chain at your health facility and go to the outreach immunization sites.

The total possible time for vaccines in the CTC is **four days** including transport, storage and immunization time.

---

# 5. How to plan for using the controlled temperature chain

As with any regular outreach immunization activities, you must carefully plan the schedule for when and where to organize the sessions when you are using the CTC. This is essential, as the maximum time that the vaccines can be kept in the CTC is four days.

Total time allowed in a CTC = time for transport and/or storage and immunization.

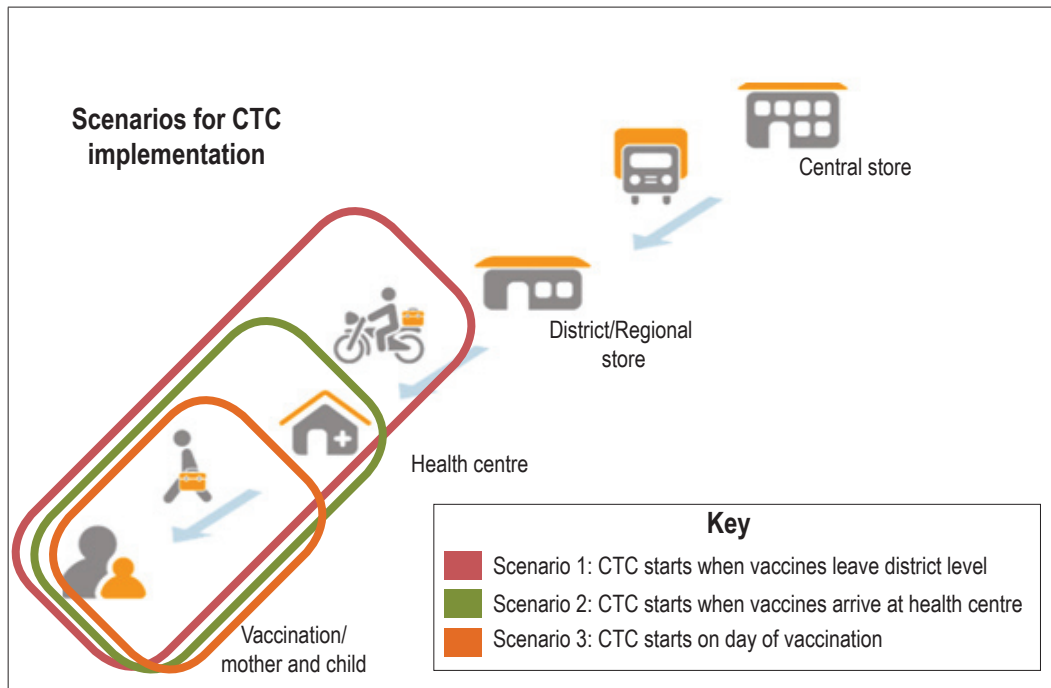
## 5.1 When to start using the controlled temperature chain

In general, and as shown in Figure 4, you can start using the CTC at three different points.

- When you collect the vaccines at the district store.
- When the vaccines arrive at the health centre and you take them out of the traditional +2°C to +8°C range cold chain.
- When you depart for your outreach immunization sessions.



Figure 4: Different starting points for the CTC



**Scenario 1: Vaccine is removed from cold chain at point of transport from district level to health centre and placed into CTC with peak temperature threshold indicators**

- **Day 1:** Vaccine is removed from the cold chain and transported to the health centre without ice.
- **Day 2–3:**
  - *Option A:* Multi-day overnight outreach (2 days/2 nights).
  - *Option B:* Two days of outreach, each originating from the health centre each morning. Vaccine and diluents are stored overnight at ambient temperature.
- **Day 4:**
  - *Option A:* Travel back to health centre from multi-day outreach (safety margin).
  - *Option B:* Conduct another day of immunization using CTC practice.

*This scenario is best suited to situations where ice-making capacity at district level is limited and distances between district and health centre involve less than a day of travel. This scenario is suitable for health centres without functional cold chains, but will require more than one delivery from the district level to the health centre during the campaign.*

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## Scenario 2: Vaccine is removed from cold chain *upon arrival at health centre*

- **Day 1:** Vaccine arrives at the health centre and is removed from the traditional +2°C to +8°C range cold chain. Depending on time of arrival, immunization with the vaccines in a CTC may begin today.
- **Day 2–3:**
  - *Option A:* Multi-day overnight outreach (2 days/2 nights).
  - *Option B:* Two days of outreach, each originating from the health centre each morning. Vaccine and diluents are stored overnight at ambient temperature.
- **Day 4:**
  - *Option A:* Travel back to health centre from multi-day outreach (safety margin).
  - *Option B:* Conduct another day of immunization using CTC practice.

*This scenario is best suited to situations where* ice-making capacity at district level is sufficient, and distances between district and health centre are long, especially those requiring over a full day of travel. This scenario is also ideally suited to health centres that want to take advantage of the full CTC ‘window’ for longer multi-day outreach. This scenario is suitable for health centres without functional cold chains, but will require more than one delivery from the district level to the health centre during the campaign.

## Scenario 3: Vaccine is removed from cold chain *on day of immunization activities/outreach*

- **Day 1–3:** At the start of immunization activities, the vaccine is removed from the traditional +2°C to +8°C range cold chain.
  - *Option A:* Multi-day overnight outreach (3 days/3 nights).
  - *Option B:* Three days of outreach, each originating from the health centre each morning. Vaccine and diluents are stored overnight at ambient temperature.
- **Day 4:**
  - *Option A:* Travel back to health centre from multi-day outreach (safety margin).
  - *Option B:* Conduct another day of immunization using CTC practice.

*This scenario is best suited to situations where* health centres have functional cold chain with adequate space for the campaign vaccines. This scenario requires ice-making capacity at district level to be sufficient for transport. This scenario is ideally suited to health centres that want to take advantage of the full 4-day possibility offered by using the CTC for longer multi-day outreach, or conduct day outreach without requiring more than one delivery of vaccine from the district level during the campaign.

You should make plans for your immunization sessions based on which of the above scenarios suits your situation.

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## 5.2 Estimate the size of the target population

Because vaccines cannot be returned to the fridge after four days of use in a CTC, it is important not to remove more vaccine than can be used from the fridge. The size of the target population to be immunized during an immunization campaign with meningitis A vaccines is different from the target population for your regular immunization sessions. In an immunization campaign with the meningitis A vaccine, all persons between ages 1–29 should be immunized. This corresponds to about 70% of the total population living in the catchment area.

This figure is then the basis for estimating your vaccine needs, and the amount of vaccine you place into the CTC, in the same way as you estimate vaccine needs for regular immunization sessions, including the wastage rate.

## 5.3 Prepare a workplan for organizing the immunization sessions

Planning an immunization session using CTC provides new flexibility. As you plan when and where to organize your immunization sessions during the campaign, you should consider how the CTC flexibility can allow you to reach the most number of people in your target population and reduce transportation-related costs (for people and ice packs). As you have learned earlier in this module, the maximum time that the vaccines can be kept in the CTC is four days. This is an important consideration when preparing your workplan.

If you are starting CTC from the health centre, there are different options you can consider as you develop your strategy.

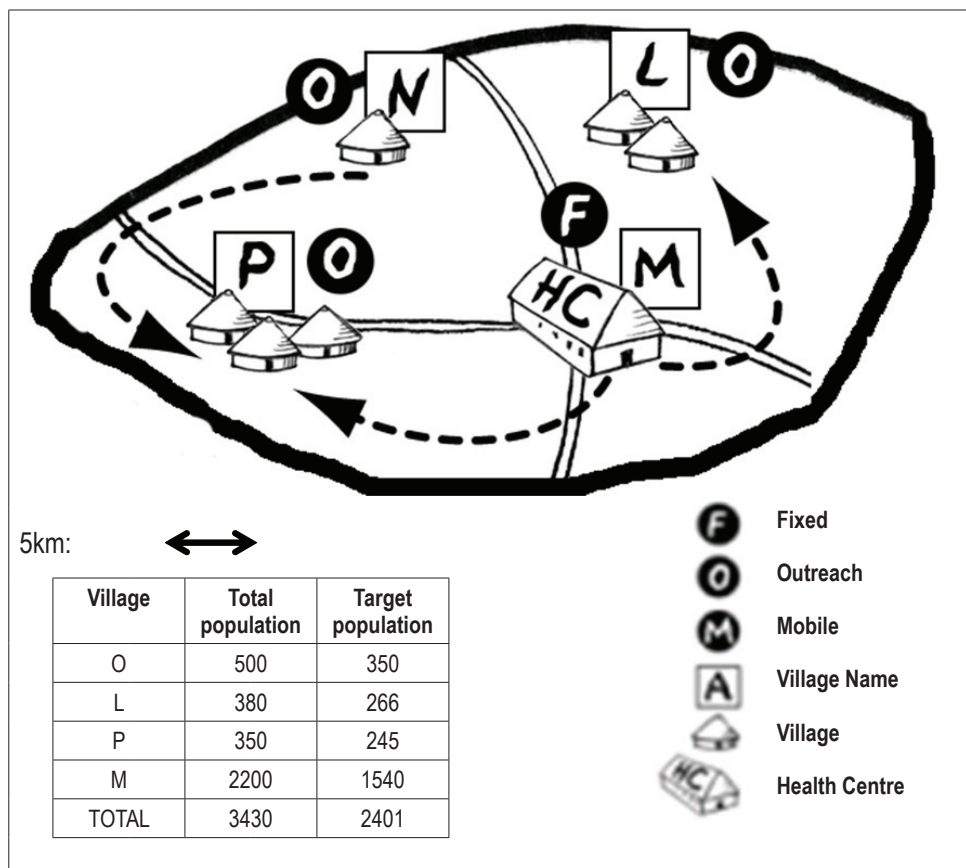
- 1) Functional cold chain at health centre, nearby populations
  - Vaccines are removed from the cold chain for day of vaccination (*no ice packs needed, no risk of freezing diluent*).
- 2) Remote and hard-to-reach areas
  - Teams are able to stay overnight for up to three days, enabling them to reach more of those in the target population (*rather than returning each night to the health centre*).
- 3) No cold chain/lack of cold-chain space at health-centre level
  - Vaccines can be stored in a CTC for four days (*eliminating up to eight trips to the district level*).

For planning your immunization session using CTC, it will be important to consider the regular steps, keeping the new CTC options in mind.

- 1) Review the operational map of your health centre's catchment area. If you do not already have one, you need to prepare a simple map. Figure 5 below shows a simple map with the distribution of population in its catchment area.
- 2) Consider if people who are not living in the villages can easily reach an immunization session in a village, or if you need to set up separate immunization sessions.

- 3) The next thing to consider when making your workplan is when the vaccine is removed from the traditional +2°C to +8°C range cold chain. Review the different scenarios in section 5.1 above and decide which one is applicable to your situation.
- 4) Consider the geographical situation. Some villages might not be so far away from a distance point-of-view, but might be difficult to reach due to mountainous terrain or bad roads.
- 5) Estimate the time it will take to immunize the target population in each immunization session that you are planning. Also, take into consideration how many vaccinators there will be in each team. This will help you determine how many persons you can immunize per session, and therefore how many sessions you will be able to do per day.

Figure 5: Map showing the distribution of the population in the catchment area<sup>3</sup>



<sup>3</sup> Adapted from: Immunization in Practice. A practical guide for health staff. Module 5: Planning immunization sessions to reach every infant. Geneva, World Health Organization, 2004.

Table 1: Example of session plan for health facility

Village / town	Total population	Target population (70% of total population for this exercise)	Session type Fixed / outreach	Date of immunization session	Transport for outreach	Person(s) responsible



**Now do Exercise C — written exercise and group discussion**

When you reach this point, you are ready to do Exercise C. Turn to the section of the module that contains the exercises, located towards the back of the module, and find the exercise. Follow the instructions to prepare your answers. When everyone is ready, there will be a group discussion.

---

## 6. Manage vaccines during the immunization session

The set-up of an immunization session using the CTC does not vary from that of a normal session. The place where you give immunizations during an outreach immunization session may be in a building or in the open air. If in a building, it should be well lit and ventilated. If in the open air, and in a hot climate, it should be in the shade.

Ensure that:

- there is a separate entrance and exit so that people may move in and out of the session more quickly and easily;
- the waiting area is clean, comfortable, and in a hot climate, out of the sun;
- people are effectively guided to the entrance, the stations and the exit by means of signs or the arrangement of chairs, tables and ropes, or other items;
- the number of people at the immunization and other stations are limited, so there is no danger of crowding;
- everything you need is within reach on, or near, your immunization table.

### 6.1 Prepare and use the vaccines at the immunization session

The steps for vaccine preparation are much the same when using the CTC as in a regular immunization session using the traditional +2°C to +8°C range cold chain. Steps 1–3 below are steps that you are familiar with; step 4 is new and specifically for when using the CTC.

Before you use any vaccine you must do the following:

- 1) Check the labels of the vaccine and diluent. If the label is not attached, discard the vial or diluent.
- 2) Check the expiry date. You must discard vials and diluents if the expiry date has already passed.
- 3) Check the vaccine vial monitor (VVM). If it indicates the vaccine has passed the discard point, you must discard that vial immediately.
- 4) Check the peak temperature threshold indicator. If it indicates a peak exposure has been reached (the whole circle is black), you must discard all the vaccine that is still in the vaccine carrier, even if the VVM has not reached its discard point.

**Figure 6: Vaccine carrier with vaccine vials, a peak temperature threshold indicator, but no icepacks**



The Meningitis A vaccine is a lyophilized vaccine that requires reconstitution. The reconstitution process is the same using the CTC as when using the traditional +2°C to +8°C range cold chain; however, the diluent does not need to be cooled before reconstitution.

When reconstituting the vaccine:

- always use diluent provided by the manufacturer for the specific vaccine that you are using;
- for the Meningitis A vaccine, used under a CTC, you do not need to cool the diluents before mixing it with the vaccine;
- do not reconstitute the vaccine until you are ready to immunize;
- once reconstituted, the vaccine should be kept out of direct sunlight but in the shade, away from dirt and debris. You have to ensure the reconstituted vaccine is not exposed to temperatures above 40°C.
- Discard reconstituted vaccine after six **hours** or at the end of the immunization session, whichever comes first.

**Remember**

The reconstituted MenAfriVac™ vaccine can be kept for a maximum of six hours when using the CTC.

## 6.2 Monitor adverse events following immunization

Injection safety is equally important when you are using CTC as it is when using the regular cold chain. Below are listed examples of incorrect immunization practices and possible severe reactions following immunization using incorrect practices. Review the list in Figure 7 and reflect upon your own practices during an immunization session.

Surveillance of adverse events following immunization (AEFI) is a key component of successful immunization activities. You should use the same procedures to monitor and track AEFIs during immunization sessions using the CTC, as you do when using the traditional +2°C to +8°C range cold chain. The AEFI reporting forms have been updated to allow you to indicate if the vaccine was kept in the CTC.

**Figure 7: Examples of incorrect immunization practices and possible severe reactions following immunization**

Incorrect practice	Examples	Possible severe reactions following immunization
Non-sterile injection	<ul style="list-style-type: none"> <li>Reuse of disposable syringe or needle</li> <li>Improperly sterilized syringe or needle</li> </ul>	<ul style="list-style-type: none"> <li>Infection, such as local abscess at injection site, sepsis, toxic shock syndrome, or death</li> </ul>
	<ul style="list-style-type: none"> <li>Contaminated vaccine or diluent</li> </ul>	<ul style="list-style-type: none"> <li>Bloodborne infection transmitted, such as hepatitis or HIV</li> </ul>
Reconstitution error	<ul style="list-style-type: none"> <li>Inadequate shaking of vaccine</li> </ul>	<ul style="list-style-type: none"> <li>Local abscess</li> </ul>
	<ul style="list-style-type: none"> <li>Reconstitution with incorrect diluents</li> </ul>	<ul style="list-style-type: none"> <li>Vaccine ineffective</li> </ul>
	<ul style="list-style-type: none"> <li>Drug substituted for vaccine or diluents</li> </ul>	<ul style="list-style-type: none"> <li>Negative effect of drug (e.g. insulin, oxytocin, muscle relaxants)</li> </ul>
	<ul style="list-style-type: none"> <li>Reuse of reconstituted vaccine at subsequent session</li> </ul>	<ul style="list-style-type: none"> <li>Death</li> </ul>
Vaccine transportation/ storage incorrect	<ul style="list-style-type: none"> <li>VVM changed colour</li> </ul>	<ul style="list-style-type: none"> <li>Vaccine ineffective</li> </ul>
	<ul style="list-style-type: none"> <li>Peak threshold indicator indicates peak exposure has been reached (if used)</li> </ul>	<ul style="list-style-type: none"> <li>Vaccine ineffective</li> </ul>
	<ul style="list-style-type: none"> <li>Clumping of adsorbed vaccine</li> </ul>	<ul style="list-style-type: none"> <li>Local reaction from frozen vaccine</li> </ul>

## 6.3 Follow-up after the outreach immunization session

When using the CTC for outreach immunization sessions, some of the tasks that you usually carry out will be a bit different. As you are not using ice packs, there is no need to check the ice packs. However, it is very important to check the following:

- VVMs to make sure that the vaccine in the vaccine carrier is safe to use; this is no different from a regular outreach immunization session.
- Check the peak temperature threshold indicator to make sure it has not changed to black (see section 3.2). If the indicator is black, you should contact your supervisor. See Annex 1: CTC Monitoring Sheet for the Controlled Temperature Chain (CTC) for the form you will need to complete during the session to monitor the indicator card.

If you are in any doubt about the reading of the peak temperature threshold indicator, do not use the vaccines and try to contact your supervisor.



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## 6.4 Manage the vaccine vials between immunization sessions

At the end of the day, vaccinators may have unopened vials. It is important to keep track of vials that have been exposed to CTC conditions, to ensure the four-day limit is not passed. Therefore, if there are unopened vials remaining, you should follow the following steps:

- When you come back to the health centre after your outreach immunization sessions, mark the vials that you take from the CTC. You can use a pen to make the markings (see Figure 8).
  - If you are on a multiday outreach trip and are not returning to the health centre, you are advised to mark all remaining vials at the end of each day
- Put all the marked vials together and store, either at ambient temperature below 40°C, or in the cold chain.
  - Be careful to keep all marked CTC vaccines together and separate from other MenAfriVac™ vials that have not yet been put in a CTC.
- Make sure that the marked vaccine vials are used first in the next immunization session.
- If marked vials are not used the subsequent day, add a second line to the label (see Figure 8), and pay special attention to ensuring those vials are used first the next day. The same should be done for the third day.
- At the end of the fourth day, any unused vials with three markings on them must be discarded.

**Figure 8: Photo of markings on a vaccine vial that has been exposed to two days of CTC use. The markings identify the vials that should be used first.**



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## 7. Monitoring vaccines in a controlled temperature chain

As CTC is a new way of working, it will be important for vaccinators to record key information on the CTC practices, and for supervisors to check on the CTC implementation at each supervisory visit.

In Annex 1 you will find a monitoring sheet to be used to record data.

Record when the vaccine was removed from the traditional +2°C to +8°C range cold chain, on all order slips as well as in the logbook. Also, note the date and time and the VVM status. If you have been issued any 'marked' vials (i.e. vials that have already been exposed to CTC conditions), please indicate that on your form.

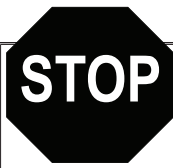
You should use your marked vials first.

When you arrive back at your health facility, or at the immunization session site, check the status of the VVM and the peak temperature threshold indicator. Note the reading of these two indicators in the logbook or the monitoring sheet, along with the date and time of arrival at the health facility of the immunization session site.

In addition you should write down:

- duration of the transport
- number of vaccine vials taken out of the traditional +2°C to +8°C range cold chain
- time when the immunization session started.

If a peak indicator reaches its expiry point, vaccinators should call their supervisors immediately. Supervisors should complete an expiration report (see Annex 2). In the case that you cannot reach your supervisor, stop vaccinating and continue to call them. Do not proceed with vaccination until your supervisor has been reached and has decided on how to proceed.



**Now do Exercise D — written exercise  
and group discussion**

When you reach this point, you are ready to do Exercise D. Turn to the section of the module that contains the exercises, located towards the back of the module, and find the exercise. Follow the instructions to prepare your answers.  
When everyone is ready, there will be a group discussion.

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## 8. Summary of important points

- CTC, the controlled temperature chain, allows vaccines to be stored and transported at temperatures outside the traditional +2°C to +8°C range cold chain for limited periods of time, under monitored and controlled conditions, as appropriate to the stability of the antigen and provided the vaccine is labelled with a VVM.
- The new CTC label for MenAfriVac™ states that The MenAfriVac™ vaccine can be stored under a controlled temperature chain (CTC) at 40°C for not more than four days immediately prior to administration, provided that the vaccine has not reached its expiry date and the vaccine vial monitor (VVM) is still valid. It can be kept at up to 40°C for up to six hours after reconstitution.
- A VVM is a label that changes colour when the vaccine vial has been exposed to heat over a period of time. Before opening a vial, you must check the status of the VVM to verify that the vaccine has not been damaged by heat. Manufacturers attach VVMs to vials of most vaccines.
- The peak temperature threshold indicators **do not replace** VVMs. The peak temperature threshold indicator measures **PEAK** exposure to heat, while the VVMs measure **CUMULATIVE** exposure to heat over time.
- A peak temperature threshold indicator is a small, round sticker on a card. The sticker has the form of a black circle with a grey circle in the middle. The sticker changes colour irreversibly when it is exposed to a peak temperature for a maximum period of time; the grey colour in the middle turns black and thus the whole circle is black. The indicator changes color when the vaccine has been exposed to a **peak temperature** (i.e. a temperature over 40°C), which means the vaccine may no longer be effective and should not be used. You should immediately inform your supervisor if this happens.
- The standard vaccine carrier is still the preferred option for transporting vaccines in a CTC. The vaccine carrier has the advantage that it is associated with immunization activities, both by you and by the community.
- The CTC timeline is the time counted from when you take the vaccines out of the traditional +2°C to +8°C range cold chain until any remaining vaccines are placed back in the traditional cold chain. This period of time can be a **maximum of four days**. Once the vaccine is removed from the cold chain, its CTC use has started.
- Once reconstituted, the vaccine should be kept out of direct sunlight and in the shade, away from dirt and debris. You have to ensure the reconstituted vaccine is not exposed to temperatures above 40°C.

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- Discard reconstituted vaccine after **six hours** or at the end of the immunization session, whichever comes first.
  - The organization of your immunization sessions depends on when you are going to start using the CTC:
    - CTC starts with the departure from the district.
    - CTC starts with the arrival at the health centre.
    - CTC starts with outreach.
  - The size of the target population to be immunized, during an immunization campaign with meningitis A vaccines, is different from the target population for your regular immunization sessions. In an immunization campaign with the meningitis A vaccine, all persons between ages 1–29 should be immunized. This corresponds to about 70% of the total population living in the catchment area.
  - You need to prepare an immunization activities and route plan for when and where you are going to immunize.
  - If you come back to the health centre after your outreach immunization sessions with unused vials, mark the vials with a line on the label. If you are on a multiday outreach trip and are not returning to the health centre, you are advised to mark all remaining vials at the end of each day. Put all the marked vials together and store, either at ambient temperature below 40°C, or in the cold chain. Be careful to keep all marked CTC vaccines together and separate from other MenAfriVac™ vials that have not yet been put in a CTC. Make sure that the marked vaccine vials are used first in the next immunization session. If marked vials are not used the subsequent day, add a second line to the label and pay special attention to ensuring that those vials are used first the next day. The same should be done for the third day. At the end of the fourth day, any unused vials with three markings on them must be discarded.

At the end of the fourth day,  
any unused vials with three markings  
on them must be discarded

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# 9. Self-assessment questions

*Answer the self-assessment questions below to check what you have learnt. Then, check your answers in the next section.*

1) What is the controlled temperature chain?

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2) How do you monitor the controlled temperature chain?

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3) What is the peak temperature threshold indicator?

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4) a) How is the peak temperature threshold indicator different from the vaccine vial monitors?

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b) where is the peak temperature threshold indicator placed?

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5) a) What does “time allowed in a CTC” mean?

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b) What is the time allowed in the CTC for the MenAfriVac™?

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- 6) Read the status of the two indicators below and write in the third column if you can **continue to use the vaccines** or if you have to **discard** them and contact your supervisor. Mark the answer you think is correct with an X.

The status of the VVM is:	The status of the peak temperature threshold indicator is:	I will:	
		continue to use the vaccines	discard the vaccines and contact my supervisor
Inner square lighter than the outer circle	The inner circle of the sticker is white		
Inner square lighter than the outer circle	The inner circle of the sticker is black		
Inner square same colour as the outer circle	The inner circle of the sticker is white		
Inner square same colour as the outer circle	The inner circle of the sticker is black		
Inner square darker than the outer circle	The inner circle of the sticker is white		
Inner square darker than the outer circle	The inner circle of the sticker is black		

- 7) List at least four factors to consider when planning the immunization sessions for a Meningitis A immunization campaign, using a CTC.

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# 10. Answers to self-assessment questions

*If you had difficulty answering any question, turn back and study the section indicated below (in parentheses). If you do not understand something, discuss it with a facilitator.*

- 1) What is the controlled temperature chain?

The controlled temperature chain (CTC), allows vaccines to be stored and transported at temperatures outside the traditional +2°C to +8°C range cold chain for limited periods of time, under monitored and controlled conditions, as appropriate to the stability of the antigen and provided the vaccine vial is labelled with a VVM.

(Section 2)

- 2) How do you monitor the controlled temperature chain?

By using two kinds of temperature monitors; the vaccine vial monitors (VVM) and the peak temperature threshold indicator.

(Section 3)

- 3) What is the peak temperature threshold indicator?

A peak temperature threshold indicator is a small round sticker on a card. The sticker takes the form of a black circle with a white circle in the middle. The sticker changes colour irreversibly when it is exposed to a peak temperature for a maximum period of time; the white colour in the middle turns black and thus the whole circle is black. The indicator changes colour when the vaccine has been exposed to a peak temperature (i.e. a temperature over 40°C), which means the vaccine may no longer be effective and should not be used.

(Section 3.2)

- 4) How is the peak temperature threshold indicator different from the vaccine vial monitors?

- a) The peak temperature threshold indicator measures **PEAK** exposure to heat, while the VVMs measure **CUMULATIVE** exposure to heat.
- b) One peak temperature threshold indicator is placed in the vaccine carrier during vaccination sessions. If a CTC is used for transport, one indicator is placed in the secondary box (in the carton with six boxes of 50 vials each, 300 vials in total) or in the cold box.

(Section 3.2)

- 5) a) What does “time allowed in a CTC” mean?  
The total time in a CTC is the time for transport, storage and immunization time.  
(Sections 4 and 5)
- b) What is the time allowed in the CTC for the MenAfriVac™?  
Four days, assuming that peak temperature threshold indicator and a VVM is used.  
(Section 4)
- 6) Read the status of the two indicators below and write in the third column if you can **continue to use the vaccines** or if you have to **discard** them and contact your supervisor. Mark the answer you think is correct with an X.

The status of the VVM is:	The status of the peak temperature threshold indicator is:	I will:	
		continue to use the vaccines	discard the vaccines and contact my supervisor
Inner square lighter than the outer circle	The inner circle of the sticker is white	X	
Inner square lighter than the outer circle	The inner circle of the sticker is black		X
Inner square same colour as the outer circle	The inner circle of the sticker is white		X
Inner square same colour as the outer circle	The inner circle of the sticker is black		X
Inner square darker than the outer circle	The inner circle of the sticker is white		X
Inner square darker than the outer circle	The inner circle of the sticker is black		X

- 7) List at least four factors to consider when planning the immunization sessions for a Meningitis A immunization campaign.
- Time when the CTC will start to be used.
  - Size and location of the target population.
  - Geographical situation and transports available.
  - Route planning, given new CTC flexibility.
  - External ambient temperature.
- (Section 5)

**The End**

Congratulations on finishing this module

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# 11. Exercises for the module

How to use the controlled temperature chain  
(CTC) during an outreach immunization session



**Exercise A**  
**Written exercise and discussion:**



The purpose of this exercise is to reflect and think about what the CTC will mean to you in your work in planning for, and organizing, an immunization session.

At this stage, you have not yet read about how the CTC is functioning and how it will affect your work. However, think about your first reaction when learning about the CTC. Write down your thoughts and reactions in the space below. Do not just write 'yes' or 'no' but justify/explain why you are answering 'yes' or 'no'. You will use these notes for the group discussion.

- 1) Do you think it will help you in your work?

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- 2) Do you think it will make things more complicated?

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3) Does it worry you that there is a new technology that will change the way you work?

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When you have finished writing,  
discuss your answers with your facilitator.



When the group has finished this discussion, **GO BACK** to section 3 and read until the next stop sign (end of section 3.3).



### Exercise B

Demonstration, written exercise and discussion:



The purpose of this exercise is to familiarize yourself with the peak temperature threshold indicator. Your facilitator will distribute one indicator card to each one of the course participants and you will be given some time to look at the card by yourself. When you have done so, answer the questions below in preparation for the group discussion.

1) Do you think that the peak temperature threshold indicator looks clear and easy to use?

a) If yes, describe why you think so.

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b) If no, describe why you think not.

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2) What do you think will be the biggest challenges/difficulties using the peak temperature threshold indicator?

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When you have finished writing,  
discuss your answers with your facilitator.

	When the group has finished this discussion, <b>GO BACK</b> to section 4 and read until the next stop sign (end of section 5).
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### Exercise C

#### Written exercise and discussion:



The purpose of this exercise is to practise making a workplan for the immunization sessions during a Meningitis A CTC campaign.

Use the information in Figure 5 in section 5.3 above, and the table below. The campaign will start 1 April 2013. You have two trained health workers that can work with you as vaccinators during the campaign. You have one car and one motorbike available for transport.

You should be prepared to justify your workplan and explain how you have used the CTC flexibility in your work, where appropriate.

Village / town	Total population	Target population (70% of total population for this exercise)	Session type Fixed / outreach	Date(s) of immunization session	Transport for outreach	Person(s) responsible

When you have finished writing, discuss your answers with your facilitator.



When the group has finished this discussion, **GO BACK** to section 6 and read until the next stop sign (end of section 7).





### Exercise D

#### Written exercise and discussion:



It is the first day of the campaign, and you report to the health centre in the morning to collect your vaccines for use in a CTC. Based on the information provided below, please complete the CTC monitoring form in Annex 1.

<b>Monday, 13 September — first day of the campaign</b>	
<b>Target population:</b>	350 people
<b>Number of marked vials:</b>	0
<b>Time of departure from health centre:</b> <ul style="list-style-type: none"><li>• Threshold indicator: good</li><li>• VVM: good</li></ul>	08:00
<b>Time of arrival at vaccination post:</b> <ul style="list-style-type: none"><li>• Threshold indicator: good</li></ul>	09:15
<b>Immunization session start time:</b> <ul style="list-style-type: none"><li>• Threshold indicator: good</li></ul>	09:30
<b>Depart for health centre:</b>	14:00
<b>Arrive at health centre:</b> <ul style="list-style-type: none"><li>• Threshold indicator: good</li></ul>	15:15
<b>Number of unopened vials remaining:</b>	3

NOTE: Team will be departing for a two-day outreach trip and will need to take enough vaccines for Tuesday, 14 September and Wednesday, 15 September.

<b>Tuesday, 14 September — second day of the campaign</b>	
<b>Target population:</b>	200 people (Day 1) + 300 people (Day 2)
<b>Number of marked vials:</b>	3
<b>Time of departure from health centre:</b> <ul style="list-style-type: none"><li>• Threshold indicator: good</li><li>• VVM: good</li></ul>	08:10
<b>Time of arrival at vaccination post:</b> <ul style="list-style-type: none"><li>• Threshold indicator: good</li></ul>	09:00
<b>Immunization session start time:</b> <ul style="list-style-type: none"><li>• Threshold indicator: good</li></ul>	09:10
<b>Depart for next village:</b>	15:00
<b>Arrive at next village:</b> <ul style="list-style-type: none"><li>• Threshold indicator: good</li></ul>	16:00
<b>Number of unopened vials remaining:</b>	32

Wednesday, 15 September — third day of the campaign	
Target population:	300 people
Number of marked vials:	32
Time of departure from health centre:	08:00
<ul style="list-style-type: none"> <li>• Threshold indicator: good</li> <li>• VVM: good</li> </ul>	
Time of arrival at vaccination post:	09:00
<ul style="list-style-type: none"> <li>• Threshold indicator: good</li> </ul>	
Immunization session start time:	09:10
<ul style="list-style-type: none"> <li>• Threshold indicator: good</li> </ul>	
Depart for next village:	12:00
Arrive at next village:	14:00
<ul style="list-style-type: none"> <li>• Threshold indicator: not good</li> </ul>	
Number of unopened vials remaining:	10

When you have finished writing,  
discuss your answers with your facilitator.



When the group has finished this discussion, **GO BACK** to section 7 and read until the end of the module.

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# Annex 1:

## Monitoring sheet for the controlled temperature chain (CTC)

# Annex 1:

## Monitoring sheet for the Controlled Temperature Chain (CTC) for use during MenAfriVac™ immunization campaigns

Name of Health Centre: ..... Team: .....

(To be kept during the whole immunization campaign)

	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date
<b>BEFORE DEPARTURE</b>												
Number of new vials taken out of the cold chain <b>PLUS</b> Number of marked vials remaining from previous days												
Time of verification of the VVM and the peak temperature threshold indicator (hh.mm)												
Peak temperature threshold indicator (Still good = 0 Threshold reached = 1)												
<b>BEFORE THE IMMUNIZATION SESSION</b>												
Time when immunization session started												
Peak temperature threshold indicator (Still good = 0 Threshold reached = 1)												

	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date
<b>AT THE END OF THE DAY (before leaving the site of the immunization session)</b>												
Time of departure												
Peak temperature threshold indicator (Still good = 0 Threshold reached = 1)												
<b>ON ARRIVAL AT THE HEALTH CENTRE</b>												
Time of arrival at health centre												
Peak temperature threshold indicator (Still good = 0 Threshold reached = 1)												
Number of marked vaccine vials remaining												
<b>ONLY FOR THE SUPERVISOR</b>												
Number of discarded vaccine vials <b>(ONLY</b> vaccine vials that have not been opened, but have to be discarded due to the fact that the temperature threshold has been reached, or if the four-day limit has passed. Please also complete the peak indicator expiration report).												

**NOTE:** If your peak threshold indicator has expired, please call your supervisor immediately. Your supervisor will fill in an expiration report and complete the last row. You do not need to continue to complete the form, unless you receive a new batch of vaccines. In this case, please start a new column.

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# Annex 2:

## CTC Peak indicator expiration report

Supervisor's Name: \_\_\_\_\_ Phone Number: \_\_\_\_\_

Health Centre: \_\_\_\_\_ Type of team:  fixed  mobile

Date: \_\_\_\_\_ Time: \_\_\_\_\_

### Details of the situation

Location/village where the vaccination was taking place: \_\_\_\_\_

Time team arrived at: \_\_\_\_\_

Time when the indicator expired: \_\_\_\_\_

Number of vials the team had at the start of the day: \_\_\_\_\_

Number of vials remaining: \_\_\_\_\_

### Why do you think the indicator expired?

- Direct exposure to sunlight  Vaccine carrier was left open  During transport
- Other (please provide details) \_\_\_\_\_  Unknown

Notes/comments: \_\_\_\_\_

### Action taken (tick all that apply)

- Collection of unusable vials (indicate number of vials \_\_\_\_\_)
- Provision of new vials (if yes, indicate how many \_\_\_\_\_)
- Advice given to the team on how to avoid this kind of situation in the future

If yes, what advice was given \_\_\_\_\_

\_\_\_\_\_  
**Signature** \_\_\_\_\_ **Date** \_\_\_\_\_

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