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THE VACCINE VIAL MONITOR

Questions and Answers

NOTE

Revision 2 is the standard version of this document.

Revision 1 is a special revision for use specifically in the United Republic of Tanzania.



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Documentation on the Vaccine Vial Monitor includes:

- The Vaccine Vial Monitor -- Training Guidelines (WHO/EPI/LHTM/94.2)
- The Vaccine Vial Monitor -- Questions and Answers (WHO/EPI/LHIS/94.7/Rev.1)
(Special version for use in United Republic of Tanzania)
- The Vaccine Vial Monitor -- Questions and Answers (WHO/EPI/LHIS/94.7/Rev.2)
(Standard version)
- Vaccine Vial Monitor Poster (CCPS/20)

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1. HOW THE VACCINE VIAL MONITOR (VVM) WORKS

1.1. What is a vaccine vial monitor?

A vaccine vial monitor (VVM) is a label made of heat-sensitive material which is placed on a vaccine vial to register cumulative heat exposure over time.

The combined effects of time and temperature cause the monitor to change colour, gradually and irreversibly. A direct relationship exists between the rate of colour change and temperature:

- The lower the temperature, the slower the colour change.
- The higher the temperature, the faster the colour change.

Monitors can be used on vaccine vials, droppers or ampoules.

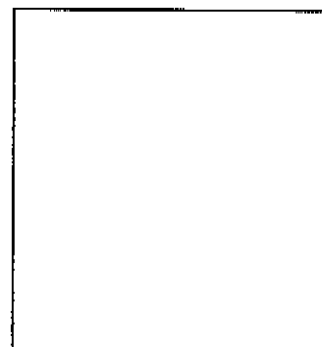
1.2. Does the vaccine vial monitor measure vaccine potency?

No, the vaccine vial monitor does not directly measure vaccine potency but it does give information about the main factor which affects potency: heat exposure over a period of time.

The vaccine vial monitor does not register information about other factors which contribute to vaccine degradation, such as sunlight and age (time).

1.3. What does the vaccine vial monitor look like?

The vaccine vial monitor is a circle with a small square inside it. It can be printed on a product label or the cap of the vaccine vial.



1.4. How does the vaccine vial monitor work?

The vaccine vial monitor has a heat sensitive component which registers a gradual colour change with exposure to heat.

- In some models the inner square is made of heat sensitive material which is light at the starting point and becomes darker with exposure to heat.
- In other models, the outer circle is made of heat sensitive material which is dark at the starting point and becomes lighter with exposure to heat.

However, this is a technical difference and the basic guidelines for reading the monitor are the same for both types.

At the starting point, the inner square is a *lighter* colour than the surrounding circle. As long as the level and/or duration of heat does not damage the vaccine, the inner square remains lighter than the surrounding circle.

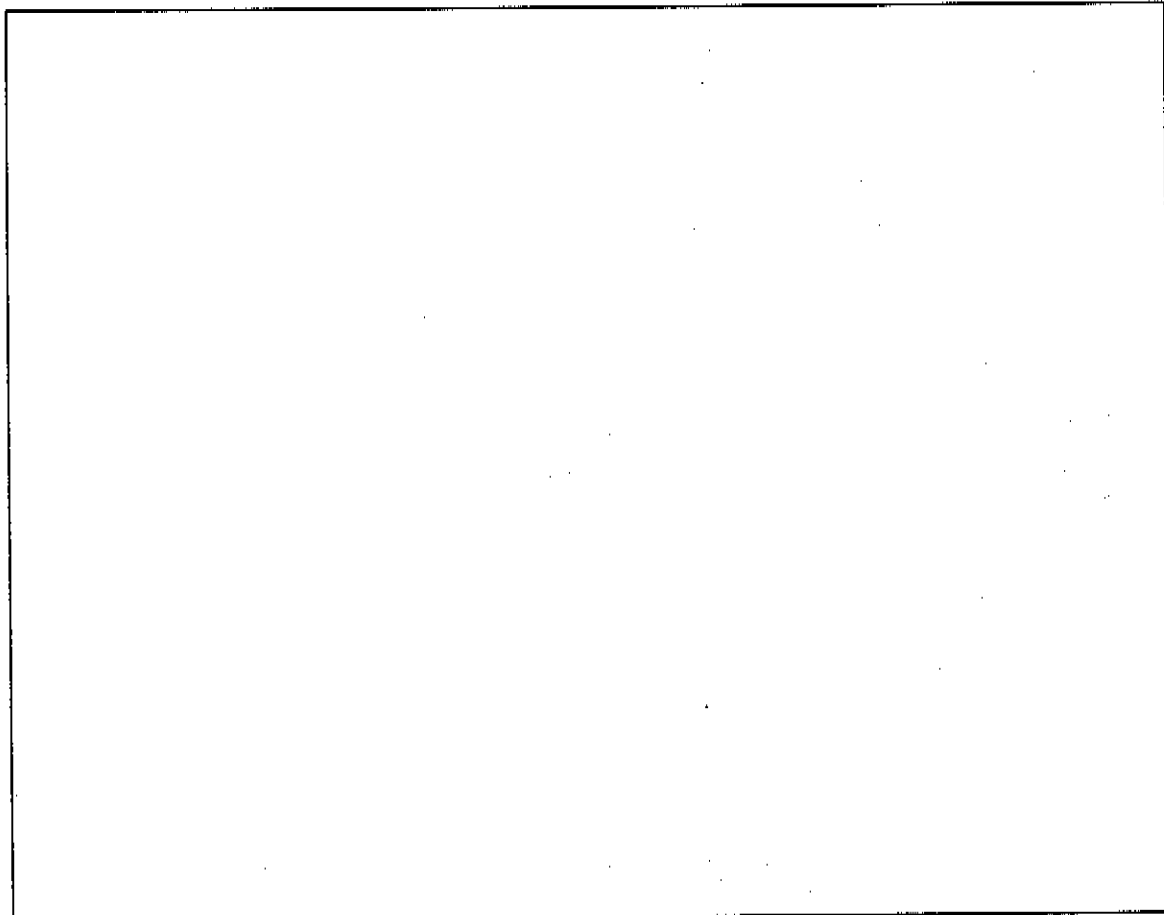
At the discard point, the inner square is the same colour as the surrounding circle. This reflects an unacceptable level of heat exposure which will have damaged the vaccine.

1.5. What are the rules for reading the vaccine vial monitor?

The point to focus on is the colour of the inner square relative to the colour of the surrounding circle:

- Rule 1: If the inner square is lighter than the outer circle, the vaccine may be used.
- Rule 2: If the inner square is the same colour as, or darker than, the outer circle, the vaccine must not be used.

A simple glance at the monitor will be enough to show whether the vaccine can be used or not.



1.6. Does the vaccine vial monitor change colour immediately when it is exposed to temperatures above 8°C?

No. The vaccine vial monitor reflects the heat stability of the vaccine to which it is attached and doesn't, therefore, change colour immediately with a brief exposure to moderate heat.

Vaccines have a level of heat stability which enables them to withstand temperatures outside the cold chain, above 8°C, for a limited amount of time. The rate at which the vaccine vial monitor changes colour reflects the rate at which the quality of the vaccine changes with heat exposure.

1.7. If vaccine is left at room temperature, how long will it take the vaccine vial monitor to change from the "start point" to the "discard point"?

This depends on the room temperature which varies greatly, according to the place, season and time of the day. The table below shows times recorded for a vaccine vial monitor attached to a vial of OPV.

Constant temperature, day and night	Time for VVM on a vial of OPV to reach "discard point"
Room temperature: 20°C	20 days
Room temperature: 25°C	8 days
In a refrigerator: 4°C	500 days

1.8. If vaccine is returned to a refrigerator after being outside the cold chain, will the colour change reverse?

No. The colour change is irreversible. The vaccine vial monitor indicates the total, accumulated heat exposure which the vaccine has been subjected to.

1.9. If the vaccine inside the refrigerator freezes, will the vaccine vial monitor register any change?

No. The vaccine vial monitor is not affected by freezing temperatures so it cannot give any information with regard to freezing.

1.10. How does the vaccine vial monitor cope with variations in heat tolerance between different types of vaccine?

Vaccine vial monitors are manufactured in specific batches for each type of vaccine. Each monitor thus matches the exact sensitivity of the vaccine to which it is attached.

1.11. What testing and quality control procedures are used to ensure that the vaccine vial monitor will perform correctly?

Each batch of vaccine vial monitors is tested twice to ensure that the monitors will change colour correctly in response to heat exposure. The first test is conducted at the factory before shipment and the second by the vaccine manufacturer before despatch. A special instrument, a colour reflectance densitometer, is used for the test.

The vaccine vial monitors were subjected to extensive independent laboratory tests before WHO approved their use.

2. ADVANTAGES AND COSTS INVOLVED

2.1. Why should a vaccine vial monitor be used?

A vaccine vial monitor enables the health worker to know whether vaccine has been damaged by heat or whether it is still good.

Vaccine itself exhibits no visible change with heat exposure. Before the development of the vaccine vial monitor, health workers had no means of identifying whether vaccine had suffered damage from heat exposure at any point during transport and/or storage.

National recommendations for vaccine handling have consequently been very conservative to ensure protection from the harmful effects of heat. Health workers have been trained to discard all vaccines after a break in the cold chain, even if the break is only suspected. If a health centre refrigerator malfunctions overnight, the vaccine is thrown away as soon as the problem is discovered. In some places health workers are instructed to discard all vaccine that has been taken to the field twice without being used, even if no heat exposure has occurred. These precautions against *possible* heat damage result in large amounts of usable vaccine being discarded -- often unnecessarily.

The vaccine vial monitor, however, changes this situation. Its gradual and irreversible colour change makes it possible to assess cumulative heat exposure and the remaining shelf life of vaccines, even with vials which have been out of the cold chain or stored in a malfunctioning refrigerator.

WHO recommends that vaccine vial monitors be used in order to:

- monitor the heat exposure of every vial of vaccine, and
- reduce vaccine wastage.

2.2. Can the vaccine vial monitor be used to help in storage and cold chain management?

Yes. The vaccine vial monitor gives a visual measure of the heat exposure of each vial and this enables the health worker to:

- *Use vaccine selectively.* For instance, vials with minimal heat exposure can be selected for use in outreach sessions or mobile services.
- *Estimate remaining shelf life of vaccines and rotate inventories.* Vials which register more heat exposure can be selected for use before those with less.
- *Identify cold chain problems or confirm problems suggested by monitor marks or refrigerator thermometers.* Each significant exposure to heat registers some colour change on the vaccine vial monitor; in some cases it may be possible to check where this has happened.

2.3. Will vaccine vial monitors raise the cost of vaccines?

Yes. Vaccine buyers will have to pay a little more for vaccines with a vaccine vial monitor attached. For polio vaccine, each vaccine vial monitor adds less than 5% to the cost a 10-dose vial.

However, it is expected that the cost increase will amount to much less than the money that will be saved by reducing the quantity of wasted vaccines.

3. USING A VACCINE VIAL MONITOR

3.1. If the vaccine vial monitor has not reached "discard point", can the vaccine still be used if it has passed its expiry date?

No! Vaccine must never be used if it has passed its expiry date.

The expiry date is calculated on the assumption that vaccine will be stored within an appropriate range of temperatures (0-8°C) throughout the cold chain. Even under correct storage conditions, however, vaccine undergoes gradual degradation due to factors such as simple ageing, exposure to light and/or freezing temperatures. The expiry date takes these factors into account so, once a vaccine has passed its expiry date, it cannot be expected to stimulate sufficient immunity.

3.2. If vials have a vaccine vial monitor, do they still need to be kept in the cold chain?

Yes. The vaccine vial monitor doesn't change the vaccine's sensitivity to heat exposure. It simply gives a visible sign to show how much of the vaccine's "resistance" has been used up, i.e. when heat exposure has exceeded the limit for that vaccine..

All vaccines are sensitive to heat and will stay potent longer if they are kept refrigerated. Each vaccine has a certain level of resistance to small amounts of heat which is variable for different types of vaccine -- polio vaccine, for example, has the least resistance. Careful cold chain handling preserves the vaccine's ability to withstand any accidental or unavoidable heat exposure.

3.3. Can opened vials of polio vaccine be used again the following day if the vaccine vial monitor has not reached "discard point"?

Yes. Opened vials of polio vaccine may be used in subsequent immunization sessions until a new shipment of vaccine arrives, provided that the following conditions are met:

- the vaccine's expiry date has not passed;
- the vaccine vial monitor shows that the vaccine can be used (i.e. it has not been damaged by over exposure to heat);
- opened vials of vaccine which have been taken out of the health centre for immunization activities (e.g. outreach, national immunization days) are discarded at the end of each day.

3.4. Can opened vials of measles, yellow fever and BCG vaccine be used again the following day if the the vaccine vial monitor has not reached "discard point"?

*No! Opened vials of measles, yellow fever and BCG vaccines cannot be used beyond one immunization session. They **must** be discarded at the end of each day, regardless of the vaccine vial monitor reading. The monitors for these vaccines will be attached to the vial cap so will normally be discarded when the vaccine is being reconstituted.*

[Measles, yellow fever and BCG are more heat stable than OPV before reconstitution. However, once they are opened and the diluant is added, they become less stable.]

3.5. Should other monitors, such as the Freezwatch or 3M Cold chain monitor, still be used?

Yes. FreezeWatch indicators and 3M cold chain monitor cards track refrigerator temperatures. They are not replaced by vaccine vial monitors.

3.6. If the information provided by a cold chain monitor differs from the information of the vaccine vial monitor, which reading is the more accurate?

Providing the readings do not relate to freezing temperatures, the reading of the vaccine vial monitor will be more accurate. It will give an exact indication of the level of heat exposure for the specific vial to which it is attached.

4. GETTING STARTED WITH VACCINE VIAL MONITORS

4.1. Which vaccines will be labelled with the vaccine vial monitor?

Initially oral polio vaccine will be labelled with the vaccine vial monitor. Measles vaccine will follow shortly. These two vaccines are the first to receive the vaccine vial monitor because they are the most heat-sensitive. Specifications for vaccine vial monitors for other EPI vaccines, including BCG, DPT and Hepatitis B, are being prepared and should be available soon.

4.2. How will the vaccine vial monitor be integrated into the current immunization programme?

Extensive training at several levels must precede the introduction of the vaccine vial monitor. Cold room personnel and all staff responsible for vaccine storage and handling, from the central store to the peripheral health centres will be trained to read and interpret the vaccine vial monitor.

Health workers in the periphery will be trained to check every vaccine vial monitor before administering a vaccine. They will report any damaged vaccine to their supervisors who will in turn pass such reports on to the next level in the system.

4.3. What are the guidelines for the initial period when there might be vials with vaccine vial monitors and some without in the health centre stocks?

The guiding rule is to use the vials without vaccine vial monitors first.