

Vaccine Vial Monitors: FAQs

What are VVMs?

VVMs, vaccine vial monitors, are small stickers that adhere to vaccine vials and change color as the vaccine is exposed to heat, letting health workers know whether the vaccine can be safely used for immunization.

How do VVMs work?

VVMs contain a heat-sensitive material that registers the cumulative heat exposure of the vial over time. The combined effects of time and temperature cause the inner square of the VVM to gradually darken irreversibly. This ensures that health care workers can clearly identify which vaccine vials have reached their preset limit for cumulative heat exposure and should not be used.

What are the benefits of VVMs?

VVMs offer a wealth of benefits in addition to being able to track a vaccine vial's exposure to heat, such as:

- **Quality Control.** In the past, heat-damaged vaccines were sometimes unknowingly delivered to children, or good vaccines were thrown out because health care workers feared they had gone bad. Through using VVMs, health workers can tell just by looking at the color of the inner square which vaccines have not been exposed to too much heat and are therefore okay to use for immunization.
- **Expanded Coverage.** VVMs can facilitate immunization program efforts to expand coverage, especially to difficult and remote locations. Some countries use VVMs to take vaccines beyond the reach of the cold chain. VVMs have assisted in polio and tetanus campaigns globally and in delivering vaccines to mothers and children following home deliveries.
- **Reduced Wastage.** The availability of VVMs on vaccines helped the World Health Organization (WHO) to create new policies on the handling of multidose vials of vaccines allowing open vials of some liquid vaccines to be used for more than a single day, saving millions of dollars. In addition, VVMs allow countries



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VVMs in Action

During the May 2006 earthquake in Yogyakarta, Indonesia, electricity went out for several days, leaving health facilities without power for their refrigerators.

In the past, power outages such as the one in Yogyakarta would have resulted in thousands of vaccine vials being discarded for fear they were no longer effective and safe to use. VVMs showed that most vaccines were undamaged, despite the heat, and still usable—saving 50,000 doses of vaccine that otherwise would have been thrown away.

to safely use vaccines, despite cold chain interruptions (see box above).

- **Stock Management.** VVMs enable health care workers to make informed decisions about which vaccines to use. By reading the VVMs, health workers can identify vaccines that have received some heat exposure but are still good and preferentially select those vaccines to use first.

Does each vial need its own VVM?




Yes. VVMs measure the cumulative heat exposure of the vial they are adhered to. It is dangerous and inaccurate to generalize the reading from one vial to another.

How do you use a VVM?

VVMs are quick and easy to interpret—see the picture below. After confirming that the expiry date has not passed, health workers follow two simple rules:

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 color as or darker than the outer circle, do NOT use the vaccine.

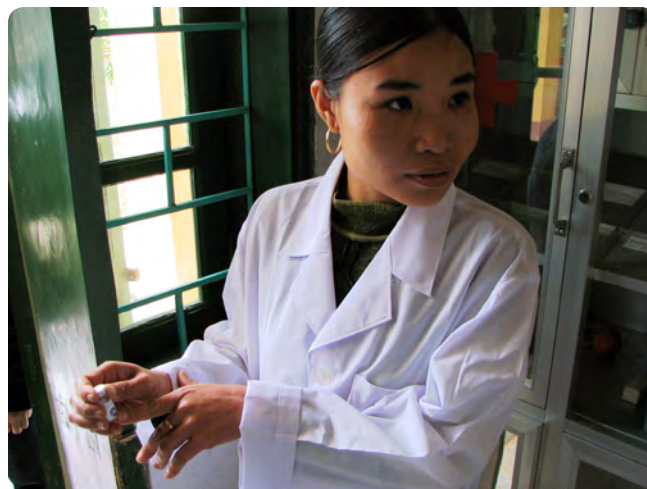
| | | |
|-------------------|---|---|
| Start point |  | Square lighter than circle. If the expiry date has not passed, USE the vaccine. |
| Endpoint |  | Square matches the circle. Do NOT use the vaccine. |
| Endpoint exceeded |  | Square darker than the circle. Do NOT use the vaccine. |

Are all VVMs the same?

No. There are four different VVMs, each designed for different types of vaccines depending on the vaccine's heat stability.

| CATEGORY | Days to Endpoint* at +37°C | Days to Endpoint at +25°C | Time to Endpoint at +5°C |
|-------------------------------------|----------------------------|---------------------------|--------------------------|
| VVM 30: High stability | 30 | 193 | > 4 years |
| VVM 14: Medium stability | 14 | 90 | > 3 years |
| VVM 7: Moderate stability | 7 | 45 | > 2 years |
| VVM 2: Least stable | 2 | N/A | 225 days |

*Endpoint: The point at which time-temperature exposure has altered the color of the active surface (inner square) so that it exactly matches the reference surface (outer circle). At this point and thereafter the vaccine should no longer be used.



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Do VVMs provide information on the potency of vaccines?

No, VVMs do not provide information on the potency of a vaccine. Vaccine potency is influenced by factors other than heat, such as age or time to expiry. Some vaccines are also damaged by freezing. The square of the VVM darkens in line with heat stability loss and provides an indication when the cumulative heat exposure of a vaccine vial has reached its preset limit and can no longer safely be used, and they perform that function exceptionally well.

Are VVMs reliable?

Yes. VVMs have been subjected to rigorous scientific testing for WHO prequalification. In addition to tests conducted by the supplier, Temptime (formerly LifeLines Technology, Inc.), both vaccine manufacturers and WHO's independently contracted laboratories have confirmed that VVMs meet WHO specifications. Many vaccine manufacturers test samples from every lot of VVMs received before they are released for use. WHO routinely audits vaccine manufacturers, and VVMs are included in the audit itinerary.

Over 1,000 lots of various categories of VVMs totaling more than 3 billion VVMs have been supplied to more than 20 prequalified vaccine manufacturers around the world. All field incidents are reported and centralized through the WHO pharmacovigilance process for investigation and resolution. Among all the incidents which have been reported about the VVM, all investigations have proven that there were no VVM failures in over 14 years; this demonstrates the extraordinary reliability of the VVM.

Have VVMs been tested in the field?

Yes. WHO and ministries of health have conducted a myriad of tests with VVMs in both routine services and national immunization programs. The studies conducted in Bhutan, India, Kenya, Tanzania, Turkey, and Vietnam have shown that VVMs can be effectively used by health workers and can be used to reduce vaccine wastage rates and substantially reduce immunization program costs.

Does using VVMs increase the cost of the vaccine?

Adding a VVM to a vaccine vial does increase its cost. Vaccine manufacturers buy VVM labels or vial labels with VVMs at prices between US\$0.036 to \$0.059 per label (prices reflect 2010 data) depending on the type of VVM used and the quantity ordered. Manufacturers may also need to acquire specialized labeling machinery and have other costs associated with handling and testing VVMs. However, when the cost increases for VVMs are passed on to immunization programs, they are offset by cost savings and improved vaccine effectiveness.

PATH estimates that over the next ten years, VVMs will allow health care workers to recognize and replace 368 million doses of inactive vaccines and deliver an additional 1.5 billion doses in remote settings—actions that could save more than 140,000 lives and reduce morbidity for countless others.

Do all vaccines have VVMs attached?

Today, VVMs are available for nearly all vaccines used in immunization programs in developing countries. WHO requires VVMs for vaccine prequalification and the United Nations Children's Fund specifies them on vaccines they purchase. In addition, the GAVI Alliance specifies that all new vaccines funded through its vaccine fund be labeled with VVMs.

Is Temptime the sole supplier of VVMs?

Yes. Despite continued efforts to identify and develop technologies with at least half a dozen potential manufacturers, Temptime is the only supplier of VVMs at this time.

What is the benefit of having a VVM on a vaccine that is very heat stable, such as hepatitis B?

The VVM is the only tool that can show the cumulative heat exposure of each individual vaccine vial. If there is evidence of cold chain failure for an extended period of time and there is no vaccine vial monitor to verify exposure, then health workers are advised to not use the vaccines. This can lead to significant wastage of vaccine.

Some of the most heat-stable vaccines are the most susceptible to freeze damage. Use of VVMs may allow these vaccines to be safely stored at slightly higher temperatures to avoid inadvertent freezing.

Finally, VVMs are needed in areas where the cold chain is weak or nonexistent and to facilitate access to hard-to-reach populations. Timely delivery of the birth dose of hepatitis B vaccine is essential to prevent perinatal transmission of the hepatitis B virus, and the availability of VVMs on the vaccine can help to ensure that it can be transported and provided to newborns delivered at home immediately following birth.

Where can I get more information?

WHO: www.who.int/immunization_standards/vaccine_quality/en/

PATH: www.path.org/projects/vaccine_vial_monitor.php

Temptime: www.temptimecorp.com/PublicPages/HEATmarker.aspx

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