WHO/V&B/02.35
ORIGINAL: ENGLISH

Getting started with vaccine vial monitors

Vaccines and Biologicals

World Health Organization

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

This document was produced by the
Access to Technologies
of the Department of Vaccines and Biologicals

Ordering code: WHO/V&B/02.35
Printed: December 2002

This document is available on the Internet at:
www.who.int/vaccines-documents/

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Contents

Abbreviations

°C	degrees centigrade
BCG	bacillus Calmette-Guérin (tuberculosis vaccine)
CCM	cold chain monitor
DT	diphtheria–tetanus (vaccine)
DTP	diphtheria–tetanus–pertussis (vaccine)
EEFO	earliest-expiry-first-out
EPI	Expanded Programme on Immunization
Hib	*Haemophilus influenzae* type b (vaccine)
KAP	knowledge, attitude and practices
NID	national immunization day
OPV	oral polio vaccine
PATH	Program for Appropriate Technology in Health
Td	tetanus toxoid and diphtheria (reduced component) (vaccine)
TT	tetanus toxoid
UNICEF	United Nations Children's Fund
VVM	vaccine vial monitor
WHO	World Health Organization

Revision history

Originally issued as *Vaccine vial monitor and open vial policy – questions and answers* (WHO/EPI/LHIS/96.01).

Rewritten and renamed November 2002

Acknowledgements

This document was prepared jointly by WHO/V&B/ATT and the Program for Appropriate Technology in Health (PATH) with funding from USAID under the HealthTech Programme. It was reviewed by Dr Mercy Essel Ahun (Immunization Programme Manager, Ghana), Dr Nguyen Van Cuong (National EPI Secretary-General, Viet Nam), Ms Mary Catlin (University of Arizona, USA), Mr Chris Caulfield (LifeLines Technology, Inc.) and Dr Thaddeus Prusik (LifeLines Technology, Inc.). The local language version of this document was used in workshops in Viet Nam for training health workers on the use of vaccine vial monitors with measles vaccine for field-testing purposes. The kind assistance and contributions of the above persons and the National Immunization Programme of Viet Nam are gratefully acknowledged.

1. How a vaccine vial monitor works

1.1 What is a vaccine vial monitor?

A vaccine vial monitor (VVM) is a label containing a 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 inner square of the VVM to darken gradually and irreversibly. The rate of colour change increases with temperature.

1.2 Does a VVM measure vaccine potency?

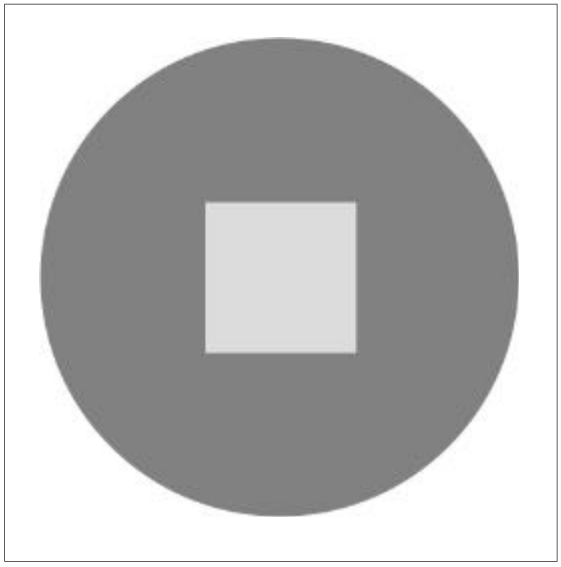
No, the VVM does not directly measure vaccine potency but it gives information about the main factor that affects potency: heat exposure over a period of time.

The VVM does not register information about freezing factor that may contribute to vaccine degradation.

1.3 What does a VVM look like?

The VVM is a circle with a small square inside it. It is printed on a product label or attached to the cap of a vaccine vial or tube or to the neck of an ampoule. (Fig. 1).

Fig. 1. Vaccine vial monitor (showing no heat exposure)



1.4 How does a VVM work?

The **inner square** of the VVM is made of heat-sensitive material that is light in colour initially and **becomes darker** when exposed to heat.

The inner square is initially lighter in colour than the outer circle. It remains so until the temperature and/or the duration of heat reaches a level that is likely to degrad the vaccine beyond the acceptable limit.

At the discard point the inner square is the same colour as the outer circle. This indicates that the vial has been exposed to an unacceptable level of heat and that the vaccine may have degraded beyond the acceptable limit. The inner square continues to darken as heat exposure continues, until it is much darker than the outer circle. If the inner square becomes as dark as or darker than the outer circle the vial must be discarded.

Fig. 2. VVM locations

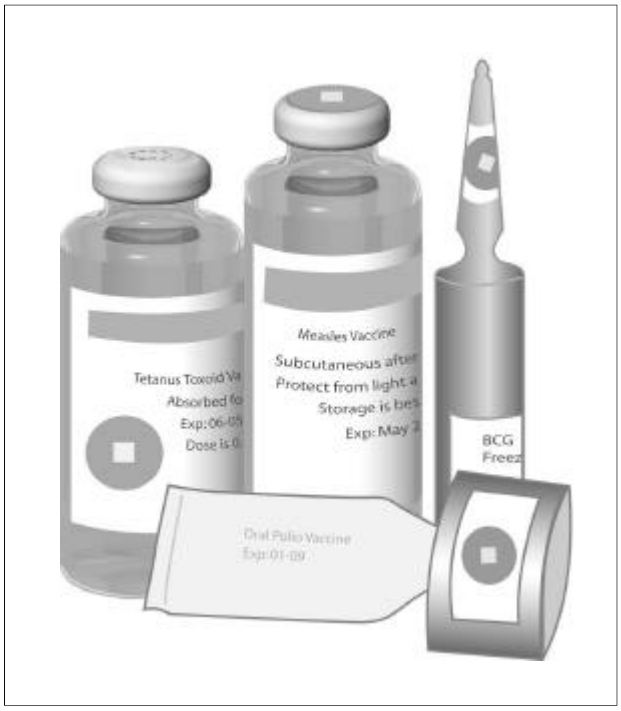
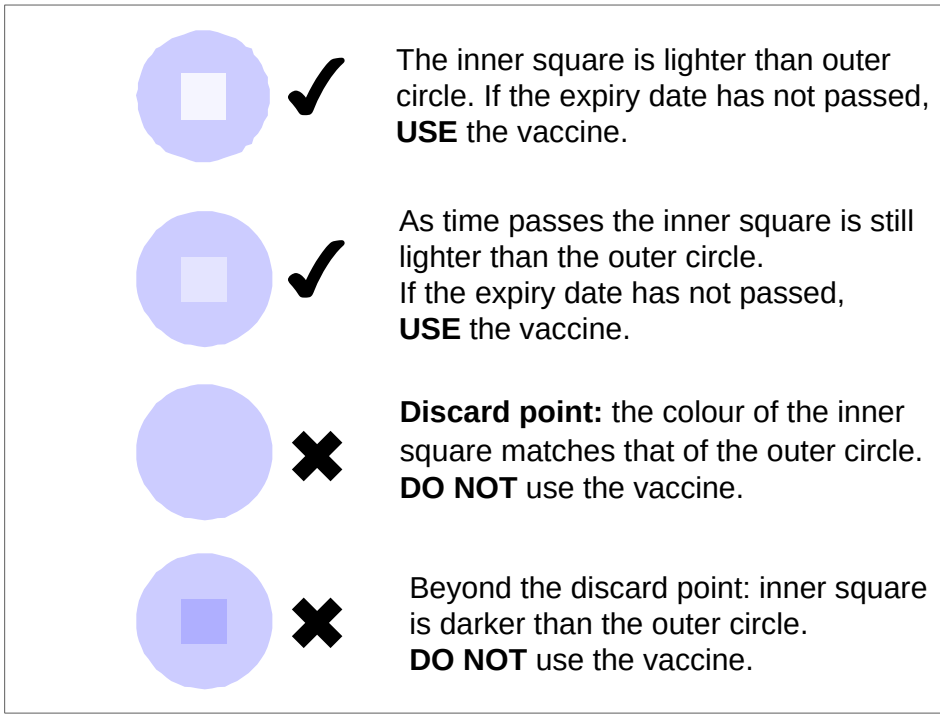


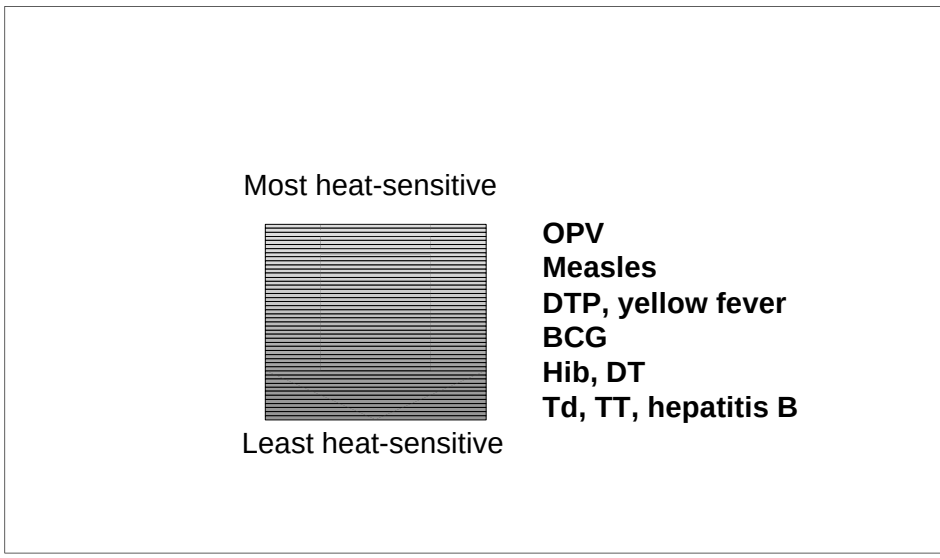
Fig. 3. How to read a VVM



1.5 Are there different types of VVM for different vaccines?

Yes, there are four types of VVM for vaccines of differing heat stability. Some vaccines are more **sensitive to heat** than others. The commonly used EPI vaccines can be ranked according to their sensitivity to heat as follows.

Fig. 4. Heat stability of vaccines



The table below describes VVM reaction rates by category of heat stability.

VVM reaction rates by category of heat stability

Category: (Vaccines)	No. days to end point at +37°C	No. days to end point at +25°C	Time to end point at +5°C
VVM30 High stability	30	193	> 4 years
VVM14 Medium stability	14	90	> 3 years
VVM7 Moderate stability	7	45	> 2 years
VVM2 Least stable	2	NA*	225 days

***VVM (Arrhenius) reaction rates determined at two temperature points**

The reactions of VVMs vary in accordance with the category of vaccine to which they are assigned. VVM2, which is assigned to OPV, the most heat-sensitive vaccine, reaches its end-point in 48 hours at 37 °C, whereas VVM30 on hepatitis B vaccine, one of the most heat-stable vaccines, takes 30 days to reach its end-point at this temperature. However, vaccines made by different manufacturers may have different heat stability characteristics and may therefore be assigned to different categories by WHO. Manufacturer X's BCG might use a VVM30 while manufacturer Y's BCG needs a VVM14.

1.6 What are the rules for reading a VVM?

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

- Rule 1: If the inner square is lighter than the outer circle the vaccine can be used (provided that the expiry date has not passed).
- Rule 2: If the inner square is the same colour as or darker than the outer circle the vaccine must not be used.

1.7 Does a VVM immediately change colour when exposed to temperatures above 8°C?

No. The VVM reflects the heat stability of the vaccine to which it is attached. It does not undergo an immediate colour change in response to brief exposure to moderate heat.

Vaccines have a level of heat stability that enables them to withstand temperatures above 8 °C, outside the cold chain, for a limited time. The rate at which a VVM changes colour reflects the ability of the vaccine in question to withstand heat.

1.8 If a vaccine is left at room temperature, how long does it take for a VVM to change from start point to discard point?

This depends on the room temperature and varies greatly with the place, season, time of day and type of vaccine. The table below shows sample times recorded for VVMs attached to vials of OPV and hepatitis B vaccine, representing the most heat-sensitive and least heat-sensitive vaccines respectively (with the assumption of no previous heat exposure history).

Constant temperature, day and night	Time for VVM on vial of OPV to reach discard point	Time for VVM on vial of hepatitis B vaccine to reach discard point
5°C (in a refrigerator)	225 days	5197 days
20°C (room temperature)	20 days	385 days

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

No. The colour change is irreversible as is the damage to the vaccine. The VVM indicates the accumulated heat to which the vaccine has been subjected.

1.10 If a vaccine inside a refrigerator freezes, will a VVM register any change?

No. A VVM does not indicate freezing and provides no information on this matter.

1.11 How does a VVM cope with variations in heat tolerance between different types of vaccine?

VVMs are manufactured with four specific time-temperature sensitivities. Each type of VVM is designed to mimic the heat stability of the vaccine to which it is attached.

1.12 What testing and quality control procedures are used to ensure that a VVM performs correctly?

Each batch of VVMs is tested twice with a colour reflectance densitometer in order to ensure that the VVM changes 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 dispatch.

Before WHO approved the use of VVMs, all aspects of this technology were subjected to extensive independent laboratory testing and field trials.

1.13 How does the VVM message relate to the vaccine cold chain monitor card?

The vaccine cold chain monitor (CCM) card, packaged with each consignment of vaccine from UNICEF, indicates when the temperature limits of the cold chain have been passed. The VVM takes the monitoring procedure one step further by showing the impact of any such temperature change on each vial of vaccine.

The CCM is a useful managerial tool for checking the arrival of vaccine shipments at central and provincial stores and can also be used in conducting national cold chain surveys. The VVM provides guidance on the use of each vial of vaccine.

2. Advantages and costs

2.1 Why should a VVM be used?

A VVM enables health workers to know whether a vaccine has been damaged by heat.

Vaccines exhibit no visible change as a consequence of heat exposure. Before the development of the VVM, health workers had no means of identifying whether vaccines had suffered damage from heat exposure at any point during transportation and/or storage.

National recommendations for vaccine handling have consequently been very conservative, in order to prevent the use of vaccines damaged by heat. Health workers have been trained to discard all vaccines after any break or suspected break in the cold chain. 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. Large amounts of usable vaccine are discarded as a consequence of these precautions against possible heat damage.

The gradual and irreversible colour change of the VVM makes it possible to assess cumulative heat exposure and the remaining shelf-life of a vaccine, even if vials have been out of the cold chain or stored in a malfunctioning refrigerator.

WHO recommends that VVMs be used for:

- ensuring that vaccine administered has not been damaged by heat;
- reducing vaccine wastage;[1]
- facilitating immunization outreach and increasing access and coverage;
- pinpointing cold chain problems;
- managing vaccine stocks.

2.2 Do VVMs raise the cost of vaccines?

Yes. Buyers have to pay a little more for vaccines with VVMs attached. However, a greater amount is saved by reducing the quantity of wasted vaccines.

[1] In some cases, VVM introduction may initially increase wastage. VVMs may lead to discards as they expose weaknesses in the cold chain that passed unseen before VVM introduction.

3. Using a vaccine vial monitor

3.1 If the VVM has not reached the discard point, can a vaccine still be used if it has passed its expiry date?

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

The expiry date is calculated on the assumption that the vaccine is stored within an appropriate range of temperatures (2-8°C) throughout the cold chain. Even under correct storage conditions, however, vaccines undergo gradual degradation because of such factors as aging and exposure to light. Once a vaccine has passed its expiry date it cannot be expected to stimulate sufficient immunity.

3.2 If a vial carries a VVM, does it need to be kept in the cold chain?

Yes, most of the time, depending on the vaccine and the temperature. All vaccines are sensitive to heat and if kept refrigerated they remain potent for longer than would otherwise be the case. The VVM does not change a vaccine's heat stability. It simply gives a visible indication of the extent to which the vaccine's resistance to heat has been used up, i.e. when heat exposure has exceeded the limit for the vaccine in question. Each vaccine has a certain level of resistance to small amounts of heat. OPV has the lowest resistance. Careful cold chain handling preserves a vaccine's ability to withstand any accidental or unavoidable heat exposure.

Some vaccines, especially hepatitis B and TT, can be taken out of the cold chain if the VVM is properly used to monitor heat exposure. These circumstances should be carefully planned and monitored.

3.3 Under what circumstances, if any, can vaccines bearing VVMs be taken out of the cold chain?

Vaccines with VVMs can be taken out of the cold chain only if health workers and others handling the vaccines have been trained to interpret VVM readings correctly and if any vial bearing a VVM that has reached its end-point is discarded.

Managerially, however, it is wise to maintain vaccine in the cold chain for as long as possible during distribution. This ensures the maximum viable life in the field.

A policy permitting the use of vaccine outside the cold chain can be implemented either generally for all routine immunization activities or on a limited basis in certain areas or under special circumstances, such as:

- national immunization days;
- hard-to-reach geographical areas;
- immunizations provided in the home;
- cool seasons;
- storage and transportation of freeze-sensitive vaccines (DTP, TT, DT, Td, hepatitis B and Hib vaccines) where the risk of freezing is greater than the risk of heat exposure.

Remember that freeze-dried vaccines (measles, BCG, yellow fever, and freeze-dried formulations of Hib) should not be transported to their point of use if the availability of ice cannot be guarenteed. Ice is necessary in order to keep the vaccines cool after they have been reconstituted.

3.4 Should other monitors, such as freeze indicators or CCMs, still be used?

Yes. Freeze indicators and CCMs track temperatures during transportation. VVMs are not a substitute for them.

3.5 If the information provided by a CCM differs from that indicated by a VVM, which reading is the more accurate?

As mentioned above, CCMs monitor the cold chain, whereas VVMs monitor the vaccine in individual vials.

If the readings do not relate to freezing temperatures the VVM readings are the more accurate. They give an exact indication of the levels of heat exposure of the vials to which the VVMs are attached.

3.6 Is there a limit to the number of times an unopened vial can be taken for outreach (or used in an NID)?

No, not as long as the colour of the VVM indicates that excessive heat damage has not occurred.

3.7 Should vaccines with VVMs showing some heat exposure but not yet at the discard point be handled differently to other vaccines?

Yes. These vaccines must be distributed first. The VVM enables the storekeeper to pick out the batches that have been most exposed rather than adopting the earliest-expiry-first-out (EEFO) approach.

3.8 Can VVMs be used to help in storage and cold chain management?

Yes. VVMs give a visual measure of the heat exposure of each vial. This enables the health worker to:

- use vaccine selectively so that, for instance, vials with minimal heat exposure can be selected for use in outreach sessions or mobile services;
- estimate the remaining shelf-life of vaccines and rotate inventories, so that the vials with the greatest heat exposure can be selected for use before the others;
- identify cold chain problems or confirm problems suggested by VVMs or refrigerator thermometers; each significant exposure to heat produces a colour change on the VVM; in some cases it may be possible to investigate where this exposure has happened;
- reduce wastage by selecting the vials on which the VVMs are nearest to the end-point and in which the vaccine is still usable.

If health workers are thoroughly trained in the use of VVMs the EEFO policy for vaccine handling can be modified. In larger stores, however, where vaccines are kept in their cartons and the VVMs are not visible, the EEFO policy may still be the most appropriate management option.

3.9 How can the impact of VVMs on EPI be evaluated?

Conduct a knowledge, attitudes and practices (KAP) survey, based on a standard protocol. WHO and other agencies may be willing to assist with this type of evaluation.

Alternatively, introduce a checklist of points to be considered by district supervisors, including the following.

- Are health workers interpreting VVMs correctly?
- Are the vaccines bearing VVMs being correctly handled?
- What is the level of vaccine wastage attributable to heat exposure now that VVMs are being used?
- Are there any negative consequences of using VVMs?
- Are there any unexpected benefits of using VVMs?
- Do health staff have ideas for other ways in which VVMs could promote a more efficient use of EPI resources?

4. Getting started with vaccine vial monitors

4.1 Which vaccines carry VVMs?

All OPV supplied through UNICEF has been labelled with VVMs since 1996. VVMs began to be used with other EPI vaccines in 2001. By November 2002, VVMs were available on some vials of BCG, yellow fever, measles, MR, MMR, hepatitis B, and tetanus-toxoid vaccines supplied through UNICEF. In the coming years, it is expected that VVMs will be available on all vaccines supplied through UNICEF.

4.2 Can VVMs be included on vaccines that are not purchased through UNICEF?

Yes. Countries or agencies purchasing their own vaccines should include WHO-approved VVMs in the specifications provided to the vaccine manufacturers.

4.3 How will VVMs be integrated into the current immunization services?

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

Health workers at the periphery must be trained to check every VVM before administering a vaccine. They will report any damaged vaccine to their supervisors, who will pass this information to the supervisor at the next level of the system.

4.4 What are the guidelines for the initial period when there may be vials with and without VVMs in health centre stocks?

Vaccines with VVMs should be sent to the areas with the poorest cold chains. Once this has been done the vials without VVMs must be used first.

Vials with VVMs should not be used as proxy indicators of heat exposure for vials without VVMs, which should be handled as previously.

5. Training

5.1 Which categories of personnel require special training?

All staff who handle vaccines, including stock managers, workers who transport vaccines, health workers and NID volunteers require training on the interpretation of VVMs and the vaccine handling policy applicable to vials bearing VVMs.

In addition, district managers must learn about the changes in the monitoring system with respect to vaccine discarded once a VVM has reached its end-point.

5.2 How can training be provided?

Health workers who are already in post can learn about VVMs during refresher courses or special training, such as is given before NIDs.

New health staff should learn about VVMs during their basic training. The interpretation of VVMs and the related policies should be introduced into curricula.

6. Impact on programme operations

6.1 How does the availability of VVMs affect WHO policy on the use of opened multi-dose vials of liquid vaccine in subsequent immunization sessions?

VVMs provide additional information on the heat exposure status of opened vials of liquid vaccines (DTP, TT, DT, Td, hepatitis B, OPV and liquid formulations of Hib), which can now be used for up to four weeks under this policy.[2]

The introduction of the policy can be tied to the availability of VVMs on these vaccines. The decision on this matter depends on the risk of heat exposure and the flexibility of health workers in dealing with changes.

6.2 How is vaccine consumption affected by the use of VVMs and the implementation of the multi-dose vial policy?

Vaccine wastage is expected to fall, especially in areas where, on average, fewer than 10 immunizations with the affected liquid vaccines are given per session.

The wastage factor should be checked and adjusted by measuring vaccine wastage changes, particularly in areas where:

- wastage is already high;
- the cold chain is weak;
- vaccine is beginning to be taken out of the cold chain.

Wastage may increase in areas where the cold chain is defective or where vaccine is taken out of the cold chain for long periods in hot weather.

[2] See *WHO policy statement: The use of opened multi-dose vials of vaccine in subsequent immunization sessions* (WHO/V&B/00.09).

6.3 How are EPI strategies affected by these changes?

Lower rates of vaccine wastage associated with the multi-dose vial policy should encourage the re-establishment of the policy of immunization at every opportunity and more frequent immunization sessions.

In the past, high vaccine wastage rates discouraged EPI managers from advocating immunization at every opportunity, even though missed opportunity surveys have consistently shown that significant improvements in immunization coverage can be achieved and sustained by immunizing on this basis.

VVMs may extend the reach of mobile, NID and outreach operations and thus raise immunization coverage. In the past, immunization was curtailed when ice packs melted and it was feared that vaccines might have lost their potency. VVMs, however, show whether there has been any heat damage. If there has not, immunization can continue.

6.4 How should we monitor vaccine wastage once VVMs are in use?

Quantities of vaccine discarded because of a VVM indication of excessive heat exposure should be specifically noted on inventory forms and reported to supervisors, who should review the vaccine wastage statistics and strengthen the cold chain, supervise vaccine administration or change vaccine orders as appropriate.

6.5 How can VVMs be introduced into EPI?

At central level

- Convene a national policy meeting in order to review the WHO literature on VVMs, to decide on the changes to be made in local vaccine handling policies, and to develop a national strategy for their introduction. This meeting should produce a written official statement:
  - outlining the changes in national vaccine handling policy;
  - making the necessary changes to vaccine inventory forms;
  - scheduling the necessary briefings, training and distribution of materials;
  - quantifying the training materials needed;
  - indicating the source of funds.
- Train district-level managers in preparation for the arrival of VVMs on all vaccines.

At district level

- Request district managers to instruct heath centre personnel on the interpretation of VVMs and the new vaccine-handling policies as soon as possible after the first batches of vaccine with VVMs reach the field.

NOTE: Failure to inform managers and health workers is not likely to cause damage or disruption to EPI. However, the benefits of using VVMs will be delayed until training has been completed.

6.6 Can opened vials of measles, yellow fever, BCG and freeze-dried Hib vaccine be used the day after an immunization session if the the VVM has not reached the discard point?

No! Opened vials of measles, yellow fever, BCG and freeze-dried Hib vaccine cannot be used after an intial immunization session. They **must** be discarded within six hours of reconstitution or at the end of the session, whichever comes first. The VVMs for these vaccines are attached to the vial caps and should be discarded when the vaccine is being reconstituted.

6.7 Can logistics be improved by using VVMs to enable vaccine storage or delivery out of the cold chain?

Yes, especially for heat-stable vaccines such as hepatitis B and TT. Possible improvements include:

- longer, farther outreach to isolated areas;
- reduced freezing of vaccines;
- elimination of the need to find additional cold chain capacity during campaigns;
- village-level home storage of vaccines for faster outreach;
- constant availability of vaccines in clinics that do not have refrigeration.

However, it is important to note the following points.

- VVMs must be monitored and vaccines must be used until the discard point is reached.
- Because different vaccines have different heat stabilities, time and ambient temperature must be accounted for when the vaccines are out of the cold chain.
- Ice is needed for freeze-dried vaccines in order to keep reconstituted vials cold during sessions.

Annex 1:

Questionnaire for a KAP survey of the impact of VVMs on the delivery and use of vaccines[3]

Name: .....

Position: .....

Health centre: .....

District: .....

Province: .....

1	Have you given immunizations using OPV with VVMs?	Yes	No	
2	Have you been trained in the use of VVMs?	Yes	No	
3	Are you aware of any policy regarding VVMs and vaccine use?	Yes	No	
	If yes, what is the policy?			
4	Do you think VVMs can detect whether a vaccine is damaged by heat?	Yes	No	
5	Are you confident that VVMs are accurate? If not, explain why.	Yes	No	
6	Do you discard OPV when:			
	a) the colour of the VVM inner square matches that of the outer circle;	Yes	No	
	b) the VVM inner square is lighter than the outer circle;	Yes	No	
	c) the VVM inner square is darker than the outer circle?	Yes	No	
7	Do you save open OPV vials for subsequent immunizations:			
	a) at fixed sites;	Yes	No	
	b) after outreach?	Yes	No	
8	Do VVMs make you feel more confident about saving open OPV vials?	Yes	No	

[3] This KAP survey questionnaire can be used for all liquid vaccines with attached VVMs. The necessary adjustments to the text should be made.

9	Do you save open vials of other vaccines as well?				
	a) at fixed sites;			Yes	No
	b) after outreach?			Yes	No
	If you save open vials of vaccine, which are saved?				
	BCG	DTP	Tetanus toxoid		
	Yellow fever	Measles	Hepatitis B		
10	With VVMs, have you changed the way you:				
	a) keep and transport vaccines?			Yes	No
	If yes, in what way?				
	b) maintain the cold chain?			Yes	No
	If yes, in what way?				
11.	How have the VVMs been helpful to you?				
12	Observations on vaccine storage at health centre				
	a) Number of opened vaccine vials				
	OPV				
	Measles (DANGER: opened vials must be discarded immediately)				
	DTP				
	TT				
	BCG (DANGER: opened vials must be discarded immediately)				
	Hepatitis B				
	DT				
	Reconstituted Hib (DANGER: opened vials must be discarded Immediately)				
	Liquid Hib				
	b) Number of vials past expiry date (discard these vials)				
	c) Number of vaccine vials with VVMs at discard point (discard these vials)				

Annex 2:

Questionnaire for a KAP survey of the impact of VVMs on the delivery and use of measles vaccine[4]

Name: .....

Position: .....

Health centre: .....

District: .....

Province: .....

1	Have you given immunizations using measles vaccine with VVMs:	Yes	No	
	a) at a fixed site;			
	b) as an outreach activity?			
2	Have you been trained in the use of VVMs?	Yes	No	
3	Do you think VVMs can detect whether a vaccine is damaged by heat?	Yes	No	
4	Are you confident that VVMs are accurate? If not, explain why.	Yes	No	
5	Did you discard any measles vaccine during campaign activity because the VVM showed that it had been heat-damaged?	Yes	No	
6	Were you able to save any measles vaccine after a cold chain break because the VVM showed that it was not heat-damaged?	Yes	No	
7	Do you refer to measles VVM readings:			
	c) before reconstitution;	Yes	No	
	b) after you reconstitute the vaccine?	Yes	No	
8	What is the correct rule for deciding when reconstituted measles vaccine should be discarded? Circle (a), (b) or (c).			
	(a) Whenever the vial is completely used, regardless any time limitation.			
	(b) Within six hours after reconstitution or at the end of the session. Whichever comes first.			
	(c) Within 12 hours.			

[4] This KAP survey questionnaire can be used for all freeze-dried vaccine presentations with attached VVMs. The necessary adjustments to the text should be made.

9	Do VVMs make you feel more confident about handling measles vaccine?	Yes	No	
10	With VVMs, have you changed the way you:			
	a) keep and transport vaccines?	Yes	No	
	If yes, in what way?			
	b) maintain the cold chain?	Yes	No	
	If yes, in what way			
11	Do you have any comments on VVMs?			

The Department of Vaccines and Biologicals was established by the World Health Organization in 1998 to operate within the Cluster of Health Technologies and Pharmaceuticals. The Department's major goal is the achievement of a world in which all people at risk are protected against vaccine-preventable diseases.

Five groups implement its strategy, which starts with the establishment and maintenance of norms and standards, focusing on major vaccine and technology issues, and ends with implementation and guidance for immunization services. The work of the groups is outlined below.

The *Quality Assurance and Safety of Biologicals team* team ensures the quality and safety of vaccines and other biological medicines through the development and establishment of global norms and standards.

The *Initiative for Vaccine Research* and its three teams involved in viral, bacterial and parasitic diseases coordinate and facilitate research and development of new vaccines and immunization-related technologies.

The *Vaccine Assessment and Monitoring team* assesses strategies and activities for reducing morbidity and mortality caused by vaccine-preventable diseases.

The *Access to Technologies team* endeavours to reduce financial and technical barriers to the introduction of new and established vaccines and immunization-related technologies.

The *Expanded Programme on Immunization* develops policies and strategies for maximizing the use of vaccines of public health importance and their delivery. It supports the WHO regions and countries in acquiring the skills, competence and infrastructure needed for implementing these policies and strategies and for achieving disease control and/or elimination and eradication objectives.

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