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17 JUL 2000

Making use of Vaccine Vial Monitors

Flexible vaccine management for polio supplementary immunization activities

DEPARTMENT OF VACCINES AND BIOLOGICALS

World Health Organization
Geneva

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CALL NO. CH-131 000 ACC. NO. 07069

AUTHOR WHO-

TITLE Making use of vaccine Vial Monitors – Flexible VM for polio Supplementary

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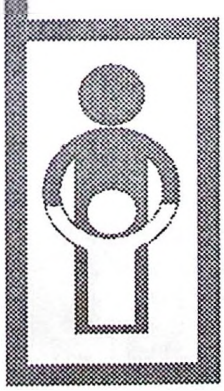

DEPARTMENT OF VACCINES AND BIOLOGICALS

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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
Expanded programme on Immunization Team
of the Department of Vaccines and Biologicals

Ordering code: WHO/V&B/00.14
Printed: April 2000

This document is available on the Internet at:
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Contents

1. Introduction

All countries where polio transmission is not yet interrupted have one or several of the following characteristics in common:

- a large proportion of difficult-to-reach populations, either due to geographic inaccessibility, or the persistence of pockets with limited access to health services (high population density, nomads, deprived groups, etc.);
- destroyed or unreliable transport infrastructure;
- insufficient and/or inoperable cold chain equipment;
- lack of sufficiently trained technical staff;
- insecurity due to ongoing conflict, mines, etc.

The heat sensitivity of oral polio vaccine (OPV) and the ensuing necessity to keep the vaccine cool is one of the major complicating factors for the implementation of polio campaigns under these conditions.

However, because of the short duration of campaigns for polio eradication and the presence of the vaccine vial monitor (VVM, see chapter 3) on the OPV vials, it is now possible to implement a more flexible cold-chain strategy than could previously be envisaged.

Although this strategy is especially appropriate for countries in conflict, post-conflict, or with insufficient infrastructure, it should not be limited to them. Any national immunization day (NID), even one conducted among easily-accessible populations, can be more effective if it adopts a more flexible approach.

These guidelines are designed specifically for OPV use during national immunization days/subnational immunization days (NIDs/SNIDs) and mop-ups only. A full-scale cold chain is necessary if measles vaccine is added to NIDs, since this vaccine does not have a VVM and degrades rapidly in ambient temperatures after reconstitution.

2. The 'traditional' cold chain for campaigns

The traditional cold chain employed during campaigns uses predominantly refrigerators and freezers for the storage of vaccines and cold boxes and vaccine carriers for their transport. The presence of ice is ensured at all times during transport and at the vaccination site and is a prerequisite for the continuation of the work of the teams.

The heat sensitivity of the vaccines and the impossibility to monitor heat exposure justified this cold chain model.

However, this model does have a number of disadvantages:

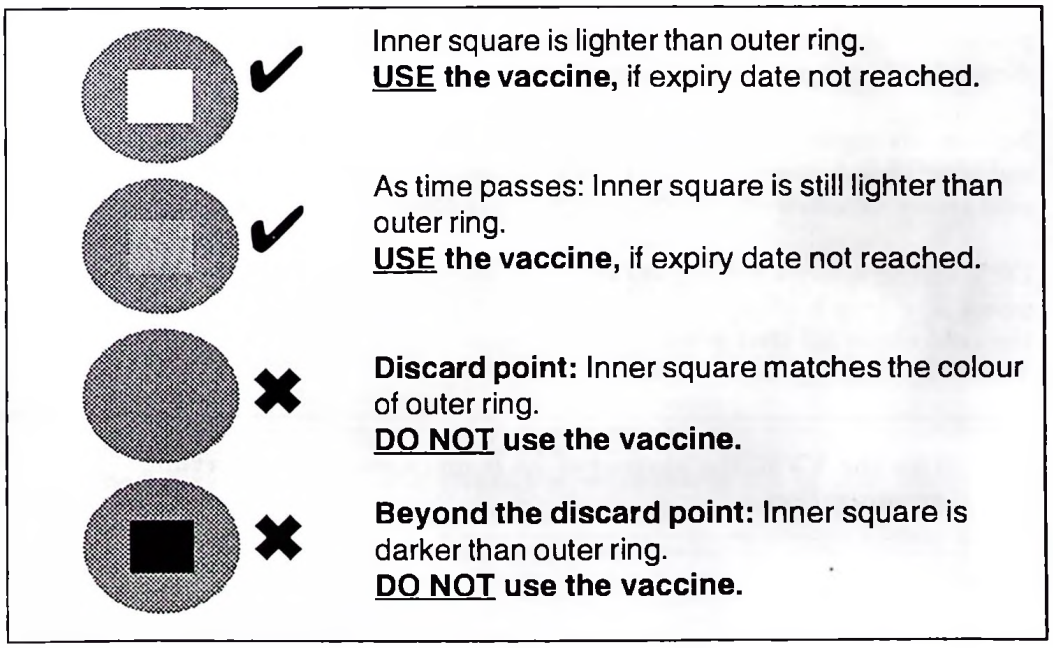
- It makes it difficult to reach populations with limited access, because of:
  - the cold life of the equipment in relation to the distance to be travelled;
  - the (seasonal) lack of accessibility of these populations due to the nature of the terrain;
  - the weight and volume of equipment, which increase with travelling time and distance;
  - the amount of equipment required to cover remote and/or dense populations;
  - lack of flexibility due to the inherent necessity of requiring ice all the time at every stage.
- A cold chain designed specifically for NIDs is relatively costly:
  - a cold chain designed for NIDs may be badly adapted to routine services, because the latter are less demanding in terms of freezing capacity and may require different types of equipment all together (less compression appliances, generators, etc.);
  - equipment will run around the clock to satisfy the need for icepacks to keep vaccines cool.
- Traditional cold chain management has a top-down approach leaving little room for creative problem solving by health staff: in the traditional cold chain no ice means no immunization.

3. The vaccine vial monitor

Oral polio vaccine is the most heat sensitive of all vaccines used in the Expanded Programme on Immunization (EPI). Storage and transport have to comply with good cold chain practices. However, cumulative heat exposure can now be monitored with the help of the vaccine vial monitor (VVM),[1] which can be found on all OPV supplied by UNICEF since 1997.

A heat sensitive square within a circle (figure 1) changes colour under the combined influence of heat and time. If after exposure to heat for a certain amount of time, the square reaches the same colour, or becomes darker than the circle, the vial should be discarded.

Figure 1: the VVM



[1] Vaccine vial monitor – Training guidelines. WHO/EPI/LHIS/96.04 (update planned for 2000). Vaccine vial monitor and open vial policy. WHO/EPI/LHIS/96.01 (update on multi-dose vial policy in process).

OPV, supplied by WHO accredited manufacturers, retains **satisfactory potency for at least 48 hours at an ambient temperature of 37°C.** The VVM reaches the point where OPV should be discarded before that.

At lower temperatures the loss of potency is considerably slowed down and the time it takes the VVM to reach the discard point increases subsequently.

Table 1 gives the WHO/UNICEF specification of VVMs for OPV. It shows that, for example, **at 25°C** continuous ambient temperature the VVM will reach the **discard point only after 7 days.**

Table 1: VVM reaction rate for OPV[2]

Continuous ambient temperature	Number of days before VVM on OPV will reach discard point
+ 37°C	1.5 - 2 days
+ 25°C	7 days
+ 4°C	180 days (6 months)
- 20°C	2 years

The VVM allows the user to see at any time if **OPV can still be used in spite of possible cold chain interruptions.** If necessary, health staff and management can then take the required corrective measures.

Besides this important corrective management based on VVM monitoring, it is feasible and justifiable to use the **VVM to plan a more flexible, less stringent and cheaper cold chain,** which is of particular importance for NIDs.

OPV can be safely used beyond the cold chain until the VVM reaches the discard point. The length of time will depend on ambient temperatures and **the quality of the cold chain till that point.**

With the VVM, the absence of ice is not a reason to interrupt immunization

[2] Equipment performance specifications and test procedures. E6: Temperature monitoring devices. WHO/EPI/LHIS/97.09.

The advantages of the use of VVMs during NIDs are:

- teams can **go further in time as well as geographically,** due to less bulky equipment and decreased dependence on re-supply of ice;
- difficult access and weak cold chain cease to be reasons not to immunize population groups usually missed during NIDs and routine services;
- because fewer icepacks are required, freezing can be faster and with less equipment;
- cold chain costs can decrease due to these factors;
- health worker and stock manager can decide which vials to use first or in nearby areas with good cold chain on the basis of VVM status;
- **reduction of wastage.** With the help of the VVM several countries have abandoned the policy of discarding OPV vials at the end of a session or in case of cold chain failure. This has led to important reduction in wastage from a previous 25% to 10% or lower. Experience in many countries now shows that few VVMs reach the discard point during the campaigns.

Proactive management should lead to a tailor made cold chain, combining VVM and equipment specifications on the one hand with excellent micro planning and sensitized health workers on the other. This as opposed to the traditional top-bottom and "ice everywhere" approach.

Annex 1 presents the main facts regarding the VVM and is meant to be used as an information sheet or as training materials.

3.1 Important VVM reminders

- The VVM gives only information about the vial to which it is attached. **It can not be used as indicator of heat exposure to other vaccines,** because the cold chain history of the latter may be very different.
- The **expiry date of a vial has priority over the VVM.** If the expiry date is reached, the vial should be discarded even if the VVM suggests the vial can still be used.

> **The better the overall cold chain, the more teams can benefit from the VVM during the NIDs**

4. The fast chain

4.1 What is it?

The fast chain is a cold chain strategy that seeks to increase the effectiveness of campaigns by a reduction of the dependence on cold chain equipment through pro-active management and short supply lines.

The number of refrigerators and freezers required for intermediate storage is kept to a strict minimum through the **intense use of cold boxes as secondary distribution points** after vaccines leave the central/regional stores.

Although the fast chain was already applied before vaccine vials had VVMs, the combination of both increases even further the possibilities for a flexible cold chain during NIDs.

4.2 What is the advantage?

The elements described above reduce dependence on refrigerating and freezing systems at peripheral level.

The fast chain, in combination with the VVM, has the following advantages:

- **difficult to access populations** can be reached without installing additional equipment at peripheral level;
- installation of a specific NIDs cold chain with its excessive need of ice and probable incompatibility with the routine programme requirements, can be prevented;
- the cold chain can be **cheaper**, although this may be offset by the increased need for freezing equipment at central level.

5. When is a flexible cold chain required?

Clearly, by reducing the dependence on cold chain equipment and increasing the flexibility of the teams, the fast chain and the use of VVMs are ideal for any country or region where the infrastructure makes it difficult to implement the traditional cold chain.

However, there is **no reason to limit either of them to these difficult conditions.** On the contrary, they should really be seen as the first step of **the cold chain of the future,** which will have the following characteristics:

- strengthening of central and regional stores;
- VVMs on all vaccines;
- increased flexibility at peripheral levels.

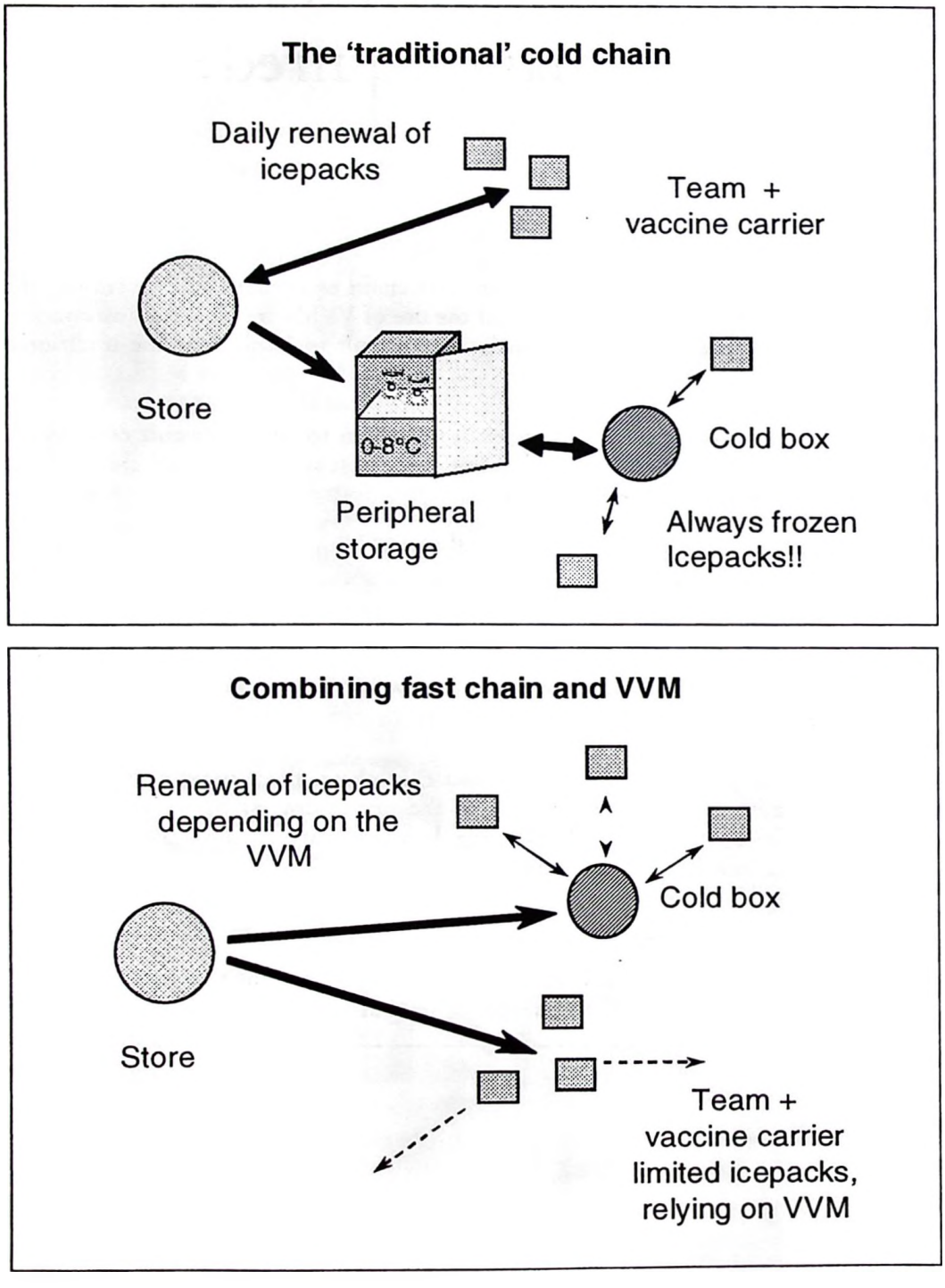
The fast cold chain and the VVM can be used in any country implementing NIDs with OPV only.[3]

Even for a country with a well-established cold chain, there is no need to stretch icepack freezing and storage capacity to the maximum, or provide teams with materials, which are too heavy, thus limiting their flexibility. Figure 2 gives an example of a traditional and flexible cold chain.

> **With the fast chain and the VVM, population groups that are usually missed during NIDs, can be immunized.**

[3] Since vitamin A does not require to be kept cool, its addition to polio NIDs is irrelevant for the cold chain strategy.

Figure 2: The typical set for a flexible cold chain



6. Planning issues for a flexible cold chain

When planning for a flexible NIDs cold chain the following key elements have to be considered:

1) It is the task of **management at central and regional level** to determine the length of time OPV can be safely taken beyond the cold chain. This must be based on:
   - The duration of the campaign.
     Inversely, the duration may be adapted to achieve an optimal cold chain strategy.
   - **The quality of the cold chain till that point.** If central and regional storage and transport conditions are sub-standard, the VVM will start changing colour before the actual campaign.
   - Ambient temperatures. **The highest temperature for the country should normally be taken.** To prevent possible confusion, a lower temperature should only be taken if it refers to a region where planning and implementation are clearly separate from the other regions.
   - The VVM specification (see tables 1 and 2), respecting a **good safety margin.**
   - Cold life[4] of the type of vaccine carriers and cold boxes used in the country/region. The cold life of the equipment decreases with the decrease of the number of icepacks.
     - Options 1: the cold life of the cold box should cover supply, duration of campaign and the return of left over vaccines to the store.
     - Option 2: the cold life only needs to cover supply, because either vaccine is not brought back or icepacks can be re-supplied.

OPV can be safely used beyond the cold chain until the VVM reaches the discard point.

[4] The cold life of cold boxes and vaccine carriers is the time it takes between the moment frozen icepacks are put in the box/carrier until the moment any of the vaccines reaches +10°C. The cold life of all boxes/carriers is given in the Product Information Sheets (see the English edition WHO/EPI/LHIS/97.01 and the Supplement WHO/EPI/LHIS/98.03).

2) Once the general context is defined, the equipment and number of icepacks for the teams must be determined at district level through **rigorous micro planning.**

3) Vaccines should be **kept in central/regional stores as long as possible** before the NIDs/SNIDs/Mop-up.

Table 2: Example how to adapt the amount of equipment to the ambient temperatures

Length of time away from the centre, *without re-supply of icepacks*	**Equipment (ambient temperatures 25-35°C)**	**Equipment (ambient temperatures > 35°C)**
< 24 hours	each team 1 carrier without icepacks*	each team 1 carrier with 1-2 icepacks
24 – 72 hours	each team 1 carrier with all its icepacks	each team 2 carriers: 1 with vaccine and 1 with extra icepacks
4 – 6 days	1 carrier per team and 1cold box for each 4 teams	1 carrier per team and 1 cold box for each 4 teams

* Managers may decide to give 1 icepack for the ease of mind of the teams.

4) Because of the limited cold life of the cold boxes, transport to regions where the fast chain is applied, needs to take place at the latest possible time before the beginning of the campaign and requires therefore very rigorous planning.

5) Cold boxes can be used to transport icepacks and vaccines for a number of teams to a secondary distribution point (see figure 2).

6) Freezing the correct quantity of icepacks may have to start up to 8 days before the campaign. If generators are used, they will have to run for 24 hours a day to achieve satisfactory freezing.

7. Hints

7.1 Teaching and believing VVM

- To gain confidence in VVM, EPI managers should not hesitate to test for themselves the extent to which OPV can safely be taken out of the cold chain (see figure 3).

> **The proof of the pudding is the eating: test VVMs yourself !!**

- When **health workers are trained** in the use of the VVM it is strongly recommended to **bring VVM samples** to show during the workshop that OPV can be taken out of the cold chain for a certain length of time. **Only a practical demonstration is convincing.**
- The teams must be clearly instructed to keep vaccines cool at all time, monitor the VVM and **continue immunizing until the VVM has reached the discard point**, or until the end of the campaign.
- Teams must understand they can use **their own imagination** to solve problems and overcome obstacles in reaching **all children in their catchment area.** This is quite different from the traditional cold chain approach and convincing trainers are crucial to get the message across.

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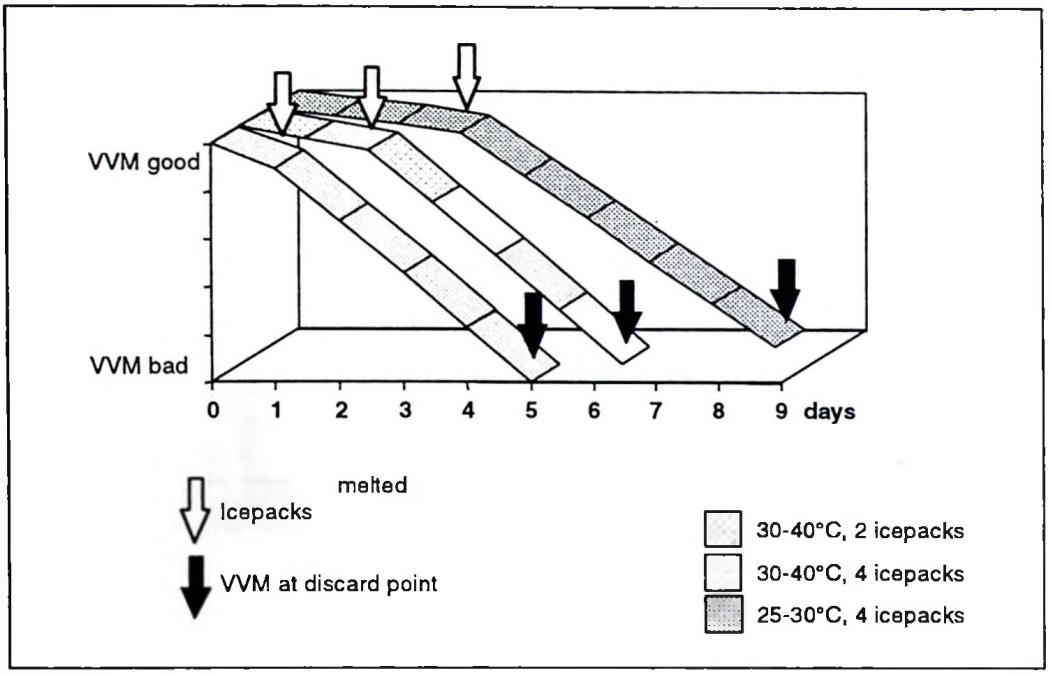
Figure 3: Testing VVM in the field



7.2 Melting icepacks

Teams may be confronted with melting icepacks before completion of the campaign. However, teams must **continue immunizing**, until:

- they have finished the work; or
- the VVM has reached the discard point, whichever is shorter.

Teams need to be told to cool the vaccines by whatever means at their disposal:

- replace the lid immediately after removal of a vial;
- wrap vials and/or the vaccine carrier in a wet cloth;
- keep the vials out of the sun at all time;
- put vaccine carriers in a windy spot;
- trainers need to insist that health workers use their own creativity to cool the vaccines.

Every degree the temperature of the vaccines is brought down will considerably decrease the risk of damage due to heat. When these precautions are respected, the teams can finish immunizing their target population before the vaccine is irreversibly damaged.

7.3 Vials at the end of the campaign or session

- **If OPV vials are opened**, but with doses left at the end of a session, they can be safely used for subsequent sessions, as long as the VVM is good and the vial is not obviously contaminated. To prevent contamination opened vials should not be submerged under water.
- Vials of which the **VVM has started to change colour**, without reaching the discard point, should be kept frozen and used in nearby areas during the beginning of the next round, or during the routine programme.
- **Unopened OPV vials**, whose VVM has not reached the discard point, should be brought back and stored properly to be used for the following round, or for the routine EPI.
- If there is **no ice left for the return trip**, the vaccines needs to be kept as cool as possible as described above. The stock manager will decide whether the vaccine can be used for following activities, using the VVM as a management decision tool.

7.4 What to do in case of shortages/surpluses

In case of shortages of equipment there are alternative strategies to think of. The VVM allows more flexibility.

7.4.1 Shortage of storage capacity for OPV at –20°C

- Store OPV in cold boxes before the NIDs, while regularly renewing the icepacks.
- Store vaccine in refrigerators instead of freezers shortly before the NIDS, provided the VVM has not yet started changing colour

7.4.2 Shortage of vaccine carriers

- Any other type of non-metallic container can be used to transport the vaccines.
- Vaccine carriers from neighbouring counties/districts can be borrowed.
- Use the vaccine carrier as distribution point, from where a few teams can undertake trips to small remote villages for a few hours. Any type of non metallic container can be used.

7.4.3 Shortage of cold boxes

- Use a cold box for more teams: calculate or take a cold box to find out how many icepacks and vaccines it can contain.
- Send the teams only vaccine carriers and no cold box, even to the remote areas. Re-supply with ice if necessary.

7.4.4 Shortage of icepacks

- Use the icepacks of the cold box for the vaccine carriers. If you use this option, make sure the icepacks of the cold box fit in the vaccine carrier.
- Put fewer icepacks in a carrier.
- Use plastic bags to freeze water, but prevent OPV to be floating in water.

7.4.5 Shortage of freezing capacity

- Store OPV in refrigerators instead of freezers to liberate capacity.
- Start freezing in advance and store frozen icepacks in cold boxes.
- Ask neighbouring counties/districts to freeze icepacks for you.
- Use domestic freezers to freeze icepacks.
- Ask the private sector (restaurants, fish and ice factories) to make freezing capacity available.
- Apply all possibilities given under 'Shortage of icepacks'.

7.4.6 Shortage/surplus of vaccine

Remote areas can usually not, or only with great difficulty, be re-supplied with vaccine during the NIDs. In addition, their population size is often only known with a large margin of uncertainty. To prevent a shortage and interruption of the campaign, it is crucial the teams in these areas receive **additional vaccine from the start**.

For all areas it is equally crucial that the **handling of surplus vaccine** be dealt with in the initial planning.

Vaccine **quantities distributed** during the **second round** must be based on the **evaluation** of the first round.

Annex 1:
VVM Fact sheet

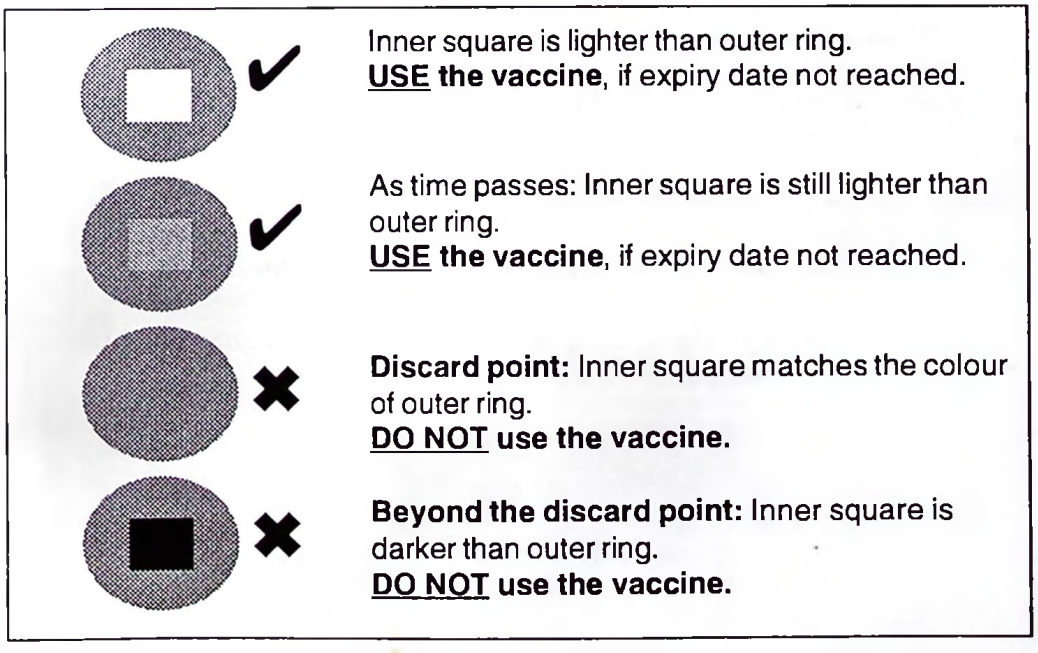
For a cheaper and more flexible cold chain during NIDs

Oral Polio Vaccine is the most heat sensitive of all EPI vaccines. However, **cumulative heat exposure of OPV** can now be **monitored** with the help of the **vaccine vial monitor (VVM)**, which indicates if a vial can still be used.

OPV, supplied by WHO pre-qualified manufacturers, retains **satisfactory potency for 48 hours at 37°C** continuous ambient temperature. The VVM reaches the point where OPV should be discarded (the discard point) before that.

At 25°C ambient temperature the VVM reaches the discard point after **seven days**.

The VVM



Therefore, the VVM allows concluding at any time if OPV can be used **in spite of possible cold chain interruptions**. Health staff and management can act accordingly with corrective measures if required.

Besides these corrective actions, the VVM can be used pro-actively to **plan a more flexible and cheaper cold chain**, which is of particular importance during NIDs.

OPV can be safely used beyond the cold chain until the VVM reaches the discard point. The length of time depends on the ambient temperature and the quality of the cold chain till that point.

The advantages of the use of VVMs during NIDs are:

- teams can go **further in time as well as geographically,** due to less bulky equipment and decreased dependence on re-supply of ice. Difficult access and weak cold chain cease to be reasons not to **immunize population groups usually missed during nids and the routine services**
- decreased burden of the cold chain: less freezing, smaller quantities of equipment
- decreased cold chain costs due to these factors.

The VVM must be pro-actively integrated in the NID planning:

- teams **returning daily** to vaccine distribution points do **not need frozen icepacks** (some managers may decide to give one icepack per day merely for the ease of mind of the teams)
- teams staying away longer do not have to be supplied with ice for the full length of their absence
- all teams must be clearly instructed that **the absence of ice is not a reason to interrupt immunization.**

Experience in numerous countries has now convincingly confirmed the advantages of the VVM.

The **potential benefits of the VVM** during the NIDs highly depend on **the quality of the cold chain before that**.

Proper storage and transport of opv is vital at all levels.

To gain confidence, EPI managers are encouraged to **test VVMs in their own region**.

To **convince health workers** of the merits, vials with VVMs must be brought to NIDs training workshops.

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.

The Department replaces the former Global Programme for Vaccines and Immunization. Five teams implement its "bench-to-bush" strategy, which starts with the establishment of norms and standards, focusing on major vaccine and technology issues, and ends with implementation and guidance for vaccination programmes. The work of the teams is outlined below.

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

The **Vaccine Development Team** coordinates and facilitates the 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 **Expanding Immunization Team** (EPI) 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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