Module 2

Selecting Safe and Effective Vaccines

This module reviews the criteria required for the selection of safe and effective vaccine.

Objectives:

After completing this module, participants will be able to check vials for:

- expiry dates
- signs of contamination
- signs of exposure to freezing
- signs of exposure to too much heat
- correct diluent for reconstitution

Time:

1 hour

Key topics:

- Checking vials and labels to ensure vaccine safety
- Determining whether a vaccine is contaminated
- Using the correct diluent with the appropriate vaccine
- The importance of discarding reconstituted vaccine within 6 hours of mixing
- Reading vaccine vial monitors (VVMs)

Trainer's aids:

- Quiz (pages 24-26)
- Practical Exercise (page 27)
- VVM Illustration (page 28)
- Case Study (pages 29-30)
- VVM Instructions (page 31)

Handouts:

VVM Instructions (page 31)

Trainer preparation:

- Review the module in advance.
- Make photocopies of VVM Instructions (page 31) for distribution in preparation for Practical Exercise.

Selecting Safe and Effective Vaccines

Vaccines are very sensitive. Age, heat, sunlight, cold, or use of the wrong diluent can make vaccines ineffective. In some cases, the use of contaminated vaccine can be lethal. An important aspect of injection safety is ensuring the use of safe and effective vaccines and medications. In this module, we will review the procedures for checking vaccine vials and labels.

Read the Labels on the Vaccine and Diluent Vials: Check the Expiry Date

Before you use any vaccine or diluent, check the following information:

- Is the label still attached to the vial?
- Is it the right vaccine and its specific diluent?
- Has the vaccine or diluent passed its expiry date?

Assess for Contamination

If contamination is suspected, discard the vial. Germs can be present in lethal quantities long before they are visible.

- Check the vial to be sure there are no leaks or cracks.
- Check the solution for a change in appearance or floating particles.
- If the top of an opened vial has been submerged in water, assume the vial is contaminated and discard it.
- If the top of the vial has been pierced with a used (non-sterile) needle or a sterile needle on a used syringe, assume the contents are contaminated and discard it.
- If a vaccine has been reconstituted for more than 6 hours, assume that it is contaminated and discard the vial (also see Module 3, Reconstituting Vaccines Safely).
- If the vial has been opened more than 4 weeks, WHO recommends that it be discarded.

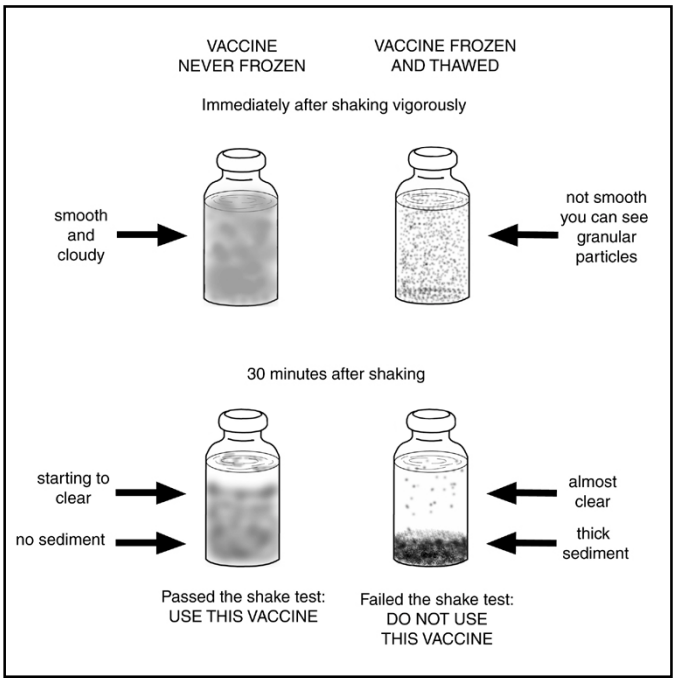
These vials must be discarded. Remember: *"When in doubt, throw it out."*

Assess if Cold-Sensitive Vaccine Has Been Frozen

Confirm that cold-sensitive vaccines and their diluents have not been frozen.

- Discard vials of DPT, DT, Td, TT, hepatitis B, diluents, and Hib if it is certain or highly probable that they have frozen.
- If the refrigerator log shows subfreezing temperatures, the "shake test" can be used to determine if vials of DPT, DT, Td, or TT may have been frozen (see Figure 4).

Figure 4. The shake test



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When vaccinators shake a possibly frozen and an unfrozen vaccine vial of the same type from the same manufacturer, the frozen vaccine will have sediment separate from the liquid more rapidly, and will eventually have sediment at the bottom of the vial. Vials containing an aluminum hydroxide adjuvant, such as DPT, TT, DT, or Td, that fail the "shake test" should not be used.

However, the shake test is not perfect. It is subjective, requires experience, and does not reliably identify all of the vials of DPT, DT, TT, and Td which may have been damaged by freezing. For those who would like more information, instructions for the shake test are available from WHO in the poster "Has your DPT or TT Vaccine Been Frozen?" Specify order number CCPS/02 [4001] when ordering.

- Hepatitis B and Hib vials should be discarded if frozen or suspected of freezing. It is not currently known if the "shake test" works on these vaccines. While hepatitis B vaccine is easily damaged by freezing, it is not known if liquid Hib vaccine can withstand freezing. Studies are underway.
- Diluents should not be frozen because the vials may crack, allowing contaminants like pathogens and dirt to enter.

Assess Exposure to Heat: Read the Vaccine Vial Monitors

A vaccine vial monitor (VVM) is a label made of heat-sensitive material that is placed on a vaccine vial to show cumulative heat exposure over time. VVMs have two important benefits:

- VVMs ensure that only good vaccine is used.
- VVMs reduce wastage of good vaccine.

Check that the vaccine has not been exposed to an excessive amount of heat.

- If the vial has a VVM, check to see if the inner square is lighter than the outside circle. Discard the vial if the inner square is the same color or darker than the outside circle.
- If the vial does not have a VVM, check the temperature log and the cold-chain monitoring cards. If the vial has been exposed to temperatures above 8°C, discard the vial.

Trainer's Note

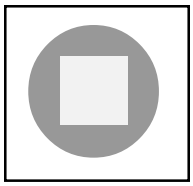
- **Distribute VVM Instructions (Handout, page 31) to participants before beginning this next session.**

Reading Vaccine Vial Monitors

The VVM is printed on the vial label or cap. It looks like a square inside a circle (see Figure 5).

Starting in the year 2001, VVMs will begin to appear on all vaccines purchased by UNICEF.

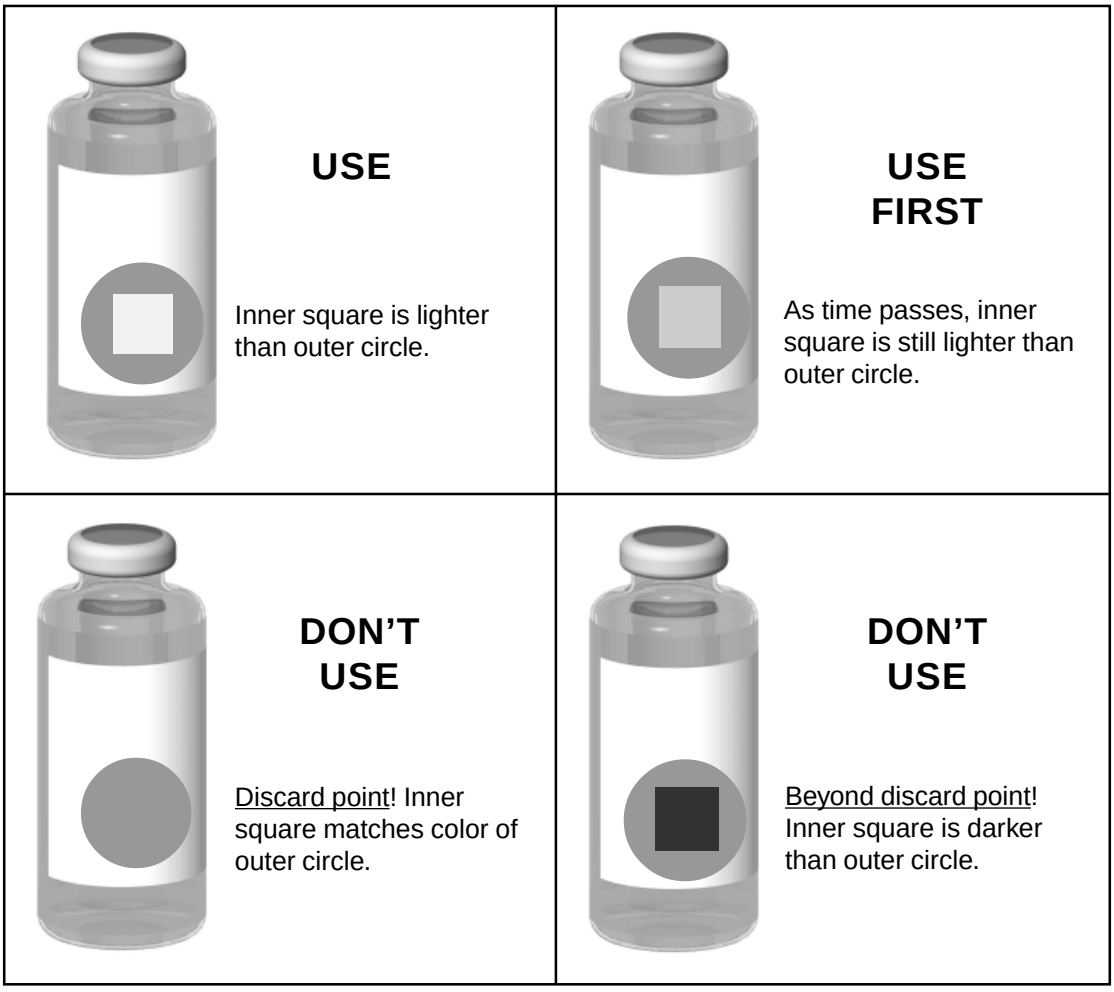
Figure 5. VVM



VVMs show the cumulative, irreversible heat exposure to which a vial has been exposed. The VVM is tailored to the specific heat stability of the vaccine to which it is attached. As the vial is exposed to more heat, the square becomes darker and darker. Use only vials of vaccine in which the inner square on the VVM is lighter than the outside circle.

By looking at the VVMs, health workers can determine which vials of vaccine are still usable, and which have been exposed to more heat than others. **Vials with VVMs where 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.** In this way, health workers can minimize the number of vials that have to be discarded. In countries where the WHO policy on multi-dose vials has been adopted, VVMs allow countries to save liquid vaccines (DPT, DT, TT, Td, OPV, hepatitis B, and liquid Hib) for subsequent sessions. This will decrease the wastage of vaccine in opened vials.

Figure 6. Instructions for reading VVMs



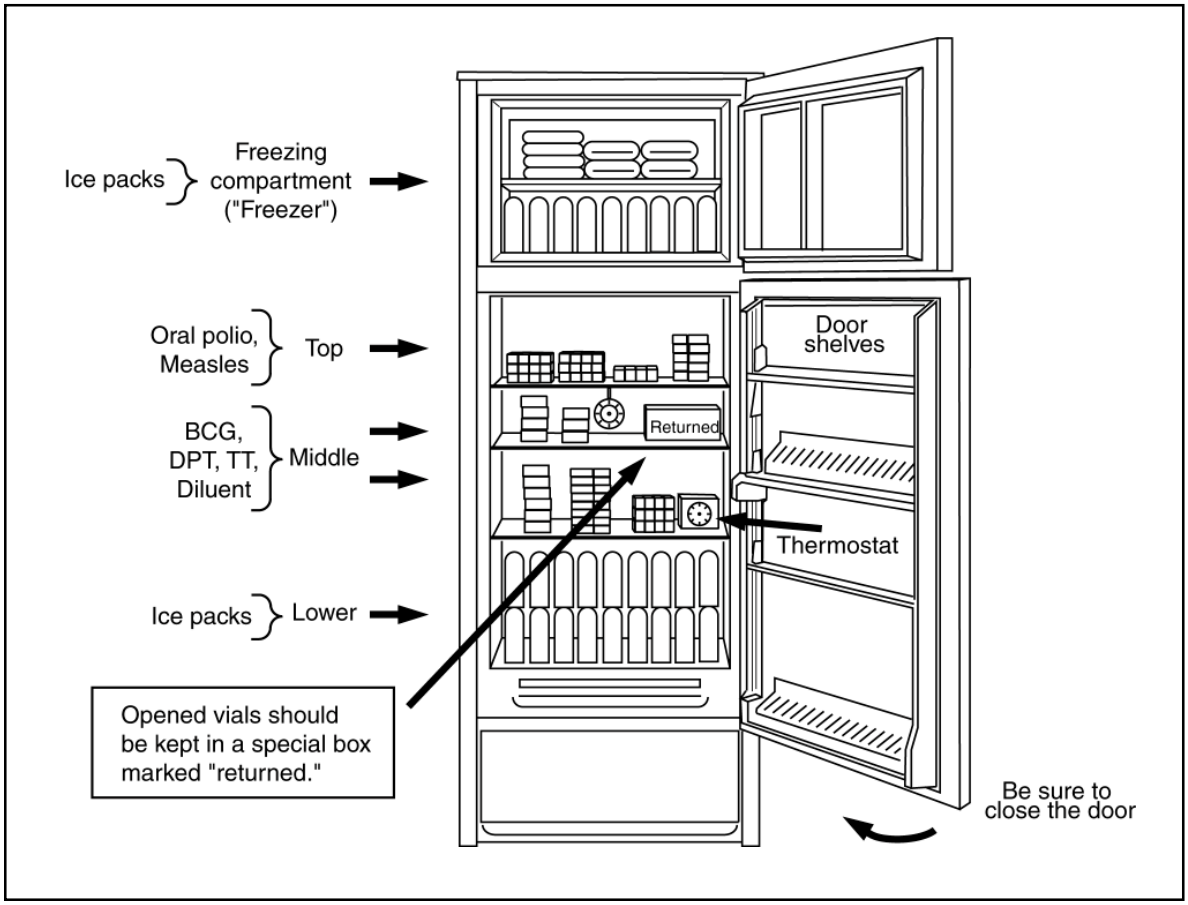
Other Tips to Keep Vaccines Safe

Fill the syringe only when the patient is ready to receive an injection.
Manually prefilled syringes are likely to become contaminated.

Do not combine partially opened vials of vaccine.
Combining partially opened vials of vaccine into another vial contaminates the vaccine.

Opened vials should be kept in a special box in the refrigerator marked "returned."
If your work site saves opened vials of OPV, DPT, DT, TT, Td, hepatitis B, and liquid Hib, these vials should be put in a box marked "returned" in the refrigerator and used before unopened vials during the next session (see Figure 7). **Remember: reconstituted vaccines must be used within 6 hours after reconstitution.**

Figure 7. Vaccine refrigerator with "returned" box for opened vials



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Trainer's Note

- **Review Key Points of Module 2.**
- **Conduct Quiz (pages 24-26).**
- **Conduct Practical Exercise: "How To Read Vaccine Vial Monitors" (page 27).**
- **Review Case Study: "The Unlabelled Vaccines in the Vaccine Carrier" (pages 29 and 30).**

Key Points

- Check vaccine vials for expiration, contamination, and signs of exposure to excessive heat or excessive cold before use.

- Fill the syringe only when the patient is ready to receive an injection.

- Do not combine partially opened vials of vaccine.

- Assume a vial is contaminated if:
  - there are leaks or cracks in the vial; **OR**
  - there is a change in appearance or floating particles; **OR**
  - the top of the opened vial has been submerged in water; **OR**
  - the top of the vial has been pierced by a used needle, or a sterile needle on a used syringe; **OR**
  - freeze-dried vaccine has been opened for more than 6 hours after reconstitution; **OR**
  - a vial has been opened for more than 4 weeks.

- If the label has come off, discard the vial.

- If the vaccine's expiry date has passed, discard the vial. Vaccines must never be used past their expiry date.

- VVMs show cumulative heat exposure. The vial has not been heat damaged if the inner square is lighter than the outside circle.

- Vials with VVMs whose inner square has begun to darken but is still lighter than the outer circle should be used before vials whose squares are lighter.

Quiz

Quiz Questions

1. Name four things that a health worker must check before filling a syringe from a vial.

2. Is the following statement true or false? "The syringe should be filled only when the patient is ready to receive an injection."

Trainer's Note

Give this quiz orally to stimulate classroom discussion. After the discussion for each question, repeat the correct answer. At the end of the quiz, review this module's Key Points again.

3. Name five situations in which you should assume the vaccine is contaminated.

4. Why use vaccine vial monitors (VVMs)?

5. What should be done when the inner square of the VVM is the same color or darker than the outside circle?

6. True or false? "Vials with VVMs that have just started to change color should be used before vials whose VVMs have not changed color."

7. For each vial shown in the VVM Illustration on page 28, state whether or not the vial can be used.

Quiz Answers

1. Name four things that a health worker must check before filling a syringe from a vial.

   Examples:
   - *Check for a label on the vial.*
   - *Check the **expiry date** of the vial.*
   - *Check for signs of contamination.*
   - *Check to make sure that freeze-sensitive vaccines and diluent have not been frozen.*
   - *Check to make sure that the vaccine has not been exposed to excessive heat.*

2. Is the following statement true or false? "The syringe should be filled only when the patient is ready to receive an injection."

   True.

3. Name five situations in which you should assume the vaccine vial is contaminated.

   - *There are leaks or cracks in the vial; **OR***
   - *There is a change in appearance or floating particles; **OR***
   - *The top of the opened vial has been submerged in water; **OR***
   - *The top of the vial has been pierced with a used needle, or a sterile needle on a used syringe; **OR***
   - *Freeze-dried vaccine has been opened for more than 6 hours after reconstitution (see Module 3, Reconstituting Vaccines Safely); **OR***
   - *The vial has been opened for more than 4 weeks.*

4. Why use vaccine vial monitors (VVMs)?

   VVMs help health workers determine whether vaccines have been damaged by exposure to too much heat. In addition, VVMs reduce vaccine wastage during cold-chain breakdowns. If vials have VVMs with an inner square that is the same color or darker than the outside circle, health workers should discard the vials. In countries where the WHO policy on multi-dose vials has been adopted, VVMs allow workers to save liquid vaccines (DPT, OPV, DT, TT, Td, hepatitis B, and liquid Hib) for subsequent sessions.

5. What should be done when the inner square of the VVM is the same color or darker than the outside circle?

   The vaccine vial should be discarded.

6. Is the following statement true or false? "Vials with VVMs that have just started to change color should be used before vials whose VVMs have not changed color."

   True, if the inner square is still lighter than the outer circle.

7. For each vial shown in the VVM Illustration, page 28, indicate whether or not the vial can be used.

   - *The inner square is lighter than the outside circle.* ***USE the vaccine.***
   - *The inner square has darkened slightly, but still is lighter than the outside circle.* ***USE this vaccine first.***
   - *The inner square matches the color of the outside circle.* ***DO NOT use the vaccine.***
   - *The inner square is darker than the outside circle.* ***DO NOT use the vaccine.***

Practical Exercise

How to Read Vaccine Vial Monitors (VVMs)

The trainer will show the illustration on page 28 to the group and ask the following questions:

1. Which vial has been exposed to the most heat?

2. Which vial has been exposed to the least heat?

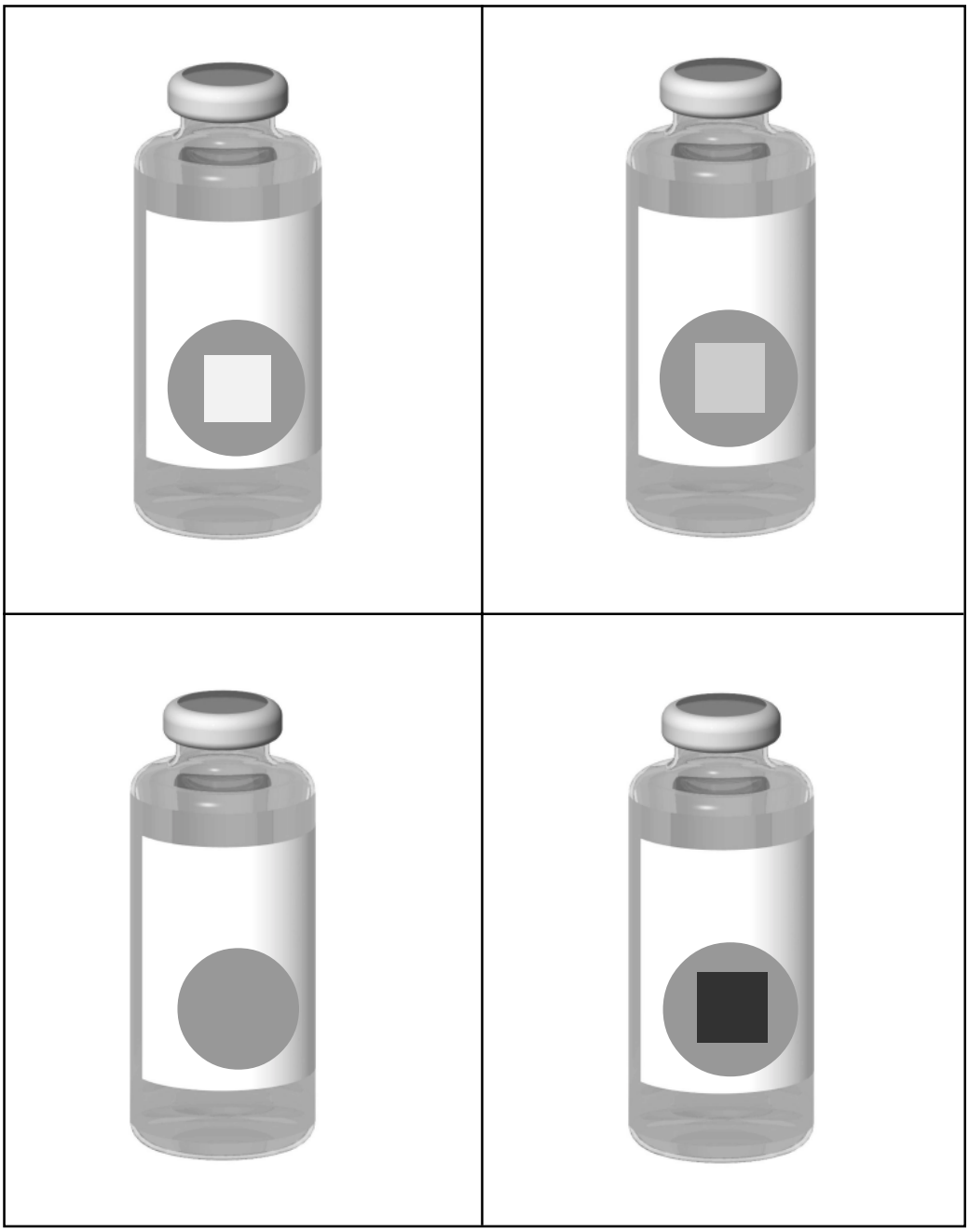
3. Which vial should be used first?

4. Which vial should be discarded?

Answers are provided on page 31.

VVM Illustration

Four Unlabelled Illustrations of VVMs



NOTE: photocopying may change the appearance of VVMs. Before using photocopies, check that the top two vials have VVMs with squares lighter than the surrounding circles.

Case Study

The Unlabelled Vaccines in the Vaccine Carrier

When Nurse Santina opens the vaccine carrier during an outreach session to take out some DPT vaccine, she sees a lot of water in the carrier. Earlier in the day, she had not been able to find any ice packs, so she had filled the container with loose ice instead. Apparently, the lid had not been closed and the ice melted. Now everything is wet. Nurse Santina finds that the water has washed the labels off of some of the vials.

Questions for Discussion

1. **What was Nurse Santina's mistake?**
2. **What should she do to avoid making this mistake again?**

She says to herself, "I think those vials are DPT. All our DPT was new last week. These people have come a long way for their DPT immunizations, and I don't want to disappoint them."

She gives four babies an injection of 0.5 ml of liquid from one of the vials. Thirty minutes later, the babies' mothers rush back to the health center. They are frightened and angry because their children became unconscious.

Later, a senior nursing officer comes to discuss what has happened. She says: "It appears that when the vaccine carrier was packed, someone gave you the insulin that had been stored in the refrigerator. You gave injections of insulin instead of vaccine."

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Answers to Case Study Questions

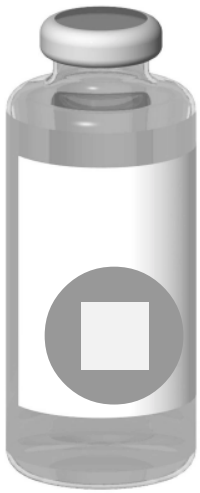
1. What was Nurse Santina's mistake?

   Nurse Santina's mistake was giving an injection from a vial without a label.

2. What should she do to avoid making this mistake again?

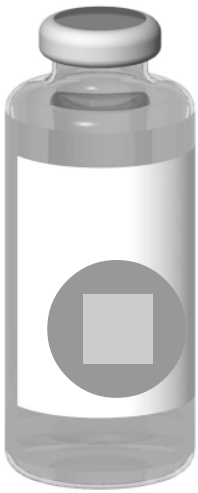
   She should discard vials without labels.

Handout: VVM Instructions



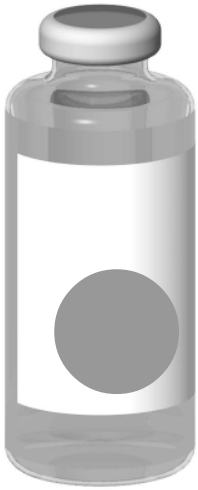
USE

Inner square is lighter than outer circle.



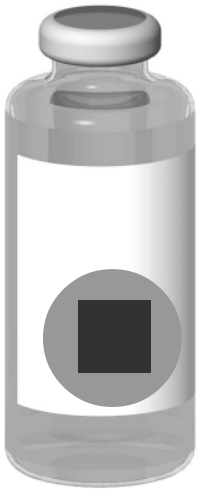
USE FIRST

As time passes, inner square is still lighter than outer circle.



DON'T USE

Discard point! Inner square matches color of outer circle.



DON'T USE

Beyond discard point! Inner square is darker than outer circle.

Notes: