





<b>Instruction Sheet</b>	<b>Learning Guide #04</b>
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This learning guide is developed to provide you the necessary information regarding the following content coverage and topics –□

- ✓ Vaccines safety
- ✓ Cold chain management
- ✓ Maintaining cold chain minor operational defects

This guide will also assist you to attain the learning outcome stated in the cover page. Specifically, upon completion of this Learning Guide, you will be able to –

- describe vaccine safety
- describe cold chain management
- maintain cold chain minor operational defects

**Learning Instructions:**

1. Read the specific objectives of this Learning Guide.
2. Follow the instructions described in number 3 to 16.
3. Read the information written in the “Information Sheets 1”. Try to understand what are being discussed. Ask your trainer for assistance if you have hard time understanding them.
4. Accomplish the “Self-check 1” in page 4.
5. Ask from your trainer the key to correction (key answers) or you can request your trainer to correct your work. (You are to get the key answer only after you finished answering the Self-check 1-3).
6. If you earned a satisfactory evaluation proceed to “Information Sheet 2”. However, if your rating is unsatisfactory, see your trainer for further instructions or go back to Information sheet 1.
7. Submit your accomplished Self-check. This will form part of your training portfolio.
8. Read the information written in the “Information Sheet 2”. Try to understand what are being discussed. Ask your trainer for assistance if you have hard time understanding them.
9. Accomplish the “Self-check 2” in page 7.
10. Ask from your trainer the key to correction (key answers) or you can request your trainer to correct your work. (You are to get the key answer only after you finished answering the Self-check 2).
11. Read the information written in the “Information Sheets 3”. Try to understand what are being discussed. Ask your trainer for assistance if you have hard time understanding them.
12. Accomplish the “Self-check 3” in page 9.
13. Ask your trainer the key to correction (key answers) or you can request your trainer to correct your work. (You are to get the key answer only after you finished answering the Self-check 3).
14. If you earned a satisfactory evaluation proceed to “Operation Sheet 1” in page 9; However, if your rating is unsatisfactory, see your trainer for further instructions or go back to Information sheet 3.
15. Read the “Operation Sheet 1 and try to understand the procedures discussed.



<b>Information Sheet-1</b>	<b>Vaccines safety</b>
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### 1.1. Vaccines safety

Vaccines are safe and effective. Because vaccines are given to millions of healthy people — including children — to prevent serious diseases, they're held to very high safety standards.

How are vaccines tested for safety?

Every licensed and recommended vaccine goes through years of safety testing including:

Testing and evaluation of the vaccine before it's licensed by the Food and Drug Administration (FDA) and recommended for use by the Centers for Disease Control and Prevention (CDC)

Monitoring the vaccine's safety after it is recommended for infants, children, or adults.

Vaccines are tested before they're recommended for use

Before a vaccine is ever recommended for use it's tested in labs. This process can take several years. FDA uses the information from these tests to decide whether to test the vaccine with people.

During a clinical trial, a vaccine is tested on people who volunteer to get vaccinated. Clinical trials start with 20 to 100 volunteers, but eventually include thousands of volunteers. These tests take several years and answer important questions like:

Is the vaccine safe?

What dose (amount) works best?

How does the immune system react to it?

Throughout the process, FDA works closely with the company producing the vaccine to evaluate the vaccine's safety and effectiveness. All safety concerns must be addressed before FDA licenses a vaccine.

Every batch of vaccines is tested for quality and safety.

Once a vaccine is approved, it continues to be tested. The company that makes the vaccine tests batches to make sure the vaccine is:

- ✓ Potent (It works like it's supposed to)
- ✓ Pure (Certain ingredients used during production have been removed)
- ✓ Sterile (It doesn't have any outside germs)

FDA reviews the results of these tests and inspects the factories where the vaccine is made. This helps make sure the vaccines meet standards for both quality and safety.



Vaccines are monitored after they're recommended to the public.

Once a vaccine is licensed and recommended for use, FDA, CDC, and other federal agencies continue to monitor its safety.

Check out this info graphic for details on how vaccines are developed, approved, and monitored. There are many different parts of the national vaccine monitoring system

The United States has one of the most advanced systems in the world for tracking vaccine safety. Each of the systems below supplies a different type of data for researchers to analyze. Together, they help provide a full picture of vaccine safety.

**Vaccine Adverse Events Reporting System (VAERS):** VAERS is an early warning system managed by CDC and FDA that is designed to find possible vaccine safety issues. Patients, health care professionals, vaccine companies, and others can use VAERS to report side effects that happen after a patient received a vaccine. Some side effects might be related to vaccination while others might be a coincidence (happen by chance). VAERS helps track unusual or unexpected patterns of reporting that could mean there's a possible vaccine safety issue that needs further evaluation.

**The Vaccine Safety Datalink (VSD):** VSD is a collaboration between CDC and several health care organizations across the nation. VSD uses databases of medical records to track vaccine safety and do research in large populations. By using medical records instead of self-reports, VSD can quickly study and compare data to find out if reported side effects are linked to a vaccine.

✓ What are the risks of vaccination?

Any vaccine can cause side effects. Usually, these side effects are minor — a low-grade fever, fussiness and soreness at the injection site. Some vaccines cause a temporary headache, fatigue or loss of appetite.

✓ How safe is vaccination?

Most childhood vaccines are 90% to 99% effective in preventing disease. And if a vaccinated child does get the disease, the symptoms are usually less serious than in a child who hasn't been vaccinated. There may be mild side effects, like swelling where the shot was given, but they do not last long.

✓ Who is responsible for vaccine safety?

The FDA and the CDC are the government offices in charge of vaccine safety

✓ What are the risks of not vaccinating?

Those most at risk include: People with weakened immune systems due to other diseases or medications they are taking. People with chronic medical conditions like lung, heart, liver, kidney disease or diabetes. Newborn babies, who are too young to be vaccinated against most diseases



<b>Self-Check -1</b>	<b>Written Test</b>
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**Directions:** Answer all the questions listed below. Use the Answer sheet provided in the next page:

1. Who is responsible for vaccine safety? (3 points)

A. CDC      B. WHO      C. UNICEF      D. EFDA

**Note: Satisfactory rating - 3 points**

**Unsatisfactory - below 3 points**

**Answer Sheet**

Score = _____
Rating: _____

Name: \_\_\_\_\_

Date: \_\_\_\_\_

**MCQ**

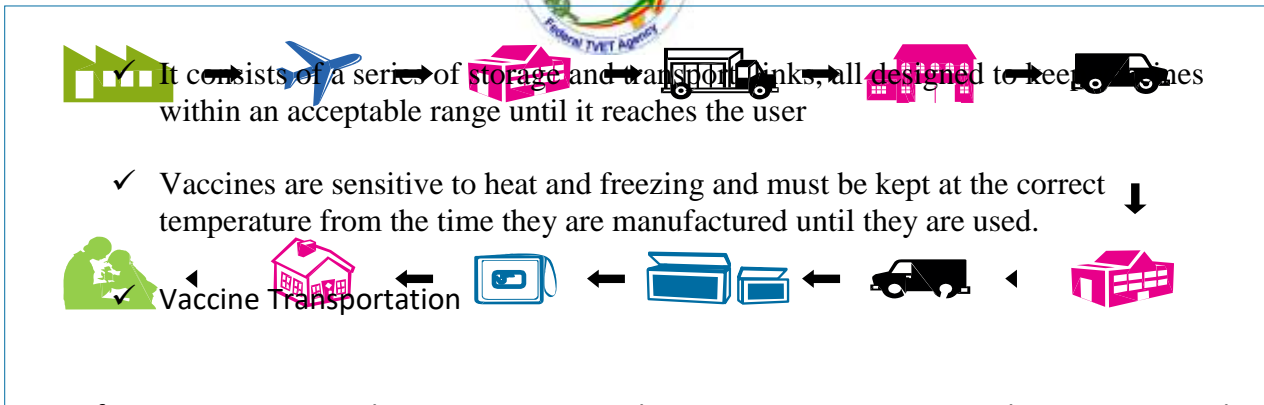
1. \_\_\_\_

<b>Information Sheet-2</b>	<b>Cold chain management</b>
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2.1 . Cold chain management

2.1.1 Definition

- ✓ The cold chain is the system used for keeping and distributing vaccines and other and distributing vaccines and other



From Manufacturer -----> national airport -----> central vaccine stores -----> regional store -----> zonal stores -----> district - health center -----> health post or child & mother.

Vaccine Manufacturer	Air Transport (+2° to 8°C & -15° to -25°C)	Primary Store (GMSD &/State) WIC (+2° to 8°C) & WIF (-15° to -25°C)	Refrigerated / Insulated Van (+2° to 8°C & -15° to -25°C)	State Store WIC (+2° to 8°C) & WIF (-15° to -25°C)	Insulated Van (+2° to 8°C & -15° to -25°C)
Mother & Child	Sub-Centre/ Session Sites	Vaccine Carrier (+2° to 8°C)	Primary Health Centre ILR +2° to 8°C & All Vaccines in ILR	Insulated Van (+2° to 8°C)	District Vaccine Store ILR (+2° to 8°C) & DF (-15° to -25°C)

### 2.1.2 The cold chain equipment

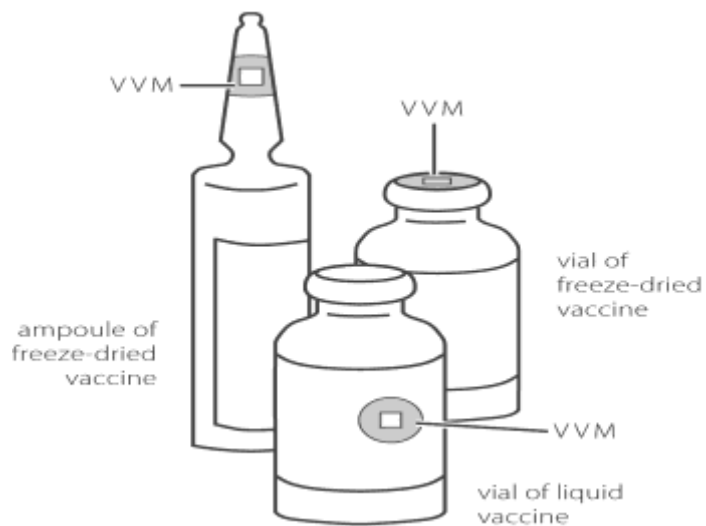
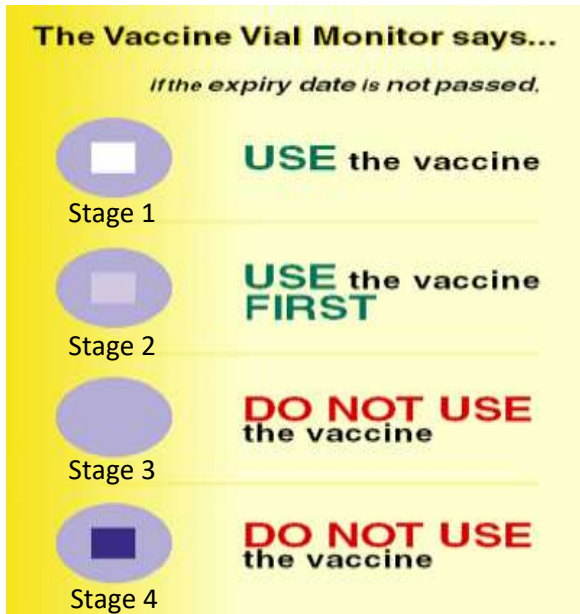
Different levels within the health care system need different equipment for transporting and storing vaccines and diluents at the correct temperature.

- ✓ Primary vaccine stores: need cold or freezer rooms, freezers, refrigerators, cold boxes and sometimes refrigerator trucks for transportation.
- ✓ Intermediate vaccine stores: depending on their size and capacity need cold and freezer rooms, and/or freezers, refrigerators and cold boxes
- ✓ Health facilities: need refrigerators with freezing compartments, cold boxes and vaccine carriers
  - ✓ Cold Boxes
  - ✓ Isotherm container which is lined with frozen icepacks to keep large quantities of vaccines .icepacks to keep large quantities of vaccines between 2° C- 8° C for several days.
- ✓ Vaccine carriers :Isotherm container which is lined with frozen icepacks to keep small quantities of vaccines between 2°C-8° C for 24 to 72 hours. used for vaccination sessions and short journey.



- ✓ Cold chain monitoring equipment: The purpose of cold chain monitoring equipment is to keep track of the temperature to which vaccines and diluents are exposed during transportation and storage.
  - The different monitors are:
- ✓ Vaccine vial monitors (VVM)
- ✓ Vaccine cold chain monitor card
  - ✓ Thermometers
  - ✓ Freeze indicators

### VVM



### Vaccine Cold Chain Monitor Card

- ✓ A vaccine cold chain monitor is a card with an indicator strip that changes color when the vaccines are exposed to temperatures too high.
- ✓ The vaccine cold chain card is used to estimate the length of time that vaccine has been exposed to high temperatures exposed to high temperature.

### Thermometers

- ✓ Used to monitor temperatures of refrigerators and /or cold boxes
- ✓ Dial thermometers tend to lose their accuracy over time.

### Freeze watch

Irreversible temperature indicator which shows if a product, such as vaccine, has been exposed to freezing temperatures. If exposed to freezing temperatures. If exposed to temperatures below 0°C for more than 1 hour the vial releases the colored liquid.

### Freeze indicators

Freeze Tag : electronic temperature measuring circuit with LCD display. If indicator exposed circuit with LCD display. If indicator exposed to temperatures below 0 °C for more than 1 hour the display changes to alarm.



<b>Self-Check -2</b>	<b>Written Test</b>
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**Directions:** Answer all the questions listed below. Use the Answer sheet provided in the next page:

1. What are the risks of not vaccinating?(3 points)
  - A. People with weakened immune systems
  - B. people having Diarrhea
  - C. people with convulsive disorder
  - D. all of the above

**Note: Satisfactory rating - 3 points**

**Unsatisfactory - below 3 points**

**Answer Sheet**

Score = \_\_\_\_\_

Rating: \_\_\_\_\_

Name: \_\_\_\_\_

Date: \_\_\_\_\_

**MCQ**

1.\_\_\_\_





### Information Sheet-3

### Maintaining cold chain minor operational defects

#### 3.1. Maintaining cold chain minor operational defects

- Vaccine refrigerators:
  - ✓ A refrigerator works well only if it is properly installed, cleaned and defrosted regularly.
  - ✓ Thick ice in the freezer compartment does not keep the refrigerator cool, it makes the refrigerator work harder and use more power,
  - ✓ refrigerator work harder and use more power, gas or kerosene.
  - ✓ You should DEFROST the refrigerator when the ice becomes more than 0,5 cm thick or once a ice becomes more than 0,5 cm thick or once a month.
    - How to defrost and clean a refrigerator
      - ✓ Take out all the most heat sensitive vaccines (OPV, measles, BCG, yellow fever) and transfer them to a cold box lined with frozen ice packs
      - ✓ Take out all the freeze sensitive vaccines (DTP, DT,Td, hepatitis B, ) and diluents, and transfer them to a cold box lined with conditioned ice packs
      - ✓ Turn off the power supply to the refrigerator Leave door open and wait for the ice to melt
      - ✓ Clean the inside and the door seal with a clean wet cloth and turn the refrigerator on again.



### Equipment required for performing defrost and clean a refrigerator

- cold box
  - frozen ice-packs
  - Refrigerator
  - vaccines like (OPV , measles ,BCG)
  - Power supply
  - wet cloth
- Maintaining cold boxes and vaccine carriers
    - ✓ Must be dried after their use
    - ✓ If left wet with closed lids, they become moldy and the seal will be affected
    - ✓ Store them with the lid open when not used, if possible
    - ✓ Don't store them outside under the sunlight, it can cause cracks and reduce the efficiency of the cold box.

<b>Self-Check -3</b>	<b>Written Test</b>
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**Directions:** Answer all the questions listed below. Use the Answer sheet provided in the next page:

1. You should DEFROST the refrigerator when the ice becomes more than ---(3 points)
  - A. 0.2cm thickness
  - B. 0.3cm thickness
  - C. 0.4cm thickness
  - D. 0.5cm thickness

**Note: Satisfactory rating - 3 points**

**Unsatisfactory - below 3 points**

### Answer Sheet

		Score = _____
Midwifery Level III	Vision :01 Sep. 2019: Copyright Info/Author: Federal TVET Agency	Rating: _____ Page 10 of 13



Name: \_\_\_\_\_

Date: \_\_\_\_\_

**MCQ**

1.\_\_\_\_

**Operation Sheet 1**

**Manage cold chain**

**Steps for defrost and clean a refrigerator:**

Step 1 :Take out all the most heat sensitive vaccines (OPV, measles, BCG, yellow fever) and transfer them to a cold box lined with frozen ice packs

Step 2:Take out all the freeze sensitive vaccines (DTP, DT,Td, hepatitis B, ) and diluents, and transfer them to a cold box lined with conditioned ice packs

Step 3:Turn off the power supply to the refrigerator Leave door open and wait for the ice to melt

Step 4:Clean the inside and the door seal with a clean wet cloth and turn the refrigerator on again



<b>LAP Test</b>	<b>Practical Demonstration</b>
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Name: \_\_\_\_\_ Date: \_\_\_\_\_

Time allowed for procedure two is -30min

You are required to perform :

Task 1: defrost and clean a refrigerator

<b>List of Reference Materials</b>
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- 1- Ethiopia. Blended Learning immunization Module for the Health Extension Programme.
- 2- Ministry of health.
- 3- Ethiopia. Refresher Training for Frontline Health Workers in Expanded Program of
- 4- Immunization (EPI). EPI target diseases, vaccines and their administration. Module1.
- 5- Addis Ababa: ministry of health: 2010.
- 6- Ethiopia. Refresher Training for Frontline Health Workers in Expanded Program of
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- 8- Practice Standards and Guidelines for Nurses and Midwives



- 9- with Prescriptive Authority 2010
- 10- Organización Panamericana de la Salud. Curso de gerencia para el manejo efectivo del Programa Ampliado de Inmunización, 2006.  
[http://www1.paho.org/english/ad/fch/im/isis/epi\\_mod/spanish/home.asp](http://www1.paho.org/english/ad/fch/im/isis/epi_mod/spanish/home.asp).
- 11- Movilización social para el control del cáncer en Colombia, 2007. Ministerio de la Protección Social. Instituto Nacional de Cancerología. República de Colombia.
- 12- [http://www.cancer.gov.co/documentos/SerieDocumentosTecnicos/Serie\\_N2\\_2007.pdf](http://www.cancer.gov.co/documentos/SerieDocumentosTecnicos/Serie_N2_2007.pdf) .
- 13- Pan American Health Organization. EPI plan of action software: user's quick guide. 2006.
- 14- Moraes IHSD. Informações em saúde: da prática fragmentada ao exercício da cidadania. São Paulo: Editora Hucitec/Rio de Janeiro: ABRASCO; 1994.

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