PRODUCT SAFETY DIRECTORATE

ETHIOPIAN FOOD AND DRUG AUTHORITY

ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI) SURVEILLANCE COURSE FOR HEALTH PROFESSIONALS

Facilitator's Guide

EFDA/MNL/001

First edition

Pages 58

August 2022

Foreword

Concerted global and national efforts have been exerted to stop the spread of COVID19 and address the human and economic impacts of COVID19 on the society. It is widely understood that COVID19 has posed considerable challenges to health systems all over the world. Countries were forced to strike a balance between maintaining basic health services and coping with the health impacts of the pandemic. Ethiopia has successfully managed to lead a well-coordinated response plan that included distribution of essential medical supplies, prevention, diagnosis, and care of COVID19 patients.

On a global scale, efforts have been undergoing to develop effective vaccines. Like any other medicine, vaccines pass through a number of stringent preclinical and clinical trials to investigate their safety and efficacy. These trials happen in controlled set of conditions. Accordingly, medicines including vaccines can exhibit other benefits and adverse events when they are used at a wider scale within the population. Hence, health systems should be able to monitor these events so as to protect the safety of their citizens.

EFDA has been working to ensure the availability of quality assured COVID-19 vaccine through providing emergency use authorization (EUA) and monitoring of safety and conducting AEFI surveillance. EFDA has established COVID19 vaccine safety monitoring taskforce at national level and AEFI investigation taskforces were established at nine RHBs; and implemented interventions to strengthen the five regional PV centers for this purpose. Orientations were given to more than 4,500 health professionals from health facilities and regional regulators on AEFIs monitoring and reporting. Manual and electronic reporting tools were prepared and distributed to health professionals. Moreover, weekly update of AEFIs of COVID19 vaccine was compiled and disseminated at national level.

It is believed that this training manual will strengthen the national effort to strengthen monitoring of vaccine safety and conducting AEFI surveillance. It will undoubtedly standardize capacity building efforts and contribute to better identification, reporting, investigation, and causality assessment of AEFIs following.

Finally, I would like to express my gratitude to all those who extended their effort in the development of this training course. I would also like to encourage users of the training course manual to send their comments regarding the manual to the EFDA via website: http://www.efda.gov.et or P.O. Box 5681, Addis Ababa, Ethiopia.

Heran Gerba

Director General,

Ethiopian Food and Drug Authority

APPROVAL STATEMENT OF THE MINISTRY

Acknowledgments

The Ethiopian Food and Drug Authority would like to express its heart felt appreciations to the experts and their respective institutions who were involved in the development of this training manual. *Adverse Events Following Immunization (AEFI) for Healthcare Professionals training* will contribute to the national effort to protect the safety of our population from the adverse effects of vaccines. Accordingly, our gratitude is extended to the following individuals and their organizations whose role was critical in the development of this training manual.

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Finally, we would like to thank the USAID Global Health Supply Chain program-Procurement and Supply Management (GHSC-PSM) project, Global Alliance for Vaccines and Immunization (GAVI) and Tony Blair Institute for Global Change (TBI) for their overall support for the successful development of this training manual.

Acronyms

ADE	Adverse Drug Event
ADR	Adverse Drug Reaction Adverse Event Following Immunization
EFDRE	Federal Democratic Republic of Ethiopia
EFDA	Ethiopian Food and Drug Authority
M&E	Monitoring and Evaluation
MDR	Multidrug resistance
MOH	Ministry of Health
WHO	World health organization
XDR	Extensive drug resistant

Contents

Introduction to the manual

Immunization is one of the most effective public health interventions for protecting the individual and the public from vaccine-preventable diseases (VPDs). Immunization has saved millions of lives. Modern vaccines are safe and effective. However, like other medicinal products, vaccines are not free from adverse reactions. As vaccine are biological preparation or antigen and may contain multiple components (excipients) and each component may have unique safety implications. In this connection vaccines rarely cause serious adverse reactions, and common reactions are minor and self-limited. We monitor the safety of vaccines by looking for adverse events following immunizations (AEFI). (AEFI) is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.

The system of monitoring or AEFI surveillance involves detection, notification, reporting, investigation and causality assessment. Each step requires adequate knowledge for not only improving the safety monitoring but also has implication in the immunization program management. Irrespective of the specific cause, an AEFI may lead to public suspicions of vaccines and clients may refuse further immunization, making them susceptible to VPDs which are disabling and life-threatening.

The goals of this training is to equip health professionals in AEFI surveillance system thereby to improve the efficiency and quality of AEFI surveillance activities – and thus strengthen the quality of immunization programmes at facility, regional and national levels – and to ensure the immunization safety of all recipients of vaccines.

This course needs training of trainers (TOT) and basic trainings in all regions of the country. The training will be given in selected training centers with proper infrastructure and facility.

The following are the core competency of this training manual:

- National immunization program
- National pharmacovigilance system
- Vaccines and monitoring
- Prevention and Management of
- surveillance system

- detection and Reporting
- investigation and Causality
- Action, Response and communication
- for Covid 19 vaccine
- Monitor and evaluate in surveillance system

Course Syllabus

Course Description: These three days training is designed to equip participants to strengthen surveillance system, ensuring the protection of citizens in vaccine safety and immunization program. The course contains: National immunization program, National pharmacovigilance system, Vaccines and monitoring, Prevention and Management of , surveillance system, detection and Reporting, investigation and Causality, Action, Response and communication, for Covid 19 vaccine and Monitor and evaluate surveillance system and beyond.

Course Goal

- To provide the necessary knowledge, skill, and attitude on safety (AEFI) monitoring of vaccines, thereby contributing to the success of immunization program of the country.

Participant learning objectives

At the end of this training course participants will be able to:

- Discuss the national EPI program
- Understand the National PV system
- Explain the Basic Concepts of Vaccines and AEFI

- Promote the Prevention and Management of AEFI
- Understand the AEFI Surveillance System
- Equip with AEFI detection and reporting
- Illustrate the AEFI Investigation and Causality Assessment
- Understand the Action, Follow-up, and Communication to AEFI
- Promote the AEFI for COVID-19 Vaccines
- Monitor and Evaluate surveillance related activities in different immunization program levels and beyond

Training Methods

- Brainstorming
- Case study
- Drill exercise
- Interactive lecture
- Demonstration
- Reflection
- Small group discussion
- Question and answer
- Individual reading

Training Materials

- Participant manual
- Facilitator guide
- Power Point presentations
- guide
- National AEFI guide
- AEFI reporting formats
- AEFI investigation form

Participant Selection Criteria

- ADE guideline
- LCD Projector
- Flipchart and Markers
- Masking tape
- Computer

The target group for this training course are healthcare professionals (physicians, pharmacists Nurse, health officer …) and experts/officers and EPI/PHEM program managers from regions, ministry of health and its agencies, RHB and ZoHD/Sub city Health office, WoHO and development partners who provide technical support are target audiences of this training course.

Facilitator / Trainer Selection Criteria

Facilitators of the first round shall be selected from training course developing technical team. Trainers for this course should be health professionals who have TOT in _ training course for healthcare professionals‘ and have proven experiences in adult learning techniques (ALT). At least four trainers per day for the whole duration of the training are needed for each training session. It is strongly recommended to use multidisciplinary team approach among the trainers.

Methods of Evaluation

A. Course Evaluation

- Daily evaluation
- End of training evaluation
- Participant oral feedback

B. Trainees Evaluation

- ***Formative*** o Direct observation with feedback
  o Group activities and presentations o Individual reflections for questions o Case studies o Attendance and recap o Pretest
- ***Summative***
  - o ***For basic training***
    - Progressive assessment (trainee daily performance): -15%
    - Written exam (post-test) - 85% o ***For TOT training***
    - *Progressive assessment* (trainee daily performance):- 10%
    - Review of trainee‘s work using assignments:- 10%
    - Teach back:- 20%
    - Posttest:- 60%

Certification Criteria

- Certificates will be provided to basic training trainees who have scored ≥75% and above on summative assessment and attended 100% of the course. For TOT trainees,

certificate shall be provided to those who have scored 85% and above on summative assessment and attended 100% of the course.

Course Duration

- Two days for basic and four days for TOT

Suggested Class size

- Suggested training class size: shall not be more than 25 participants per training venue

Training Venue

- The training will be conducted at the nationally recognized IST centers/CPD providers having appropriate facilities.

General Guidance for Trainers

The **general guidance for trainers** is designed to allow participants and trainers to know each other, describes course goal, objectives and schedule. Participants will also establish group norms and complete pre-test exam.

Facilitator preparation before the Session:

Facilitator should make sure that the following flipcharts remain available and posted at the start of each day of the course; they will be referred to on a regular basis throughout the duration of the course:

- Participant expectations
- Acronyms
- Parking Lot
- Group Norms

Furthermore, make sure that the below mentioned materials are ready

- Name tag for each participant
- Training material packages are placed for each participant on the tables before they arrive in the training room.

Activities during the session

Name tag and welcoming - 5 minute

Name Tag - As participants enter the training room, one facilitator should greet each participant and ask him/her to make a name tag and wear it and also to create a name tent.

Welcome **-** Start the course by welcoming participants and introducing yourself. Tell participants that if they have any administrative questions, concerns with the hotel, or problems, let the course administrator know so that they can help them solve the problem or guide them in the right direction.

Getting to know each other - Years of experience Flip chart – 10 minute

Ask participants and facilitators to introduce each other, while introducing themselves, let they introduce their names, profession, position in the facility, years of experience and knowledge and experience in safety monitoring (AEFI). Don‘t forget to display the introductory components (names, profession, position in the facility, years of experience) on flipchart so that each participant to follow.

Also assign one facilitator to write number of years of experience for each participant on separate flipchart. Facilitators should also take note of the responses regarding the special skills and knowledge that participants are bringing to the training.

After all the participants have been introduced, the facilitator should quickly summarize the years of experience and comment that the number represents the total years of experience of all participants in the course. The facilitator should then point out the participant expertise represented in the room and note that this expertise will be drawn upon as appropriate during the different sessions of the training.

Participant Expectations, Goals, and objectives – Interactive Lecture – 10 minutes

Tell the participants that, now we‘d like to spend a few minutes hearing some of their expectations for the course. Ask participants to write their expectations on a paper.

- Then ask the participants to open the —**Course Syllabus”** in their participant manual.
- Allow participants to review the course description, goals, learning objectives, methods of evaluation and certification criteria for 3 minutes.
- Ask different participants turn by turn to read aloud each learning objective to the large group. The facilitator may clarify as needed.
- Tell them to relate their written expectations with the goals and objectives of the course and ask participants to tell which of the objectives will meet their expectation/s.

Workshop Schedule – Interactive Lecture – 5 minutes

Ask participants to look at the course schedule, which is already distributed: Review the outline of the schedule with participants, pointing out features such as the "regular" hours, any likely exceptions, time set aside for reviews.

Other Course related Issues – Interactive Lecture – 10 minutes

Coaching: Encourage participants to let the facilitators know at any time if they need someone to help them with the course material. Reassure them that the facilitators are happy to help out at any time.

Acronym List: Note that in our technical work we regularly use acronyms; for example and ADE is one of the many acronyms that will be used in the course. Explain that we will try not to overuse acronyms, but to help everyone we will keep a list of them on the flipchart: Acronyms. Hang the flipchart and write up the first acronym.

Parking Lot: Refer to Flipchart: **Parking Lot.** Comment that during sessions participants may think of questions or raise issues that are not directly related to the topic of the session being presented. In such cases, the Facilitator may decide to wait until a later time in the course to answer these questions or to discuss these issues at greater length. These questions/issues will be placed in the —parking lot‖. Explain that the timing of some sessions may not permit the facilitators to spend a lot of time dealing with questions, and therefore the —parking lot‖ is a way of ensuring that the question is not forgotten.

Group Norms: Display Flipchart: **Group Norms**. Tell the participants that we will be working together for the next three/five days and that it will be helpful if we can establish some

—ground rules‖ that will help us to work together in an effective way and without distractions. Ask the participants to propose rules or guidelines that we can follow during the course and write on the flipchart. However, do not spend more than 5minutes generating this list or reaching consensus. These should include:

- Wear name tags everyday
- Start trying to name everyone in the room
- Listen carefully to everyone‘s ideas
- Attend workshop 100% of the time
- Be punctual
- Avoid side talk
- Cell phones: silent mode
- Active participation And any other?

When the list is complete, post the sheet near the entrance/exit door where it can be easily seen always and referred to as needed during the course.

Housekeeping & Administration Issues: Mention a few housekeeping & admin issues with participants if they have not already been taken care of:

- Location for health (tea/coffee) breaks
- Location for lunch (if lunch is arranged)
- Location of washrooms/toilets
- Smoking policy
- Payment of travel expenses and per diems

Pre-test evaluation – Individual exercise - 20 minutes

Tell participants that there will be pre-test and post-test evaluation. The purpose of this pre-test and post-test is to evaluate their understanding on the course contents before and after the course. Remind the certification criteria for this training. Tell them that they are going to work on pre-test for the next 20 minutes.

Inform them to write a code, by putting in front of abbreviation of discipline or area of work and the first letter of the participant and his father name. For example, if the participant name is Wondie Alemu and he is working as pharmacist: the code will be **– Ph – WA**.

After participants finished the pre-test, make sure that the pre-test mark is registered on a flip chart by a participant code and make it posted visibly for all participants.

Course Schedule

Training Course on Antimicrobial Prevention and Containment for Health professionals

Organized by: _____

Venue: _____ **Date: _____**

Time	Topic	Presenter/Facilitator	min
Day One: _____			
8:30-9:00	Registration of participants	Organizers	
9:00-10:00	Welcoming Address/Opening Speech/Introductory activity		
10:00-10:30	Pretest		
10:30-10:45	**Tea Break**	**Organizers**	
10:45-11:15	Overview of National Immunization Program		
11:15- 11:45	Overview of National Pharmacovigilance System		
11:45-12:30			
12:30-2:00	**Lunch Break**	**Private**	
2:00- 3:00			
3:00-3:45			
3:30-3:45	**Tea Break**	**Organizers**	
3:45- 4:30			
4:30- 5:30			
Day Two: _____			
8:30-9:00	Recap of Day One	Participants/organizers	
9:00-9:45			
Time	**Topic**	**Presenter/Facilitator**	**min**

9:45-10:15			
10:15-10:30			
10:30-10:45	**Tea Break**	**Organizers**	
10:45- 11:15			

12:30-2:00	**Lunch Break**	**Private**	
2:00- 3:30	Overall Discussion		
3:30-3:45	**Tea Break**	**Organizers**	
3:45- 5:30	Certification, Group picture and Closing Remarks	Participants/organizers	

Chapter 1: Overview of National Immunization program

Session Description

The session provides participants to get the fundamental concept and an update the national expanded program on immunization. The session begins with describing the changing scope of immunization and its system. This is followed by rationale for revision of implementation guideline and implementation strategies and modalities. Besides, the session enumerates conditions and contraindications for vaccination.

Primary Objective: To provide participant an update on the national program of immunization.

Enabling objectives:

- To describe the scope of the national immunization program
- To discuss the national strategies for implementation of EPI
- To identify the conditions and contraindications for vaccinations
- To explain the national immunization schedule

Session Outline:

- Introduction
- Scope of national Immunization program
- National EPI Implementation Guideline and strategies
- Conditions and contraindications for vaccinations

Duration: 55 minutes

Summary of activities

S.No.	Activity	Method of delivery	Duration	Materials
1.	Introduction	Participants' reflection, Interactive PPT presentation, and discussion.	10 min	**LCD, Laptop, flip chart & marker**
2.	Scope of national Immunization program	Interactive PPT presentation & discussion	10 min	
3.	Components of immunization Implementation strategies	Interactive PPT presentation & discussion	10 min	
4.	National EPI Implementation Guideline and strategies	Interactive PPT presentation & discussion	10 min	
5.	Conditions and contraindications for vaccinations	Participants' reflection, interactive PPT presentation & discussion	10 min	
6.	Session Summary	Interactive discussion	5 min	

Preparation before the session:

- Read well the training materials (facilitator guide, participant manual and ppt presentations)
- Read the references indicated at the end of the session in the participant manual
- Prepare brainstorming ideas before the presentation

Activity 1: Introduction (10 minutes)

- In 2 minutes, introduce the chapter and its outline by describing the learning objectives by displaying from the PowerPoint on slide no.2-3
- Start the presentation by displaying introductory activity on slide 4 and take reflection from 2 or 3 participants on their understanding of vaccines included in national EPI.
- Describe historical background of EPI in Ethiopia slide no 6
- Lastly, ask participants if they have any question and address them accordingly.

Activity 2: scope of immunization (10 minutes)

- On slide 7, briefly describe changes of EPI scope
- On slide 8, display national immunization schedule and discuss
- Close the sub-topic by asking participants if there is any query and address them accordingly.

Activity 3: Components of immunization system (10 minutes)

- Start the sub-topic by displaying Figure 1.1. from slide no 9 and discuss on the components of immunization system (slide 9-10)
- Lastly, ask participants if they have any question and wrap up the sub-topic.

Activity 4: National EPI Implementation Guideline and strategies (10 min)

- Explain the utilization of life cycle approach from slide 11 and Continue the session by discussing the reasons for revising implementation guideline on the same slide
- From slide no. 12, discuss about the strategies of national EPI
- Then, describe about the three modalities of EPI program implementation
- Describe about pharmacovigilance guideline for private health facilities from slide 13
- Continue the session, by displaying the role and responsibilities of private health facilities from slide no. 14
- Afterwards, ask participants if they have questions and clarify them accordingly

Activity 6. Conditions and contraindications for vaccinations (10minutes)

- Start the sub-session by asking participants, from slide 15, on the conditions contraindicated to immunization and common misperception they have encountered in the community and take reflection from 3 participants.
- Then, describe about contraindications of vaccination from slide 16
- In slide 17, display factors not affecting immunization and discuss
- Ask participants if they have questions and clarify them accordingly

Activity 7. Session summary (5 minutes)

- Ask participants if they have understood and appreciated the chapter.
- Then, ask participants if they have any question and provide answers.
- Display chapter summary from slide no 18 and ask a volunteer participant to read

Close the chapter by thanking the participant for their active participation

Chapter 2: Basic Concepts of Vaccines & Adverse Events Following Immunization

Chapter description:

This chapter will explain the different types of vaccine and main components of a vaccine. The chapter will also describe about the main types of vaccine reactions and categories of adverse events following immunization(AEFI) based on frequency and severity.

Primary Objective: To equip participants with basic concepts on vaccines and AEFI

Enabling objectives:

By the end of this session, the participant should be able to:

- Define vaccine
- Explain common types of vaccines,
- List types of vaccine components and explain their functions,
- Explain the different types of AEFI

Session outline

- ✓ Introduction
- ✓ Definition and types of vaccines
- ✓ Components of vaccine
- ✓ Adverse events following immunization

Duration: 70 minutes

Summary of activities

S.No.	Activity	Method of delivery	Duration	Materials
4.	Introduction	Participants' reflection, Interactive PPT presentation, and discussion.	15min	**LCD, Laptop, flip chart & marker**
5.	Definition and types of vaccines	Interactive PPT presentation & discussion	15 min	
6.	Components of vaccine	Interactive PPT presentation & discussion	10 min	
4.	Adverse events following immunization	Participants' reflection, interactive PPT presentation & discussion	25 min	
5.	Session Summary	Interactive discussion	5 min	

Preparation before the session:

- Read well the training materials (facilitator guide, participant manual and ppt presentations)
- Read the references indicated at the end of the session in the participant manual
- Prepare brainstorming ideas before the presentation

Activity 1: Introduction (10 minutes)

- In 2 minutes, introduce the chapter and its outline by describing the learning objectives by displaying from the PowerPoint on slide no.2.
- Start the presentation by displaying introductory activity on slide 4 and take reflection from 2 or 3 participants on their understanding on the difference between vaccines and conventional drugs from slide 5.
- Describe overview on the safety of vaccine slide no 6-7

- Lastly, ask participants if they have any question and address them accordingly.

Activity 2: Definition and types of vaccines (10 minutes)

- On slide 7, ask participants about the different types and components of vaccines and take reflection from 3 participants. Then, display the definition of vaccine on the same slide.
- On slide 8, display national immunization schedule and discuss
- Discuss on the different types of vaccine from slide no. 9-11. Add your summary on the previous reflection of the participants.

Activity 3: Components of vaccine (15 minutes)

- Start the sub-topic by displaying slide no 10 and discuss on the components of vaccines (10-11)
- From the participant's manual make participants read the question on page 21 and discuss on how do the vaccines work and impact they have on diseases?
- Lastly, ask participants if they have any question and wrap up the sub-topic.

Activity 4. AEFI (25 minutes)

- Start the sub-session by asking participants, from slide 12, about the safety of vaccines and take reflection from 3 participants.
- Then, let the participants read the difference between vaccines and conventional drugs from the manual and summarize by displaying slide 14-16
- In slide 17, define what AEFI is
- Discuss on the classification of AEFI from slide 18-19
- For 2 minutes, make participants read case study 4.1 on page no 21 and let them reflect
- Continue the sub session by discussing on vaccine reactions (slide 20-24)
- On slide 25, compare serious and severe reactions
- Afterwards, display slide no 26 and discuss about frequency of AEFIs
- Ask, participants if they have questions and clarify them accordingly

Chapter 3: Prevention and Management of AEFI

Session description

The focus of this course is to develop an understanding on prevention and management of AEFI

Session Objective

The primary objective of this chapter is to equip participants at local, regional and national level with the technical knowledge to prevent and manage AEFI.

Enabling objectives:

Upon the completion of this chapter, trainees are expected to

- Explain Prevention and Management of vaccine reactions
- Explain Prevention and Management of anaphylaxis
- Discuss Prevention and Management of Immunization Error-Related Reactions
- Discuss Prevention and Management of Immunization Anxiety-Related Reactions
- Explain general preventive and management approaches of coincidental events

Session Outline

- Activity 1: Introduction
- Activity 2: Prevention and Management of vaccine reactions
- Activity 3: Prevention and Management of anaphylaxis
- Activity 4: Prevention and Management of Immunization Error-Related Reactions
- Activity 5: Prevention and Management of Immunization Anxiety-Related Reactions
- Activity 6: General preventive and management approaches of coincidental events
- Activity 7: Summary

Summary of activities

S. No.	Activity	Method of delivery	Duration	Materials
1	Session introduction	Experience sharing and Interactive presentation	10 min	PowerPoint Flip chart
2	Prevention and Management of vaccine reactions	Brainstorming and Interactive presentation	20 min	
3	Prevention and Management of anaphylaxis	Case study, individual and group reading, Interactive presentation	30 min	
4	Prevention and Management of Immunization Error-Related Reactions	Case study, individual and group reading & reflections, Q & A, Interactive presentation	40 min	PowerPoint

5	Prevention and Management of Immunization Anxiety-Related Reactions	Case study, individual and group reading & reflections, Q & A, Interactive presentation	30 min	
6	Session summary	Question and Answer, Discussion and Summary	10 min	

Time allowed: 140 minutes

Preparation before the session

Read the training material well and the references indicated below and internalize Prevention and Management of Vaccine Reactions well before the session.

- National AEFI guideline
- WHO vaccine safety basics manual
- Guidelines for managers of immunization programmes on reporting and investigating adverse events following immunization

Activity 1: introduction (10 minutes)

- Introduce the session by describing the session outline, primary and enabling objectives of the session: From the PowerPoint slide no. 2 – 4 in 3 minutes.
- Ask 2 volunteer participants to reflect their experiences on encountered AEFI and write their responses on the flip chart – take 4 minutes.
- Briefly discuss background information on prevention and management of AEFI: From the PowerPoint slide no. 5-6 – take 3 minutes.

Activity 2: Prevention and Management of Vaccine Reactions (20 minutes)

- Begin the session by asking participants to brainstorm prevention and management of vaccine reactions. Display activity 2 from the PowerPoint slide no. 7 for discussion in 5 minutes.
- Elaborate the prevention and management of vaccine reactions: Interactive presentation using PowerPoint slide no. 8 in 5 minutes.
- Ask participants to read in pair table 3.1 for 5 minutes. Then, summarise key points using the participant manual (page no.) in 5 minutes

Activity 3: Anaphylaxis: Recognition, Prevention and Management (30 minutes)

- Form participants into five groups to see the case study and answer the follow-up questions (participant manual page no.). Then, receive reflections from two randomly selected groups and write their answers on the flip chart (5 minutes)
- Summarize the case study through presenting the following key points in 5 minutes:

Answer to case study

Recognition

- Respiratory: wheezing, chest pain, shortness of breath, uvular swelling
- Gastrointestinal: epigastric pain, cramping type of abdominal pain
- Skin: itching and rash starting from lower extremities which progressively involve all over the body
- MSS: myalgia
- CNS: Headache
- V/S: high grade fever, tachycardia (PR=122) and hypotension (80/50)

Management

- Adrenaline
- Diphenhydramine
- Dexamethasone
- Cimetidine
- Salbutamol
- Normal saline
- Oxygen if SaPo2 is below 90%

- Discuss how anaphylaxis can be recognized and distinguished from other differential manifestations using interactive presentation (PowerPoint slide no 9-11) in 10 minutes
    - Ask participants to read table 3.2 and table 3.3 during interactive presentation.
- Ask each participant to read management of suspected anaphylaxis or collapse after vaccination (on participant manual page no.) for 5 minutes.
- Receive 2 reflections from the large audience and summarise key management approaches using the participant manual (page no.) in 5 minutes

Activity 4: Prevention and Management of Immunization Error-Related Reactions (40 minutes)

- Ask participants to read in pair the case studies found on participant manual (page no.) and receive reflections from three participants in 15 minutes.
- Summarize the case study using the following key answers in 10 minutes

Answers to questions for the case study

- What is the diagnosis of this child?
    - Sterile abscess following vaccination

- How do you manage the post-injection abscess?
  - Incision and drainage procedure was performed by the pediatric surgeon after
  - giving a prophylactic dose of an antibiotic, ceftriaxone 50mg/kg/day (intramuscular) for 3 – 5 days with Ibuprofen 4 mg/kg thrice daily and, mupirocin ointment twice daily for local application.
  - The baby recovered completely on fifth day post-drainage and no recurrence was observed.
- How do you prevent such type of immunization error?
  - WHO's vaccine safety basics learning manual suggests, to administer the aluminum containing vaccines intramuscularly and not subcutaneously to ensure the safety of vaccination.

Case Study

- Why type of immunization error encountered?
  - Vaccine Storage and Handling
- What type of precaution and measure should be taken to avoid such error.
  - If a vaccine is even one day over its expiration date, it should not be used. Rotate stock in your storage unit (which means make sure your vaccine that expires soonest is the closest to the front and easiest to reach in your storage unit), and establish a regular schedule for checking your storage unit for expired vaccine.
- What to do after such an error:
  - If a dose of expired vaccine is inadvertently given, it should be repeated. If the expired dose is a live virus vaccine, you must wait at least 4 weeks after the expired dose was given before repeating it. If the error is detected the same day, a repeat dose can be administered that day. The repeat dose of an expired inactivated vaccine can be given on the same day or any other time. If you prefer, you can perform serologic testing to check for immunity for certain vaccinations (e.g., measles, rubella, hepatitis A, and tetanus), although this may be more expensive and may produce negative test results, and if so, revaccination would be indicated.

Case Study

- What type of immunization error encountered

- Error in vaccine prescribing

- What type of precaution and measure should be taken to avoid such error.
  - An individual with a known immunodeficiency that contraindicated use of any live vaccines

- Discuss immunization error related reactions and strategies used to avoid/minimie them using PowerPoint slide no. 14-15 in 15 minutes

Activity 5: Prevention and Management of Immunization Anxiety-Related Reactions (30 minutes)

- Divide trainees into five groups and ask them to select a group leader to facilitate the discussion of the case study in 5 minutes.
- Select one participant from each group to present their reflections and comment the case study using the following discussion points in 5 minutes.

Comments for the case study

A history of syncope is a risk factor for a vasovagal reaction. The adverse social media message probably increased AG's anxiety before and fear during immunization manifested as an acute stress response accompanied by chest pain. Her symptoms immediately after immunization are consistent with an acute stress response (sympathetic system activation), exacerbated by the effect of adrenaline, which is a sympathetic stimulant, and by receiving a second injection, as she was afraid of needles, and by fear transmitted by the vaccinator, who thought this was anaphylaxis.

Interventions that would have been useful include:

1. **Before immunization:**
   - Identification of individual risk factors,
   - Communication about and explanation of stress symptoms and
   - vaccinating her first or in privacy.
2. **During immunization:**
   - Use of pain management techniques (see section 3.4.1),
   - vaccinating her seated or lying down and allowing her to remain supine for 10–15 minutes after immunization and
   - use of muscle tension to raise her blood pressure and avoid syncope (see section 3.4.1).
3. **After immunization:**

- Clinical differentiation between syncope and anaphylaxis to avoid use of adrenaline (another injection) and unnecessary hospitalization and
- feedback to the vaccinator to avoid mismanagement of similar incidents in the future.

As AG was hospitalized for a serious AEFI, an investigation of the case and an assessment of causality would be indicated, followed by appropriate communication to both the patient and her family and to the vaccinator, with recommendations and interventions to decrease the risk for future misdiagnosis

- Ask participants to read in pair and then give them 15 minutes for discussion
- Then ask the participants to reflect on the following main points
    - Distinguish anaphylaxis and anxiety related reactions
    - Identify individuals with potential risk factors for developing IARR
    - Discuss screening procedures
    - Management of IARR
    - Measures to be taken to reduce/prevent/minimize IARR
- Then facilitate discussion and summarize each main points using PowerPoint slide no 16) in 5 minutes

Activity 6: Coincidental events (10 minutes)

- Ask the participants to read in pair the case study for 5 minutes
- Select two participants and receive their reflections and discuss the case study using the following key answers in 5 minutes.

Answers to the case study

- What type of AEFI was experienced
    - Coincidental event.
- What kind of precaution is needed to identify the real AEFI cases
    - Vaccines are normally scheduled early in life, when infections and other illnesses are common, including manifestations of an underlying congenital or neurological condition. It is therefore possible for many events, including deaths, to be falsely attributed to vaccine through chance association.

- Summarize the main points using PowerPoint slide no 17) in 5 minutes

Activity 7: Session summary (10 minutes)

- Ask the participants if they have questions and discuss and summarize the session using PowerPoint slide no 17) in 5 minutes

Chapter 4: Overview of the National Pharmacovigilance system

Session Description

This session describes the importance of Medicines Safety Monitoring/Pharmacovigilance as one of the major regulatory functions mandated to the Ethiopian Food and Drug Authority (EFDA) for ensuring Safety, Efficacy and Quality of Medicines after they are made available for use in the market. Moreover, it also describes the National Pharmacovigilance System and Role of healthcare professionals (HCPs) in medicines/vaccines safety monitoring.

Primary objective: To enable participants understand the overall system of pharmacovigilance in Ethiopia

Enabling Objectives

After completion of this session, the participant is expected to:

- Define pharmacovigilance and related terminologies
- Explain the importance of pharmacovigilance
- Describe the national pharmacovigilance system
- Explain the role of HCPs in medicines/vaccines safety monitoring

Session outline

- Introduction
- Pharmacovigilance and related terminologies
- Pharmacovigilance
- Important terminologies in PV
- National pharmacovigilance system
- Roles and responsibilities of healthcare professionals in pharmacovigilance

Duration: 65 minutes

Summary of activities

S.No.	Activity	Method of delivery	Duration	Materials
1.	Introduction	Participants' reflection, Interactive PPT presentation, and discussion.	10 min	**LCD, Laptop, flip chart & marker**
2.	Brief overview of Pharmacovigilance	Interactive PPT presentation & discussion	10 min	
3.	Important terminologies in Pharmacovigilance	Interactive PPT presentation & discussion	15 min	
4.	The National pharmacovigilance system	Participants' reflection, interactive PPT presentation & discussion	15 min	
5.	Roles and responsibilities of healthcare professionals in pharmacovigilance	Participants' reflection, interactive PPT presentation & discussion	10 min	
6.	Session Summary	Interactive discussion	5 min	

Preparation before the session:

- Read well the training materials (facilitator guide, participant manual and ppt presentations)
- Read the references indicated at the end of the session in the participant manual
- Prepare brainstorming ideas before the presentation

Activity 1: Introduction (10 minutes)

- In 2 minutes, introduce the chapter and its outline by describing the learning objectives by displaying from the PowerPoint on slide no.2.
- Start the presentation by displaying introductory activity on slide 4 and take reflection from 2 or 3 participants on their understanding of the drug development lifecycle and its limitations. Then, display figure 4.1 on slide 5.
- Describe the importance of drug safety monitoring from slide no 6-7
- Lastly, ask participants if they have any question and address them accordingly.

Activity 2: Brief overview of pharmacovigilance (10 minutes)

- On slide 9, briefly describe the historical background of PV
- Continue the sub-session by displaying the word PHARMACOVIGILANCE on slide 8 and ask participants what they understand by the term and how they would define pharmacovigilance.
- Then, reveal the definition from the slide
- Discuss on the aims and activities of PV from slide no 9
- Lastly, ask participants if they have any question and address them accordingly.

Activity 3: Important terminologies in PV (15 minutes)

- Refer participants to the participant manual titled "**important terminologies in PV**" and request them to read aloud the terminologies along with their definition.
- Then, project selected terms and clarify further on slide 10-12.
- Ask participants if they have questions and clarify them accordingly

Activity 4: The National Pharmacovigilance System (15 min)

- Start the sub-session by ask participants on why pharmacovigilance is needed in Ethiopia and its status and take reflection from 3 participants.
- Continue the session by explaining the legal framework of pharmacovigilance in Ethiopia from proclamation 1112/2019, slide 18-20.
- Explain efforts made in improving drug safety monitoring and summarize, slide 21
- Afterwards, ask participants if they have questions and clarify them accordingly

Activity 4. Roles and responsibilities of healthcare professionals in pharmacovigilance (10minutes)

- Start the sub-session by asking the role and responsibilities of healthcare professionals in pharmacovigilance activities and take a few responses at a random.
- Explain each role of healthcare professionals from slide no 25-
- Ask participants if they have questions and clarify them accordingly

Trainer's note: the key players/stakeholders in the national pharmacovigilance system will be discussed in chapter 5.

Activity 7. Session summary (5 minutes)

- Ask participants if they have understood and appreciated the chapter.
- Then, ask participants if they have any question and provide answers.
- Display chapter summary from slide no 11 and ask a volunteer participant to read
- Close the chapter by thanking the participant for their active participation.

Session 5: AEFI surveillance system in Ethiopia

Session description:

The session introduces the AEFI surveillance system of Ethiopia with particular emphasis on what, how, and whenAEFI should be detected, recorded reported, investigated analyzed with the involvement of all relevant stakeholders with respective roles and responsibilities. Hence, appropriate information will be obtained on a given AEFI, and a timely response is provided to prevent vaccine-related harms and ensure the public trust of immunization.

Session objective:

At the end of this session,participants will be able to understand and describe the rationale behind conducting vaccine safety surveillance, the different components of AEFI surveillance system and the roles and responsibilities of stakeholders of the AEFI surveillance system

Enabling Objective:

- Describe the rationale behind conducting AEFI surveillance
- Explain the different components of AEFI surveillance cycle
- Understand AEFI surveillance methods
- Understand the role of different stakeholders of the AEFI surveillance system

Session outline:

- Introduction to AEFI surveillance
- Objectives of AEFI Surveillance
- AEFI surveillance cycle
- Types of AEFI Surveillance system
- Roles and Responsibilities of stakeholders of national AEFI surveillance system
- Session Summary

Duration: 60 Minutes

Summary of activities

S. No.	Activity	Method of delivery	Duration	Materials needed
1	Introduction to AEFI surveillance	Interactive presentation using PPT	5 min	Participant manual, Trainers', PPT Slides, Flip chart, white board marker, LCD projector
2	Objectives of AEFI Surveillance	Interactive presentation using PPT	10 min	
3	AEFI surveillance cycle	Interactive presentation using PPT	5 min	
4	Types of AEFI Surveillance system	Interactive presentation using PPT	10 min	
5	Roles and Responsibilities of stakeholders of national AEFI surveillance system	Group Work and Interactive presentation using PPT	25 min	
6	Session Summary	Interactive presentation	5 Min	

Preparation before the session

The facilitator should read the training materials (participant manual, trainer's guide, and PPT slide) well and other important references such as the National AEFI guidelines, EFDA Proclamation 1112/2019 and WHO AEFI surveillance guidelines.

Activity 1: Introduction to AEFI surveillance (5 min):

- Start the session by explaining the session description and objectives. Introduce the participants on basic concepts of AEFI surveillance using PPT (slide number 2-4.)

Activity 2: Objectives of AEFI surveillance system (10 min):

- Conduct an interactive lecture on general and specific objectives of AEFI surveillance using PPT (Slide number 5-8.)

Activity 3: AEFI surveillance cycle (5 min):

- Conduct an interactive presentation about the AEFI surveillance cycle by presenting the picture and highlighting each component(Slide number 9)

Activity 4: **Types of AEFI Surveillance system (10 min)**

- Ask the participants about the types of AEFI surveillance systems they know and their respective advantages and disadvantages.Entertain some reflections from participants. Conduct an interactive presentation on a passive and active AEFI surveillance system(Slide Number 13)

Activity 5: Roles and Responsibilities of stakeholders of national AEFI surveillance system (25 min)

- Group participants based on the number of total participants of training, institutions they come from and allocated time. Give direction on how to proceed and present discussion points assisting them throughout the discussion session(Slide number 14) ((10 min)
- Summarize the group discussion with interactive presentation on stakeholders of the AEFI surveillance system both at the national and sub-national level (slide number 15-28) (15 min).

Activity 6. Session summary (5 min)

- Ask participants whether there is any point that needs more clarity and entertain a few points. Then summarize the session by displaying summary points on (slide number 29)

Chapter 6: AEFI detection, notification and reporting

Chapter description:

The chapter introduces participants with components of AEFI reporting system and the different types of AEFI reporting tools. The chapter describes the detection/identification and notification of AEFI. It focuses on what, when, how, who and for whom to report adverse events. It is designed to improve these important functions of the country's pharmacovigilance system by encouraging participants to be more vigilant for the safety of vaccine recipients and to create awareness on the mechanisms and the different reporting tools.

Chapter objective:

At the end of this chapter, participants will be able be explain about AEFI detection, notification, components of AEFI reporting system and different types of reporting tools.

Enabling objective:

- Describe the basics of AEFI detection, notification, and reporting
- Identify components of reporting system
- Recognize various reporting tools
- Describe AEFI reporting during campaign
- Identify the barriers of AEFI reporting

Chapter outline:

- Introduction to AEFI detection, notification and reporting
- Components of AEFI reporting system
- Types of AEFI Reporting tools
- AEFI reporting during campaign
- Barriers of AEFI reporting

Summary of activities

Total allocated time: 100 min

S. No.	Activity	Method of delivery	Duration	Materials
1	Session description and objective	Interactive presentation	5 min	PowerPoint Paper based AEFI reporting tools and e-reporting tools. Power Point
2	Introduction to AEFI detection, notification and reporting	Interactive presentation	10 min	
3	**Components of AEFI reporting system**	Interactive presentation	20 min	
4	Types of reporting tools (paper based AEFI reporting, mobile based reporting, and E-reporting)	Demonstration	30 min	
5	AEFI reporting during campaign and private sector reporting	Question and reflection, PPT presentation	20 min	
6	Barriers of AEFI reporting	Question and reflection, PPT presentation	10	
7	Session summary	Reflection and discussion	5 min	

Preparation before the session

Read the training material well and the references indicated below and internalize AEFI reporting tools well before the session.

- National AEFI guideline
- WHO vaccine safety basics manual
- Global manual on surveillance of Adverse Event Following Immunization
- Instructions on Med safety app and e-reporting
- Paper based AEFI report form

Activity 1. Session introduction (5 min)

- Display slide No 1-3 and introduce the session by giving brief information about session description and enabling objectives.

Activity 2. AEFI detection and reporting system (10 min)

- Make an interactive presentation using slide No 4-11. Elaborate:
  - Detection is an important first step
  - Suspicion alone is sufficient for reporting.

Activity 3. Components of AEFI reporting-(20 minutes)

- Display and present slide No 5-10 and emphasize on which AEFIs should be reported, report timeline and reports should follow the standard reporting tools.
- Ask participants to be in pair and read the flow chart on Ethiopia AEFI Reporting – Routing, Timeline and Action on PM for 5 minutes. Then ask if they have ever reported AEFI through this channel? Describe any challenge encountered?
- Summarize the flow chart using slide 11.

Activity 4. Demonstration of AEFI reporting tools (30 min)

- **Demonstrate the yellow page.**
  - Describe each of the components that need to be filled in the form by describing the importance of each item. Then show how to fold the form after filling the necessary data.
- **Demonstrate the mobile based reporting tool**
  - Use the instruction provided in the manual on how to use the mobile based reporting tool.
  - Show how to download, install, create account, and fill the required data using internet connected mobile phone.
  - Guide them through the process.
- **Demonstrate the computer based reproting tool**
  - Use the instruction provided in the manual on how to use the e-reproting tool in a computer
  - Guide them to enter www.fmhaca.gov.et-serivces-e-Reporting
  - Show how to create account and fill the required data using internet connected computer.
  - Guide them through the process by displaying the website using an internet connected computer.
- In addition to the above reporting means, please inform participants that they can report an AEFI by sending scanned copy of legibly filled standard AEFI reporting form to an email address of pharmacovigilance@efda.gov.et or they can call and notify/report AEFIs through a toll free phone call service.

Activity 5: AEFI reporting during campaign and private sector reporting (20 min)

- Ask volunteer participants to reflect on questions on slide no. 20 and discus on the response.

- Ask participants to read and explain the important reasons of ensuring safety surveillance during mass immunization and special immunization programs.
- Display and summarize the key measures that are important to consider for AEFI management and monitoring during mass immunization and special immunization programs using slide no. 21-22
- Please inform participants that vaccine recipient may visit private health care facilities for AEFI. This is a good opportunity for the HCP to detect and report AEFIs to the health offices and authorities.

Activity 6: Barriers of AEFI reporting (10 min)

- Ask participants to highlight their experiences related to factors that were barriers for not reporting AEFIs.
- Then, summarize using the barriers listed in PM using slide no. 26.
- Emphasize that staff must be encouraged to report adverse events without fear of penalty. The aim is to improve systems or provide further training, and not to blame individuals.

Activity 7. Session summary (5 min)

- Ask the participants if there is anything left unclear and discuss and summarize the session using points listed by slide no.27.

Session 7: AEFI Investigation and Causality Assessment

Session description:

This chapter introduces the basics of AEFI investigation and causality assessment of serious adverse events (SAEs) and other AEFIs of concern. The chapter emphasizes steps and procedures on how the reported AEFIs are investigated to obtain more information. In addition, it explains the need and steps for analysing information to establish a possible causal link or relationship between the serious AE that occurred after immunization and the vaccine taken.

Session Objective

At the end of this session, participants will be able to understand and describe AEFI investigation and causality assessment.

Enabling Objectives:

- Explain AEFI investigation
- Describe AEFI causality assessment

Session Outline:

- AEFI investigation
  - Introduction about investigation and its objectives
  - What, who, and when should be AEFI investigated?
  - Steps in investigating AEFI's
  - Investigation of AEFI with fatal outcome and AEFI cluster
  - Outcome of AEFI investigation
  - Type of data that should be collected and how the data be collected and recorded
- AEFI Causality assessment
  - Introduction to causality assessment

- Selection of cases for causality assessment
- Preparation for AEFI causality assessment and causality assessment team
- Steps in causality assessment
- Categories of causally assessed AEFI cases
- Response and action after causality assessment

- Session Summary

Allocated time: 80 Minutes

Summary of Activities

S. N	Activity	Method of delivery	Duration	Materials
1	Introduction about investigation and its objectives	Interactive lecture using PPT Group discussion and reflection	5 Min	LCD Projector , Flip chart PPT slide, Training Manual Trainer's guide, White board Marker
2	What, who, and when should be AEFI investigated?	Interactive presentation using PPT	5 Min	
3	Type of AEFI data that should be collected and how the data be collected and recorded	Interactive presentation using PPT	5 Min	
4	Steps in investigating AEFI's	Interactive presentation using PPT	10 Min	
5	Investigation of AEFI with fatal outcome Investigating AEFI clusters Outcome of AEFI investigation	Interactive presentation using PPT	5 Min	
6	Basics of causality assessment	Interactive presentation using PPT	5 Min	
7	Selection of cases for causality assessment	Interactive presentation using PPT	5 Min	
8	Preparation for AEFI causality assessment	Interactive presentation using PPT	5 Min	

	Causality assessment team			
9	Steps in causality assessment	Interactive presentation using PPT	5 Min	
10	Categories of causally assessed AEFI cases	Interactive presentation using PPT	5 Min	
11	Response and action after causality assessment General guidance of action, response, and communication during AEFI surveillance	Interactive presentation using PPT	20 Min	
12	Session Summary	Interactive presentation using PPT	5 Min	

Preparation before the session

- The facilitator should read well the training materials (participant manual, trainer's guide and PPT slide) well and other references including the national Pharmacovigilance Guideline, EFDA Proclamation, proclamation 1112/2019, AEFI Training manual, AEFI investigation form and WHO AIDE Memoir checklist on AEFI causality assessment

Activity 1: **Introduction about the investigation and its objectives (10 min)**

- The facilitator starts the session by inviting participants to read the session description and objectives (Slide# 3)
- Facilitator starts the presentation by asking participants about what will be done once the AEFI report is received by the national PV center and what they understand of the term investigation and its objective. Entertain some reflections from participants (Slide #5)
- Conduct an interactive presentation on the investigation and its general and specific objectives using PPT (Slide # 6)

Activity 2: What, Who, and when should be AEFI investigated? (10 Min)

- Ask the participants about the need for conducting of investigation for all AEFI types of AEFI. If their response is no, ask what type of AEFI report is subjected to investigation. Entertain some reflections from participants (Slide #8).

- Summarize the discussion by mentioning the type of AEFIs that need further investigation. Explain about each of the following conditions that require investigation-using PPT (Slide # 9)
    - All serious cases of AEFIs
    - Clusters and events above the expected rate and severity
    - Evaluation of suspected signals
    - Other AEFIs
- Conduct an interactive presentation using PPT by explaining the people that need to be involved in the AEFI investigation by mentioning each of the subnational stakeholders and additional subnational stakeholders that need to be added when necessary (Slide # 10)
- Explain to the participants about the timeline for the AEFI investigation and remind them the investigation should begin as soon as possible, ideally in 24 hours but maximum within seven days of notification by the health worker (Slide # 11)

Activity 3: Type of AEFI data that should be collected and how the data be collected and recorded (5 Min)

- Conduct an interactive lecture and explain the type of data to be collected during the investigation including investigation of the vaccine(s), administration techniques and procedures, and service in action (Slide # 11)
- Also orient (demonstrate) the participants how data should be recorded by using the AEFI Investigation form annexed at the participant manual (Slide #12)
- Describe the way how data should be collected from clinical examinations; interviews with the client or caregiver; review of patient registers; observation of immunization administration, vaccine handling, and storage; examination of health facility records and laboratory reports (Slide # 13)

Activity 4: Steps in investigating AEFI's (10 min)

- Describe the details of the steps in the AEFI investigation and show the importance of each of the following steps in the comprehensiveness of the whole process using PPT (Slide #14-26)
    - Confirm information from the AEFI reporting form
    - Collect data about the patient and the event
    - Collect data about the Vaccine and the immunization service
    - Formulate a hypothesis
    - Test a hypothesis
    - Conclude the investigation

- Emphasize that the investigation needs to identify all cases in the community and find out the outcomes for all who received the suspect vaccine. The risk of an adverse event should be compared for those who received the vaccine versus those who did not

Activity 6: **Investigation of AEFI with fatal outcome, AEFI clusters and outcome of investigation (5 Min)**

- Conduct a lecture using PPT about the rationale and procedures for the investigation of AEFI with fatal outcomes and AEFI cluster (Slide # 27-28)

Activity 7: Basics of causality assessment (5 min)

- Conduct an interactive lecture using PPT on the general overview of causality assessment and explain that causality assessment is a critical part of AEFI monitoring and enhances confidence in the national immunization program and regulation of the safety and quality of the product. Also add that Causality assessment is important for:
    - Identification of vaccine-related problems;
    - Identification of immunization error-related problems;
    - Excluding coincidental events;
    - Detection of signals for potential follow-up, testing of hypothesis and research; and
    - Validation of pre-licensure safety data with the comparison of post-marketing surveillance safety data (Slide # 29-33)

Activity 8: Selection of cases for causality assessment (5 min)

- Describe that not all AEFI incidents that are reported need to have a formal causality assessment performed. Provide the types of serious AEFI that causality assessment needs to be carried out after investigation using PPT (Slide # 34-35)

Activity 9: Preparation for AEFI causality assessment and Causality assessment team (5 Min)

- Conduct an interactive lecture that describes the three prerequisites that every AEFI report should fulfil before causality assessment is going to be conducted (Slide #...)
- Briefly describe the National pharmacovigilance advisory committee, their duties and responsibilities, their composition, and the use of a TOR for their activities in causality assessment (Slide #36-37)

Activity 10: Steps in causality assessment (5 Min)

- List the four steps in causality assessment and the significance of each for the whole purpose of classifying the cause-and-effect relationship of the vaccine and the encountered AEFI (Slide # 38)
- Describe the interrelationship between the four steps mainly assessing the eligibility of the SAE, using the checklist, using the WHO algorithm, and the final classification (Slide #38-41)

Activity 11: Categories of causally assessed AEFI cases (5 Min)

- Conduct an interactive lecture on the categories of causally assed AEFI cases using PPT. Briefly describe the five different categories of causality assessment that will be obtained after the final classification of the cause-effect relationship by the advisory committee which is majorly classified into two and then sub-classified further into eight categories (Slide # 42)

Activity 12: Response and action after causality assessment (10 min)

- Conduct an interactive brief lecture on the responses and actions that should be taken after causality assessment results using PPT ((Slide # 43)
- Invite all participants to read their participant manual regarding aactions to safeguard the public during an investigation and action that should be taken at a peripheral level and check their understanding by entertaining reflections from by random section of participants (Slide # 45)
- Conduct brief presentation on response, communication with Parents and other members of the Community with regard to results AEFI (Slide #6)

Activity 13: Session Summary (5 min)

- Ask participants whether there is any point that needs more clarity and entertain unclear points from participants and summarize the session by displaying summary points of the session on (Slide # 47-49)

Chapter 8: Vaccine Risk Communication

Chapter description: This course is to designed to provide participants an insight on vaccine risk communication

Primary Objective: The primary objective of this chapter is to equip trainees with the technical knowledge on appropriate vaccine risk communication.

Enabling objectives:

By the end of this session, participants are expected to:

- Explain the concept of vaccine risk communication and its benefits
- Outline effective strategies to improve vaccine safety communication
- Apply principles to specific situations to decide appropriate actions to take when safety communication problems arise.
- Outline the challenges in communicating the risks of immunization to parents and healthcare providers, especially when an AEFI has occurred.

Session Outline

- Session 1: Principles of effective communication
- Session 2: Communication with Stakeholders
- Session 3: Communicating with media

Preparation before the session:

- Read well the facilitator guide, participant manual and PPT presentations well before.

Duration: 60 minutes

Summary of activities

SN	Activity	Method of delivery	Time	Materials
1.	Introduction of the session	Presentation	5 minutes	LCD, laptop, flip chart, marker, ppt slides, video animation.
2.	Principles of effective communication	Interactive presentation & PPT	10 minutes	
3.	Communication with Stakeholders	Individual reading & PPT	15 minutes	
4.	Communicating with media	Participant make 5 group, Individual reading Participant reflection	15 minutes	
5.	Media Management post AEFI	Interactive presentation & PPT	10 minutes	
6.	Session Summary	Question and Answer	5 minutes	

Preparation before the session:

- Read well the facilitator guide, participant manual and PPT presentations well before.
- Read references listed at the end of the participant manual for each chapter as needed.

Activity 1. Introduction of the session (5')

- First tell the participants what this chapter is about, mainly from the session description.
- Then ask participants to read the learning objectives aloud one by one from the PPT on slide no 4
- Ask if there is any objective which not clear and elaborate objectives as is necessary.

Activity 2. Principles of effective communication (10')

- Start by explaining what principles of effective communication, the need and the purpose of effective communication. Then, explain to the participants the following 7 points using participants manual on page no ……
- Discuss the benefit and challenge of communication by displaying PPT slide no 7 to 8.

Activity 3. Communication with different Stakeholders (15')

- Tell the participants to be in pair and the need of communication with stakeholders. Then discuss the answers as a large group using the following answer.
- Tell to the participants about key points to consider when communicating with the vaccine recipient (patient or client) or parents and guardians of the patient, community and health staff and by displaying PPT slide no 10.
- Then explain the role of health care worker in community communication on AEFI
- Discuss in detail point by point the response of communication element once an AEFI has occurred and by displaying PPT slide no 11.
- Give an individual reading about communication with health care staff using the participant manual page no…….

Activity 4 Communicating with media (15')

- Participates make in 5 group with individual reading
- Allow two participants to share their reflections on the advance preparedness, database of journalists, Information packages, draft media release, spokesperson system, orientation workshop, field visit for media, and media management during AEFI crises
- Discuss in detail point by point about media monitoring, release and conference by displaying PPT slide no 13-15.

Activity 5. Media Management post AEFI (10 min)

- Display slide # 16 and explain to participants about keeping promises to the media, providing answers to unanswered questions and keeping media informed about subsequent developments
- After interactive presentation, summarize the key points using participant manual page no=
- Discuss in detail point by point about dealing with rumors and misinformation, common causes of rumors, and words of advice by displaying PPT slide no 17& 18.
- Summarize the key point after interactive presentation using participant manual page no=

Activity 6: Session Summary (5 Minutes)

- Summarize the presentation, review the Session Summary presented in slide no 19 and answer final questions.

Chapter 9: Adverse Events following Immunization for COVID-19 Vaccines

Chapter description:

This chapter provides participants with concept of different COVID-19 vaccine development platforms and familiarize with common characteristics. In addition it will enable participants to understand commonly reported AEFIs and Adverse Event of Special Interest (AESI) following the use of these vaccines.

Chapter Objectives

At the end of this chapter, participants will be able to identify common AEFIs/AESI related to COVID-19 vaccination.

Enabling Objectives

At the end of this session, the participant will be able to:

- Understand various types of COVID-19 vaccines development platforms
- Describe the common characteristic of COVID-19 vaccines
- Identify common AEFIs related to COVID-19 vaccines
- Discuss AESIs related to COVID-19 vaccines

Summary of activities

Total allocated time: 100 min

S. No.	Activity	Method of delivery	Duration	Materials
1	Session description and objectives	Interactive presentation	5 min	PowerPoint Paper based AEFI reporting tools and e-reporting tools. Power Point
2	Types of COVID-19 vaccines, development platforms and mechanisms	Individual reading and Interactive presentation	20 min	
3	**Characteristics of COVID-19 vaccines**	Individual reading and Interactive presentation	10 min	
4	AEFIs related to COVID-19 vaccines - General AEFIs related to COVID-19 vaccines - Vaccine Specific AEFIs related to COVID-19 vaccines	Reflection, Individual reading and Interactive presentation	30 min	
5	Adverse Events of Special Interest to COVID-19 vaccines	Individual reading and Interactive presentation	15min	
6	Homologous Boosting and Heterologous mixing of COVID-19 vaccines	Interactive presentation	15min	
7	Session summary	Reflection and discussion	5 min	

Preparation before the session

Read the training material well and the references indicated below and internalize AEFI reporting tools well before the session.

- COVID-19 Vaccines: Safety, Surveillance Manual, WHO 2020.
- Interim recommendations for heterologous COVID-19 vaccine schedules, WHO 2021.

Activity 1. Chapter introduction (5 min)

- Display slide No 3 and introduce the session by giving brief information about session description and enabling objectives.

Activity 2. Types of COVID-19 vaccines, development platforms and mechanisms (20 min)

- Ask the introductory question on slide #4 and receive 2 reflections for each.
- Then, make an interactive presentation using slide No 5-7. Explain COVID-19 vaccines bring new types of development platforms.
- Ask participants to read 'How does COVID-19 vaccines work' section on their PM for 2 minutes. Then summarize this part using slide#8.

Activity 3. Characteristics of COVID-19 vaccines (10 minutes)

- Ask participants to read table 9.2 'Characteristics of COVID-19 vaccines' section on their PM for 5 minutes.
- Then summarize this part using slide#9.
    - Explain the difference in effectiveness of COVID-19 vaccines against different COVID-19 virus variants.

Activity 4. Common AEFIs related to COVID-19 vaccines (30 min)

- **General AEFIs related to COVID-19 vaccines**
    - Display slide #10 and explain the safety of vaccines in the national EPI programs.
    - Then ask the group discussion questions in the same slide.
    - Receive reflections and continue presenting slide #11-13.
- **Vaccine Specific AEFIs related to COVID-19 vaccines**
    - Display slide#14-21 and make an interactive presentation on AEFIs specific to the following COVID-19 vaccines; Please emphasize on local and systemic AEFI prevalence reported during clinical trials for each vaccine. Focus on differences.
        - AstraZeneca
        - Sinopharm
        - Pfizer and
        - Janson
- Then, present and explain the global and national AEFI reports of COVID-19 vaccines reported to WHO UMC, as of August 2022 using slide#22-24.

Activity 5: Adverse Events of Special Interest to COVID-19 vaccines (15 min)

- Display slide#25 and make an interactive presentation on Adverse Events of Special Interest to COVID-19 vaccines;

- Please emphasize on the need to report them using the available reporting options.
- Then, ask the participants to read the examples of AESI on their PM.
- Proceed presenting slide#26-28 on selected AESI including Thrombotic and thromboembolic events and Myocarditis and pericarditis.

Activity 6: Homologous Boosting and Heterologous mixing of COVID-19 vaccines (15 min)

- Ask participants what Homologous Boosting and Heterologous mixing mean?
- Then tell them that why boosting and when is mix and match is needed? Also explain how to make a mix and match using the vailable vaccines using the PM.

Activity 7. Chapter summary (5 min)

- Ask the participants if there is anything left unclear and discuss and summarize the session using points listed by slide no.30.

Chapter 10: Monitoring and Evaluation of surveillance

Duration: Duration: 70 min

Chapter description: This chapter enables the participants to identify monitoring and evaluation parameters of , Indicator characteristics and indicators. In addition, it enables trainees to have the skill and knowledge for monitoring and evaluating related activities.

Primary Objective: By the end of this chapter, participants will be to monitor and evaluate surveillance related activities in different immunization program levels and beyond.

Enabling Objectives:

- Recognize the significance of monitoring and evaluation in
- Identify in selecting good quality indicators
- understand selected performance indicators

Summary of activities

S. No.	Activity	Method of delivery	Duration	Materials
1	Introduction	Large group discussion with reflection	10 min	Flip chart Training manual
2	Performance indicators	Large group discussion, interactive presentation and group discussion	10	
3	Reporting	question and answer, reflection and discussion	35 min	
4	Summary	Interactive PPT presentation & discussion.	10 min	

Preparation:

- Before delivering this session, please read well the participant manual, trainer guide and PPT of this training material.
- Please be familiar with the national AEFI guide before delivering this session.

Activity 1. Introduction (10 min)-Large group discussion with reflection

- Introduce the session by describing the learning objectives from the PowerPoint slide from number 2&3.

- Display PPT slide #4 and ask participants to answer the question. Allow 2 participants to reflect on it. Then, explain the similarity and differences from the PM.
- Finally, explain the benefits of routine monitoring and evaluation and in relation to .

Activity 2. Indicators Characteristics (45 min)-

Large group discussion, interactive presentation and group discussion

- Ask participants to answer questions on PPT slide #5.
- Conduct an interactive presentation on performance indicators using PPT slide #6.
- Then, inform participants that the performance indicators for AEFI shall specific and measurable.
- Also inform the participants that, there are few indicators selected on AEFI related activities and we will see them one by one through group discussion.
- Then group the participants in to four and assign the 4 indicators each receiving 1 and make the group to discuss on each indicator and its respective description for 10 minutes. Then each group will reflect a summary on each indicator for 5 minutes. Provide additions, or corrections as necessary on each group for 1 minute.

Activity 3. indicators (KPIs) (10 minutes)-

Question and answer, reflection and discussion

- Display questions on slide number 8 and ask 1 volunteer to reflect on each question. Then explain the benefits of reporting continuously. Inform them that even though there is no separate reporting structure for AEFI, it shall be considered as part of other reports.

Activity 4. Session Summary (5 mins)

- Entertain if there is unclear point from the participant and then summarize the session by displaying slide #9.

Pre/posttest

Code_____

surveillance training for health professionals

I. Choose the best answer and encircle it.

1. Which of the following statement is true about National Immunization program

A.

B.

C.

D. All

Answer key

1. D 2. x 3. y 4.