Product safety Directorate,
Ethiopian Food and Drug Authority

Pharmacovigilance Training for Healthcare Professionals
Trainer's Guide

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National Pharmacovigilance Training for Healthcare Professionals

Trainer's Guide

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Addis Ababa, Ethiopia

Foreword

Ethiopian Food and Drug Authority (EFDA) is the national regulatory authority vested by law to control medicines and food that aim to improve the quality, safety, and efficacy of medicines and food to ensure the safety and quality of health services throughout the country. It is widely known that the sector is growing in line with the overall growth and transformation plan of the country and that the sector is being guided by the health regulatory sector transformation plan (HRSTP), which is consistent with the national focus on quality improvement, patient safety and considers the national priority public health programs.

Access to medicine, in general, is increasing but inadequate pharmacovigilance (PV) capacity to effectively monitor, prevent, detect, manage, and report adverse drug events (ADEs) locally remains a challenge. The increasing number of clinical trials, the introduction of new drugs/regimens in major public health programs (PHPs) including HIV and TB, the large-scale mass drug administration and immunizations programs being deployed through PHPs in the country need to develop/strengthen the PV system for patient safety.

The EFDA has been leading the efforts to strengthen the national PV system in the health care system. As part of these efforts, the development of training material to build the capacity of healthcare professionals on PV was determined to be necessary. PV is ‘‘the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems.”

Thus, the development of this training manual is an important step to addressing knowledge, skill, and attitude gaps identified to enhance the national monitoring and reporting of ADE thereby improving patient safety. Since this PV training material was designed as an answer to observed gaps, it is my belief that health system/program managers and experts involved in education, mentoring, and supportive supervision of PV at the health facility level will find it useful.

I would like to take this opportunity to thank all who participated in the design and development of this training manual. I would also like to encourage users of the manual to send their comments regarding the manual to the authority via the website: http://www.efda.gov.et or P.O. Box 568 , Addis Ababa, Ethiopia.

Heran Gerba (B. Pharm, MSc)

Director General, Ethiopian Food and Drug Administration (EFDA)

APPROVAL STATEMENT OF THE MINISTRY

The Federal Ministry of health of Ethiopia has been working towards standardization and institutionalization of In-Service Trainings (IST) at national level. As part of this initiative the ministry developed a national in-service training directive and implementation guide for the health sector. The directive requires all in-service training materials fulfill the standards set in the implementation Guide to ensure the quality of in-service training materials. Accordingly, the ministry reviews and approves existing training materials based on the IST standardization checklist annexed on the IST implementation guide.

As part of the national IST quality control process, this National Pharmacovigilance Training IST training package has been reviewed based on the standardization checklist and approved by the ministry in May, 2022.

Assegid Samual Cheru
Human Resource Development Directorate
Director
Ministry of Health, Ethiopia

Acknowledgment

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Acronyms/Abbreviations

ADR/E	Adverse Drug Reactions/Events
DTC	Drug and Therapeutic Committee
DTP	Drug Therapy Problem
EFDA	Ethiopian Food and Drug Administration
EHSTG	Ethiopian Hospital Service Transformation Guideline
EPSA	Ethiopian Pharmaceutical Supply Agency
ESA	Ethiopian Standard Agency
MOH	Federal Ministry of Health
HSTP	Health Sector Transformation Plan
IST	In-service Training
KAS	Knowledge, Attitude and Skill
MDT	Multidisciplinary Team
MRN	Medical Registration Number
OPD	Out-patient Department
SOP	Standard Operating Procedure
USAID	United States Agency for International Development
PV	Pharmacovigilance

Contents

Introduction to the manual

Monitoring the safety and quality of medicines after they are put in the market is a key regulatory function towards ensuring rational medicine use and meeting the goal of protecting the public from drug related harms. To ensure this goal, various activities have been implemented in the national pharmacovigilance system.

As awareness creation and training on PV is vital to enable healthcare providers understand and practice ADE monitoring and reporting. Hence, various events of trainings and face to face discussions at facilities have been conducted for healthcare professionals. In addition, tools necessary for executing PV including ADE reporting forms, allergy card, and IEC materials have been revised, printed, and distributed.

Inclusion of topics on PV into the pre-service curriculum of health teaching institutions was also a milestone activity performed during the past few years. The establishment of six decentralized PV centers at selected university hospitals in the country, the development of roadmap for the national PV system, the establishment of electronic reporting and mobile application to report ADEs, carrying out of several investigations on serious ADEs and performing of causality assessment to obtain the necessary scientific recommendations were also other significant system strengthening activities carried out .

Additional capacity building activities such as assessment and supportive supervision have also been carried out to strengthen the adverse event following immunization (AEFI) monitoring and reporting. Further, active surveillance as a cohort event-monitoring program (CEM) on ART medicines, active drug safety monitoring and management (aDSM) on MDR-TB medicines and adverse event following immunization on anthelmintic mass drug administration (AE-f-MDA) programs have also been conducted.

Reports were monthly received and those reports with serious ADEs have been analyzed. Regulatory measures were taken on medicines that have caused ADRs and on product quality defects. The measures have been communicated to the various stakeholders. This drug safety information has also been shared to the WHO database vigiflow on a routine basis so that the country could benefit from receiving and sharing information with the international world.

Despite the efforts made to strengthen the national PV system, still there are many challenges remaining. The national PV system situational analysis conducted in 2018 and feedbacks of experts working in the area identified the following gaps, including:

- Low number and variety of ADEs reporting by healthcare providers.
  - ✓ According to WHO, the expected number of ADE reports is 200 per 1 million inhabitants in a country (Ethiopia is expected to generate at least 20,000 reports annually).
  - ✓ Currently the number of reports being received is very low (less than 1000 per year).
- Poor knowledge and attitude regarding the importance of PV at all levels.
- Inadequate ADE monitoring, diagnosis, management, and prevention in health facilities.
- Poor level of awareness on eleoronic reporting mechanism among healthcare providers.
- Poor collaboration between PV and the various public health programs.
- Absence of standardized in-service training programs on PV for healthcare providers.

In the attempt to address such problems, various activities are being conducted by EFDA and stakeholders. In line with this, a national PV in-service training material has been developed to build the capacity of healthcare professionals (HCPs). By following the principles of instructional design, a group of experts in this area designed and developed a draft training material based on the national guideline on PV, ADE monitoring system/ PV training manual for health teaching institutions, national SOPs on PV, different national PHP guidelines including HIV, TB, malaria, non-communicable diseases (NCD), mass drug administration (MDA) for neglected tropical disease (NTD) and guidelines issued by WHO.

The syllabus was designed to enhance healthcare professionals' knowledge, skills, and attitude in critical areas of PV competencies so that they could meaningfully contribute to patient safety. The training material was further enriched by appropriate experts from MOH, EFDA, universities, hospitals, and development partners. This training material contains Participant's Manual, Trainers' Guide, and PowerPoint presentations. The training course considers participants as the focus of the learning process and activities in the sessions are designed to be moretrainee-focused. A modular approach is followed in the material design and development and will be implemented in the delivery. This course requires a Training of Trainers (TOT) and basic training to be conducted in all regions. The training will be given in selected training centers with proper infrastructure and facilities.

Core Competencies

Upon completion of this course, trainees are expected to attain the following core competencies:

- Differentiate ADE, ADR, and medication error
- Manage ADEs
- Report ADEs using different reporting mechanisms
- Investigate ADEs
- Perform causality assessment
- Recognize the role of PV in major PHPs
- Identify the roles and responsibilities of national key stakeholders in PV

Course Syllabus

Course Description

This 4-days course is designed to equip participants with the knowledge and skill on monitoring, diagnosis, management, and reporting of ADEs to improve patient safety. The course addresses a brief overview of pharmacoepidemiology (PE) and its relationship with PV, basic concepts of PV, ADE components, investigations and causality assessment of ADR, diagnosis, management and prevention of ADRs, monitoring and ensuring medication safety, the national PV system and PV in PHPs.

Course Goal

To provide participants with the necessary knowledge, skill, and attitude required to ensure the safety and quality of patient care within the healthcare continuum.

Course objectives

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

- Identify the link between pharmacoepidemiology and PV
- Discuss the need and importance of PV the in health care system
- Differentiate the components of ADEs
- Describe the national PV system in Ethiopia
- Monitor, diagnose, manage, and prevent ADEs
- Report ADEs using different reporting mechanisms
- Explain how to investigate ADEs
- Perform causality assessment
- Recognize the rationale of PV in PHPs
- Identify the roles and responsibilities of national key stakeholders in PV

Training methods

- Interactive lecture/presentation
- Reflection
- Small group discussions
- Brainstorming
- Exercises
- Large group discussions
- Case study
- Demonstration
- Video
- Reading

Training materials

- Participant's manual
- Trainer's guide
- PowerPoint presentations
- National ADE reporting form
- National pharmacovigilance guideline
- National aDSM SOP
- Computer with LCD Projector
- White board and white board markers
- Flipchart, flip chart hanger and writing marker

Participant selection criteria

The primary target group for this course is HCPs working in health facilities. In addition, experts working in EFDA, MOH, universities, Regional Health Bureaus (RHBs), Zonal Health Departments (ZHDs), Woreda Health Officers (WoHOs,) and partners who are supporting the PV system and capacity are target audiences.

Facilitator/Trainer selection criteria

Trainers for this course should be HCPS who have a TOT training certificate in this PV training course. For the first round, experts who participated in material development will be served as trainers.

Methods of evaluation

A. Participant

- **Formative**
  - Observation through checklists
  - Group activities and presentations
  - Individual reflections for questions
  - Case studies
- **Summative**
  - Progressive assessment (trainee daily performance): 20%
  - Post-test (written exam) - 80%
  - For TOT: progressive assessment (20%), Teachback-20% and Post-test (60%)

B. Course

- Daily evaluation

- End of course evaluation
- Post-test

Certification criteria

- For basic and TOT training trainees, the certificate will be provided to those who have scored ≥70% and ≥80%, respectively on summative assessment and who have 100% attendance on the course for both basic and TOT trainings. .
- **Continuing educational Unit(CEUs)=**15 CEUs

Course Duration

- Four days (4) for the basic training and six days (6) for the TOT

Suggested class size

- Suggested training class size shall be 20 - 25 participants per training venue.

Training Venue

- The training will be conducted at a nationally recognized CPD center.

Course Schedule

Training Course on Pharmacovigilance for Healthcare Professionals

Organized by: ----------

Venue: ---------- Date: ----------

Time	Topic	Presenter	Facilitator
Day 1: _____			
8:30-8:45 AM	Registration of participants	Organizer	
8:45-9:00AM	Welcoming Address /Opening Speech	EFDA	
9:00-9:10 AM	Introductory activity	Facilitator	
9:10-9:40AM	Pre-test	Facilitator	
	Overview on Pharmacoepidemiology		
9:40-10:00AM	Introduction	Presenter	
10:00 AM-10:15 PM	Study designs and measurements in epidemiology	Presenter	
10:15AM-10:30AM	**Health Break**	**Organizer**	
10:30AM-11:15AM	Surveillance systems in monitoring adverse health events	Presenter	
11:15AM-12:20AM	Types of a surveillancsystems for medication safety	Presenter	
12:20AM-12:30AM	Chapter summary	Presenter	
12:30-1:30PM	**Lunch Break**	**Private**	
	Basic concepts of Pharmacovigilance (PV)		
1:30PM-1:35PM	Introduction	Presenter	
1:35-PM-1:45PM	Overview on drug development process	Presenter	
1:45PM-2:30PM	Pharmacovigillance	Presenter	
2:30PM-3:25PM	Components of adverse drug events (ADEs)	Presenter	
3:25PM-3:30PM	Chapter summary	Presenter	

3:30 PM-3:45PM	**Health Break**	**Organizers**	
	Diagnosis ,management, prevention ,investigation and causality assessment of ADEs		
3:45 PM-5:30PM	Diagnosis, Management, and Prevention of ADEs	Presenter	
Day 2: _____			
8:30-8:45AM	Recap of day one	Participants	
8:45-9:50AM	Investigation of ADEs	Presenter	
9:50-10:30AM	Causality assessment of ADEs	Presenter	
10:30-10:45AM	**Health Break**	**Organizers**	
	ADEs Monitoring and Reporting in Ethiopia		
10:45AM-11:00AM	Introduction	Presenter	
11:00AM-12:30PM	The national ADE monitoring and reporting system	Presenter	
12:30PM-1:30PM	**Lunch Break**	**Private**	
1:30PM-3:30PM	Demonstration of reporting tools	Presenter	
3:30PM-3:45PM	**Health Break**	**Organizers**	
3:45PM-5:20PM	Roles and responsibilities of stakeholders in the national PV system	Presenter	
5:20PM-5:30PM	Chapter summary	Presenter	
Day 3: _____			
8:30AM-8:45AM	Recap of day two	**Participants**	
	PV in public health programs		
8:45AM-9:45AM	Pharmacovigilance in expanded program of immunization (AEFIs)	Presenter	
9:45AM-10:30AM	PV in Anti –TB medicines	Presenter	

10:30AM-10:45AM	**Health break**	**Organizer**	
10:45AM-11:45AM	PV of medicines used in HIV	Presenter	
11:45-12:30PM	PV for Anti- malaria medicines	Presenter	
12:30PM-1:30PM	**Lunch Break**	**Private**	
1:30PM-2:30PM	PV in mass drug administration (MDA)	Presenter	
2:30PM-3:30PM	PV in non-communicable diseases (NCD) medicines	Presenter	
3:30-3:45PM	**Health Break**	**Organizer**	
3:45-5:00PM	PV in reproductive, maternal ,neonatal and child health medicines	Presenter	
5:00-5:15PM	Daily evaluation	Participants	
Day 4: _____			
8:30-9:15AM	Post- test	Participants	
9:15-9:45AM	End of course evaluation	Participants	
9:45-10:30AM	Closing remark and certification	**Organizer**	
10:30-10:45AM	**Health Break**	**Organizer**	
10:45-12:30AM	Admin issues and End of program	Participants	

Course Facilitator Preparation for this Training

Purpose of this guide: This guide is used to aid training organizers during the organization and facilitation of this training event.

1. Checklist of instructional materials needed (non-reusable)

Items needed by each small group	Number needed per participant, facilitator	Total number	Day needed	READY
Participant Manuals				
Participant's Manual	1 for each participant and facilitator		Day 1	
Facilitator Guides				
Facilitator Guide	1 for each facilitator		Day 1	
Miscellaneous				
Pretest, Post-test	2 per participant plus 1 for each facilitator (the answer is in the TG)		Day 1	
Training banner (1mx3m)	1 per training event		Day 1	
Certificate of completion (signed by respective officials)	1 per participant		Day 6	
Daily course evaluation form	8 per participant		Day 1	
End of course evaluation form	1 per participant		Day 7	

2. List of other supplies and equipment needed in the classroom

Supplies needed for each facilitator and participant during the course:

- Notebook
- File folder or cloth bag (avoid binders with punching)
- Pen
- Highlighter

Supplies needed for the classroom (to be given/used when needed)

- White paper (A4)
- Adhesive tape
- Scotch tape
- Scissor

- Stapler and staples
- Extra pens
- Rubber bands
- Paper clips
- Blank flipchart pad
- Whiteboard markers (non-permanent)
- Laptop computer
- LCD projector
- Computer and printer

3. Venue

The venue should be comfortable for adult learning and adequate in size to accommodate the number of participants invited. To train two groups, two separate rooms will be required, preferably one of the rooms should be large enough to conduct plenary sessions.

4. Timetable for preparation

Prepare a realistic timetable, including all the preceding steps. Planning times will vary according to local circumstances.

Tasks your timetable needs to include:

Task	Estimated Time Needed	Done	Comments
1. Prepare budget breakdown with funds available			
2. Arrange/hire course facilitators/trainers			
3. Gather training materials, use the checklist			
4. Reserve the venue			If venue is unknown, visit to ensure suitability
5. Reserve meals and lodging if applicable			
6. Compile a list of participants			
7. Send invitation letters to participants and institutions			
8. Design and print course completion certificates			
9. Order printing of training banner to be prnted			
10. Purchase or arrange the above supplies for participants, facilitators, and groups			

11. Print and/or copy all the necessary training materials (participant manual, trainer guide, SOP, competency tests, pretest/post-test, daily and end-of- course evaluation forms)			
12. Arrange for a secretary or administrative assistant to work from 2 to 3 days before the course begins to the end of the course or one day later. Also, arrange finance personnel to handle financial issues in the event.			
13. Arrange for course closing ceremony (optional)			

5. Facilitators' meetings

It is important to schedule a daily meeting of all facilitators and the course organizer at the close of each day to review progress, discuss challenges, solve problems, and to plan for the following day. This may last from 10-30 minutes, depending on the situation and how things are proceeding.

Facilitator techniques common to all courses

1. How to give pre-and post-test

Explain to participants that the purpose of the pretest is to give facilitators a sense of baseline knowledge of the group and is not an evaluation. Allow sufficient time. Provide a code for each participant to be used for pre-and post-test. Do not discuss answers to the questions when the test is finished, as the same test will be given as the post-test but explain that all material will be covered in the course. At least two persons should score the test on the same day it is given so that facilitators can gear each course to the level of knowledge of participants.

2. Reading

When the facilitator manual says participants should read part of the manual or guideline module, you can have participants read silently on their own, or ask for a volunteer to read a section in a loud, clear voice. Whichever method you choose depends on factors such as the level of education of the group, differing levels within the group, their understanding of English, and what the group prefers. Make sure everyone is on the same page before beginning. If you are reading aloud, make sure that all participants who are willing, get chances to read during the course (do not force anyone). Sometimes it is helpful to ask someone to read who seems

particularly sleepy or inattentive to wake them up. You may also choose a mixture of silent reading and reading aloud.

3. Explanations and lecturing

At times, the facilitator is directed to explain certain important concepts. Explanations should be short and to the point, using a flipchart and/or referring to the manual. Avoid lecturing as this is not an effective way to learn. Occasionally, when pressed for time, it may be feasible to present certain material as a short, interactive lecture, rather than having participants read through a number of pages themselves, but this should not be the norm.

4. Energizers

Ask individual participants to be responsible for a few exercises or songs during the course of each day to make things livelier when attention is lagging or when people are tired, but the day is not over. This should be decided as part of "housekeeping" activities at the start of each day. The facilitators should also have some energizers of their own to offer.

5. Recap

Prepare review questions for the subjects covered each day and at the beginning of each day ask participants randomly and let them answer and discuss.

Introduction to the Course/Training

PREPARATION IS THE KEY!

It is important that you read this facilitator guide from cover to cover. Also, make sure that you know the details of the Participant Manual very well. It is recommended that you acquaint yourself with the teaching methodologies, various activities, and practical sessions including Expert Patient Trainers and Hospital Visit. Make sure all materials including, manuals, exercises, and formats needed for the training are prepared before the session begins including written flip charts. Think and get prepared on how to encourage participation and evaluate your training program.

ON 1ST DAY:

Registration: All participants and facilitators coming to this course should be registered on separate registration format prepared by the organizers of the course.

As participants enter the training room, one facilitator should greet each participant.

A. Welcome, introduction and participants' expectations:

Start the course by welcoming participants and introducing yourself and your roles in this training. Let all facilitators and other organizers (if any) introduce themselves.
Then, tell them the following points about the course:

- The title of the course is National Pharmacovigilance Training for Healthcare Professionals|
- This is a 4-day course and it will end on this date starting from today.|
- The training is organized by:|
    - Government bodies: _____.
    - Funding partners: _____.

Then, ask participants to introduce each other turn by turn by showing the following points on a flipchart so that they follow it (the flipchart should be ready ahead of time)

- Name|
- Their facility/workplace|
- Pharmacist|
- Years of experience in general and in Clinical Pharmacy, if any|

Then summarize this by a statement about the participants' mix in terms of the level of education and year of experience and tell them that it is important for facilitators.
Then, ask participants to write down their expectations from this training in their notebook. Tell them they will later identify which of their expectations were in the course and which were not.
Facilitators and organizers should make sure that the following flipcharts remain available and posted in the hall throughout the course. They will be referred to as needed:

- Participants' expectations|
- Group norms|
- Parking Lot|

A. Course Goals and Objectives – Interactive Lecture – 15 minutes

Display course goals and objectives of the training which are written on a flip chart and tell participants to look it up. Tell them to relate their written expectations on the displayed goals and objectives. Ask participants to raise their hand and tell which goals and objective will meet their

expectations. Also, inform them to roughly see the core competencies in their participant manual which are expected after finishing this course.

How to handle topics not specifically covered?

A comment that, while some of the topics mentioned in the expectations may not be covered through specific sessions, they may be discussed throughout the course in other topics (site one or two specific examples as appropriate). Remind participants that from the self-introductions it was obvious that a lot of different expertise exist among the participants as well as the facilitators. Therefore, they should feel free to tap the expertise of others in the group. The comment that in any course such as this where participants come from numerous places, much learning can take place between participants as from the facilitator to the participant and that participants should take advantage of this opportunity. Mention also that due to time and priority issues, some topics may simply not be covered, but that participants are free to discuss among themselves during breaks, lunches, or in the evenings.

B. Workshop Schedule – Lecture – 5 minutes

Ask participants to turn to their participants' workbook: Course Schedule or separate schedule is given. Review the outline of the schedule with participants, pointing out features such as the "regular" hours, any likely exceptions, a time set aside for reviews.

Note how the goals and objectives that were just reviewed are related to some of the sessions-judging by their titles.

Mention that certificates will be distributed on the last day of the course and that 100% attendance is required to receive the "Certificate of Completion". Participants that have not participated will not receive a certificate.

C. Other Course-related Issues – Lecture – 10 minutes

Training methodology:

Tell participants that their active participation is critical to fulfilling the training objectives/outcomes. Remind them that unlike the usual PowerPoint-based training, this course employs' various participant-centered approaches which are very important in delivering the course effectively. These training methodologies/approaches include:

- Interactive presentations|

- Individual reading and reflection|
- Think-pair-share|
- Group discussions and exercises|
- Roleplays|
- Expert patient training|
- Site visits and others.|

Coaching

Encourage participants to let the facilitators know at any time if they need someone to help them with the course material. The facilitators are happy to help at any time. We can also ask for a volunteer coach from the group to work with anyone who needs extra assistance.

Parking Lot

Refer to Flipchart: Parking Lot. The comment that during sessions, participants may think of questions or raise issues that are not directly related to the topic of the session is 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 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.

Acronym List

Note that in our technical work we often at times use acronyms.; Explain that we will try not to overuse acronyms, but to help everyone, see the list of them in their manual. Ask facilitators if there are missed abbreviations in each session.

NB: Creation of name tent: Later, provide white sheets of paper to all participants and markers to create a name tent. Show them how to do it.

D. Group Norms and Final Points – Large Group Discussion – 5 minutes

Group Norms

Display Flipchart: Group Norms. Tell the participants that we will be working together for the next week 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 distraction. Ask the participants to propose rules or guidelines that we can follow during the course. For each norm that is proposed, ask the large

group if we have the consensus and then note the norm on the flipchart. Seek clarification (if needed) to reach group consensus. However, do not spend more than 5 minutes generating this list or reaching consensus. These should include:

- Always display your name tents in front|
- Do not sit in the same place every day|
- Start trying to name everyone in the room. (There might be a game later where this becomes important)|
- Listen carefully to everyone's ideas|
- Attend the workshop 100% of the time|
- When the list is complete, post the sheet near the entrance/exit door where it can always be easily seen and referred to as needed during the course.|

Housekeeping and Administration Issues

Mention a few housekeeping and admin issues with participants if they have not already been taken care of:

- Tea breaks|
- Location of restrooms|
- Per diem and transportation|

Note: Tell participants that if they have any administrative questions, concerns with the hotel, or problems, please let the course administrator know so that we can help them solve the problem or guide them in the right direction.

Homework

Note that there will be homework assigned for participants to complete in the evenings. It shouldn't take long but will better prepare them for the sessions the following day. Tonight's homework is to review the whole participant's manual so that they will be familiar with the basic content and terms.

E. Course evaluation by participants

Participants should be able to contribute to the quality of this training. Accordingly, daily evaluations should be filled by each participant and the feedbacks obtained should be used to improve the overall training organization for the next day's sessions. One agendas for each day's

discussion (at the end of the day) should be trainees' feedbacks. Trainees' feedbacks on the days' sessions should be collected on the ***Daily Participant Feedback Form.***

After the completion of the course, trainees should fill the overall course evaluation about each session in terms of the relevance of subject matter, adequacy of the allocated time, and trainer's ability. They also evaluate the overall organization of the training and fulfillment of expected competencies. Overall feedbacks are collected on the ***Overall Course Evaluation Form.***

Chapter 1: Overview of Pharmacoepidemiology

Primary Objective:

- At the end of this session, participants will equip themselves with a basic understanding of the concepts and practice of PE and Epidemiology in relation to medicine safety.|

Enabling Objectives:

- Recognize the role of PE in medicine safety
- Differentiate epidemiologic study designs and measurements used in PE
- Discuss the role of surveillance in the monitoring of health adverse events

Allocated time: 1:20 HRs

Summary of activities

SN	Activity	Method of delivery	Duration/ min	Materials
1	Introduction	Lecture using PPT, brainstorming	15 min	Powerpoint (PPT) Projector Flip chart PPT slide Training manual Trainer's guide Marker
2	Study designs and measurements in epidemiology	Interactive presentation using PPT, Individual reading, Discussion	30 min	
3	Surveillance systems in monitoring adverse health events	Discussions, Individual reading, and reflection, Interactive PPT presentation	30 min	
4	Session summary	Presentation using PPT	5 min	

Preparation before the session

The facilitator should read the training materials (participant manual, trainer's guide and power point (PPT) well and other important references before the session.

Activity 1: Introduction (20 min)

- Begin the session by randomly inviting participants to read session description and objectives of the session.
- Tell them that the session starts with an introduction about pharmacoepidemiology, and the role of PE in PV

- Then, briefly discuss on definition and scope of epidemiology using PPT (slide #2)
- Show the question on slide #3 and ask participants what they understand about the term Pharmacoepidemiology (PE) and Pharamcovigilance (PV) and their relationship.
- Summarize this activity using PPT slide #4-5

Activity 2: Study designs and measurements in epidemiology (30 min)

- Conduct interactive presentation highlighting major categories of study designs using PPT slide # 6-8|
- Ask participants why experimental study design is preferred over observational study design (slide # 8) and note their answer on flip chart and summarize the discussion as:|
    - Provide stronger evidence of the effect (outcome) with maximum confidence and assurance
    - Yield more valid results, as variation is minimized and bias controlled
    - Determine whether experimental treatments are safe and effective under "controlled environments" (as opposed to "natural settings" in observational designs)
- Then**,** briefly discuss on categories of common epidemiologic measurements (slide #9).
- Raise discussion on the difference between incidence and prevalence (slide #10) and note participants' response on flip chart while participants are reflecting and summarize the discussion as:
    - **Prevalence:** Deals with proportion of people who have the disease. It measures the amount of disease that is present already in a population and useful only for diseases of long duration (months or years)
    - **Incidence:** Deals with no of new cases of disease that develop over time. It measures the rapidity with which newly diagnosed patients develop over time
- Conduct brief presentation on measure of association and measures of potential impact using PPT (slide #11-12).

Activity 3: Surveillance systems in monitoring adverse health events (30 min)

- Ask participants what surveillance means and its importance (slide # 13).
- Entertain some responses from the participants and summarize the discussion using PPT (slide # 14)

- Invite two participant to read on each of key sources of data for surveillance and main activities in surveillance/monitoring adverse health event and clarify any unclear points (slide #15)
- Tell participants to discuss in pair and reflect on the difference between active and passive surveillance, their classification, strength & limitation (slide 16 #).
- Entertain reflections from pair discussion and summarize main points using PPT (slide #17-22))

Activity 4: **Chapter Summary (5 min)**

- Ask participants whether there is any point that needs more clarity and entertain a few points. (slide #23)|
- Then summarize the session by going through the points on slide #24.|

Chapter 2: Basic Concepts of Pharmacovigilance

Allocated time: 2: 10 HRs

Primary Objective:

At the end of this chapter, participants will be able to explain the significance of pharmacovigilance in drug safety monitoring

Enabling Objectives:

- Describe drug development process, pre marketing, and post marketing surveillances|
- Discuss importance of pharmacovigilance|
- Recognize components of ADEs|

Session Outline/ Summary of Activities

S. No.	Activity	Method of delivery	Duration	Materials
1	Introduction	Interactive presentation using PPT and video	20 min	Flip chart Training manual, Video
2	Drug development process, pre marketing and post marketing surveillances	Interactive presentation	35 min	
3	Pharmacovigilance	Interactive PPT presentation, discussion, reading	20 min	
4	Components of ADEs	Individual reading and participant reflection Interactive presentation using PPT /small group discussion	50 min	
5	Session Summary	Interactive presentation	5 min	

Preparation before the session

Read the training materials well and the references indicated below as needed before the session.

- Pharmacovigilance participants manual, trainer guide and PPT presentation.|

- The importance of Pharmacovigilance: Safety Monitoring of Medicinal Products, WHO, 2002.|
- Watch and understand the thalidomide video|

Activity 1: Introduction (20 minutes)

- Introduce the session by describing the learning objectives (slide # 2)|
- In the next 5 minutes, ask participants whether they have information about thalidomide tragedy|
- Show the participants the thalidomide tragedy video and ask their reflection (13 minutes)|

Activity 2: Drug development process, pre marketing and post marketing surveillances (35 minutes)

- Display the power point presentation of the drug development process (slide 3)|
- Discuss the steps of drug development starting from the preclinical (animal experimentation) up to Phase IV studies as follows|
- **Pre-clinical experiments**|
  - Purpose is to evaluate the efficacy and safety of the new compound.
  - **Pharmacological studies**- to understand the metabolism and kinetics of the drug its metabolite
  - **Toxicological studies**- to know the acute toxicities, organ toxicities, carcinogenicity, teratogenecity and mutagenecity of the drug and its metabolite
- **Clinical Trials**|
  - If the pre-clinical experiments are found to be adequate, the new compound becomes a candidate for clinical trial.
  - Have three phases
  - **Phase I**
    - New medicine is administrated to man for the first time.
    - It is conducted in about 20-50 healthy volunteers.
    - The aim is to make a preliminary evaluation of pharmacologic properties of the new drug in humans
  - **Phase II**
    - The new medicine is tried out on limited number of selected and willing patients (150-350) suffering from the diseases for which the drug is intended to treat.
    - The purpose of phase II of clinical trial is:-

- ✓ To establish or determine possible therapeutic uses.
- ✓ To refine therapeutic dosage range.
- ✓ Further evaluate the safety and pharmacokinetics

- **Phase III**
  - Known as broad clinical trial or large scale, controlled trial.
  - Trial is carried out on much larger (250-4,000) and more varied patients over a long period.
  - It provides additional data, which are statistically satisfactory to the verification of the efficacy and safety.
  - Generally, requires comparison of the new treatment with already established terms of treatment.

- Conduct an interactive power point presentation about pre and post marketing safety surveillances (slide 4-6)
- While presenting, compare and contrast pre marketing and post marketing safety surveillances and importance of conducting post marketing safety surveillances

Activity 3: Pharmacovigilance (20 minutes)

- Conduct an interactive power point presentation on definition, aims, and scope of pharmacovigilance using slide 7-10.
- Allow the participants to read the terminologies used in pharmacovigilance section in their participant manual in pair and take a reflection from 2 groups (10 minutes)
- Entertain if there is any ambiguity about the terminologies and clarify accordingly.

Activity 4: Components of ADEs- 55 minutes

- Introduce participants about ADEs and their components by displaying slide #11
- Divide participants into five small groups. Then assign one of the following discussion topics for each group. Let them discuss the points in the participant manual for the next 10 minutes:
  - Discussion topic 1 ADR classification by type
  - Discussion topic 2 ADR classification by severity
  - Discussion topic 3 Risk factors for occurence of ADR
  - Discussion topic 4 Medication errors (types, factors associated with MEs)
  - Discussion topic 5 Product quality defect (rating and categories)
- Then let each group present using FLIP CHART to the larger group- let them use 5 minutes each.
- Allow them to ask questions and raise unclear points and summarize the important points using #12-14

Activity 5: Session Summary (5 minutes)

- Summarize the session by displaying slide # 10 and ask and respond to any questions the participants may have.|

Chapter 3: Diagnosis, Management, Prevention, Investigation and Causality Assessment of ADEs

Time Alloted: 3:30 HRs

Primary Objective:

At the end of this chapter, participants will be able to:

- Describe ADEs, conduct diagnosis, management of ADRs, and ADE investigation and causality assessment.

Enabling Objectives:

- Explain diagnosis, management, and prevention of ADRs
- Describe the process of ADE investigation.
- Discuss causality assessment of ADRs

Summary of Activities

SN	Activity	Method of delivery	Duration/ minutes	Materials
	3.1. Diagnosis, Management, and Prevention of ADEs			
1	Diagnosis of ADEs	Interactive PPT presentation	30 min	LCD, Flipchart Participant manual, Trainer guide
2	Management of ADRs	Pair discussion & participant reflection, experience sharing, QA	15 min	
3	ADE prevention strategies	Think-pair-share	10 min	
4	Case studies	Small group discussions	30 min	
5	Session Summary	Interactive presentation	5 minutes	
	3.2. Investigation and Causality Assessment of ADEs			
6	Introduction to ADE investigation and rationale	Interactive presentation using PPT	20 min	
7	Investigation of Adverse Events and SAEs	Individual reading and reflection Interactive presentation using	45 min	

		PPT and participant manual		
8	Investigation of product quality defect (PQD)	Interactive presentation using PPT	20 min	
9	Introduction and rationale of causality assessment	Interactive presentation using PPT and brainstorming	20 min	
10	Methods for conducting Causality	Interactive presentation using PPT	20 min	
11	Chapter Summary	Interactive presentation using PPT	5 min	

Detailed Activities

Preparation before the session

Read the participant manual, trainer guide, PowerPoints and other tools well before the session

Activity 1: Diagnosis of ADEs: 30 minutes

- Ask participants to read the learning objectives (in the participant`s manual) aloud one by one and then let them study the introductory case individually.
- Ask 2 participants to reflect on their answers but do not give them answers.
  - Tell them that they will get all the answers while they go through this session.
- Explain the need of training healthcare professionals about ADR diagnosis by focusing on the following points
  - ✓ Mostly ADR diagnosis is overlooked during clinical practice
  - ✓ To achieve something nearer to ideal practice more attention needs to be given to training health professionals in diagnosis, management and prevention of ADRs
  - ✓ Health professionals are more likely to identify and report important ADRs if they have confidence in their ability to diagnose manage and prevent such reactions
- Make Interactive presentation on ADR diagnosis approaches using slide #2-4
- Ask participants if they have any question and address them accordingly.

Activity 2: **Management of ADRs: 15minutes**

- Ask participants about challenges they have faced (or they know) while managing ADRs.
  - Challenges could include: lack of experience, absence of appropriate dosage form (eg. Loose form of RHZE), higher cost of alternative medicines, etc.

- Then inform the participants to read in pair management of ADRs section for 5 minutes. Then ask if they have any question.
- Summarize important points on management of ADRs by focusing on decisions for the management of ADRs is made based on severity of the ADR, severity of disease and benefit/harm assessment.
- And remind them to report the ADR.
- Remind them the introductory case by letting them to see on their participant manual page 31. Ask them to answer the questions and make sure that their answers are correct by using the following answer key

A. What is going on in this patient?

Answer: Angioedema manifests as local erythematous edema, which frequently involves the tongue, lips, eyelids, and mucous membranes of the mouth, nose, and throat. Drugs can cause this anaphylactoid reaction. For example, ACE inhibitors have been associated with this adverse effect in about 0.1% to 0.2% of individuals treated with this drug. It is not dose related and occurs with all ACE inhibitors. K.J. presents with classic symptoms of angioedema and does not have symptoms of a true anaphylactic reaction, further strengthening the diagnosis of drug-induced angioedema.

B. How do you analyze the situation?

Answer: K.J. presents with classic symptoms of angioedema and does not have symptoms of a true anaphylactic reaction, further strengthening the diagnosis of drug-induced angioedema.
It happened 1 week after K.J. began Enalapril, the temporal relationship is reasonable.

C. How do you manage if the patient is experiencing ADR?

Answer: Because angioedema occurs with all ACE inhibitors, K.J. must avoid all drugs in this class. Similar to the ACE inhibitors, angioedema to ARB can occur at any time during treatment. In K.J.'s case, it would be best to avoid ARB and ACE inhibitors. Instead, other antihypertensive agents that have little effect on cholesterol (e.g., calcium channel blockers) should be used.

D. Was it possible to prevent this? How?

- **Answer:** Yes, the patient should have been counseled about the potential occurrence and early symptoms and communication to the health care provider. The patient should be advised not to take this medication /class in the future.

Activity 3. ADE prevention strategies: 10 minutes

- Tell participants to be in pairs and read through and discuss the ADE prerevention Strategies section in the participant manual for 5 minutes
- Ask three pairs to reflect on the major prevention strategies.
- Follow their answers using the participant manual and make corrections as necessary and summarize with the helpful tips on slide no. 5.

Activity 4: Case studies: 30minutes

- Divide participants into 4 groups and let each group discuss on one case for 10 minutes.
- Let a representative from 2 groups present their answers and allow the other 2 groups to complement the missed points.
- Address questions if there are any from participants and conclude this activity by telling the answer for the case stuidies. .

Answer keys to the case 1

A. How would you analyze this situation? What investigations would you carry out?

Answer : Collect relevant findings (symptoms and laboratory values like ALT…)

Identify the potential offending agents …sulfadiazine, Efavirenz…

Temporal relationship was better for Efavirenz

Re-challenge without recurrence excluded the potential role of Tenofovir and Lamivudine

B. If you think it is an ADR, which medicine or medicines might be responsible? How did you arrive at this conclusion?

Answer : The sudden onset of rash followed by fever and a cholestatic hepatitis within 2 to 3 weeks of starting Efavirenz suggests an immunoallergic form of drug induced liver disease. A similar type of liver injury can occur with sulfadiazine, but the timing was better for Efavirenz. A possible role for Tenofovir and Lamivudine (300 mg) appeared unlikely because of the lack of recurrence with re-challenge.

C. If you think it is an ADR, how do you manage it?

Answer: We need to assess the severity of the reaction and the disease and weigh the risk benefit analysis. Based on these parameters the severity of the reaction is life threatening and all drug were discontinued and after stabilization the patient was re-challenged with all medications except the offending agent which was replaced with Atazanavir.

Answer keys to the case 2

A. How do you analyze the situation?

Answer: A.K. was seen again in the ED a day later after starting chloroquine with complaints of abdominal pain, severe headache, vomiting, and a "bitter taste" in the mouth. The major side effects of chloroquine (e.g., nausea, abdominal pain, pruritus, vertigo, headache, and visual disturbances) usually are associated with large doses such as those needed for A.K.'s therapy. The gastrointestinal (GI) complaints and severe headache experienced by A.K. are consistent with chloroquine therapy, and the bitter taste he described is experienced by all patients who are given chloroquine.

B. How do you manage if the patient is experiencing ADR?

Ans. The severe nausea and vomiting may have dehydrated A.K., and he should be encouraged to replenish his fluids. Because A.K. also will be taking primaquine after the course of chloroquine, he should be told that he probably will experience some GI upset with this drug as well. Abdominal cramps associated with primaquine may be relieved by antacids or by taking the drug after meals.

C. Was it possible to prevent this? How?

Answer. Yes, the patient could have been advised to take the medication after a meal or with an antiacid if he had a previous history of PUD.

Activity 5: Session Summary: 5 min

- Entertain if there are points that need clarity from participants and then summarize the session in relation to the learning objectives by displaying slide #6|

Activity 6: Introduction to ADE investigation, rationale and causality asssesmnet (20 min)

- Introduce the session briefly by going through the session description, and objectives. Tell the participants what to expect from this session using the session outline (5min).|
- Read the following introductory discussion points and receive a response from 2 participants regarding whether they encountered SAE or PQD that was investigated and their involvement and experience|
- Present slides #2-3 to introduce participants to ADE investigation (5min)|
- Present and discuss the rationale of SAE investigation using PPT (slides #4-5)|

Activity 7: Investigation of ADEs and SAEs (45 min)

- Give the participants 5 min to read about determining case eligibility for investigation and determination of the responsible person/ institution to investigate an ADE (participant manual page number 49-50)|
- Show slide #6 and ask volunteer participants to reflect on whether all reported ADEs are eligible for investigation and carry out the discussion about who should investigate an SAE (5 min).|
- Present slides #7-11 and discuss all the detailed points by using PowerPoint and from the partcipant manual page no|50-51
- Discuss in detail on the following points:|
    - Confirming the information provided in the report and add missing information (if any).
    - Checking if more than one case should be included in the same investigation and gather and verify basic information on each case.
    - Direct observation of treatment site (institution).
    - Gathering information on the suspected medicine and obtain a sample
    - Using the available standard form (investigation form)

Activity 8: Investigation of product quality defect (20 min)

- Ask volunteer participants to define PQD and the three classes of PQD|
- Present and discuss all the detailed points about PQD investigation by usingpowerpoint (slides #12-14) and from the manual page no 51-53|
- Emphasize mainly on the investigation process of PQD|
- Present on slide #15 and discuss the need for recording /documenting using investigation form|

Activity 9: Introduction and rationale of causality assessment (20 min)

- Start the session by requesting a participant to read session description, primary objective, enabling objective and session outline (5min).|
- Ask the introductory discussion question from the manual and give a chance for volunteer participants to reflect their experience whether they encountred an SAE where| causality assessessment was done at national level and the provison of the categorization to stakeholders (5 min)

- Present slides #.(2-3) to introduce participants about causality assessment (5min)|
- Ask volunteer participant to answer question number one on slide # 4 and fill the gap afterwards by using power point slinen # 5 (5min)|
- Ask volunteer participant to answer question number 2 on slide #6|
- Complement participants' answer by using power point slide # 6|

Avtivity 10: Methods for conducting Causality (20min)

- Give a brief introduction about the two types of algorithms using power point side # 7|
- Provide to each of the participants a printed copy of the WHO-UMC causality categories.|
- Use slides # 8 and discuss each category in detail and give them a chance to ask questions and reflect on that as appropriate.|
- Discuse about the process after completing the causality assessment by using power point slide #9|

Activity: Session summary (5min)

- Entertain unclear points from participants taking into consideration points not addressed during discussion (3 minutes)|
- Give a brief summary to participants (slide no.10) (2min)|

Chapter 4: Adverse Drug Events Monitoring and Reporting in Ethiopia

Primary objective:

At the end of this chapter, participants will be able to:

- Describe the national ADE monitoring and reporting system.

Enabling objectives: At the end of this chapter, participants will be able to:

- Identify the importance of ADE monitoring
- Describe the national ADE monitoring and reporting system
- Complete the ADE reporting tools
- Identify the roles and responsibilities of stakeholders in national PV system

Allocated Time: 3:10 HRs

Summary of Activities

SN	Activity	Method of delivery	Duration	Materials
1	Introduction	Presentation	20 min	- Flip chart - training manual, - EFDA Proclamation, ADE reporting tools (yellow form, Medsafety app, e-reporting), - Internet connection - Pratcipant manual and trainer guide
2	National ADE monitoring and reporting system	Interactive presentation, think-pair-share, demonstration, case study	45 min	
3	Demonstration of reporting tools	Demonstration, case study, interactive presentation	90 min	
4	Roles and responsibilities of stakeholders in national PV system	Group discussion and reflection.	20 min	
5	Session summary	Reflection and discussion	15min	

Preparation before the session

Read the participant manual, trainer guide and the PowerPoint well and internalize ADE reporting tools well before the session.

Detailed activities

Activity 1: Introduction (20 min)

- Introduce the session by giving brief information about the chapter using the description, objectives and chapter outline. (3 min)|
- Pose the following questions as icebreaker and discuss on partcipants experience of an ADE that occurred on a patient and what they did, their role in national PV system and the type of their role|
- Explain about the mandates of EFDA, its legal support and some background information about PV system in Ethiopia using PowerPoint slides # 2-5. (10 min)|

Activity 2: National ADE monitoring and reporting system (45 min)

- Demonstrate by presenting the schematic diagram which describes ADE reporting, and feedback flow as in the PowerPoint slide #6 and present using PPT (10 min)|
- Make pairs according to the participants' sitting arrangement. Tell them to read and discuss in pair from their participant manual on the section that discusses on what to report, who should report and when should be reported (10 min)|
- Give a chance for different pairs to answer questions #1 and 2 on PowerPoint slide # 7 and give clarification if there is any misunderstanding or unclear point. (5 min)|
- Ask volunteer participants to share their experience about how to report an ADE and encourage them to share their experiences in reporting. (5 min)|
- Present on how to report an ADE and describe the available tools using PowerPoint slide # 8. Tell them that detail demonstration will be made on the tools later in the presentation. (5 min)|
- Conduct an interactive presentation on what happens after reporting of an ADE using the PowerPoint slide #9, describe the various processes at EFDA pharmacovigilance center. Show a sample of regulatory measure letters on products on slide no. 10. (10 min).|

Activity 3: Demonstration of reporting tools (90 min)

- **Yellow form (30 min)**

- **Demonstrate the yellow page reporting form** by describing:|

- Where to get the form
- Components that need to be filled in the form by describing the importance of each item
- How to fold the form after filling the necessary data and
- Where to send the form

- Provide the yellow ADE reporting form and tell the participants to practice filling the form using the provided cases at the partcipants manual.|

Case study 1: Product quality defect

Case study 2: Adverse drug reaction

➢ Medsafety mobile app (30 min)

- **Demonstrate the mobile based reporting tool|**
  - Use the instruction provided in the manual on how to use the mobile based reporting tool
  - Guide them through the process to download, install and create account
  - Enable them to understand the steps and report an ADE throught the tool by using the case studies provided above.

➢ E-reporting (30 min)

- **Demonstrate the e-reporting tool|**
  - Use the instruction provided in the manual on how to use the e-reproting tool in a computer or smartphone
  - Guide them to enter www.fmhaca.gov.et services, e-reporting , create an account
  - Enable them to understand the process of reporting and practice how to report an ADE through the tool by using the case studies provided above.
- **After all demonstration is completed:|**
  - Give a chance for partipants to comment about the cases if there are missed pieces of information which are important for reporting.
  - Take a sample from each reporting tool and give a chance for the participant to comment what the reports lacks, if any.
  - Address any practical issues the participants may raise regarding reporting tools.

Activity 4: Roles and responsibilities of stakeholders in national PV system (30 min)

- Interactively present the role and responsibility of health professionals and health facilities on slides # 12-13. (5 min)

- Group the participants into five groups and give them 2 stakeholders (except health professionals and health facilities) to closely read their roles and responsibilities in national PV system.
    - Remind participants to use the participant manual for their group discussion. (10 min)
- Let each group reflect the major roles and respnsibilites of the stakeholders in 2 minutes (10 min)
- Give a chance for individuals who had a question and respond accordingly. (5 min)

Activity 6: Session summary (15 min)

- Ask participants if the the objectives of the session are met.
- Ask the participants if there is anything left unclear and clarify accordingly.
- Then summarize the session on PowerPoint slide #14.

Chapter 5: Pharmacovigilance in Public Health Programs

Chapter Objective:

At the end of this chapter, participants will be able to:

- Explain the importance, rationale, and peculiar activities of pharmacovigilance in national public health programs.

Enabling Objective: at the end of this chapter, participants will be able to:

- ✓ Explain the importance of PV in selected public health programs
- ✓ Explain the rationale of PV in selected public health programs
- ✓ To know the peculiar activities of PV in selected public health programs.

Time Allotted: 6 HRs

Session Outline/ Summary of Activities

S/N	Activity	Method of delivery	Duration/ min	Materials
	5.1. Pharmacovigilance in Expanded Program of Immunization (AEFIs)			
1	Introduction, Vaccine Classification and their common AEFIs	Interactive presentation with PPT and think-pair-share	20 min	LCD Projector Flip chart Training manual Trainer's guide Marker LCD Projector Flip chart
2	Adverse Events Following Immunization (AEFI)	Interactive presentation with PPT,	45 min	
3	AEFI investigation	Interactive presentation with PPT, individual reading, and demonstration	30 min	
4	AEFI causality assessment	Interactive presentation with PPT	15 min	
	5.2. Pharmacovigilance in TB program			
6	Introduction and Rationale	Interactive presentation with	15 min	

	for PV of TB medicines	PPT, brainstorming,		Training manual Trainer's guide Marker
7	Active TB drug-safety monitoring and management (aDSM)	Interactive presentation with PPT,	35 min	
8	Demonstration AE line listing	Case study, demonstration	45 min	
5.3. Pharmacovigilance of medicines used in HIV, malaria, mass drug administration, non-communicable diseases and RMNCH				
9	Group discussion on PV of HIV, malaria, mass drug administration, non-communicable diseases and RMNCH medicines	Group discussion and presentation, Interactive presentation with PPT,	105 min	
10	Session summary	Large group discussion with Q&A	15 min	

Detail activities

Activity 1: Introduction, Vaccine Classification, and their common AEFIs (20 min)

- Introduce the session by describing the chapter and the session by going through the description, objectives, and outline from the participant manual
- Define and explain vaccines from PowerPoint slide # 2(3 min).
- Present and explain each component of the vaccine from PowerPoint slide #3 (4 min).
- Tell the participants to be in pairs and read about the classification of vaccines and their common AEFIs from the participant manual, page no. 77 (5 minutes)
- Ask 3 participants to answer questions displayed on PowerPoint slide # 5 (3min).
- Entertain the question and summarize the classification of vaccines and their common AEFIs. (2 min)

Activity 2: Adverse Events Following Immunization (AEFI) (45 minutes)

- Interactively present and explain the definition of AEFIs, serious AEFIs, and cluster AEFIs using slides #6-8 (5 min)
- Present and explain the classification of AEFIs and their specific definition using slides # 9-10.
- Open the floor for discussion and reflection and entertain if there are unclear points from participants. (5 min)
- Show slide #11 and ask participants to answer why monitoring the safety of vaccines is necessary? (3 min)
- After receiving 3 answers, tell the following as to why safety monitoring of vaccines is necessary: (2 min)
    - Vaccines are almost always biological products – Subject to widespread variation even between batches
    - All vaccines require special conditions of storage – usually cold storage
    - Vaccines are large molecules usually administered parenterally – Some vaccines may be given orally
    - Vaccines are normally given in "schedules" which must be adhered to – For whole populations and/or age groups
    - Vaccines given mostly to PREVENT disease
    - Vaccines are supposed to protect whole populations ("herd immunity")
- Ask participants about the difference and similarities between vaccine and other medicine and receive not more than 3 answers. (5 min)
- Show slides #12-1 and quickly go through the slides highlighting the major differences between vaccines and other medicines. (5 min)
- Tell participants that, now, you move to another important subject: **AEFI surveillance.**
- Remind participants that main objective of AEFI surveillance is to detect early and appropriately respond to adverse events following immunization. It reduces negatives health impacts of vaccines and enhances program credibility.
- Show them slide #15 and present and explain the AEFI surveillance cycle. (5 min)

- Continue the presentation and show them slide #16 and present and explain the immediately reportable AEFIs. Try to provide specific examples. (5 min)
- Tell participants to turn to the participant manual and demonstrate the AEFI reporting form and AEFI line list. (15 min)
- Display the case-based AEFI reporting routes, timeline, and action on slide 20. Explain and discuss the activities conducted at each level during reporting. (5 min)

Activity 3: AEFI investigation (30 minutes)

- Tell participants that
    - "*The reporting of an AEFI will usually be followed by a case investigation or, when there is a cluster of AEFIs, by a series of case investigations.*"
- Project slide #19 and tell participants the goal and purpose of the investigation. (5 min)
- Remind participants that: (2 min)
    - "*The health worker will complete the AEFI Reporting Form and report. The WEO along with the woreda rapid response team (RRT) will carry out the investigation*."
    - EFDA, national AEFI Committee, National EPI, regional AEFI task forces and zonal regulatory bodies are expected to support the investigation of the case according to their capacity at their level if desired by WEO
- Present slide #20 and explain case eligibility for AEFI investigation. (3 min)
- Tell participants to turn to page 83 and 84 and individually read subsections: *When to investigate? How to investigate AEFI?(5 min)*
- Entertain any questions the participants might have on these subject. (5 min)
- Present slide # 21 and explain each step step in AEFI investigation (5 min)
- Inform participants to see the annexed AEFI investigation form and demonstrate all session of the AEFI investigation form (5 min)
- Entertain if there are unclear points from participants and open the floor for discussion & reflection. (5 min)

Activity 4: AEFI causality assessment (15 minutes)

- Present and explain the definition of causality and causality assessment using slide #23 (5 min)

- Present slides #23- 30 and interactively explain the need for causality assessment and case selection for causality assessment, prerequisite for assessing causality of AEFI, causality assessment step, final classification of an AEFI after causality, and AEFI causality assessment committee (10 min)
- Entertain if there are unclear points from participants and open the floor for discussion & reflection.

Activity 5: Summary on AEFI investigation and causality assesmnet (5 min)

- Summarize the session using power point (slide #31).
- Ask participants to ask questions or reflect any points of concern from the session and respond accordingly.

Activity 6: Introduction and Rationale for PV of TB medicines (15 min)

- Start the session by going through the session description and objectives. Ask participants if they have any more things in mind that they need to discuss regarding PV of anti-TB medicines
- Interactively present PPT slide # 2 and ask participants if they have any questions on the issues raised and answer accordingly. If particpants raise points in to be discussed in next activities, tell them so politely and move to the next.
- Ask 2 -3 participants what they think is the reasons for PV of TB medicines note their answers on flip chart.
- Let them read the rationale of PV for anti TB medcines from the participant manual. After few minutes, ask participants to look at the list they generated (on the flip chart) and compare it to what they just read. Entertain if any questions.
- Ask them to silently and individually read table 1 about common Adverse Events of Interest in TB treatment for 5 minutes from partcipant manual
- Address questions they may raise based on the information contained in the table.

Activity 7: Active TB drug-safety monitoring and management (aDSM): (80 min)

- Conduct an interactive presentation using power point on the concept of aDSM, goal of aDSM, components of aDSM, types /packages of aDSM slides #2-11 (10 min)

- Ask participants to pair and read the seection on how to detect ADEs in aDSM. Let 2 volunteers reflect on what they read and summarize with the points on slide ≠ 12-16 (15 min)
- Make an interactive presentation using power point on recording and reporting in aDSM (slide ≠ 17-18).
- Summarize Recording and Reporting using figure 5.1 on slide≠ 19 (10 min)

Activity 8: Demonstration AE line listing (45 min)

- Tell participants to open their AE line listing form on their participant manual **and explain the sections on the form showing the form on power point slide**≠ 20 **(10 min)**
  - **Case Study on filling of AE line listing (35min)**
    - Ask participants to read cases on their participant manual for **5 minutes.**
    - **Tell** participants to open their AE line listing form on their participant manual**.**
    - Complete the AE line listing form using the information on the case
    - Check participants if they have questions on the case while they are completing the form; entertain accordingly.
    - **After** checking 2-3 participants filled the ADE reporting form display the answer sheet for AE line listing.
    - Answer sheet for ADE case and demonstration
      - Please refer the answer sheet on the the same to display to participants with power Point slide ≠ 23**:** AE Linelisting form for new TB medicines &drugs in STR Answer.xlsx
    - **Activity 9: Summary on PV on anti TB medcines: (**5 minutes)
      - Summarize the session with the points on slide ≠ 24-25
      - Ask participants if there is any thing nt clear from the discussions and address accordingly.
    - **Activity 10: Group discussion on PV of HIV, malaria, mass drug administration, non-communicable diseases and RMNCH medicines (105 min)**
      - Start the session by going through the objectives of the session in 2 minutes.

- Empahsize that like the previous two program medicines, they will now discuss the PV of medicines for HIV, malaria, mass drug administration, non-communicable diseases, and RMNCH.
- Divide the participants into five groups. Make sure that the participants have equal number of members and with an appropriate mix of professionals (prescribers, dispensers, etc.)
- Let them select chairperson and secretary and give them one of the following topics:
  - ✓ Pharmacovigilance of Antiretroviral Drugs
  - ✓ Pharmacovigilance (PV) for Anti-malarial medicines
  - ✓ Pharmacovigilance in Mass Drug Administration (MDA)
  - ✓ Pharmacovigilance in non-communicable disease (NCD) medicines
  - ✓ Pharmacovigilance in RMNCH medicines

Tell the part that they are expected to read from the participant manual and discuss the major points discussed therein.

Their discussions should focus on:

- The rationale of PV for these medicines
- The major ADEs
- Monitoring and management of ADEs
- Documentation and reporting of ADEs
- Any particular point of discussion in each group of medicines

Tell them that they are expected to discuss for 20 minutes and summarize the major points on a flipchart within 10 minutes.

Please follow each team while writing on the flipchart. Make sure that the writings are in block letters, and should be legible and large enough to be seen from the back of the room.

Let each group representative present based on the flipchart posted on the stand for 7 minutes. After each team presents, the facilitator summarizes the major points for the next 7 minutes based on the PowerPoint.

And ask participants if there is any point that is not clear and address it accordingly.

Activity 10: Summary of PV of HIV, malaria, MDA, NCDs, and RMNCH medicines (15 minutes)

- After all groups have presented their assigned discussion points, open question and answer session so participants could raise questions regarding the PV of these medcines. As much as possible, let them focus on real experiences from the workplace . Address the points raised after allowing other participants to give theirr thoughts.

Annex

Annex 1: Pre/post Training Test

National Pharmacovigilance Training for Health Care Professionals

Pre/Post test

Name: _____ Date _____

Code: _____

Instruction: *choose and circle the best answer*

1. Which one of the following is true about drug surveillance?
    A. Spontaneous reporting is proactive by its nature.
    B. Spontaneous reporting is an example of passive surveillance.
    C. In passive surveillance, active measures are taken to detect adverse events.
    D. In active surveillance, reporting is entirely dependent on the initiative and motivation of the reporters.
2. One of the following explains why health events are monitored.
    A. To detect sudden changes in disease occurrence and distribution
    B. To follow secular (long-term) trends and patterns of disease
    C. To detect changes in health care practices
    D. All
    E. None
3. All the following points should be considered in the diagnosis and management of ADR except
    A. the possibility of the drug interaction
    B. the background frequency of the event
    C. whether the event is pharmacologically plausible
    D. If the patient experience ADR, discontinue the drug immediately
4. Which of the following statements is wrong about ADR diagnosis and management?
    A. Defining and classifying an ADR Correctly can help determine management

B. ADRs may not be treated the same as other ADEs
C. If a patient is taking medicines, the differential diagnosis should include the possibility of ADR.
D. All ADR types are preventable.

5. One of the following is not helpful to reduce the occurrence of ADR.
   A. Always avoid poly-pharmacy
   B. Identify high-risk patient populations and monitor
   C. Give prophylaxis if any
   D. Empower patients and health care providers
   E. Drugs should always be of the best possible quality
6. Which one of the following is False about Adverse drug events(ADE)?
   A. ADR is similar to ADE
   B. Product quality defect may cause ADR
   C. Medication error may cause ADR
   D. Preventing ADR may minimize treatment cost
7. The EFDA definition of ADE includes.
   A. Adverse drug reactions
   B. Product quality defect
   C. Medication Error
   D. All
8. All the following are the rationale for pharmacovigilance in NCDs except
   A. Improve patient care and safety in relation to the use of medicines
   B. NCD patients take poly-pharmacy
   C. Pharmacovigilance system is cost effective, compared with the cost of ADR management
   D. The safety of drugs used for NCDs is not established.
9. Identify the wrong statement.
   A. The high toxicity and narrow therapeutic index of chemotherapeutic agents makes oncology pharmacovigilance essential.
   B. The frequency of ADRs occurrence can be reduced by decreasing the number of drugs prescribed

C. ADRs are not common in patients on chemotherapy

D. Early detection of ADRs may help in minimizing the harm

10. Which of the following is False about monitoring ADRs?

A. Monitoring patients in first days of using cardiovascular drugs could help in preventing ADRs.

B. Depending on reactions to prescribed drugs, health care providers should be promptly informed for advice

C. Monitoring adverse drug reactions in patients using chronic medications is a matter of importance

D. None

11. All are included under ADEs following mass drug administration except

A. Adverse reaction to the medicine

B. Operational error

C. ADE due to destruction of the parasite

D. A and B

E. None

12. Identify the wrong statement about management of ADE following Mass drug administration (MDA)

A. Proper and early treatment should be provided to patients regardless of the diagnosis.

B. Mild adverse events are common and expected.

C. Serious adverse events are common and should be reported soon.

D. It is important to establish a referral system prior to MDA.

E. None

13. Why we need pharmacovigilance program for antimalarial drugs?

A. There is high consumption of antimalarial drugs

B. Presumptive treatment of fever with antimalarials is common

C. Informal use of antimalarial drugs may increase the risk of ADR

D. All

14. Which of the following drug- side effect combination is wrong?

A. Chloroquine -Nausea and vomiting

B. Quinine- visual and auditory abnormalities
C. Primaquine – hemolytic anemia
D. Artemisinin – hepatitis

15. Which one of the following is the guiding principles for the management of ARV drug toxicity?
    A. Determine the seriousness of the toxicity.
    B. Consider other disease processes
    C. Manage the adverse reaction according to its severity.
    D. All
16. ARVs drug toxicities like abnormal distribution of body fat (lipodystrophy) and lactic acidosis classified as
    A. Early SEs that are uncomfortable to the patient but not dangerous (common or rare)
    B. Early and potentially serious side effects
    C. Side effects occurring later during treatment.
    D. All
17. An AEFI is any untoward medical occurrence which follows immunization and is necessarily have a causal relationship with the usage of the vaccine
    A. True
    B. False
    C. Unknown
18. Which of the following AEFIs cases is/are eligible for immediately reportable and should be investigated?
    A. Serious AEFIs
    B. Cluster AEFIs
    C. AEFIs with unexpected frequency
    D. AEFIs with unexpected relationship with the vaccination
    E. all
19. Which of the following activities should be performed by a health facility to be considered implementing aDSM?

A. Active and systematic clinical and laboratory assessment during treatment to detect drug toxicity and ADEs.
B. Management of all AEs detected in patients with treatment with new and repurposed drugs and novel regimens.
C. Systematic collection of standardized data on any ADE detected and reporting to the concerned authority.
D. All the above
E. A & C

20. Which one of the following statements is false?
    A. Any suspected adverse drug event should be reported as soon as possible.
    B. Delay in reporting is useful to gather accurate and reliable data about the event.
    C. Serious ADRs must be reported within 24 hours after identification by health professionals.
    D. Reporting while the patient is still in the health institution will give a chance to the reporter to clear any ambiguity.
21. Which one is excluded from the case eligibility for ADE Investigation?
    A. Event reported is suspected due to medication errors leading to serious adverse events
    B. All reported product quality defects
    C. All serious adverse events
    D. Cluster of cases(events)
    E. None
22. Which of the following regulatory measures is taken by EFDA after the ADE investigation findings?
    A. Communication to MAHs for specific corrective action(s) arising from the investigation.
    B. Product Recall
    C. Issue a safety alert giving advice to users and Health professionals.
    D. Communication to respective bodies about the product including action need to be taken.
    E. All

23. “Dizziness 45 minutes after ingestion of an oral antihypertensive drug with no concomitant drugs, AE stops on stopping drug & restarts when taken again” based on the WHO-UMC causality assessment method the causality categories of the event has an association of:

A. Possible
B. Probable
C. Certain
D. Unlikely
E. Unclassiable

24. Which of the following is not the limitation of pre-marketing studies?

A. They have limited sample size
B. They are too narrow
C. They have short duration
D. They include all population groups
E. None

25. Identify the wrong statement

A. Almost all medicines have undesired side effects
B. The thalidomide disaster led to the establishment of the drug regulatory mechanisms of today
C. Phase III clinical trial is known as post-marketing surveillance
D. An effective pharmacovigilance system ensures the monitoring of medicines, their availability, and safe use.
E. None

Annex 2: **Answer key for Pre and Post training test**

1. B
2. D
3. D
4. D
5. A
6. A
7. D
8. D
9. C
10. D
11. E
12. C
13. D
14. D
15. D
16. C
17. B
18. E
19. D
20. B
21. E
22. E
23. D
24. D
25. C