Workshop on establishing/strengthening a national immunization safety surveillance programme

Participant’s workbook

Vaccines and Biologicals

World Health Organization
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## Abbreviations

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<th>Abbreviation</th>
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<tr>
<td>ADR</td>
<td>adverse drug reaction</td>
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<tr>
<td>AEFI</td>
<td>adverse events following immunization</td>
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<tr>
<td>BCG</td>
<td>Bacille Calmette-Guérin (vaccine)</td>
</tr>
<tr>
<td>CASP</td>
<td>Critical Appraisal Skills Programme</td>
</tr>
<tr>
<td>DT</td>
<td>diphtheria and tetanus</td>
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<tr>
<td>DTP</td>
<td>diphtheria–tetanus–pertussis (whole-cell) vaccine</td>
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<tr>
<td>EPI</td>
<td>Expanded Programme on Immunization</td>
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<td>GTN</td>
<td>Global Training Network</td>
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<tr>
<td>HepB</td>
<td>hepatitis B vaccine</td>
</tr>
<tr>
<td>Hib</td>
<td><em>Haemophilus influenzae</em> type b vaccine</td>
</tr>
<tr>
<td>IPV</td>
<td>inactivated polio vaccine</td>
</tr>
<tr>
<td>MMR</td>
<td>measles–mumps–rubella</td>
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<tr>
<td>MOH</td>
<td>Ministry of Health</td>
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<td>NIP</td>
<td>national immunization programme</td>
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<td>NRA</td>
<td>national regulatory authority</td>
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<tr>
<td>OPV</td>
<td>oral polio vaccine</td>
</tr>
<tr>
<td>PRP</td>
<td>polysaccharide capsule</td>
</tr>
<tr>
<td>RR</td>
<td>relative risk</td>
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<tr>
<td>Td</td>
<td>adult tetanus–diphtheria vaccine</td>
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<tr>
<td>VAPP</td>
<td>vaccine-associated paralytic poliomyelitis</td>
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<td>WHO</td>
<td>World Health Organization</td>
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A. Introduction and purpose of the workshop

The occasional severe adverse event or cluster of adverse events associated with the use of vaccines in national immunization programmes (NIPs) may rapidly become a serious threat to public health. As vaccine-preventable diseases become less frequent as a result of effective immunization programmes, more attention will focus on adverse events following immunization (AEFIs). It is essential that national monitoring and reporting systems for vaccine safety are efficient and adequately coordinated to deal with such events and public concerns. This includes rapid evaluation of the risk to public safety when vaccine-related adverse events occur as well as appropriate and timely action to minimize such risks. This is particularly important during mass immunization campaigns.

In addition to unforeseen crises, a fairly constant cluster of adverse events can be expected to occur in all immunization programmes. If this is not handled well, hard-won public health gains can be lost or compromised. Appropriate handling of AEFIs involves the rapid and appropriate detection, assessment, management and prevention of such events, including a sound communications plan.

The workshop aims to introduce participants to a proactive approach to detection and investigation of adverse events and an appropriate response to them. This response includes communication with the public, particularly via the media. The workshop provides programme managers and regulators with the necessary information and skills to formulate anticipatory strategies, while at the same time developing communications skills that will allow them to interact successfully with the public and parents.

This is a workbook for training those individuals responsible for vaccine safety in their country. It aims to provide them with the understanding, skills and information necessary to develop (or strengthen) systems to ensure the safety of all vaccines given by the national immunization programme.
The specific objectives of the training programme are as follows:

1. To provide the participant with an appreciation for the importance of a national immunization safety programme.

2. To provide the participant with the knowledge and skills to:
   a) evaluate, develop and strengthen the detection and reporting system for AEFIs within a country;
   b) investigate an AEFI or clusters of AEFIs;
   c) analyse and assess data on AEFIs;
   d) decide on and carry out corrective and other action in response to an AEFI or cluster of AEFIs;
   e) evaluate the actions taken in response to an AEFI or cluster of AEFI;
   f) understand the need for communication skills and the creation of a media plan.

3. To provide an understanding of the importance and the respective roles of the National Regulatory Authority (NRA), the NIP and other players in ensuring the safety of vaccines used in immunization programmes.

4. To promote collaboration and communication between:
   - the NRA
   - the NIP
   - the Ministry of Health (MoH)
   - the health professions
   - the media
   - patients and parents, and
   - the public.

Finally there is an overarching objective, which is for participants to develop a draft plan for developing or strengthening a national immunization safety programme for implementation on return to their country. It is also the objective of WHO to create a worldwide immunization safety surveillance network which supports and relies on the trainees and their institutions.

The objectives of the training will be accomplished through slide presentations, discussions, workshops, assignments, role-playing activities and individual presentations. It is hoped that the training will serve as a catalyst for participants to create awareness and develop capacity in immunization safety in their countries, the goal being to protect the public from real or perceived risks associated with immunization and to improve the quality of national immunization programmes.
C. Workshop description

The training workshop lasts approximately five and a half days and consists of 17 modules. Each module deals with a specific topic (e.g. case investigation, causality assessment, risk-benefit assessment and decision-making etc.) and has a specific set of objectives which are accomplished through various activities. In general a hands-on problem-based approach is used for most of the training. The activities consist of slide presentations, workshops, presentations, role-playing activities and group discussions.

The penultimate module involves an assignment which has to be worked on by the participants during the course of the entire training period. This assignment consists in the development of an action plan for when participants return to their countries. These action plans will be presented on the last day and will serve as a tool to assess whether the short-term objectives of the workshop have been accomplished. The long-term objectives will be assessed during follow-up visits to the participating countries to establish whether the action plans have in fact been implemented and to determine the relative efficacy of the systems in place.
C. Workshop description

The training workshop lasts approximately five and a half days and consists of 18 modules. Each module deals with a specific topic (e.g. case investigation, causality assessment, risk-benefit assessment and decision-making etc.) and has a specific set of objectives which are accomplished through various activities. In general a hands-on problem-based approach is used for most of the training. The activities consist of slide presentations, workshops, presentations, role-playing activities and group discussions.

The penultimate module involves an assignment which has to be worked on by the participants during the course of the entire training period. This assignment consists in the development of an action plan for when participants return to their countries. These action plans will be presented on the last day and will serve as a tool to assess whether the short-term objectives of the workshop have been accomplished. The long-term objectives will be assessed during follow-up visits to the participating countries to establish whether the action plans have in fact been implemented and to determine the relative efficacy of the systems in place.
Module 1:
Welcome and introduction

Purpose
The purpose of this module is to provide you with a basic overview of the training course and to allow you to acquaint yourself with other participants.

Objectives
By the end of this module you should:

- have had an overview of the goals, objectives and structure of the training programme;
- have become familiar with the other participants and the facilitators.

Activities

- Official opening and welcome
- Exercise 1: Ice-breaker

Exercise 1.1
The exercise is carried out in pairs. Choose a partner you are not familiar with or have not met before. You should spend 5–7 minutes talking about yourself to your partner. This should include a few personal insights such as hobbies, favourite food, music etc. The purpose of the exercise is to get to know other members of the group better, and to practice speaking concisely and listening actively. At the end of the five minutes you will introduce your partner to the entire group, describing him/her in two minutes.

Overview of the training programme by the lead facilitator
Module 2:
Introduction to immunization safety surveillance

Purpose

The purpose of this module is to provide you with a basic overview of the importance of a national immunization safety surveillance system and the basic elements of such a system. It will provide an overview of the key actors in immunization safety at a national and international level and will describe and discuss the activities of these actors.

Objectives

By the end of this session you should be able to:

- state the importance of immunization safety surveillance at a national and international level;
- state the goals and strategy of the Immunization Safety Priority Project (ISPP), the Global Training Network (GTN) and the Vaccine Safety Advisory Committee of the WHO;
- explain the importance of an AEFI surveillance programme and the basic elements of such a programme;
- explain the importance of an effective national regulatory system in ensuring the safety of vaccines;
- identify special issues relating to AEFIs occurring during immunization campaigns.

Activities

*Slide presentation – 1-introvax.ppt*
Module 3:
Similarities and differences between vaccines and other medicines

Purpose
During this module, you will reflect on the basic ways in which vaccines differ from, and are similar to, other medicines. This discussion is intended to highlight why a special monitoring system for immunization safety needs to be established within a country and the special issues that need to be considered when a vaccine-specific surveillance programme is developed.

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

- identify the similarities and differences between vaccines and other pharmaceutical products particularly relating to
  - a) procurement
  - b) storage
  - c) handling
  - d) efficacy and
  - e) safety

Activities

Discussion (see Exercise 3.1) facilitated by slide presentation: 2-differ.ppt

Exercise 3.1 General discussion on the differences and similarities between vaccines and other medicines

While both the NIP and the NRA ultimately work towards improving public health, the nature, perspective and function of these two bodies differ considerably. Many of the functions performed by the NRA and EPI programmes are mutually beneficial. Therefore it is important that these two public health bodies collaborate with each other, particularly with regards to immunization safety surveillance. It is particularly important that both immunization staff and regulators recognize that vaccines used in immunization programmes may require specialized systems for ensuring their safety, efficacy and quality.
During this session, the facilitator will guide you through a discussion on how you think vaccines differ from other medicines in relation to the following categories:

- the process of procurement, storage and handling of non-vaccine medicines compared to vaccines
- issues relating to promotion of these products for public use
- matters relating to monitoring, evaluating, and ensuring the safety and efficacy profile of the product

Consider in your discussion how and to what extent these various similarities and differences will affect an immunization safety monitoring programme and how such a programme could address these challenges. In addition, consider how these differences and similarities could affect the public’s perception of the safety of vaccines and the role of the immunization programmes.

At the end of the discussion, the facilitator will provide you with key points that may or may not have been identified during your discussion and will also summarize additional points that were mentioned in your discussion.
Module 4:  
Overview of AEFI profile of vaccines used in immunization programmes

Purpose
This session is intended to provide the participant with a basic overview of the vaccines used in most immunization programmes and the known adverse event profile of these vaccines.

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

- state the nature of vaccines used in immunization programmes
- describe the safety profile of the following vaccines: BCG, diphtheria–tetanus–pertussis (DTP), Haemophilus influenzae type b, hepatitis B, measles–mumps–rubella (MMR), oral polio vaccine (OPV) and yellow fever
- explain special precautions in, and contraindications to, the use of vaccines
- describe certain clinically important adverse events following immunization such as the following: anaphylaxis, hypotonic hyporesponsive episodes (HHE), toxic shock syndrome, seizures, disseminated BCG infection, suppurative lymphadenitis, encephalopathy/encephalitis, brachial neuritis and vaccine-associated paralytic poliomyelitis.

Activities

*Slide presentation and discussion: 3-basicvax.ppt*

These are no exercises for this module. However, questions and discussion will be raised during the course of the presentation.
Module 5: Country presentations by participants

Purpose
This session allows you to describe the system for AEFI surveillance in your country and to highlight the strengths and challenges faced by the NIP, NRA, and/or the MoH in dealing with AEFIs.

Objectives
By the end of this session you should be able to:

- list the strengths, weaknesses and special characteristics of your country’s system of vaccine safety surveillance, with particular emphasis on the way in which the immunization programmes and the regulatory authority function in this regard
- describe the characteristics of the immunization safety surveillance, and of NRAs and NIPs of other countries in order to consider ways in which your country’s system could be strengthened.

Activities

Exercise 5.1: Country presentations by participants

Prior to your arrival, you were requested to prepare a brief 5–10 minute presentation on the current status of immunization safety surveillance in your country. This presentation will be delivered to the group during this module. As has been described in the letter sent to you prior to the workshop, the basic content of the presentation should be as follows:

Basic content of the presentation should be as follows:

- Briefly mention the NIP coverage rates.
- Mention how vaccines are obtained for the NIP.
- Briefly describe the system for licensing of vaccines.
- Describe the current system in place within the immunization programme (or NRA) which deals with vaccines safety.
- Briefly describe the current system in place within the regulatory authority which deals with the safety of medicines in general.
• Describe past experiences with regard to real or perceived vaccines safety issues which did negatively impact on the national immunization programmes.
• Describe the communication links between the regulatory authority and immunization programmes (if any).

The talk should be as brief as possible and should not include detailed discussion of immunization schedules, campaigns, regulatory procedures for licensing etc. but rather focus on issues directly relevant to vaccine safety and post-marketing surveillance in your country. It would be preferable if you and other participants from your country were to prepare a joint presentation.

It is important that you pay careful attention to all the presentations during these sessions as discussion over the next few days will relate directly to what is presented. Moreover, this is a unique opportunity for you to compare your experiences with those of other countries in the region and learn from them.

After all the presentations you will be able to ask questions and comment on them.

Audio-visual equipment will be provided for your presentation.

At the end of the session you will all have to agree on one or two AEFI experiences that have been shared then. These will be for participants to critically evaluate later in the training, as a learning tool during Module 8.

Hint: This is also an opportunity for you to develop your presentation skills!
Module 6:  
Review of previous day’s activities

Purpose
At the beginning of each day, you will be given the opportunity to reflect and reach consensus on the discussions and lessons learnt from the previous day’s workshop.

Objectives
By the end of this session you should have agreed as a group on what was discussed the previous day and on the key messages to be taken from the day’s presentations and discussions.

Activities

Exercise 6.1:  Review of the previous day’s discussions
At the end of each day, a participant will be randomly selected from the group to facilitate a brief discussion the following morning on the activities and discussions of the previous day.

This participant will ask the group to summarize the previous day’s activities as follows:

- What major areas were discussed?
- What were the crucial lessons learned in these areas?
- Any other comments?

The participant will note on a flip chart or overhead transparency all points raised by the group so that the group can reach consensus on these points.

Note: This discussion should last no longer than 25 minutes
Module 7:
Case investigation

Purpose

During these sessions trainees will learn the basic principles of conducting a thorough investigation into an adverse event/cluster of events.

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

- explain the definition of an AEFI and the types of AEFIs that may occur
- identify which AEFI cases warrant a detailed case investigation
- explain why it is important to conduct a thorough case investigation
- given a specific situation, identify the steps to be followed to conduct a thorough case investigation in response to the initial reporting of AEFIs
- identify the factors to be considered when assessing the causal relationship between a vaccine and an adverse event.

Activities

*Slide presentation: 4-investigating.ppt*

*Exercise 7.1: Case investigation and*

*Exercise 10.1: Risk-benefit assessment and strategy*

During these exercises you will be divided into small groups. Each group will be given a specific AEFI case or cluster which requires further investigation and action. After each case description is a series of questions which you will be required to answer as a group. Select a chairperson and rapporteur within your groups before starting the discussion. The chairperson ensures that the discussion addresses the questions and that all participants within the group have an equal opportunity to participate. The rapporteur should also be involved in the discussion, but ensures that the important points and decisions arising out of the discussion are documented and presented during the feedback session. Overhead transparencies and pens will be provided for the feedback presentations.
During the feedback session, the rapporteur should provide the following:

- a brief overview of the case
- the group’s response to each of the questions
- important questions and concerns which may have been expressed by the group during the discussion
- a chance for other members of the group to add any more comments to the presentation.

The total duration of the presentation by each group should be no more than 15–20 minutes. Participants from other groups will be allowed the opportunity to ask questions and make comments for an additional 5–10 minutes.

**Hint:** You may utilize the references provided such as

- Surveillance of adverse events following immunization: field guide for managers of immunization programmes
- Supplementary information on vaccine safety: Part 2, background rates of adverse events following immunization

**Case 1**

You are in charge of AEFI within the NIP of your country, Fictitia. You are contacted one morning by the regional immunization officer in West Apolia, Fictitia about the following reactions which occurred following immunization.

Three infants died this week at one centre in Fictitia after administration of measles vaccine. Symptoms, developing within five hours post-immunization, were fever, rash, vomiting, and diarrhoea, and were described by the attending health worker as “toxic shock syndrome.”

The parents of the children as well as the health workers at the clinic are extremely upset and have blamed the vaccine. They have already called the local newspapers and local radio station.

You are now required to handle this problem urgently.

**Exercise 7.1**

Questions for case investigation and causality assessment workshop

1. Establish a case definition for this cluster of reported adverse events.
2. Consider the various possible causes for the adverse events, and how one might decide on the respective likelihood of each.
3. Based on your answer, develop a detailed plan for an investigation into the AEFI. Describe what additional information would be useful for this particular case.
4. Consider the possible causes for such an event and assess the likelihood of each.
Once you have completed this workshop and have presented your discussions during the feedback session, consult your facilitator to establish what the cause of these reactions were.

**Exercise 10.1  (from Module 10)**

**Questions for risk-benefit and strategy workshop**

1. Given the growing public interest in the situation and the potential damaging effect on the immunization programme, how would you have reacted as:
   a) the regional immunization programmes manager
   b) manager of the national EPI programme and
   c) head of the NRA?

2. Describe a stepwise plan of how you will go about fixing the problem you have identified during your case investigation.

3. What is your expected outcome for these actions and how do you plan on measuring how effective your actions are?

4. Would you communicate this information to the regulatory authority? Give a reason for your answer. If yes, when, how and what action would you expect them to carry out?

**Case 2**

You are the relatively new pharmacovigilance officer at the NRA of Fictitia. Your regulatory authority has an adverse drug reaction reporting system that allows health care professionals to report all adverse reactions to your unit. On a six-monthly basis you review all the cases reported to you during that period of time. During this evaluation you notice the following alarming trend.

From January to June three separate AEFI clusters were registered with, respectively, three, five and four cases of “collapse” that occurred up to five minutes following immunization with measles vaccine. All 14 cases presented with hypotonia; 11 became pale; seven cases had cyanosis, dyspnœa and increased saliva secretion; three patients had depressed respiration and one patient died; others recovered in less than one hour.

The reports were submitted by the doctors who took care of the infants at the hospital where they were transferred after the event.

**Exercise 7.1**

**Questions for case investigation and causality assessment workshop**

1. What is your plan of action once you discover this trend? Who would you consult and inform?

2. Assuming you decide to set up an investigation team, who would you invite to be part of this team?

3. You also plan on establishing a causality assessment advisory committee. What expertise would you invite onto this committee?
4. Establish a case definition.

5. Consider the various possible causes for the adverse events, including how one might decide on the respective likelihood of each. Eventually, decide on a working hypothesis.

6. Based on your answer, develop a detailed plan for investigating the AEFI.

Once you have completed this workshop and have presented your discussions during the feedback session, consult your facilitator to establish what the possible cause of these reactions were.

**Exercise 10.1 (Module 10)**

**Questions for risk-benefit and strategy workshop**

1. Discuss the risks and benefits of continuing to immunize children with measles vaccine, or continuing to use the particular implicated measles vaccines (i.e. before you have established the cause of the events).

2. Now that you are aware of the probable cause of the reactions, consider what you would do as the drug safety officer to avoid such a delay in your response to such reactions. What kind of system or operating procedures would you implement to fix this problem?

3. What is your expected outcome for these actions and how do you plan on measuring the effectiveness of your actions?

4. Who will you communicate your plans to? How will you do this? When?

**Case 3**

You are the Chief of the Medicines Regulatory Authority in Fictitia. On Thursday morning 10 February, while driving to work you hear on the radio that two children in the country have died after vaccination. The reporter on the radio goes on to suggest that the regulatory authority has not as yet registered the acellular pertussis vaccines that is much safer than the whole cell vaccine currently being used in the immunization programmes in your country. The reporter comments that in countries like the USA the safer vaccines are already being used routinely in the immunization programmes. The reporter suggests that perhaps the national regulatory authority is not as concerned about the safety of children as the regulators in more developed countries are.

On arrival at your office you find a fax from the director of the national immunization programmes describing the two deaths reported on the radio. He had apparently also not been notified of these reactions until a week ago. The regional officer of the immunization programmes who had been notified of these deaths had not reported them earlier to head office because he felt that the matter needed to be dealt with at regional and not national level.

The details of the case are as follows:
Case 1 – Rene Jackson (14 weeks)

Rene is one of twins. She was vaccinated on 12 January, together with the other twin (it was her third vaccination – she received Hib-DTP3, hepatitis B and OPV3). Both had a medical check-up the previous day. She was found to have no problems and her twin brother had a sub-febrile temperature. An outbreak of rubella had been confirmed in the area by laboratory tests.

She was taken to a day-care centre the next day (13 January). She received a feed at 12:30 and was put to sleep. Half an hour later she was found to be hypotonic, sighing and unresponsive.

The child was rushed to a hospital and admitted in coma, with a diagnosis of post-vaccination encephalopathy (pertussis component). The child was put on life-saving machines until 20 January and then declared dead. Investigations started from 17 January 2000, including an inspection of the site of vaccine delivery and vaccine used. The case is under medico-legal enquiry and results of the post-mortem will be available after a few weeks.

Case 2 – Alicia Mason (12 weeks)

This child was vaccinated on 12 January at a different clinic in the province and died the same day. The child developed high fever in the afternoon of the vaccination day. The mother gave the child paracetamol syrup and applied a menthol rub at the site of the injection. After looking for transport for two hours she took the child to the grandfather. He called an ambulance, but when it arrived the child was dead. The body was taken to the mortuary and the death certificate was issued the next day giving dehydration (diagnosis based on sunken fontanelle) as the cause of death.

The case was reported directly to the media on 24 January by Alicia’s grandmother’s employer. She was urged to do this when she heard from a friend of hers about the previous case. The child was already buried by then. There was no information on past medical history or vaccination history.

Exercise 7.1

Questions for case investigation and causality assessment workshop

1. What is your plan of action once you read the fax?

2. Given the details of the cases and the potential damaging effect of such information, how would you have reacted as the regional officer of the EPI services?

3. Assume now that you are the EPI manager and that you decide to set up an investigation team. Who would you invite to be part of this team?

4. You also plan on establishing a causality assessment committee consisting of experts. List a maximum of five experts you would like to have on such a committee.

5. Establish a case definition.
6. Consider the various possible causes for the adverse events, including how one might decide on the respective likelihood of each.

7. What is your working hypothesis. Based on you answer, develop a detailed plan for investigating the AEFI.

Once you have completed this workshop and have presented your discussions during the feedback session, consult your facilitator to establish what the possible cause of these reactions was.

**Exercise 10.1  (Module 10)**

**Questions for risk-benefit and strategy workshop**

1. Identify the major problems/challenges that you see yourself having to deal with as the EPI manager in this case. Classify them according to the following:
   - dealing with the actual cases reported – with the parents, grandparents, and health care workers;
   - dealing with communication system between the immunization programmes and the regulatory authority;
   - dealing with the media reports.

2. Describe a clear strategy for dealing with this crisis.

3. What is your expected outcome for these actions and how do you plan on measuring the effectiveness of your actions?

4. Who would you communicate this information to? How? When?

**Case 4**

Because of the high incidence of meningitis C in the city of Fantasia (population of about 700 000 people) and several smaller cities around it, it was decided to immunize the populations at risk with meningococcal C polysaccharide vaccine. This included Fantasia and the neighbouring cities. Two different brands of vaccine were used in the immunization campaign. A couple of hours after the campaign started, the national immunization programmes office started to receive phone calls from emergency rooms of hospitals in the area. Among the 30 000 people vaccinated up to that time, 5000 people had sought medical care for treatment of acute symptoms which included fever, abdominal pain, nausea, vomiting, and headache. Angry crowds were reported to be gathering around the immunization programmes offices in Fantasia and cases of violence against the immunization staff were being reported at clinics. These reports were confined to Fantasia. There were no such reports from the neighbouring cities.

**Exercise 7.1**

**Questions for case investigation and causality assessment workshop**

1. What is your plan of action once you learn about this very worrying trend? Who would you consult and inform?

2. Assuming you decide to set up an investigation team, who would you invite to be part of this team?

3. Establish a case definition.
4. Consider the various possible causes for the adverse events, including how one might decide on the respective likelihood of each. Eventually decide on a working hypothesis.

5. Based on your working hypothesis, develop a detailed plan for investigating the AEFI.

Once you have completed this workshop and have presented your discussions during the feedback session, consult your facilitator to establish what the possible cause of these reactions were.

**Exercise 10.1  (Module 10)**

**Questions for risk-benefit and strategy workshop**

1. Discuss the risks and benefits of continuing with the campaign. Consider your response assuming you do not know the results of the investigation, and your response after you obtain the results of the investigation. Would your response be different?

2. Identify the challenges facing the NRA and NIP.

3. Now that you are aware of the probable cause of the reactions how would you fix the problem and address the challenges mentioned above?

4. What is your expected outcome for these actions and how do you plan on measuring the effectiveness of your actions?

5. Who will you communicate your plans to? How will you do this? When?

**Case 5**

You are the head of the NRA which licenses all measles vaccines, including those made by the NIP of Fictitia. One Friday morning you receive a telephone call from a very angry and upset paediatrician complaining that the vaccines you have allowed to be used in the country were “killing children”.

After a very difficult conversation you receive the following information from the paediatrician.

Three children aged one to two years received measles vaccine on Wednesday morning 12 November 1993 at the same centre, and within about half an hour showed symptoms of fever, vomiting, and diarrhoea. One of the children recovered, while the other two died 15–17 hours after vaccination.

The paediatrician has already threatened to take this information to the press.

There has never been such a report before (bear in mind that your country does not have a system in place to conduct post-marketing surveillance).
**Exercise 7.1**

Questions for case investigation and causality assessment workshop

1. What is your plan of action once you put the telephone down. Who would you consult and inform?

2. Given the details of the case and the potential damaging effect of such information how would you have reacted as:
   a) the Medical Director of the company manufacturing the vaccine;
   b) manager of the national EPI services; and
   c) Chair of the national drug regulatory authority?

3. Assume that you decide to set up an investigation team. Who would you invite to be part of this team?

4. What are the various possible causes for the adverse events. Decide what is the likelihood of each.

5. Based on you answer, develop a detailed plan for investigating the AEFI.

Once you have completed this workshop and have presented your discussions during the feedback session, consult your facilitator to establish what the possible cause of these reactions was.

**Exercise 10.1 (Module 10)**

Questions for risk-benefit and strategy workshop

1. Why do you think such a situation arose?

2. Discuss the risks and benefits of continuing to immunize children with measles vaccine, or continuing to market the particular implicated measles vaccines.

3. The measles vaccine that is implicated is by far the cheapest and most affordable one you have available in the country. You are concerned that public anxiety will result in a lack of faith in the vaccine and a drop in coverage. You are still uncertain of the cause of these reactions. All the actors have asked you to suggest a plan of action to handle this (including the MoH). As the head of the immunization programmes, develop a strategy to handle this problem. Consider in your strategy what you would consider the responsibility and functions of the following key actors:
   a) the manufacturer of the vaccine;
   b) the chairperson of the regulatory authority;
   c) the media/public relations officer within the department of health.

4. Describe what you plan to do to remedy this situation and possibly prevent further such situations.

5. What is your expected outcome for the actions you have decided to take and how do you plan on measuring how effective your actions are?
Module 8:
Critical review of actions taken
during past experiences with
vaccine safety concerns

Purpose
This session allows the participants to reflect on and critically analyse past experiences, particularly those that have taken place in the participants’ countries.

Objectives
By the end of this session you should be able to:

- explain the importance of a properly functioning AEFI surveillance system;
- given specific problems experienced with handling AEFIs in the past, reflect on how these can serve as a means of identifying weaknesses within the AEFI system;
- describe the critical factors for a successful AEFI system.

Activities: Discussion

*Exercise 8.1: Plenary discussion*

During this session, there will be discussions on one or two of the experiences of crises shared by the participants during the third module. At the end of the third module the group would have selected one or two examples of crises experienced in their countries. These experiences should be briefly described again to the participants, including the actions taken by the EPI, NRA, MoH and any other key players. The group will then discuss the situation and consider the following:

1. Would this be considered a crisis situation? Why?
2. How was the situation handled in terms of:
   a) detection and reporting;
   b) assessment and evaluation;
   c) decisions made and action taken;
   d) monitoring the outcome of the action;
   e) communication with the patient, parents, health care workers and the public?
3. What lessons can be learned from this experience?
Module 9:
Basic principles of causality assessment

Purpose
Causality assessment is the assessment and classification of the likelihood of a causal association between a drug (including vaccines) and an adverse event. This section is meant to provide you with the basic principles that underpin decisions on the causal association between an event and the administration of a vaccine. It also explains the importance of assessing causality and the special challenges relating to vaccines in this regard.

Objectives
By the end of this session you should be able to:

- explain the importance of assessing the causal relationship between a vaccine and an adverse event;
- describe the basic principles of establishing a causal association between an adverse event and the administration of a vaccine;
- explain the special challenges in establishing a causal association between a vaccine and an AEFI;
- given a specific situation, decide on what investigations and factors need to be considered when assessing causality in individual cases.

Activities

Slide presentation: 5-causalvax.ppt

Exercise 9.1: Case examples

At the end of the slide presentation you will be given a few cases of AEFIs reported to an immunization programmes or NRA drug safety centre. Review these cases as a group and discuss the causal association between the reaction and the vaccine.

Your answer should state whether you think the causal relationship is a vaccine reaction, a programmatic error, coincidental or unknown.

- What is your level of certainty – i.e. definite, probable, possible, unlikely or unclassifiable?
- Explain what factors were considered when making a decision on causality.
- Explain other possible causes for the reaction.
Module 10: Understanding the basic principles of risk-benefit assessment, and decision-making

Purpose

This module is intended to provide you with the basic principles which underpin risk-benefit assessment and decision-making when a new risk has been identified for a vaccine.

Objectives

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

• define basic concepts of the risk-benefit evaluation process;
• given a particular situation, explain the importance of conducting an assessment of an AEFI or cluster in order to determine how to respond to these;
• identify the factors that need to be considered when making a decision related to immunization policy after a new safety risk has been identified;
• explain the basic approaches to options analysis and good decision-making practices.

Activities

Slide presentation: 6-riskben.ppt

Exercise 10.1: Making decisions and taking action during crises

(see Exercises for module 7 on case investigation)

During this exercise you will be divided once again into the same small groups as in Exercise 7.1. In Exercise 7.1 you conducted a case investigation to establish the facts and possible cause of the AEFIs. This exercise deals with action to be taken during such a crisis situation. Answer the questions under the section “Questions for risk-benefit and strategy workshop”, considering how each situation would need to be handled in real life. Once again, select a chairperson and rapporteur within your groups before starting the discussion. Overhead transparencies and pens will be provided for the report-back presentations.

During the feedback session, the rapporteur should provide the following:

• the group’s response to each of the questions;
• important questions and concerns which may have been expressed by the group during the discussion;
• a chance for other members of the group to add any more comments to the presentation.

The total duration of the presentation by each group should be no more than 10 minutes. Participants in other groups will be allowed the opportunity to ask questions and make comments for an additional 5–10 minutes.

Hint: You may utilize any of the references provided, particularly the following:


b) Slide presentation on risk-benefit assessment and decision-making.
Module 11:
Risk perception by patients and parents

Purpose
During this session, you will consider the manner in which risks associated with immunization are interpreted and perceived by patients and parents in order to better understand how to address the concerns and fears of those who are directly or indirectly exposed to AEFIs.

Objectives
By the end of this session you should be able to:

- describe the factors which need to be taken into consideration when communicating to parents and health care providers about AEFIs;
- identify the predictors of risk acceptability and the decision-making heuristics which may influence decisions about the risks and benefits of immunization that are made by parents and vaccinees.
- describe the challenges in risk communication to parents and health care providers with direct or indirect exposure to AEFIs;
- given a particular situation, communicate directly with parents and health care providers who have concerns about the safety of vaccines.

Activities

Exercise 11.1: Role-play or discussions (see below)

Slide presentation and group discussion: 7-Risk perception.ppt

Exercise 11.1: Discussion

Discuss how you would approach the following individuals as the EPI manager:

- a parent has a child who has developed clinically proven VAPP (vaccine-associated paralytic poliomyelitis) during an OPV campaign;
- the nurse who immunized the child that developed VAPP (the nurse has submitted her resignation and is considering ending her career as a nurse);
- a paediatrician concerned about the safety of several vaccine antigens used during a single visit.
If necessary and if time allows, the group may consider a role-play exercise, with one participant acting as the EPI manager and another as the parent or the paediatrician. This role-play exercise should precede the discussion.
Module 12: Evaluating the vaccine safety literature

Purpose

The body of literature published on AEFI is growing and not always accurate. The purpose of this module is to provide trainees with a basic overview of the skills involved in reviewing critically the biomedical literature on AEFI. The unbiased and thorough assessment of concerns about a vaccine’s safety is of utmost importance. Regulators and immunization programmes staff need to develop skills in this process and understand the basic principles of making rational decisions based on the evidence available.

Objectives

By the end of this session you should be able to:

• explain the importance of reviewing the literature on vaccine safety;
• apply the process involved in critically assessing the biomedical literature on vaccines safety;
• explain the importance of conducting an unbiased assessment of evidence before responding to a concern raised in the literature;
• describe the basic principles involved in establishing the local relevance of study findings.

Duration: Preparatory reading – 45 minutes
Slide presentation – 60 minutes
Workshop – 60 minutes
Feedback session – 45 minutes
Activities:

*Slide presentation: 8-Liteval.ppt*

**Exercise 12.1: Discussion and reaching a consensus**

On day one of the training you were provided with a published article and were asked to review it critically. Before the workshop commences you will be asked to vote on your decision about the results of the study. After the slide presentation you will divide into three working groups. During the workshop, you will assess the paper based on the questions asked in Appendix 2. Depending on the type of study you have been given to critique, choose between the case control and cohort study design assessments. During the session, you will have to come to an agreement on your responses to the 10 questions asked in the questionnaire. A rapporteur should be selected by the group to represent the group. During the feedback session, the rapporteurs will be given three voting cards reflecting a Yes (J), No (L) and Not sure (K) for use during the feedback session. The findings and conclusions reached for each of the questions by the three groups will be compared and discussed. At the end of the session the whole group should decide on their final conclusions about the publication, and whether the study findings are valid and applicable to their local settings.
Module 13: Communication skills: introduction

Purpose
During this session you will learn about the new climate in which communications with the public takes place, and, in particular, the special challenges facing public health workers involved in handling AEFIs.

Objectives
By the end of this session you will be able to:
- understand the new climate within which communication with the public takes place;
- appreciate the special challenges and opportunities presented to public health workers managing adverse events following immunization;
- understand the media and their goals and objectives.

Activities
Video introduction

*Slide presentation: 10-New climate.ppt*

*Exercise 13.1: Interviewing a representative from the media*

*Objective:* To discuss issues relating to communication of AEFI information to the media with a representative of the press.

During this session you will have the opportunity to ask a representative from the media (a journalist or a television reporter) about his/her work. The media representative will provide you with some insight into the media's perspective of reporting information on crises. The media representative will usually be from the country within which the training is being hosted. You will be given the opportunity to ask questions and discuss issues relating to communication with the public through the media.

Alternatively, a role play exercise or other exercise will be carried out which illustrates the possible negative repercussions of poor interaction with the media.

*Slide presentation: 11-mediaintro.ppt*
Purpose

During this session you will identify and develop the skills needed for working with the media.

Objectives

By the end of the session you will develop five communication skills to deal effectively with AEFIs including how to:

- simplify complex information;
- develop key messages;
- inform the press;
- present a positive, confident image;
- respond to difficult questions.

Activities

*Slide presentation: 12-simplifying.ppt*

*Exercise 14.1: Simplifying complex messages*

This exercise provides practice in simplifying public health messages to make them more effective. Once again break into your small groups for this exercise. Summarize and simplify the complicated text provided into a small number of bullet points that explain the material to the average public. Discuss in a group, decide on the best bullet points and prioritize them. Select a rapporteur to present your group’s work in the plenary.

The rapporteur should write his or her group’s “bullet points” on a flip chart or overhead, or have them as a slide presentation. These messages will be used in a later exercise in Module 15 and therefore will need to be kept for such use. Each group should be able to discuss and explain the rationale for selecting its key public health messages.
New vaccine introduced by Ministry of Health – *Haemophilus influenzae* type b disease

The Ministry of Health has decided to introduce “Hib” vaccine for the first time for all children starting in October. *Haemophilus influenzae* type b (Hib) is a gram-negative bacterium that lives only in the human nasopharynx. The most serious manifestation of Hib infection is meningitis, with a case fatality rate of 3–5% in industrialized, and up to 30% in developing countries. Meningitis is followed by permanent neurological defects in 20% of survivors. Pneumonia is the most common presentation in developing areas, and causes at least 350,000 deaths in children per year, worldwide.

Children less than one year of age are at highest risk of disease, and disease is rare in children more than five years old. Failure to breastfeed, household overcrowding, and day care attendance have been shown to be independent risk factors for infection. Epidemics do not occur, though the disease may occur following an initial case in a sibling or day care attendee.

Rapid diagnosis and treatment with antibiotics are essential for optimal outcome in cases of meningitis. Third generation cephalosporins or chloramphenicol are often used for empirical treatment until antimicrobial susceptibility is known. In developing countries, acute respiratory tract infections are treated with ampicillin or cotrimoxazole.

Although chemoprophylaxis has been recommended for close contacts, this would prevent only 1–2% of all disease even if optimally applied. The only practical public health means of making an impact on this disease is immunization.

Effective vaccines comprised of the polysaccharide capsule ("PRP") and various protein carriers (diphtheria toxoid, a diphtheria toxoid-like protein, tetanus toxoid, and the outer membrane protein complex from a meningococcus) – the so-called Hib conjugate vaccines – are now available. The vaccines are used in over 25 countries as part of the routine infant immunization programme, administered at the same time as, or combined in the same syringe with, DTP. In all countries routinely using Hib conjugate vaccines, Hib-related disease has dropped dramatically.

No serious side effects have been reported in recipients of Hib conjugate vaccines. A small proportion of children develop mild fevers and soreness for a day or two at the site of the injection.

In view of the demonstrated safety and efficacy of the Hib conjugate vaccine, Hib vaccine should be included as appropriate to national capacities and priorities, in routine infant immunization programmes. In geographical areas where the burden of Hib disease is unclear, efforts should be made to evaluate the magnitude of this problem.

**Summary**

At the end of this session, reflect back on what has been learned in this exercise.
Exercise 14.2: Key messages

Key messages are fundamental to managing communication, regardless of whether they are for managing crises or for encouraging routine vaccination. They are used in written and verbal communications (e.g. during an interview). Identifying key messages ensures that, regardless of what is said or written, these messages are communicated to the target audience.

The objective of this exercise is to develop key messages and present them in a press statement and during an interview with the media. Break into your small groups for the exercise. Review the details of the case you used during Modules 7 and 10 (case investigation and risk-benefit assessment workshops). As a group decide on three to five key messages in the form of bullet points and prioritize them. Select a rapporteur to present these bullet points in the plenary.

Summary

At the end of the session reflect back on what has been learned about developing key messages.

Slide presentation 13-press release.ppt

Exercise 14.3: Preparing a press release

The objective of this exercise is to provide you with the skills needed to develop a press release.

Using all the information you have obtained so far, draft a clear and concise press statement to communicate the key messages to the public on the case that your group has been provided with. Use the notes provided below to assist you in drafting this press release. During the plenary session you or any other member of your group will be asked to present this press statement at a press conference (during Exercise 14.4).

Be prepared to discuss the timing, advantages and disadvantages of using a press release with the facilitator.

Components of a press release

Your news release is to acquaint the reporter with the news. It should provide pertinent information and entice the reporter into following up on the story. The components of a news release are listed below:
Content

- A news release should be held together by a central theme. Determine what the objective of the news release is and whom you are trying to reach.
- Your news release should have a strong lead sentence. The lead is the most important sentence in your news release. It should convey the most important point in the news release. The lead should include as many of the five Ws (who, what, when, where, why) as possible. One way to determine your lead is to list all the points you want to make, prioritize them, and choose one for your lead. The remainder of your news release should consist of short paragraphs that support your lead sentence.
- A news release should present all the relevant facts in a logical order. It should be straightforward, lively and informative. Avoid jargon, medical terms, acronyms, and lots of data.
- If you have a quote in your news release it should convey some information that isn’t elsewhere in the release. Quotes make a story more readable and more real.

Format

- All news releases should contain certain essential elements. Two pages of copy are more than sufficient for the majority of news releases.

Headline

- The headline helps the editor quickly determine if the news release needs immediate attention or if it can wait. The headline should be short and to the point.

Release date

- It is acceptable to begin the text of the news release with the name of the city where the news is taking place or from which the announcement you’re making originates. If there is no restriction on when your news release can be used, write “For Immediate Release” at the top of the page. An acceptable alternative is to place the date at the top left side of the page and include only the name of the city and the release date (For example: Edmonton, August 23, 1999).

Layout

- If you have more than one page of text, centre the word “more” at the bottom of the first page. This tells the editor there is additional information. On the last page just below the final paragraph of the release, centre the number –30–. This means the end of text.

Contact

- At the very end of the news release, provide the name, title, organization name and telephone number of the contact person. You can cite more than one contact person but the key is to ensure that the contact person is knowledgeable and reachable.
Exercise 14.4:  Presentation skills

Objective

To practice projecting a positive, confident image. This will provide a benchmark for measuring any improvement in level of presentation skills as the workshop progresses.

Instructions

One person from each working group will be asked to role-play a spokesperson from the Ministry of Information and read aloud the press release developed during Exercise 13.4. This presentation will be filmed and, after filming, the facilitator will play back the videotape, soliciting comments from both the reader and the ‘audience,’ and make comments on each presentation: what was done well, what could be improved. Consider both the presentation skills of the reader as well as the content of the press release.

Begin the press release as follows:

Good morning. I am ...(name) with the MoH. Thank you all for coming today. We have an announcement about....

The remaining participants should critique the presenter and the contents of the press release in terms of:

1. ability to convey the identified key messages clearly;
2. attitude;
3. body language;
4. confident image.

During the discussion, the participants will be asked to provide their comments about the press release. These comments will assist the participants to recognize their strengths and weaknesses.

Summary

At the end of the session, you will be asked to reflect back on what has been learned in developing a press statement and presenting a positive image.
**Exercise 14.5: Interviewing skills**

In this exercise you will learn how to respond to difficult questions from members of the media. You should be able to handle difficult, unexpected, controversial or unpleasant questions from members of the media, and at the same time present a balanced view on the safety and efficacy of the vaccine/s in question. You will also put into practice the points you learnt about presenting a confident image, an appropriate attitude and good body language. Break into small groups and review the press release you developed. After the review ask the group members to identify difficult questions that could arise from the media based on their own press release. They should also be prepared with responses to these possible difficult questions. Prepare to play the role of the EPI manager and be interviewed on camera about the press release.

The remaining participants should critique the presenter and the contents of the press release in terms of:

1. ability to convey the identified key messages clearly;
2. attitude;
3. body language;
4. confident image.

During the discussion, the participants not directly involved in the interview will be asked to provide their comments about the press release. These comments will assist the participants in recognizing their strengths and weaknesses in order to improve on their interviewing skills.

**Summary**

At the end of this exercise, reflect on what has been learned about dealing with difficult questions.
Module 15: Communications and media planning

Purpose

This section will allow you to gain a basic understanding of the importance of developing communications plans to address future vaccines safety concerns.

Objectives

By the end of the session the participants should be able to:

- explain the importance of communications/media planning;
- explain the communications planning process;
- describe, through examples, how communications plans support successful programmes.

Activities

*Slide presentation: 15-Communications plan*

*Exercise 15.1*

You have reviewed the basic components of good communications practice and have developed a better understanding of the media and its function. Now it is time for you to develop a communications plan.

The object of this exercise is to allow you to draw up a communications plan/strategy that can be used when an issue needs to be highlighted or promoted or when the public needs to be made aware of vaccine initiatives or safety issues.

Divide into two groups (all NRA staff in one group and all immunization programme staff in the other). Use the scenario which you used in Exercise 14.1 above, which involves the introduction of a new vaccine into a population. Bear in mind that the vaccine has not been used in this population before, but is generally believed to be safe. You are keen to encourage the use of this vaccine in the community, while at the same time implementing a safety monitoring programme to monitor AEFIs. In this scenario, the NRA is responsible for assessing the safety of the vaccine once it has been released onto the market. It is also the home of the pharmacovigilance programme that wishes to encourage reporting of adverse drug reactions, including AEFIs.
Based on this information, each group has to work out a communications plan/strategy to promote their key messages. You have to focus on five areas:

a) What is the objective of the communication, for the NRA and for the NIP?
b) Formulate 3-5 key messages as the NRA (NRA group) and the NIP (NIP group). This has already been partly achieved through the “simplifying messages” workshop. You may wish to modify these messages based on your role as an NRA or NIP representative.
c) Decide who the audience needs to be.
d) Who are your partners and how would you enlist the support of these partners?
e) Which media would be the most ideal vehicle?
f) Which strategy would best suit that media?

Each group will report back their ideas to the entire group through a rapporteur. The plan will be critiqued by the entire group.

**Communications plan template**

**Background**

- a situation analysis that explains the context for the communications initiative being undertaken;
- examination of the strengths, weaknesses of opportunities and threats to your programme;
- information on what happened in the past, what is currently happening, and what is expected to happen.

**Target Audiences**

- a target audience is the group most affected by, or most influential in promoting, an idea, policy, event, decision or product;
- tailoring communications plans to fit various target audiences depends on your ability to identify the audiences and their characteristics through informal and formal research methods and to translate this information into a sensitive understanding of their needs;
- what is it that the audience wants to know and how can the message be tailored to them?

**Goal**

- a big picture statement about what you want to achieve;
- the goal is generally to inform, persuade, motivate or achieve mutual understanding.
Objectives (two types – informational and motivational)

- provide two or three statements that will support the achievement of your goal;
- create focused and measurable goals and answer the question “what do we hope to accomplish?”

Strategies

- the strategy details what tools will be used to reach the audience (news release, special event, advertising, brochures and posters);
- the strategy is a plan of action that provides guidelines and themes for the overall effort.

Messages

- ensure repetition and consistency of messages;
- take into account the characteristics of the audience and their literacy level;
- the message should be tied to the objectives of the communication plan (what you hope to accomplish).

Evaluation

- review of radio, print and television coverage is the most common format for reviewing your communications plan;
- measurement of audience comprehension can be achieved through a sample survey of the target audience;
- the evaluation process is “linked” to the strategies (or tools).

Slide presentation: 16-Rumours and Crises.ppt

Exercise 14.2: Case study – “Crisis communications plan template”

The objective of this exercise is to let you know how the crisis communications plan template helps to manage the crisis. If you have the template ready, it will save time during a crisis. You will be able to handle the situation efficiently.

Part of this exercise can be done now while the rest needs to be done during the crisis. You should be aware of all the steps mentioned in the template and be confident that they can follow it:

- what groups are interested in pro- and anti-immunization messages?
- the potential problems that might occur in the absence of balanced messages on immunization;
- the major players in understanding and changing the problem;
- what actions need to be taken and by whom?
Summarize these points and be prepared to present the results of these discussions in the plenary.

**Handout: Case study – crisis communications plan template**

The purpose of a crisis communications plan is not to prevent crises – they’re going to happen anyway. It is to prevent crises from becoming disasters. It is a good idea to have a crisis communications plan in place before you get a crisis.

1. The first thing your crisis communications plan should have is a definition of a crisis. For example, a definition frequently used is anything that could result in a significant risk to public health or public safety.

2. Write a brief description of the goals and objectives of the crisis communications plan.

3. Establish a crisis management team. This team would be called together in any given crisis.

4. Prepare a list of all those inside and outside the organization who should be informed when a crisis occurs. How would this team differ or link with the investigation team, the causality assessment advisory committee, the NRA, and the EPI program?

5. Prepare a list of spokespersons. Keep this list short since the more voices your organization speaks with the greater the chance that you will issue conflicting or confusing information.

6. Ensure all spokespersons get appropriate media training.

7. Distribute a media relations policy about how to handle media inquiries to all employees who are likely to be contacted by the media. In most cases this should be simply to refer media calls to the designated spokespersons. Ensure all employees understand who the designated spokespersons are in the organization.

8. List possible crisis situations and outline appropriate communication responses and appropriate spokespersons.

9. Identify and assign all tasks that might have to be performed during the various crisis situations you foresee. This could include notifying various publics, arranging news conferences, writing and distributing news releases, or providing meeting rooms and equipment.

10. Distribute relevant parts of the plan to each employee. The full plan should be distributed to permanent members of the crisis management team.

**Putting the plan into effect**

Meet with senior management to evaluate if the situation is indeed a crisis and how it might affect the organization. Obtain all the facts, double-check them and distribute the information quickly. More importantly, ensure the information is right. Agree on the overriding tone and key messages before you handle any media inquiries. Prepare a list of key messages, news release and backgrounder, and distribute to senior management and, most importantly, to the spokespersons.
1. Once you have all the facts and obtained feedback on your press statement, issue the statement. This statement clarifies the nature and dimensions of the crisis and outlines what you are doing about it.

2. Distribute the press statement to all staff so they hear what’s happening from you rather than learn about it on the news.

3. Ensure the media know who the spokespersons are and where to reach them, and that the spokespersons remain on site.

4. If the crisis is ongoing, issue a press statement whenever a significant development occurs, or on a regular basis.
Module 16:  
Developing a strategic response to AEFIs

Purpose

During this module, you will consider all that was discussed during the preceding few days and consider how you and the colleague from your country will work together and with others to develop a combined plan of action, and to implement or strengthen the AEFI monitoring system.

Objectives

By the end of this module you should:

? develop a plan of action for the implementation/strengthening of a surveillance system for adverse events following immunization;
? list the elements necessary when considering how to improve AEFI surveillance in your country;
? be able to integrate all the knowledge acquired during the workshops to ensure that the system for AEFI surveillance in your country will be practical, sustainable and efficient.

Activities

**Exercise 16.1: Setting up a plan of action**

Plan for the implementation/strengthening of a surveillance and management system for adverse events following immunization

You will be given instructions on this module on Day 1 of the training. This is perhaps the most important part of the training course as it gives you and your colleagues time to reflect on how to implement or improve on the existing AEFI programme in your country.
Instructions

- You should get together with other participants from your country during the course of the week to complete this module.
- The questions and assignments should be completed in as much detail and be as accurate and practical as possible so that you can implement this plan on returning to your country.
- You may use the evenings to continue to discuss the form and complete it so that it can be discussed the following morning at the feedback session.
- If there is more than one participant from a particular country, one participant will serve as the rapporteur for that country and report back on the plan to the whole group during the morning session. Another participant should serve as the facilitator during the discussion session.
- Presentations back to the group must be brief (no more than 10 minutes) and should describe the most important and critical steps to be taken by that group/country. (For example, there is no need to read out or describe the definitions of the adverse events agreed upon by the group.)
- The designated rapporteur for each country group will be provided with transparencies and pens to prepare the final presentation on the plan of action on behalf of his/her country. This presentation will be done on the morning of day 6.
- A paper copy of the completed questionnaire must also be submitted to one of the course facilitators no later than the end of day 5.

You may use the planning draft in Appendix 3 to assist with compiling your answers for the following questions.

Countries with no AEFI monitoring system in place

Countries with very similar health infrastructures and with no AEFI systems in place could work together on these questions. This should be discussed with the facilitator at the end of the first day.

1. Draw a diagram showing the way in which you anticipate information about the AEFI to flow from the time an AEFI takes place. You may use the attached model developed by WHO as a basis and modify this according to your country’s needs.

Include in your flow diagram the working relationship between your country’s NIP, NRA and the communications department within the MoH. Show what their respective roles are in terms of AEFI, and describe the nature of collaboration between these and other partners with respect to AEFI. (This part of the exercise will be done in the workshop at the end of Day 3.)

1. Describe how you will obtain political commitment for implementing an AEFI programme.
2. Develop an AEFI case report form and case investigation form. You may use the WHO examples reproduced in the AEFI Field Guide as a basic model and adapt them as necessary. Ensure that all the essential questions are included in the forms so that all relevant information is collected.
3. Describe a proposed case investigation process. Include in your answer information on which AEFI will be investigated, by whom, and how this investigation will take place.

4. Describe how data management and analysis of AEFI reports will be done (nature and frequency of analysis and responsible officer).

5. Prepare a plan for an AEFI advisory group or committee. Describe the profile of experts you will call on to participate in such a group. Also describe the nature of the group, their functions and who will support them, and what mandate they will have.

6. Describe what mechanisms will be used to train and provide feedback to health professionals and immunization staff on AEFI.

7. Describe a public awareness and communication strategy which could be developed in your country for immunization and vaccine safety, particularly during crises.

8. Develop key indicators for measuring the efficiency of your AEFI surveillance programme. The following are examples:
   - timeliness of reporting;
   - completeness of reporting;
   - percentage of cases investigated according to plan;
   - percentage of cases investigated on time;
   - percentage of cases with proper action taken;
   - timeliness of analysis;
   - timeliness of feedback.

Countries with an existing AEFI system in place:

1. Present a diagram describing the way in which AEFI information flows from the time an AEFI takes place. You may use the attached model as a basis and modify it according to your country’s specific situation. Highlight the strengths and weaknesses of the system, using your country’s flow diagram.

In your diagram describe the working relationship between your country’s NIP, NRA and the communications department within the MoH. Show their respective roles in terms of AEFI and describe the nature of collaboration between these and other partners with respect to AEFI. (This part of the exercise will be done in the workshop at the end of Day 3)

1. Present the AEFI case report and case investigation forms used in your country. Describe their strengths and weaknesses in terms of eliciting all the necessary information for assessing cases.

2. Describe the case investigation process (including which AEFI are investigated, how and by whom).

3. Describe how data management and analysis of AEFI reports occurs (nature and frequency of analysis and responsible officer) and whether this is efficient. Describe any plans for improving this system.
4. Describe the nature of an AEFI advisory committee (or other form of system whereby AEFI investigations are assessed and actions recommended). Describe the strengths and weaknesses of this review system and how it can be improved.

5. Describe a public awareness and communications strategy in place in your country for immunization and safety. Describe strengths, weaknesses and how it can be improved.

6. Describe what happens during a crisis in your country and what the strengths and weaknesses of your system are for handling such crises. How would you improve on this?

7. Describe what mechanisms are in place for feedback on AEFI and for training of immunization staff and health professionals on AEFI. How can this be improved?

8. What is the ability of your current AEFI monitoring programme to obtain the following possible parameters for evaluating the efficiency of the programme?
   - timeliness of reporting;
   - completeness of reporting;
   - percentage of cases investigated according to plan;
   - percentage of cases investigated on time;
   - percentage of cases with proper action taken;
   - timeliness of analysis;
   - timeliness of feedback.
Module 17: Establishing a way forward, thanks and closure

Purpose

The purpose of this final session is to wrap up the workshop, hand out the certificates and allow the participants to evaluate the training institution.

Objectives

During this session you should:

- reflect on what was learnt during the training workshop and how this training could be better improved in the future;
- recognize the importance of continuing to collaborate and keeping contact with fellow participants.

Activities

- Collection of assessment of the training institution forms
- Discussion on the way forward
- Official thanks by the facilitator
- Handing out of certificates
- Closure

Exercise 17.1: Discussion on the way forward

- During this discussion you will be asked the following questions:
- Should you continue to collaborate with each other as a group? If so, why and how?
- What support, if any, is required from WHO and others?
- What are the strengths and weaknesses of this training programme and how can it be improved?
- When can WHO expect to visit your country for a follow-up on AEFI activities?
1. Immunization safety surveillance: guidelines for managers of immunization programmes on reporting and investigating adverse events following immunization. WPRO/EPI/99.01, Manila, 1999


Web sites

World Health Organization: Vaccines and Biologicals:
http://www.who.int/m/topics/vaccines_immunizations/en/index.html

Centres for Disease Control and Prevention (USA)
www.cdc.gov
www.cdc.gov/nip/vacsafe

New Zealand Ministry of Health
http://www.moh.govt.nz/moh.nsf/wpg_Index/News+and+Issues-Index
(see under Health Topics: immunization)
http://www.imac.auckland.ac.nz/

Canadian Division of Immunization

Australia

The immunization action Coalition:
http://www.immunize.org/

Medline

Medscape (for reviews and updated medical news)
http://www.medscape.com/Home/Topics/PrimaryCare/PrimaryCare.html

The Brighton Collaboration
http://brightoncollaboration.org

Immunization Action Coalition
http://www.immunize.org/safety/general.htm

Institute for Vaccine Safety
http://www.vaccinesafety.edu/

Children’s Hospital of Philadelphia – Common concerns about vaccines
http://vaccine.chop.edu/concerns.shtml
Appendix 1:  
Draft letter of welcome for participants  

{Participant’s name}  
{Address}  
{Date}  

De {Participant’s name}  

GTN course: adverse events following immunization (AEFI) {city, country, dates of training}  

We are delighted that you have been selected to attend the Global Training Network workshop on adverse events following immunization (AEFI) to be held in {city} from {period of training}. We have received your application and hope that you will benefit from participating in this training course.  

In this letter we will be providing you with some practical information as well as an assignment in preparation for the workshop.  

About the training course: The training will begin on Sunday afternoon {date of commencement} at 14:00 and will end by 17:00 on Saturday {final day of training}. The training programme has been designed to address your specific needs as much as possible and therefore depends on your undivided attention and active participation in the course.  

The workshop aims to provide you with the skills, awareness and information needed to develop or strengthen systems in your country by which the national immunization programmes and national regulatory authority collaborate with each other and with other key players to minimize and prevent risks of harm associated with immunization or perceived to be associated with immunization.
The specific objectives of the training are:

1. To provide an appreciation for the importance of a national immunization safety programme.

2. To provide the knowledge and skills to:
   a) develop or strengthen the detection and reporting system for AEFIs within a country;
   b) investigate an AEFI or clusters of AEFIs;
   c) analyse and assess data on AEFIs;
   d) decide on and carry out corrective and other action in response to an AEFI or cluster of AEFIs;
   e) evaluate the actions taken in response to an AEFI or cluster of AEFI.

3. To develop an understanding of the importance and the respective roles of the national regulatory authority (NRA), the national immunization programme (NIP) and other role players in ensuring the safety of vaccines used in immunization programmes.

4. To promote collaboration and communication between:
   - the NRA;
   - the NIP;
   - the Ministry of Health;
   - the health professions;
   - the media;
   - patients and parents;
   - the public.

5. To provide the opportunity to participants to consider and present a draft plan for developing or strengthening a national immunization safety programme for implementation on return to their country.

The objectives of the training will be accomplished through various techniques including slide presentations, discussions, workshops, assignments, role-playing activities and individual presentations. It is hoped that the training will serve as a catalyst for you to create awareness and develop capacity in immunization safety within your country with the goal of protecting the public from real or perceived risks associated with immunizations and improving the quality of NIP.

**Country presentation by trainees:** On the first day of the course, you and the colleague from your country (where applicable) will be required to make a presentation of no more than ten minutes during which you will:

1. Briefly mention the national immunization coverage rates.
2. Mention how vaccines are obtained for the NIP.
3. Mention whether there is a national control laboratory for vaccines quality testing.
4. Describe the current system in place within the immunization programmes (or NRA) which deals with vaccines safety.
5. Briefly describe the current system in place within the regulatory authority which deals with the safety of medicines in general.

6. Describe past experiences with regard to real or perceived vaccines safety issues which had a negative impact on the national immunization programmes.

7. Explain how the matter was handled and how the information was communicated to the public via the media.

8. Describe the communication links between the regulatory authority and immunization programmes (if any).

The talk should not include detailed discussion of immunization schedules, campaigns etc.

Your stay in {city}:

**Airport transfer:** When you arrive in Cape Town you will have to take a taxi to {hotel name and directions, if possible}. The taxi usually costs approximately {approximate cost of taxi to hotel}.

**Accommodation:** You will be staying at {hotel name}. The details of the hotel are as follows:

{Hotel name}
{Physical address}
{Telephone number}
{Fax number}

Breakfast will be provided for by the hotel.

**Clothing:** Cape Town has a Mediterranean-type climate with winter rains and dry summers. Daytime temperatures in July range from 4–20°C with colder evenings. It is advisable to dress in layers with at least a warm sweater or jacket, particularly since you are likely to be indoors during the day. You will need warmer clothing for the evening and windy afternoons. A pair of good walking or hiking shoes are a definite must for those interested in the tours and climbing up Table Mountain.

**Training venue:** The training will take place at the {Conference venue and address of separate from hotel}

**Daily allowance:** On your arrival we will provide you with a daily allowance of {per diem costs} which includes/ excludes the cost of your accommodation.

**Any meal preferences:** Please let us know in advance if you have any meal preferences (e.g. vegetarian, Halaal, Kosher) as soon as possible.

**Visa and health insurance:** Please be reminded that you are responsible for obtaining your own visa for South Africa. It is essential that you have obtained your visa for {country name} prior to your departure to the course. In addition you are responsible for obtaining traveller’s health insurance for yourself.
We hope that you will find your journey and training in [city] beneficial and enjoyable. Please contact me should you require any further clarification.

Yours sincerely

{Facilitator’s name}
Course coordinator
AEFI training course
Global Training Network
{GTN centre}
{Tel: }
{Fax: }
{Email:}

Questionnaire

Please tear off this part of the letter, complete it and return it as soon as possible (by two weeks prior to commencement of training) to {course administrator} at: {fax: } or {email}

Practical details:

Do you have any meal preferences? (vegetarian, kosher, Halal etc)

Kindly provide us with your flight arrival and departure details:

Arrival:

Airline............................................. Flight No: .........................

From: ................................. To: ............................. Arrival time: .................

Departure:

Airline............................................. Flight No: .........................

From: ................................. To: ............................. Departure time: .................
Appendix 2:
Critical appraisal skills questionnaires

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Critical appraisal skills programme:
Making sense of evidence

Twelve questions to help you make sense of a cohort study

General comments

- Three broad issues need to be considered when appraising a cohort study.
  - Are the results of the study valid?
  - What are the results?
  - Will the results help locally?

The 12 questions on the following pages are designed to help you think about these issues systematically.

- The first two questions are screening questions and can be answered quickly. If the answer to those two is “yes”, it is worth proceeding with the remaining questions.
- There is a fair degree of overlap between several of the questions.
- You are asked to record a “yes”, “no” or “can’t tell” to most of the questions.
- A number of italicized hints are given after each question. These are designed to remind you why the question is important. There will not be time in the small groups to answer them all in detail!

---

* Critical Appraisal Skills Programme (CASP) 2000. All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise without the prior permission of CASP. However, organizations may reproduce or use the publication for non-commercial educational purposes provided the source is acknowledged. Enquiries concerning reproduction or use in other circumstances should be addressed to CASP.
A. Are the results of the study valid?

<table>
<thead>
<tr>
<th>Screening questions</th>
<th>Yes</th>
<th>Can’t tell</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Did the study address a clearly focused issue?</td>
<td>☐</td>
<td>☐</td>
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</tr>
<tr>
<td>HINT: A question can be focused in terms of:</td>
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<tr>
<td>• the population studied</td>
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<td>• the risk factors studied</td>
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<td>• the outcomes considered</td>
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<tr>
<td>• is it clear whether the study tried to</td>
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<tr>
<td>• detect a beneficial or harmful effect?</td>
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<tr>
<th>2. Did the authors use an appropriate method to answer their question?</th>
<th>Yes</th>
<th>Can’t tell</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>HINT: Consider</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>• Is a cohort study a good way of answering the question under the circumstances?</td>
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<td></td>
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<tr>
<td>• Did it address the study question?</td>
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Is it worth continuing?

<table>
<thead>
<tr>
<th>Detailed questions</th>
<th>Yes</th>
<th>Can’t tell</th>
<th>No</th>
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<tbody>
<tr>
<td>3. Was the cohort recruited in an acceptable way?</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>HINT: We are looking for selection bias which might compromise the generalizability of the findings:</td>
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<tr>
<td>• Was the cohort representative of a defined population?</td>
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<tr>
<td>• Was there something special about the cohort?</td>
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<tr>
<td>• Was everybody included who should have been included?</td>
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<tr>
<th>4. Was the exposure accurately measured to minimize bias?</th>
<th>Yes</th>
<th>Can’t tell</th>
<th>No</th>
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<tr>
<td>HINT: We are looking for measurement or classification bias:</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>• Did they use subjective or objective measurements?</td>
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<tr>
<td>• Do the measures truly reflect what you want them to (have they been validated)?</td>
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<tr>
<td>• Were all the subjects classified into exposure groups using the same procedure?</td>
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<tr>
<th>5. Was the outcome accurately measured to minimize bias?</th>
<th>Yes</th>
<th>Can’t tell</th>
<th>No</th>
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<tbody>
<tr>
<td>HINT: We are looking for measurement or classification bias:</td>
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<tr>
<td>• Do the measures truly reflect what you want them to (have they been validated)?</td>
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<tr>
<td>• Has a reliable system been established for detecting all the cases (for measuring disease occurrence)?</td>
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<tr>
<td>• Were the measurement methods similar in the different groups?</td>
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<tr>
<td>• Were the subjects and/or the outcome assessor blinded to exposure (does this matter)?</td>
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</table>

58 Workshop on establishing/strengthening a national immunization safety surveillance programme. Participant’s workbook
6. Have the authors identified all possible confounding factors?
   List the ones you think might be important, that the authors missed.

   **B. Have they taken account of the confounding factors in the design and/or analysis?**
   HINT: Look for restriction in design, and techniques e.g. modelling, stratified, regression, or sensitivity analysis to correct, control or adjust for confounding factors

<table>
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<tr>
<th>Yes</th>
<th>Can't tell</th>
<th>No</th>
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7. A. Was the follow-up of subjects complete enough?

   **B. Was the follow-up of subjects long enough?**
   HINT:
   - The good or bad effects should have had long enough to reveal themselves
   - The persons that are lost to follow-up may have different outcomes than those available for assessment
   - In an open or dynamic cohort, was there anything special about the outcome of the people leaving, or the exposure of the people entering the cohort?

<table>
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<tr>
<th>Yes</th>
<th>Can't tell</th>
<th>No</th>
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8. What are the results of this study?
   HINT:
   - What are the bottom line results?
   - Have they reported the rate or the proportion between the exposed/unexposed, the ratio/the rate difference?
   - How strong is the association between exposure and outcome (RR)?
   - What is the absolute risk reduction (ARR)?

9. How precise are the results?
   HINT:
   - Size of the confidence intervals.

10. Do you believe the results?
   HINT:
   - Big effect is hard to ignore!
   - Can it be due to bias, chance or confounding?
   - Are the design and methods of this study sufficiently flawed to make the results unreliable?
   (Consider Bradford Hill criteria (e.g. time sequence, dose-response gradient, biological plausibility, consistency)

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<tr>
<th>Yes</th>
<th>Can't tell</th>
<th>No</th>
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Is it worth continuing?

<table>
<thead>
<tr>
<th>C. Will the results help me locally?</th>
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<tbody>
<tr>
<td>11. Can the results be applied to the local population?</td>
</tr>
<tr>
<td>HINT: Consider whether</td>
</tr>
<tr>
<td>• The subjects covered in the study could be sufficiently different from your population to cause concern.</td>
</tr>
<tr>
<td>• Your local setting is likely to differ much from that of the study</td>
</tr>
<tr>
<td>• Can you quantify the local benefits and harms?</td>
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<tr>
<td>Yes ☐</td>
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<table>
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<tr>
<th>12. Do the results of this study fit with other available evidence?</th>
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<tbody>
<tr>
<td>Yes ☐</td>
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</table>

One observational study rarely provides sufficiently robust evidence to recommend changes to clinical practice or within health policy decision-making.

However, for certain questions observational studies provide the only evidence.

Recommendations from observational studies are always stronger when supported by other evidence.
General comments

- Three broad issues need to be considered when appraising a case control study.
  - Are the results of the study valid?
  - What are the results?
  - Will the results help locally?

The 11 questions on the following pages are designed to help you think about these issues systematically.

- The first two questions are screening questions and can be answered quickly. If the answer to those two is “yes”, it is worth proceeding with the remaining questions.
- There is a fair degree of overlap between several of the questions.
- You are asked to record a “yes”, “no” or “can’t tell” to most of the questions.
- A number of italicized hints are given after each question. These are designed to remind you why the question is important. There will not be time in the small groups to answer them all in detail!
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<tr>
<td>● is it clear whether the study tried to</td>
</tr>
<tr>
<td>● detect a beneficial or harmful effect?</td>
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<tr>
<td>Yes</td>
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<td>![ ]</td>
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| 2. Did the authors use an appropriate method to answer their question? |
| HINT: Consider |
| ● Is a case control study an appropriate way of answering the question under the circumstances? (is the outcome rare or harmful?) |
| ● Did it address the study question? |
| Yes | Can’t tell | No |
| ![ ] | ![ ] | ![ ] |

Is it worth continuing?

<table>
<thead>
<tr>
<th><strong>Detailed questions</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Were the cases recruited in an acceptable way?</td>
</tr>
<tr>
<td>HINT: We are looking for selection bias which might compromise the validity of the findings:</td>
</tr>
<tr>
<td>● Are the cases defined precisely</td>
</tr>
<tr>
<td>● Were there cases representative of a defined population (geographically and/or temporally)?</td>
</tr>
<tr>
<td>● Was there an established reliable system for selecting all the cases?</td>
</tr>
<tr>
<td>● Are they incident or prevalent?</td>
</tr>
<tr>
<td>● Is there something special about the cases?</td>
</tr>
<tr>
<td>● Is the time frame of the study relevant to the disease/exposure?</td>
</tr>
<tr>
<td>● Was there a sufficient number of cases selected?</td>
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<tr>
<td>Yes</td>
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</table>

| 4. Were the controls selected in an acceptable way? |
| HINT: We are looking for selection bias which might compromise the generalizability of the findings: |
| ● Were the controls representative of a defined population (geographically and/or temporally)? |
| ● Was there something special about the controls? |
| ● Was the non-response high? Could non-respondents be different in any way? |
| ● Are they matched, population based or randomly selected? |
| ● Was there a sufficient number of controls selected? |
| Yes | Can’t tell | No |
| ![ ] | ![ ] | ![ ] |
5. **Was the exposure accurately measured to minimize bias?**

   HINT: We are looking for measurement, recall or classification bias:
   - Was the exposure clearly defined and accurately measured?
   - Did the authors use subjective or objective measurements?
   - Do the measures truly reflect what they are supposed to measure? (have they been validated)
   - Were the measurement methods similar in cases and controls?
   - Did the study incorporate blinding where feasible?
   - Is the temporal relation correct (does the exposure of interest precede the outcome?)

<table>
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<tr>
<th>Yes</th>
<th>Can’t tell</th>
<th>No</th>
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</table>

6. **A. What confounding factors have the authors accounted for?**

   List the other ones you think might be important, that the authors missed (genetic, environmental and socioeconomic)

<table>
<thead>
<tr>
<th>Yes</th>
<th>Can’t tell</th>
<th>No</th>
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</table>

   **B. Have the authors taken account of the potential confounding factors in the design and/or in their analysis?**

   HINT:
   - Look for restriction in design, and techniques e.g. modelling, stratified, regression, or sensitivity analysis to correct, control or adjust for confounding factors.

<table>
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<tr>
<th>Yes</th>
<th>Can’t tell</th>
<th>No</th>
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</table>

7. **What are the results of the study?**

   HINT:
   - What are the bottom line results?
   - Is the analysis appropriate to the design?
   - How strong is the association between exposure and outcome (look at the odds ratio)?
   - Are the results adjusted for confounding and might confounding still explain the association?
   - Has adjustment made a big difference to the OR??

<table>
<thead>
<tr>
<th>Yes</th>
<th>Can’t tell</th>
<th>No</th>
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8. **How precise are the results?**

   How precise is the estimate of risk?

   HINT:
   - Size of the p-value
   - Size of the confidence intervals
   - Have the authors considered all the important variables?
   - How was the effect of subjects refusing to participate evaluated?
One observational study rarely provides sufficiently robust evidence to recommend changes to clinical practice or within health policy decision-making.

However, for certain questions observational studies provide the only evidence.

Recommendations from observational studies are always stronger when supported by other evidence.
Appendix 3:
Planning an AEFI strategy

Country name: ........................................................................................................................................

1. What is the goal of the AEFI system?

Example

- To minimize the risks associated with the use of vaccines and to strengthen the EPI programme

2. What are the general objectives of the AEFI monitoring system?
   a) To minimize the negative impact of adverse events on public health.
   b) To ensure the sound functioning and quality of the national EPI programme.
   c) What are the specific objectives of the AEFI monitoring system?

Example

- rapid detection of essential information about problematic AEFIs;
- rapid and thorough investigation of the AEFI/s;
- rapid and effective response to AEFIs (including corrective action);
- effective communication of AEFI information and response to patients, caregivers and the public;
- measuring the outcome or efficacy of corrective action; and
- adequate education, training and support of key personnel.
Action plan for implementation

1. How will you obtain political commitment for the implementation of this plan?

<table>
<thead>
<tr>
<th>Activity</th>
<th>Responsible</th>
<th>Achievement date</th>
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<tbody>
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</tbody>
</table>
2. Which adverse events do you think should be reported through this system? (WHO definitions for some of these adverse events may be found in the references provided)

<table>
<thead>
<tr>
<th>Adverse events</th>
<th>Definition (this section may be completed after the training if time does not allow)</th>
<th>Time-frequency of reporting notification</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>
Nature of system (active versus passive, sentinel versus comprehensive)

3. How will you go about including the private health sector in your AEFI monitoring programme?

<table>
<thead>
<tr>
<th>Activity</th>
<th>Responsible</th>
<th>Date of completion</th>
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</tbody>
</table>
4. Who should report AEFIs?
5. How should AEFIs be reported? (describe the reporting pathways)
   *(Hint: Participants may use the attached flow diagram to serve as a basic model which can be modified based on the country's particular situation.) Use an additional page*
6. Briefly describe how forms for reporting and investigation will be developed? (level of detail, critical information to be collected) – refer to attached forms as references.

<table>
<thead>
<tr>
<th>Types</th>
<th>Critical elements of information</th>
<th>Responsible</th>
<th>Date of completion</th>
<th>Cost of printing in US$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporting</td>
<td></td>
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</tr>
<tr>
<td>Investigation</td>
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</tbody>
</table>

7. Describe how data management and analysis of AEFI reports will occur (nature and frequency of analysis and responsible officer)

8. Describe the feedback mechanism which will be implemented for AEFIs (i.e. nature of the feedback system, who feedback will be targeted to, frequency of feedback)
9. Development of guidelines for reporting, case investigations etc.

Responsible officer(s) ___________________________________________________

Completion date: _______________________________________________________

Cost of printing (US$): _________________________________________________

10. Training and education

<table>
<thead>
<tr>
<th>Target/number of trainees</th>
<th>Type of training/duration</th>
<th>Responsible</th>
<th>Cost in US$</th>
<th>Completion date</th>
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</tbody>
</table>

Workshop on establishing/strengthening a national immunization safety surveillance programme. Participant's workbook
11. Decide on respective responsible officers

<table>
<thead>
<tr>
<th></th>
<th>Central</th>
<th>Regional</th>
<th>District</th>
</tr>
</thead>
<tbody>
<tr>
<td>Point focal (coordinator)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reporting at various levels</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Investigation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Analysis at various levels</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Spokespersons</td>
<td></td>
<td></td>
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<tr>
<td>Response and action</td>
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</tbody>
</table>

12. What will be the respective roles of the EPI programme and the NCA?

**EPI:**

**NRA:**

13. What will the system of coordination with different partners be?

14. Describe the formation of an expert committee on causality assessment (terms of reference, membership, functioning, date of establishment)
15. Describe a public awareness and communication strategy

<table>
<thead>
<tr>
<th>Activity</th>
<th>Responsible</th>
<th>Cost (US$)</th>
<th>Date of completion</th>
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</thead>
<tbody>
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</tbody>
</table>

16. Briefly describe the crisis management plan and how it will differ (if necessary) from the routine AEFI system (you may use additional paper if required):

__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________

17. Explain briefly how, when and by whom monitoring and evaluation of AEFI monitoring programme will occur

How ____________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
When (i.e. how often) ___________________________________________________

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Appendix 4:
The reporting process for AEFIs

Fig. 1. The reporting process for adverse events following immunization (AEFIs)

<table>
<thead>
<tr>
<th>Health care worker</th>
<th>Supervisor</th>
<th>NIP coordinator</th>
<th>NRA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recognizes AEFIs</td>
<td>Stimulates reports, Investigates, Filters</td>
<td>Receives reports, Transmits reports, Triages, Works with environment. Manages data</td>
<td>Receives reports, Transmits reports, Shares database, Evaluates reports, Takes action, Notifies</td>
</tr>
<tr>
<td>Reports AEFIs</td>
<td>Provides feedback, Manages data, Proposes classification</td>
<td>Manages data</td>
<td>Ensures response</td>
</tr>
<tr>
<td>Treats patient/ refers patient for treatment</td>
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</tbody>
</table>

NIP, national immunization programme; NRA, national regulatory authority
## Appendix 5:
Draft programme

### Day 1 programme: Monday

<table>
<thead>
<tr>
<th>Facilitator</th>
<th>Module</th>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>08:30 – 09:30</td>
<td>60 min</td>
<td>Introduction and welcome with Icebreaker</td>
</tr>
<tr>
<td>1</td>
<td>09:30 – 10:00</td>
<td>30 min</td>
<td>Completion of questionnaire</td>
</tr>
<tr>
<td>1</td>
<td>10:00 – 10:30</td>
<td>30 min</td>
<td>Basic overview of course material and instruction to the trainees</td>
</tr>
<tr>
<td></td>
<td>10:30-10:45</td>
<td></td>
<td><strong>Tea break</strong></td>
</tr>
<tr>
<td>2</td>
<td>10:45 – 12:00</td>
<td>75 min</td>
<td>Introduction to immunization safety (1-introvax.ppt)</td>
</tr>
<tr>
<td>3</td>
<td>12:00 – 13:00</td>
<td>60 min</td>
<td>Similarities and differences between vaccines and other medicines: Discussion (2-differences.ppt)</td>
</tr>
<tr>
<td></td>
<td>13:00 – 14:15</td>
<td></td>
<td><strong>Lunch break</strong></td>
</tr>
<tr>
<td>5</td>
<td>14:15-15:30</td>
<td>75 min</td>
<td>Country presentations (part 1)</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>Assessment of progress from previous assessment</td>
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<tr>
<td></td>
<td>15:30 – 15:45</td>
<td></td>
<td><strong>Tea break</strong></td>
</tr>
<tr>
<td>5</td>
<td>15:45 – 16:30</td>
<td>45 min</td>
<td>Country presentations (part 2)</td>
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<td></td>
<td>Assessment of progress from previous assessment</td>
</tr>
<tr>
<td>12</td>
<td>16:30 – 17:00</td>
<td>30 min</td>
<td>Reading of selected vaccine safety article for preparation of Module 12.</td>
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<td></td>
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<td>(Explanation of requirements for Module 17 – Planning and set-up)</td>
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</tbody>
</table>
Day 2 programme – Tuesday – Understanding vaccines and their adverse effect profile

<table>
<thead>
<tr>
<th>Facilitator</th>
<th>Module</th>
<th>Time</th>
<th>Activity</th>
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</thead>
<tbody>
<tr>
<td>Participant</td>
<td>6</td>
<td>09:00 – 09:15</td>
<td>15 min</td>
</tr>
<tr>
<td>4</td>
<td>09:15 – 10:30</td>
<td>75 min</td>
<td>Overview of vaccines used in immunization programmes and discussion (3A-Bascivax1.ppt)</td>
</tr>
<tr>
<td>7</td>
<td>10:30 – 10:45</td>
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<td><strong>Tea break</strong></td>
</tr>
<tr>
<td>4</td>
<td>10:45 – 11:15</td>
<td>30 min</td>
<td>Overview of vaccines used in immunization programmes and discussion (3A-Bascivax2.ppt)</td>
</tr>
<tr>
<td>7</td>
<td>11:15 – 12:15</td>
<td>60 min</td>
<td>Basic principles of conducting a case investigation (4-Investigating.ppt)</td>
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<tr>
<td>7</td>
<td>12:15 – 13:00</td>
<td>45 min</td>
<td>Facilitated workshop on case investigation – working groups</td>
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<tr>
<td>7</td>
<td>13:00 – 14:15</td>
<td></td>
<td><strong>Lunch break</strong></td>
</tr>
<tr>
<td>7</td>
<td>14:15 – 14:45</td>
<td>30 min</td>
<td>Facilitated workshop on case investigation – working groups</td>
</tr>
<tr>
<td>7</td>
<td>14:45 – 15:30</td>
<td>45 min</td>
<td>Feedback session by participants</td>
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<tr>
<td>7</td>
<td>15:30 – 15:45</td>
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<td><strong>Tea break</strong></td>
</tr>
<tr>
<td>8</td>
<td>15:45 – 17:00</td>
<td>75 min</td>
<td>Critical review of actions taken during past experiences &amp; discussion on crisis management</td>
</tr>
<tr>
<td>Facilitator</td>
<td>Module</td>
<td>Time</td>
<td>Activity</td>
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<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Participant</td>
<td>6</td>
<td>08:00 – 09:15</td>
<td>Overview of day 2</td>
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<td></td>
<td>9</td>
<td>09:15 – 10:30</td>
<td>Presentation and discussion on causality assessment of AEFI (5-Causality.ppt)</td>
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<td>10</td>
<td>10:30 – 10:45</td>
<td>Tea break</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>10:45 – 11:30</td>
<td>Basic principles of risk-benefit assessment and decision-making (6-Riskbenefit.ppt)</td>
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<tr>
<td></td>
<td>10</td>
<td>11:30 – 13:00</td>
<td>Workshop on risk-benefit assessment and decision-making</td>
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<tr>
<td></td>
<td>10</td>
<td>13:00 – 14:15</td>
<td>Lunch break</td>
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<tr>
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<td>10</td>
<td>14:15 – 15:00</td>
<td>Feedback session on risk-benefit assessment and decision-making</td>
</tr>
<tr>
<td></td>
<td>16</td>
<td>15:00 – 15:30</td>
<td>Workshop: Developing a strategy to deal with AEFI (7-Planning.ppt)</td>
</tr>
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</table>
Day 4 programme – Thursday – Risk-benefit assessment and decision-making

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<th>Module</th>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>11</td>
<td></td>
<td>09:00 – 10:00</td>
<td>60 min Presentation on risk perception and communicating with parents and health care workers (7-Riskperception.ppt)</td>
</tr>
<tr>
<td>12</td>
<td></td>
<td>10:00 – 10:30</td>
<td>30 min Slide presentation on evaluation of the vaccine safety literature (8-litreview.ppt)</td>
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<td></td>
<td>10:15 – 10:45</td>
<td>Tea break</td>
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<tr>
<td>12</td>
<td>10:45 – 11:45</td>
<td>60 min</td>
<td>Discussion on literature paper</td>
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<tr>
<td>12</td>
<td>11:45 – 12:45</td>
<td>60 min</td>
<td>Reaching a consensus and discussing how to respond to the paper</td>
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<td></td>
<td>13:00 – 14:15</td>
<td>Lunch break</td>
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<tr>
<td>13</td>
<td>14:15 – 15:00</td>
<td>45 min</td>
<td>Introduction to communication via the media: A new climate presentation and discussion of the implications (10-Newclimate.ppt)</td>
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<tr>
<td></td>
<td>15:00 – 16:00</td>
<td>60 min</td>
<td>Understanding the media: Workshop 13.1 and slide presentation: 11-mediaintro.ppt</td>
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<td>16:00 – 16:15</td>
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<td>Tea break (video presentation)</td>
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<tr>
<td>14</td>
<td>16:15 – 17:00</td>
<td>45 min</td>
<td>Simplifying messages: Slide presentation and exercise 14.1 with feedback 12-simplifying.ppt</td>
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</table>
Day 5 programme – Friday – Partnership-building with the media

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<tr>
<th>Facilitator</th>
<th>Module</th>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>14</td>
<td></td>
<td>08:30 – 09:30</td>
<td>60 min</td>
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<tr>
<td>14</td>
<td></td>
<td>09:30 – 10:00</td>
<td>30 min</td>
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<td></td>
<td>10:00 – 10:15</td>
<td>15 min</td>
<td>Tea break</td>
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<tr>
<td>14</td>
<td></td>
<td>10:15 – 11:30</td>
<td>75 min</td>
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<tr>
<td>14</td>
<td></td>
<td>11:30 – 13:00</td>
<td>90 min</td>
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<td>13:00 – 14:15</td>
<td></td>
<td>Lunch break</td>
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<td>14</td>
<td></td>
<td>14:45 – 15:30</td>
<td>45 min</td>
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<td>15:30 – 15:45</td>
<td></td>
<td>Tea break</td>
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<tr>
<td>15</td>
<td></td>
<td>15:45 – 17:00</td>
<td>75 min</td>
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</table>
Day 6 Programme – Saturday – Partnership-building with the media, wrap-up and closure

<table>
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<th>Module</th>
<th>Time</th>
<th>Activity</th>
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</thead>
<tbody>
<tr>
<td>16</td>
<td>09:00-10:00</td>
<td>60 min</td>
<td>Preparation of country presentations</td>
</tr>
<tr>
<td>16</td>
<td>10:00 – 10:30</td>
<td>30 min</td>
<td>Country presentations</td>
</tr>
<tr>
<td></td>
<td>10:30 – 10:45</td>
<td></td>
<td><em>Tea break</em></td>
</tr>
<tr>
<td>16</td>
<td>10:45 – 12:00</td>
<td>75 min</td>
<td>Country presentations</td>
</tr>
<tr>
<td>17</td>
<td>12:30 – 13:00</td>
<td>60 min</td>
<td>Establishing the way forward, thanks and closure</td>
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</tbody>
</table>
The Department of Vaccines and Biologicals was established by the World Health Organization in 1998 to operate within the Cluster of Health Technologies and Pharmaceuticals. The Department’s major goal is the achievement of a world in which all people at risk are protected against vaccine-preventable diseases.

Five groups implement its strategy, which starts with the establishment and maintenance of norms and standards, focusing on major vaccine and technology issues, and ends with implementation and guidance for immunization services. The work of the groups is outlined below.

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

The **Initiative for Vaccine Research** and its three teams involved in viral, bacterial and parasitic diseases coordinate and facilitate research and development of new vaccines and immunization-related technologies.

The **Vaccine Assessment and Monitoring team** assesses strategies and activities for reducing morbidity and mortality caused by vaccine-preventable diseases.

The **Access to Technologies team** endeavours to reduce financial and technical barriers to the introduction of new and established vaccines and immunization-related technologies.

The **Expanded Programme on Immunization** develops policies and strategies for maximizing the use of vaccines of public health importance and their delivery. It supports the WHO regions and countries in acquiring the skills, competence and infrastructure needed for implementing these policies and strategies and for achieving disease control and/or elimination and eradication objectives.