

TRAINING MODULE

Introduction of Pentavalent Vaccine with *Haemophilus influenzae b* (Hib) in Timor-Leste



Expanded Program on Immunization



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TARGET AUDIENCE

The training module is meant to assist health managers and immunization program managers and facilitators to conduct training for health workers for introduction of Haemophilus influenzae type b (Hib) in pentavalent (DPT+HepB+ Hib) vaccine in the immunization program. The intention is to provide information that is practical as well as technically and operationally sound. This training should enable the health workers to smoothly introduce the pentavalent vaccine in their immunization services and also counsel the community members and mothers about the vaccine and its benefits for their children and the community.

This training module has been developed by the EPI division in the Ministry of Health with technical support from UNICEF and inputs from the EPI Technical Working Group.

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ABOUT THE TRAINING

Purpose of this training module

1. To educate vaccinators about *Haemophilus influenzae* type B (Hib) disease.
2. To train vaccinators in safe and proper pentavalent vaccination.
3. To decrease drop-out rates and increase coverage by improving vaccinators' ability to communicate with parents, other caretakers, and local leaders about Hib vaccination and immunization in general.

Who should receive this training?

Health workers who give childhood vaccinations, and their supervisors, will benefit from this training.

Objectives: By the end of this session, participants will be able to:

- cite key facts about Hib infection and disease, including how it is transmitted and its symptoms
- demonstrate correct pentavalent vaccine administration techniques
- describe appropriate pentavalent vaccine storage
- communicate more effectively with parents of children being vaccinated

Timeframe: The amount of time needed to present this module can vary from approximately 3 hours to 4 hours.

Preparation prior to training:

- Review all **Trainer's Notes** and contents before initiating the training.
- Photocopy participant handouts (one copy per trainee).

Trainer's Notes:

1. At the beginning of the training session, introduce yourself. Ask participants to introduce themselves and give information about their background and experience.
2. Point out that there are varying levels of experience within the group, and that everyone can benefit from the experiences and ideas of other group members.
3. Present the timeframe and objectives, and explain what participants will be able to do better after this training session.

4. You may wish to ask participants to explain their expectations for the training session. They may mention important training needs that you had not anticipated, but which can easily be incorporated into the session.

Training schedule: (Total 3 hours)

Session Name	Content	Method	Duration
Session 1: General Information on training	Objectives of training, Introduction of Facilitator and participants, framing of ground rules (keeping to time, participatory, one person speaks at a time, raise hand for questions)	Discussion	15 mins
Session 2: Introduction	Background and Immunization schedule	Discussion using Flip chart or White Board	30 mins
Session 3: Why do we need the pentavalent vaccine?	Rationale for Hib vaccine & the Hib disease	Discussion using Flip chart followed by presentation	45 mins
Session 4: Pentavalent vaccine	Details about the vaccine and vaccination method	Discussion with presentation followed by Case Scenarios	60 mins
Session 5: Evaluation & Feedback	True and False Exercise (done in group) and feedback of training	True and False Exercise done with presentation Feedback recorded on flip chart through group discussion	30 mins

Session 2: INTRODUCTION

READ THE CHAPTERS ON BACKGROUND & IMMUNIZATION SCHEDULE IN THE OPERATIONAL GUIDELINES

Trainer's Notes:

1. Lead a discussion using some of these questions:
 - Why is the government implementing the vaccination programme?
 - Can one of you tell me what the immunization coverage in your area is? And in Timor-Leste?
 - Can one of you describe the present vaccination schedule?
2. List answers on a flipchart paper and discuss with the group. End this session by saying that Pentavalent vaccine will replace the existing tetravalent vaccine in the schedule.
3. Rectify any incorrect answers by providing the information below.

KEY POINTS:

- **The overall objective of the immunization programme is to reduce under-five morbidity and mortality caused by vaccine-preventable diseases among children in Timor-Leste.**
- Immunization is one of the key interventions to help save lives of children. From 2003 to 2010, full immunization coverage in Timor-Leste has tripled from 18% to 53%. Timor-Leste has also successfully completed a validation exercise for elimination of Maternal and Neonatal tetanus. Although the surveillance and reporting systems need to improve, there has been no polio case detected since 1996.
- The Government of Timor-Leste, through the Ministry of Health, is committed to ensuring that all Timorese children are reached and provided with high quality immunization services and vitamin A supplements.
- The present Immunization schedule is given below:

THE IMMUNIZATION SCHEDULE

The Expanded Program on Immunization serves the following target groups:

All children under 1 year of age (0-11 months)

All women of childbearing age (including pregnant women)

The recommended vaccines are the following:

- BCG - Bacillus Calmette-Guerin
- OPV - Oral Polio Vaccine
- DPT - Diphtheria, Pertussis, Tetanus
- HepB - Hepatitis B
- TT - Tetanus Toxoid
- Measles - Measles
- DT - Diphtheria and Tetanus
- DTP-HepB - Diphtheria, Tetanus, Pertussis, and Hepatitis B

Immunization Schedule for Infants <1 (from birth up to 12 months of age)

Type of vaccine	When administered
BCG, OPV 0	At birth (or as soon as possible after birth)
OPV1, DTP-HepB1	At 6 weeks
OPV2, DTP-HepB2	At 10 weeks (or 4 weeks after OPV1, DPT1, HepB1-Hib1)
OPV3, DTP-HepB3	At 14 weeks (or 4 weeks after OPV2, DPT2, HepB2-Hib2)
Measles	At 9 months

Note: The new pentavalent vaccine (DPT-HepB-Hib) will replace the existing tetravalent vaccine (DPT-HepB). The new vaccine will give protection to children against 5 diseases – diphtheria, pertussis, tetanus, hepatitis B, and haemophilus influenzae type b.

Note: The schedule of the new pentavalent vaccine is same as existing tetravalent vaccine, i.e. at 6, 10 and 14 weeks.

Session 3: WHY DO WE NEED THE VACCINE?

READ THE CHAPTERS ON RATIONALE FOR Hib VACCINE & THE Hib DISEASE IN THE OPERATIONAL GUIDELINES

Trainer's Notes:

1. Lead a discussion using some of these questions:
 - Have you ever seen a child with pneumonia? What were the symptoms? Did the child survive?
 - Have you ever seen a child with meningitis? What were the symptoms? Did the child survive?
 - Have you ever heard of Hib disease? What can you tell me about it?
2. List answers on a flipchart paper and discuss with the group. Make the presentation 1. Conclude this session by summarizing that pentavalent vaccination with Hib vaccine is the best way to protect against pneumonia and meningitis due to Hib and that pentavalent vaccination can protect against 5 diseases.
3. Rectify any incorrect answers by providing the information below.

KEY POINTS:

- **Pneumonia** is an infection of the lungs. It is a common cause of mortality in children under 5. The symptoms include fast breathing, chest indrawing, cough, and fever.
- **Bacterial meningitis** is an inflammation (swelling) of the membranes that cover and protect the spinal cord and brain. Bacterial meningitis is deadly unless treated immediately with the correct antibiotics. Even with proper treatment, 3-25% of affected children may die. Fifteen to 35% of children who survive Hib meningitis are left with permanent disabilities such as difficulty in movement, learning disabilities and hearing loss.
- Haemophilus influenzae type b (Hib) is a bacterium associated with a number of severe childhood diseases, namely infection of the brain membrane (pyrogenic meningitis), pneumonia, sepsis and infection of other internal organs and bones. Hib accounts for roughly half of the pyrogenic meningitis cases in the age group of 6 months to 2 years, and is also estimated to be responsible for 20% of pneumonia cases in this age group. Hib is most serious in young children (upto 2 years); after age 5 years there is little risk in getting disease. One out of 20 children who get

Hib meningitis die and 10-30 % of survivors have permanent brain damage.

- Pneumonia is a leading cause of child deaths in Timor-Leste. According to the HMIS 2011 Report, 509 cases of severe pneumonia were identified in children (0-5 years) by the IMCI programme. The 6 hospitals of Timor-Leste reported that 1,830 cases of pneumonia and 51 cases of meningitis were admitted for treatment in the age group 0-5 years in 2011. In addition, the hospitals reported 36 deaths due to pneumonia in children and 11 deaths due to meningitis in children under 5 years of age. The government has planned to introduce Hib vaccine as part of the pentavalent vaccine (DPT, Hep B, Hib) in order to prevent children from dying due to pneumonia or meningitis caused by Hib.
- Hib vaccine has been included in routine childhood vaccination programmes in more than 150 countries, in all regions of the world. As a consequence, invasive Hib disease has been practically eliminated in many industrialized countries, and its incidence has been dramatically reduced in some parts of the developing world.
- Like measles, Hib is passed from an infected person to an uninfected via droplets of saliva when an infected individual coughs or sneezes. Hib can also be spread when children share toys and other objects that they have put in their mouth. The probability of transmission increases when children spend prolonged periods of time together. Children are often asymptomatic carriers of the Hib bacteria, showing no signs or symptoms but still able to infect others.
- Hib disease is most common in children under five years of age. Children between the ages of 4 to 18 months of age are most at risk (WHO, 2006). It is important to immunize children and prevent disease very early in life. At birth, antibodies from the mother sufficiently protect most infants. When the child reaches 2 or 3 months of age, the level of maternal antibodies decreases and the risk of Hib infection increases. By the age 5 years, most children will have already developed their own immunity against Hib so, Hib disease after the age of five years is rare.
- Diagnosis and treatment of Hib disease is difficult.
- Immunization with Hib vaccine is the only practical way to prevent Hib disease. Children should receive three doses before the age of 1 year. Hib vaccines are safe and efficacious. Immunization against Hib is a cost effective strategy for disease prevention.

Note: The Hib component of the pentavalent vaccine will only protect against pneumonia and meningitis caused by Hemophilus influenza type b. The child can still get pneumonia or meningitis from other causes.

Note: In spite of its name, Haemophilus influenzae type b does not cause influenza (i.e., the “flu”) or the common cold. Hib is not the same as HIV or Human Immunodeficiency Virus, the virus that causes AIDS. Similarly, Hib is not the same as HepB or Hepatitis B, the virus that causes infection (hepatitis) and cancer of the liver.

Note: Earlier, tetravalent vaccine was used in Timor-Leste for protecting children against four diseases- diphtheria, pertussis and tetanus and hepatitis B.

*NOW, **new pentavalent vaccine** will protect children against FIVE DISEASES - diphtheria, pertussis and tetanus and hepatitis B and Haemophilus influenza type b (Hib)*

Session 4: THE PENTAVALENT VACCINE

READ THE CHAPTERS ON PENTAVALENT VACCINE AND STEPS TO INTRODUCE VACCINE IN THE OPERATIONAL GUIDELINES

Trainer's Notes:

1. Make the presentation 2. Encourage discussions and questions.
2. End the session with the following case scenarios.

KEY POINTS:

- The formulation that the EPI in Timor-Leste will provide is Liquid Pentavalent Vaccine (LPV). The vaccine has 5 antigens (DPT+ HepB+ Hib) in a single formulation.
- The Liquid Pentavalent Vaccine in the EPI will be available in 10-dose presentation.
- Pentavalent vaccine should be stored at temperature of 2-8 degree Celsius, in the basket of ILR and should never be frozen. Conditioned ice packs should be used during transportation to prevent freezing. The vaccinator should perform the shake test on vaccine that may have been frozen, and vaccine that fails the test should be returned to SAMES.
- A three dose primary series will be considered routine. The first dose is given to children at six weeks of age or older. The vaccine may be given at the same time as DTP, OPV, and HepB vaccines, at 6, 10 and 14 weeks. The interval between (Hib vaccine) doses should be at least one month.
- The dose of pentavalent vaccine is 0.5 ml. The mode of administration is the same as for DPT vaccine. Pentavalent vaccine is used directly from the vial and given by intramuscular injection in the antero-lateral aspect of the mid-thigh.
- Hib vaccine has not been associated with any serious adverse effects. However, redness, swelling and pain at the site of injection may occur in as many as 25% of those who have been vaccinated. Such reactions usually start within 1 day after immunization and last for 1–3 days.
- All Hib containing vaccines (i.e., pentavalent vaccine) are safe and efficacious. They provide 85 to 95% protection after completion of the schedule.
- Multi-dose vial policy for pentavalent vaccine is same as for DPT-HepB.
- Healthworkers may use existing columns for DPT or HepB for entry of pentavalent vaccine by over-writing with hand. This should be done till

the new formats are printed to include pentavalent vaccine (tally sheets, reporting forms, MCH registers, stock registers, Lisio)

- Seek commitment and support for introduction of pentavalent vaccine from various other departments & ministries like police, MSS, schools etc., and NGO partners, church, faith based groups and community leaders.
- Health workers should allocate time for briefing the suco chief, aldeia chief and other local leaders and influencers about the new vaccine and the benefits for children and the community. Please refer to the “Questions that parents may ask and possible responses” in the handout for health workers.

Completing the DPT Series

Note: If a child has already received one or two doses of DPT-Hep B (tetraivalent), then you should finish that child’s series of three doses with one or two doses (as appropriate) of pentavalent vaccine, maintaining the minimum interval of 4 weeks between doses. The ideal ages for the three doses are 6, 10, and 14 weeks; however, if this is not possible, then the second and third doses should be given as soon as possible once 4 weeks have passed since the previous dose.

This guideline is to allow smooth transition from tetraivalent (DPT-HepB) to pentavalent (DPT-HepB-Hib) vaccine and avoid confusion by use of two kinds of vaccine at the same time.

Case Scenario 1. After the pentavalent vaccine has been launched across the country, a mother comes to the immunization session with a child of age 6 weeks who has received BCG at birth. How will you immunize the child?

Ans: Give the first dose of pentavalent and OPV, counsel the mother/caretaker to watch for possible side effects and advise to return after 4 weeks for the second dose of pentavalent and OPV.

Case Scenario 2. After the pentavalent vaccine has been launched across the country, a mother comes to the immunization session with a child of age 10 weeks who has received BCG at birth and first dose of tetravalent at 6 weeks. How will you immunize the child?

Ans: Give the dose of pentavalent and OPV, counsel the mother/caretaker to watch for possible side effects and advise to return after 4 weeks for the third dose of pentavalent and OPV.

Case Scenario 3. After the pentavalent vaccine has been launched across the country, a mother comes to the immunization session with a child of age 6 months who has received BCG at birth and all three doses of tetravalent and OPV. The mother requests that her child be given the new vaccine. How will you counsel the mother?

Ans. Explain to the mother that the pentavalent vaccine is not entirely new. The vaccine contains DPT and Hep B, which is similar to the tetravalent vaccine. The only new part of the vaccine is the Hib vaccine. Hence, there is no need to repeat the schedule of 3 vaccine doses with pentavalent. In addition, the children who have not received the new pentavalent vaccine will also get protection from Hib disease because of “herd immunity”, i.e. when a large number of children in a community are immunized against a particular disease, the other unimmunized children in the same community also get protection from disease. Counsel the mother and advise her to return at nine months for measles vaccination and Vitamin A supplementation.

Note: The introduction of pentavalent vaccine should be viewed as an opportunity to strengthen overall routine immunization service delivery.

Recording Pentavalent Doses

Note: Health workers may use existing columns for DPT or HepB for entry of pentavalent vaccine by over-writing with hand. This should be done till the new formats are printed to include pentavalent vaccine (tally sheets, reporting forms, MCH registers, stock registers, Lisio)

Session 5: EVALUATION & FEEDBACK

Trainer's Notes:

1. This will consist of a group evaluation exercise (True or False) and discussions on feedback on the training
2. Use the presentation 3. Encourage discussions and further questions. Ask individuals to respond first for each True and False Question, then ask the group to re-affirm. As far as possible, give every participant a chance.
3. Finally, ask the participants to share their feedback on the training (Content, methodology and arrangements). Record feedback on Flip chart.
4. End the session by thanking all the participants and the staff and colleagues who helped in organizing the training.
5. Share the feedback and evaluation findings with National EPI manager and EPI focal point at District level.

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HAND OUT FOR HEALTH WORKERS

GUIDE FOR HEALTH WORKERS

Frequently Asked Questions

Why are we Introducing Pentavalent vaccine in Timor-Leste?

The change from tetravalent (DPT-Hep B) to pentavalent (DPT-Hep - Hib) means that the DPT-containing injections will now protect children against some forms of serious meningitis and pneumonia, as well as other, less common infections caused by Hib. Pneumonia, as you know, is one of the leading causes of infant and child morbidity and mortality in the country. Meningitis is a very serious disease whose prevalence in Timor-Leste is not accurately known.

The beauty of pentavalent vaccine is that it requires essentially no additional effort from either health workers or from parents, yet it provides protection against a number of additional diseases caused by Hib.

What is the dosage schedule for the new pentavalent vaccine?

The schedule of the new Pentavalent vaccine is same as existing tetravalent vaccine, i.e. at 6, 10 and 14 weeks.

What is the presentation and storage temperature?

The Liquid Pentavalent Vaccine (LPV) in the EPI will be available in 10 dose presentation. Pentavalent vaccine should be stored between 2-8 degree Celsius and should never be frozen. Conditioned ice packs should be used during transportation to prevent freezing

How do you vaccinate children who have already received previous doses of tetravalent vaccine?

If a child has already received one or two doses of DPT-Hep B (tetravalent), then you should finish that child's series of three doses with one or two doses

(as appropriate) of pentavalent vaccine, maintaining the minimum interval of 4 weeks between doses. The ideal ages for the three doses are 6, 10, and 14 weeks; however, if this is not possible, then the second and third doses should be given as soon as possible once 4 weeks have passed since the previous dose.

This guideline is to allow smooth transition from tetravalent (DPT-HepB) to pentavalent (DPT-HepB-Hib) vaccine and avoid confusion by use of two kinds of vaccine at the same time.

What is the dosage and route of vaccination?

The dose of pentavalent vaccine is 0.5 ml. The mode of administration of pentavalent vaccine is the same as DPT vaccine. Pentavalent vaccine is used directly from the vial and given by intramuscular injection in the antero-lateral aspect of the mid-thigh in infants. Pentavalent (DTP-HepB-Hib) vaccine SHOULD NOT be given in buttock or administered intradermally because, firstly, there is risk of damaging the nerves in the area and, secondly, the vaccine will not produce adequate antibody response.

How will you record and report the pentavalent vaccination?

Health workers may use existing columns for DPT or HepB for entry of pentavalent vaccine by over-writing with hand. This should be done till the new formats are printed to include pentavalent vaccine (tally sheets, reporting forms, MCH registers, stock registers, Lisio)

Will there be a change in the Open/Multi-Dose Vial Policy?

The existing open/multi-dose vial policy for DPT-HepB vaccine should be followed for pentavalent (DPT-HepB-Hib). This policy has the potential to reduce vaccine wastage rates by up to 30%, resulting in a significant annual savings in vaccine costs

Which are the Adverse Events following Immunization (AEFI) with pentavalent vaccine?

Hib vaccine has not been associated with any serious adverse effects. However, redness, swelling and pain at the site of injection may occur in as many as 25% of those who have been vaccinated. Such reactions usually start within 1 day after immunization and last for 1–3 days. Less commonly, children may develop fever or can become irritable for a short period.

All AEFI cases, including those following pentavalent vaccine should be reported as per the guidelines for AEFI surveillance and response operational guidelines. As with the use of all vaccines, all vaccinated children should remain under observation for not less than 30 minutes for possibility of occurrence of immediate or early allergic reactions.

Questions that Parents May Ask and Suggested Responses

What does this new vaccine mean for me and my child?

The pentavalent vaccine means that your child will gain protection against some forms of serious diseases such as pneumonia and meningitis in addition to the protection that was given by the old vaccine against diphtheria, tetanus, pertussis, and hepatitis B. The good news is that to receive this extra protection, you and your children do not need to make any more effort. The new vaccine is given at the same times and places as the old one. The new vaccine is no more likely to cause side effects than the old one.

Can you tell me more about the diseases the new vaccine will protect against?

The new vaccine will add protection against various diseases, but the most important ones are pneumonia and meningitis. Pneumonia is a serious respiratory disease that is one of the main causes of child deaths in Timor-Leste. Meningitis is a very serious infection in the cover of the brain or other places that can kill or severely disable a child. It is important to realize that both of these diseases can be caused by different bacteria (germs). The new pentavalent vaccine will protect against one of the germs that cause pneumonia but not against all of the causes of pneumonia. The pentavalent vaccine will protect against the germ that causes most cases of meningitis. Countries that have introduced this vaccine have seen a tremendous decline in meningitis cases.

Are there any other ways to make my family safe from these diseases?

The new vaccine is the only practical way to prevent meningitis. There are various good practices, in addition to immunization, that can reduce a child's risk of suffering from pneumonia. These include:

- +giving breast milk only for a baby's first 6 months
- +not allowing babies to be exposed to smoke from fires or cigarette smoking
- +keeping children well-fed and well nourished
- +keeping children or others with respiratory infections away from young children.
- +ensuring that children receive Vitamin A supplementation

Note: The introduction of pentavalent vaccine should be viewed as an opportunity to strengthen overall routine immunization service delivery.

- PROTECT EVERY CHILD FROM PNEUMONIA AND MENINGITIS CAUSED BY Hib.
- THREE DOSES OF PENTAVALENT VACCINE CAN PROTECT THE CHILD AGAINST FIVE DISEASES – DIPHTHERIA, PERTUSSIS, TETANUS, HEPATITIS B and HAEMOPHILUS INFLUENZA TYPE b.

Ministry of Health,

Republica Democratica de Timor-Leste, 2012

