

# Republic of the Philippines Department of Health OFFICE OF THE SECRETARY

April 14, 2014

**DEPARTMENT MEMORANDUM**No. 2014 - 0155

FOR:

ALL UNDERSCRETARIES, ASSISTANT SECRETARIES, DIRECTORS OF BUREAUS, DOH-REGIONAL OFFICES, AND SPECIALTY HOSPITALS, CHIEFS OF MEDICAL CENTERS AND HOSPITALS, AND OTHERS CONCERNED

SUBJECT: Administration of Pneumococcal Conjugate Vaccine – 13 (PCV 13)

Infections caused by *Streptococcus pneumoniae*, the pneumococcus, are responsible for substantial morbidity and mortality especially in children under 5 years. It is a leading cause of diseases such as meningitis, bacteremia, and pneumonia, as well as less severe conditions such as sinusitis and otitis media in children under five years worldwide.

S. pneumonia includes > 90 serotypes. In pre-vaccination era, 6-11 of these serotypes accounted for less than or equal to 70% of all invasive pneumococcal disease worldwide. The WHO estimates that in 2008, out of the about 8.8 million global annual deaths amongst children aged under 5 years, 476 000 (333 000) - 529 000) were caused by pneumococcal infections. In developing countries case-fatality rates among younger infants may reach 20% for pneumococcal septicemia and 50% for meningitis.

In the Philippines, from 2005 Pneumonia is 1<sup>st</sup> leading cause of morbidity while year 2006 it is 3<sup>rd</sup> cause of infant mortality rate and in, leading cause of child morbidity aged 1-4 years Pneumonia is 1<sup>st</sup> with rate of 23.18 while septicemia is at 9<sup>th</sup> with rate of 4.27. (DOH Health Statistics)

Children with pneumonia may have a range of symptoms depending on their age and the cause of the infection. Bacterial pneumonia usually causes children to become severely ill with high fever and rapid breathing. Some common symptoms of pneumonia in children and infants include rapid or difficulty in breathing, cough, fever, chills, headaches, loss of appetite and wheezing. Children under five with severe cases of pneumonia may struggle to breathe, with their chest moving in or retracting during inhalation. Young infants may suffer convulsions, unconsciousness, hypothermic, lethargy and feeding problems.

Pneumococci causing pneumonia may reach the lungs through different routes. The bacterial pathogens may also spread through contaminated air droplets or may result from blood borne infections. During or shortly after birth, babies are at higher risk of developing pneumonia from coming into contact with organisms in the birth canal or from contaminated substance during delivery. Pneumococci are usually transmitted through respiratory droplets from nasopharynx, particularly from infants and young children which thought to be main reservoir of this agent.

The risk of serious pneumococcal disease remains high during the first 24 months of life. Pneumococcal disease is associated with high mortality, especially when the timely antibiotic treatment is not available. While pneumonia has been consider as an "old disease" in developed and progressing countries, the Philippines is still struggling to fight this killer among infants and children.

The Department of Health (DOH) continues to strengthen advocacy in the control of pneumonia through a comprehensive approach which include but not limited to exclusive breastfeeding up to 6 months, adequate nutrition, and vaccination for infants and children.

While pneumococcal conjugate vaccines have impact on pneumococcal disease as mentioned above, other immunization helps prevent children from developing infections that directly cause pneumonia (e.g. Haemophilus influenza type b –Hib) and may prevent infections that can lead to pneumonia as complications (e.g. measles and pertussis). Thus, three (3) vaccines have the potential to significantly reduce child deaths from pneumonia - measles containing vaccine, Hib vaccine and PCV.

#### A. Coverage

All infants 6 weeks -11 months old. This shall be integrated in the essential vaccination of all infants and children in these priority areas.

# B. Recommended Schedule of Pneumococcal Conjugate Vaccine Immunization

1. The primary infant series consist of three (3) doses of PCV13. Infant shall receive the PCV13 following the recommended schedule below:

Dose (0.5 ml, intramuscular, upper thigh)	Minimum Age to be Given		
1st Dose	1 ½ months (6 weeks)		
2 <sup>nd</sup> Dose	2 ½ months (10 weeks)		
3 <sup>rd</sup> Dose	3 ½ months (14 weeks)		

# C. Co-administration of PCV-13 vaccine

The PCV-13 can safely be administered at the same time as other routine childhood vaccination if administered in a separate syringe at a separate injection sites. This may include Oral Polio Vaccine (OPV), Rotavirus Vaccine (RV) and Pentavalent (DPT-HepB-HiB) vaccines.

# D. Contraindications

PCV-13 should <u>not</u> be given to anyone who has had severe allergic reactions to a prior dose or to any component of the vaccine, including diphtheria toxoid. Infants with moderate or severe illness (temperature  $\geq$  39 °C) should not be vaccinated until they improved. Mild illness such as upper respiratory tract infections is <u>not</u> a contraindication.

# E. Pneumococcal Conjugate Vaccine-13 (PCV-13)

It protects against severe forms of pneumococcal disease, such as meningitis, pneumonia and bacteremia. It will not protect against these conditions if they are caused by agents other than pneumococcus or by pneumococcal serotypes not present in the vaccine.

The PCV-13 vaccine is presented as a liquid adsorbed vaccine in suspension for injection. It is a 1-dose glass vial with rubber bung and a vaccine vial monitor (VVM) on the cap.

In using the vaccine, the vial should be shaken before use. Check the VVM and expiry date for validity. Draw up 0.5 ml with an auto-disable syringe (ADS). Keep the vaccine cool with other vaccines during the session.

Before administering the PCV-13, the health worker shall:

- Determine the infant's age and previous immunization status before deciding which vaccine dose to provide. Ensure that the infant is 6 weeks to 11 months old.
- Establish if the infants is healthy before administering the vaccine (i.e. no fever over 38°C, diarrhea and/or vomiting).
- Screen each infant for contraindications such as allergies to any previous vaccine prior to vaccine administration, taking medications (steroids) that may impair his/her immune response to the vaccine.

# F. Storage and Transport of the PCV-13 Vaccines

DOH shall provide the PCV-13 vaccines to all the health facilities offering immunization services through the DOH Regional Offices (DOH-ROs).

PCV-13 vaccines should be stored between +2°C to +8°C and should NEVER be frozen. Previously frozen vaccines may cause "aseptic" abscess. However, if there is doubt perform "Shake Test". Strictly, conduct a twice a day temperature monitoring in every vaccine storage.

# G. Recording and Reporting

Record the date and site of injection (right or left) each dose of the PCV-13 was administered to the infant in the immunization card of the infants/Mother and Child Book, Early Childhood and Development (ECCD) Card and in the Target Client List (TCL). In the Remarks column, draw 3 columns and indicate column 1 as PCV1, column 2 as PCV2 and column 3 as PCV3.

Children who did not complete the 3-dose schedule should indicate the reason(s) missed. Include in the *monthly*, *quarterly* and *summary* FHSIS reporting the number of infants given the PCV1, PCV2, and PCV3. The indicators shall be calculated as follows:

### H. Immunization Safety

PCV-13 is safe and well tolerated. Severe adverse reactions attributable to the vaccine are extremely rare. Mild side effects such as soreness at the injection site, and transient fever of ≥39°C has been reported in less than 5% of vaccines. It is important to note that, as DPT-HepB-HiB vaccine may be given at the same visit as PCV-13, the children may also have reactions to the pentavalent vaccine. It is important to emphasize to parents that although this vaccine is safe, the side effects as stated above may occur.

#### Mild reactions:

Irritability, crying: very common

Swelling and tenderness at injection site: common in about 1 in 2

Transient fever > 39°C: about 1 in 20

# **Severe Reactions:**

Rare allergic reactions: dermatitis in 1 in 1000

# I. Reporting of Adverse Events Following Immunization (AEFI)

Adverse events after the receipt of the vaccine, even if it is not clear that the vaccine caused the adverse event, should be reported following the existing DOH Issuance Administrative Order No. 2010-0017, "Guidelines in Surveillance and Response to Adverse Events Following Immunization (AEFI).

For strict compliance.

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# ANNEX A: Immunization Schedule for Infants, Philippines

Antigen	AGE						
	At Birth	1 ½ months	2 ½ months	3 ½ months	9 months	12 months	
BCG Vaccine	galait galait				-		
Hepatitis B Vaccine							
DPT-HepB-HiB (Pentavalent Vaccine)		The state of the s					
Oral Polio Vaccine				II E			
Inactivated Polio Vaccine							
Pneumococcal Conjugate Vaccine				Section 1		,	
Rotavirus Vaccine		13					
Measles Vaccine					1000		
Measles-Mumps-Rubella Vaccine	and the second					1925	