



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

May 10, 2022

DEPARTMENT MEMORANDUM

No. 20217 2022-0204

TO: ALL UNDERSECRETARIES, ASSISTANT SECRETARIES, DIRECTORS OF CENTERS FOR HEALTH DEVELOPMENT; MINISTER OF HEALTH – BANGSAMORO AUTONOMOUS REGION IN MUSLIM MINDANAO; CHIEFS OF MEDICAL CENTERS AND HOSPITALS; ALL LOCAL GOVERNMENT UNITS; AND OTHERS CONCERNED

SUBJECT: Guidelines on the Shifting from Pneumococcal Conjugate Vaccine 13 (PCV13) to Pneumococcal Conjugate Vaccine 10 (PCV10) in the Routine Immunization for Children

I. BACKGROUND

Pneumonia is the leading cause of morbidity and mortality among children under five (5) years of age. In the country, among the most common serotypes of *Streptococcus pneumoniae*, the bacteria that causes pneumonia, are serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F. This is according to the 2015-2019 Invasive Pneumococcal Disease (IPD) isolate surveillance of the Research Institute of Tropical Medicine (RITM).

To prevent the fatalities and other diseases caused by *S. pneumoniae* such as Acute Otitis Media (AOM), meningitis and sepsis, the National Immunization Program (NIP) introduced the Pneumococcal Conjugate Vaccine (PCV) in 2013 in regions BARMM and CARAGA. This was later expanded to all the regions in the year 2014 as the country is still struggling with the high number of cases of pneumonia in children and its complications, most especially in children < 24 months of age.

The World Health Organization (WHO), in 2019, released a position paper stating that both PCV 10 and PCV 13 have substantial impacts against pneumonia, vaccine type (VT) invasive pneumococcal disease, and nasopharyngeal (NP) carriage in a variety of settings. The choice of product to be used in a country should be based on programmatic characteristics, vaccine supply, vaccine price, the local and regional prevalence of vaccine serotypes and antimicrobial resistance patterns.

As such, PCV underwent reassessment by the Health Technology Assessment Council (HTAC). Recently, they released their recommendations to utilize the PCV indicated for the most important pneumococcal serotypes that are relevant to the country. Moreover, they also stated that the price at which both vaccines will be offered during the actual purchase shall be taken into consideration. Hence, the decision to shift to PCV10 and release this policy for guidance on the implementation for PCV 10 administration.

II. OBJECTIVE

This Memorandum aims to provide technical guidelines among our program managers, implementers, service providers and immunization partners in public health facilities such as rural health units (RHU), barangay health stations (BHS), and public hospitals on the shifting from single-dose vial PCV13 to multi-dose vial PCV10 to continue protection of children against PCV-related diseases.

III. GENERAL GUIDELINES

- A. All infants 6 weeks up to 12 months shall be given the complete three (3) doses of PCV10 according to the recommended schedule.
- B. Catch-up immunization for PCV10 shall follow the algorithm in Administrative Order (AO) 2021-0045 'Guidelines on the Conduct of Routine Immunization for Children'.
- C. Regular and appropriate microplanning, coordination, and social mobilization shall be undertaken by all LGUs and local health workers to implement the shifting to PCV10.
- D. Adverse Drug Event From Immunization shall be monitored and reported according DOH Issuance Administrative Order No. 2010-0017 "Guidelines in Surveillance and Response to AEFIs"
- E. PCV10 shall be included in vaccination reports during the conduct of catch-up immunization. It shall be reflected in the Field Health Services Information System (FHSIS) appropriately.

IV. SPECIFIC GUIDELINES

A. Coverage

- 1. All infants 6 weeks up to 12 months shall be given the complete three (3) doses of PCV10 according to the recommended routine immunization schedule below. The health care workers (HCWs) must ensure that all infants follow the recommended schedule for PCV.

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

- 2. In case the child misses the schedule, the catch-up immunization for PCV10

shall follow the algorithm for PCV as presented in Administrative Order 2021-0045 'Guidelines on the Conduct of Catch-up for Routine Immunization for Children'.

B. Vaccine

PCV10 is a 4-dose formulation presented as a liquid adsorbed vaccine in suspension for injection. It must be kept cool, but not frozen. Opened vials with remaining unutilized doses should be discarded after six (6) hours from first opening or at the end of each immunization session within the day whichever comes first.

C. Preparatory Activities

1. Orientation shall be conducted to the Centers for Health Development (CHDs) and Provincial/City/Municipal Health Offices with emphasis on the rationale for the product switch from PCV13 to PCV10.
2. Proper planning and coordination in anticipation of the procurement activities, logistics, distribution, and delivery necessary for smooth transition from PCV13 to PCV10 vaccines shall be performed by all implementing agencies.
3. Necessary modifications shall be made to include the PCV10 in the vaccine and immunization supply allocation and distribution plan at the national, regional and local levels.
4. All concerned officers shall ensure timely and adequate requisition, delivery and receipt of the PCV10 vaccines and supplies.
5. Analysis shall be conducted on inventory, distribution, utilization, and wastage reports submitted by provinces/cities.

D. Implementation

1. Administration

a. Before administering the PCV10, the health worker shall:

- Determine the infant's age and previous immunization status before deciding which vaccine doses to provide. Ensure that the infant is between 6 weeks to 12 months old. IF the infant has received his/her first and/or second dose of PCV13, **administer PCV10 as second and/or third dose.**

Note: Utilize all remaining stocks of PCV13 before using PCV10 for routine immunization.

- Establish if the infant is healthy or active before administering the vaccine (i.e. no fever over 38°C, severe 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 their immune response to the vaccine.
- b. PCV10 shall be given 0.5 mL, intramuscularly at the upper thigh. Its administration site shall be different from the administration site of other concurrent vaccines (ie. PCV - right upper thigh and pentavalent vaccine - left upper thigh).
 - c. The PCV10 can safely be administered concurrently with other vaccines scheduled such as Oral Polio Vaccine (OPV) and pentavalent vaccines. However, the vaccine must not be mixed with other vaccines in the same syringe.

It is recommended that the oral vaccines shall be given first; followed by the injectable vaccines

- d. PCV10 should not 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 $\geq 39^{\circ}\text{C}$) should not be vaccinated until they improve. Mild illness such as upper respiratory tract infection, mild diarrhea, otitis media, or skin rashes are not a contraindication for vaccination. Furthermore, breastfeeding infants, malnourished or on antibiotics are not contraindications for vaccination.

2. Storage and Transport

- a. DOH shall provide the PCV10 vaccines to all the health facilities offering immunization services through the Centers for Health Development (CHDs).
- b. PCV10 vaccines should be stored between $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ and should NEVER be frozen. Previously frozen vaccines may cause "sterile" abscesses. However, if there is doubt that the vaccines have been frozen, a "Shake Test" should be performed. Monitoring of vaccine temperature should be strictly conducted at least twice a day in every vaccine storage.
- c. Every health facility with refrigerators for vaccine storage shall post a door sticker on proper handling and storage of the PCV10. Likewise, the same sticker shall be posted on the cover of the vaccine carriers. This shall remind the health worker on the proper handling of the vaccine; that is:
 - After opening, this vaccine vial should be handled in the same manner as a reconstituted BCG or measles vaccine vial.
 - Discard any unused dose at the end of the immunization session or after six hours from opening, whichever comes first.
 - During the immunization session, opened PCV10 vials should be

placed inside the vaccine carrier with appropriate and pre-conditioned ice packs. Opened vials should never be returned inside the refrigerator.

3. Immunization Safety

- a. PCV is safe and well tolerated. Severe adverse reactions attributable to the vaccine are extremely rare.
- b. Mild side effects such as soreness at the injection site, and transient fever of ~39°C have been reported in less than 5% of vaccinees. It is important to note that, as DTP-HepB-Hib vaccine may be given at the same visit as PCV, the child may also have reactions to the pentavalent vaccine. If these 2 vaccines are co-administered, it is best to inject these vaccines in separate limbs for proper monitoring of local injection site reactions, in case this may happen.
- c. 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 vaccine recipients
 - Transient fever >39°C: about 1 in 20 vaccine recipients
 - Severe Reactions:
 - Rare allergic reactions: dermatitis in 1 in 1000 vaccine recipients

E. Monitoring and reporting of Adverse Events Following Immunization

1. All detected AEFIs both minor and serious, shall be reported to the nearest health facility. The existing DOH guidelines on AEFI surveillance and response (Administrative Order (A.O.) No. 2016-2006 '*Revised Guidelines on Surveillance and Response to Adverse Events Following Immunization*') shall be observed for this purpose.
2. AEFI cases needing hospitalization shall be managed and referred to the appropriate health facility following A.O. 2016-0025: Guidelines on the Referral System for Adverse Events.

F. Recording and Reporting

1. All children 6 weeks to 23 months of age administered with PCV shall be included in the reports regularly.
2. Record the date each dose of the PCV10 was administered to the infant in the immunization card of the infant/Mother and Child Book, Early Childhood and Development (ECCD) Card and in the Target Client List (TCL).

3. In the Remarks column, indicate reasons for missed dose for those children who have not completed the three-dose schedule.
4. 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:

$$\% \text{ infants given PCV1} = \frac{\# \text{ of infants given PCV1}}{\text{Total \# of infants 0-11 months old}} \times 100$$

$$\% \text{ infants given PCV2} = \frac{\# \text{ of infants given PCV2}}{\text{Total \# of infants 0-11 months old}} \times 100$$

$$\% \text{ infants given PCV3} = \frac{\# \text{ of infants given PCV3}}{\text{Total \# of infants 0-11 months old}} \times 100$$

$$\% \text{ infants given PCV3 as Catch-up} = \frac{\# \text{ of infants 12-23 months given PCV3}}{\text{Total \# of infants 0-23 months old}} \times 100$$

V. REPEALING CLAUSE

Other related issuances, namely, DM 2014-0155 entitled '*Administration of Pneumococcal Conjugate Vaccine - 13 (PCV13)*', DM 2014-0207 entitled '*Administration of Pneumococcal Conjugate Vaccine - 13 (PCV13)*' and DM 2013-0204 entitled '*Administration of Pneumococcal Vaccine-10 (PCV10) for infants in ARMM and CARAGA*' not consistent with the provisions of this Order are hereby revised, modified, or rescinded accordingly. Nothing in this Order shall be construed as a limitation or modification of existing laws, rules and regulations.

VI. EFFECTIVITY

This Department Memorandum shall take effect immediately.

By the authority of the Secretary of Health


MARIA ROSARIO SINGH-VERGEIRE, MD, MPH, CESO II
Undersecretary of Health

Annex A. Citations

Department of Health. (2013). *Administration of Pneumococcal Vaccine-10 (PCV10) for infants in ARMM and CARAGA*. Manila: DOH

Department of Health. (2014). *Administration of Pneumococcal Conjugate Vaccine - 13 (PCV13)*. Manila: DOH

Health Technology Assessment Council (2015). *Reassessment of 10- versus 13-valent Pneumococcal Conjugate Vaccines (PCV) in the Philippines*. Manila: DOH

World Health Organization. (2019). Weekly epidemiological record 94, 85-104. *Pneumococcal conjugate vaccines in infants and children under 5 years of age: WHO position paper- February 2019*. Switzerland: Geneva.

Department of Health. (2018). *Field Health Services Information System (version 2018)*. Manila: DOH