



Republic of the Philippines
Department of Education
 REGION X - NORTHERN MINDANAO
 DIVISION OF MALAYBALAY CITY

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Division Advisory
 No. 021 series of 2022

TO : Assistant Schools Division Superintendent
 Chief Education Supervisors, CID and SGOD
 Public Elementary and Secondary School Heads
 All Others Concerned

FROM : **VICTORIA V. GAZO, PhD, CESO V**
 Schools Division Superintendent

DATE : March 01, 2022

RE : **DISSEMINATION OF DOH MEMORANDUM No. 2022-0041, S. 2022:
 INTERIM GUIDELINES ON THE MANAGEMENT AND
 ADMINISTRATION OF TOZINAMERAN COVID-19 MRNA VACCINE
 (NUCLEOSIDE-MODIFIED) (COMINARTY) PFIZER COVID-19 VACCINE
 TO PEDIATRIC POPULATION AGE 5-11 YEARS OLD.**

1. This Office hereby informs the field on **DOH MEMORANDUM No. 2022-0041, S. 2022: INTERIM GUIDELINES ON THE MANAGEMENT AND ADMINISTRATION OF TOZINAMERAN COVID-19 MRNA VACCINE (NUCLEOSIDE-MODIFIED) (COMINARTY) PFIZER COVID-19 VACCINE TO PEDIATRIC POPULATION AGE 5-11 YEARS OLD.** (Please see attachment).

2. Widest dissemination and compliance to this memorandum is desired.

Encl.:

As stated

Copy Furnished:
 SGOD-School Health Unit
 Records Unit



Address: Sayre Hi-way, Purok 6, Casisang, Malaybalay City
 Telefax No.: 088-314-0094; Telephone No.: 088-813-1246
 Email Address: malaybalay.city@deped.gov.ph



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

January 24, 2022

DEPARTMENT MEMORANDUM

No. 2022 - 0041

FOR: ALL UNDERSECRETARIES AND ASSISTANT SECRETARIES; DIRECTORS OF BUREAUS, SERVICES AND CENTERS FOR HEALTH DEVELOPMENT; MINISTER OF HEALTH - BANGSAMORO AUTONOMOUS REGION IN MUSLIM MINDANAO; EXECUTIVE DIRECTORS OF SPECIALTY HOSPITALS AND NATIONAL NUTRITION COUNCIL; CHIEFS OF MEDICAL CENTERS, HOSPITALS, SANITARIA AND INSTITUTES; AND OTHERS CONCERNED

SUBJECT: Interim Guidelines on the Management and Administration of Tozinameran COVID-19 mRNA vaccine (nucleoside-modified) [Cominarty] Pfizer COVID-19 Vaccine to Pediatric Population Ages 5-11 Years Old

I. RATIONALE

The Department of Health (DOH), together with other government agencies, has been proactive in developing policies that guide government sectors, non-government organizations (NGO), and private entities in the implementation of various efforts for COVID-19 vaccination. As new evidence emerges and various decisions at different levels are made every day, there is a need to align policy directions towards ensuring timely, effective, and coordinated response for COVID-19.

In the context of the prior issuance of Emergency Use Authorization (EUA) by the Philippine Food and Drug Administration (FDA) dated December 22, 2021, and based on issuances from the World Health Organization (WHO) and Centers for Disease Control (CDC) Advisory Committee on Immunization Practices (ACIP), the DOH recommends the expansion of the COVID-19 vaccination program to include the pediatric population ages 5 - 11 years old.

In view of the foregoing, this Department Memorandum (DM) is issued to provide guidance to all concerned agencies of the National Vaccination Operations Center (NVOC), Regional Vaccination Operations Centers (RVOCs) or Centers for Health Development (CHDs), Local Vaccination Operations Center (LVOCs) or Local

Government Units (LGUs), Provincial Health Offices (PHOs), City Health Offices (CHOs), Rural Health Units (RHUs), Implementing Units, and Vaccination Sites, both public and private, on the management and administration of the Tozinameran COVID-19 mRNA vaccine (nucleoside-modified) [Cominarty] Pfizer COVID-19 Vaccine as part of the implementation of the rollout of the COVID-19 vaccination to the pediatric population ages 5 - 11 year olds. It is further clarified that Department Circular Nos. 2021-0464, 2021-0464-A, 2021-048 and other relevant issuances shall cover pediatric population ages 12 - 17 year olds.

II. OBJECTIVES

This issuance provides interim guidelines on the management and administration of Tozinameran COVID-19 mRNA vaccine (nucleoside-modified) [Comirnaty] Pfizer COVID-19 Vaccine referred to as Pediatric Pfizer COVID-19 vaccine in this guidelines to pediatric population ages 5-11 year olds.

III. DEFINITION OF TERMS

- A. Assent - refers to the willingness of the child to be vaccinated. If a child is below seven (7) years old, no formal assent shall be needed as long as there is no manifestation of dissent. For children ages seven to eleven (7-11) years old, a verbal assent shall be acceptable.
- B. Child-Caring Agency - refers to duly licensed and accredited agency by the Department of Social Welfare and Development (DSWD) that provides twenty-four (24) hour residential care services for abandoned, orphaned, neglected, or voluntary committed children as stipulated in Article 1, Section 3(i) of RA No. 8552 "Domestic Adoption Act of 1998".
- C. Guardian - refers to the legal or judicial guardian.
 - 1. Legal guardian - refers to a guardian of the minor by express provision of law without the need for judicial appointment, as in the case of the parents over the persons of their minor children or those exercising substitute parental authority of the minor child in accordance with Article 216 of the Family Code.
 - 2. Judicial guardian - refers to a guardian appointed by the court over the person and/or property of the ward to represent the latter in all his civil acts and transactions.
- D. Parent - refers to the legitimate, illegitimate, or adoptive father or mother of the minor child. Adoption for the purpose of this Department Circular shall refer to legal adoption.

- E. Pediatric Population - refers to a group of the population between birth and 18 years of age.
- F. Informed Consent - refers to the patient's right to a clear, truthful and substantial explanation, in a manner and language understandable to the patient, of all proposed procedures, whether diagnostic, preventive, curative, rehabilitative or therapeutic, wherein the person who will perform the said procedure shall provide his name and credentials to the patient, possibilities of any risk of mortality or serious side effects, problems related to recuperation, and probability of success and reasonable risks involved.

IV. GENERAL GUIDELINES

- A. The pediatric population ages 5-11 years old shall be recommended to be vaccinated with the *Tozinameran COVID-19 mRNA vaccine (nucleoside-modified) [Comirnaty] Pfizer COVID-19 Vaccine* approved for use to the aforementioned age group based on the EUA issued by the Philippine FDA *(Copy of the EUA may be accessed at the FDA website: <https://www.fda.gov.ph/wp-content/uploads/2022/01/EUA-Pfizer-10mcg-5-11-website.pdf>)*.
- B. Vaccination of the 5-11 years old pediatric population shall be implemented simultaneously with the current eligible priority groups.
- C. The COVID-19 vaccination process in vaccination sites including the registration, screening, counselling, vaccine recipient reporting, Adverse Effects Following Immunization (AEFI) monitoring and referral shall follow DOH Department Memorandum 2021-0099 otherwise known as Interim Omnibus Guidelines for the Implementation of the National Vaccine Deployment Plan for COVID-19 and other relevant policies.
- D. Instructions for COVID-19 vaccination providers and administrators on storage and handling, dosing and schedule, administration, contraindications, warnings, adverse reactions, and use with other vaccines shall follow Philippine FDA EUA and the product information. *(Copy of the product label may be viewed at the FDA website: <https://www.fda.gov.ph/wp-content/uploads/2022/01/Comirnaty-10-mcg-Conc-DFI-IM-Product-Information-for-HCPs-EN.pdf>)*
- E. Protocols for the management of AEFI and Adverse Events of Special Interest (AESI) shall follow the provisions of the approved COVID-19 Vaccine for children with EUA of the FDA, succeeding guidelines from the FDA, and other recognized professional organizations and regulatory bodies, as new evidence arise.

V. IMPLEMENTING GUIDELINES

A. Implementation Roll-out

1. The vaccination rollout to 5-11 years old shall be implemented and shall commence in a phased approach.
 - a. Phase 1: Pilot rollout in designated vaccination sites in the National Capital Region (NCR) as determined by the LGUs and the NVOC.
 - b. Phase 2: Expansion of the vaccination rollout in the NCR, pilot rollout in designated vaccination sites in other regions. The Phase 2 shall commence a week after the Phase 1 Program Implementation Review.
2. All 5-11 years old children are eligible to be vaccinated in either Phase 1 or 2, subject to health screening and assessment.

B. Vaccination Strategies

1. The LVOCs may utilize various vaccination strategies to ramp up vaccination of the 5-11 years old.
 - a. For the pilot runs, the LVOCs shall utilize the fixed site strategy with the designation of vaccination sites solely for the vaccination of 5-11 years old.
 - b. After the pilot runs, the LVOCs may utilize the temporary post strategy where vaccination sites shall be established in barangays, orphanages, schools (elementary and kindergarten), among others.
 - c. The NVOC shall determine if the implementation of mobile vaccination strategy may be implemented once the rollout to 5-11 year old children is stabilized.

C. Allocation and Distribution of COVID-19 Vaccines

1. The NVOC and RVOCs shall allocate COVID-19 vaccines to LVOCs based on the projected 5-11 years old population in their respective area of jurisdiction.
2. The NVOC and RVOCs may directly allocate and distribute COVID-19 vaccines to priority areas based on the unvaccinated 5-11 years old.

D. Vaccine Administration, Storage, Handling and Preparation

1. Dosage/Form and vaccine administration

- a. Pfizer COVID-19 vaccine for 5-11 year old children is a 10 microgram/dose concentrate for dispersion for injection (IM) COVID-19 mRNA vaccine (nucleoside modified).
- b. One dose (0.2 mL) of Pfizer COVID-19 vaccine for 5-11 years old contains 10 micrograms of Tozinameran
- c. The second dose of the Pfizer COVID-19 vaccine shall be given three (3) weeks after the first dose to complete the vaccination course.

2. Packaging

- a. Pfizer COVID-19 vaccine for 5-11 years old comes in a multidose vial which shall be diluted before use. One (1) vial (1.3 mL) contains 10 doses of 0.2 ml after dilution.
- b. Verify that the vial contains pediatric doses of Pfizer COVID-19 vaccine. It shall come with a stopper and an orange flip-off plastic cap with aluminum seal.

3. Shelf life and Storage

- a. Pfizer COVID-19 vaccines for 5-11 years old shall arrive either frozen at -90° to -60°C or at 2°C to 8°C.
- b. The vaccines may be stored for six (6) months at -90°C to -60°C.
 - i. When stored at -90°C to -60°C, A 10-vial pack shall be thawed at 2°C to 8°C for four (4) hours. An individual vial shall be thawed at room temperature (up to 30°C) for 30 minutes. Once thawed, this may be stored at 2° to 8°C for 10 weeks within the 6-month shelf life.
 - ii. Upon moving the vaccine to 2 °C to 8 °C storage, the updated expiry date shall be written on the outer carton and the vaccine shall be used or discarded by the updated expiry date. The original expiry date shall be crossed out.
 - iii. Unpunctured vials may be stored in the refrigerator at 8° to 30°C for a total of 12 hours.

- iv. Once thawed, do NOT refreeze the vaccine.

E. Vaccination Teams

1. LVOCs and partners shall designate a dedicated team/s for designated vaccination sites for 5-11 years old to avoid medication errors given the difference in the product formulation of the pediatric Pfizer COVID-19 vaccines compared to adult formulation Pfizer COVID-19 vaccines.
2. All members of the vaccination teams dedicated to designated vaccination sites for 5-11 years old are required to undergo training specific for Pfizer COVID-19 vaccines for 5-11 years old provided by NVOC.

F. Pre-registration and Scheduling

1. Master listing of pediatric vaccination ages 5-11 years old shall not be required. Targets of each LGU shall be based on the PSA's projected population for children ages 5-11.
2. However, pre-registration based on the processes required by the LVOCs shall be necessary to ensure ease in planning and determination of logistics, human resource and COVID-19 vaccine requirements.

G. Vaccination Site Preparation

1. LVOCs shall identify and utilize a dedicated vaccination site for the vaccination of 5-11 years old in accordance with the Department Memorandum No. 2021-0406 entitled "*Interim Guidelines on the Identification and Utilization of COVID-19 Vaccination Sites*". Other population groups shall not be vaccinated in designated vaccination sites for 5-11 years old.
2. COVID-19 vaccination sites are encouraged to establish facilitative mechanisms for persons with special needs, such as but not limited to Persons with Disabilities. Vaccination sites shall ensure sufficient assistive devices/equipment such as wheelchairs, handrails, among others, to aid the vaccine recipients in the vicinity.
3. To manage possible cases of anxiety-related symptoms or syncope, vaccination sites shall ensure that beds or cots in the post-vaccination monitoring area are present and available for use.
4. Pfizer COVID-19 vaccines for 5-11 years old shall preferably be stored in a dedicated vaccine refrigerator or other cold storage equipment.

5. The vaccination site shall be large enough, child-friendly and well-ventilated to accommodate the presence of the vaccine recipient's parent/guardian.

H. Vaccination Process

1. Waiting Area / Registration

- a. The vaccine recipient shall be accompanied by a parent/guardian at the vaccination site.
- b. The following documents shall be presented in the registration area (*Refer to Annex A for list of proof of filiation and valid identification cards*):
 - i. Proof of filiation or relationship between the child and the accompanying adult or other supporting document proving authority to give informed consent or assent.
 - ii. Valid identification cards.

2. Health Education and Informed Consent/Assent Area

- a. The vaccination team shall ensure that the vaccine recipient and his/her parent/guardian are informed of the benefits, risks and possible side effects of the COVID-19 vaccines.
- b. The vaccination team may utilize applicable digital technology and provide fact sheets to vaccine recipients and parents/guardians to convey valuable information about the COVID-19 vaccine, contact details of referral facilities in case of Adverse Events Following Immunization (AEFI) and/or Adverse Events of Special Interest (AESI), and necessary information for receiving the second dose, including vaccination schedule.
- c. After thorough health education to both the vaccine recipient and the parent/guardian, and prior to vaccine administration, the informed consent shall be given and signed by the parent/guardian, and the assent shall be given by the vaccine recipient:
 - i. If a child is below seven (7) years old, no formal assent shall be needed, as long as there is no manifestation of dissent from the child. Documentation of non-dissent shall be required as part of the Informed Assent Form.
 - ii. If a child is seven to eleven (7-11) years old, written assent shall be requested, and documented by the child's signature. A verbal assent

shall also be acceptable. Documentation of verbal assent shall be required as part of the Informed Assent Form.

3. Health Screening and Assessment Area

- a. A thorough health screening and assessment, using the Health Declaration and Screening Form, shall be conducted by a trained health personnel. Both the vaccine recipient and the parent/guardian may provide the information requested by the health screener.
 - i. For vaccine recipients with COVID-19 infection, they may receive vaccination after the recommended isolation period provided there is no fever during the previous 24 hours and there has been substantial improvement in respiratory symptoms of the acute illness.
 - ii. For vaccine recipients that are close contacts of COVID-19 cases, they may receive vaccination after 14 days of quarantine.
 - iii. For vaccine recipients that have been given other non-COVID-19 vaccines for other conditions, the preferred interval is 14 days. Nevertheless, the child may be given a COVID-19 vaccination within this interval if deemed necessary by the attending physician.
- b. Weighing of the vaccine recipient shall be included in the process for proper computation of appropriate dose of paracetamol to be advised to the parent or accompanying adult, once the vaccine recipient experiences fever after vaccination.
- c. Medical certification shall be required for the pediatric vaccine recipients with the following comorbidities :
 - i. Medical complexity
 - ii. Genetic conditions
 - iii. Neurologic conditions
 - iv. Metabolic/ endocrine diseases
 - v. Cardiovascular diseases
 - vi. Obesity
 - vii. HIV Infection
 - viii. Tuberculosis
 - ix. Chronic Respiratory Diseases
 - x. Renal Disorders
 - xi. Hepatobiliary Diseases
 - xii. Immunocompromised state due to disease or treatment
- d. The medical certification shall provide information of the vaccine recipient's comorbidity/ies and shall indicate that the vaccine recipient can

receive the COVID-19 vaccine after thorough assessment and evaluation on the date of certification. *(Refer to Annex B for the detailed list of comorbidities and Annex C for the copy of the template for medical certification)*

- e. Blood pressure taking prior to vaccination shall not be required but can be done at the discretion of the vaccination team in the vaccination sites.
- f. Only vaccine recipients cleared by the vaccination team to receive the COVID-19 vaccine shall proceed to the vaccine administration area.
- g. Deferred vaccine recipients shall be provided with sufficient information when they are eligible to receive the COVID-19 vaccine.

4. Vaccine Administration Area

- a. Before administering the COVID-19 vaccine, the vaccinator shall check for the following:
 - i. Presence of the signed informed consent and assent form, as applicable.
 - ii. Presence of the signed health screening form as cleared by the health screener.
 - iii. Verify that the vial of the Pfizer COVID-19 vaccine has an orange plastic cap and read the label.
- b. The vaccine recipient shall receive the required dosage as stipulated in the EUA by the Philippine FDA. There are no weight requirements for the Pfizer COVID-19 vaccination and COVID-19 vaccine dosage does not vary by patient weight.
- c. Dilution of Pfizer COVID-19 vaccines for 5-11 years old
 - i. Once thawed, the vaccine shall be diluted in its original vial with 1.3 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.
 - ii. Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.3 mL air into the empty diluent syringe.
 - iii. Gently invert the diluted dispersion ten (10) times. Do NOT shake.
 - iv. The diluted vaccine shall come as a white to off-white dispersion with no particulates visible. Diluted vaccines shall NOT be used if particulates or discolouration are present.
 - v. The diluted vials shall be marked with the appropriate date and time.

d. Preparation

- i. After dilution, the vial shall contain 2.6 mL from which 10 doses of 0.2 mL can be extracted.
- ii. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab and withdraw 0.2 ml for each dose of vaccine.
- iii. Discard any unutilized vaccine within 12 hours after dilution.

e. Appropriate syringes and ancillaries shall be used according to the manufacturer's product instructions. The recommended syringe for inoculation is a gauge 0.2 low dead-volume AD syringe. The low dead-volume syringe and needle combination shall have a dead volume of no more than 35 microliters. Tuberculin or 1 cc syringe with 0.1 ml increments may be used as an alternative.

f. The prepared vaccine is preferably administered intramuscularly in the deltoid area. The vastus lateralis muscle of the anterolateral thigh may also be used.

g. The parent/guardian shall be physically present during the vaccine administration. The vaccinator shall inform the vaccine recipient and the parent/guardian of the vaccine brand, the doses required and the possible adverse effects following immunization.

h. If the parents/guardians/household members of the pediatric population ages 5-11 years old are not yet vaccinated with COVID-19 vaccines, they shall be referred to the LVOC/LGU and shall be scheduled for vaccination.

5. Post-Vaccination Monitoring Area

a. After vaccination, the vaccine recipient shall stay for post-vaccination monitoring in case of any severe allergic reaction and anaphylaxis and for immediate treatment. The vaccine recipient shall be monitored for 15 minutes if without any known allergies or history of anaphylaxis, and for 30 minutes if with known allergies or history of anaphylaxis.

b. The vaccination team shall advise the accompanying adult on proper management in case pediatric vaccine recipients experience AEFI.

- i. Calculate the appropriate dose of paracetamol to be given once with fever (temperature $> 37.8^{\circ}\text{C}$) based on weight of the vaccine recipient:
 1. Give approximately 10-15 mg/kg/dose every 4-6 hours. If computation falls between whole numbers, choose the lower dose.

2. Instruct the parent or guardian of the child that if a child has a fever (body temperature of $>37.8^{\circ}\text{C}$), give paracetamol immediately and after 4-6 hours.
 3. If fever persists after giving two (2) doses of paracetamol, seek medical advice from a pediatrician.
- c. The vaccination team shall also remind the parents/guardians to receive the vaccines appropriate for their age that are available in public health facilities (e.g. measles-rubella vaccine, tetanus vaccine) and in private health facilities.

I. Adverse Events Following Immunization

1. All designated vaccination sites shall inform and ensure awareness of each and every recipient and their patient/guardian of the following:
 - a. Most frequently reported AEFIs as referenced in the FDA's Emergency Use Authorization and other product information available at www.fda.gov.ph/list-of-fda-issued-emergency-use-authorization/.
 - b. Symptomatic relief or management for reactogenic reactions encountered, or AEFIs that are expected to occur soon after vaccination, (i.e. vaccination site pain, warmth, erythema, malaise, headache, bleeding) as aligned with DM 2021-0218, with the subject "*Further Clarification on the National Vaccination Deployment Plan on Health screening and management of AEFI.*"
 - c. A responsive and functional 24/7 hotline, contact information, and/or designated referral facility in their area which recipients or their guardians can contact for any concern, particularly for consultation and steps to take regarding post-vaccination AEFIs.
 - d. Coverage of financial risk protection provided by the Philippine Health Insurance Corporation (PHIC), more specifically the Vaccine Injury Compensation Package (VICP) as specified in PhilHealth Circular 2021-0007 for A1 or A2 assessed cases by the National AEFI Committee. Moreover, the PHIC benefits that shall remain in effect in cases of hospitalization, as well as other available financial and medical assistance, should be communicated.
2. All healthcare providers, regardless whether they have administered the COVID-19 vaccines, providing care in any setting, regardless of the nature of employment, shall continually update themselves on the following:

- a. Current operational definition of serious AEFIs for the detection, notification, and reporting as referenced in DM 2021-0220.
 - b. Latest clinical practice guidelines across all diseases regardless of their current specialty, with emphasis on the diagnosis and management of the most frequently encountered or familiar adverse events following immunization, as stipulated in DM 2021-0218. Particularly, the healthcare providers must be well informed on the recognition and management of specific events including but not limited to anaphylaxis, myocarditis, pericarditis, and immunization stress-related response (ISRR).
 - c. Latest local guidelines in the referral or care coordination of their patients within their health care provider network.
 - d. Latest service capabilities and referral hotlines of facilities or individual service providers within their localities, particularly for the fields of allergology, cardiology, neurology, and hematology based on the present working impression.
 - e. Hotlines, offices, websites and other contact information of government and non-government resources for medical financial assistance of patients.
 - f. Contact information, and process of filling out and submitting the most recent version of the Case Investigation Form (CIF) for AEFI of COVID-19 vaccines, to the hospital or local epidemiology surveillance units, with special attention to reported AEFI cases that all healthcare providers, or the patient/s and/or their respective families, have clinical suspicion with.
 - g. Extent of the immunity from liability of the Republic Act 11525 and its Implementing Rules and Regulations may cover them.
3. All LVOCs shall assume the responsibility of ensuring reiteration and dissemination of available guidelines for immediate management and response for specific adverse events of the vaccines that will be administered to ages 5-11 years old (anaphylaxis, myocarditis, pericarditis, and immunization stress-related response). LVOCs must ensure the following:
 - a. Dissemination of materials by the Philippine Society of Allergy, Asthma, and Immunology (PSAAI) and guidelines on the assessment, diagnosis, and management of severe allergic reactions caused by COVID-19 vaccines.
 - b. At least one complete AEFI/AESI kit per composite team to manage AEFIs including presentations of allergic reactions. *It must be noted that some*

emergency drug dosages for the pediatric population are different from adult individuals.

- c. Awareness of all healthcare providers in anticipation of AEFIs from 5-11 years old with comorbidities and increased understanding of AEFIs documented and related to specific vaccines, such as myocarditis from mRNA vaccines.
 - d. Awareness of immunization-stress related reactions (ISRR) or anxiety-related reactions from COVID-19 vaccines, how they are recognized or assessed, their difference from an allergic reaction/ anaphylaxis, and how to properly manage these symptoms.
4. All LVOCs must educate all vaccine recipients and their guardians that some of the AEFIs that they experience might be similar to the symptoms of COVID-19 such as sore throat, runny nose, and/or cough. In line with this, LVOCs shall also clearly emphasize and reiterate to all disease reporting units including all health facilities and vaccinated individuals and their guardians that the vaccine will not cause COVID-19.
 5. All LVOCs shall ensure that reporting lines for vaccination sites and disease reporting units, including all health facilities and hospitals, are aligned, checked and functional. This involves ensuring the participation of non-hospital reporting sites such as private clinics and physicians upon encountering AEFIs in surveillance and response. As a reference, steps in the AEFI Surveillance Cycle as well as the accountable offices are found in *Annex I*. For health systems preparation for response, DM 2021-0218, with the subject "Further Clarification on the National Vaccination Deployment Plan on Health Screening and Management of Adverse Events Following Immunization", and NVOC Advisory No. 59 with the subject, "Reiteration on the Implementation of Post-Vaccination Education and Reporting of Adverse Events Following Immunization (AEFI)" may serve as a reference.
 6. The latest Case Investigation Form (version 2) must be used in reporting all serious and non-serious AEFI cases for the pediatric vaccination rollout and is accessible through the link, <http://bit.ly/aefic19ph>.
 7. All serious and non-serious AEFI cases must also be encoded in the VigiFlow system.
 8. The clinical practice guidelines and references, such as other pertinent infographic materials, may be accessed through <http://bit.ly/COVID-19CPGs>.

J. Report

1. The 5-11 years old pediatric population shall be categorized as:
 - a. 5-11 years old with comorbidities: Pediatric A3 (5-11 years old)
 - b. 5-11 years old without comorbidities: Rest of the Pediatric Population or ROPP (5-11 years old)

K. Demand Generation and Communications

1. LVOCs shall utilize the LGU Demand Generation playbook updated for pediatric COVID-19 vaccination to update their microplans. LVOCs shall provide bimonthly updates to CHDs on their implementation, including social listening data as prescribed in the playbook.
2. CHDs shall provide bimonthly updates to Task Group Demand Generation and Communications (TG DGC) on the progress of activities based on microplans.
3. CHDs shall ensure feedback mechanisms and social listening by:
 - a. Reporting frequently asked questions, misinformation, and rumors weekly to the TG DGC,
 - b. Disseminating surveys and ensuring achievement of minimum respondents,
 - c. Promoting the use of the Katuwang na Impormasyon para sa Responsableng Aksyon (KIRA) chatbot.
4. LVOCs and RVOCs shall follow the crisis communications protocol in accordance with Department Memorandum 2021-0224, entitled "Interim Guidelines on Adverse Events Following Immunization (AEFI) Community Management and Crisis Communications Related to COVID-19 Vaccines."
2. The information systems utilized by the National COVID-19 Vaccine Deployment and Vaccination Program shall be updated and upgraded to include the aforementioned categories.
3. All LGUs shall submit the required data requirements for the pediatric ages 5-11 years old to the Vaccine Administration System (VAS - Line List) and Vaccination Operations Reporting System (VORS) on a daily basis.

For dissemination and strict compliance.

By Authority of the Secretary of Health:



Digitally signed by
Vergeire Maria Rosario
Singh
Date: 2022.01.28
17:25:59 +08'00'

MARIA ROSARIO S. VERGEIRE, MD, MPH, CESO II
Undersecretary of Health
Public Health Services Team

ANNEX A. REQUIREMENTS TO PROVE FILIATION/ GUARDIANSHIP FOR PEDIATRIC COVID-19 VACCINATION

A. At least one (1) of the following documents shall be presented to prove filiation or guardianship:

1. In case the minor is accompanied by his/her parent:

a. The best evidence of filiation for the accompanying parent shall be an original copy or a certified true copy of the Birth Certificate issued by the Philippine Statistics Authority (PSA). In lieu of the PSA-issued Birth Certificate or certified true copy of the same, a copy of the Certification issued by the Local Civil Registrar of the City or Municipality where the vaccine recipient was registered shall be acceptable. The Certification shall set forth the following:

- i. LCR Registry Number;
- ii. Page and book number of the entry of registration;
- iii. Date of Registration;
- iv. Name of Child;
- v. Sex;
- vi. Date of Birth;
- vii. Place of Birth;
- viii. Name of the Mother;
- ix. Citizenship of the Mother;
- x. Name of the Father, if applicable;
- xi. Citizenship of the Father, if applicable;
- xii. Date of Marriage of the parents, if applicable; and
- xiii. Place of Marriage, if applicable.

b. In case the vaccine recipient does not have a copy of the original or certified true copy of his/her birth certificate or a Certification from the Local Civil Registrar, secondary documents shall be acceptable as long as the same is coupled with a valid government identification card issued to the parent and the vaccine recipient. The following are the secondary documents that may be presented (The list is not in order of preference):

- i. Authenticated medical certificate of the child bearing the name of the parent, issued by the hospital or the DOH;
- ii. Baptismal Certificate of the child with the name of the parent/s;
- iii. School ID or records of the child (transcript of records, Form 137, etc.) bearing the name of the parent;
- iv. PhilHealth, Social Security System (SSS), Government Service Insurance System (GSIS) forms indicating that the vaccine recipient is a beneficiary and a child of the parent. In lieu of physical copies, the parent may show his/her online account of the PhilHealth, SSS and GSIS online portal showing his/her filiation with the child;
- v. Copies of insurance policies, health card membership, life plan, memorial plan and similar policies wherein the vaccine recipient is the child of the parent and the said policies were taken on behalf of the latter. In lieu of physical copies, the parent may show his/her online account of the online portal of the said service and health providers, showing his/her filiation with the child;
- vi. Barangay Certification issued by the Barangay Captain indicating that the parent/s and the child is personally known to the latter and setting forth the filiation of the said individuals, as attested by one (1) other witness who personally knows the child and the parent;
- vii. If the parent is a Solo Parent, a copy of the Solo Parent identification card from the City or Municipal Social Welfare and Development Office, a Local Social Welfare and Development Office, Tallaq or Faskh certification from the Shariah court or any Muslim Barangay or religious leader, provided that the name of the child is indicated therein;
- viii. Court Decree of Adoption, in case the child is adopted;
- ix. PWD ID of the child, if available, wherein the name of the parent is indicated in the ID pursuant to DOH AO No. 2017-0008 or the *"Implementing Guidelines of Republic Act 10754, otherwise known as "An Act Expanding the Benefits and Privileges of Persons with Disability", for the Provision of Medical and Health-related Discounts and Special Privileges;*
- x. Other public documents enumerated under Memorandum Circular 04-12, or the *"Clarification on the Scope of Public Documents under Republic Act No. 9225"* dated October 18, 2004 issued by the Office of the Civil Registrar General, as applicable.

- c. In case the parent is residing abroad or cannot accompany their own children on the day of the scheduled vaccination, the accompanying adult may present a Special Power of Attorney executed by either parent of the minor designating the minor's companion to assist in the vaccination process. (If executed abroad, the SPA must be apostilled, if applicable, or authenticated by the Philippine Embassy/Consulate). The following documents may serve as an alternative document to the Special Power of Attorney:

- i. Notarized authorization letter;
- ii. written affidavit of parent /guardian under an oath with a public official such as the notary public or a person authorized to do so (eg. Barangay Officials) with presentation of a valid government ID; or
- iii. Barangay Certification issued by the Barangay Captain, the parent/ guardian will be accompanied by one witness personally known to the latter who can attest that the parent/ guardian is indeed the parent/ guardian of the child. Together, they will meet the Barangay Captain before issuing the Certification.

2. In case the minor is accompanied by his/her legal or judicial guardian (The list is not in order of preference):

- a. Affidavit of Guardianship executed by the Guardian;
- b. Court decree or order of Guardianship, or Letter of Guardianship issued by a Family Court;
- c. Affidavit of Kinship;
- d. PWD ID of the child, if available, wherein the name of the guardian is indicated in the ID pursuant to DOH AO No. 2017-0008;
- e. Authenticated medical certificate of the child bearing the name of the guardian, issued by the hospital or the DOH;
- f. Baptismal Certificate of the child with the name of the guardian;
- g. School ID or record of the child which bears the name of the guardian;
- h. PhilHealth, SSS, GSIS forms indicating that the vaccine recipient is a beneficiary and a child under the guardianship of the accompanying adult. In lieu of physical copies, the parent may show his/her online account of the PhilHealth, SSS and GSIS online portal showing his/her relationship with the child;

- i. Copies of insurance policies, health card membership, life plan, memorial plan and similar policies wherein the vaccine recipient is the child under the guardianship of the accompanying adult and the said policies were taken on behalf of the latter. In lieu of physical copies, the parent may show his/her online account of the online portal of the said service and health providers, showing his/her relationship with the child;
- j. Barangay Certification issued by the Barangay Captain indicating that the guardian and the child are personally known to the latter and setting forth the relationship of the said individuals, as attested by one (1) other witness who personally knows the child and the parent.
- k. If the accompanying person is a Solo Parent, a copy of the Solo Parent identification card from the City or Municipal Social Welfare and Development Office, a Local Social Welfare and Development Office, Taliaq or Faskh certification from the Shariah court or any Muslim Barangay or religious leader, provided that the name of the child is indicated therein.

3. In case the minor is under the custody of a Child-Caring Agency:

- a. A certified list of agencies as duly licensed and accredited by the Department of Social Welfare and Development (DSWD) shall be provided by the DSWD, including the corresponding heads/officers of the said agencies authorized to act as guardians of the children under their care. The said list shall be the basis to verify the names of the accompanying adult in order to determine his/her authority to give informed consent or assent, as the case may be.
- b. The Child-Caring Agency may also opt to provide the DOH a certified list of the names of the minor vaccine recipients who will be vaccinated and the name of their authorized accompanying adults, attaching photocopies of their valid IDs. If so, both the vaccine recipients and the accompanying heads/officers shall be required to present the actual valid government ID corresponding to the one submitted by the Agency. For the accompanying heads/officers, they shall be required to present the valid ID issued by the Child-Caring Agency issued under their name.

4. In case the above-mentioned mechanisms are not feasible, based on the assessment of the vaccination team after it has conducted due diligence in ensuring that the vaccine recipient has difficulty in obtaining the primary documents, the accompanying adult and the vaccine recipient shall present the following documents:

- a. In case of an abandoned child whose birth or parentage is unknown, a copy of the Certificate of Foundling and the valid ID issued by the Child Caring Agency to the accompanying heads/officers.
- b. Affidavit of Guardianship executed by the accompanying heads/officers and the valid ID issued by the Child-Caring Agency.
- c. Authenticated medical certificate of the child bearing the name of the accompanying heads/officers, issued by the hospital or the DOH;
- d. Baptismal Certificate of the child with the name of the accompanying heads/officers;
- e. School ID or record of the child which bears the name of the accompanying heads/officers;
- f. Barangay Certification issued by the Barangay Captain indicating that the accompanying heads/officers and the child are personally known to the latter and setting forth the relationship of the said individuals, as attested by one (1) other witness who personally knows the child and the accompanying heads/officers.
- g. For purposes of verifying the identity of the accompanying adult, the valid ID issued by the Child-Caring Agency and a separate government issued ID shall be presented by the latter.

Valid identification cards or documents with photo of the parent/guardian and the vaccine recipient to verify documents shall be presented. These are the list valid identification cards of parent/guardian:

1. SSS Card
2. GSIS Card
3. Unified Multi-Purpose Identification (UMID) Card
4. Land Transportation Office (LTO) Driver's License
5. Professional Regulatory Commission (PRC) ID
6. Philippine Identification (PhilID)
7. Overseas Workers Welfare Administration (OWWA) E-Card
8. Commission on Elections (COMELEC) Voter's ID or Voter's Certificate
9. Senior Citizen ID
10. Philippine Postal ID

11. Seafarer's Record Book

12. Valid or Latest Passport

13. Others

B. Additional protocols in getting assent/ consent of the pediatric population

1. Under Article 38 of the Republic Act (RA) No. 386 or the New Civil Code of the Philippines, minors are still considered to be under parental authority and do not have the capacity to give their consent. Under Article 220 of the Family Code, the parents and those exercising parental authority shall have, with respect to their unemancipated children or wards, the right and duty "to enhance, protect, preserve and maintain their physical and mental health at all times" as well as "to represent them in all matters affecting their interests." As such, the vaccine recipient's parent shall provide the consent before the vaccine recipient shall receive the COVID-19 vaccines, which are still under EUA.
2. In case that the parent or court-appointed guardian is dead, absent or cannot be located or unsuitable to give the needed consent, the substitute parental authority or legal guardianship shall be exercised by the surviving grandparent according to Art. 214 of the Family Code.
3. In default of grandparents, the substitute parental authority shall be exercised by the oldest brother or sister, over twenty-one years of age, unless unfit or disqualified, or the child's actual custodian, over twenty-one years of age, unless unfit or disqualified, in accordance with Art. 216 of the Family Code.
4. In case of foundlings, abandoned, neglected or abused children and other children similarly situated, parental authority shall be entrusted in summary judicial proceedings to heads of children's homes, orphanages and similar institutions duly accredited by the DSWD or its city/municipal counterparts.
5. In case the parent/guardian refuses to give consent to the vaccination despite the desire and willingness of the minor child to have himself/herself vaccinated, or there are no persons that may legally exercise parental authority over the child, the State may act as *parens patriae* and give the necessary consent. Therefore, the proper officer representing the State as *parens patriae* may sign the consent form. In this regard, the DSWD or its city/municipal counterparts shall serve as the proper office who shall represent the State.

ANNEX B. List of Comorbidities Requiring Medical Clearances indicated in DC No. 2021-0464

- a. **Medical complexity:** long term dependence on technical support e.g. tracheostomy associated with developmental delay and/or genetic anomalies.
- b. **Genetic conditions:** Down's Syndrome (Trisomy 21), Glucose-6-phosphate dehydrogenase deficiency (G6PD), genetic disorders affecting the immune systems such as primary immunodeficiency disorders, thalassemia, and other chromosomal abnormalities.
- c. **Neurologic conditions:** Seizure Disorder, Autism Spectrum Disorders (ASDs), Cerebral Palsy, Stroke in the Young, Chronic Meningitis e.g. Tuberculosis, chronic neuromuscular diseases, and chronic demyelinating diseases.
- d. **Metabolic/endocrine diseases:** Diabetes Mellitus (DM), Hypothyroidism, Diabetes Insipidus (DI), Adrenal insufficiency, Hypopituitarism, and other hereditary metabolic diseases.
- e. **Cardiovascular diseases:** Hypertension, Congenital Heart Diseases (CHDs), Cardiomyopathy, Rheumatic Heart Disease (RHD), Mitral Valve Disease, Pulmonary Hypertension with Right Heart Failure.
- f. **Obesity:** BMI > 95th percentile for age and height.
- g. **HIV infection**
- h. **Tuberculosis:** Pulmonary (collapse/consolidations, with empyema, and miliary), Extrapulmonary, (pleural effusion, pericarditis, abdominal, genitourinary, central nervous system, spinal column, bone, joint, cutaneous, ocular and breast), and Disseminated (involvement of two (2) or more organs).
- i. **Chronic Respiratory Diseases:** Chronic Lung Diseases (Bronchiectasis, Bronchopulmonary Dysplasia, Chronic Aspiration Pneumonia), Congenital respiratory malformation, Restrictive Lung Diseases, neuromuscular disorders, syndromic with hypotonia, skeletal disorders, chronic upper and lower airway obstruction (Severe Obstructive Sleep Apnea, Tracheomalacia, Stenosis, Bronchial Asthma).
- j. **Renal Disorders:** Chronic Kidney Diseases, Nephrotic Syndrome, End-Stage Renal Disease (ESRD), patients on dialysis and continuous ambulatory peritoneal dialysis (CAPD), Glomerulonephritis (e.g. lupus nephritis), Hydronephrosis.

- k. **Hepatobiliary Diseases:** Chronic Liver Disease, Cirrhosis, Malabsorption Syndrome.
- l. **Immunocompromised state due to disease or treatment:** Bone marrow or stem cell transplant patients, solid organ transplant recipients, haematological malignancies (leukemia, anemia, thalassemia), cancer patients on chemotherapy, severe aplastic anemia, autoimmune or autoinflammatory disorders requiring long-term immunosuppressive therapy (e.g. Systemic Lupus Erythematosus, Rheumatoid Arthritis), patients receiving immune-modulating biological therapy [e.g. Anti - Tumor Necrosis Factor (TNF), rituximab, among others], patients receiving long-term systemic steroids [$> one (1)$ month], functional asplenia, patients who underwent splenectomy.

ANNEX C. MEDICAL CERTIFICATION FOR PEDIATRIC POPULATION WITH COMORBIDITIES

(maybe accessed through bit.ly/RESBAKUNAVaxSpecific)



COVID-19 PEDIATRIC VACCINATION (5-17 YEARS OLD)

of the Philippine National COVID-19 Vaccine Deployment and Vaccination Program as of January 21, 2022

MEDICAL CERTIFICATION FOR COVID-19 PEDIATRIC VACCINATION (5-17 YEARS OLD WITH COMORBIDITIES)

Date: _____

TO WHOM IT MAY CONCERN:

This is to certify that

(Name of Patient)

(Age)

years old, from

(Address)

is a diagnosed case of:

- ☐ I have thoroughly explained the risks and benefits of COVID-19 vaccination
- ☐ Based on evaluation done on the date of certification, the patient can receive a COVID-19 vaccine
- ☐ The parent / legal guardian is aware that the vaccine recipient will still be subjected to health screening at the vaccination site, and that IF symptoms arise, re-evaluation is necessary prior to vaccination

This medical certificate is being issued for the COVID-19 Vaccine Deployment and Vaccination Program of the Philippines

(Physician's Name and Signature)

(Professional Regulation Commission ID No)

ANNEX D. INFORMED CONSENT AND ASSENT FORMS FOR PEDIATRIC VACCINATION (5-11 YEAR OLDS)

(maybe accessed through bit.ly/RESBAKUNAVaxSpecific)



COVID-19 PEDIATRIC VACCINATION (5-17 YEARS OLD) INFORMED CONSENT FORM AND ASSENT FORM FOR PFIZER-BIONTECH COVID-19 VACCINE of the Philippine National COVID-19 Vaccine Deployment and Vaccination Program as of January 21, 2022

I understand that while most side effects are minor and resolve on their own, there is a small risk of severe adverse reactions, such as, but not limited to allergies, and that should prompt medical attention be needed referral to the nearest hospital shall be provided immediately by the Government of the Philippines. I have been given contact information for follow up for any symptoms which may be experienced after vaccination.

I understand that by signing this Form, the minor has a right to health benefit packages under the Philippine Health Insurance Corporation (PhilHealth). In case he/she suffers a severe and/or serious adverse event, which is found to be associated with the Pfizer-BioNTech COVID-19 vaccine or its administration I understand that the right to claim compensation is subject to the guidelines of PhilHealth.

I authorize releasing all information needed for public health purposes including reporting to applicable national vaccine registries, consistent with personal and health information storage protocols of the Data Privacy Act of 2012.

Nonetheless, I understand that despite such authorization and consent given by me to release all personal and sensitive information for public health purposes, I remain entitled to the rights afforded to a Data Subject under the Data Privacy Act of 2012.

I have reviewed the information on risks and benefits of the Pfizer-BioNTech COVID-19 vaccine in Section 1 above and understand its risks and benefits. In providing my consent below, I confirm that I have the legal authority to give consent for the vaccination of the minor named above with the Pfizer-BioNTech COVID-19 vaccine.

I hereby give consent to the vaccination of the minor named above with the Pfizer-BioNTech COVID-19 vaccine. I affirm that I have understood and reviewed the information included in Section 1 herein. (If this consent is not signed, dated and returned, the minor will not be vaccinated).

Signature over Printed Name of the Parent/Guardian

Date

If you choose not to have your child/ward vaccinated, please list down the reason/s:

Section 3: Minor's Assent for Vaccination

I ACKNOWLEDGE THAT:

I am being asked to decide if I

(Minor's Name)

, want to be vaccinated with the Pfizer-BioNTech COVID-19 vaccine

(Age)

I have understood the information about the Pfizer-BioNTech COVID-19 vaccine which will be vaccinated to me, and I confirm that I have understood the same.

I asked several questions about the Pfizer-BioNTech COVID-19 vaccine and got answers to the same. I understand that I can ask questions and raise concern about COVID-19 vaccination anytime.

I understand the risk of the administration of the vaccine including the outcomes (that while most side effects are minor and resolve on their own, there can be a risk for adverse reactions in rare circumstances.)

I know that I can stop at any time in the process of vaccination without anyone reprimanding me. The attending physician will still take care of me.

I want to receive the COVID-19 vaccine at this time.

- ☐ If the minor is not capable of giving assent due to neurological circumstances and moderate to severe intellectual impairment, the parent or the authorized parental substitute can sign on his/her behalf.
- ☐ If the minor is seven to twelve (7-12 years old), a verbal assent is acceptable. The parent or the authorized parental substitute shall instead sign below to signify that the minor has provided the above information to the minor and that the minor has assented to receiving the COVID-19 vaccine.
- ☐ If the minor is below seven (7) years old, a verbal assent from the minor is not required. The parent or the authorized parental substitute shall instead sign below to signify that the minor had no manifestations of distress to receiving the COVID-19 vaccine.

Signature over Printed Name of the Minor / Parent / Guardian

Date

If you choose not to get vaccinated, please list down the reason/s:

(maybe accessed through bit.ly/RESBAKUNAVaxSpecific)



HEALTH DECLARATION SCREENING FORM FOR PFIZER

of the Philippine National COVID-19 Vaccine Deployment and Vaccination Program as of January 21, 2022

Q2 an

If any of the white boxes is checked, **DEFER** vaccination.



COVID-19 PEDIATRIC VACCINATION (5-17 YEARS OLD)

HEALTH ASSESSMENT ALGORITHM FOR PFIZER

of the Philippine National COVID-19 Vaccine Deployment and Vaccination Program as of January 21, 2022

