Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

July 10, 2023

DEPARTMENT MEMORANDUM
No. 2023 - 0256

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; CHIEFS OF MEDICAL CENTERS, HOSPITALS, SANITARIA AND INSTITUTES; AND OTHERS CONCERNED**

SUBJECT: **Revised Interim Guidelines on the Management and Administration of COVID-19 Vaccine Pfizer Bivalent**

I. BACKGROUND

The Department of Health issued Department Memorandum (DM) 2023-0178, with the subject "*Interim Guidelines on the Management and Administration of COVID-19 Vaccine Pfizer Bivalent*" on May 25, 2023, to provide guidance to all concerned agencies on the management and administration of the COVID-19 Vaccine Pfizer Bivalent.

To enhance accessibility of the vaccines, the Public Health Services Team and Executive Committee provided technical directions for expanding the management and administration of the vaccine. Thus, this DM is issued to provide guidance to all concerned agencies, Regional Vaccination Operations Centers (RVOCs) or Centers for Health Development (CHDs) and the Ministry of Health - Bangsamoro Autonomous Region in Muslim Mindanao (MOH-BARMM), Local Vaccination Operations Center (LVOCs) or Local Government Units (LGUs), Provincial/City/Municipal Health Offices (P/C/MHOs), Rural Health Units (RHUs), Implementing Units, and Vaccination Sites, both public and private, on the expanded management and administration of the COVID-19 Vaccine Pfizer Bivalent. In anticipation of gradually increasing supply, a phased approach shall be pursued wherein initially, individuals belonging to Priority Groups A1 (healthcare workers), A2 (senior citizens), and A3 (adults with comorbidities) are eligible to be given the COVID-19 Vaccine Pfizer Bivalent as 1st, 2nd, or 3rd booster for adults given at least four (4) to six (6) months after completion of their latest COVID-19 vaccine dose.

II. GENERAL GUIDELINES

A. The COVID-19 Vaccine Pfizer Bivalent roll-out shall employ a **phased approach** to prioritize the protection of the healthcare workers and of the most vulnerable population and healthcare capacity, while expansion of stock availability is being pursued.

1. **Phase I**

    a. The COVID-19 Vaccine Pfizer Bivalent shall be given as a **1st, 2nd, or 3rd booster dose for individuals aged 18 years old and above belonging to priority groups A1 (healthcare workers), A2 (senior citizens), and A3 (adults with comorbidities), and their sub-priority groups (A1.1 to A1.9 or Expanded A1; A2.1 to A2.2; Expanded A3), at least four (4) to six (6) months after inoculation with their latest COVID-19 vaccine dose.**

    b. **Facility-based implementation** shall be observed for the pilot roll-out in select sites in all regions such as in the hospitals and/or health facilities (city health office, rural health units).

2. **Succeeding phases**

    a. Other population groups shall be made eligible, subject to availability of stocks and other changes in context, such as relevant regulatory authorization, technical recommendations and executive directions.

    b. Expansion of eligibility and changes thereto shall be released through a separate issuance.

B. In identifying which COVID-19 vaccine and their interval is recommended for corresponding population groups and vaccination history, refer to **Annex A**.

C. The COVID-19 vaccination program, including expansion of eligibility for additional / booster doses of other COVID-19 vaccine products, shall adopt future EUA or regulatory amendments from the FDA and recommendations from the HTAC on the provision of the COVID-19 Vaccine second booster doses. Copies of the EUA and product information for vaccine recipients and healthcare providers may be accessed at www.fda.gov.ph/list-of-fda-issued-emergency-use-authorization.

D. The DOH Public Health Services Team (PHST) or Field Implementation and Coordination Team (FICT) may issue out clarificatory guidelines and advisories, as deemed appropriate.

E. The FICT shall conduct an orientation of this guideline to CHDs. The CHDs shall be in charge of building the capacity of LGUs/LVOCs/Implementing Units/Vaccination Sites within their geographic area of jurisdiction. The LGUs/LVOCs shall ensure all members of their workforce (e.g. program manager or coordinator, vaccination site supervisor, health screener, vaccinator, health educator, AEFI composite team, supply or logistics personnel, encoder, data manager) are oriented and/or trained on the conduct of vaccination, including COVID-19 Vaccine Pfizer Bivalent.

F. **Allocation and Distribution of Vaccines**

1. The Disease Prevention and Control Bureau (DPCB) shall request the latest or applicable data from the Epidemiology Bureau (EB) for the preparation of a proposed allocation list.

2. The FICT shall review the proposed allocation list in terms of feasibility for implementation and shall conduct a consultation with CHDs. All comments shall be forwarded to the DPCB for finalization of the allocation list.

3. The DPCB shall then endorse the approved allocation list to the Supply Chain Management Service (SCMS) as the basis for the distribution of the COVID-19 Vaccine.

4. The RVOCs/CHDs may directly allocate and distribute COVID-19 vaccines to vaccination sites, in coordination with LVOCs/LGUs.

5. All other procedures regarding supply chain management shall follow DM 2022-0488, with the subject "*Interim Operational Guidelines on the COVID-19 Vaccines Cold Chain and Logistic Operations Process Flow for All Public and Private Health Facilities and Offices*", Department Circular (DC) 2021-0439, with the subject "*Operational Guidelines on the Reverse Logistics of COVID-19 vaccines*" and all other relevant policies, guidelines, and advisories released by the DOH.

6. RVOCs and LVOCs may decide on reallocation or redistribution of received doses, upon discussion with corresponding implementing units, based on speed of vaccination, viability of vaccines received, and other findings, as deemed appropriate.

G. Access vaccination materials such as the informed consent form, health screening, and assessment forms through this link: https://bit.ly/PfizerBivalentBoosterForm.

H. All LVOCs/LGUs shall encode all COVID-19 vaccination events, including third booster administration through the corresponding information system. In consideration of the transition of information systems, reporting guidelines in the corresponding information system shall be released and disseminated by the Epidemiology Bureau.

I. Pursuant to Administrative Order No. 2023-0007, known as the *"Revised Omnibus Guidelines on the Surveillance and Management of Adverse Events Following Immunization (AEFI)*", all disease reporting units (DRUs), including public and private health institutions and facilities, and vaccination sites shall strictly comply and report all AEFIs regardless of case severity through the VigiFlow pending the national implementation of the contextually adapted AEFI Information System through the release of an official issuance.

J. Protocols for the management of AEFIs and Adverse Events of Special Interest (AESIs) shall follow the provisions of the approved COVID-19 vaccine EUA of the FDA, succeeding guidelines from the FDA, and other recognized professional organizations and regulatory bodies, as new evidence arises. Interim AEFI Pathways may be accessed at: https://bit.ly/COVIDVaxFactsheets.

III. SPECIFIC GUIDELINES

A. No Wrong Door Policy in All Vaccination Sites

1. Current stocks of COVID-19 vaccines shall be used for primary series, additional dose, and booster dose vaccination for all eligible populations based on prevailing guidelines.

2. For vaccine recipients who seek to **complete the necessary COVID-19 primary series and booster doses**, as eligible to their priority group, shall be provided, scheduled, or advised to have their recommended COVID-19 vaccination. If the requesting party is not eligible for a COVID-19 vaccine, they shall be offered other primary care services, based on life stage. For further details, the Omnibus Health Guidelines per Life Stage may be accessed at https://bit.ly/OmnibusHealthGuidelines

B. Contextualized Local Implementation

1. All LGUs shall ensure that COVID-19 vaccination is integrated and offered routinely and regularly through their primary care facilities.

2. LVOCs/LGUs shall plan out their operational approach based on their prevailing context and historical experience to maximize coverage and efficiency in utilization of available stocks (e.g. facility-based, fixed site, pharmacies, outreach, house-to-house or mobile vaccination, after-hours, scheduled appointments, walk-in, drive-through or a combination of any of the above). The following may serve as a guide in strategizing operations:

    a. Maximize all options for feasible vaccination sites and adopt settings-based approaches to bring vaccination to settings that people already frequent, such as fixed posts (health centers, *barangay* health stations, hospitals). Temporary posts in *barangays* or in accessible public places (malls) and the deployment of mobile vaccination may also be considered. Vaccination may be integrated with any national and local vaccination campaigns.

    b. Create a master list using house-to-house visitation activities to determine the remaining unvaccinated for scheduling of vaccination.

    c. If deemed necessary, focus limited resources and traffic demand to a single or a few implementing units or vaccination sites. Employ mobile or house-to-house vaccination to reach out to individuals with mobility challenges.

    d. Queue management: Decide whether to adopt scheduled appointments, walk-ins, or a combination of both depending on the latest experience, human resource availability, and technical capacity for scheduling appointments and following up with recipients.

    e. Suggested vaccination strategies per population group are detailed in **Annex B**.

C. Integrated Health Service Delivery

1. LVOCs/LGUs shall gradually integrate all services intended at the primary care level, as guided by the Omnibus Health Guidelines, which can be accessed through https://bit.ly/OmnibusHealthGuidelines.

2. Utilize primary care facilities such as Rural Health Units (RHU) and *Barangay* Health Stations (BHS) for routine immunization activities across life stages integrating COVID-19 vaccinations.

3. Vaccination sites shall offer and recommend other routine health services corresponding to the vaccine recipient's life stage (e.g. reproductive health, nutrition, immunization, deworming, health screening services for various diseases or disorders, linkage or coordination for further management, if necessary), provided that provision of medicines, drugs, or vaccines do not have a contraindication to co-administration, or that the additional service provided does not unduly delay the vaccination site processes. The following operational strategies may be used:

    a. Incorporate screening forms, prompts, or questions to elicit clinical suspicion of a disease, or to identify the need for promotive or preventive health services.

    b. Add stations with assigned human resources to perform the above task, while vaccine recipients are waiting for their turn in the post-vaccination monitoring area, or between other stations.

D. Micro Planning and Mapping

1. All LGUs and implementing units shall continuously develop their micro plans and map out their vaccination workforce, implementing units, and vaccination sites during the COVID-19 vaccination roll-out.

2. To vaccinate the remaining unvaccinated, comprehensive macro- and micro plans shall be established entailing the placement of vaccination sites at strategic locations and the provision of context-specific service delivery strategies. The following strategies are recommended to target the unvaccinated:

    a. Coordinate with local leaders and community health workers to identify vaccine-hesitant individuals, and explore and address specific reasons behind the hesitation.

    b. Focus social mobilization activities in the identified *barangays*. Ensure the presence of key influencers/champions in the *barangay*, highlighting the benefits of vaccination through the influencers' testimonies. Small group discussions are the preferred mode to provide more personal messaging to address personal concerns.

    c. Focus on the deployment of more vaccination teams to these identified areas, including volunteers from medical societies, civil society organizations, private sectors, and faith-based organizations.

d. Streamline the vaccination process to mirror routine vaccination activities, such as, but not limited to, symptomatic screening for COVID-19 symptoms, shortening and simplifying the health screening checklist.

e. Form more vaccination teams for mobile vaccination and temporary post-vaccination, as needed. Provide daily quota per vaccination team based on the target per *barangay* or catchment area.

E. Vaccination Process

1. The vaccination site shall ensure the following, across all steps in the recommended process flow for vaccine administration from registration, health education, screening, vaccine administration, and post-vaccination monitoring:

   a. Strictly adhere to minimum public health standards, especially on appropriate distancing, adequate ventilation based on the threshold set by Department of Labor and Employment (DOLE) Department Order 224-21, otherwise known as "*Guidelines on Ventilation for Workplaces and Public Transport to Prevent and Control the Spread of COVID-19*", and administrative controls against crowding;

   b. Render available Information, Education, and Communication (IEC) materials such as, but not limited to, videos, pamphlets, flipcharts, leaflets, and brochures, in any area of the vaccination site, especially in the waiting area and post-vaccination monitoring area. IEC materials on "Sa Boosters: PinasLakas campaign" may be accessed through https://bit.ly/PinasLakasAssets, while IEC materials specific to COVID-19 Pfizer Bivalent vaccines as boosters may be found at https://bit.ly/BivaxPilotMaterials.

   c. Give priority to senior citizens, pregnant women, and persons with disabilities. Provide separate lanes for the pediatric population.

   d. There is no need to pool vaccine recipients to maximize a single vial cognizant of the need to provide timely provision of needed doses of COVID-19 vaccine to intended recipients.

2. Health Education and Informed Consent Area

   a. Depending on the eligibility, vaccine recipients shall submit the necessary documents to the vaccination team. **Annex C** contains the list of vaccination requirements per eligible population group, list of valid identification cards, proof filiation, and list of comorbidities requiring medical clearance and certification.

   b. Dedicate a health education area for the whole vaccination site where IEC materials shall be available. Set up a projector or a flipchart for health education purposes. Ensure that an adequately oriented and approachable health educator is available at all times to provide vaccine recipients with the necessary information and to answer any questions.

c. Explain benefits, risks and possible side effects of the COVID-19 vaccines. Seek informed consent prior to the vaccine administration. A guide on the proper process of securing an informed consent is found in **Annex D.**)

d. Adult vaccine recipients shall sign two (2) copies of the informed consent form. One (1) copy shall be provided to the patient and one (1) to be kept by the vaccination team.

e. This step can be integrated with other steps to streamline the processes in the vaccination site.

3. Health Screening Area

a. If applicable, assign a personnel to scan the patient's QR or Unique Code. Clinically assess eligible vaccine recipients for COVID-19 symptoms, comorbidities, and other important clinical information. Follow contraindications and precautions stated in the EUA of the FDA, as well as recommendations from the HTAC for all vaccines.

b. For the adult population, screen for potential allergies to vaccine components, food, and medicines, pregnancy, vaccination with other COVID-19 vaccines, history of bleeding disorders, possible symptoms of COVID-19 infection, exposure to COVID-19, vaccination with other non-COVID vaccines. Blood pressure measurement prior to vaccination of the adult population shall not be required but may be done at the discretion of the vaccination team in the vaccination sites.

c. Use the latest health screening form in screening eligible vaccine recipients. Forms shall be regularly updated based on latest available evidence, and the latest version shall remain publicly available for download.

d. While doctors are preferred as health screeners for vaccination, if there is a shortage, **health screeners, trained nurses** shall be deployed or assigned, under the supervision of the vaccination site supervisor. Vaccine recipients may accomplish the screening form prior to the vaccination day through LGU-facilitated house-to-house screening or facilitated self-assessment guidance to the public. The on-site vaccination team shall validate the content of the forms prior to vaccination.

e. **Temporarily** defer vaccination until resolution of the following conditions:

    i. **Persons who are presenting with symptoms** such as fever/chills, headache, cough, colds, sore throat, myalgia, fatigue, weakness, loss of smell/taste, diarrhea, shortness of breath/difficulty in breathing, and rashes shall be referred to a physician for clinical evaluation. Vaccinate only after full recovery from the **acute illness** as certified by their attending physician based on current management guidelines.

ii. **Persons who have active COVID-19 infections.** However, vaccine recipients who have recovered or completed treatment in line with the latest protocols on isolation or quarantine period can be vaccinated without restarting the vaccine dose schedule.

iii. **Persons who have received any non-COVID-19 vaccine dose in the past 14 days or plan to receive another vaccine following COVID-19 vaccination**. This is to standardize implementation and limit confounding variables during the Adverse Event Following Immunization (AEFI) case investigation and causality assessment. However, urgent vaccination such as anti-rabies, tetanus, or immunoglobulins for animal bite and other life-threatening or critical situations may be given, provided that it is a shared decision between the patient and the attending health care professional.

iv. Ensure that only patients presenting with a **hypertensive emergency** (sBP> 180 and/or dBP >120 plus with signs and symptoms of organ damage) shall be deferred vaccination. Vaccination shall be rescheduled until the condition is clinically controlled. Elevated BP readings without any signs and symptoms of organ damage are not a cause for deferral of vaccination. However, individuals with elevated blood pressure not classified as hypertensive emergency shall be observed 30-60 minutes after vaccination to monitor for evolving signs or symptoms of hypertensive emergency.

v. Pregnant and lactating women shall NOT be given vaccines contraindicated for this special population. Pregnant and lactating women in their first trimester may be vaccinated provided it is a joint decision by the patient and the attending physician, evidenced by a medical clearance.

f. For vaccine recipients who have been temporarily deferred, their booster dose may be provided immediately after the prescribed periods in the deferment guidelines without a maximum time interval unless otherwise indicated.

4. Vaccination Administration

a. Specific vaccine administration strategies (dosage, interval) may be adopted per vaccine following the most updated product specifications or clinical practice guidelines that shall be regularly updated based on the best available evidence.

b. At the vaccination administration area, the vaccinator shall:

i. Thoroughly review the informed consent, health screening, and declaration forms to verify the eligibility of the vaccine recipient and ensure that the mentioned forms are properly signed.

ii. Review the information in the vaccination card to determine the date and the vaccine brand of the second booster dose administered, and calculate the dose interval.

iii. Verify the vaccine brand, formulation, and expiration date of vaccine to be administered.

- Shelf life of vaccines are extended as COVID-19 manufacturers update their data and evidence on the stability of their products. The local EUA holders submit their request for amendment to the FDA and extensions are processed per batch and per brand after the completion of the updated stability studies.

- The monitoring sheet with the complete batch and lot numbers, printed expiration dates and the latest extension of shelf life may be viewed through: https://bit.ly/C19ShelfLifeExtensionMonitoring

- Check the monitoring sheet regularly and cascade to the implementing units as needed.

- Print out or ensure an updated digital copy is available in all vaccination sites at all times. The monitoring sheet may be used as reference of vaccination teams and vaccine recipients to clarify the shelf life extension of the vaccine batches being administered in their site.

iv. Prepare and administer the vaccine using the correct technique indicated in vaccine-specific guidance based on its product specifications.

v. Prior to inoculation, check the appropriateness of the product for the vaccine recipient and ensure the vaccine to be administered is not expired and has been stored in the appropriate temperature. Strictly comply with the instructions of the product label of the vaccine product. Specific vaccine administration strategies may be adopted per vaccine.

vi. Draw vaccines from a designated clean medication area that is not adjacent to areas where potentially contaminated items are placed. Multi-dose vials to be used for more than one patient shall not be kept or accessed in the immediate patient treatment area. To prevent contamination of the vial, cleanliness and absence of potentially contaminated equipment shall be ensured at all times.

vii. Ensure that vials do not contain any indications of possible contamination and chemical reactions due to mishandling (e.g. discoloration, presence of particulates), as provided in the vaccine-specific policies issued by the DOH. In such cases, these vials shall be disposed following set protocols as outlined in Department Memorandum No. 2021-0031, otherwise known as, Interim Guidelines on the Management of Health Care Wastes Generated from COVID-19 Vaccination.

viii. Prepare and disinfect the skin prior to vaccine administration by using the following steps:

- Apply a 60-70% alcohol-based solution (isopropyl alcohol or ethanol) on a single use swab or cotton-wool ball. Do not use methanol or methyl-alcohol as these are not safe for human use.
- Wipe the area from the center of the injection site working outwards, without going over the area.
- Apply the solution for 30 seconds then allow it to dry completely.
- Avoid touching the disinfected area to avoid cross-contamination.

ix. Administer the vaccine intramuscularly, in the deltoid muscle.

x. Record the vaccine administration and other pertinent information on the vaccination card.

5. Post-vaccination monitoring area

a. The vaccination team at the post-vaccination monitoring area shall be composed of two (2) composite teams and shall check and ensure the completeness of the contents of the AEFI Kit per composite team:

i. To monitor and provide response: Paramedic/Nurse/Midwife

ii. To conduct surveillance: Surveillance Officer/Nurse/Midwife/ Pharmacist

b. The AEFI/ AESI composite team shall monitor the vaccine recipient and observe for any adverse reaction. After the observation, the vaccination team shall provide the following information to the vaccine recipient:

i. Signs and symptoms to observe and watch out for

ii. Instructions and steps on how to seek clinical care and report AEFI events

iii. Use AEFI management pathway

c. Bring vaccine recipients who experience AEFI during the post-vaccination monitoring period to designated health facilities within their healthcare provider networks. The LGU shall ensure capacity of the facilities to provide health care in response to the event and ensure the timely detection, notification, reporting, and investigation of the AEFIs.

d. The vaccination team shall ensure that the vaccine recipient is essentially well before leaving the vaccination site.

e. Update the vaccination card of the recipient to ensure completion of the vaccination process and to enable monitoring of adverse events. If there is a need to print a new card, the LVOC/LGU or implementing unit shall print based on the template set by the DOH. The updated vaccination card template may be accessed through this link: http://bit.ly/COVID19_VaccinationForms.

F. Vaccine Demand and Uptake

1. The CHDs/RVOC/LVOC shall:

   a. Disseminate COVID-19 vaccine IEC materials and ensure alignment of localized materials following the guidelines of the Sa Boosters: PinasLakas campaign (https://bit.ly/PinasLakasAssets). Full guidance on the PinasLakas campaign implementation is accessible at Department Memorandum 2022-0352 entitled "Guidelines on the Implementation of the 'Sa Boosters: PINASLAKAS' Social and Behavior Change Communication Campaign" (https://bit.ly/PinasLakasDM2022). IEC materials specific to COVID-19 Pfizer Bivalent vaccines as boosters may be found at https://bit.ly/BivaxPilotMaterials.

   b. Ensure the functionality of their crisis communications protocols aligned with DM 2021-0224: Interim Guidelines on Adverse Events Following Immunization (AEFI) Community Management and Crisis Communications Related to COVID-19 Vaccines.

   c. Update demand generation and communications microplans (https://bit.ly/DGCMicroplan_ver2) and recalibrate according to insights from communities, coverage data from LGUs, and operational strategies relevant to the local context to target those remaining unvaccinated, especially vulnerable groups. These shall be submitted every 5th of the month to pinaslakas@doh.gov.ph.

   d. Ensure feedback mechanisms and social listening by a) reporting frequently asked questions, misinformation, and rumors through the bimonthly cascade of CHD Health Promotion Units with the Health Promotion Bureau, and b) promoting the use of the DOH's official KIRA chatbot (https://m.me/OfficialDOHgov) to get vetted information (Magtanong kay KIRA), report fake news and misinformation, and provide citizen feedback (Magreport kay KIRA) to collect data on community-level vaccine hesitancy issues and generate insights to recalibrate plans.

2. Vaccination Sites and LGUs shall:

   a. Utilize the latest messaging house and key messages cascaded by the Health Promotion Bureau. They shall ensure that brand-agnostic messaging is maintained at all times and that vaccination should remain apolitical and should not be used as platforms for any campaign-related activities.

b. Plan and implement demand generation and communication activities in accordance with the DILG Memorandum Circular 2021-019, titled *"Guidelines on the Implementation of Demand Generation Activities in support to the National COVID-19 Vaccine Deployment Plan"* and ensure coverage of all priority population groups.

c. Ensure the utilization of both offline and community level social mobilization and demand generation strategies, especially to reach vulnerable populations.

d. Provide regular updates to the CHD on targets and coverage data at local level, progress of their microplan, and other collected social listening data. These information shall be used to recalibrate strategies and demand generation and communications microplans to target those remaining unvaccinated, especially vulnerable groups.

IV. REPEALING CLAUSE

DM 2023-0178, with the subject *"Interim Guidelines on the Management and Administration of COVID-19 Vaccine Pfizer Bivalent"* is hereby repealed.

V. SEPARABILITY CLAUSE

In the event that any provision or part of this Order be declared unauthorized or rendered invalid by any court of law or competent authority, those provisions not affected by such declaration shall remain valid and effective.

VI. EFFECTIVITY

This Department Memorandum shall take effect immediately.

TEODORO J. HERBOSA, MD
Secretary of Health

List of Annexes

(See **bit.ly/DMPfizerBivalent_ListofAnnexes** for the Annexes)

A	Vaccine Selection, Dosing and Interval per population group
B	Suggested Vaccination Strategies per population group
C	Vaccination Requirements
D	Proper Process of Securing an Informed Consent