

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

March 11, 2021

DEPARTMENT CIRCULAR

No. 2021- 010

TO:

ALL DEPARTMENT UNDERSECRETARIES AND ASSISTANT SECRETARIES; CENTER FOR HEALTH DEVELOPMENT AND MINISTRY OF BANGSAMORO AUTONOMOUS REGION IN MUSLIM MINDANAO (BARMM); AND BUREAU DIRECTORS; SPECIAL AND SPECIALTY HOSPITAL DIRECTORS; CHIEF OF MEDICAL CENTERS, HOSPITALS AND SANITARIA; AND OTHER CONCERNED OFFICES

SUBJECT: <u>Clarification on Provisions of Department Memorandum 2021-0099</u> <u>entitled the "Interim Omnibus Guidelines for the Implementation of</u> <u>the National Vaccine Deployment Plan for COVID-19"</u>

On February 23, 2021, the Department of Health issued Department Memorandum 2021 – 0099 entitled "Interim Omnibus Guidelines of the Implementation of the National Vaccine Deployment Plan for COVID -19" to provide the overall guidance to implementers on vaccine administration of the National Deployment and Vaccination Plan. This reiteration shall clarify policy directions for the ongoing implementation of the COVID-19 vaccine deployment program:

A. Strict Implementation of the Prioritization Framework and Vaccine Administration

- 1. All designated vaccination sites, including their corresponding oversight health facility or local government unit, shall be accountable for ensuring allocation and administration of the COVID-19 vaccines only to eligible recipients based on the prioritization framework indicated in DM 2021-0099.
- 2. Vaccines under Emergency Use Authorization (EUA) of the Philippine Food and Drug Administration are strictly not allowed for selling. Violations to this provision is punishable by law in pursuant to the Republic Act No. 9711, otherwise known as the Food and Drug Administration Act of 2009.
- 3. Non-compliance to the EUA, prioritization framework, and vaccine administration guidelines shall be used as additional consideration in future allocations and public reporting of performance, further elaborated in subsequent guidelines to be issued.

Building 1, San Lazaro Compound, Rizal Avenue, Sta. Cruz, 1003 Manila • Trunk Line 651-7800 local 1113, 1108, 1135 Direct Line: 711-9502; 711-9503 Fax: 743-1829• URL: http://www.doh.gov.ph; e-mail: ftduque@doh.gov.ph 4. Centers for Health Development shall ensure compliance of vaccination sites to the the terms and conditions of the COVAX facility and other multilateral negotiation agreements that indicate possible suspension of all or part of its funding or vaccine allocation to the country if it has reason to suspect that funds, equipment, supplies, or approved vaccine have been misused or used for purpose other than for the programme described in the country's application.

B. Masterlisting and Allocation Planning for all Priority Group A1 populations:

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1. Accountable units for each sub priority group of Priority Group A1 shall be as follows:

Sub-priority Group	Accountable Unit
Priority A1.1 COVID-19 referral hospitals designated by the DOH;	Hospital chiefs, consolidated by NVOC and CHD
Priority A1.2 Public and private hospitals and infirmaries providing COVID-19 care, as prioritized based on service capability, starting from level 3 hospitals, to level 2 hospitals to level 1 hospitals, and then infirmaries; Among hospitals with a common service capability, the order of priority shall be from facilities owned by the DOH, then facilities owned by LGUs, and then facilities owned by private entities;	Hospital chiefs, consolidated by NVOC and CHD
Priority A1.3 Isolation and quarantine facilities such as temporary treatment and monitoring facilities and converted facilities (e.g. hotels, schools, etc) that cater to COVID-19 suspect, probable, and confirmed cases, close contacts, and travellers in quarantine;	LGUs by province/ HUC/ ICC, except for national quarantine and isolation facilities through NVOC
Priority A1.4 Remaining hospitals including facilities of uniformed services not catering to COVID-19 cases;	Hospital chiefs, consolidated by NVOC and CHD
Priority A1.5 Government owned primary care based facilities such as Urban Health Centers, Rural Health Units and Barangay Health Stations, birthing homes, and Local Health Offices to include members of BHERTS, contact tracers, social workers;	LGUs by province/ HUC/ ICC
Priority A1.6 Stand-alone facilities, clinics and diagnostic centers, and other facilities otherwise not specified (e.g. clinics, dialysis centers, dental clinics,	LGUs by province/ HUC/ICC

and COVID-19 laboratories), dealing with COVID-19 cases, contacts, and specimens for research purposes, screening and case management coordinated through their respective local government units; and	CHDs for laboratories
This shall include all health workers that are not based in any health facility.	NVOC for staff involved in screening and border control through NGAs such as BOQ
Priority A1.7 Closed institutions and settings such as, but not limited to, nursing homes, orphanages, jails, detention centers, correctional facilities, drug treatment and rehabilitation centers, and Bureau of Corrections.	LGUs by province/HUC/ICC

- 2. Each accountable unit shall ensure implementation of the following functions:
 - a. Conduct of open calls for master listing of eligible populations
 - b. Conduct verification of eligibility for the priority group

- c. Submit updated masterlists and attested endorsement of total number of eligible population using official institution letterhead signed by head of institution to the appropriate Vaccine Operations Centers (VOC) on the designated deadlines
- d. Incorporate all members of the subpriority group in local plans for microplanning
- 3. Regional Vaccine Operations Centers (RVOC) shall ensure validation of masterlists through the following methods:
 - a. Separate counting and reporting of LGU masterlist submissions between facilitybased and non-facility based Priority A1 eligible recipients, preferably with appropriate sub prioritization category (A1-1.A1.7)
 - b. Strict requirement of a signed attestation form by the Medical Center Chief or Local Chief Executive that includes the number of endorsed eligible population and compliance to the prioritization framework for eligibility
 - c. RVOC validation of outlier facilities who have submitted attested masterlists, which may include the following flags:
 - i. Outliers (upper and lower 10%) of masterlist submissions by hospital type
 - ii. Community facility workers higher than average workers in hospitals
 - iii. Health facility masterlists more than 3 times their licensing data on health human resource

- d. Random checks for eligibility of persons submitted through masterlists by the Regional and National VOC as necessary
- 4. Local Government Units (LGUs) shall lead in the master listing of all Priority Groups:
 - a. All health care workers in stand alone facilities, non-health facilities or those conducting private practice as indicated in Priority Group A1.6 shall coordinate with their respective LGUs for masterlisting.
 - b. All private workers and businesses shall ensure internal masterlists are provided to the LGU for consolidation and oversight in overall allocation and planning.
 - c. Local DOH offices shall coordinate with LGUs for the schedule of registration and masterlisting of the next priority eligible groups, and communicate the same to the public.

C. Masterlisting and Allocation Planning for Priority Group A2

1. Sub-prioritization shall be as follows:

- a. Priority A2.1. Institutionalized senior citizens including those in registered nursing homes and other group homes with elderly working together (e.g. convents).
- b. Priority A2.2. All other senior citizens, including bed-ridden senior citizens at home
- 2. Allocation of vaccines to Priority Group A2 shall ensure the following:
 - a. Allocation of vaccines to senior citizens shall be done only after those masterlisted in Priority Group A1 have been provided doses in the scheduled vaccination days
 - b. Only vaccines with appropriate Emergency Use Authorization (EUA) and Health Technology Assessment for the respective age groups shall be allocated and provided to Priority Group A2
 - c. Allocation of vaccines to LGUs shall be based on completion of masterlists, adequacy of validation mechanisms, and readiness for implementation for Priority Group A2
- 3. Masterlisting should ensure appropriate reach of eligible population:
 - a. For institutionalized senior citizens, LGUs shall coordinate directly with institutions to ensure complete coverage. Unregistered group homes and institutions should be overseen by the LGUs especially for AEFI monitoring

post-vaccination and encouraged to be registered with the Department of Social Welfare and Development.

- b. For other senior citizens, LGUs shall conduct open calls for masterlisting through advertisement in social media, posting announcements in public or commercial spaces, coordination with institutions and group homes within their locality, or home visitation by LGU staff for bed ridden seniors.
- c. Senior citizens with special conditions (i.e. bedridden, those who are in a vegetative state, and those with limited life expectancy) shall obtain medical clearance from their attending physicians to discuss vaccine specific risks and benefits of vaccination to the unique situation of the patient.
- 4. Implementation guidelines for Priority Group A2 shall include the following provisions:
 - a. LGUs shall ensure official notification of eligibility and scheduling of eligible senior citizens
 - b. LGUs should facilitate transportation of senior citizens to vaccination centers through shuttles or allowing private transportation
 - c. Vaccination sites shall ensure that informed consent for the COVID-19 vaccination follow hierarchy of legally authorized representatives from national ethical guidelines
 - d. The Department of Health shall develop alternative formats of current templates such as informed consent forms and other materials shall be made available for senior citizens to ensure readability through simpler formatting and larger fonts
 - e. Vaccination sites shall ensure that waiting and monitoring areas shall be compliant to minimum health standards and conducive for senior citizens such as ensuring adequate ventilation and temperature control

D. Interim Clinical Guidelines for Implementation

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- 1. To harmonize and standardize implementation of the National COVID-19 Vaccine Deployment Program, the following interim clinical guidance are recommended by the iNITAG to be updated based on best available evidence:
 - a. To standardize implementation and limit confounding variables during Adverse Event Following Immunization (AEFI) causality investigations, the recommended interval between a COVID-19 and a non-COVID-19 vaccine is 14 days.

b. For individuals with an anaphylactic reaction to the first COVID-19 vaccine received, eligible vaccine recipients may be given complete dose of a different available vaccine provided there is (a) minimum interval of 14 days, (b) second vaccine does not contain the same excipients as the first vaccine, and (c) clearance from an allergology specialist.

- c. For eligible COVID-19 vaccine recipients needing urgent vaccination such as with anti rabies, tetanus, or immunoglobulins for animal bite, the recommended vaccine series must be completed first.
 - i. If an eligible COVID-19 vaccine recipient is for the first dose, there must be a 14 days interval from completion of treatment.
 - ii. If an eligible COVID-19 vaccine recipient is for the second dose, there must be a 14 days interval from completion of treatment. There is no need to repeat the first dose.
- d. Vaccination has no effect on RT-PCR test results. Serological testing or other diagnostic tests to detect current or previous infection with SARS-CoV-2 before vaccination is NOT necessary nor recommended before vaccination.
- e. Deferment of vaccination should be advised for eligible vaccine recipients that are found to have the following during health screening:
 - i. For those with active disease or other symptoms, defer and schedule until resolution of symptoms. For patients with COVID-19 symptoms, patients may be referred for COVID-19 testing if warranted, and deferred until they are fully recovered consistent with DOH guidelines.
 - ii. For those patients presenting with sBP > 180 and/or dBP >120 with signs and symptoms of organ damage (Hypertensive Emergency), defer vaccination and refer to the emergency room immediately. Reschedule vaccination until this condition is controlled. For patients with blood pressure elevation not considered as hypertensive emergency, administer vaccination site. All patients with persistent blood pressure elevation must be advised to seek clinic consultation for proper medical evaluation.
- f. For individuals with a prior history of COVID-19 infection, vaccination should be deferred after 90 days from recovery or completion of treatment. However, healthcare workers directly providing care to COVID-19 cases may be given the vaccine before this period provided a recommended interval of 14 days from recovery or completion of treatment are met.
- g. For individuals who became COVID-19 positive after receiving the first dose of vaccine, they should not be given the 2nd dose. For standardization and

effective implementation of AEFI monitoring and causality investigation, vaccination can be restarted after 90 days with a new first dose of vaccine.

- The DOH shall consolidate all current Clinical Practice Guidelines for reference of implementers at http://bit.ly/COVID19CPGs. The following Clinical Practice Guidelines are adopted as references for the National COVID-19 Immunization Program:
 - a. Position Statements of the Philippine Society of Allergy, Asthma, and Immunology on COVID-19 Vaccines and their Adverse Reactions. Released on March 19, 2021, www.psaai.org.
 - b. Joint Statements of the Philippine Heart Association (PHA) and the Philippine Society of Hypertension (PSH) on Elevated Blood Pressure Readings During COVID-19 Vaccination.Released on March 19, 2021.
 - c. Philippine Society for Microbiology on COVID-19 Vaccines and the Immunocompromised Host (ICH). Released on February 12, 2021

E. Health Registration and Screening During Vaccination Process

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- 1. During registration, each potential vaccine recipient shall be provided a copy of the vaccine specific fact sheet summarizing contents of the EUA, health declaration screening form and informed consent forms upon arrival to vaccination posts.
- 2. The health declaration screening form shall be used in screening the eligible vaccine recipients. Specific health screening (e.g. age, allergy to vaccine components) may be adopted per vaccine and shall be issued in vaccine specific guidelines.
- 3. Local Vaccine Operations Centers (LVOCs) shall ensure the production of materials for vaccine recipients and vaccination sites, using templates prescribed by the DOH, as necessary.

F. Legitimate Deferrals of Eligible Vaccine Recipients and Subsequent Allocation

- 1. All vaccination sites shall implement deferral of vaccination for all eligible vaccine recipients under the categories listed in DM 2021-0099, hereinafter referred to as legitimate deferrals.
- 2. Legitimate deferrals shall be allocated and provided vaccines at the time they will be allowed to be vaccinated. Heads of institutions shall forward deferred eligible recipients to the Local Vaccine Operations Center (LVOC) for planning and subsequent inclusion in future allocations.
- 3. Each vaccine recipient shall be allocated a complete dose regimen of the same vaccine depending on available supply. In the event of arrival of new doses of the same brand of vaccines, the allocation list shall be expanded consistent with the prioritization

same brand of vaccines, the allocation list shall be expanded consistent with the prioritization framework. Release of supply batched shall utilize the First In First Out approach in consideration of vaccine expiry and operational considerations.

4. To ensure uniform implementation of health screening, vaccine administration, and management of adverse events following immunization, national medical societies are requested to develop, update, and cascade brand or type-specific clinical practice guidelines for the COVID-19 vaccine deployment program. DOH guidelines shall be continually updated based on these recommendations.

G. Right of Refusal

- Considering the institutionalised prioritization criteria and order of priority
 populations recommended by the iNITAG, the EUA issued by the FDA where the use
 of Sinovac vaccine among healthcare workers directly providing care to COVID-19
 cases, though not contraindicated, is not recommended based on existing evidence,
 and the current absence of any available other COVID19 vaccine, Sinovac shall be
 administered to consenting members of Priority Group A1, without prejudice to
 their immediate eligibility to receive the other vaccine brands which may be available
 at a later date. Subsequently, implementation guidelines stated in DM 2021-0114
 "Guidelines on the Management and Administration of the Initial 600,000 Donated
 SARS COV-2 Vaccine (Vero Cell) Inactivated CoronoVac (Sinovac) Doses" shall
 remain in effect until there are changes to its EUA
- 2. Right of refusal provision is not applicable to other priority groups and other vaccines wherein there are no special precautions in its Emergency Use Authorization

H. Disposal of Personal Protective Equipment (PPE)

Healthcare waste management and disposal shall be in line with provisions in prior released issuances:

- 1. DOH Healthcare Waste Management Manual 4th edition (April 2020)
- 2. Annex A. Infection Prevention and Control Practices of Department Memorandum No. 2020-0072, Otherwise known as the "Interim Guidelines for 2019 Novel Coronavirus Acute Respiratory Disease (2019-nCoV ARD) Response in Hospitals and Other Health Facilities"
- 3. Department Memorandum No. 2021- 0031, entitled "Interim Guidelines on the Management of Health Care Wastes Generated from COVID-19 Vaccination."

F. Reporting Guidelines

- 1. All designated vaccination sites shall ensure reporting vaccination day performance through the following platforms:
 - a. End of day report in the prescribed template submitted through the DOHDataCollect Quick Count application for all vaccination sites or through

the standardized reporting template using the .xls file format and uploaded to <u>https://tinyurl.com/dailyVASreport</u>

- b. Full patient details of all vaccine recipients shall be sent through an excel format to the DICT for integration with the Vaccine Information Management System (VIMS) by uploading their files to <u>http://bit.ly/VIMSVASupload</u>. The DICT shall ensure accuracy of reported data before submission to NVOC and transmittal to TG Demand Generation and Communication.
- c. Adverse Events Following Immunization (AEFI) are any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine. AEFIs are classified as a notifiable health event of public health concern in accordance with the 2020 Revised Implementing Rules and Regulations of Republic Act No. 11332, or the Mandatory Reporting of Notifiable Diseases and Health Events of Public Health Concern Act. All health care providers and vaccination sites shall proactively detect and notify AEFIs from COVID-19 until one year after the latest dose of the vaccine recipient, as aligned with the instructions from the Emergency Use Authorization granted by the Food and Drug Administration for COVID-19 vaccines, through the following processes:
- d. All health care providers shall proactively detect AEFIs by asking for vaccination history among all patients seen, and classify seriousness based on established definitions.
- e. Serious AEFIs shall be prioritized in notification, reporting and response efforts, including but not limited to clinical management, care coordination or referrals, and crisis communication. Serious AEFIs are (a) AEFIs that result in any of the following outcomes: death; hospitalization or prolongation of an existing hospitalization; persistent or significant disability or incapacity; congenital anomaly or birth defect; or (b) AEFIs that may be life-threatening; or (c) AEFIs that require intervention to prevent any of the above-mentioned outcomes; or (d) AEFIs that are classified by the Department of Health, as recommended by the National AEFI Committee, as a medically important event or reaction.
- f. Upon detection, all health care providers shall accomplish the case investigation form (CIF) for AEFI, as downloadable from bit.ly/CIF-2021
- g. For minor or non-serious AEFIs, all health care providers shall only be required to fill out all fields in page 1 of the CIF.
- h. For serious AEFIs, all health care providers shall be required to fill out page 1 immediately for initial notification and reporting purposes, without compromising provision of patient care. For the subsequent pages, health care providers, local and regional epidemiology and surveillance units (ESU) shall cooperate and collaborate to comprehensively complete the other pages.
- i. For serious AEFIs, immediate notification shall be done to the respective LVOC and/or LESU, and RVOC and/or RESU based on locally set or regionally set mechanisms.

j. For serious AEFIs, immediate notification shall be provided to the Epidemiology Bureau in the following format sent to 09278234328 (Globe) or 09392108316 (Smart):

FORMAT	EXAMPLE
Name, Age, Sex, Hospital,	Juan Dela Cruz, 54/M, UP-PGH,
Date of Vaccination, Signs	Vaccinated March 2, 2021, Dizziness,
and Symptoms, Date of Onset	March 2, 2021 Given oral hydration and
of Symptoms, Management,	observed as out-patient, Sign/ symptoms
Outcome	resolved and sent home

- k. All hospitals, through their designated hospital ESUs, shall encode page 1 of the CIF from all newly detected AEFIs within their institution directly to VigiFlow at vigiflow.who-umc.org before 6:00PM of each day, including weekends and holidays.
- 1. All non-hospital health care providers, such as but not limited to local health offices, government and non-government non-hospital vaccination sites, government and non-government non-hospital health facilities, shall submit page 1 of the CIF for encoding by their LVOCs through their local ESUs.
- m. Local ESUs shall encode newly detected or newly received reports by directly to VigiFlow at vigiflow.who-umc.org before 6:00PM of each day, including weekends and holidays.
- n. For serious AEFIs, all local ESUs and hospital ESUs shall update their respective RESUs or their representatives designated by the CHDs by submitting updated CIFs and informing of the latest clinical status, investigation status, and other pertinent information on a daily basis.
- o. The Vaccine Safety Surveillance and Response Teams of the Local Vaccination Operations Centers shall regularly coordinate with all government and nongovernment health care providers within their geographic jurisdiction to widen the capture of AEFI CIF, monitor timeliness of notification of AEFIs with particular attention to serious AEFIs, render appropriate clinical management and care coordination or referrals, and comprehensively investigate serious AEFIs.
- p. Food and Drug Administration (FDA) Regional Field Offices, by virtue of Article VIII, Section 5.e, of the Implementing Rules and Regulations of RA 9711, shall perform their stated role "To implement the established postmarketing surveillance system in monitoring health products and incidents of adverse events involving such products in coordination with the Product Research and Standards Development Division of each Center", in alignment with Section VI.H.2. of FDA Circular No. 2020-0036, wherein "the FDA together with concerned offices of the DOH shall conduct post-authorization monitoring to track product deployment, additional relevant information, and the status from the manufacturer concerning full-product life-cycle. Post-

authorization monitoring shall include adverse effects following immunization (AEFI) or adverse drug reactions (ADR)."

- i. FDA Regional Field Offices shall regularly check for newly encoded reports of serious AEFIs from VigiFlow, at least three times a day everyday, including weekends and holidays.
- ii. FDA Regional Field Offices shall confer immediately with the RESU to validate and conduct investigation on newly notified serious AEFIs.
- iii. When the Regional Epidemiology and Surveillance Unit is the first one to be notified through other channels of communication of a serious AEFI, the RESU shall inform the FDA Regional Office.
- iv. FDA Regional Offices shall be primarily in charge in investigating specific sections of the Case Investigation Form pertaining to vaccine product quality, and cold chain and transport.
- 2. The Task Group on Demand Generation shall develop guidelines on the following:
 - a. Reporting of COVID-19 vaccination statistics, including determination of official channels and cadence of release of the official vaccines bulletin; and
 - b. Process and structure of crisis communications for AEFI, including prescribed holding statements.

G. Updates on Issuances, Templates, and Reference Materials

- 1. All implementers shall conduct its COVID-19 vaccination program in consideration of the additional released issuances:
 - a. Department Memorandum 2021-0123: Interim Guidelines for the Management and Administration of the AstraZeneca (ChAdOx1-S [recombinant]) COVID-19 Vaccine
 - b. Department Memorandum 2021-0114: Guidelines on the Management and Administration of the Initial 600,000 Donated SARS COV-2 Vaccine (Vero Cell) Inactivated CoronoVac (Sinovac) Doses
 - c. Department Memorandum 2021-0116: Interim Guidelines on the Identification and Utilization of COVID19 Vaccination Sites
- 2. All standard templates for the vaccination day such as health screening forms, fact sheets, informed consent form shall continue to be updated in the following link: <u>bit.ly/RESBAKUNAMaterials</u>. All vaccination sites are recommended to use most updated versions of templates.
- 3. All implementers shall disseminate updated materials from <u>bit.ly/RESBAKUNAMaterials</u> in their official platforms. Access to reference materials is provided through the following links:

- a. For LVOCs/LGUs/other local partners or groups, the COVID-19 Vaccines Champions Kit may be downloaded at <u>bit.ly/COVIDVaccinesPHChampionsKit</u>.
- b. Policies issued by the government regarding COVID-19 vaccination may be accessed at <u>bit.ly/COVIDVaccinePolicies</u>.
- c. Information on COVID-19 vaccines may be verified through <u>https://doh.gov.ph/vaccines</u> and <u>covid19.gov.ph/vaccine</u>.

Implementation of the strategies to mitigate the spread and reduce morbidity and mortality due to COVID-19 which includes COVID-19 Vaccination with the Prevention, Detection, Isolation, Treatment and Reintegration strategy shall be a shared responsibility of the National Government, LGUs, private sector, and of the public.

The National Vaccines Operations Center, through the DOH Centers of Health Development, shall ensure effective cascade of all new guidelines and evidence related to the National COVID-19 Vaccine Deployment Program to all implementers.

For information of all concerned and strict compliance.

By Authority of the Secretary of Health:

MARIA ROSARIO SINGH-VERGEIRE, MD, MPH, CESO IV

OIC-Undersecretary for Health Public Health Services Team