Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

February 23, 2021

DEPARTMENT MEMORANDUM
No. 2021 - 0099

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

SUBJECT: **Interim Omnibus Guidelines for the Implementation of the National Vaccine Deployment Plan for COVID-19**

I. RATIONALE

In light of the absence of definitive treatment for COVID-19, it is expected that COVID-19 morbidity and mortality will continue to increase. The development of vaccines against COVID-19 is among the solutions that will greatly mitigate the increasing cases in the country, complemented by already existing measures and practices in place.

The Department of Health (DOH), through the Task Group COVID-19 Immunization Program, and in consultation with all agencies comprising the COVID-19 Vaccine Cluster, developed a comprehensive plan for vaccine deployment and vaccination. The National Deployment and Vaccination Plan (NDVP) for COVID-19 Vaccines seeks to provide the overall operational guidance in the implementation of the COVID-19 vaccine deployment and vaccination program in the Philippines. However, there is a need to supplement/update the National Deployment and Vaccination Plan given new developments.

To ensure safety and efficacy of vaccines to be administered to the public, ONLY vaccines which are granted with Emergency Use Authorization (EUA) by the Philippine Food and Drug Administration and positive recommendation from the Health Technology Assessment Council (HTAC) will be purchased by the government.

Likewise, policy decisions and recommendations are informed based on the recommendations of technical experts, convened to provide independent recommendations to the DOH, Vaccine Cluster, and IATF on vaccine implementation. These expert groups include the interim National Immunization Technical Advisory Group (NITAG), Technical Advisory Group for COVID-19, Health Technology Assessment Council, National Adverse Event Following Immunization Committee, and Vaccine Expert Panel.

These interim omnibus guidelines on COVID-19 vaccination shall provide the overall guidance to implementers on vaccine administration of the National Deployment and Vaccination Plan.

II. GENERAL GUIDELINES

A. Implementation of the Prevention, Detection, Isolation, Treatment, and Reintegration Strategies shall remain the cornerstone of response to prevent further transmission, and shall be a shared responsibility of the national government, local government units (LGUs), private sector, and the public.

B. COVID-19 vaccination shall be used as one of the major strategies to complement the existing measures and practices to mitigate the spread and reduce morbidity and mortality due to COVID-19.

C. The external agencies engaged in COVID-19 response shall comply with their specific roles and corresponding operational guidelines issued by the National Task Force (NTF) for COVID-19 response.

D. Minimum public health standards, which include physical distancing, hand hygiene, cough etiquette, and wearing of masks and face shields among others, shall be strictly implemented during the implementation of the NVDP.

E. General policy directions and program implementation of the vaccination plan shall be guided by technical expertise of vaccine expert groups, as independent recommending bodies to the National Government.

F. As a general rule, only vaccines granted Emergency Use Authorization (EUA) by the Philippine Food and Drug Administration (FDA) following FDA Circular 2020-036 and positive recommendations from the Health Technology Assessment Council (HTAC) shall be procured, distributed, and administered while an FDA-issued Certificate of Product Registration is unavailable. Separate guidelines detailing procedures for the acceptance and management of donations shall be issued.

G. Specific instructions provided in the EUA of COVID-19 vaccines granted by the FDA, and recommendations from the HTAC shall be judiciously taken into consideration in the planning and allocation of the Vaccine Cluster of the NTF Against COVID-19, distribution and program management of the regional and local Vaccine Operations Center, and the administration of vaccines by health care providers.

H. All vaccine recipients shall be monitored for the manifestation of any adverse reaction following immunization (AEFI) and referred to the appropriate facility for management.

I. Efficient information systems shall be in place to support operationalization of the vaccine implementation plan.

J. Policy cascade shall be facilitated by the NTF, DOH, Department of the Interior and the Local Government, Philippine Information Agency, and other lead agencies to ensure that vaccination plans of local government units (LGUs) are in line with the overall vaccination plan of the National Government.

K. PhilHealth shall cover individuals who will develop AEFI warranting hospitalization through new or existing benefit packages. PhilHealth shall publish relevant guidelines regarding coverage on AEFI.

III. IMPLEMENTING GUIDELINES

A. Prioritization Criteria

1. Due to competing global demand, vaccine supply is expected to start low and gradually increase in the succeeding months. As such, it is appropriate to adopt a phased implementation approach for the National Vaccine Deployment Program, following the objectives of ensuring reduction of mortality from COVID-19 and preservation of health system capacity, and strategically aligning the demand of priority populations to the expected vaccine supply, with three phases:

    a. Phase 1: Potentially limited supply of COVID-19 vaccine doses available - Concentrating efforts on **critical populations** based on risk of exposure and mortality;

    b. Phase 2: Large number of vaccine doses available - Ensuring access for the general population, particularly to the **working population**; and

    c. Phase 3: Sufficient supply of vaccine doses for entire population (surplus of doses) - Ensuring equitable access to **all populations**, monitoring uptake and coverage, and re-strategizing to increase uptake in populations with low coverage.

2. The National Government shall pool all available vaccine supply, regardless of whether donated, procured or sourced through tripartite agreements. Vaccinations shall follow the phased implementation approach and that vaccines are provided to the identified population groups following the prioritization schedule in consideration of the recommended age group and/or sector indicated in the EUA. As such, LGUs and private sector companies that entered into tripartite agreements shall abide by all relevant NVDP policies issued by NTF and DOH.

3. Sub-prioritization shall be determined by the Department of Health upon recommendation of the iNITAG conducted within a priority population group through selection of geographic areas if there is insufficient incoming supply of vaccines. Sub-prioritization shall be based on:

    a. COVID-19 burden of disease (current active cases, attack rate per 100,000 population in the past 4 weeks, and population density); and

    b. Vaccination site and/or Local Government Unit readiness, in particular, its supply chain capability, to mount a vaccination campaign.

4. Further sub-prioritization shall be conducted if there is noted insufficient incoming supply of vaccines even after employment of the sub-prioritization criteria. This shall be based on exposure and mortality risk..

5. As the need arises, methods of sub-prioritization for other priority groups may be further developed and threshed out in succeeding issuances after initial roll-out and consultation with relevant stakeholders.

B. Priority Population Groups

1. The priority population groups for COVID-19 immunization are as follows:

Phase 1 - Priority Eligible A	
A1	Frontline workers in health facilities both national and local, private and public, health professionals and non-professionals like students in health and allied professions courses with clinical responsibilities, nursing aides, janitors, barangay health workers, etc.
A2	Senior citizens aged 60 years old and above
A3	Adults with comorbidities not otherwise included in the preceding categories
A4	Frontline personnel in essential sectors both in public and private sectors, including uniformed personnel, and those in working sectors identified by the IATF that are directly client facing and cannot dutifully meet minimum public health standards
A5	Poor population based on the National Household Targeting System for Poverty Reduction (NHTS-PR) not otherwise included in the preceding categories
Phase 2 - Priority Eligible B	
B1	Teachers, Social Workers
B2	Other Government Workers
B3	Other essential workers
B4	Socio-demographic groups at significantly higher risk other than senior citizens and poor population based on the NHTS-PR
B5	Overseas Filipino Workers
B6	Other Remaining Workforce
Phase 3 - Priority Eligible C: Rest of the Filipino population not otherwise included in the above groups	

2. For priority group A1, all workers in a health facility shall be taken as a group. Facilities or institutions of prioritization, in the following order of precedence, may be sub-prioritized based on (a) historical admission of COVID-19 cases and (b) allocated and occupied COVID-19 beds:

   a. COVID-19 referral hospitals designated by the DOH;

b. 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;

c. 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;

d. 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;

e. Remaining hospitals including facilities of uniformed services not catering to COVID-19 cases;

f. 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;

g. Stand-alone facilities, clinics and diagnostic centers, and other facilities otherwise not specified (e.g. clinics, dialysis centers, dental clinics, 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

h. 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.

3. Sub-prioritization for other priority groups, and their respective exhaustive lists, shall be released in succeeding issuances.

C. Zoning Allocation Process for Vaccines with Sensitive Handling

1. Based on prioritization criteria and indicative supply by batch, allocation of vaccines for vaccination sites shall be by geographic zones incorporating pragmatic considerations such as availability of appropriate storage facilities, vaccination sites, or access roads.

2. Centers for Health Development (CHD), as well as the Ministry of Health - Bangsamoro Autonomous Region in Muslim Mindanao, guided by the Field Implementation and Coordination Team (FICT), shall determine the appropriate zoning for each region.

3. Each zone shall jointly develop micro plans for the joint undertaking of the vaccination program, especially regarding choice of vaccination sites or storage facilities, designation of human resources for vaccination and adverse event monitoring, transport of potential vaccine recipients, scheduling, health care provider referral for AEFI and follow-up processes, among others.

4. Each health facility, local government, or institution shall submit an attestation of the total number of potential vaccine recipients to the CHD for file keeping. Attestation forms must be in official letterheads signed by the head of the institution and must include total number of eligible vaccine recipients, total number of validated vaccine recipients willing to be vaccinated, their quick substitution list and rationale for choice of alternate facility, and confirmation that identified recipients and sites are consistent with national guidelines for the COVID-19 immunization program.

5. CHDs, with the guidance of FICT, shall allocate vaccines per zone in accordance with tray, batch, and logistic considerations.

6. If there are remaining stocks for delivery, FICT shall identify next eligible facilities using the prioritization framework.

D. Preparation of the Quick Substitution List (QSL)

1. To minimize vaccine wastage, vaccination sites or zones shall prepare a quick substitution list (QSL) in case of non-attendance of the initially identified eligible recipients of the vaccines.

2. QSLs shall include eligible recipients from facilities or sites within the same zone, province, highly urbanized city, or independent component city, provided that identification of recipients is based on the same priority group. QSLs shall not include eligible recipients from vaccination sites included in the allocation list of the current batch of vaccines.

3. During the vaccination day, and in case of non-attendance, the hospital should first attempt to vaccinate its healthcare workers that are scheduled in the succeeding days.

4. If the initial list of identified recipients is exhausted, the vaccination site can then tap the recipients from the QSL. Vaccination of eligible recipients from the next priority group shall be the option of last resort.

5. It should be noted that no patient in active disease or with COVID-19 symptoms, as defined in Department Memorandum No. 2020-0512 entitled "Revised Omnibus Interim Guidelines on the Prevention, Detection, Isolation, Treatment, and Reintegration Strategies for, should be vaccinated.

6. Preparations for transporting vaccines to the QSL should be part of microplanning.

E. Masterlisting

1. The COVID-19 Vaccine Information Management System - Immunization Registry (VIMS-IR) shall be the official platform for master listing and pre-registration of individuals for COVID-19 vaccination.

2. Data standards and masterlisting processes shall be reviewed after the Phase 1 pilot in workers in frontline health services before implementation in succeeding phases. This includes the ability for External systems to be used to

submit the necessary information following the Minimum Required Data Fields for Vaccine Registration Systems.

3. DOH CHDs shall consolidate a list of eligible potential vaccine recipients.

4. Compliance to the data privacy act in processing personal information shall be ensured by the CHDs.

5. All health facilities and LGUs shall submit required data for masterlisting to the province/ highly urbanized cities/independent component cities, through any of the following methods:

    a. Vaccine Information Management System - Immunization Registry (VIMS-IR);

    b. Information system of the LGU linked to the VIMS-IR through an application program interface (API) or through the secured file transfer protocol (SFTP) of VIMS-IR;

    c. Dataset consistent with prescribed formats for bulk uploading through the information system; or

    d. Dataset consistent with prescribed formats for bulk uploading through the assistance of DOH CHDs.

    e. For areas without connectivity, individuals within the priority sectors can manually fill out a physical form and submit it to the Human Resource Office of the facility. The HR Office shall consolidate it for submission to the LGUs. The LGU shall then encode the forms to the system and submit it to the CHDs. HR Offices of hospitals, CHDs, and LGUs shall dedicate a personnel to accommodate manual submissions, although electronic submissions are most preferred for the VIMS-IR

F. Microplanning

1. Microplanning shall be conducted by all LGUs and implementing units, after submission of masterlists, QSLs and/or training of health workers. A readiness assessment tool shall be used to assess and monitor the implementation of the plan, and determine and address identified issues and gaps (www.tinyurl.com/covidvaccineRA & www.tinyurl.com/microplanningc19).

2. The following critical steps in microplanning shall be conducted:

    a. Determination of the number of eligible populations for COVID-19 vaccination in the facilities. Alternatively, upon guidance of the DOH CHD Director IV, a QSL shall be provided to the implementing facility;

    b. Identification of implementing departments/units in the facility, of the number of vaccination sites/posts, and of an operational spot map;

    c. Designation of supervisors, vaccination teams, Adverse Events Following Immunization (AEFI)/ Adverse Events of Special Interest (AESI) composite teams, and other personnel needed and available for the vaccination activity;

d. Identification of vaccination teams needed based on the number of eligible population;

e. Listing of all vaccination posts/geographic sites, including non-health facilities (e.g. schools, covered courts), with updated addresses, geographic coordinates, and landmarks;

f. Assignment of potential vaccine recipients and teams to an implementing unit / vaccination post/site;

g. Assessment of cold chain capacity at all levels and cold chain equipment needed;

h. Estimation of eligible population groups, either willing or not willing to be vaccinated;

i. Estimation of the vaccine requirement, AEFI emergency kit and ancillary supplies needed;

j. Timely delivery of vaccines and ancillary logistics;

k. Training of human resources for health;

l. Preparation of a Daily Vaccination Session Plan (daily itinerary);

m. Development of a communication plan for facility and/or community advocacy, social mobilization, partnership and engagement;

n. Development of a supervision and monitoring plan and schedule;

o. Preparation of an AEFI/AESI management, surveillance and response plan. This includes training on how to manage AEFI, risk communication and reporting; and

p. Development of a waste management plan, clearly describing how, when, where, and who will collect, transport and discard immunization waste, including PPE wastes, consistent with Department Memorandum 2021-0031 entitled "Interim Guidelines on the Management of Health Care Wastes generated from COVID-19 vaccination".

3. Micro plans shall be validated and consolidated per zone, province, highly urbanized city, or independent component city, ensuring collection and consolidation from levels of municipalities. The province/ HUC/ ICC shall submit consolidated microplans to the CHDs for concurrence, assessment of gaps, technical assistance, and finalization.

4. Status of micro plans shall be consolidated nationally through the FICT for progress and performance monitoring. Local government readiness shall be considered in allocation and distribution plans of the national government.

5. Local governments and health care provider networks in zones shall ensure that designated vaccination sites fulfill standards set by the Department of Health. The Regional Vaccine Operations Center (RVOC) shall ensure readiness of identified vaccination sites by providing technical assistance, corrective actions,

and conduct of simulation. Allocation of vaccines shall be dependent on readiness of the vaccination sites for vaccine-specific requirements. A separate issuance shall be provided to outline the standards and quality assurance for vaccination sites.

6. All LGUs shall designate referral hospitals within their health care provider networks for the management of AEFI/AESI. All vaccination sites shall be linked to a licensed health facility for accountability, with clearly identified health care provider network relationships for referral, and case management.

7. All CHDs and the Ministry of Health - Bangsamoro Autonomous Region in Muslim Mindanao shall establish and regularly convene Regional AEFI Committees (RAEFIC) within their areas of jurisdiction. The RAEFIC shall primarily conduct the causality assessment of investigated AEFIs, review the status of safety surveillance, and provide expert recommendations to the Regional Vaccine Operations Center for the improvement of the immunization program.

8. All Local Vaccine Operations Center shall set up 24/7 hotlines through various means of communication for the general public to convey their general concerns on vaccination and referral for AEFIs.

G. Logistics, storage, and handling

1. Shipment and acceptance of vaccines and ancillary immunization commodities shall follow the Department Memorandum No. 2021-0053 entitled, "Interim Guidelines on the Shipment and Acceptance of the COVID-19 Vaccines and Ancillary Immunization Commodities."

2. Vaccines shall be inspected by the DOH Inspection and Acceptance Committee for COVID 19 Vaccines and Related Ancillary Supplies, which was reconstituted through Department Personnel Order No. 2021-0215, upon arrival at the main warehouse facility prior to distribution to vaccination sites. The Inspection and Acceptance Committee shall ensure that vaccines are of good quality upon arrival and that full documentary requirements are present, including but not limited to the shipping documents, invoice, and packing list. Similarly, CHDs, LGUs, and identified recipients shall assess the quality of vaccines upon receipt.

3. Cold chain management requirements shall be maintained from manufacturing, storage, and distribution of vaccines to ensure integrity of vaccine compounds. Vaccine cold chain storage facilities shall be assessed by the Research Institute for Tropical Medicine and Supply Chain Management Service of the DOH. Particular requirements and constraints on temperature maintenance for transport, storage and administration of vaccines shall be maintained.

4. As the different types of vaccine require varying temperature storage requirements, (1) ultra-cold (-70°C to -80°C), (2) frozen (-15°C to -25°C), and (3) refrigerated (2°C to 8°C), vaccine-specific policies shall be developed in consideration of differences in handling and storage requirements of vaccines.

5. Transport of vaccines and other ancillary commodities shall be assisted by uniformed personnel such as the Philippine National Police and others as may be designated to ensure vaccine security.

6. CHDs, LGUs, and identified recipients of vaccines and ancillary commodities shall develop their distribution plan appropriate to their situation, including inspection process prior to acceptance and timelines to avoid vaccine spoilage.

H. Training of Health Care Workers

1. The Regional Vaccine Operation Center shall conduct orientation and training to all health staff from local health offices and other stakeholders for COVID-19 vaccination. In light of the ongoing pandemic, online training is recommended. For those conducting face-to-face training, adherence to MPHS shall be strictly enforced at all times.

2. EPI Managers shall verify the awareness of health personnel on important knowledge for the COVID-19 vaccination program, including but not limited to IPC measures during mass vaccination, vaccine-specific management, and AEFI/AESI management.

I. Vaccination Process

1. *Pre-vaccination screening*

   a. Eligible vaccine recipients belonging to special populations like those in immunodeficiency state and 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.

2. *Scheduling*

   a. Each potential vaccine recipient included in the masterlist shall be assigned to a specific vaccination site and a specific vaccination team. Prior to the vaccination, the potential vaccine recipient will be provided with a vaccination date and time schedule, and a unique identifier which he/she will bring to the vaccination post, to ensure smooth implementation of the vaccination activity and to avoid congestion in the vaccination site/post.

   b. No walk-in vaccination shall be accommodated since vaccines allocated for the day are sufficiently assigned for the projected number of vaccinations to be conducted in a day.

   c. Vaccine recipients identified in the pre-determine QSL shall be made aware of possible schedules for substitution in case of non-attendance of the originally scheduled recipients.

   d. Scheduling for vaccination shall be made by local governments or zones, in accordance to available supply and deliveries. The VIMS platform shall also enable use of information and communications technology for scheduling, notification, and vaccination reminders.

3. *Registration*

   a. All potential vaccine recipients shall be registered using their unique identifiers as identified during the masterlisting process such as but not limited to full name and birthday, PhilHealth Identification Number (PIN), system generated alphanumeric or QR or Unique Codes, or similar.

   b. PhilHealth shall ensure availability of mechanisms to retrieve PIN of all recipients with current membership prior to vaccination day or on-site, and facilitate registration of recipients who are not yet registered under the National Health Insurance Program guided by PhilHealth Circular No. 2018-0008.

   c. All potential vaccine recipients shall also present any government issued identification card such as PRC license, driving license, UMID, PhilHealth ID, passport. In case of no government ID with picture, patients may present any government documents such as cedula, barangay certificate, birth certificate.

   d. Each potential vaccine recipient should be provided a copy of the vaccine specific fact sheet summarizing contents of the EUA, health screening form and informed consent forms upon arrival to vaccination posts. For reference, sample templates for the Pfizer-BioNTech COVID-19 Vaccine can be accessed in this link: bit.ly/RESBAKUNAMaterials

   e. As deemed appropriate and necessary by the Local Vaccine Operations Center (LVOC)/implementing unit, the EUA of the vaccine can be supplemented with the provision of other IEC materials developed by TG Demand Generation and Communications, as contained in the following link: http://bit.ly/COVID19VaxMaterials4Partners

4. *Screening*

   a. At the screening area, the personnel assigned shall scan the patient's QR or Unique Code. Eligible vaccine recipients shall be clinically assessed for COVID-19 symptoms, comorbidities, and other important clinical information. Contraindications and precautions stated in the EUA of FDA, as well as recommendations from the HTAC, shall be followed for all vaccines.

   b. Using both the VIMS Vaccination Post System (VPS) and hard copy of the screening form, the health worker shall update the profile of potential recipients and determine whether or not they are eligible for vaccination.

   c. Individuals not belonging to special population groups may have their health profiling, provision of informed consent, and screening on the same day of vaccination.

   d. The health screening form shall be used in screening the eligible vaccine recipients. ***(See Annex A)*** Specific health screening (e.g. age, allergy to vaccine components) may be adopted per vaccine and shall be issued in vaccine-specific guidelines. Likewise, health screening for vaccination shall follow clinical practice guidelines of medical societies, which should be

regularly updated based on best available evidence. The recommendations from the Philippine Society for Microbiology and Infectious Diseases (PSMID) including recommendations from NITAG are adopted to develop the interim decision algorithm for the COVID-19 vaccination program.

i. The vaccination of persons falling under the following categories **must be deferred and rescheduled** until resolution of specific conditions:

   (a) Persons 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. These individuals may be vaccinated with the COVID-19 vaccine only after full recovery from the acute illness as certified by their attending physician based on current management guidelines.

   (b) Persons with a history of exposure to a confirmed or suspected COVID-19 case in the past 2 weeks may be vaccinated only after completion of the 14-day quarantine period.

   (c) Confirmed COVID-19 patients may be vaccinated after 90 days from the last day of isolation or treatment, regardless of disease severity.

   (d) Persons who received convalescent plasma or monoclonal antibodies for COVID-19 may be vaccinated 90 days from the last day of plasma/ monoclonal antibody treatment.

   (e) Women belonging to Priority A1 of workers in frontline health facilities who are in their first trimester of pregnancy may be vaccinated after the first trimester.

   (f) Persons who received any other type of vaccine in the past 2 weeks should be rescheduled after completion of two weeks interval.

ii. Immunocompromised persons under the following category shall consult their attending physician or a primary care provider to obtain clearance prior to vaccination for appropriate patient education on the risks and benefits of vaccination. Specific qualifiers indicated shall be considered in the assessment of the health care worker.

   (a) For persons with autoimmune disease, if the patient is in remission.

   (b) For persons living with HIV, if the patient's current CD4 count is low and if the patient is on treatment.

(c) For persons with cancer or malignancy, if the patient is undergoing or have immediate plans for chemotherapy, or is in remission.

(d) For transplant patients, if the patient is on immunosuppressants or in remission.

(e) For persons who use steroids, if the dose and duration of steroid use is more than 2 weeks or dose is higher than 20 mg daily for prednisone.

(f) For persons who are elderly, bedridden, in a vegetative state, or with poor prognosis such as those with limited life expectancy of less than 6 months.

iii. Additional precautions must be implemented to the following:

(a) Persons with a history of bleeding disorders or currently taking anticoagulants should be vaccinated using a gauge 23-25 syringe. Firm pressure shall be applied after vaccination to avoid formation of a hematoma.

(b) Persons with a previous history of anaphylaxis, with allergies to food, egg, medicines, and persons experiencing asthma shall be observed for 30 minutes after vaccination.

(c) Persons who do not meet any of the criteria otherwise stated shall be observed for 15 minutes after vaccination.

iv. Persons falling under the following categories may be vaccinated with the COVID-19 vaccine:

(a) Breastfeeding women

(b) Persons who received immune globulins

5. *Health Education*

a. There shall be a dedicated health education area for the whole vaccination site/post. In this area, Information, Education, and Communication (IEC) materials, such as pamphlets, leaflets, and brochures shall be made available. Also, a projector or a TV shall be set up in this area, or the least, a flipchart, for health education purposes.

b. The general process for the health education area shall be aligned with the steps detailed in the Philippine National COVID-19 Deployment and Vaccination Plan for COVID-19 Vaccines.

i. Grouping the vaccine recipients (if applicable, to at least 6-12 individuals).

ii. Sharing an explainer video (or explainer poster, for areas that may experience technical difficulties) on COVID-19 vaccines to the group of vaccine recipients.

iii. Encouraging the vaccine recipients to ask questions and clarifications and then addressing issues that they may have.

iv. If not yet previously covered in the shared explainer, providing information on the COVID-19 vaccine made available at the vaccination site - what it is, how it protects, administration and possible side effects.

v. Explaining to the vaccine recipients that he or she may opt to receive the 2nd dose from another facility provided that the 2nd dose is the same brand as the 1st dose.

vi. Instructing the patient on post-vaccination care:

(a) Put an ice pack/ice on the injection site for 15 minutes three times a day, in the first 24 hours after vaccination. Report any AEFI to the clinic/hospital.

(b) For any serious AEFI, proceed immediately to the nearest Emergency Room.

vii. Providing additional IEC materials (pamphlets with FAQs, etc) at suitable reading levels to the vaccine recipients and available in recipients' local language. The following link provides for IEC materials developed by TG Demand Generation and Communications that can be used in vaccination sites: http://bit.ly/COVID19VaxMaterials4Partners

viii. Providing Vaccine Information Statements (VIS) or EUA forms, if required.

ix. Asking the vaccine recipients to sign the final consent form.

x. Directing the patient to the Screening Area.

c. Vaccine recipients shall sign two (2) copies of the informed consent form. One copy shall be provided to the patient and one kept by the vaccination facility.

d. The informed consent form shall be made available online so that vaccine recipients may download it in advance and sign it on the day of vaccine administration after dialogue with the vaccine administrator.

e. The informed consent form shall contain the following pertinent information:

i. Statement specifying that the vaccine recipient understands that the vaccine is an investigational drug and that they were shown the fact sheet of the EUA;

ii. Statement declaring that the vaccine recipients were assessed using the health screening form to ensure that those who are at risk will be managed and referred appropriately;

ii. Statement declaring that the vaccine recipients were assessed using the health screening form to ensure that those who are at risk will be managed and referred appropriately;

iii. Name of the specific facility or the primary care provider that the vaccine recipient may contact or visit for follow up after vaccination in case of any symptoms; and

iv. Statement disclosing that all data collected throughout the COVID-19 vaccination program will be used for public health purposes.

f. Different IEC materials and informed consent forms may vary for each vaccine due to the different legal requirements for each supply agreement.

6. *Vaccine Administration*

a. The potential vaccine recipient shall wait in a designated area prior to immunization. The Safety Officer shall ensure that physical distancing measures are implemented in the waiting area at all times.

b. The potential vaccine recipient shall be directed to the Vaccination Area where the vaccine will be administered. The vaccinator shall check that the vaccine to be administered is not expired and has been stored in the appropriate temperature and shall strictly comply with the instructions of the product label of the vaccine product.

c. Only licensed physicians or nurses may be vaccinators for vaccines under Emergency Use Authorization. Pharmacists may administer FDA-approved vaccines provided that they undergo training from Professional Regulation Commission-accredited institutions. Midwives may assist in the vaccination.

d. Vaccines shall be drawn up in 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 should 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.

e. Prior to inoculation, vaccinators shall 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.

f. Once vaccinated, the QR or Unique Code shall be scanned and the vaccination details (e.g. date of vaccination, vaccine manufacturer, batch number, lot number, name of vaccinator and signature) shall be recorded in the Vaccination Post System (VPS) and immunization card.

g. Specific vaccine administration strategies may be adopted per vaccine. Likewise, these shall follow clinical practice guidelines of medical

a. After vaccination, the vaccine recipient shall be observed for adverse events for 15 minutes at the post-vaccination monitoring area. If the recipient has a previous history of asthma, anaphylaxis, and or allergies to food, egg, medicines, the observation time shall be extended to 30 minutes. The post-vaccination monitoring area must be closely linked with an identified referral health facility. In the event of life-threatening adverse events manifesting as anaphylaxis or severe allergic reactions, health care providers in the post-vaccination monitoring area must be able to provide emergency treatment and resuscitative measures, such as administration of live-saving medicines and basic life support. In case of limited human resource of health availability, those who can provide the necessary treatment even if beyond their respective service capability or professional capacity, shall not be liable for any harm involved as long as the benefit of providing treatment outweighs the risk of not providing treatment in dire situations with a high likelihood of death.

b. Upon release from observation, vaccination staff must inform the vaccine recipient of specific facility, hotlines, and contact numbers for follow up and for reporting of any AEFI.

c. A standardized physical vaccination card (***see Annex B***) shall be given to vaccine recipients to ensure completion of the two doses and to enable monitoring of adverse events. The physical vaccination card must be printed by the facility/LGU in line with printing standards set by the DOH. The scheduled date for the second dose shall be indicated in the 2nd dose box in the physical vaccination card.

d. An electronic version of the vaccination record shall be made available through a secured search platform developed by Department of Information and Communications Technology (DICT) for designated users to verify the vaccination status of patients in the Vaccine Information Management System or VIMS.

e. Vaccine recipients who experience adverse events following immunization (AEFI) during the post-monitoring period at the vaccination site shall immediately be brought to designated health facilities within their healthcare provider networks. The LGU shall ensure capacity of the facilities to provide healthcare in response to the event and ensure the timely detection, notification, reporting and investigation of AEFIs.

8. Patient Follow-up

a. Monitoring of AEFI shall be done up to 1 year from date of vaccination through the vaccination site or through the vaccine recipient's primary care provider. LGUs shall ensure the availability of primary care providers, in compliance to standards set forth by DOH and PhilHealth, and that all vaccine recipients are assigned to a primary care provider for monitoring for at least a year post-vaccination.

b. LGUs shall ensure that vaccine recipients are notified and reminded about their second dose, follow-up, and other relevant announcements utilizing

both local mechanisms and information and communications technology platforms.

J. Adverse Event Following Immunization (AEFI) and Referral

1. AEFIs shall be defined as any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. AEFIs may be classified based on seriousness, or based on cause.

    a. Serious AEFIs are defined as events that results in any of the following outcomes:

        i. death;
        ii. hospitalization or prolongation of an existing hospitalization;
        iii. persistent or significant disability or incapacity;
        iv. congenital anomaly or birth defect;

        Or an event that may be
        v. life-threatening; or
        vi. a medically important event or reaction

    b. Non-serious, or minor AEFIs are AEFIs that are not included or categorized as serious AEFIs, or do not pose a potential risk to the health of the recipient.

        i. Non-serious AEFIs include, but are not limited to, local adverse events (such as pain, swelling, redness) and systemic reaction (fever) that are expected after immunization as part of the immune response of the vaccine recipient to induce immunity.

        ii. Non-serious AEFIs should also be carefully monitored because they may signal a potentially larger problem with the vaccine or vaccination or have an impact on the vaccination acceptability; in general.

    c. An adverse event of special interest (AESI) is a pre-specified medically-significant event that has the potential to be causally associated with a vaccine product that needs to be carefully monitored and confirmed by further special studies.

        i. Shortlisting of conditions to be considered as AESIs for active surveillance, and their respective notification and reporting process shall be provided in a separate issuance, and regularly reviewed upon expert recommendations.

    d. Cause-specific definitions of AEFIs are as follows:

        i. Vaccine product-related reactions are AEFIs caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product.

        ii. Vaccine quality defect-related reactions are AEFIs caused or precipitated by a vaccine that is due to one or more quality defects

of the vaccine product including its administration device as provided by the vaccine manufacturer.

iii. Immunization error-related reactions are AEFIs caused by inappropriate vaccine handling, prescribing or administration.

iv. Immunization anxiety-related reactions are AEFIs arising from anxiety about the immunization.

v. Coincidental events are AEFIs caused by something other than the vaccine product, immunization error or immunization anxiety.

2. The health care providers who administered the COVID-19 vaccine to recipients shall be primarily in charge of regularly monitoring AEFIs among those individuals until one year after vaccination.

   a. All vaccine recipients shall monitor themselves for any adverse events within the prescribed time frame, and regularly report to their respective primary care provider on their experience.

   b. All vaccination sites shall ensure that proper and appropriate guidance is communicated to and understood by each vaccine recipient regarding the regular monitoring of their health status, with mechanisms and schedules for follow-up.

   c. All local vaccination operations centers shall ensure that vaccination sites regularly and actively monitor the vaccine recipients they have provided services for.

      i. In case of unavailability of the vaccination site within the time frame of monitoring due to closure, or other causes; change in residence of the vaccine recipient, or other causes that may hinder the monitoring of AEFIs from the vaccine recipient, the LVOC shall enact mechanisms to ensure that adequate monitoring is still conducted among these vaccine recipients.

3. Health care providers shall appropriately manage patients' conditions according to clinical assessment regardless of the seriousness or causality of the AEFI.

   a. If a health care provider sees that the patient warrants further evaluation and clinical management, referrals shall be coursed through the respective health care provider networks within their locality.

   b. All vaccination sites shall provide corresponding assistance to vaccine recipients experiencing AEFIs.

   c. All vaccination sites shall ensure that proper and appropriate guidance is communicated to and understood by each vaccine recipient regarding the contact information or health facilities for the vaccine recipient's primary referral in case of health emergencies outside the vaccination site.

   d. All vaccination sites shall ensure that serious AEFI cases are provided with immediate assistance which may include hospitalization and transport to the appropriate health facility, within the configuration of their respective health

care provider network. PhilHealth coverage of hospitalizations shall be in accordance with the rules and regulations of the National Health Insurance Program. Transportation arrangements shall be provided by the vaccination site, in coordination with existing service providers in the locality, and the local government unit in charge.

e. All vaccination sites shall prepare for AEFIs during the vaccination proper in terms of human resource capacity, medications and commodities, as recommended by clinical practice guidelines and expert recommendations.

f. All health facilities shall be prepared to receive AEFIs within their respective service capability. They shall also fortify mechanisms on referral and ensure that contingency plans are in place.

g. Local vaccination operations centers (LVOC) shall ensure that health facilities are prepared to receive AEFIs within their respective service capability, and mechanisms for and contingency plans for referral are in place.

h. RVOCs, CHDs, RAEFICs, and LVOCs shall regularly monitor and assess the status of safety surveillance at the sub-national level, including but not limited to AEFI monitoring, through formal and informal feedback and provide corresponding responsive risk communication and immunization safety interventions.

i. At the national level, the Sub-Task Group Safety Surveillance and Response, shall lead in overseeing the functionality of stakeholders in performing their respective functions across the safety surveillance cycle.

4. 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.

   a. All health care providers shall notify and report AEFIs regardless of seriousness, to the local vaccinations operations centers and to the National Government through the appropriate electronic platform, with the minimum data fields requested, within the appropriate time frame requested.

   b. All government and non-government licensed hospitals serving as vaccination sites shall submit directly to an electronic platform through their Hospital Epidemiology and Surveillance Units.

   c. All other vaccination sites shall submit through the respective local vaccination operations center providing oversight to their operations.

   d. All local vaccination operations centers at the municipal and component city levels shall ensure that the vaccination sites within their respective jurisdiction of oversight observe proper, timely and accurate notification of detected AEFIs.

e. All regional, local vaccination operations centers, and hospital vaccination sites shall designate an AEFI focal person for coordination, capacity-building, and authorization purposes.

5. Local Vaccination Operations Centers shall ensure the functionality of an AEFI Investigation Team that shall conduct timely and comprehensive AEFI investigations following the standard epidemiological investigation principles to be continually reviewed based on guidance from the World Health Organization, with expert recommendations from the National AEFI Committee.

    a. All health care providers shall cooperate with the AEFI Investigation Team in terms of provision of copies of medical records and other paraphernalia that may aid investigation and causality assessment, in accordance with Republic Act 113322 or the "Mandatory Reporting of Notifiable Diseases and Health Events of Public Health Concern Act".

6. The National and Regional AEFI Committees shall determine the final causality assessment through systematic methodologies, in accordance with the latest guidance from the World Health Organization, and other reputable organizations.

    a. AEFIs that shall undergo detailed case investigation and causality assessment will be based on the guidance from the COVID-19 Vaccines: Safety Surveillance Manual of the World Health Organization, with expert recommendations from the National AEFI Committee.

7. Data, information generated from the AEFI monitoring system, and recommendations from the National AEFI Committees shall be utilized in the continuing quality improvement of the immunization program and upholding of vaccine safety.

K. Data and Record Management

1. The VIMS, developed and maintained by the DICT, shall be used as the main platform for vaccine related interventions for immunization, supply chain and logistics management. The following information systems developed by the DOH shall be linked to the VIMS:

    a. The COVID-19 Bakuna Center Registry (CBCR), a complete listing of all vaccination sites in the country both in public and private shall be used by the local and national government in monitoring and managing vaccination sites being set-up across the whole country. Registration in the CBCR is important most especially in coordinating with third-party logistics.

    b. The Vaccination Quick Count, a dashboard which will visualize critical indicators from the vaccination sites on a daily basis, shall provide regional and local vaccination operations centers (RVOCs and LVOCs) with timely data. It will provide insights on what is happening on the ground especially on areas that require urgent actions. Following are the roles and responsibilities on its implementation:

i. The vaccination site supervisor shall be in charge of the daily reporting at vaccination sites.

ii. The CHDs shall be responsible for managing and responding to inquiries on the system and compliance to data submissions.

2. LGUs with existing information systems or applications who expressed interest to connect to national COVID-19 vaccination information systems shall coordinate with the DICT. CHDs, through the RVOC shall assist to facilitate this process.

3. Any paper record for individual vaccination including the informed consent form shall be classified as a permanent vaccination record. All health facilities shall have proper storage protocols in compliance to health record management guidelines to ensure safekeeping and data protection.

4. Any paper record at vaccination sites is under the responsibility of the vaccination site supervisor. The supervisor is also responsible for daily reporting in the vaccination quick count.

5. All authorized entities that have the mandate or legitimate purpose to process COVID-19 vaccination-related data shall be considered as personal information controllers (PIC). LGUs shall be responsible for the management of all personal data collected from barangays and local vaccination sites in their jurisdiction while CHDs shall be accountable for all personal data from regional vaccination centers including those endorsed/migrated to their system. As PICs, they are expected to uphold transparency, legitimate purpose and proportionality in all the stages of data processing (i.e., collection, duplication, storage, disposal, etc.). They shall practice the highest applicable protection measures in processing personal and sensitive personal information in accordance with the standards for data privacy and security as prescribed in the Data Privacy Act of 2012; issuances by the National Privacy Commission (NPC) and DICT; and other applicable legislations. At the minimum, CHDs shall enforce the following:

    a. They must have a designated or appointed Data Protection Officer or Compliance Officer for Privacy, who shall be accountable for all data privacy-related activities.

    b. Privacy Notice or Privacy Policy shall be posted on conspicuous places within the vaccination facility. Paper-based forms used in collecting personal data shall indicate all information needed by the data subject, such as:

        i. contact information of the data protection officer;

        ii. data processing that will be done to their personal data; and

        iii. individuals that will have access to their personal data.

    c. In case of breach or report of possible breach, units are advised to follow the prescribed procedures from NPC Circular No. 2016-03: Personal Breach Management.

L. Demand Generation Activities

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

2. LGUs shall provide regular updates to the CHDs on their identified microplan demand generation and communication activities, and on their collected social listening data, as provided and described in the Demand Generation Playbook (tinyurl.com/DemGenPlaybook).

3. CHDs shall provide bimonthly updates to the TG Demand Generation and Communications on the progress of activities based on microplans.

4. CHDs shall ensure feedback mechanisms and social listening by a) reporting frequently asked questions, misinformation, and rumors weekly to the TG Demand Generation and Communications, b) disseminating the online sectoral survey monthly, and c) consolidating encoded submissions of the COVID-19 vaccines face-to-face survey by provinces and highly urbanized cities.

5. CHDs shall disseminate COVID-19 vaccine IEC materials and ensure alignment of localized materials with the *RESBAKUNA: Kasangga ng BIDA* branding guidelines.

M. Templates

All standard templates, collaterals, and FAQs may also be accessed at DOH website or through the following link: bit.ly/RESBAKUNAMaterials.

This Order shall take effect immediately.

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

ANNEX A. Health Assessment Form

Access the document here: bit.ly/RESBAKUNAMaterials

HEALTH DECLARATION SCREENING FORM
of the Philippine National COVID-19 Vaccine Deployment and Vaccination Program

ASSESS THE PATIENT	YES	NO
Age more than 16 years old?	☐	☐
Has no allergies to PEG or polysorbate?	☐	☐
Has no severe allergic reaction after the 1st dose of the vaccine?	☐	☐
Has no allergy to food, egg, medicines and no asthma?	☐	☐
➢ If with allergy or asthma , will the vaccinator able to monitor the patient for 30 minutes?	☐	☐
Has no history of bleeding disorders or currently taking anti-coagulants?	☐	☐
➢ If with bleeding history, is a gauge 23 - 25 syringe available for injection?	☐	☐
Does not manifest any of the following symptoms: ☐ Fever/chills ☐ Headache ☐ Cough ☐ Colds ☐ Sore throat ☐ Myalgia ☐ Fatigue ☐ Fatigue ☐ Weakness ☐ Loss of smell/taste ☐ Diarrhea ☐ Shortness of breath/difficulty in breathing	☐	☐
Has no history of exposure to a confirmed or suspected COVID-19 case in the past 2 weeks?	☐	☐
Has not been previously treated for COVID-19 in the past 90 days?	☐	☐
Has not received any vaccine in the past 2 weeks?	☐	☐
Has not received convalescent plasma or monoclonal antibodies for COVID-19 in the past 90 days?	☐	☐
Not Pregnant?	☐	☐
➢ If pregnant, 2nd or 3rd Trimester?	☐	☐
Does not have any of the following diseases or health condition? ☐ HIV ☐ Cancer/ Malignancy ☐ Underwent Transplant ☐ Under Steroid Medication/ Treatment ☐ Bed ridden, terminal illness, less than 6 months prognosis	☐	☐
If with the abovementioned condition, has presented medical clearance prior to vaccination day?	☐	☐

VACCINATE

Recipient's Name:

Birthdate: **Sex:**

Signature of Health Worker:

HEALTH ASSESSMENT ALGORITHM

of the Philippine National COVID-19 Vaccine Deployment and Vaccination Program

ASSESS THE VACCINE RECIPIENT
Is the patient any of the following?

- Age < 16 years old
- With allergy to PEG or polysorbate
- With severe allergic reaction after the 1st dose of the vaccine

YES → **DO NOT VACCINATE**

NO ↓

With allergy to food, egg, medicine?

YES → **SPECIAL PRECAUTION**
OBSERVE FOR 30 MINS

NO ↓

Have history of bleeding disorders or currently taking anti-coagulants?

YES → **SPECIAL PRECAUTION**
USE GAUGE 23-25. APPLY FIRM PRESSURE.

NO ↓

VACCINATE

DEFER

Manifesting any of the following symptoms:

- Fever/chills, headache, cough, colds, sore throat, myalgia, fatigue, weakness, loss of smell/taste, diarrhea, shortness of breath/difficulty in breathing

NO ↓ — YES → **REFER TO MD. RESCHEDULE AFTER FULL RECOVERY.**

Have history of exposure to confirmed or suspected COVID-19 case in the past 2 weeks?

NO ↓ — YES → **RESCHEDULE AFTER QUARANTINE COMPLETION**

Have been previously treated for COVID-19 in the past 90 days?

NO ↓ — YES → **RESCHEDULE AFTER 90 DAYS**

Have received convalescent plasma or monoclonal antibodies for COVID-19 in the past 90 days?

NO ↓ — YES → **RESCHEDULE AFTER 90 DAYS**

Pregnant?

NO ↓ — YES → **RESCHEDULE IF IN FIRST TRIMESTER**

Have received any vaccine in the past 2 weeks?

NO ↓ — YES → **RESCHEDULE**

- With autoimmune disease?
- Diagnosed with HIV?
- Diagnosed with Cancer/Malignancy?
- Underwent transplant?
- Under steroid treatment or medication?
- Bed ridden, terminal illness, less than 6 months prognosis

NO ↓ — YES → **GET CLEARANCE FROM ATTENDING PHYSICIAN**

ANNEX B. Vaccination Card

Access the document here: bit.ly/RESBAKUNAMaterials

COVID-19 Vaccination Card

Please keep this record card, *which includes medical information about the vaccines you have received.*

ID no. -

Last Name First Name M.I Suffix

Address _____ Contact No. _____

Date of Birth. _____ Sex _____ Philhealth No. _____ Category _____

Dosage Seq.	Date (mm/dd/yy)	Vaccine Manufacturer	Batch No.	Lot No.
1st Dose	/ /			
	Vaccinator Name:		Signature:	
2nd Dose (Schedule: / /)	/ /			
	Vaccinator Name:		Signature:	

Health Facility Name: _____ Contact No.: _____

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