Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

19 November 2021

DEPARTMENT MEMORANDUM
No. 2021 - 0492

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

SUBJECT: **Interim Guidelines on the Administration and Management of COVID-19 Vaccine Booster/Additional Doses to Priority Group A2: Senior Citizens ages 60 years old and above and Priority Group A3: Adults with Comorbidities**

I. RATIONALE

On November 15, 2021, the Philippine Food and Drug Administration (FDA) issued an amendment in the Emergency Use Authorization (EUA) to allow administration of additional/booster doses to the following specific populations:

1. Health care professionals and workers 18 years of age or older with frequent institutional or occupational exposure to SARS-COV2;
2. Individuals who may fail to mount an adequate response to a primary series of vaccines such as senior citizens and patients 18 years of age or older who are diagnosed with immunocompromised conditions; and
3. Persons 18 through 60 years of age with comorbidities and at high risk of developing severe COVID-19

Implementation for booster vaccination in healthcare workers started on November 17 consistent with guidelines set forth in Department Memorandum (DM) No. 2021-0484 also known as *Interim Operational Guidelines on the Administration of COVID-19 Vaccine Booster Doses to Priority Group A1: Essential Workers in Frontline Health Services (A1.1 to A1.7).*

Following the objectives of the National COVID-19 Vaccine Deployment and Vaccination Program in ensuring reduction of mortality from COVID-19 and preservation of health system capacity, the DOH issues these interim guidelines for the administration of COVID-19 additional and booster doses to the Priority Groups A2: Senior Citizens and A3:

Adults with Comorbidities. This DM shall be applicable to all concerned agencies of the NVOC, Regional Vaccination Operations Centers (RVOCs) or Centers for Health Development (CHDs), Local Vaccination Operations Center (LVOCs) or Local Government Units (LGUs), Provincial Health Offices (PHOs), City Health Offices (CHOs), Rural Health Units (RHUs), Implementing Units, and Vaccination Sites, both public and private.

II. OBJECTIVES

This Department Memorandum (DM) provides interim operational guidelines on the administration and management of COVID-19 vaccine booster doses to Priority Group A2 or Senior Citizens ages 60 years old and above and Priority Group A3 or adults with comorbidities.

III. DEFINITION OF TERMS

A. **Additional dose** - a dose which would be needed as part of an extended primary series for target populations where the immune response rate following the standard primary series is deemed insufficient as indicated in the EUA issued by the FDA. The objective of an additional dose in the primary series is to optimize or enhance the immune response to establish a sufficient level of effectiveness against disease. In particular, immunocompromised individuals often fail to mount a protective immune response after a standard primary series, but also older adults may respond poorly to a standard primary series.

B. **Booster dose** - refers to doses administered to a vaccinated population that has completed a primary vaccination series, when, with time, vaccine effectiveness has fallen below a rate deemed sufficient in that population, as indicated in the EUA issued by the FDA. The objective of a booster dose is to restore vaccine effectiveness from that deemed no longer sufficient.

C. **Heterologous dose** - refers to the administration of a COVID-19 vaccine of a different brand from the vaccine that was used to complete the primary vaccine series.

D. **Homologous dose** - refers to the administration of a COVID-19 vaccine of the same brand from the vaccine that was used to complete the primary vaccine series.

E. **Primary vaccination dose series** - refers to the number of doses as prescribed in the product-specific EUA provided by the FDA, either a two-dose or a one-dose series

IV. GENERAL GUIDELINES

A. The following COVID-19 vaccines are indicated for use as booster/ additional doses for Priority Group A2 and A3 as indicated in the approved EUA issued by the Philippine FDA (*Refer to **Annex A** for the copy of the EUA)*:
   1. BNT162b2 (Pfizer -BioNTech) COVID-19 vaccine
   2. mRNA-1273 (Moderna) COVID-19 vaccine
   3. CoronaVac (Sinovac) COVID-19 vaccine
   4. ChAdOx-1S recombinant (AstraZeneca) COVID-19 vaccine

B. Instructions for COVID-19 vaccination providers and administrators on storage and handling, dosing and schedule, administration, contraindications, warnings, adverse reactions, and use with other vaccines shall follow the product-specific EUA provided by the FDA and vaccine specific guidelines issued by the DOH. Copies of the EUA may be accessed at https://www.fda.gov.ph/list-of-fda-issued-emergency-use-authorization/.

C. Protocols for the management of Adverse Effects Following Immunization (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 Adverse Event Following Immunization (AEFI) Pathways may be accessed at bit.ly/RESBAKUNAFactsheets.

D. Registration, screening, counselling, vaccine recipient reporting, and AEFI monitoring and referral shall follow Department Memorandum 2021- 0099 *or "Interim Omnibus Guidelines for the Implementation of the National Vaccine Deployment Plan for COVID-19"*, DM 2021-0175 *or "Further Clarification of the National Deployment and Vaccination Plan for COVID-19 Vaccines and Additional Guidelines for Sinovac Vaccine Implementation"*, DM 2021-0218 *or "Further Clarification on the National Vaccination Deployment Plan on Health Screening and Management of Adverse Events Following Immunization"*, DM 2021-0220 or *"Interim Guidelines on Adverse Events Following Immunization (AEFI) Community Management and Crisis Communications Related to COVID-19 Vaccines"*, and other relevant policies issued by the DOH.

V. IMPLEMENTING GUIDELINES

A. Eligible Groups

1. Priority Group A2: Senior Citizens ages 60 years and above are medically indicated and shall receive either homologous or heterologous booster doses.

2. Priority Group A3: Individuals with Comorbidities in immunocompromised state are medically indicated and shall receive homologous or heterologous

additional doses as part of the primary series based on the recommendation of their attending physician. As such, this group shall have an additional dose to be classified as a fully vaccinated individual.

Section III.D.1 of the DM No. 2021-0157 or "Implementing Guidelines for Priority Group A3 and Further Clarification of the National Deployment and Vaccination Plan for COVID-19 Vaccines" on Priority Group A3 eligibility is clarified to include immunocompromised conditions identified by the WHO-SAGE. *(Refer to **Annex B** for the definition of immunocompromised persons from the WHO-SAGE "Interim Recommendations for an extended primary series with an additional vaccine dose for COVID-19 vaccination in immunocompromised persons as of October")*:

i. Immunodeficiency state

ii. HIV

iii. Active cancer or malignancy

iv. Transplant recipients

v. Patients under immunosuppressives

3. Priority Group A3: Individuals with Comorbidities in immunocompetent state (other comorbidities not mentioned under Section VI. A.1.b) may be provided either a homologous or heterologous booster dose.

B. Vaccination Rollout of Booster/Additional Doses

1. The vaccination to Priority Groups A2 and A3 shall be rolled out in a phased approach:

   a. Phase I: The vaccination rollout shall include the following:

      i. Administration of booster doses to Priority Group A2: Senior Citizens

      ii. Administration of third doses as part of the extended primary vaccination series to Priority Group A3: Individuals with Comorbidities in immunocompromised state.

   b. Phase II: the vaccination rollout shall include the following:

      i. Administration of booster doses to Priority Group A3: Individuals with Comorbidities in immunocompetent state (other comorbidities).

2. The Priority Groups A2 and A3 shall be given the option to choose whether he/she shall receive a homologous or a heterologous booster dose, depending on the availability of vaccine brands in the vaccination site.

C. Allocation of COVID-19 Vaccines as Booster Doses and Additional Doses

1. The NVOC shall allocate and distribute COVID-19 vaccines for booster doses and additional doses specific to the COVID-19 vaccine dose requirement of each region according to the recorded number of eligible populations which are computed based on the recommended dose interval.

2. The CHDs shall allocate COVID-19 vaccines based on the computed number of Priority Group A2 due to receive the booster and A3 due to receive the additional dose and per attestation of the dose requirement of the LVOC/LGU.

3. The LVOC/LGU shall determine the dose requirements per brand based on the computed number of Priority Group A2 and A3 due to receive the booster and additional doses, respectively.

4. The utilization of COVID-19 vaccines allocated as primary dose series for the administration of booster/additional doses is highly discouraged as provisions of COVID-19 vaccines for booster/additional doses will be distributed accordingly.

D. Administration of Booster Doses

1. The Priority Groups A2 and A3 shall receive a single dose of COVID-19 vaccine of either a homologous or a heterologous booster or additional dose depending on the eligibility, at least six (6) months after completion of the primary dose series of the following vaccines: Pfizer-BioNTech, Moderna, Sinovac, Gamaleya, and AstraZeneca COVID-19 vaccines; and at least three (3) months after completion of the primary dose series of Ad26.COV2.s (Janssen) COVID-19 vaccine.

2. The following volumes shall be administered:
   a. Pfizer-BioNTech COVID-19 vaccine: 0.3 ml/dose
   b. Moderna COVID-19 vaccine: 0.25 ml/dose (half of the regular dose)
   c. Sinovac COVID-19 vaccine: 0.5 ml/dose
   d. AstraZeneca COVID-19 vaccine: 0.5 ml/dose

3. The Priority Groups A2 and A3 may choose to receive the same brand as their primary series (homologous booster) or another brand (heterologous booster). (*Refer to **Annex C** for the Summary Table on Recommended Booster Dose Combination for Priority Groups A2 and A3*):

a. As a homologous booster or additional dose:

   i. Individuals given with the Sinovac COVID-19 primary dose series may be given with a Sinovac COVID-19 vaccine dose as a booster/additional dose.

   ii. Individuals given with the Pfizer COVID-19 primary dose series may be given with a Pfizer COVID-19 vaccine dose as a booster/additional dose.

   iii. Individuals given with the Moderna COVID-19 primary dose series may be given with a Moderna COVID-19 vaccine dose as a booster/additional dose.

   iv. Individuals given with the AstraZeneca COVID-19 primary dose series may be given with a AstraZeneca COVID-19 vaccine dose as a booster/additional dose, with special precautions as stated in the EUA.

b. As a heterologous booster or additional dose:

   i. Individuals given with the Sinovac COVID-19 primary dose series may be given with AstraZeneca, Pfizer, or a Moderna COVID-19 vaccine dose as a booster/additional dose.

   ii. Individuals given with AstraZeneca COVID-19 primary dose series may be given with Pfizer, or a Moderna COVID-19 vaccine dose as a booster/additional dose.

   iii. Individuals given with Gamaleya Sputnik V primary dose series may be given with AstraZeneca, Pfizer, or a Moderna COVID-19 vaccine dose as a booster/additional dose.

   iv. Individuals given with Ad26.COV2.s (Janssen) COVID-19 primary dose series may be given with AstraZeneca, Pfizer, or a Moderna COVID-19 vaccine dose as a booster/additional dose.

   v. Individuals given with a Pfizer COVID-19 primary dose series may be given with AstraZeneca or Moderna COVID-19 vaccine dose as a booster/additional dose.

   vi. Individuals given with a Moderna COVID-19 primary dose series may be given with AstraZeneca or Pfizer COVID-19 vaccine dose as a booster/additional dose.

4. Vaccination Teams shall consider the following guidance in the administration of booster/additional doses:

   a. New vaccine platforms (e.g. mRNA) are not recommended to be boosted with old vaccine platforms (e.g. inactivated).

b. Vector-based vaccines (e.g. Astrazeneca) are recommended to be boosted with a different vaccine platform, due to the theoretical possibility of pre-existing immunity attenuating or weakening the immune response on the second or third dose.

c. Vaccine recipients with a previous history of adverse reactions after administration of COVID-19 vaccine and populations with higher risk for adverse reactions (such as the elderly, people with comorbidities, people prone to blood clots, myocarditis, and anaphylaxis) shall consult their attending physician for the recommended boosting strategy.

E. Vaccination Process

1. The vaccination process shall primarily follow the steps stipulated in the DM No. 2021-0099, entitled *"Interim Omnibus Guidelines for the Implementation of the National Vaccine Deployment Plan for COVID-19"*.

2. The Priority Groups A2 and A3 may proceed to any vaccination site to receive their booster/additional dose.

3. The member of the vaccination team assigned in the registration area shall ensure that the following documentary requirements are available:
   a. Original vaccination card showing the completion of 2nd dose for a 2-dose vaccine regimen and one dose for Ad26.COV2.s (Janssen) vaccine
   b. Valid identification card
   c. Medical Certificate for Priority Group A3: Individuals with Comorbidities in immunocompromised state.

4. The vaccination team shall ensure that the vaccine recipients are informed of the benefits, risks, and possible side effects of each boosting strategy prior to giving them the option to choose.

5. The informed consent for booster dose shall be used in giving consent to the administration of booster dose. The form can be accessed in this link: bit.ly/RESBAKUNAMaterials (*Refer to **Annex D** for the template*). The form shall be willingly filled up and signed by the vaccine recipient.

6. The health screening form for booster dose shall be used in screening the eligible vaccine recipients. The form can be accessed through this link: bit.ly/RESBAKUNAMaterials (*Refer to **Annex E** for the template*). In the health assessment area, the assigned health screener shall ensure that the health checklist has been properly filled-up.

7. The vaccination team shall provide another vaccination card for the given booster dose containing the appropriate data necessary as stipulated in bit.ly/RESBAKUNAMaterials (*Refer to **Annex F** for the template*).

8. Vaccination sites shall have processes to ensure efficiency in the simultaneous conduct of primary dose and additional/booster dose vaccination. These may include:
   a. Dedicate a separate lane for booster/additional doses
   b. Clear markings for directions on the vaccination sites
   c. Use different vaccine carriers for COVID-19 vaccine brands allocated and dedicated for booster/additional doses.

F. Vaccination Reporting

1. All vaccination sites shall record the vaccination event and encode/report the dose administered as a booster/additional dose to the systems/tools deployed by the Department of Information and Communications Technology.

2. All participating vaccination sites shall report their accomplishments, including the quick count numbers on the doses administered and the inventory and the completed linelist, to the LGU where the vaccination is located, on a daily basis. Likewise, the LGUs shall submit the following:

   a. Quick counts on vaccination accomplishment and inventory to the VORS daily.

   b. Required vaccination information of the vaccine recipients through a linelist to the VAS Line List Upload Tool (https://vaslinelist.dict.gov.ph) within 24 hours after the vaccination activity.

3. The VORS data fields shall be updated to include the booster/additional dose for Priority Group A2 and Priority Group A3. Likewise, the linelist shall be updated to include a new column with header "Booster/Additional dose".

G. Adverse Events Following Immunization

1. Response, including clinical management, navigation and referral, surveillance and communication shall work hand-in-hand at every level of the health system. All public and private health facilities regardless of service level capability, must have an established referral system for prompt management of AEFI, including but not limited to anaphylaxis, myocarditis and/or pericarditis and other cardiovascular events and rhythm disorders, thrombotic thrombocytopenia syndrome or vaccine-induced thrombosis with thrombocytopenia, immune thrombocytopenic purpura, seizure disorders, Guillain-Barré Syndrome, Bell's palsy, erythema multiforme, transverse myelitis, capillary leak syndrome, thromboembolic events, aseptic

encephalitis, acute disseminated encephalomyelitis, acute kidney injury, acute liver injury, acute pancreatitis, rhabdomyolysis, and subacute thyroiditis. Complaints arising from the lack of patient-centered referral systems may disallow vaccination sites from operating.

2. AEFI reporting shall prioritize events suspected by the healthcare provider and/or vaccine recipients to be caused by or related to the vaccination. For this, the latest version of the AEFI Case Investigation Form (CIF) shall be used in all AEFI cases of COVID-19 vaccines, regardless of seriousness. The fillable and printable file versions, together with the training materials, may be accessed and downloaded through the link, **bit.ly/aefic19ph**, under the folder "AEFI Case Investigation Form". The printable version is attached under **Annex G**.

3. The AEFI CIF must be completely and accurately filled before submission to the respective ESUs. Hospital, Local, and Regional ESUs, have the right to return incompletely filled or incoherently narrated forms to submitting health care providers. Reporting serious AEFI SHALL require approval from RESUs as the "approving authority" prior to submitting to VigiFlow. Failure to comply may have considerable delays on case validation, investigation, and overall processing and progress of the case. The Regional and National AEFI Committees and their respective Secretariat reserve the right to return endorsed cases submitted for assessment if essential documents are excluded or absent, or remarks are deemed incomplete or inadequate from the transmitted reports or documents

4. Previously published guidelines relevant to AEFI shall remain in effect for all recipients of vaccines under the COVID-19 Vaccination Program, regardless of age group, vaccine brand, booster or additional dose. The list of official issuances relevant for AEFI surveillance, response and crisis communication are summarized in **Annex H**.

H. Messaging or Reminders to Vaccination Sites

Vaccination sites shall emphasize the following messaging and reminders:

1. Getting additional/ booster shots is still voluntary but recommended to people who are at a higher risk for severe COVID-19 or with higher exposure to the disease: A1, A2, A3.

2. Additional/ Booster doses are NOT YET recommended for the general population.

3. Eligible individuals may get their additional doses (a) consistent with the EUA and the DOH guidelines, and (b) based on available supply.

4. The DOH and all our experts are continuously adjusting recommended policies based on evolving evidence about COVID-19.

5. While the government has started additional doses for priority groups, it is still important to ensure enough coverage for the primary series and reach the unvaccinated.

For dissemination and strict compliance.

By Authority of the Secretary of Health:

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

ANNEX A: COVID-19 Vaccines EUA for Additional/ Booster Doses

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

15 November 2021

MARIA ROSARIO S. VERGEIRE, MD, MPH, CESO II
Undersecretary
Public Health Services Team
Department of Health- Central Office
Rizal Avenue
Sta. Cruz, Manila

Subject: **COVID-19 Vaccines (Additional / Booster Doses)**

Dear Undersecretary Vergeire,

This refers to your request dated October 22, 2021 asking the Food and Drug Administration (FDA) to review and amend the Emergency Use Authorization issued to COVID-19 Vaccines to allow the administration of additional / booster doses.

Based on our evaluation, the recommendation of the Department of Science and Technology Vaccine Expert Panel (DOST-VEP), and the recognition and reliance accorded to emergency use authorizations given by mature and established National Regulatory Authorities (NRAs) such as the United States of America, European Union, and United Kingdom, the Department of Health (DOH) is given authorization for the emergency use of COVID 19 vaccine additional / booster dose as listed in ANNEX A.

The scope of this authorization shall be limited to the following populations:

1. Healthcare professionals and workers 18 years of age or older with frequent institutional or occupational exposure to SARS-CoV-2;
2. Individuals who may fail to mount an adequate response to a primary series of vaccines such as senior citizens and patients 18 years of age or older who are diagnosed with immunocompromised conditions; and
3. Persons 18 through 60 years of age with comorbidities and at high risk of developing severe COVID-19.

Please be informed that the recommendation of the DOST-VEP for the booster combinations is based only on available data on third dose from Phase 2 and 3 trials. As only the immunogenicity data was considered, we reiterate that there are no established correlates of protection. Therefore, the recommendation and authorization on the use of boosters may change as more data becomes available. The FDA remains firm that during this time of public health emergency, the benefits of vaccination still outweigh the risks.

To date, the following EUA holders have applied for variation for homologous and/or heterologous use of boosters: Pfizer, Inc., AstraZeneca Pharmaceuticals (Phils).,IP Biotech, Inc. and Philippine Archipelago International Trading Corporation (PAITC). Heterologous combinations were also reviewed based on the list recommended by the Health Technology Assessment Council (HTAC).

The foregoing considered, DOH shall assume primary responsibility for the use of COVID-19 Vaccines as booster doses under EUA, including but not limited to the mandatory submission of adverse event reports following immunization. Thus, the highest care in the implementation of the COVID-19 boosters should be observed. Please coordinate with the vaccine manufacturers for implementation of proper pharmacovigilance measures.

In the interest of achieving the optimal effects of vaccination in the population, FDA maintains that it is important to complete the recommended doses of the primary regimen in the majority of the public, and the administration of COVID-19 boosters should be considered when a significant proportion of eligible individuals have been vaccinated.

Also attached is a list of recommendations and precautions from the DOST-VEP (ANNEX B) for your guidance.

Sincerely,

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

ANNEX A: ADDITIONAL/BOOSTER COMBINATIONS

Primary Vaccine	Proposed additional dose	Recommended interval from last dose
1. Pfizer	Pfizer	At least 6 months
2. Pfizer	Moderna[2]	
3. Pfizer	AstraZeneca	
4. Pfizer	Janssen	
5. Pfizer	Sputnik Light	
6. Sinovac	Sinovac	
7. Sinovac	Pfizer	
8. Sinovac	Astrazeneca	
9. Sinovac	Moderna[2]	
10. Sinovac	Janssen	
11. Sinovac	Sputnik Light	
12. Astrazeneca	Astrazeneca	
13. Astrazeneca	Pfizer	
14. Astrazeneca	Moderna[2]	
15. Astrazeneca	Sputnik Light	
16. Janssen	Janssen[1]	At least 2-3 months
17. Janssen	Astrazeneca[1]	
18. Janssen	Pfizer[1]	
19. Janssen	Moderna[1]	
20. Moderna	Moderna[2]	At least 6 months
21. Moderna	Pfizer	
22. Moderna	Janssen	
23. Moderna	Astrazeneca	
24. Moderna	Sputnik Light	
25. Sputnik V Component 1 & Component2	Pfizer	
	Astrazeneca	
	Moderna[2]	
26. Sputnik Light	Astrazeneca[1]	
27. Sputnik Light	Pfizer[1]	
28. Sputnik Light	Moderna[1]	

[1] For 2nd dose

[2] 50 ug vaccine dose as 3rd dose/booster for Moderna

ANNEX B: RECOMMENDATIONS AND PRECAUTIONS FROM THE DOST-VEP

1. New vaccine platforms (i.e. mRNA) are not recommended to be boosted with old vaccine platforms (i.e. inactivated).
2. The recommendation for the booster combination is based on the available third (3^{rd}) dose from the Phase 2 and 3 trials.
3. The theoretical possibility of pre-existing immunity to vector-based vaccines (i.e. Chimpanzee Ad5, Human Ad26) attenuating the immune response on 2^{nd} or 3^{rd} doses could be lowered with the use of another or different vector. As an example, Astrazeneca using a Chimpanzee Adenovirus vector is recommended to be boosted with Human Adeno26 vector-based vaccines such as Sputnik Light and Janssen, or vice versa.
4. Higher adverse reactions are expected among heterologous boosting especially with mRNA vaccines thus should be considered especially for populations with higher risk for adverse reactions (i.e. elderly, people with comorbidities, people prone to blood clots, myocarditis, and anaphylaxis, etc)
5. It is noted that no vaccine for 3^{rd} booster shot is superior to other COVID-19 vaccines based on the current available evidence as the recommendation is only based on immunogenicity data and there is still no established correlates of protection.
6. The interval recommendation for the additional dose/3^{rd} dose/booster is based on immunogenicity data generated from the immunocompromised and elderly which is 2-3 months post-2^{nd} dose, while at least 6 months for the general population (18 years old and above). Definition of immunocompromised patients will follow the definition set by PSMID/HTAC.
7. Testing of antibody levels (i.e. RBD antibody from Abbott or other medical device companies) for the immunocompromised may be recommended to assess further booster requirements for the said group.
8. Public health precautions and risk management plans (i.e. referral system for the management of AEFIs and reporting) should continue to be implemented.
9. Evolving data will be monitored to assess if current recommendations still stand or if any amendment/s will be needed.

ANNEX B. Definition of Immunocompromised Persons from the WHO-SAGE Interim Recommendations on for an extended primary series with an additional vaccine dose for COVID-19 vaccination in immunocompromised persons as of Oct 26, 2021

(may be accessed at https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-immunocompromised-persons)

Definition of immunocompromised persons for the purpose of these recommendations

Persons with immunocompromising conditions and those receiving immunosuppressive treatment are considered immunocompromised persons. For the purposes of these interim recommendations, only moderately to severely immunocompromised persons will be addressed, as defined in Table 1 (see Annex 1 for literature review methods). This definition applies to all vaccine-eligible age groups.

Table 1. Definition of immunocompromised persons, as included in these recommendations

Group	Details
Active cancer	• Active immunosuppressive treatment for solid tumour or haematological malignancy (including leukaemia, lymphoma, and myeloma), or within 12 months of ending such treatment
Transplant recipients	• Receipt of solid organ transplant and taking immunosuppressive therapy • Receipt of stem cell transplant (within 2 years of transplantation, or taking immunosuppressive therapy)
Immunodeficiency	• Severe primary immunodeficiency • Chronic dialysis
HIV	• HIV with a current CD4 cell count of <200 cells/μl, evidence of an opportunistic infection, not on HIV treatment, and/or with a detectable viral load (i.e. advanced HIV disease)
Immunosuppressives	• Active treatment causing significant immunosuppression, including high-dose corticosteroids, alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents, tumour-necrosis factor (TNF) blockers, or other highly immunosuppressive drugs • Immunosuppressive chemotherapy or radiotherapy within the past 6 months

ANNEX C: Recommended Booster Dose Combination for Priority Groups A2 and A3

Primary Vaccination	Interval for Booster	Homologous Booster	Heterologous Booster
Sinovac	At least 6 months	Sinovac	Astrazeneca Pfizer Moderna
Astrazeneca	At least 6 months	AstraZeneca*	Pfizer Moderna
Pfizer	At least 6 months	Pfizer	Astrazeneca Moderna
Moderna	At least 6 months	Moderna	Astrazeneca Pfizer
Gamaleya Sputnik	At least 6 months	-	Astrazeneca Pfizer Moderna
Janssen	At least 3 months	-	Astrazeneca Pfizer Moderna

*Precaution included in the FDA EUA

ANNEX D. Informed Consent Form for Booster Doses of COVID-19 Vaccine
(may be downloaded at **bit.ly/BoosterVaccinationForms)**

INFORMED CONSENT FORM FOR ADDITIONAL/BOOSTER DOSES OF COVID-19 VACCINE
of the Philippine National COVID-19 Vaccine Deployment and Vaccination Program as of November 19, 2021

Name: **Birthdate:** **Sex:**

Address:

Occupation: **Contact Number:**

Health facility: **Primary COVID-19 Vaccine Series:**

INFORMED CONSENT

I confirm that I have been provided with and have read the COVID-19 Vaccine Moderna / Pfizer-BioNTech / AstraZeneca / Sinovac Emergency Use Authorization (EUA) Information Sheet and the same has been explained to me. The FDA has amended the Emergency Use Authorization for these COVID-19 Vaccines to allow its use as additional/booster dose for specific populations in light of new scientific evidence.

I confirm that I have been screened for conditions that may merit deferment or special precautions for additional/booster dose vaccination as indicated in the Health Screening Questionnaire.

I have received sufficient information on the benefits and risks of receiving a additional/booster dose of the COVID-19 vaccine and I understand the possible risks if I am not vaccinated with an additional/booster dose.

I was provided an opportunity to ask questions, all of which were adequately and clearly answered. I, therefore, voluntarily release the Government of the Philippines, the vaccine manufacturer, their agents and employees, as well as the hospital, the medical doctors and vaccinators, from all claims relating to the results of the use and administration of, or the ineffectiveness of a additional/booster dose of COVID-19 vaccines.

I understand that while most side effects are minor and resolve on their own, there is a small risk of severe adverse reactions, such as, but not limited to allergies and blood clots associated with low platelet counts (vaccine-induced thrombotic thrombocytopenia), heart conditions (e.g. myocarditis and pericarditis) and that should prompt medical attention be needed, referral to the nearest hospital shall be provided immediately by the Government of the Philippines. I have been given contact information for follow up for any symptoms which I may experience after vaccination.

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

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

I hereby give my consent to receive an additional/booster dose of the COVID-19 Vaccine Moderna / Pfizer-BioNTech / Sinovac / AstraZeneca.

_____ _____
Signature over Printed Name Date

In case eligible individual is unable to sign:
I have witnessed the accurate reading of the consent form and liability waiver to the eligible individual; sufficient information was given and queries raised were adequately answered. I hereby confirm that he/she has given his/her consent to be vaccinated with the COVID-19 Vaccine Moderna / Pfizer-BioNTech / Sinovac / Astrazeneca

_____ _____
Signature over Printed Name Date

If you chose not to get an additional/booster dose vaccine, please list down your reason/s:

INFORMED CONSENT FORM PARA SA ADDITIONAL/BOOSTER DOSE NG COVID-19 VACCINE
of the Philippine National COVID-19 Vaccine Deployment and Vaccination Program as of November 19, 2021

Name: **Birthdate:** **Sex:**

Address:

Occupation: **Contact Number:**

Vaccination Sites: **Primary COVID-19 Vaccine Series:**

INFORMED CONSENT

Kinukumpirma ko na ako ay nabigyan at nabasa ko ang Emergency Use Authorization *Information Sheet* para sa COVID-19 Vaccine Moderna / Pfizer-BioNTech / Sinovac / AstraZeneca, at lubos na naipaliwanag ang nilalaman nito sa akin. Inamendahan ng Philippine Food and Drug Administration ang Emergency Use Authorization ng COVID-19 Vaccines para maibigay bilang additional/booster dose para sa piling populasyon, nang naaayon sa pinakabagong datos na nakalap

Kinukumpirma ko na ako ay sumailalim sa health screening para sa mga kundisyon na maaaring maging dahilan para ipagpaliban ang pagtanggap ko ng additional/booster dose ng bakuna, o mangailangan ng karagdagang pag-iingat (*special precaution*) sa pagbabakuna alinsunod sa *Health Screening Questionnaire*.

Ako ay nakatanggap ng sapat na impormasyon tungkol sa benepisyo (*benefits*) at maaaring peligro (*risks*) ng nasabing pagkuha ng additional/booster dose ng bakuna sa COVID-19. Naiintindihan ko rin ang mga posibleng kahinatnan ko kung sakaling hindi ako magpabakuna ng additional/booster dose.

Ako ay nabigyan ng pagkakataong magtanong tungkol sa pagbabakuna, at lahat ng ito ay nabigyan ng sapat at malinaw na kasagutan. Dahil dito, kusang loob kong pinapawalan ang Pamahalaan ng Pilipinas, ang manufacturer ng bakuna, kanilang mga ahente at empleyado, kabilang na ang ospital, mga doktor at magbabakuna, mula sa lahat ng *claims* kaugnay sa resulta ng paggamit at pagbigay ng bakuna, o bisa ng COVID-19 Vaccines.

Naiintindihan ko na karamihan sa *side effects* ay banayad at magreresolba nang kusa, at may posibilidad na makaranas ako ng malubhang *(severe) adverse reaction*, tulad ng *allergy, blood clots na may kaugnayan sa mababang bilang ng platelet (vaccine-induced thrombotic thrombocytopenia) o kondisyon sa puso (hal: myocarditis or pericarditis)*. Kung kakailanganin ko ng agarang atensyong medikal, maaari akong dalhin sa pinakamalapit na ospital ng Pamahalaan. Ako ay binigyan ng impormasyon kung saan ko pwedeng isangguni ang anumang sintomas na aking mararamdaman matapos magpabakuna.

Sa paglagda ko dito sa *informed consent form*, naiintindihan ko rin na ako ay may karapatan sa *health benefit packages* ng Philippine Health Insurance Corporation (PhilHealth) kung sakaling ako ay makaranas ng malubhang (*serious/severe) adverse event*, kaugnay ng COVID-19 Vaccine o sa pagbigay nito. Naiintindihan ko din na ang karapatan na humingi ng (*to claim*) *compensation* ay nababatay sa *guidelines* ng Philhealth.

Binibigyan ko ng pahintulot ang pamahalaan na gamitin ang mga impormasyong ukol sa akin para sa *public health*, kasama na ang pag-ulat sa na-aangkop na *national vaccine registries*, alinsunod sa mga protocol ng *Data Privacy Act ng 2012*

Ako ay kusang loob na pumapayag na makatanggap ng additional/booster dose gamit ang COVID-19 Vaccine Moderna / Pfizer-BioNTech / Sinovac / AstraZeneca.

_____ _____
Signature over Printed Name Date

Kung sakaling ang indibidwal ay hindi makakapirma:

Patunay ito na nasaksihan ko ang tapat na pagbasa nitong INFORMED CONSENT at liability waiver sa indibidwal na magpapabakuna. Sapat ang impormasyong naibigay at nasagot ang lahat ng kanyang katanungan . Kinukumpirma ko na nagbigay ang indibidwal ng kanyang pahintulot para mabakunahan gamit ang COVID-19 Vaccine Moderna / *Pfizer-BioNTech / Sinovac / Astrazeneca.*

_____ _____
Signature over Printed Name Date

Kung piniling hindi kumuha ng additional/booster dose ng bakuna, ilista ang dahilan:

ANNEX E. Health Declaration Screening Forms and Health Assessment Algorithm Forms for COVID-19 Booster Vaccination

(may be downloaded at **bit.ly/BoosterVaccinationForms)**

COVID-19 ADDITIONAL/BOOSTER DOSE VACCINATION
HEALTH DECLARATION SCREENING FORM
of the Philippine National COVID-19 Vaccine Deployment and Vaccination Program as of November 19, 2021

ASSESS THE PATIENT	NO	YES
Has received and completed the primary dose series of any COVID-19 vaccines AND has received an additional/booster dose? *Primary dose series:* ➢ *Two doses of Pfizer-BioNTech, Moderna, Sinovac, Gamaleya, AstraZeneca; or* ➢ *One dose of Janssen*		
If has received and completed two doses of Pfizer-BioNTech, Moderna, Sinovac, Sinopharm, Gamaleya, AstraZeneca, has it only been less than 6 months since then? Or, if has received and completed one dose of Janssen, has it only been less than 3 months since then?		
Below 18 years old?		
Had a severe allergic reaction to any ingredient of the vaccine currently being offered? Or had a severe allergic reaction after receiving any COVID-19 vaccine?		
Has allergy to food, egg, medicines? Has asthma?		
➢ If with allergy or asthma, will monitoring the patient for 30 minutes be a problem?		
Has history of bleeding disorders or currently taking anti-coagulants?		
➢ If with bleeding history or currently taking anti-coagulants, is there a problem securing a gauge 23 - 25 syringe for injection?		
Has SBP ≥160 mmHg and/or DBP≥ 100 mmHg WITH signs and symptoms of organ damage?		
If initially with SBP ≥160 mmHg and/or DBP≥ 100 mmHg WITHOUT signs and symptoms of organ damage, is there a problem maintaining a blood pressure of <160/100 mmHg after monitoring two times every fifteen minutes?		
Manifests any one of the following symptoms? ☐ Fever/chills ☐ Headache ☐ Cough ☐ Colds ☐ Sore throat ☐ Myalgia ☐ Rashes ☐ Fatigue ☐ Weakness ☐ Loss of smell/taste ☐ Diarrhea ☐ Shortness of breath/difficulty in breathing ☐ Nausea/ Vomiting ☐ Other symptoms of existing comorbidity		
Has history of exposure to a confirmed or suspected COVID-19 case in the past 14 days?		
If previously diagnosed with COVID-19, is recipient STILL undergoing recovery or treatment?		
Has received any vaccine in the past 14 days or plans plan to receive another vaccine 14 days following vaccination?		
Has received convalescent plasma or monoclonal antibodies for COVID-19 in the past 90 days?		
If in the 1st trimester of pregnancy, is there any objection to vaccination from the presented medical clearance from the attending physician?		
Has any of the following diseases or health conditions? ☐ HIV ☐ Cancer/Malignancy and currently undergoing chemotherapy, radiotherapy, immunotherapy or other treatment ☐ Underwent transplant ☐ Under steroid treatment or medication ☐ Bed ridden, terminal illness, less than 6 months prognosis ☐ With autoimmune disease		
➢ If with any of the abovementioned condition, is there any objection to vaccination from presented medical clearance prior to vaccination day?		

Recipient's Name: **Sex:**

Parent's/ Legal Guardian's Name: **Wt (kg)**

Birthdate: **BP:** **Temp:**

Signature of Health Worker: **HR:** **RR:** **O2 sat:**

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

** Please keep this health screening form as part of the patient's official vaccination and medical record.*

COVID-19 ADDITIONAL/BOOSTER DOSE VACCINATION HEALTH DECLARATION SCREENING FORM

ng Philippine National COVID-19 Vaccine Deployment and Vaccination Program nitong Nobyembre 19, 2021

SURIIN ANG BABAKUNAHAN	NO	YES
Nakatanggap at nakumpleto na ang primary dose series ng kahit anong COVID-19 vaccine AT nakatanggap na ng additional/booster dose? *Primary dose series:* ➢ *Dalawang doses ng Pfizer-BioNTech, Moderna, Sinovac, Gamaleya, AstraZeneca; or* ➢ *Isang dose ng Janssen*		
Kung nakatanggap at nakumpleto na ang dalawang doses ng Pfizer-BioNTech, Moderna, Sinovac, Sinopharm, Gamaleya, AstraZeneca, mas mababa sa anim na buwan mula nang nabakunahan nito? O, kung nakatanggap ng isang dose ng Janssen, mas mababa sa tatlong buwan mula ng nabakunahan nito?		
Edad ay mas mababa sa 18 taong gulang?		
May malubhang alerhiya sa kahit anong sangkap ng bakunang maaring maibigay sa araw na ito? O dating nagka malubhang alerhiya matapos makatanggap ng kahit anong COVID-19 vaccine?		
May alerhiya sa pagkain, itlog, gamot? May hika (asthma)		
➢ Kung may alerhiya o hika, may problema ba sa pag-monitor sa pasyente ng 30 minuto?		
May sakit kaugnay ng pagdudugo o sa kasalukuyan ay umiinom ng anti-coagulants (pampalabnaw ng dugo)?		
➢ Kung may sakit kaugnay ng pagdudugo o kasalukuyang umiinom ng anti-coagulants (pampalabnaw ng dugo), mayroon bang problema sa pagkuha/paggamit ng gauge 23-35 na siringhilya (syringe) para sa pagturok?		
May SBP ≥160 mmHg at/o DBP≥ 100 mmHg NA MAY KASAMANG signs and symptoms ng organ damage?		
Kung may SBP ≥160 mmHg at/o DBP≥ 100 mmHg NANG WALANG signs and symptoms ng organ damage,may problema ba sa pagpapanalti ng blood pressure na <160/100 mmHg matapos ang monitoring ng dalawang beses sa bawat 15 minuto?		
Mayroon ng kahit alinman sa sumusunod na sintomas? ☐ Lagnat / panginginig dahil sa lamig ☐ Sakit ng ulo ☐ Ubo ☐ Sipon ☐ Panansakit ng lalamunan ☐ Panansakit ng kalamnan ☐ Rashes ☐ Pagkapagod ☐ Pangingimi ☐ Kawalan ng panlasa o pang-amoy ☐ Pagtatae ☐ Hirap sa paghinga ☐ Pagkahilo/pagsusuka ☐ Iba pang sintomas ng co-morbidity		
May exposure sa taong confirmed o suspect na kaso ng COVID-19 nitong nakaraang 14 na araw?		
Nagpositibo sa COVID-19 at kasalukuyang ginagamot pa / hindi pa recovered?		
Nakatanggap ng kahit anong bakuna nitong nakaraang 14 na araw o pinaplanong tumanggap ng kahit anong bakuna sa susunod na 14 na araw matapos magpabakuna?		
Ginamot o nakakuha ng convalescent plasma o monoclonal antibodies para sa COVID-19 nitong nakaraang 90 na araw?		
Kung nasa unang tatlong buwan (first trimester) ng pagbubuntis, may pagtutol ba sa pagbakuna na nakasaad sa medical clearance mula sa kanilang doktor (attending physician)?		
Mayroon ng kahit alinman sa sumusunod na sakit o kundisyon? ☐ Na-diagnose ng Human Immunodeficiency Virus (HIV) ☐ Na-diagnose ng kanser (cancer/malignancy) at kasalukuyang sumasailalim sa chemotherapy, radiotherapy, immunotherapy, o iba pang treatment? ☐ Sumailalim sa organ transplant? ☐ Kasalukuyang umiinom ng steroids? ☐ Nakaratay na lang sa kama (bed-ridden), may sakit (terminal illness) na hindi tataas sa anim (6) na buwan ang taning? ☐ May autoimmune disease?		
➢ Kung may alinman sa mga nabanggit, tutol ba ang doktor sa pagbakuna sa dalang medical clearance bago ang araw ng pagbakuna?		

Pangalan ng babakunahan:: **Kasarian:**

Pangalan ng Magulang / Legal Guardian: **Wt (kg)**

Birthdate: **BP:** **Temp:**

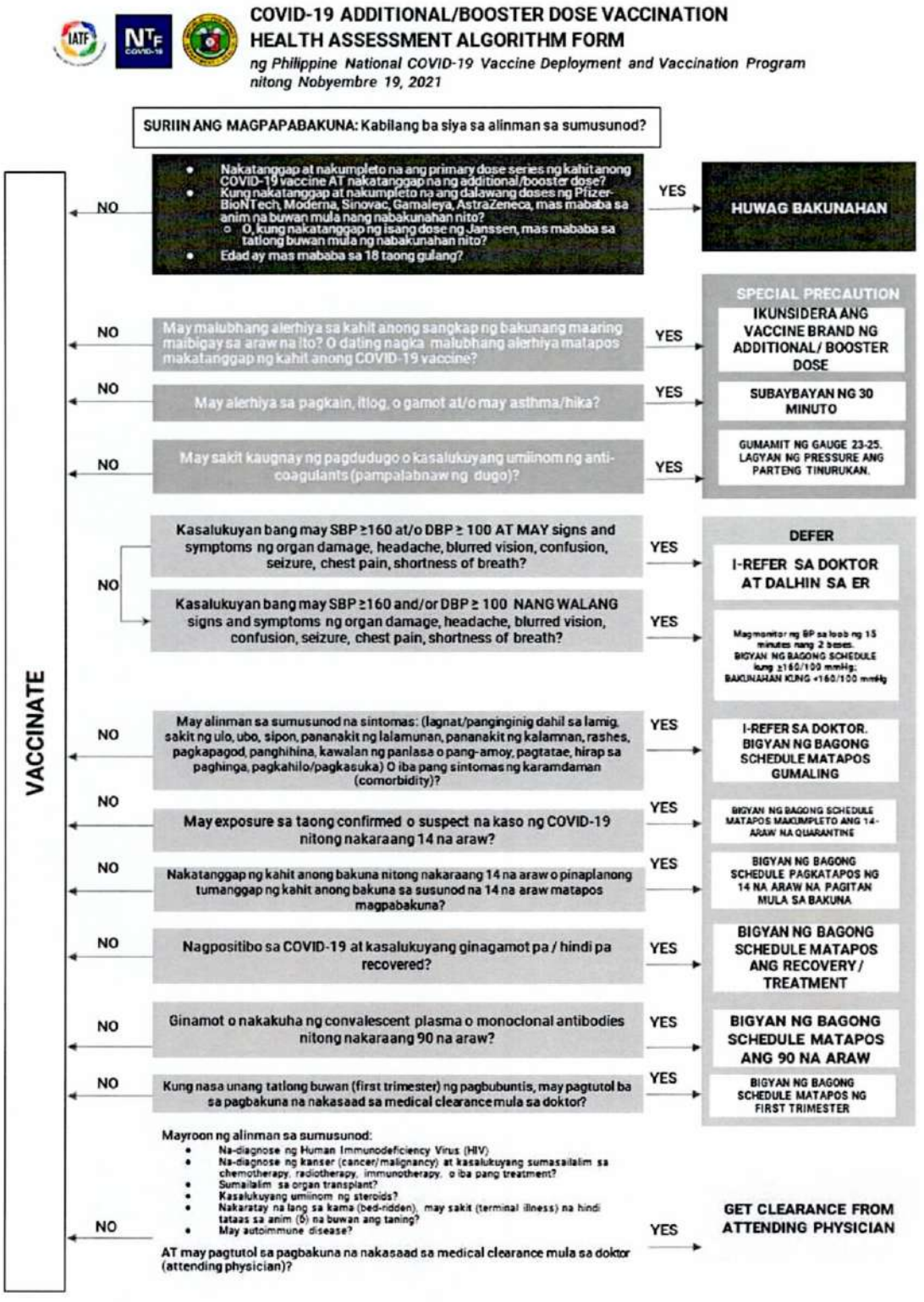
Lagda ng Health Worker: **HR:** **RR:** **O2 sat:**

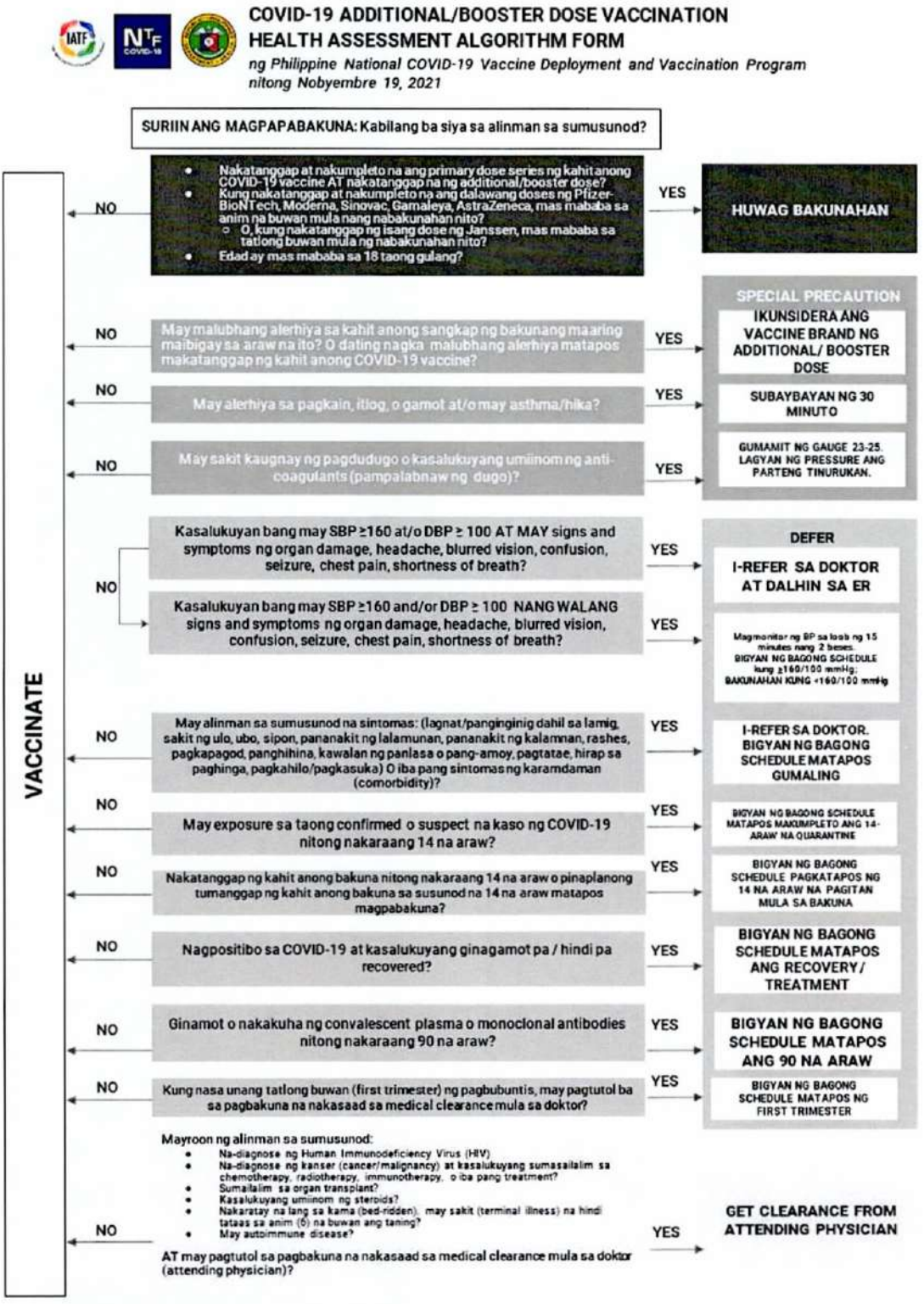
VACCINATE

Kung alinman sa puting kahon ang may tsek, **IPAGPALIBAN** muna ang pagbabakuna

** Please keep this health screening form as part of the patient's official vaccination and medical record.*

X


COVID-19 ADDITIONAL/BOOSTER DOSE VACCINATION
HEALTH ASSESSMENT ALGORITHM FORM
ng Philippine National COVID-19 Vaccine Deployment and Vaccination Program
nitong Nobyembre 19, 2021
SURIIN ANG MAGPAPABAKUNA: Kabilang ba siya sa alinman sa sumusunod?
VACCINATE
Nakatanggap at nakumpleto na ang primary dose series ng kahit anong COVID-19 vaccine AT nakatanggap na ng additional/booster dose?
Kung nakatanggap at nakumpleto na ang dalawang doses ng Pfizer-BioNTech, Moderna, Sinovac, Gamaleya, AstraZeneca, mas mababa sa anim na buwan mula nang nabakunahan nito?
O, kung nakatanggap ng isang dose ng Janssen, mas mababa sa tatlong buwan mula ng nabakunahan nito?
Edad ay mas mababa sa 18 taong gulang?
YES
HUWAG BAKUNAHAN
NO
SPECIAL PRECAUTION
May malubhang alerhiya sa kahit anong sangkap ng bakunang maaring maibigay sa araw na ito? O dating nagka malubhang alerhiya matapos makatanggap ng kahit anong COVID-19 vaccine?
YES
IKUNSIDERA ANG VACCINE BRAND NG ADDITIONAL/ BOOSTER DOSE
May alerhiya sa pagkain, itlog, o gamot at/o may asthma/hika?
YES
SUBAYBAYAN NG 30 MINUTO
May sakit kaugnay ng pagdudugo o kasalukuyang umiinom ng anti-coagulants (pampalabnaw ng dugo)?
YES
GUMAMIT NG GAUGE 23-25. LAGYAN NG PRESSURE ANG PARTENG TINURUKAN.
DEFER
Kasalukuyan bang may SBP ≥160 at/o DBP ≥ 100 AT MAY signs and symptoms ng organ damage, headache, blurred vision, confusion, seizure, chest pain, shortness of breath?
YES
I-REFER SA DOKTOR AT DALHIN SA ER
Kasalukuyan bang may SBP ≥160 and/or DBP ≥ 100 NANG WALANG signs and symptoms ng organ damage, headache, blurred vision, confusion, seizure, chest pain, shortness of breath?
YES
Magmonitor ng BP sa loob ng 15 minutes nang 2 beses. BIGYAN NG BAGONG SCHEDULE kung ≥160/100 mmHg; BAKUNAHAN KUNG <160/100 mmHg
May alinman sa sumusunod na sintomas: (lagnat/panginginig dahil sa lamig, sakit ng ulo, ubo, sipon, pananakit ng lalamunan, pananakit ng kalamnan, rashes, pagkapagod, panghihina, kawalan ng panlasa o pang-amoy, pagtatae, hirap sa paghinga, pagkahilo/pagkasuka) O iba pang sintomas ng karamdaman (comorbidity)?
YES
I-REFER SA DOKTOR. BIGYAN NG BAGONG SCHEDULE MATAPOS GUMALING
May exposure sa taong confirmed o suspect na kaso ng COVID-19 nitong nakaraang 14 na araw?
YES
BIGYAN NG BAGONG SCHEDULE MATAPOS MAKUMPLETO ANG 14-ARAW NA QUARANTINE
Nakatanggap ng kahit anong bakuna nitong nakaraang 14 na araw o pinaplanong tumanggap ng kahit anong bakuna sa susunod na 14 na araw matapos magpabakuna?
YES
BIGYAN NG BAGONG SCHEDULE PAGKATAPOS NG 14 NA ARAW NA PAGITAN MULA SA BAKUNA
Nagpositibo sa COVID-19 at kasalukuyang ginagamot pa / hindi pa recovered?
YES
BIGYAN NG BAGONG SCHEDULE MATAPOS ANG RECOVERY/ TREATMENT
Ginamot o nakakuha ng convalescent plasma o monoclonal antibodies nitong nakaraang 90 na araw?
YES
BIGYAN NG BAGONG SCHEDULE MATAPOS ANG 90 NA ARAW
Kung nasa unang tatlong buwan (first trimester) ng pagbubuntis, may pagtutol ba sa pagbakuna na nakasaad sa medical clearance mula sa doktor?
YES
BIGYAN NG BAGONG SCHEDULE MATAPOS NG FIRST TRIMESTER
Mayroon ng alinman sa sumusunod:
Na-diagnose ng Human Immunodeficiency Virus (HIV).
Na-diagnose ng kanser (cancer/malignancy) at kasalukuyang sumasailalim sa chemotherapy, radiotherapy, immunotherapy, o iba pang treatment?
Sumailalim sa organ transplant?
Kasalukuyang umiinom ng steroids?
Nakaratay na lang sa kama (bed-ridden), may sakit (terminal illness) na hindi tataas sa anim (6) na buwan ang taning?
May autoimmune disease?
AT may pagtutol sa pagbakuna na nakasaad sa medical clearance mula sa doktor (attending physician)?
YES
GET CLEARANCE FROM ATTENDING PHYSICIAN
NO


COVID-19 ADDITIONAL/BOOSTER DOSE VACCINATION
HEALTH ASSESSMENT ALGORITHM FORM
ng Philippine National COVID-19 Vaccine Deployment and Vaccination Program
nitong Nobyembre 19, 2021
SURIIN ANG MAGPAPABAKUNA: Kabilang ba siya sa alinman sa sumusunod?
VACCINATE
Nakatanggap at nakumpleto na ang primary dose series ng kahit anong COVID-19 vaccine AT nakatanggap na ng additional/booster dose?
Kung nakatanggap at nakumpleto na ang dalawang doses ng Pfizer-BioNTech, Moderna, Sinovac, Gamaleya, AstraZeneca, mas mababa sa anim na buwan mula nang nabakunahan nito?
O, kung nakatanggap ng isang dose ng Janssen, mas mababa sa tatlong buwan mula ng nabakunahan nito?
Edad ay mas mababa sa 18 taong gulang?
NO
YES
HUWAG BAKUNAHAN
SPECIAL PRECAUTION
May malubhang alerhiya sa kahit anong sangkap ng bakunang maaring maibigay sa araw na ito? O dating nagka malubhang alerhiya matapos makatanggap ng kahit anong COVID-19 vaccine?
IKUNSIDERA ANG VACCINE BRAND NG ADDITIONAL/ BOOSTER DOSE
May alerhiya sa pagkain, itlog, o gamot at/o may asthma/hika?
SUBAYBAYAN NG 30 MINUTO
May sakit kaugnay ng pagdudugo o kasalukuyang umiinom ng anti-coagulants (pampalabnaw ng dugo)?
GUMAMIT NG GAUGE 23-25. LAGYAN NG PRESSURE ANG PARTENG TINURUKAN.
DEFER
Kasalukuyan bang may SBP ≥160 at/o DBP ≥ 100 AT MAY signs and symptoms ng organ damage, headache, blurred vision, confusion, seizure, chest pain, shortness of breath?
I-REFER SA DOKTOR AT DALHIN SA ER
Kasalukuyan bang may SBP ≥160 and/or DBP ≥ 100 NANG WALANG signs and symptoms ng organ damage, headache, blurred vision, confusion, seizure, chest pain, shortness of breath?
Magmonitor ng BP sa loob ng 15 minutes nang 2 beses. BIGYAN NG BAGONG SCHEDULE kung ≥160/100 mmHg; BAKUNAHAN KUNG <160/100 mmHg
May alinman sa sumusunod na sintomas: (lagnat/panginginig dahil sa lamig, sakit ng ulo, ubo, sipon, pananakit ng lalamunan, pananakit ng kalamnan, rashes, pagkapagod, panghihina, kawalan ng panlasa o pang-amoy, pagtatae, hirap sa paghinga, pagkahilo/pagkasuka) O iba pang sintomas ng karamdaman (comorbidity)?
I-REFER SA DOKTOR. BIGYAN NG BAGONG SCHEDULE MATAPOS GUMALING
May exposure sa taong confirmed o suspect na kaso ng COVID-19 nitong nakaraang 14 na araw?
BIGYAN NG BAGONG SCHEDULE MATAPOS MAKUMPLETO ANG 14-ARAW NA QUARANTINE
Nakatanggap ng kahit anong bakuna nitong nakaraang 14 na araw o pinaplanong tumanggap ng kahit anong bakuna sa susunod na 14 na araw matapos magpabakuna?
BIGYAN NG BAGONG SCHEDULE PAGKATAPOS NG 14 NA ARAW NA PAGITAN MULA SA BAKUNA
Nagpositibo sa COVID-19 at kasalukuyang ginagamot pa / hindi pa recovered?
BIGYAN NG BAGONG SCHEDULE MATAPOS ANG RECOVERY/ TREATMENT
Ginamot o nakakuha ng convalescent plasma o monoclonal antibodies nitong nakaraang 90 na araw?
BIGYAN NG BAGONG SCHEDULE MATAPOS ANG 90 NA ARAW
Kung nasa unang tatlong buwan (first trimester) ng pagbubuntis, may pagtutol ba sa pagbakuna na nakasaad sa medical clearance mula sa doktor?
BIGYAN NG BAGONG SCHEDULE MATAPOS NG FIRST TRIMESTER
Mayroon ng alinman sa sumusunod:
Na-diagnose ng Human Immunodeficiency Virus (HIV)
Na-diagnose ng kanser (cancer/malignancy) at kasalukuyang sumasailalim sa chemotherapy, radiotherapy, immunotherapy, o iba pang treatment?
Sumailalim sa organ transplant?
Kasalukuyang umiinom ng steroids?
Nakaratay na lang sa kama (bed-ridden), may sakit (terminal illness) na hindi tataas sa anim (6) na buwan ang tanin?
May autoimmune disease?
AT may pagtutol sa pagbakuna na nakasaad sa medical clearance mula sa doktor (attending physician)?
GET CLEARANCE FROM ATTENDING PHYSICIAN

ANNEX F. Vaccination Card with Booster Dose Record
(may be downloaded at **bit.ly/BoosterVaccinationForms)**

COVID-19 Vaccination Card ID No.

- ***Please keep this record card,*** *which includes medical information about the vaccines you have received.*
- ***Pakitago ang record card na ito,*** *kung saan mababasa ang impormasyong medikal tungkol sa bakunang iyong natanggap.*

Last Name _____ First Name _____ Middle Name _____ Suffix _____

Address _____ Contact No. _____

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

Dosage Seq.	Date (mm/dd/yy)	Vaccine Brand	Name of Vaccinator (with signature)	Batch No.	Lot No.
1st Dose	/ /				
2nd Dose	/ /				
Booster or Additional	/ /				

Health Facility Name _____ Facility Contact No. _____

OfficialDOHgov @DOHgoph (632) 8561-7800 • Local 1936 covid19ceir@doh.gov.ph

ANNEX G. *Revised AEFI COVID-19 Case Investigation Form Version 2* ***(bit.ly/aefic19ph)***

Philippine Integrated Disease Surveillance and Response

Case Investigation Form
for Adverse Events Following Immunization

V2 – 2021.07.07

For all AEFIs, regardless of seriousness, page 1 must be filled up. For identified serious AEFI cases, succeeding pages are mandatory. Immediately notify the Local Epidemiology Surveillance Unit (ESU). Please fill out all blanks and put a check mark on the appropriate box. Never leave an item blank (write N/A). Items with * (asterisk) are mandatory fields.

I. REPORTER'S INFORMATION

Name of Facility/Disease Reporting Unit (DRU)*	Facility/DRU Region and Province	Type of Facility/DRU*	Contact Number* (Landline or Mobile)
Full Name of Reporter*	Designation of Reporter	PRC Registration Number	Email address

II. PATIENT INFORMATION

First Name*	Middle Name	Last Name*	Suffix

Birthday (MM/DD/YYYY)*	Age*	Sex* ☐ Male ☐ Female, check if either applies: ☐ Pregnant ☐ Lactating	Civil status	PhilHealth Number

Nationality*

Priority Group* (when applicable) A1 ☐ A2 ☐ A3 ☐ A4 ☐ A5 ☐ B1 B2 ☐ B3 B4 ☐ B5 ☐ B6 ☐ C

Specify profession/comorbidity*: _____

COMPLETE CURRENT ADDRESS AND CONTACT INFORMATION

House No./Lot/Building*	Street/Purok/Sitio*	Barangay*

Municipality/City*	Province*	Region*	Contact Number* (Landline or Mobile)

III. VACCINATION DETAILS Check if applicable: ☐ With previously reported event (i.e. anaphylaxis) ☐ Heterologous

NOTE: Should the page be insufficient for reporting the vaccine details, please provide the latest information of the four latest doses received by the patient on this page and provide the other previous vaccination details on the same table as found in Appendix 4 as an attached sheet to this form.
For vaccinations done abroad or for those with multiple vaccination records, please attach the copy/ies of the vaccination card/s upon submission of this document.

Details	Older dose ⟶			Latest dose
1. Dose number*				
2. Name of Vaccine*				
3. Place of Vaccination* (Local/Abroad)				
4. Date of Vaccination* (MM/DD/YYYY)				
5. Time of Vaccination* (hh:mm)	AM/PM	AM/PM	AM/PM	AM/PM
6. Site of Injection* (Right/Left arm)				
7. Batch/Lot Number*				
8. Expiry Date (MM/DD/YYYY)				
9. Vaccination Site Name*				
10. Vaccination Site Country				
11. Vaccination Site Region*				
12. Vaccination Site Province*				
13. Vaccination Site City/Municipality*				
14. Vaccination Site Barangay*				
15. Diluent				
16. Date of Reconstitution (MM/DD/YYYY)				
17. Time of Reconstitution (hh:mm)	AM/PM	AM/PM	AM/PM	AM/PM
18. Diluent Batch/Lot Number				
19. Diluent Expiry Date (MM/DD/YYYY)				
20. Vaccine procured from	☐ DOH ☐ Local Gov't Unit ☐ Private ☐ Unknown ☐ Others:_____	☐ DOH ☐ Local Gov't Unit ☐ Private ☐ Unknown ☐ Others:_____	☐ DOH ☐ Local Gov't Unit ☐ Private ☐ Unknown ☐ Others:_____	☐ DOH ☐ Local Gov't Unit ☐ Private ☐ Unknown ☐ Others:_____

IV. ADVERSE EVENT/S (check all that apply)

Symptom*	Date of onset (MM/DD/YYYY)*	Time of onset (hh:mm)*	Symptom*	Date of onset (MM/DD/YYYY)*	Time of onset (hh:mm)*
☐ Chest pain		AM/PM	☐ Joint Pain		AM/PM
☐ Chills		AM/PM	☐ Muscle or body aches		AM/PM
☐ Colds		AM/PM	☐ Nausea		AM/PM
☐ Dizziness		AM/PM	☐ Numbness		AM/PM
☐ Feeling unwell (malaise)		AM/PM	☐ Rash all over the body		AM/PM
☐ Fever ≥ 38.0°C		AM/PM	☐ Tiredness		AM/PM
☐ Headache		AM/PM	☐ Vaccination site pain		AM/PM
☐ Itching		AM/PM	☐ Vomiting		AM/PM
☐ Increased BP Indicate pre- and post-vaccination blood pressure	With Hypertension?* ☐ No ☐ Yes ☐ Unknown Pre-vaccination*: _____ / _____		Post-vaccination*: _____ / _____		AM/PM

Other Symptom/s	Date of onset (MM/DD/YYYY)	Time of onset (hh:mm)
		AM/PM
		AM/PM

Outcome* ☐ **Alive**: ☐ Recovering from the reported AEFI ☐ Fully recovered from the AEFI and back to premorbid condition
☐ With permanent disability resulting from the AEFI, specify: _____

☐ **Died**: ☐ Dead on Arrival ☐ Died in the health facility ☐ Died at home
Date died (MM/DD/YYYY)*: _____

Patient Management 1. Date the patient was seen or went for a consult (MM/DD/YYYY): _____
2. Patient's Current Status:
☐ Received treatment and sent home ☐ Treated and went home against medical advice Date of discharge (MM/DD/YYYY): _____
☐ Currently admitted. Date of admission (MM/DD/YYYY): _____ Admitting diagnosis: _____

Serious case* ☐ No ☐ **Yes**, ☐ Death ☐ Life-threatening ☐ Disability ☐ Hospitalization ☐ Congenital anomaly
If answered Yes on any of these, please fill out pages 2 to 5.
☐ Other important medical event, specify: _____

NOTE: According to Republic Act No. 11332 Revised IRR Rule VI Sec. 6, "The aforementioned details are crucial and indispensable for the formulation of appropriate policies and disease response activities. Hence, health professionals conducting the interview at point of first contact shall obtain such details from a suspect case, properly informing the data subject that the information sought to be obtained is being processed in accordance with Republic Act No. 10173, or the "Data Privacy Act of 2012," and that deliberately providing false or misleading personal information on the part of the person, or the next of kin in case of person's incapacity, may constitute as non-cooperation punishable under the Act or this IRR."
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Instructions: Pages 2 to 5 of this Case Investigation Form shall be filled out by the attending physician. The Disease Surveillance Officer or any healthcare professional who attended to the patient shall fill out the form should the attending physician be unavailable.
NOTE: The operational definition of serious AEFI cases is found in Appendix 2. Please be guided accordingly.

V. EXAMINATION DETAILS		
Last Name of Physician*	First Name of Physician*	Middle Name of Physician
Contact Number*	PRC Registration Number*	Date Investigated (MM/DD/YYYY)*
Other source of Information	☐ Nurse ☐ Midwife ☐ Parent/Guardian ☐ Neighbor ☐ Barangay Health Worker ☐ Others, specify: _____	
Last Name of other source of information	First Name of other source of information	Middle Name of other source of information
Contact Number (Landline or Mobile)	PRC Registration Number (if applicable)	Relation/Designation of other source of information

VI. MODE OF EXAMINATION (check all that apply)

☐ Interview ☐ Medical record/s ☐ Physical examination ☐ Laboratory result ☐ Other/s, specify: _____

If the patient DIED	1. Was autopsy recommended or suggested to the family or next of kin? ☐ Yes ☐ No 2. If autopsy was recommended but not done, please check all the reason/s why it was not done ☐ Local unavailability of pathologist/NBI/PNP ☐ Financial challenge ☐ No consent ☐ Other reason/s: _____ 3. If verbal autopsy was done; Source's Name: _____ Source's Relationship: _____

VII. CLINICAL DETAILS -- Attach copies of ALL available documents including case sheet/s, health screening form, copy of vaccination card, discharge summary, case notes, lab and autopsy reports, prescriptions, and others. Separate sheet/s may be attached to complete the information.

1. What is your complete diagnosis or problem list?*	
2. Please narrate the chronology of the events, including the date and time of occurrence/s.* You may also use a separate sheet or attach another document listing the complete diagnosis. Refer to the Brighton Collaboration, Clinical Practice Guidelines, or International Classification of Diseases for the diagnosis.	

History and PE	**What are the findings that support the diagnosis?***	**What are the findings that DO NOT support the diagnosis?***
Review of Systems		

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Past Medical History, OB-GYN History, and Birth and Developmental History		
Family Medical History		
Personal Social History		
Physical Examination on first interaction The patient's height (in cm) and weight (in kg) may be placed here.		

3. Based on your expertise, among the diagnoses mentioned in #1, which diagnosis do you think contributed the most or triggered the series of events towards hospitalization, disability, or death?*	
4. Is this selected diagnosis, now termed as the "event being assessed", strongly supported by objective findings in the history and PE to fit a case definition, from any criteria whether in the Brighton classification, local guideline, or international guideline?* You may use a separate sheet or attach another document.	☐ **Yes**; cite the case definition, if you are aware of it. ☐ **No**; If NOT STRONGLY SUPPORTED AND DEDUCED OR SIMPLY TERMED AS "PROBABLE" OR "TO CONSIDER", which of the events in the chronology of events leading to hospitalization or death is strongly supported by history and PE to fit a case definition?

NOTE: Be specific as to which symptoms occurred prior to vaccination or are recurring since before vaccination, while manifested after findings from specialist consultation or referrals may also be included. For laboratory findings, include the date, time and normal range of values. For histopathologic, laboratory, radiologic, electrophysiological studies, you may attach them as reference. Any dermatologic findings or imaging may be attached.

NOTE: According to Republic Act No. 11332 Revised IRR Rule VI Sec. 6, "The aforementioned details are crucial and indispensable for the formulation of appropriate policies and disease response activities. Hence, health professionals conducting the interview at point of first contact shall obtain such details from a suspect case, properly informing the data subject that the information sought to be obtained is being processed in accordance with Republic Act No. 10173, or the "Data Privacy Act of 2012," and that deliberately providing false or misleading personal information on the part of the person, or the next of kin in case of person's incapacity, may constitute as non-cooperation punishable under the Act or this IRR."
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VIII. COURSE IN THE HOSPITALIZATION – You may opt to attach a medical abstract outlining the chronological course of hospitalization in SOAP format.				
Date/Time	**Subjective Findings**	**Objective Findings**	**Assessment**	**Plan/Management Done**

IX. RELEVANT PATIENT INFORMATION PRIOR TO IMMUNIZATION			
Information	**Yes / No**	**N/A**	**Remarks** **"Similar event" refers to a clinical event which had happened to the patient in the past and was ALSO experienced by the patient after COVID-19 vaccination.**
1. Did a similar diagnosis, episode/s, or event/s occur in the past, independent of any vaccination?*	☐ / ☐		
2. Was the patient exposed to a potential factor (other than vaccine) prior to the event (e.g. allergen, drug, herbal product, etc.)?*	☐ / ☐		
3. For adult women, currently pregnant? **currently breastfeeding?**	☐ / ☐ ☐ / ☐	☐ ☐	**If pregnant, indicate AOG:** The additional form for case-based survey of pregnant women inoculated with COVID-19 vaccine is provided in **Appendix 5 and must be answered in the case of pregnant individuals vaccinated.**
4. Did this patient have an illness, pre-existing condition or risk factor that could have contributed to the event?*	☐ / ☐		
5. Was or is the patient on any concurrent medication for any illness prior to the vaccination?* (indicate the name of drug, indication, doses, & date)	☐ / ☐		
6. Has the patient tested COVID-19 positive prior to vaccination?*	☐ / ☐		Specimen Collection Date (MM/DD/YYYY):
7. History of hospitalization in the past 30 days; if yes, indicate the inclusive dates and cause*	☐ / ☐		
8. Recent history of trauma; if yes, indicate the date, cause and site*	☐ / ☐		

9. Did a similar diagnosis, episode/s, or event/s occur in the past after the administration of a similar vaccine?* ☐ No ☐ Yes, complete the table

Vaccine	Relative date of vaccination	Adverse Event experienced

NOTE According to Republic Act No. 11332 Revised IRR Rule VI Sec. 6, "The aforementioned details are crucial and indispensable for the formulation of appropriate policies and disease response activities. Hence, health professionals conducting the interview at point of first contact shall obtain such details from a suspect case, properly informing the data subject that the information sought to be obtained is being processed in accordance with Republic Act No. 10173, or the "Data Privacy Act of 2012," and that deliberately providing false or misleading personal information on the part of the person, or the next of kin in case of person's incapacity, may constitute as non-cooperation punishable under the Act or this IRR."
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X. FOR THE HEALTH CARE PROVIDER	
1. As of the last assessment of the physician, what was the level of consciousness of the patient?	☐ Alert (Conscious) ☐ Verbally responsive ☐ Responsive to pain stimuli ☐ Unresponsive
2. What are the other examinations intended to be done to support the diagnosis but were not done and what are or were the limitations in not performing these studies or examinations? You may indicate lack of facility, lack of equipment, lack of fund, among others.	
3. In the medical opinion of the licensed physician or person completing these clinical details, is it possible that the illness or injury suffered by the patient after the administration of vaccine dose/s was caused by or resulted from any previous illness or injury of the patient?*	☐ No ☐ Yes; please provide details
4. Did the patient or next of kin inquire whether this event is/was caused by the vaccine?*	☐ Never manifested ☐ Once ☐ Frequently ☐ Unknown
5. Are there efforts done by the HCP to educate or reassure the vaccine recipient or next of kin that any event following immunization may not be automatically considered to be due to the vaccine and that further investigation and assessment must still be performed?*	☐ No ☐ Yes; please indicate procedures or measures taken.
6. As stated in the PhilHealth Circular No. 2021-0007, is the patient or next of kin considering to file claims for the PhilHealth Vaccine Injury Compensation Package (VICP)?*	☐ No ☐ Yes ☐ Unknown ☐ Not Applicable **DISCLAIMER:** The submission of this form to the Hospital ESU, Local ESU, Regional ESU, or EB does not automatically mean filing of claims to PhilHealth. Please go to nearest PhilHealth Office for filing of claims to the VICP.
7. Prior to discharge, is the patient or next of kin requesting for this event to be investigated and consequently undergo causality assessment?*	☐ No, the patient/next of kin declines. ☐ Yes ☐ Unknown or Not asked

XI. CONSENT FROM THE PATIENT OR NEXT OF KIN

I, the patient or parent/guardian of the patient, **hereby give consent** to the respective public health authorities to acquire pertinent information and details on the case and share these as needed, to contact the person vaccinated and/or parent or guardian regarding the event, and to conduct investigation and/or causality assessment based on the provided information, as needed.

SIGNATURE OVER PRINTED NAME OF PATIENT OR NEXT OF KIN AND DATE

I, the patient or parent/guardian of the patient, **will not provide consent** to the statements above. This shall signify and shall be agreed upon on that any claims or suits filed by the patient and/or relative in this form reflected in the future due to incomplete data shall be invalid.

SIGNATURE OVER PRINTED NAME OF PATIENT OR NEXT OF KIN AND DATE

XII. CONSENT FROM THE HEALTH CARE PROVIDER

I, the health care provider whom attended to the patient, do attest that the information stated above are factual and are based on the expertise and proper evidence collected and I hereby consent to be contacted for further follow up regarding this case as deemed necessary.

SIGNATURE OVER PRINTED NAME OF HEALTH CARE PROVIDER AND DATE

NOTE: The Disease Surveillance Officer (DSO) of the hospital is required to complete all the needed and pertinent information in this case investigation form (CIF), based on the attached documents or files, before submission to the Local Epidemiology Surveillance Unit (LESU) or the Hospital ESU (HESU). The LESU/HESU shall return the CIF to the DSO should it be incompletely or wrongly filled.

XIII. INVESTIGATION DETAILS – Please indicate whether the investigator is from the Hospital or Local ESU.

Last Name of Investigator*	First Name of Investigator*	Middle Name of Investigator
Designation of the Investigator*	Contact Number* (Landline or Mobile)	Date of Investigation (MM/DD/YYYY)*

Privacy statement

Public health authorities, to which at the national level is the Department of Health, collects personal information and other necessary data relating to adverse events following immunization (AEFIs) as stated in the Revised IRR of Republic Act No. 11332 or the "Mandatory Reporting of Notifiable Diseases and Health Events of Public Health Concern Act." The information collected in this report is used to assist in the surveillance and post market monitoring of the safety of the COVID-19 vaccines. All reports of AEFIs are assessed and encoded into the respective information system. The information collected may come from someone other than the patient to whom the personal information relates. This is in consideration of cases where the patient may be unable to report the case or where the information is passed from the next of kin/guardian or an entity other than the former mentioned.

NOTE According to Republic Act No. 11332 Revised IRR Rule VI Sec. 6, "The aforementioned details are crucial and indispensable for the formulation of appropriate policies and disease response activities. Hence, health professionals conducting the interview at point of first contact shall obtain such details from a suspect case, properly informing the data subject that the information sought to be obtained is being processed in accordance with Republic Act No. 10173, or the "Data Privacy Act of 2012," and that deliberately providing false or misleading personal information on the part of the person, or the next of kin in case of person's incapacity, may constitute as non-cooperation punishable under the Act or this IRR."
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THIS PAGE SHOULD BE FILLED OUT BY THE LOCAL ESU, LOCAL HEALTH OFFICE, OR OTHER INVESTIGATOR THAT MAY PROVIDE THE NEEDED INFORMATION.

Name of Investigator/Person answering this form*	Last Name	First Name	Middle Initial
Designation of Investigator*		**Office/Department/ESU***	

XV. IMMUNIZATION PRACTICES	Method/Manner of Investigation: ☐ Visual observation of vaccinators ☐ On-site inspection ☐ Verbal Interview
Syringes and Needles Used	**Yes / No / N/A** — **Remarks**
Were auto-disable syringes used for immunization?	☐/☐/☐
	If NO, specify the type: ☐ Glass ☐ Disposable ☐ Recycled disposable ☐ Pre-filled syringes
Specific key findings/additional observations and comments:	

Reconstitution Procedure (when applicable)	Method/Manner of Investigation: ☐ Visual observation of vaccinators ☐ Others: _____	
1. Was the same reconstitution syringe used for multiple vials of same vaccine?	☐/☐/☐	
2. Was the same reconstitution syringe used for reconstituting different vaccines?	☐/☐/☐	
3. Was there a separate reconstitution syringe for each vaccine vial?	☐/☐/☐	
4. Was there a separate reconstitution syringe for each vaccination?	☐/☐/☐	
5. Are the vaccines and diluents used as recommended by the manufacturer?	☐/☐/☐	
Specific key findings/additional observations and comments:		

Injection technique of vaccinator/s	Method/Manner of Investigation: ☐ Visual observation of vaccinators ☐ On-site inspection ☐ Checking of form	
1. Was the correct dose and route of administration followed?	☐/☐/☐	
2. Time of reconstitution mentioned on the vial (in case of freeze dried vaccines) [hh:mm:AM/PM]		
3. Was aseptic non-touch technique followed?	☐/☐/☐	
4. Was contraindication screened prior to vaccination?	☐/☐/☐	
5. How many AEFI case/s were reported from the vaccination site that administered the vaccine in the last 30 days? (If unknown, state the reason why)		
Specific key findings/additional observations and comments:		

XVI. COLD CHAIN AND TRANSPORT	Method/Manner of Investigation: ☐ Visual observation of cold chain facility/equipment ☐ Others: _____	
Last vaccine storage point	**Yes / No**	**Remarks**
1. Type of vaccine storage ☐ Freezer ☐ Refrigerator ☐ Dry Store ☐ Other, specify: _____		
2. Temperature of vaccine storage: _____ °C		
3. Was the correct procedure of storing vaccines, diluents, and syringes followed?	☐/☐	
4. Is there any other item (other than vaccines and diluents) in the refrigerator or freezer?	☐/☐	
5. Were partially used reconstituted vaccines stored in the refrigerator?	☐/☐	
6. Were unusable vaccines stored in the refrigerator?	☐/☐	
If yes, check all the apply: ☐ Expired ☐ No label ☐ VVM Stage 3/4 ☐ Frozen ☐ Other, specify: _____		
7. Were unusable diluents in the storage area?	☐/☐	
If yes, check all that apply: ☐ Expired ☐ Manufacturer not matched ☐ Cracked ☐ Dirty ampule ☐ Other, specify: _____		
Specific key findings/additional observations and comments:		

Vaccine transportation	Method/Manner of Investigation: ☐ Visual observation of vaccinators ☐ On-site inspection ☐ Checking of form	
1. Vaccine carrier used ☐ Polyurethane Foam Insulation ☐ Insulated Plastic Container ☐ Styrofoam ☐ Other, specify: _____		
2. Was the vaccine carrier sent to the site on the same day of vaccination?	☐/☐	
3. Was the vaccine carrier returned from the site on the same day of vaccination?	☐/☐	
4. For the condition of the vaccine carrier, was ice pack used?	☐/☐	
Specific key findings/additional observations and comments:		

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Name of Investigator/Person answering this form*	Last Name	First Name	Middle Initial
Designation of Investigator*		**Office/Department/ESU***	

XVII. VACCINE DETAILS (Indicate vaccines provided at the site linked to AEFI on the corresponding day)

Number of recipients immunized for each brand/type of vaccine at the vaccination site. Attach record if available.								
	Vaccine/s Given							
	Total Doses Given							

Provide an explanation for each YES answer	**Yes / No / #**	**Remarks**
When was the patient immunized? ☐ Within the first vaccinations of the session ☐ Within the last vaccinations of the sessions ☐ Unknown ☐ Within the first few doses of the vial administered ☐ Within the last doses of the vial administered ☐ Unknown		
1. Was the recommendation for the use of this vaccine NOT followed?	☐ / ☐	
2. Based on the investigation, could the vaccine (ingredient/s) administered been unsterile (i.e. breach on syringe, breach on needles used)?	☐ / ☐	
3. Based on the investigation, was the vaccine's physical condition (e.g. color, turbidity, foreign substances, etc.) abnormal at the time of administration?	☐ / ☐	
4. Based on the investigation, was there an error in vaccine reconstitution/preparation by the vaccinator (e.g. wrong product, wrong diluent, improper mixing, improper syringe filling, etc.)?	☐ / ☐	
5. Based on the investigation, was there an error in vaccine handling (e.g. break in cold chain during transport, storage, and/or immunization session, etc.)?	☐ / ☐	
6. Based on the investigation, was the vaccine administered incorrectly (e.g. wrong dose, site or route of administration, wrong needle size, etc.)?	☐ / ☐	
7. Is it possible that the vaccine given to this patient had a quality defect or is substandard or falsified?	☐ / ☐	
8. Is it possible for this event to be considered a stress-related response to immunization (e.g. acute stress response, vasovagal reaction, hyperventilation, dissociative neurological symptom reaction, etc.)?	☐ / ☐	If yes, describe, even in your own words, how the patient was or the patient's status before, during, and/or after the vaccination within the site as observed by workers, relatives, etc.
9. Specify the number of OTHER recipient/s immunized from the concerned vaccine vial/ampule		
10. Specify the number of OTHER recipient/s immunized with the concerned vaccine in the same session		
11. Specify the number of OTHER recipient/s immunized with the concerned vaccine having the same batch number in other location/s (specify location/s)	☐ Data is not being gathered at the LVOC level or is unknown	
12. At the best of your knowledge, is this case part of a known cluster of AEFI?	☐ Yes ☐ No ☐ Unknown	If yes, please provide the details on the following: 1. Number of known/recorded clustered cases: _____ 2. Did all the cases in the cluster receive vaccine from the same vial? ☐ Yes ☐ No, number of vials used in the cluster: _____

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Appendix 1. AEFI Definitions

Non-serious AEFI	Serious AEFI
An event that is not serious and that has no potential to risk to the health of the recipient of the vaccine, but must be carefully monitored as they may signal a potentially larger problem with the vaccine or the vaccination, or may have an impact on the vaccination acceptability in general.	An event that results in death, is life-threatening, requires in-patient hospitalization or prolonged existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly or birth defect. May also refer to any medical event that requires intervention to prevent one or more outcomes above.
Adverse Event of Special Interest (AESI) - An adverse event of special interest (serious or non-serious) is one of scientific and medical concern specific to the sponsor's product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor can be appropriate.	

Appendix 2. Operational Definition for Serious AEFI

1. For AEFIs that result in **death**, these are to be classified as **serious** if the health care provider examining the patient suspects that the drug resulted in or contributed to death.

2. For AEFIs that result in **hospitalization**, these are to be classified as serious if (1) the health care provider examining the patient suspects that the AEFI resulted to **admission of the patient** to the hospital or prolongation of hospitalization of the patient; AND (2) the admission is considered medically justified to deliver active medical or surgical intervention, and not just observation or medical monitoring.

    a. For AEFIs detected in **emergency visits that do NOT result in admission to the hospital; OR observation or medical monitoring are the activities performed**, the AEFI should be evaluated for the other definitions.

3. For AEFIs that result in **persistent or significant disability**, these are to be classified as serious if the health care provider examining the patient suspects that the AEFI resulted in a substantial disruption of a person's ability to conduct normal activities of daily living, specifically in significant, persistent or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities, and/or quality of life.

4. For AEFIs that result in **congenital anomaly or birth defect**, these are classified as serious if **(1)** the exposure is prior to conception or during pregnancy; AND (2) the health care provider examining the patient suspects that the drug resulted to a congenital anomaly or birth defect.

5. For AEFIs that are considered to be **life-threatening**, these are to be classified as serious if the health care provider examining the patient suspects that the patient was at substantial risk of dying at the time of the adverse event.

6. For AEFIs that require **intervention to prevent any of the above-mentioned outcomes**, these are to be classified as serious if (1) the health care provider examining the patient suspects that medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure; AND (2) either situation is suspected to be due to the exposure.

7. When further clarity is needed to define the seriousness of an AEFI, the Regional Epidemiology and Surveillance Unit shall have the authority to provide immediate guidance and classification of seriousness of the AEFI, as referred by the inquiring health care provider.

    a. The health care provider examining the patient must confer first with the RESU within their region for AEFIs that they may have doubts on the classification of seriousness.

    b. The RESU, upon application of the above guidelines, and their judicious understanding of the case, may provide the classification as to seriousness.

    c. The RESU shall regularly inform the Epidemiology Bureau of (1) these specific cases; (2) the decisions made as to classification of seriousness; and (3) considerations taken to give rise to these decisions.

    d. The Epidemiology Bureau shall regularly review the submissions of the RESUs for harmonization and further standardization of the criteria for seriousness of AEFIs.

Appendix 3. Flow of AEFI Surveillance

Surveillance Cycle Step	Definition	Purpose	Personnel responsible/involved
Detection, Notification	Identification and recognition of all cases corresponding to locally suitable AEFI case definitions, AEFI clusters, and all other events believed to be due to immunization	To recognize and detect AEFI as they occur or when appropriate, to treat or refer patients for treatment	Vaccine recipient, Parents of immunized infants and children, health care workers, staff in immunization of healthcare facilities
Reporting	Transmission of information relevant to AEFIs by means of standardized form, telephone call, direct conversation, or specific application	To provide key descriptive epidemiological data (time, place and person) that are critical for identifying clusters and for signal detection	Vaccine recipient, Parents of immunized infants and children, health care workers, staff in immunization of healthcare facilities
Investigation	Collection of pertinent details of the patient, vaccine and other drugs potentially received, the event, immunization services	To establish a more specific case definition (as needed) and formulate a hypothesis to what cause the AEFI	Healthcare worker who detected the case
Causality Assessment	Systematic review and evaluation of available data about an adverse event following COVID-19 vaccination	To determine the likelihood of a causal association between the event(s) and the vaccine received	Regional and National AEFI Committees

Case Classifications

A. Consistent causal association to immunization

A1. Vaccine product-related reaction: An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product.

A2. Vaccine quality defect-related reaction: An AEFI that is caused or precipitated by a vaccine due to one or more quality defects of the vaccine product, including the administration device, as provided by the manufacturer

A3. Immunization error-related reaction: An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and that thus, by its nature, is preventable.

A4. Immunization anxiety/stress related response: An AEFI arising from anxiety about the immunization.

B. Indeterminate

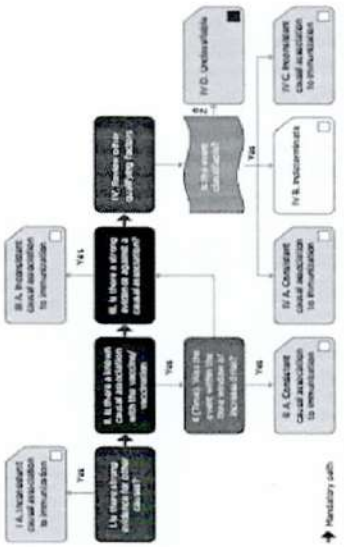
B1. Consistent temporal relationship but insufficient evidence for causality: Temporal relationship is consistent but there is insufficient definitive evidence that vaccine caused the event (it may be a new vaccine-linked event). This is a potential signal and needs to be considered for further investigation.

B2. Conflicting trends of consistency and inconsistency with causality: Reviewing factors result in conflicting trends of consistency and inconsistency with causal association to immunization (i.e. it may be vaccine-associated as well as coincidental and it is not possible clearly to favour one or the other).

C. Inconsistent causal association to Immunization (Coincidental): An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety. This could be due to underlying or emerging condition(s) or conditions caused by exposure to something other than the vaccine.

D. Ineligible and unclassifiable cases: Available information on these cases shall be filed in a repository or an electronic database for periodic review to see additional information for classification and to perform analysis on signal detection.

Algorithm (WHO Causality Assessment Manual 2019)



References

Council for International Organizations of Medical Sciences. Definition and application of terms for vaccine pharmacovigilance. Report of the CIOMS/WHO Working Group on Vaccine Pharmacovigilance. 2012. Available from http://www.who.int/vaccine_safety/initiative/tools/CIOMS_report_WG_vaccine.pdf

World Health Organization. Covid-19 vaccines: safety surveillance manual. WHO 2020. Available from https://www.who.int/docs/default-source/covid-19-vaccines-safety-surveillance-manual/covid19vaccines_manual_aefi_20210104.pdf

World Health Organization. Causality assessment of an adverse event following immunization (AEFI)): user manual for the revised WHO classification second edition, 2019 update. WHO 2019 Available from https://www.who.int/publications-detail-redirect/causality-assessment-aefi-user-manual-2019

NOTE: According to Republic Act No. 11332 Revised IRR Rule VI Sec. 6, "The aforementioned details are crucial and indispensable for the formulation of appropriate policies and disease response activities. Hence, health professionals conducting the interview at point of first contact shall obtain such details from a suspect case, properly informing the data subject that the information sought to be obtained is being processed in accordance with Republic Act No. 10173, or the "Data Privacy Act of 2012," and that deliberately providing false or misleading personal information on the part of the person, or the next of kin in case of person's incapacity, may constitute as non-cooperation punishable under the Act or this IRR."
Information provided here is for surveillance and investigation use only in the context of detection of safety signals, addressing vaccine hesitancy, and potential claims from PHIC VICP.
Information submitted here may not be used for medico-legal purposes, or performance of medical or clinical audit to the management of the health care provider/s

Appendix 4. Additional sheet for Vaccination Details

PATIENT INFORMATION			
First Name*	Middle Name	Last Name*	Suffix

VACCINATION DETAILS	Check if applicable: ☐ With previously reported event (i.e. anaphylaxis) ☐ Heterologous				
NOTE: Please provide all the necessary information. Should the page be insufficient, please use another sheet.					
Details	Oldest dose →				Later dose
1. Dose number*					
2. Name of Vaccine*					
3. Place of Vaccination* (Local/Abroad)					
4. Date of Vaccination* (MM/DD/YYYY)					
5. Time of Vaccination* (hh:mm)	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM
6. Site of Injection* (Right/Left arm)					
7. Batch/Lot Number*					
8. Expiry Date (MM/DD/YYYY)					
9. Vaccination Site Name*					
10. Vaccination Site Country					
11. Vaccination Site Region*					
12. Vaccination Site Province*					
13. Vaccination Site City/Municipality*					
14. Vaccination Site Barangay*					
15. Diluent					
16. Date of Reconstitution (MM/DD/YYYY)					
17. Time of Reconstitution (hh:mm)	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM
18. Batch/Lot Number					
19. Expiry Date (MM/DD/YYYY)					
20. Vaccine procured from	☐ DOH ☐ Local Gov't Unit ☐ Private ☐ Unknown ☐ Others:_____	☐ DOH ☐ Local Gov't Unit ☐ Private ☐ Unknown ☐ Others:_____	☐ DOH ☐ Local Gov't Unit ☐ Private ☐ Unknown ☐ Others:_____	☐ DOH ☐ Local Gov't Unit ☐ Private ☐ Unknown ☐ Others:_____	☐ DOH ☐ Local Gov't Unit ☐ Private ☐ Unknown ☐ Others:_____

Appendix 5. Additional form for case-based survey of pregnant women inoculated with COVID-19 vaccine

I. PREGNANCY INFORMATION			
Occupation of Individual* ☐ Health care worker (e.g., hospitals, treatment facilities, vaccination sites, etc.) ☐ Frontliner ☐ Others, please specify _____		**Name of Current Employer, Office or Agency**	**Work Address** Barangay: _____ City: _____ Province: _____
Confirmation of pregnancy by test* ☐ YES, please specify means of confirmation _____ ☐ NO	**Gestational age at time of vaccination*** __ weeks **Trimester*** ☐1st ☐ 2nd ☐ 3rd		**Date of Last Menstrual Period*** *(MM/DD/YYYY)* __/__/____
Current Status of Pregnancy* ☐ Still pregnant ☐ Abortion (fetal death of less than 14 weeks) ☐ Carried preterm and delivered ☐ Carried to term and delivered		**Date of delivery** *(MM/DD/YYYY)* __/__/____	**Type of Delivery**
Status of Mother* ☐ Died (maternal death) ☐ Alive (with no comorbidities) ☐ Alive (with comorbidities), specify _____	**Status of Neonate*** ☐ Died (Intrauterine fetal death – death inside the womb) ☐ Died (Born dead and non-responsive despite signs of activity prior to the puerperal stage) ☐ Alive	**Vital Statistics of the Neonate** Birth weight (grams): _____ Birth length (cm): _____ Head circumference (cm): _____ Gestational age at birth (weeks): _____	
Number of pregnancies: _____	**Number of term births: _____**	**Number of premature births: _____**	
Number of abortions (spontaneous or therapeutic): _____		**Number of living children: _____**	
II. COMORBIDITIES AND PAST MEDICAL HISTORY			
Maternal medical complication in past pregnancies ☐ Hypertensive disorders (eclampsia) ☐ Gestational diabetes ☐ Premature delivery ☐ LBW or SGA infants ☐ Neonatal death ☐ Others, please specify _____ ☐ None or not applicable			
Conditions that increase the risk for obstetric complications for current pregnancy ☐ Incompetent cervix ☐ Placenta previa ☐ Oligo-polyhydramnios ☐ Others, please specify _____ ☐ None or not applicable			
Active/recent maternal infection with HIV, HepB, Hep C, TB, Malaria, STI, maternal group B, Streptococcus, and other Chronic infections	☐ YES, please specify		☐ NO
Existing medical conditions or comorbidities prior to pregnancy			
Maternal status at the time of vaccination			
1st COVID-19 vaccine dose ☐ Normal ☐ Morbidity present, please specify morbidity and signs and symptoms _____	**2nd COVID-19 vaccine dose** ☐ Normal ☐ Morbidity present, please specify morbidity and signs and symptoms _____	**Other COVID-19 vaccine dose** ☐ Normal ☐ Morbidity present, please specify morbidity and signs and symptoms _____	
Administration of other vaccines during pregnancy*	☐ YES, please list all vaccines and date of inoculation		☐ NO
Past history of adverse reactions to vaccines before pregnancy*	☐ YES, please specify details of reaction		☐ NO
Administration of concomitant medications including immunomodulatory agents during pregnancy	☐ YES, please specify		☐ NO
Maternal use of alcohol, drugs, use of nutritional or other supplements	☐ YES, please specify		☐ NO
Receipt of blood products one month before or after vaccination	☐ YES, please specify		☐ NO

*Mandatory fields for completion

NOTE: According to Republic Act No. 11332 Revised IRR Rule VI Sec. 6. "The aforementioned details are crucial and indispensable for the formulation of appropriate policies and disease response activities. Hence, health professionals conducting the interview at point of first contact shall obtain such details from a suspect case, properly informing the data subject that the information sought to be obtained is being processed in accordance with Republic Act No. 10173, or the "Data Privacy Act of 2012," and that deliberately providing false or misleading personal information on the part of the person, or the next of kin in case of person's incapacity, may constitute as non-cooperation punishable under the Act or this IRR."
Information provided here is for surveillance and investigation use only in the context of detection of safety signals, addressing vaccine hesitancy, and potential claims from PHIC VICP. Information submitted here may not be used for medico-legal purposes, or performance of medical or clinical audit to the management of the health care provider/s

Appendix 6. List of adverse events of special interest (AESI) for lower-middle income countries as prioritized by Brighton Collaboration

AESI Tier	Tier 1	Tier 2
Description	Refers to serious AESIs observed or associated with COVID-19 vaccines in animal studies, clinical trials and post-introduction pharmacovigilance. This tier is specific for immunization errors and hospitalized cases, and appropriate for the conduct of hospital-based or sentinel-site surveillance.	These are non-serious cases, which are theoretical concerns and are relatively common. These cases can be included in a cohort-event monitoring surveillance (out-patient setting).
List	• Vaccine-associated enhanced disease* • Multisystem inflammatory syndrome in adults and children* • Myocarditis* Pericarditis* • Thrombosis with Thrombocytopenia Syndrome* • Thrombosis • Thrombocytopenia* • Acute disseminated encephalomyelitis* • Encephalitis* • Myelitis* • Acute respiratory distress syndrome* • Anaphylaxis* (*may not be hospitalized*) • Toxic Shock Syndrome • Injection site cellulitis/abscess (*may not be hospitalized*)	• Acute kidney injury** • Acute liver injury** • Anosmia/ageusia • Bell's Palsy* • Chilblain-like lesions • Erythema multiforme • Acute pancreatitis • Rhabdomyolysis • Subacute thyroiditis

**Has existing Brighton Collaboration case definitions*
***Has published laboratory-based criteria*
Note: This list is subject to periodic review and updates, following developments from the Brighton Collaboration website.

Disclaimer: For all cases presenting similar symptom as listed by Brighton Collaboration, these MAY be for investigation depending on the answers submitted in this form.

Reference: Brighton Collaboration. Suggested list of core COVID-19 adverse events of special interest (AESIs) for safety monitoring in low and middle-income countries. 2021 June 17. Available from https://brightoncollaboration.us/wp-content/uploads/2021/06/LMIC-COVID-19-core-AESI-list-v0.9-June-17-2021.pdf

PARTS OF THE CIF

		Non-Serious	Serious AEFI	
			Not for CA	For CA
Page 1	Basic Case Information	✓	✓	✓
Pages 2-5	For Clinical Investigation		✓	✓
Pages 6-7	For Community and Immunization Investigation			✓
Annexes		If applicable	If applicable	If applicable

ACCOMPLISHING THE CIF

1. Upon presentation of an event or condition, the health care provider in-charge must first be able to probe for the vaccination history from either the guardian or the patient themselves. If confirmed to be an adverse event following immunization (AEFI), proceed to accomplish the AEFI CIF.

2. The minimum required or mandatory fields are indicated with asterisks for each section of the AEFI CIF. All of the minimum required or mandatory fields have been identified and assessed for the conduct of a quality causality assessment and must be accomplished.

3. The **first page** of the AEFI CIF must be **completely and accurately** filled by the reporter upon detection for all detected and reported AEFIs, regardless of seriousness. The first page of the CIF should be submitted to report the initial findings of the case depending on the timeline in reference to the seriousness of the case. The succeeding pages may be submitted upon completion of the investigation, should the case be subjected to investigation, causality assessment, and/or have applied for VICP or have filed for claims or indemnification.

    a. For all non-serious AEFI cases, or cases that do not fit in the criteria of seriousness, only the first page of the AEFI CIF will be submitted. The non-serious AEFI case reports must be submitted to the local ESU every Thursday of the week.

    b. For all reported serious AEFI cases as determined and detected by the respective healthcare providers, regardless if it will undergo investigation or not, **the first to fifth pages of the AEFI CIF shall be filled out by the attending physician and/or corresponding health care provider** as the second to fifth pages contain the clinical investigation details. These shall be submitted by the attending physician and/or corresponding health care provider assigned to the patient, on site at the disease reporting unit or health facility - unprompted by the external ESU. Timing of submission may be as follows:

        i. Submit prior to the discharge or after the vaccine recipient has been discharged from the hospital wherein a concrete or final diagnosis may be

determined from the given course of hospitalization and the pertinent documents such as medical chart, lab results, and others may be attached or submitted, if the vaccine recipient has been admitted in the hospital or hospitalized;

ii. Submit once all pertinent and supporting documents have been gathered and may be attached to the AEFI CIF where the vaccine recipient has experienced either (1) life-threatening event, (2) disability, (3) congenital anomaly, or (4) other medically important event; or

iii. Submit once the death certificate is available or where the autopsy was done on the vaccine recipient that has died following vaccination, and other pertinent documents may be attached to support the diagnosis stated in the AEFI CIF.

c. **Pages six and seven** of the AEFI CIF contain the immunization practice and community investigation. These pages shall be filled up by the concerned individuals involved in the processes as **prompted by the respective external ESU.**

4. All vaccination sites and disease reporting units, including all health facilities, with existing AEFI reporting platforms or systems for the reporting of AEFI cases shall comply with the revisions and format discussed in ***Annex 23***.

5. Additional forms are found in the appendices. Should the Vaccination Details section found in the first page of the AEFI CIF be insufficient to encode details, an additional form is found in Appendix 4. Pregnant women who have been vaccinated and have reported AEFIs shall accomplish Appendix 5 which shall collect further information on the course of pregnancy of the individual.

6. The question on Vaccine Injury Compensation Package under section X, For the Health Care Provider, shall only be answered for vaccinated individuals and/or the next of kin when they are determined to be eligible. The question may be answered for other vaccines when it is applicable in the future.

7. When the patient and/or the next of kin decides not to give consent to the investigation, causality assessment, or filing of vaccine compensation package or leaves the section on consent unanswered, Other retrievable information provided by the attending physician or health care provider shall be obtained.

8. Furthermore, the attached revised AEFI CIF version 2 shall be used as the standard form for reporting AEFI cases from COVID-19 vaccines, until it is obsolete and/or replaced. The AEFI CIF has two formats, a printable version and the fillable/computerized version. Both files may be accessed through ***bit.ly/aefic19ph*** under the "AEFI Official Case Investigation Form" folder. It is highly recommended to use the fillable/computerized version as the format of choice to prevent misunderstanding in handwritings and for ease of submission.

CIF ATTACHMENTS

1. All the designated fields must be answered as truthfully and thoroughly as possible. Provide all the necessary information for a clinical case summary including the case's full medical history, physical evaluations, and clinical course. Attach all laboratory work-ups and diagnostic results as reference and verification of the case details provided. Remember that proper documentation will result in better interpretation, especially for imaging findings and for reference values, specific dates and times of retrieval of laboratory results.

2. An initial assessment with a valid diagnosis of the physician or medical personnel in charge of the patient must be secured before accomplishing the AEFI CIF. The diagnosis must be backed up by medical results and laboratory findings before endorsement for investigation and causality assessments of the Regional and/or National AEFI Committees. Cases to be investigated and to undergo assessments must follow the hierarchy and criteria stated in Annex D of this advisory.

3. If the reporter doubts or cannot provide a definite classification of the AEFI case, they may confer with the hospital or their local ESUs.

4. The reference on Adverse Events of Special Interest (AESI), specifically Appendix 6, shall only apply to COVID-19 vaccines.

SUBMISSION OF CIF

1. The submission of the AEFI CIF for serious AEFI cases that have been hospitalized may be done upon the discharge of the patient based on the identified hierarchy and criteria for the conduct of causality assessment of the cases. For serious AEFI cases that have died, the AEFI CIF may be submitted as soon as possible upon completion of the form.

2. For cases detected by a hospital provider, the AEFI CIF must initially be reported to the HESU. The Disease Surveillance Officer (DSO) of the hospital shall be required to completely fill up the AEFI CIF before submitting to local ESUs. The ESUs may return the AEFI CIF when it is determined that insufficient data was provided in the form and the serious AEFI case shall not undergo investigation and/or causality assessment. On the other hand, for cases detected by healthcare providers outside of the hospital setting, the AEFI CIF must be submitted to their local ESUs.

3. The respective hospital ESUs and local ESUs are in charge of collating, handling, and submitting all AEFI case reports, regardless of seriousness, based on the stipulated timelines to the DOH.

4. The AEFI CIF must be completely and accurately filled before submission to the respective ESUs. Hospital, Local, and Regional ESUs, have the right to return incompletely filled or incoherently narrated forms to submitting health care providers.

INVESTIGATION GUIDE

Diagnostic Groups for Frequently Reported Commonly Seen Serious AEFIs

Diagnostic Groups	What does NAEFIC look at in determining validity of diagnosis	What information could be collected during clinical investigation to improve validity of diagnosis and rule out differentials?
Anaphylaxis/ Severe Allergy	1. Past Medical History / Allergies 2. Acute onset <6 hours 3. PE findings ○ Skin ○ Upper airway ○ Circulatory ○ Gastrointestinal 4. Low likelihood of other diagnosis	1. Clear narrative and timeline of events for the appearance of signs/symptoms (hives, pruritus, swollen lips, flushing, dyspnea, wheeze, loss of consciousness, hypotension, severe abdominal pain) 2. Allergies to other medications 3. Past medical history of anxiety 4. Documentation of intervention and clinical response (Dose, route, site and time of administration of epinephrine)
Stroke	1. Risk factors 2. Past Medical History 3. Family Medical History 4. Hx & PE 5. Lab findings (rule out VITT)	1. CT Scan 2. Past BP findings and medications whether documented in a chart or from recall from patient or relative 3. Symptoms of focal neurological symptoms in the past, days/weeks pre-vaccination (slurring of speech, mild unilateral weakness, change in sensorium) 4. CBC with quantitative platelet count. If low Plt, add peripheral blood smear.
Acute Coronary Syndrome / Myocardial Infarction	1. Risk factors 2. Past Medical History 3. Family Medical History 4. Hx & PE	1. Hx: Quality of chest pain, difficulty of breathing, radiation of numbness 2. 12-L ECG, CXR 3. Past medical history of heart failure symptoms cardiac 4. Family medical history of early cardiac death (<50 y/o)
Sudden Unexpected Death	1. Autopsy 2. Risk factors that lead to demise	1. If not done, cite why (To properly document that autopsy has been contemplated but may not have been done due to lack of consent, availability/accessibility of autopsy) 2. Ask relatives of past medical history (past consultations, hospitalizations, medications, past laboratory findings). Usually "sudden death" is either cardiovascular or cerebrovascular. 3. Functionality of the individual hours, days to a month prior to death -- Chest pain, heart failure symptoms -- shortness of breath in short distances, upon exertion
Rule out COVID-19 if infection. While laboratory, imaging, procedures and specialist consultations strengthen the validity of the diagnosis, clinical investigation through excellent history-taking and physical examination, and properly documented narration of events is paramount to rule in the event being assessed and properly rule out other differential diagnoses. **STEP 1: ELIGIBILITY OF THE EVENT OR DIAGNOSIS USUALLY IS THE CHALLENGE.**		

ANNEX H. *List of AEFI related issuances*

1. **DM 2021-0218:** Further Clarification on the National Vaccination Deployment Plan on Health Screening and Management of Adverse events following immunization
2. **DM 2021-0220**: Key Actions for the Regional Vaccine Operations Center and Regional Epidemiology and Surveillance Units on COVID-19 Vaccine Safety, Surveillance, and Response
3. **DM 2021-0224**: Interim Guidelines on Adverse Events Following Immunization (AEFI) Community Management and Crisis Communications Related to COVID-19 Vaccines
4. **DM 2021-0425:** Interim Guidelines for the Conduct of Medical Autopsies for Deaths Following Immunization with COVID-19 Vaccine
5. **DC 2021-0247**: Immediate Provision of Access to Medical Records by Hospitals to Epidemiology and Surveillance Units to aid Investigation of Adverse Events Following Immunization
6. **DC 2021-0464:** Interim Operational Guidelines on the COVID-19 Vaccination of the Pediatric Population Ages 12-17 Years Old with Comorbidities
7. **DC 2021-0466**: Reiteration of Current Guidance on Ensuring Proper Health Screening, Clearance, and Deferral to Recipients of COVID-19 Vaccines Under the COVID-19 Vaccination Program
8. **NVOC Advisory No. 59**: Reiteration on the Implementation of Post-vaccination Education and Reporting of Adverse Events Following Immunization (AEFI)
9. Section III.F and III.J of **DM 2021-0099**: "Interim Omnibus Guidelines for the Implementation of the National Vaccine Deployment Plan for COVID-19"
10. Section I of **DC 2021-0101**: "Clarification on Provisions of Department Memorandum No. 2021-0099 entitled the "Interim Omnibus Guidelines for the Implementation of the National Vaccine Deployment Plan for COVID-19"
11. Sections B.4 and C.4 of **DM 2021-0175**: "Further Clarification of the National Deployment and Vaccination Plan for COVID-19 Vaccines and Additional Guidelines for Sinovac Vaccine Implementation"
12. **PhilHealth Circular 2021-0007**: Implementing Guidelines on the Coverage of COVID-19 Vaccine Injury due to Serious Adverse Effects Following Immunization Resulting in Hospitalization, Permanent Disability, or Death under the COVID-19 National Vaccine Indemnity Fund
13. **NVOC Advisory No. 67**: Additional Adverse Events Following Immunization (AEFI) Reporting System for Vaccination Sites, including Private Sector - Managed Vaccination Sites