Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

14 October 2021

DEPARTMENT CIRCULAR
No. 2021 - 0464

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; AND OTHERS CONCERNED**

SUBJECT : **Interim Operational Guidelines on the COVID-19 Vaccination of the Pediatric Population Ages 12-17 Years Old with Comorbidities**

I. RATIONALE

The Department of Health (DOH) has been rolling out the National COVID-19 Vaccine Deployment and Vaccination Program since March 2021. Simultaneous in the vaccination of Priority A and the Rest of the Adult Population, the DOH has recommended the vaccination of the pediatric population ages 12-17 years old with comorbidities.

In July 2021, the Strategic Advisory Group of Experts (SAGE) on Immunization of the World Health Organization (WHO) in its recommendation determined that children with certain underlying medical conditions are at increased risk of severe illness from SARS-CoV-2 infection. Further, the Philippine Pediatric Society (PPS) and the Pediatric Infectious Disease Society of the Philippines (PIDSP) released its updated recommendations on September 6, 2021 and the All Expert Group (AEG) of the DOH recommended last September 22, 2021, that the COVID-19 vaccination of the pediatric population may commence with the 12-17 years old with comorbidities.

Furthermore, the Inter-Agency Task Force for the Management of Emerging Infectious Diseases (IATF) approved the commencement of the COVID-19 vaccination of the

pediatric population starting with 12-17 years old with comorbidities. The IATF Resolution No. 141 states,

> *Further, beginning 15 October 2021, the vaccination of the pediatric population [those between the ages of twelve and seventeen (12-17) years old] with vaccines granted Emergency Use Authorization by the Food and Drugs Administration shall be piloted under a phased approach as may be determined by the National Vaccination Operations Center.*

In view of the foregoing, this Department Circular (DC) is issued to implement the roll-out of the COVID-19 vaccination for the pediatric population ages 12-17 years old with comorbidities.

II. OBJECTIVES

This Department Circular (DC) provides interim operational guidelines on the COVID-19 vaccination of the pediatric population ages 12-17 years old with comorbidities.

III. SCOPE OF APPLICATION

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

This DC shall cover the vaccination of the pediatric population ages 12-17 years old with comorbidities only. The vaccination of the rest of the pediatric population is not covered by this policy issuance.

IV. DEFINITION OF TERMS

A. Affidavit of Guardianship - refers to duly notarized written sworn statement of facts voluntarily made by the person stating that he/she is the duly appointed guardian of the minor child.

B. Affidavit of Kinship - refers to duly notarized written sworn statement of facts voluntarily made by the person stating that he/she is the nearest surviving kin.

C. Assent - refers to the willingness of the minor/child to be vaccinated. An assent form shall be accomplished by the child in addition to the Informed Consent Form

by the parent or guardian. The assent shall not replace the consent by the parent or guardian.

D. Child-Caring Agency - refers to duly licensed and accredited agency by the Department of Social Welfare and Development (DSWD) that provides twenty-four (24) hour residential care services for abandoned, orphaned, neglected, or voluntary committed children as stipulated in Article 1, Section 3(i) of RA No. 8552 "Domestic Adoption Act of 1998".

E. Guardian - refers to the legal or judicial guardian.

   1. Legal guardian - is a guardian of the minor by express provision of law without the need for judicial appointment, as in the case of the parents over the persons of their minor children or those exercising substitute parental authority of the minor child in accordance with Article 216 of the Family Code.

   2. Judicial guardian - is a guardian appointed by the court over the person and/or property of the ward to represent the latter in all his civil acts and transactions.

F. Parent - refers to the legitimate, illegitimate, or adoptive father or mother of the minor child. Adoption for the purpose of this Department Circular shall refer to legal adoption.

G. Pediatric Population - refers to a group of the population between birth and 18 years of age.

V. GENERAL GUIDELINES

A. Due to higher risk for severe disease of COVID-19, the pediatric population ages 12-17 years old with comorbidities are recommended to be vaccinated with COVID-19 vaccines with Emergency Use Authorization (EUA) from the Philippine Food and Drug Administration (FDA).

B. The COVID-19 vaccination of pediatric vaccination ages 12-17 years old with comorbidities shall be implemented in a phased approach considering vaccination coverage of other eligible priority groups, specifically on Priority Group A2: Senior Citizens per region.

C. Only COVID-19 vaccines with approved EUA issued by the Philippine FDA indicating the use to individuals 12 years of age and older shall be administered to the pediatric population ages 12-17 years old with comorbidities.

D. The COVID-19 vaccination process in vaccination sites including the registration, screening, counselling, vaccine recipient reporting, AEFI monitoring and referral shall follow (DOH) Department Memorandum 2021- 0099 and other relevant policies.

E. Instructions for COVID-19 vaccination providers and administrators on storage and handling, dosing and schedule, administration, contraindications, warnings, adverse reactions, and use with other vaccines shall follow Philippine FDA EUA.

F. Protocols for the management of Adverse Effects Following Immunization (AEFI) and Adverse Events of Special Interest (AESI) shall follow the provisions of the approved COVID-19 Vaccine for children with EUA of the FDA, succeeding guidelines from the FDA, and other recognized professional organizations and regulatory bodies, as new evidence arise.

VI. IMPLEMENTING GUIDELINES

A. Eligible Population

1. Eligible pediatric vaccine recipients with co-morbidities shall be categorized as part of Priority Group A3: Individuals with Comorbidities and shall be reported as "Pediatric A3".

2. The defined comorbidities in the "Pediatric A3" shall be as follows:

    a. **Medical complexity:** long term dependence on technical support e.g. tracheostomy associated with developmental delay and/or genetic anomalies.

    b. **Genetic conditions:** Down's Syndrome (Trisomy 21), Glucose-6-phosphate dehydrogenase deficiency (G6PD), genetic disorders affecting the immune systems such as primary immunodeficiency disorders, thalassemia, and other chromosomal abnormalities.

    c. **Neurologic conditions:** Seizure Disorder, Autism Spectrum Disorders (ASDs), Cerebral Palsy, Stroke in the Young, Chronic Meningitis e.g. Tuberculosis, chronic neuromuscular diseases, and chronic demyelinating diseases.

    d. **Metabolic/endocrine diseases:** Diabetes Mellitus (DM), Hypothyroidism, Diabetes Insipidus (DI), Adrenal insufficiency, Hypopituitarism, and other hereditary metabolic diseases.

e. **Cardiovascular diseases:** Hypertension, Congenital Heart Diseases (CHDs), Cardiomyopathy, Rheumatic Heart Disease (RHD), Mitral Valve Disease, Pulmonary Hypertension with Right Heart Failure.

f. **Obesity:** BMI > 95th percentile for age and height.

g. **HIV infection**

h. **Tuberculosis:** Pulmonary (collapse/consolidations, with empyema, and miliary), Extrapulmonary, (pleural effusion, pericarditis, abdominal, genitourinary, central nervous system, spinal column, bone, joint, cutaneous, ocular and breast), and Disseminated (involvement of two (2) or more organs).

i. **Chronic Respiratory Diseases:** Chronic Lung Diseases (Bronchiectasis, Bronchopulmonary Dysplasia, Chronic Aspiration Pneumonia), Congenital respiratory malformation, Restrictive Lung Diseases, neuromuscular disorders, syndromic with hypotonia, skeletal disorders, chronic upper and lower airway obstruction (Severe Obstructive Sleep Apnea, Tracheomalacia, Stenosis, Bronchial Asthma).

j. **Renal Disorders:** Chronic Kidney Diseases, Nephrotic Syndrome, End-Stage Renal Disease (ESRD), patients on dialysis and continuous ambulatory peritoneal dialysis (CAPD), Glomerulonephritis (e.g. lupus nephritis), Hydronephrosis.

k. **Hepatobiliary Diseases:** Chronic Liver Disease, Cirrhosis, Malabsorption Syndrome.

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

B. Implementation of Vaccination Rollout

1. The vaccination roll-out to the pediatric population which shall start with 12-17 years old with comorbidities shall only commence once the regional vaccination coverage of fully vaccinated Priority Group A2: Senior Citizens is $\geq$ 50% and the supply of COVID-19 vaccines are stable and adequate. The vaccination roll-out shall commence by region.

2. The COVID-19 vaccination rollout to the pediatric population ages 12-17 years old with comorbidities shall be implemented in a phased approach as determined by the NVOC.

    a. There shall be four (4) phases in the COVID-19 vaccination rollout to the pediatric population ages 12-17 years old with comorbidities:

        i. **First Phase:** vaccination rollout in selected hospitals in the National Capital Region (NCR) as determined by DOH, where the hospitals shall vaccinate their patients/cohorts.

        ii. **Second Phase:** vaccination rollout in hospitals as identified by the 17 LGUs of the NCR. Each LGU shall select at least one hospital for the rollout, either an LGU-managed or a private-owned hospital.

        iii. **Third Phase:** vaccination rollout in hospitals region-wide once the region reached $\geq$50% regional vaccination coverage of fully vaccinated Priority Group A2: Senior Citizens. Other regions may also conduct initial rollout in selected hospitals.

        iv. **Fourth Phase:** as determined by NVOC, the vaccination rollout to regions may be expanded utilizing regular vaccination sites.

3. The commencement of the vaccination roll-out by region shall be determined by the Regional Director of the CHD, in coordination with the NVOC.

C. Allocation of COVID-19 Vaccines

1. Only vaccines with EUA approval from the Philippine Food and Drug Administration (FDA) for 12 years and above shall be allocated to identified LVOCs, implementing units and vaccination sites.

2. The COVID-19 vaccines for the vaccination of the pediatric population ages 12-17 years old with comorbidities shall be included in the COVID-19 vaccine

allocation of the Local Government Units (LGUs) based on the number of unvaccinated individuals.

3. The NVOC shall directly coordinate with the hospitals selected to be part of the first phase of the vaccination rollout to determine COVID-19 vaccine requirements. Their allocation shall be directly delivered to the hospitals by the NVOC Cold Chain and Logistics Team.

D. Pre-registration and Scheduling

1. Master listing of pediatric vaccination ages 12-17 years old with comorbidities is not required. However, pre-registration based on the processes required by the vaccination site is necessary to ensure ease in planning and determination of logistics, human resource and COVID-19 vaccine requirements.

2. For the first phase of the vaccination rollout, the selected hospitals shall schedule their respective patients for COVID-19 vaccination. The hospitals may accommodate and schedule the vaccination of the eligible pediatric population ages 12-17 years old with comorbidities as referred by the CHOs as long as a medical certificate is presented during the vaccination schedule.

E. Requirements for Vaccination

1. A medical certification given by the attending pediatrician/physician detailing the comorbidity/ies of the vaccine recipient shall be secured prior to the vaccination schedule and shall be presented in the registration area during the vaccination schedule (*See Annex A for template*).

    a. The Medical Certification shall provide information of the vaccine recipient's comorbidity/ies and shall indicate that the vaccine recipient can receive the COVID-19 vaccine after thorough assessment and evaluation on the date of certification.

    b. The LVOCs/LGUs shall ensure that the pediatric population ages 12-17 years old with comorbidities have equitable access to a pediatrician/physician. If possible, vulnerable populations, specifically the poor population who mostly have limited access to health services, shall be provided with immediate assistance and shall be prioritized in the LGU's provision of health services.

2. Document/s to prove filiation:

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

      i. The best evidence of filiation for the accompanying parent shall be an original copy **or** a certified true copy of the Birth Certificate issued by the Philippine Statistics Authority (PSA). In lieu of the PSA-issued Birth Certificate or certified true copy of the same, a copy of the Certification issued by the Local Civil Registrar of the City or Municipality where the vaccine recipient was registered shall be acceptable. The Certification shall set forth the following:
         1. LCR Registry Number;
         2. Page and book number of the entry of registration;
         3. Date of Registration;
         4. Name of Child;
         5. Sex;
         6. Date of Birth;
         7. Place of Birth;
         8. Name of the Mother;
         9. Citizenship of the Mother;
         10. Name of the Father, if applicable;
         11. Citizenship of the Father, if applicable;
         12. Date of Marriage of the parents, if applicable; and
         13. Place of Marriage, if applicable.

      ii. In case the vaccine recipient does not have a copy of the original or certified true copy of his/her birth certificate or a Certification from the Local Civil Registrar, secondary documents shall be acceptable as long as the same is coupled with a valid government identification card issued to the parent and the vaccine recipient. The following are the secondary documents that may be presented (The list is not in order of preference):
         1. Authenticated medical certificate of the child bearing the name of the parent, issued by the hospital or the DOH;
         2. Baptismal Certificate of the child with the name of the parent/s;
         3. School ID or records of the child (transcript of records, Form 137, etc.) bearing the name of the parent;
         4. PhilHealth, Social Security System (SSS), Government Service Insurance System (GSIS) forms indicating that the vaccine recipient is a beneficiary and a child of the parent. In lieu of physical copies, the parent may show his/her online account of the

PhilHealth, SSS and GSIS online portal showing his/her filiation with the child;

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

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

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

i. Affidavit of Guardianship executed by the Guardian;

ii. Court decree or order of Guardianship, or Letter of Guardianship issued by a Family Court;
iii. Affidavit of Kinship;
iv. PWD ID of the child, if available, wherein the name of the guardian is indicated in the ID pursuant to DOH AO No. 2017-0008;
v. Authenticated medical certificate of the child bearing the name of the guardian, issued by the hospital or the DOH;
vi. Baptismal Certificate of the child with the name of the guardian;
vii. School ID or record of the child which bears the name of the guardian;
viii. PhilHealth, SSS, GSIS forms indicating that the vaccine recipient is a beneficiary and a child under the guardianship of the accompanying adult. In lieu of physical copies, the parent may show his/her online account of the PhilHealth, SSS and GSIS online portal showing his/her relationship with the child;
ix. Copies of insurance policies, health card membership, life plan, memorial plan and similar policies wherein the vaccine recipient is the child under the guardianship of the accompanying adult and the said policies were taken on behalf of the latter. In lieu of physical copies, the parent may show his/her online account of the online portal of the said service and health providers, showing his/her relationship with the child;
x. Barangay Certification issued by the Barangay Captain indicating that the guardian and the child are personally known to the latter and setting forth the relationship of the said individuals, as attested by one (1) other witness who personally knows the child and the parent.
xi. If the accompanying person is a Solo Parent, a copy of the Solo Parent identification card from the City or Municipal Social Welfare and Development Office, a Local Social Welfare and Development Office, Tallaq or Faskh certification from the Shariah court or any Muslim Barangay or religious leader, provided that the name of the child is indicated therein.

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

i. A certified list of agencies as duly licensed and accredited by the Department of Social Welfare and Development (DSWD) shall be provided by the DSWD, including the corresponding heads/officers of the said agencies authorized to act as guardians of the children under their care. The said list shall be the basis to verify the names of the accompanying adult in order to determine his/her authority to give informed consent or assent, as the case may be.

ii. The Child-Caring Agency may also opt to provide the DOH a certified list of the names of the minor vaccine recipients who will be vaccinated and the name of their authorized accompanying adults, attaching photocopies of their valid IDs. If so, both the vaccine recipients and the accompanying heads/officers will be required to present the actual valid government ID corresponding to the one submitted by the Agency. For the accompanying heads/officers, he will be required to present the valid ID issued by the Child-Caring Agency issued under his name.

d. In case the above-mentioned mechanisms are not feasible, the accompanying adult and the vaccine recipient shall bring the following documents:

i. In case of an abandoned child whose birth or parentage is unknown, a copy of the Certificate of Foundling and the valid ID issued by the Child Caring Agency to the accompanying heads/officers shall be presented.

ii. Affidavit of Guardianship executed by the accompanying heads/officers and the valid ID issued by the Child-Caring Agency shall be presented.

iii. Authenticated medical certificate of the child bearing the name of the accompanying heads/officers, issued by the hospital or the DOH;

iv. Baptismal Certificate of the child with the name of the accompanying heads/officers;

v. School ID or record of the child which bears the name of the accompanying heads/officers;

vi. Barangay Certification issued by the Barangay Captain indicating that the accompanying heads/officers and the child are personally known to the latter and setting forth the relationship of the said individuals, as attested by one (1) other witness who personally knows the child and the accompanying heads/officers.

vii. For purposes of verifying the identity of the accompanying adult, the valid ID issued by the Child-Caring Agency **and** a separate government issued ID shall be presented by the latter.

3. Valid identification cards or documents with photo of the parent/guardian and the vaccine recipient to verify documents presented:

    a. These are the list valid identification cards of parent/guardian:
        i. SSS Card
        ii. GSIS Card
        iii. Unified Multi-Purpose Identification (UMID) Card
        iv. Land Transportation Office (LTO) Driver's License
        v. Professional Regulatory Commission (PRC) ID
        vi. Philippine Identification (PhilID)
        vii. Overseas Workers Welfare Administration (OWWA) E-Card
        viii. Commission on Elections (COMELEC) Voter's ID or Voter's Certificate
        ix. Senior Citizen ID
        x. Philippine Postal ID
        xi. Seafarer's Record Book
        xii. Valid or Latest Passport
        xiii. Others

F. Vaccination Site Preparation

1. The vaccination site shall have sufficient assistive devices/equipment such as wheelchairs, handrails, among others, to aid the vaccine recipients in the vicinity.

2. The vaccination site shall be large enough to accommodate the presence of the vaccine recipient's parent/guardian.

G. Vaccination Process

1. Waiting Area / Registration

a. The vaccine recipient shall be accompanied by a parent/guardian at the vaccination site.

b. The following documents shall be presented in the registration area:

    i. A medical certification duly signed by an attending pediatrician/physician. Pediatric population ages 12-17 years old with comorbidities without a medical certification confirming that the vaccine recipient is eligible for COVID-19 vaccination based on the

list of acceptable comorbidities shall not be allowed to receive the COVID-19 vaccine.

ii. Proof of filiation or relationship between the minor and the accompanying adult or other supporting document proving authority to give informed consent or assent.

iii. Valid identification cards.

2. Health Education and Informed Consent/Assent Area

a. The vaccination team shall ensure that the vaccine recipient and his/her parent/guardian are informed of the benefits, risks and possible side effects of the COVID-19 vaccines.

b. The vaccination team may utilize applicable digital technology and provide fact sheets to vaccine recipients and parents/guardians to convey valuable information about the COVID-19 vaccine, contact details of referral facilities in case of Adverse Events Following Immunization (AEFI) and/or Adverse Events of Special Interest (AESI), and necessary information for receiving the second dose, including vaccination schedule.

c. After thorough health education to both the vaccine recipient and the parent/guardian, and prior to vaccine administration, the informed consent shall be given and signed by the parent/guardian, and the assent shall be given and signed by the vaccine recipient (*see Annex B*).

i. Under Article 38 of the Republic Act (RA) No. 386 or the New Civil Code of the Philippines, minors within the age of 12-17 years old are still considered to be under parental authority and do not have the capacity to give their consent. Under Article 220 of the Family Code, the parents and those exercising parental authority shall have, with respect to their unemancipated children or wards, the right and duty "to enhance, protect, preserve and maintain their physical and mental health at all times" as well as "to represent them in all matters affecting their interests." As such, the vaccine recipient's parent shall provide the consent before the vaccine recipient shall receive the COVID-19 vaccines, which are still under EUA.

ii. In case that the parent or court-appointed guardian is dead, absent or cannot be located or unsuitable to give the needed consent, the substitute parental authority or legal guardianship shall be exercised

by the surviving grandparent according to Art. 214 of the Family Code.

iii. In default of grandparents, the substitute parental authority shall be exercised by the oldest brother or sister, over twenty-one years of age, unless unfit or disqualified, or the child's actual custodian, over twenty-one years of age, unless unfit or disqualified, in accordance with Art. 216 of the Family Code.

iv. In case of foundlings, abandoned, neglected or abused children and other children similarly situated, parental authority shall be entrusted in summary judicial proceedings to heads of children's homes, orphanages and similar institutions duly accredited by the DSWD or its city/municipal counterparts.

v. In case the parent/guardian refuses to give consent to the vaccination despite the desire and willingness of the minor child to have himself/herself vaccinated, or there are no persons that may legally exercise parental authority over the child, the State may act as *parens patriae* and give the necessary consent. Therefore, the proper officer representing the State as *parens patriae* may sign the consent form. In this regard, the DSWD or its city/municipal counterparts shall serve as the proper office who shall represent the State.

d. Without the signed informed consent of the parent/guardian or any individual authorized to exercise as the substitute parental authority, the vaccine recipient shall be deferred for COVID-19 vaccination unless such documentary requirements are accomplished.

e. If the vaccine recipient shall not give his/her assent, he/she shall not be coerced to receive the COVID-19 vaccine.

f. In case the vaccine recipient is not capable of giving assent due to neurological comorbidities and moderate to severe intellectual impairment, the parent or the authorized parental substitute can sign on his/her behalf.

3. Health Screening and Assessment Area

a. A thorough health screening and assessment, using the Health Declaration and Screening Form per vaccine brand *(see Annex C for template)*, shall be conducted by a trained physician, preferably a pediatrician during the first and second phases of the vaccination rollout, prior to vaccine

administration. Both the vaccine recipient and the parent/guardian may provide the information requested by the health screener.

b. The vital signs of the vaccine recipient shall be taken.

c. The management of elevated blood pressure in children 12-17 years old with comorbidities shall follow the guidelines issued by the Philippine Society of Hypertension Inc.

d. A thorough assessment shall be conducted by the physician at the vaccination site to ensure that the vaccine recipient is clinically well.

e. Only vaccine recipients cleared by the physician to receive the COVID-19 vaccine shall proceed to the vaccine administration area.

f. Deferred vaccine recipients shall be provided with sufficient information when they are eligible to receive the COVID-19 vaccine.

4. Vaccine Administration Area

a. Before administering the COVID-19 vaccine, the vaccinator shall check for the following:
   i. presence of the signed informed consent and assent form,
   ii. presence of the signed health screening form as cleared by the health screener.

b. The vaccine recipient shall receive the required dosage as stipulated in the EUA by the Philippine FDA. There are no weight requirements for COVID-19 vaccination and COVID-19 vaccine dosage does not vary by patient weight.

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

d. If the parents/guardians/household members of the pediatric population ages 12-17 years old with comorbidities are not yet vaccinated with COVID-19 vaccines, they may also be vaccinated in the vaccination site together with the pediatric population or they shall be referred to the LVOC/LGU and shall be scheduled for vaccination. However, to ensure safety, a household member shall always be available to assist the vaccine recipient.

5. Post-Vaccination Monitoring Area

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

H. Adverse Events Following Immunization (AEFI) Monitoring and Case Management

1. All vaccination sites shall inform and ensure awareness of each and every recipient and their patient/guardian of the following:

a. Most frequently reported AEFIs as referenced in the FDA's Emergency Use Authorization and other product information available at www.fda.gov.ph/list-of-fda-issued-emergency-use-authorization/.

b. Symptomatic relief or management for reactogenic reactions encountered, or AEFIs that are expected to occur soon after vaccination, (i.e. vaccination site pain, warmth, erythema, malaise, headache, bleeding) as aligned with DM 2021-0218, with the subject "*Further Clarification on the National Vaccination Deployment Plan on Health screening and management of AEFI.*"

c. A responsive and functional 24/7 hotline, contact information, and/or designated referral facility in their area which recipients or their guardians can contact for any concern, particularly for consultation and steps to take regarding post-vaccination AEFIs.

d. Coverage of financial risk protection provided by the Philippine Health Insurance Corporation (PHIC), more specifically the Vaccine Injury Compensation Package (VICP) as specified in PhilHealth Circular 2021-0007 for A1 or A2 assessed cases by the National AEFI Committee. Moreover, the PHIC benefits that shall remain in effect in cases of hospitalization, as well as other available financial and medical assistance, should be communicated.

2. All healthcare providers, regardless whether they have administered the COVID-19 vaccines, providing care in any setting, regardless of the nature of employment, shall continually update themselves on the following:

    a. Current operational definition of serious AEFIs for the detection, notification, and reporting as referenced in DM 2021-0220.

    b. Latest clinical practice guidelines across all diseases regardless of their current specialty, with emphasis on the diagnosis and management of the most frequently encountered or familiar adverse events following immunization, as stipulated in DM 2021-0218. Particularly, the healthcare providers must be well informed on the recognition and management of specific events including but not limited to anaphylaxis, myocarditis, pericarditis, and immunization stress-related response (ISRR).

    c. Latest local guidelines in the referral or care coordination of their patients within their health care provider network.

    d. Latest service capabilities and referral hotlines of facilities or individual service providers within their localities, particularly for the fields of allergology, cardiology, neurology, and hematology based on the present working impression.

    e. Hotlines, offices, websites and other contact information of government and non-government resources for medical financial assistance of patients.

    f. Contact information, and process of filling out and submitting the most recent version of the Case Investigation Form (CIF) for AEFI of COVID-19 vaccines, to the hospital or local epidemiology surveillance units, with special attention to reported AEFI cases that all healthcare providers, or the patient/s and/or their respective families, have clinical suspicion with.

    g. Extent of the immunity from liability of the Republic Act 11525 and its Implementing Rules and Regulations may cover them.

3. All LVOCs shall assume the responsibility of ensuring reiteration and dissemination of available guidelines for immediate management and response for specific adverse events of the vaccines that will be administered to the pediatric population (anaphylaxis, myocarditis, pericarditis, and immunization stress-related response). LVOCs must ensure the following:

a. Dissemination of materials by the Philippine Society of Allergy, Asthma, and Immunology (PSAAI) ***Annex D*** and guidelines on the assessment, diagnosis, and management of severe allergic reactions caused by COVID-19 vaccines referenced in ***Annex E*** of this circular.

b. At least one complete AEFI/AESI kit per composite team to manage AEFIs including presentations of allergic reactions as seen in ***Annex F***. *It must be noted that some dosages for the pediatric population are different from adult individuals.*

c. Awareness of all healthcare providers in anticipation of AEFIs from the pediatric population, especially those with comorbidities and increased understanding of AEFIs documented and related to specific vaccines, such as myocarditis from mRNA vaccines. The Brighton Collaboration algorithm for diagnosing myocarditis and pericarditis are attached in ***Annex G***.

d. Awareness of immunization-stress related reactions (ISRR) or anxiety-related reactions from COVID-19 vaccines, how they are recognized or assessed, their difference from an allergic reaction/ anaphylaxis, and how to properly manage these symptoms. Some references regarding ISRR are collated in ***Annex H*** for the information of all health providers.

4. All LVOCs must educate all vaccine recipients and their guardians that some of the AEFIs that they experience might be similar to the symptoms of COVID-19 such as sore throat, runny nose, and/or cough. In line with this, LVOCs shall also clearly emphasize and reiterate to all disease reporting units including all health facilities and vaccinated individuals and their guardians that the vaccine will not cause COVID-19. References to better distinguish COVID-19 symptoms from reactogenic reactions from the vaccine can be seen in *Annex I.*

5. All LVOCs shall ensure that reporting lines for vaccination sites and disease reporting units, including all health facilities and hospitals, are aligned, checked and functional. This involves ensuring the participation of non-hospital reporting sites such as private clinics and physicians upon encountering AEFIs in surveillance and response. As a reference, steps in the AEFI Surveillance Cycle as well as the accountable offices are found in ***Annex J***. For health systems preparation for response, DM 2021-0218, with the subject "Further Clarification on the National Vaccination Deployment Plan on Health Screening and Management of Adverse Events Following Immunization", and NVOC Advisory No. 59 with the subject, "Reiteration on the Implementation of Post-Vaccination Education and Reporting of Adverse Events Following Immunization (AEFI)" may serve as a reference.

6. The latest Case Investigation Form (version 2) must be used in reporting all serious and non-serious AEFI cases for the pediatric vaccination rollout, as seen in *Annex K*. The file is also accessible through the link, http://*bit.ly/aefic19ph*. The following guidelines for the use of the Case Investigation Form (version 2) may be found under the same annex.

7. All serious and non-serious AEFI cases must also be encoded in the VigiFlow system.

8. The clinical practice guidelines and references, such as other pertinent infographic materials, may be accessed through ***http://bit.ly/COVID-19CPGs***. Particularly, the Assessment of Risk of Adverse Reactions following mRNA COVID-19 vaccination among ages 12-17 years is also found in ***Annex D***.

I. Demand Generation and Communications

1. LVOCs shall utilize the LGU Demand Generation playbook (link) updated for pediatric COVID-19 vaccination to update their microplans. LVOCs shall provide bimonthly updates to CHDs on their implementation, including social listening data as prescribed in the playbook.

2. CHDs shall provide bimonthly updates to Task Group Demand Generation and Communications (TG DGC) on the progress of activities based on microplans.

3. CHDs shall ensure feedback mechanisms and social listening by:

    a. Reporting frequently asked questions, misinformation, and rumors weekly to the TG DGC,

    b. Disseminating surveys and ensuring achievement of minimum respondents,

    c. Promoting the use of the Katuwang na Impormasyon para sa Responsableng Aksyon (KIRA) chatbot.

4. LVOCs and RVOCs shall follow the crisis communications protocol in accordance with Department Memorandum 2021-0224, entitled "Interim Guidelines on Adverse Events Following Immunization (AEFI) Community Management and Crisis Communications Related to COVID-19 Vaccines."

J. Reporting

1. All Vaccination Sites shall categorize the pediatric population ages 12-17 years old with comorbidities as "Pediatric A3".

2. Vaccination Sites participating in the first phase of the vaccination rollout, shall directly submit the daily vaccination accomplishment to the Vaccination Operations Reporting System (VORS) on a daily basis, and shall submit the vaccination information details to the Vaccine Administration System (VAS) as a line list, through the VAS Uploader, 24 hours after the vaccination schedule.

3. All LGUs shall submit required data requirements to the Vaccine Administration System (VAS - Line List) and Vaccination Operations Reporting System (VORS) on a daily basis.

4. The following data information shall be included as additional data field requirements of the VAS line list:

    a. comorbidity/ies of the vaccine recipient as stipulated in the medical certificate, and
    b. name of parent/guardian.

For dissemination and strict compliance.

By Authority of the Secretary of Health:

MYRNA C. CABOTAJE, MD, MPH, CESO III
Undersecretary of Health
Field Implementation and Coordination Team
Chair, National Vaccination Operations Center

Annex A. *Medical Certification for COVID-19 Pediatric Vaccination (12-17 Years Old with Co-morbidities)*

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

MEDICAL CERTIFICATION FOR COVID-19 PEDIATRIC VACCINATION
(12-17 YEARS OLD WITH COMORBIDITIES)

Date: _____

TO WHOM IT MAY CONCERN:

This is to certify that _____, _____
(Name of Patient) *(Age)*

years old, from _____
(Address)

is a diagnosed case of:

_____
_____
_____
_____

- ☐ I have thoroughly explained the risks and benefits of COVID-19 vaccination.
- ☐ Based on evaluation done on the date of certification, the patient can receive COVID-19 vaccine.
- ☐ Parent / Legal Guardian is aware that the vaccine recipient will still be subjected to health screening at the vaccination site, and that if symptoms arise, reevaluation is necessary prior to vaccination.

This Medical Certificate is being issued for the COVID-19 Vaccine Deployment and Vaccination Program of the Philippines.

_____, **MD**
(Name and Signature)

_____
(PRC No.)

Annex B. *Pediatric Vaccination Informed Consent Form And Assent Form For The Pfizer-Biontech Covid-19 Vaccine*

COVID-19 PEDIATRIC VACCINATION
INFORMED CONSENT FORM AND ASSENT FORM
FOR THE PFIZER-BIONTECH COVID-19 VACCINE
of the Philippine National COVID-19 Vaccine Deployment and Vaccination Program

Name of Minor:	**Birthdate:**	**Sex:**
Address:		
Name of Parent/Guardian:	**Relationship:**	
Contact Number:		
Vaccination Site:		

Section 1: Information on the risks and benefits of the Pfizer- BioNTech COVID-19 Vaccine

The Pfizer-BioNTech COVID-19 Vaccine may prevent the person vaccinated from getting severe COVID-19 infection and hospitalization. The FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 12 years of age and older under an Emergency Use Authorization (EUA). The Pfizer-BioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle of the upper arm.

Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include injection site pain, injection site redness and injection site swelling, tiredness, headache, muscle pain, chills, joint pain, fever, nausea, vomiting, diarrhea, feeling unwell, and swollen lymph nodes. Some of these side effects were slightly more frequent in adolescents 12 to 15 years old. There is a remote chance that the Pfizer-BioNTech COVID-19 Vaccine could cause temporary one-sided facial drooping and/or severe allergic reaction. Signs of a severe allergic reaction can include difficulty breathing, swelling of the face and throat, a fast heartbeat, and/or a bad rash all over the body. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Pfizer-BioNTech COVID-19 Vaccine. For this reason, a vaccination provider may ask the person receiving the vaccine to stay at the place where they received their vaccine for monitoring after vaccination.

The United States Center for Disease Control and Prevention (US CDC) and its partners are actively monitoring reports of myocarditis and pericarditis after COVID-19 vaccination.

Myocarditis is the inflammation of the heart muscle, and pericarditis is the inflammation of the outer lining of the heart. In both cases, the body's immune system causes inflammation in response to an infection or some other triggers. Both myocarditis and pericarditis have the following symptoms: chest pain, shortness of breath, feelings of having a fast-beating, fluttering, or pounding heart. Cases of myocarditis reported to the US Vaccine Adverse Event Reporting System (VAERS) have occurred after mRNA COVID-19 vaccination, especially in male adolescents and young adults, more often after the second dose usually within several days after vaccination. Most patients with myocarditis or pericarditis who received care responded well to medicine and rest and felt better quickly.

Despite the side effects, recent studies show that the COVID-19 vaccination with Pfizer-BioNTech benefits far outweigh the risks.

Section 2: Parent's/Guardian's Consent for Minor's Vaccination

I confirm that I have been provided with and have read the Pfizer-BioNTech COVID-19 vaccine and Emergency Use Authorization (EUA) Information Sheet and the same has been explained to me. The Philippine FDA has authorized the use of the Pfizer-BioNTech COVID-19 vaccine under an EUA since the gathering of scientific evidence for the approval of the said vaccine and any other COVID-19 vaccine is still ongoing.

I confirm that the minor has been screened for conditions that may merit deferment or special precautions during vaccination as indicated in the Health Screening Questionnaire.

I have received sufficient information on the benefits and risks of COVID-19 vaccines and I understand the possible risks if the minor is not vaccinated.

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 the Pfizer BioNTech COVID-19 vaccine.

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

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

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

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

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

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

Signature over Printed Name of the Parent/Guardian

Date

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

Section 3: Minor's Assent for Vaccination

I ACKNOWLEDGE THAT:

I am being asked to decide if I _____ (Minor's Name) / _____ (Age) want to be vaccinated with Pfizer-BioNTech COVID-19 vaccine.

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

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

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

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

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

(In case the minor is not capable of giving assent due to neurological comorbidities and moderate to severe intellectual impairment, the parent or the authorized parental substitute can sign on his/her behalf.)

Signature over Printed Name of the Minor (12-17 years with comorbidities)

Date

References:
1.Pfizer-BioNTech COVID-19 Vaccine Consent Form for Individuals 12-17 Years of Age. Retrieved from: https://www.mass.gov/doc/ma-consent-form-for-individuals-under-18-years-of-age-english-512202/download
2. US CDC. September 8, 2021. Myocarditis and Pericarditis After mRNA COVID-19 Vaccination. Retrieved from: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html

COVID-19 PEDIATRIC VACCINATION
HEALTH DECLARATION SCREENING FORM FOR PFIZER

of the Philippine National COVID-19 Vaccine Deployment and Vaccination Program as of October 11, 2021

ASSESS THE PATIENT	NO	YES
Below 12 years old?	☐	☐
Had a severe allergic reaction to any ingredient of the PFIZER vaccine: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6, 1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N, N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose?	☐	☐
Has severe allergic reaction or an autoimmune reaction (i.e. Vaccine-induced Thrombotic Thrombocytopenia) after the 1st dose of the PFIZER vaccine?	☐	☐
With SBP ≥160 mmHg and/or DBP≥ 100 mmHg?	☐	☐
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?	☐	☐
Had a history of myocarditis or pericarditis OR developed myocarditis/ pericarditis after a dose of mRNA vaccine?	☐	☐
Manifests any one of the following symptoms? ☐ Fever/chills ☐ Fatigue ☐ Headache ☐ Weakness ☐ Cough ☐ Loss of smell/taste ☐ Colds ☐ Diarrhea ☐ Sore throat ☐ Shortness of breath/difficulty in breathing ☐ Myalgia ☐ Nausea/ Vomiting ☐ Rashes ☐ 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 previously received one or two dose of a COVID-19 vaccine?	☐	☐
Has received convalescent plasma or monoclonal antibodies for COVID-19 in the past 90 days?	☐	☐
Pregnant?	☐	☐
If pregnant, are you in the 1st trimester?	☐	☐
Has any of the following diseases or health condition? ☐ HIV ☐ Cancer/ Malignancy (currently undergoing chemotherapy, radiotherapy, immunotherapy, or other treatment) ☐ Underwent Transplant ☐ Under Steroid Medication / Treatment ☐ Bed ridden, terminal illness, less than 6 months prognosis ☐ Autoimmune disease	☐	☐

VACCINATE

If any of the non-gray responses is checked, defer vaccination

Recipient's Name: **Sex:**

Parent's/ Legal Guardian's Name:

Birthdate:

Signature of Health Worker:

COVID-19 PEDIATRIC VACCINATION
INFORMED CONSENT FORM AT ASSENT FORM
PARA SA PFIZER-BIONTECH COVID-19 VACCINE
ng Philippine National COVID-19 Vaccine Deployment and Vaccination Program; October 11, 2021

Pangalan ng babakunahan:	**Birthdate:**	**Sex:**
Address:		
Pangalan ng magulang/guardian:	**Relasyon sa babakunahan:**	
Contact Number:		
Vaccination Site:		

Section 1: Impormasyon sa mga benepisyo at posibleng peligro ng Pfizer-BioNTech COVID-19 Vaccine

Pinahintulutan ng Philippine Food and Drug Administration ang Emergency Use Authorization ng Pfizer-BioNTech COVID-19 Vaccine sa mga edad 12 taong gulang pataas at ibibigay ng dalawang dosis na may pagitan ng tatlong linggo. Bagaman maaari pa ring mahawa sa COVID-19 ang nabakunahan, nagbibigay proteksyon ang bakuna sa pagkaospital at pagkamatay mula sa malubhang klase ng COVID-19.

Ilan sa mga naiulat na side effects ay pananakit, pamumula o pamamaga sa parteng tinurukan; pagkapagod, sakit ng ulo, pananakit ng kalamnan, panginginig, pananakit ng kasukasuan, lagnat, pagkahilo, pagkabalisa, at pamamaga ng kutani. May maliit na pagkakataong magkaroon ng malubhang allergic reaction. Ito ay karaniwang nangyayari ilang minuto hanggang isang oras matapos magpabakuna. Dahil dito, susubaybayan ang nabakunahan sa vaccination site bago pauwiin para obserbahan ang posibleng pagkakaroon ng anumang tanda ng malubhang allergic reaction tulad ng hirap sa paghinga, pamamaga ng mukha at lalamunan, mabilis na pulso, at/o pamumula sa buong katawan. Kasama sa iba pang bihirang side effect ang pansamantalang pagtaibingi ng isang bahagi ng mukha. Gayunpaman, ang mga sintomas na ito ay iimbestigahan kung may relasyon sa mismong bakuna o wala. Ang imbestigasyon ng mga angkop ng dalubhasa/eksperto ay kailangan para matukoy kung ang mga sintomas na ito ay dahil sa bakuna o nagkataon lang.

Sinisubaybayan din ng United States Centers for Disease Control and Prevention (USCDC) ang mga ulat tungkol sa myocarditis, o pamamaga ng muscle ng puso, at pericarditis, o pamamaga ng talukap ng puso, matapos magbakuna upang matukoy kung ito ay may relasyon sa bakuna sa COVID-19.
Ang pamamaga ng muscle o talukap ng puso, ay karaniwang bunga ng impeksyon. Ilan sa sintomas nito ay paninikip ng dibdib, hirap sa paghinga, mabilis na pagtibok o pagkabog ng puso. Naiulat ang mga kasong ito karaniwan 1) sa mga binatilyo at kalalakihan matapos ang pagbakuna gamit ang mga mRNA vaccine (tulad ng Pfizer at Modema), 2) matapos ang ikalawang dosis sa loob ng ilang araw. Karamihan sa naiulat na nagkaroon ng myocarditis o pericarditis at nabigyan ng lunas ay gumaling din agad.

Gayunpaman, malinaw ang mga pag-aaral at ebidensiya na ang proteksyong dala ng Pfizer-BioNTech laban sa pagkaospital at kamatayan mula sa malubhang COVID-19 ay mas matimbang sa mga posibleng peligro, at bihirang side effects nito.

Section 2: Pahintulot ng magulang / guardian sa pagbakuna ng menor de edad

Kinukumpirma ko na nabigyan at nabasa ko ang Emergency Use Authorization Information Sheet para sa Pfizer BioNTech COVID-19 vaccine, at lubos na naipaliwanag ang nilalaman nito sa akin. Sa ilalim ng EUA, patuloy ang pagkalap ng datos at ebidensiya para sa pag-apruba nito pati na rin ng iba pang bakuna sa COVID-19.

Kinukumpirma ko na ang babakunahan ay sumailalim sa health screening sa mga kundisyon na 1) maaaring maging dahilan para ipagpaliban ang pagbakuna o 2) mangailangan ng karagdagang pag-iingat sa pagbakuna alinsunod sa *Health Screening Questionnaire*.

Nakatanggap ako ng sapat na impormasyon sa benepisyo at posibleng peligro ng nasabing bakuna. Nauunawaan ko rin ang posibleng peligro ng hindi pagbakuna laban sa COVID-19.

Nabigyan ako ng pagkakataong magtanong, at lahat ito ay nasagot nang husto at malinaw. 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 ng resulta ng paggamit at pagbigay ng bakuna, o kawalang-bisa ng Pfizer BioNTech COVID-19 vaccine.

Naiintindihan ko na bagaman karamihan sa *side effets* ay banayad at gagaling nang kusa, may maliit na posibilidad na magkaroon ng malubhang *adverse reaction*, tulad ng, ngunit hindi nalilimita sa, alerhiya. Kung kakailanganin ko ng agarang atensyong medikal, dadalhin ako sa pinakamalapit na ospital ng Pamahalaan. Binigyan ako ng impormasyon kung saan maaring sumangguni para sa anumang sintomas na mararamdaman matapos magpabakuna.

Naiintindihan ko na sa paglagda ko dito, may karapatan ang nabakunahang menor de edad sa *health benefit packages* ng Philippine Health Insurance Corporation (PhilHealth) kung sakaling siya ay makaranas ng malubhang *adverse event*, na naimbestigahan at napatunayang may kaugnayan sa Pfizer BioNTech COVID-19 vaccine o pagbigay nito. Naiintindihan ko na ang karapatang humingi ng danyos perwisyo ay nababatay sa *guidelines* ng PhilHealth.

Pinahihintulutan ko ang pamahalaan na gamitin ang *mga impormasyong kailangan para sa public health* kabilang ang pag-ulat sa na-aangkop na *national vaccine registry*, alinsunod sa mga protokol ng *Data Privacy Act of 2012*. Naintindihan ko rin na kasama sa pahintulot na gamitin ang impormasyong ito ay ang patuloy na pagtaguyod ng mga karapatan ng *Data Subject* alinsunod sa *Data Privacy Act of 2012*.

Nabasa at naintindihan ko ang impormasyon tungkol sa benepisyo at posibleng peligro ng Pfizer-BioNTech COVID-19 vaccine. Sa pagpirma nito at pagbigay ng pahintulot, patunay *ito* na:

- Ako ay may *legal authority to consent* para ang menor-de-edad na pinangalanan sa itaas ay mabakunahan ng Pfizer-BioNTech COVID-19 vaccine.

Patunay ito na pinahihintulutan kong mabakunahan ang aking anak/menor-de-edad gamit ang Pfizer BioNTech COVID-19 Vaccine:

_____

Lagdsa sa itaas ng Printed Name ng magulang o Legal Guardian / Kinatawan ng Pamahalaan

_____

Petsa

Kung tumangging magpabakuna, itala ang mga dahilan:

_____

_____

_____

Section 3: Assent Form para sa babakunahang menor de edad

PATUNAY ITO NA:

Hinihingi ang desisyon ko (Name) _____ /(Edad)_____ kung gusto kong mabakunahan ng bakuna para sa COVID-19.

Nabigyan ako at naintindihan ko ang impormasyon tungkol sa bakuna para sa COVID-19 na ibibigay sa nakapangalang babakunahan sa itaas.

Nabigyan ako ng pagkakataong magtanong at nasagot ito nang husto at malinaw. Nauunawaan kong maari akong magtanong tungkol sa pagbakuna sa COVID-19 kahit kailan.

Naiintindihan ko ang posibleng peligro ng pagturok

ng bakuna. Bagaman ang karamihan sa *side effects* ay banayad at gagaling nang kusa, may maliit na pagkakataong magkaroon ng malubhang *adverse events* tulad ng alerhiya at iba pa. Kahit bihira ang mga malubhang *adverse events* sa mga naitalang ulat at pag-aaral, handa ang mga vaccination team para magbigay lunas para dito. Nauunawaan ko na malinaw sa mga pag-aaral at ebidensiya na ang proteksiyong ibibigay ng bakuna mula sa pagkaospital at pagkamatay mula sa malubhang COVID-19 ay mas matimbang sa posibleng peligro nito.

Nauunawaan kong maaaring tumigil sa alinmang proseso ng pagbakuna nang walang pagsasaway o pagbabatikos, at pagbabago sa karampatang medikal na atensyon.

Gusto kong makatanggap ng bakuna sa COVID-19 ngayon.

(Kung sakaling walang kakayahan ang bata/ menor-de-edad na makapagdesisyon dahil sa sakit tulad ng *neurological comorbodities, intellectual impairment*, ang magulang o guardian ay maaring pumirma sa ngalan niya)

Pangalan at lagda ng bata/menor-de-edad (12-17 taong gulang may sakit)

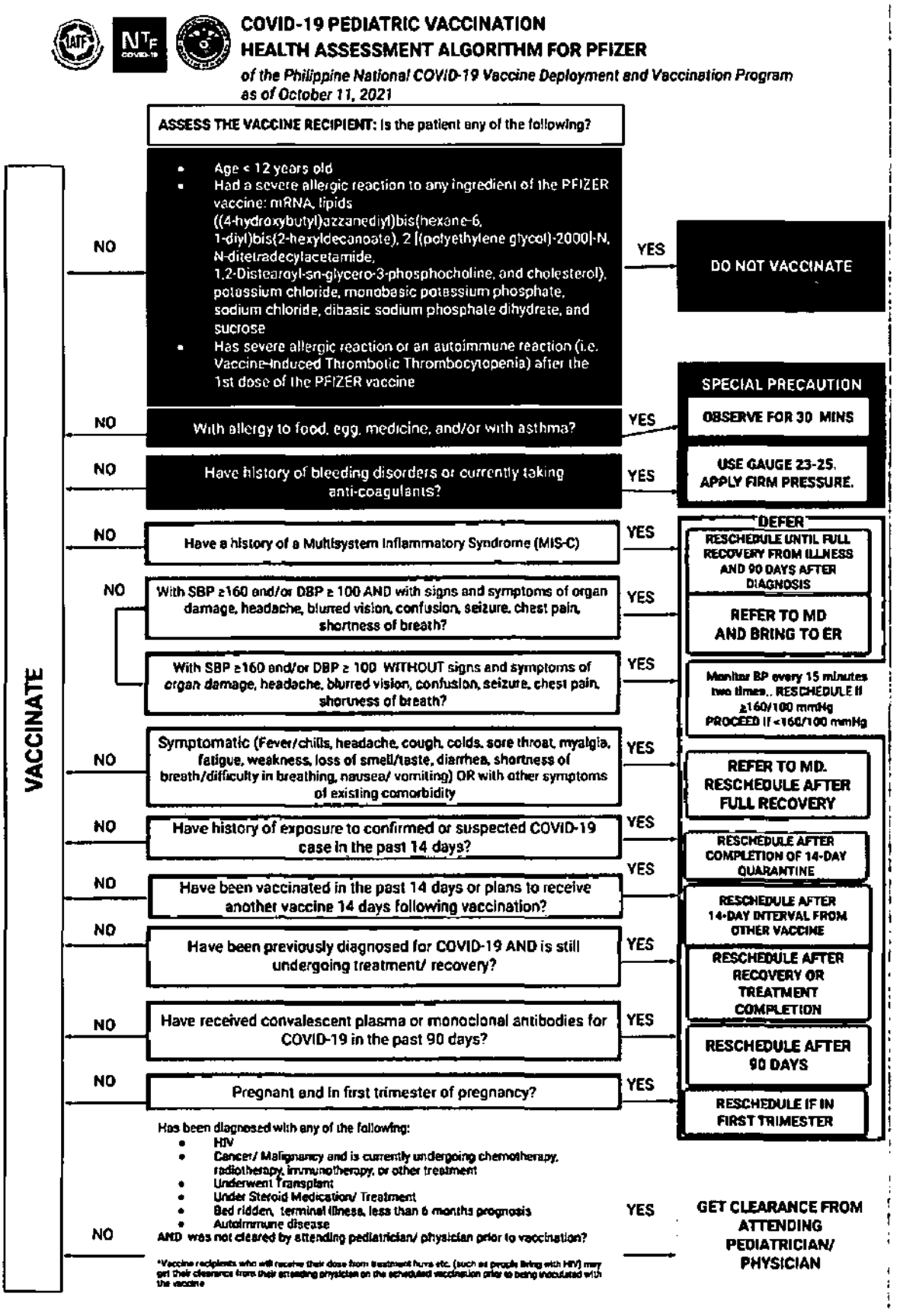
Petsa

Reference:

1.Pfizer-BioNTech COVID-19 Vaccine Consent Form for Individuals 12-17 Years of Age. Retrieved from: https://www.mass.gov/doc/ma-consent-form-for-individuals-under-18-years-of-age-english-5122021/download

2. US CDC. September 8, 2021. Myocarditis and Pericarditis After mRNA COVID-19 Vaccination. Retrieved from: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis

Annex C: *Health Assessment Algorithm and Health Declaration Screening Forms for Pediatric Vaccination*



COVID-19 PEDIATRIC VACCINATION
HEALTH DECLARATION SCREENING FORM FOR PFIZER

of the Philippine National COVID-19 Vaccine Deployment and Vaccination Program as of October 11, 2021

ASSESS THE PATIENT	NO	YES
Below 12 years old?	☐	☐
Had a severe allergic reaction to any ingredient of the PFIZER vaccine: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6, 1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N, N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose?	☐	☐
Has severe allergic reaction or an autoimmune reaction (i.e. Vaccine-Induced Thrombotic Thrombocytopenia) after the 1st dose of the PFIZER vaccine?	☐	☐
With SBP ≥160 mmHg and/or DBP≥ 100 mmHg?	☐	☐
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?	☐	☐
Had a history of myocarditis or pericarditis OR developed myocarditis/ pericarditis after a dose of mRNA vaccine?	☐	☐
Manifests any one of the following symptoms? ☐ Fever/chills ☐ Fatigue ☐ Headache ☐ Weakness ☐ Cough ☐ Loss of smell/taste ☐ Colds ☐ Diarrhea ☐ Sore throat ☐ Shortness of breath/difficulty in breathing ☐ Myalgia ☐ Nausea/ Vomiting ☐ Rashes ☐ 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 previously received one or two dose of a COVID-19 vaccine?	☐	☐
Has received convalescent plasma or monoclonal antibodies for COVID-19 in the past 90 days?	☐	☐
Pregnant?	☐	☐
If pregnant, are you in the 1st trimester?	☐	☐
Has any of the following diseases or health condition? ☐ HIV ☐ Cancer/ Malignancy (currently undergoing chemotherapy, radiotherapy, immunotherapy, or other treatment) ☐ Underwent Transplant ☐ Under Steroid Medication / Treatment ☐ Bed ridden, terminal illness, less than 6 months prognosis ☐ Autoimmune disease	☐	☐

Recipient's Name: **Sex:**

Parent's/ Legal Guardian's Name:

Birthdate:

Signature of Health Worker:

VACCINATE

If any of the non-gray responses is checked, defer vaccination

Relevant Issuances regarding Adverse Events Following Immunization in relation to the COVID-19 Vaccination Program

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. **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
5. **NVOC Advisory No. 59**: Reiteration on the Implementation of Post-vaccination Education and Reporting of Adverse Events Following Immunization (AEFI)
6. 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"
7. Section I of **DC 2021-0101**: "Clarification on Provisions of Department Memorandum 2021-0099 entitled the "Interim Omnibus Guidelines for the Implementation of the National Vaccine Deployment Plan for COVID-19"
8. 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"
9. **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
10. **NVOC Advisory No. 67**: Additional Adverse Events Following Immunization (AEFI) Repor ting System for Vaccination Sites, including Private Sector - Managed Vaccination Sites

All issuances and associated references are available at bit.ly/aefic19ph

Summary of Referenced AEFI Annexes for the Vaccination of the Pediatric Population

Annex D. *Position Statement of the Philippine Society of Allergy, Asthma, and Immunology (PSAAI)*

Narrates the PSAAI's statements on the risk assessment for allergic reaction before 1st and 2nd dose, management of adverse reactions to COVID-19 vaccines, and combining different vaccine platforms based on the mic and match or heterologous vaccines study among others.

Annex E. *Diagnosis and Management of Severe Allergic Reactions*

Provides a standard algorithm for the diagnosis and management of Severe Allergic Reactions after COVID-19 Vaccination as provided by the Philippine Society of Allergy, Asthma, and Immunology (PSAAI).

Annex F. *Details and quantities of items needed for of AEFI/AESI Kits*

Enumerates the expected inclusion of an AEFI Kit for the pediatric population per vaccination team mandatory for all vaccination sites to be used for management of AEFIs detected on site.

Annex G. *Guideline on Diagnosing and Treating Myocarditis*

Standard clinical guidelines for the diagnosis of myocarditis provided by the Brighton Collaboration and a standard treatment guideline for proper detection and management of myocarditis.

Annex H. *Reactogenic Reactions versus COVID-19 symptoms*

A guide on distinguishing the difference between reactogenic reactions from COVID-19 vaccines from COVID-19 symptoms and some recommendations on the steps to take after determining which the individual is experiencing.

Annex I. *Steps in the AEFI Surveillance Cycle*

Provides the complete picture of the AEFI surveillance cycle along with the accountable stakeholders per step. This shall be used to reiterate and educate all sites, facilities, and hospitals that are part of the vaccination program.

Annex J. *Revised AEFI COVID-19 Vaccine Case Investigation Form Version 2 and its guidelines* ***(bit.ly/AEFICIFVer2Fillable)***

Provides the latest revision of the AEFI COVID-19 CIF which allows users of the form to incorporate useful information for a quality investigation and causality assessment.

Annex D. *Position Statement of the Philippine Society of Allergy, Asthma, and Immunology (PSAAI)*

ASSESSMENT OF RISK FOR ADVERSE REACTION TO THE FIRST DOSE OF mRNA VACCINES

IN AGES 12-17 YEARS OLD

Philippine Society of Allergy, Asthma, and Immunology
October 11, 2021

LOW RISK

PROCEED WITH VACCINATION
Observe for at least 30 minutes

1. NON-ANAPHYLACTIC allergy to **oral medications**[1] (including the oral equivalent of an injectable medication)
2. NON-ANAPHYLACTIC allergy to **food, pet, insect venom, environmental, latex**, etc.[1,2]
3. DELAYED LOCAL reactions (eg, contact dermatitis) to **OTHER vaccines**[3]
4. **REACTOGENIC** reactions, LOCAL (eg, pain, redness, swelling on injection site) or SYSTEMIC (eg, fever, chills, headache, malaise) to **OTHER vaccines**
5. Well-controlled atopic dermatitis, allergic rhinitis, asthma, chronic urticaria, whether on maintenance medications or not
6. Primary or secondary immunodeficiency (after evaluation of clinical status and discussion of benefit and risks with attending physician)
7. Autoimmune disease and Cancer – (after discussing benefits and risks with attending physician)
8. Family history of allergies[1]

MODERATE RISK

PRECAUTION TO VACCINATION
Refer to a qualified specialist; Observe for at least 30 minutes in a setting fully equipped to manage severe adverse reactions

1. ANAPHYLAXIS to **oral medications, food, latex, environmental, or insect venom**[2] **or unclear allergen/etiology**[3]
2. Uncontrolled asthma (discuss with a qualified specialist adequate attack-free period*)
3. Mast cell disorder (discuss with a qualified specialist for evaluation)[4]
4. IMMEDIATE (within 6 hours) **ALLERGIC** reaction of **any severity** [urticaria, angioedema, respiratory distress (eg, wheezing, stridor), or ANAPHYLAXIS] to **OTHER vaccines** or injectable therapies
5. **History of myocarditis, pericarditis and other cardiac conditions**

HIGH RISK

CONTRAINDICATION TO VACCINATION

- IMMEDIATE (within 6 hours) **ALLERGIC** reaction of **any severity** [urticaria, angioedema, respiratory distress (eg, wheezing, stridor), or ANAPHYLAXIS] to **a component of the mRNA vaccine**[1] (eg, PEG)

* *Global Initiative For Asthma (GINA) Guidelines at https://ginasthma.org/gina-reports/*
[1] *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-B*
[2] *https://education.aaaai.org/resources-for-a-i-clinicians/reactionguidance_COVID-19*
[3] *Worm M, et al. Practical recommendations for the allergological risk assessment of the COVID-19 vaccination - a harmonized statement of allergy centers in Germany. Allergol Select. 2021 Jan 26;5:72-76.*
[4] *Rama TA, et al. mRNA COVID-19 vaccine is well tolerated in patients with cutaneous and systemic mastocytosis with mast cell activation symptoms and anaphylaxis. J Allergy Clin Immunol. 2021 Mar;147(3):877-878.*

Position Statements of the Philippine Society of Allergy, Asthma, and Immunology on COVID-19 Vaccines and their Adverse Reactions

www.psaai.org

ASSESSMENT OF RISK FOR ADVERSE REACTION TO THE SECOND DOSE OF mRNA VACCINES

IN AGES 12-17 YEARS OLD

Philippine Society of Allergy, Asthma, and Immunology

October 11, 2021

SYMPTOMS / SIGNS AFTER FIRST DOSE	RECOMMENDATION FOR SECOND DOSE
1. **No cutaneous or systemic symptoms** after the first dose	Proceed with second dose at recommended interval
2. **LOCAL** reaction (eg, erythema, induration, pruritus, painful rash[a]) around the injection site a few hours through the second week after the first dose[b,c]	Proceed with second dose at recommended interval Inject on opposite arm
3. **REACTOGENIC reactions**[d] (vaccine side effects) a few hours up to 3 days after the first dose (eg, fever, chills, fatigue; pain, erythema, or swelling at injection site; lymphadenopathy in same arm as vaccination; headache, myalgia, arthralgia, vomiting, diarrhea)	Proceed with second dose at recommended interval
4. **VASOVAGAL reactions**[d] occurring within 15 minutes after the first dose [eg, feeling warm or cold; pallor, diaphoresis, clammy skin, sensation of facial warmth; dizziness, lightheadedness, syncope (often after prodromal symptoms for a few seconds or minutes), transient hypotension with bradycardia, weakness, changes in vision (such as spots of flickering lights, tunnel vision), changes in hearing]	Proceed with second dose at recommended interval

SYMPTOMS / SIGNS AFTER FIRST DOSE	RECOMMENDATION FOR SECOND DOSE
5. Other **DELAYED** adverse reactions after the first dose (eg, delayed cutaneous reactions, thrombosis, purpura, thrombocytopenia, etc)	Refer to qualified specialist prior to the second dose
6. **IMMEDIATE MILD symptoms within the first 6 hours** after the first dose that are non-life threatening (eg, non-generalized rash, flushing without urticaria, subjective symptoms such as tingling or itching without urticaria, non-specific symptoms)	Review the history of atopy and other risk factors and refer to a qualified specialist before the second dose
7. **IMMEDIATE MODERATE NON-ANAPHYLACTIC symptoms within the first 6 hours** after the first dose (urticaria, angioedema other than laryngeal, throat clearing and itch, nasal symptoms)	Review the history of atopy and other risk factors and refer to a qualified specialist before the second dose
8. **IMMEDIATE SEVERE allergic symptoms within the first 6 hours** after the first dose such as **ANAPHYLAXIS**[e] or **OTHER SERIOUS adverse reactions as MYOCARDITIS**[c]	**Should NOT proceed with second dose** **Refer to qualified specialist**

[a] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html
[b] https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications
[c] Blumenthal KG, et al. Delayed Large Local Reactions to mRNA-1273 Vaccine against SARS-CoV-2. N Engl J Med. 2021 Mar 3.
[d] https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-D
[e] https://www.google.com/url?sa=t&source=web&rct=j&url=https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/05-COVID-Wallace-508.pdf&ved=2ahUKEwjz0vfuiaDzAhVRPHAKHWsmAlgQFnoECAcQAQ&usg=AOvVaw0bOfsNqtUIZ2YRSEKCnWE_

POSITION STATEMENTS OF THE PHILIPPINE SOCIETY OF ALLERGY, ASTHMA, AND IMMUNOLOGY ON COVID-19 VACCINES AND THEIR ADVERSE REACTIONS

August 5, 2021

These statements were developed by the COVID-19 Vaccine Adverse Reaction Task Force of the Philippine Society of Allergy, Asthma, and Immunology (PSAAI).

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WHAT'S NEW IN THIS EDITION (Updates to the March 26, 2021 Document):

1. Tables 1 and 2 include new local data from the Philippine Food and Drug Authority on adverse reactions, as well as global data on recent serious adverse reactions associated to the vaccines (page 6 and 9)
2. Clarifications on Type I allergic reactions and anaphylaxis (page 9)
3. Thrombosis with thrombocytopenia syndrome (page 7)
4. Statement 2 and tables on the risk assessment for allergic reaction before the 1st and 2nd doses (page 12)
5. Statement 3 on contraindications to COVID-19 vaccines (page 12)
6. Statement 4 on the management of adverse reactions to COVID-19 vaccines (page 15)
7. Statement on combining different vaccine platforms based on the mix and match or heterologous vaccines study (ComCov study) (page 16)

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VIRAL VECTOR VACCINES

In viral vector vaccines, the gene for COVID-19 spike protein is inserted in a different virus (the vector). A commonly used vector is the adenovirus, which is stripped off its essential genetic materials for replication, rendering it harmless. Once this vaccine is injected, the viral vector delivers the genetic code to the host cell and uses the cell's machinery to produce and express the spike protein, which triggers an immune response.

There are two types of viral vectors:

1. Non-replicating vector vaccines - the virus does not infect the cells nor make new viral particles, so only the spike protein is produced. All current COVID-19 vaccines undergoing phase 2/3 clinical trials are non-replicating viral vector vaccines.
2. Replicating vector vaccines - the virus produces new viral particles in the cells it infects, which can then infect new host cells that will also produce the vaccine antigen.

Advantage:

- The immune response triggered by the antigen involves both T cells and B cells.

Disadvantage:

- Viral vector vaccines are relatively complex to manufacture
- People who have been previously exposed to the human virus used as vector may have weaker immune response to the vaccine due to previous immunity to the vector

COVID-19 viral vector vaccines undergoing Phase IIb/III trials:

- Oxford-AstraZeneca (ChAdOx1 nCoV-19) - chimpanzee AdV
- CanSino Biologics (Ad5-nCoV)
- Gamaleya Research Institute (Gam-COVID-Vac) - Ad5/Ad26
- Janssen (Ad26.COV2-S) - AdV26

mRNA VACCINES

The mRNA vaccines are novel forms of nucleic acid vaccines. These vaccines contain the mRNA encoding the SARS CoV-2 spike proteins and use a lipid-based nanoparticle carrier system to allow penetration into the host cells. Once injected, the mRNA uses the human cell's own machinery to produce the spike proteins to stimulate an immune response. The mRNA is then degraded by the cell's own enzymes, and therefore no viral genetic material is being integrated into the host DNA.

Advantages

- Immune response involves B cells and T cells
- No live components, so no risk of the vaccine triggering disease
- Relatively easy to manufacture
- Modifiable immunogenicity, stable efficacy, absence of anti-vector immunity

Disadvantages:

- Never been licensed for use in humans
- The high immunogenicity of mRNA vaccines may also be responsible for increased reactogenicity leading to more reports of local and systemic vaccine reactions.
- Some RNA vaccines require ultra-cold storage

COVID-19 mRNA vaccines undergoing Phase IIb/III trials:

- Pfizer/BioNTech (BNT162b2/Tozinameran/Comirnaty)
- Moderna COVID-19 vaccine (mRNA-1273)

PROTEIN SUBUNIT VACCINES

COVID-19 protein subunit vaccines contain specific fragments of the spike protein of SARS-CoV-2, produced and harvested from non-human host cells. These vaccines are usually administered with an adjuvant (e.g., polysorbate, AS03 and Matrix-M). Once injected, the spike protein subunit triggers an immune response. No active viral infection occurs.

Advantages:

- Immune response involves B cells and T cells
- Well-established technology
- Suitable for people with compromised immune systems
- No live components, so no risk of the vaccine triggering the disease
- Relatively stable

Disadvantages:

- Relatively complex to manufacture
- Adjuvants and booster shots may be required
- Determining the best antigen combination takes time

COVID-19 Protein subunit vaccines undergoing Phase I to III trials:

- Sanofi Pasteur (Phase I/II)
- Novavax (Phase III)
- Clover-GSK (Phase I/II), Clover-Dynavax (Phase III)

WHOLE VIRUS

Conventionally, whole-virus vaccines can be classified as either live attenuated vaccines or inactivated vaccines. Live attenuated vaccines contain viruses with weakened virulence, while inactivated vaccines contain viruses whose genetic material has been destroyed to prevent replication. However, inactivated vaccines can still elicit an immune response. The Sinovac vaccine, Coronavac, is an inactivated whole virion vaccine, mixed with an adjuvant, an aluminum-based compound which further stimulates the immune system. Aluminum hydroxide is a known adjuvant found in many vaccines, drugs and some cosmetics.

Advantages:

- Well-established technology
- Strong immune response
- Immune response involves B cells and T cells
- Relatively simple to manufacture

Disadvantages:

- Unsuitable for people with compromised immune systems (live attenuated)
- Live attenuated vaccines may trigger disease in very rare cases
- Relatively temperature sensitive, so careful storage necessary

COVID-19 Inactivated vaccines undergoing Phase IIb/III trials:

- Sinovac (Coronavac)
- Sinopharm

Table 1. COVID-19 Vaccine Brands Granted EUA in the Philippines

Vaccine Brand	Vaccine Type	Excipients	Adverse Reaction
CoronaVac (Sinovac)	Inactivated virus	Aluminum hydroxide, disodium hydrogen phosphate, sodium dihydrogen phosphate, sodium chloride, sodium hydroxide and water Note: vial stopper is made of brominated butyl rubber	Injection site pain, pruritus, erythema, swelling and induration, chills, fever, fatigue, myalgia, diarrhea, nausea, headache, vomiting, lower abdominal pain, dizziness, cough, loss of appetite, increased blood pressure, hypersensitivity No anaphylaxis reported during phase 3 trials Locally, there have been 665 reported severe allergic reactions.[1,2] Top reported adverse reactions in the Philippines are blood pressure increase (41.29%), headache (13.37%), vaccination/injection site pain (11.59%), pyrexia (9.10%), dizziness (7.34%), rash (7.10%), malaise (5.04%), cough (4.83%), pruritus (4.53%), nasopharyngitis (3.41%).[1]
Bharat Biotech (Covaxin)	Whole virion inactivated	Aluminum hydroxide gel, TLR 7/8 agonist, 2-phenoxyethanol; phosphate buffered saline Note: vial stopper is made of butyl rubber	Injection site pain, headache, fever, body ache, abdominal pain, nausea, vomiting, no serious AE reported
ChAdOx1 nCoV-19- chimpanzee AdV (Oxford-AstraZeneca)	Viral vector	L-Histidine, L-Histidine hydrochloride monohydrate, Magnesium chloride hexahydrate, Polysorbate 80, Ethanol, Sucrose, Sodium chloride, Disodium edetate dihydrate Note: non-latex vial stopper	Injection site tenderness and pain, headache, fatigue, myalgia, malaise, pyrexia, chills, arthralgia and nausea Locally, there have been 573 reported severe allergic reactions.[1,2] Top reported adverse reactions in the Philippines are pyrexia (40.56%), headache (35.64%), vaccination/injection site pain (24.66%), malaise (23.37%), chills (17.38%), myalgia (17.27%), blood pressure increase(16.07%), fatigue (12.90%), arthralgia (8.44%), dizziness (6.39%).[1] Thrombosis with Thrombocytopenia Syndrome: UK data -four cases per million adults (1 case per 250 000) EU - 1 per 100 000

Vaccine Brand	Vaccine Type	Excipients	Adverse Reaction
Janssen	Viral vector	Citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-β-cyclodextrin (HBCD), polysorbate-80, sodium chloride Note: vial stopper not made with natural rubber latex	Injection site pain, redness of the skin and swelling headache, fatigue, myalgia, nausea, and fever Urticaria, angioedema, Locally, there have been 1 reported severe allergic reaction.[1,2] Top reported adverse reactions in the Philippines are blood pressure increase (50.00%), pyrexia (29.69%), headache (23.44%), myalgia (14.06%), arthralgia (12.50%), dizziness (10.94%), malaise(10.94%), chills (9.38%), vaccination/injection site pain (7.81%), pain (6.25%), chest pain (4.69%), vomiting (4.69%).[1] *1 case of anaphylaxis in an ongoing open-label study in South Africa (total participants = 4984)*
BNT162b2/ Tozinameran/ Comirnaty (Pfizer/ BioNTech)	mRNA	Lipids ((4-hydroxybutyl) azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N, N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, Cholesterol, Potassium chloride, Monobasic potassium phosphate, Sodium chloride, Dibasic sodium phosphate dihydrate, and Sucrose Note: non-latex vial stopper	Injection site pain, tiredness, headache, muscle pain, chills, joint pain, fever, injection site swelling and redness, nausea, feeling unwell, swollen lymph nodes, rash, itching, hives, swelling of the face no anaphylaxis reported during clinical trials, but reported anaphylaxis 4.7:1,000,000 with routine use Locally, there have been 80 reported severe allergic reactions.[1,2] Top reported adverse reactions in the Philippines are blood pressure increase (39.33%), pyrexia (19.44%), headache (13.89%), vaccination/injection site pain (9.19%), dizziness (8.52%), cough (7.45%), rash (7.23%), malaise (7.17%), dyspnea (4.87%), chills (4.31%).[1] Delayed local hypersensitivity reactions; morbilliform rashes Filler reactions (for those w/ history of injection with dermal fillers) Palpable or mammogram-detected unilateral axillary adenopathy on the same side of the injected arm mimicking breast cancer Inc. axillary lymphadenopathy or ipsilateral deltoid uptake occasionally observed on PET scans performed after mRNA vaccine administration (10.4%) Immune thrombocytopenia incidence 0.85 per 1 million persons vaccinated with mRNA vaccines No safety signals observed for Thrombosis with Thrombocytopenia Syndrome (TTS) Myocarditis/pericarditis incidence of 12.6:1,000,000 for both mRNA vaccines combined within 3 weeks of a 2nd dose of vaccine for individuals aged 12-39. Symptoms of chest pain, shortness of breath, and/or palpitations mostly occurred in male adolescents & young adults and began within a week after receipt of the 2nd dose of vaccine. Most have had resolution of symptoms but information is not yet available on potential long-term sequelae.The decision to administer to an individual with history of myocarditis or pericarditis should take into account the individual's clinical circumstances.

Vaccine Brand	Vaccine Type	Excipients	Adverse Reaction
mRNA-1273 (Moderna)	mRNA	Lipids (SM-102, **Polyethylene glycol [PEG] 2000**, Dimyristoyl glycerol [DMG], Cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), Tromethamine, Tromethamine hydrochloride, Acetic acid, Sodium acetate, and Sucrose. Note: non-latex vial stopper	Injection site pain, tenderness, swelling, redness, swelling of the lymph nodes in the same arm of the injection, fatigue, headache, muscle pain, joint pain, chills, nausea, vomiting, fever, **anaphylaxis 2.8:1,000,000 with routine use** Locally, there have been 4 reported severe allergic reactions.[1,2] Top reported adverse reactions in the Philippines are vaccination /injection site pain (50.97%), pyrexia (18.53%), headache (17.37%), limb discomfort (10.81%), malaise (7.72%), myalgia (6.56%), chills (6.18%), fatigue (5.41%), pain (5.02%), blood pressure increase(4.63%).[1] Delayed local hypersensitivity reactions; local injection site reactions, urticarial eruptions, morbilliform rashes; most with first dose reactions did not have a second dose reaction. (See also Pfizer data above for comments on mRNA vaccines.)
Gam-COVID-Vac (Sputnik V)	Non-replicating, two-component vector (adenovirus) rAD type 26 and rAd type 5	Tris (hydroxymethyl) aminomethane, sodium chloride, sucrose, magnesium chloride hexahydrate, Sodium EDTA, **polysorbate 80**, ethanol, water for injection Note: Vial stoppers are made of pharmaceutical rubber (by Wests Pharmaceutical services)	Flu-like illness, injection site reactions, headache, asthenia, rash 14 allergic reactions out of the 122 rare adverse events No serious adverse event found as being associated w/ vaccination (Phase 3 trial) Locally, there have been 7 reported severe allergic reactions.[1,2] Top reported adverse reactions in the Philippines are blood pressure increase (69.30%), pyrexia (6.54%), heart rate increased (5.87%), headache (5.54%), rash (4.70%), dizziness (3.69%), vaccination/injection site pain (3.36%), dyspnea (2.85%), cough (2.52%), chills (2.01%).[1] Headache, myalgia, arthralgia, fever, local, gastrointestinal reactions. Mild-moderate allergic reactions (1.38% of 22,179 vaccine-related reactions) Anaphylaxis 5 cases of 22,179 vaccine-related reactions (total 1,181,292 doses given) (Argentina Ministerio de Salud, March 15, 2021)

[1] https://www.fda.gov.ph/wp-content/uploads/2021/07/Reports-of-Suspected-Adverse-Reaction-to-COVID-19-Vaccines-as-of-25-July-2021.pdf

[2] Adverse reactions experienced after vaccination are considered **serious** when it resulted to any of the following criteria: in-patient hospitalization/prolongation of existing hospitalization, significant disability/incapacity, life-threatening (e.g. anaphylaxis) and death, birth defect or congenital malformations, considered to be medically important event.

Shown below are cumulative reports from the start of the vaccination program on 01 March 2021 until 25 July 2021, according to the Philippine Food and Drug Administration.[1]

Table 2. Distribution of reports of adverse reactions for each vaccine[1]

Vaccine	Date started	Number of individuals partly vaccinated[b]	Number of fully vaccinated individuals[b]	Total number of reports[a]	Reports of non-serious events	Reports of serious events
CoronaVac	01 Mar 2021	6,731,423	4,207,601	20,788	20,123	665
AstraZeneca	07 Mar 2021	2,860,996	654,070	28,390	27,817	573
Sputnik V	04 May 2021	218,948	62,662	596	589	7
Comirnaty	13 May 2021	1,231,998	950,281	1,785	1,705	80
Moderna	30 June 2021	69,742	294	259	255	4
Janssen	20 July 2021	-	214,406	64	63	1
TOTAL		**11,113,107**	**6,089,314**	**51,882**	**50,552**	**1,330**

Data source: [a]VigiFlow, [b]NVOC daily report as 6PM, 25 July 2021

Notes: Additional information may become available in individual cases which may change the figures presented

[b]An individual is considered partly vaccinated if they have received only one dose of a two-dose vaccine course. An individual is considered fully vaccinated if they have received a single-dose vaccine or both doses of a two-dose vaccine

[c]Data concerning various vaccines are not directly comparable. COVID-19 vaccines profile varies, they have not been used for equal periods of time and they have been administered to number of people with different profiles including various age and sex.

[1]https://www.fda.gov.ph/wp-content/uploads/2021/07/Reports-of-Suspected-Adverse-Reaction-to-COVID-19-Vaccines-as-of-25-July-2021.pdf

POSITION STATEMENTS REGARDING COVID-19 VACCINE ADVERSE REACTIONS

REACTOGENIC AND ALLERGIC REACTIONS

STATEMENT 1.

Adverse reactions to vaccines may occur and can range from reactogenic reactions to allergic reactions. A REACTOGENIC REACTION is not the same as an ALLERGIC REACTION.

What is a reactogenic reaction?

A reactogenic reaction is an inflammatory response that occurs after vaccination.

When vaccine antigens enter the body, they are recognized as potential pathogens (via pathogen associated molecular patterns) by the pathogen recognition receptors that are found on peripheral immune cells. This results in the synthesis and release of pyrogenic cytokines (IL-6, TNF-a, & PGE2) in the tissues or bloodstream, mimicking the response to natural infection. When this happens, a series of events occur – phagocytosis, release of mediators, activation of complement and cellular recruitment. These same events lead to the development of local and systemic inflammatory reactions. The reactions may occur within the first three days of vaccination and resolve within 1-3 days of onset. These symptoms are

observed to be more frequent following the second dose of the vaccine and among younger persons compared to older persons.
Majority of these reactions from COVID-19 vaccines are local reactions which include pain, swelling and tenderness on the injection site. Leaking of these mediators and products of inflammation into the circulation can also result in systemic side effects. Most systemic post-vaccination reactions are mild to moderate in severity, which include headache, fatigue, malaise, muscle pain, chills, fever and vomiting.

What is Allergy?

An allergy or hypersensitivity reaction is an exaggerated immune response to a usually harmless substance.

The reactions are categorized into four principal groups, types I-IV.

A **Type I or immediate reaction** is usually an IgE-mediated reaction which can manifest as urticaria, flushing, vomiting, abdominal cramps, rhinitis and asthma usually within 6 hours after exposure to the allergen. Anaphylaxis (appendix A and B), which is a severe immediate type reaction, is highly likely if 2 or more organ systems are involved and can manifest as: urticaria, pruritus, flushing, angioedema, dyspnea, wheezing, vomiting, abdominal cramps, syncope, hypotension in most cases (hypertension may occur in 12.9% of these anaphylactic events) and tachycardia that usually occur within 6 hours. However, hypotension or respiratory compromise may be the only manifestation of anaphylaxis after exposure to a known allergen. Biphasic anaphylaxis may happen in 0.4-15% of anaphylactic episodes, wherein symptoms may abate and recur usually 6 hours to as late as 72 hours after the resolution of the initial symptoms. The pathophysiology, however, of COVID-19 vaccine-induced anaphylaxis can either be IgE-mediated, or non-IgE-mediated (complement-mediated or direct activation of Mas-related G protein-coupled receptor X2 or MRGPRX2), which can lead to mast cell degranulation and release of inflammatory mediators. The clinical presentation of Non-IgE mediated anaphylaxis is identical to the IgE-mediated type of reaction.

The diagnosis of anaphylaxis during the acute event is based on the clinical presentation and a history of a recent exposure to an offending agent. There are no laboratory tests available in an emergency department or clinic setting to confirm a diagnosis of anaphylaxis in real time. However, laboratory tests such as serum tryptase obtained during or shortly after the acute event can help to support the clinical diagnosis of anaphylaxis. Tryptase is a mast cell marker released during anaphylaxis.

In patients who present with symptoms that are not very characteristic, or those who do not completely fulfill the criteria for anaphylaxis after receiving the COVID-19 vaccine, elevated levels of total serum tryptase may be useful for distinguishing anaphylaxis from other conditions in the differential diagnosis, such as vasovagal reactions, myocardial shock, or benign flushing.

Tryptase is best taken between 30 to 90 minutes after the reaction and may remain elevated up to 6 hours. A second sample should be collected at least 24 hours after all signs and symptoms have resolved to serve as a baseline sample for comparison. A rise in total tryptase levels above baseline may be more sensitive than a single tryptase level. The minimal elevation of the acute total tryptase level that is considered to be clinically significant is suggested to be ≥(2 + 1.2 x baseline tryptase levels) in units of ng/mL or mcg/liter.

An elevated serum tryptase level supports the diagnosis, but a normal level cannot refute the diagnosis.

Specimen collection

In the Philippines, ImmunoCAP tryptase determination is available at the Fe Del Mundo Medical Center. Serum and plasma (EDTA or heparin) samples from venous blood can be used. Collect blood samples and prepare serum or plasma according to standard procedures. Keep specimens at 2 °C to 8 °C for up to one week, or else at –20 °C.

Anaphylaxis is rare in mRNA COVID-19 vaccines, with an estimated incidence of 2.8 per 1 million doses in Moderna vaccine and 4.7 per 1 million doses in Pfizer/BioNTech vaccine. Polyethylene glycol or PEG, an excipient in mRNA vaccines, is also found in medications and in some vaccines. It has been implicated as a rare cause of anaphylaxis and may cross react with polysorbate found in most COVI-19 vaccines. Aluminum hydroxide is known to activate TH2 immunity and thus, is a potential allergenic excipient found in whole virion vaccines (Coronavac, Sinopharm). It has been implicated in local allergic contact dermatitis to vaccines; however, anaphylaxis to this component is even rarer.

A **Type II reaction** is an antibody mediated cytotoxic/cytolytic reaction wherein the antibodies (IgG/IgM) are directed against the individual's own cell. This leads to cytotoxic action by killer cells or activation of the complement system leading to cytolytic reactions. Examples are anemia and thrombocytopenia.

Reports on blood clotting with thrombocytopenia (Thrombosis with thrombocytopenia syndrome or TTS) have been described following the AstraZeneca vaccine and the Janssen vaccine. Data from the European Union suggest the risk of 1 in 100,000 while UK data describe the risk at 4 cases per million. Venous or arterial thrombosis usually occurs in the brain and abdomen, 4-30 days after vaccination, accompanied by thrombocytopenia and positive platelet factor 4 (PF4) antibodies similar with heparin-induced thrombocytopenia. While US data report that TTS is usually observed among younger, female patients, published reports on TTS in Europe indicate a higher age range and that up to 40% of cases are males. Platelet counts are less than 150. A high index of suspicion among patients who present with severe headache, visual changes, abdominal pain, nausea and vomiting, back pain, shortness of breath, leg pain or swelling and hematologic symptoms such as petechiae, easy bruising, or bleeding should suggest TTS. Diagnostics include a complete blood count showing

thrombocytopenia, elevated D- dimer, low or normal fibrinogen levels and positive PF-4 assays. Imaging to find thrombosis based on the patient's symptoms should also be included.

A **Type III reaction** is an immune complex-mediated reaction wherein the IgG or IgM antibodies form complexes with the antigens which are deposited in the tissues and activate the complement system causing local or systemic damage. Examples are the Arthus reaction and serum sickness.

A **Type IV reaction** is a cell mediated reaction which can cause delayed type hypersensitivity reactions such as maculopapular eruptions. Theoretically, any vaccine can produce these allergic reactions; however, these are rare occurrences.

RISK ASSESSMENT OF ADVERSE REACTIONS AND VACCINATION RECOMMENDATIONS

STATEMENT 2.

Evaluating risk factors for allergic reactions to COVID-19 vaccine is important to safely administer the vaccine. Pre-existing allergic conditions, triggers and severity of previous allergic manifestations are valuable information for risk stratification. (See Tables on Risk Assessment)

STATEMENT 3.

The contraindications to the second dose of COVID-19 vaccination are severe immediate allergic reaction such as ANAPHYLAXIS, and known serious adverse reactions such as thrombotic thrombocytopenic syndrome, myocarditis and pericarditis to a previous dose of COVID-19 vaccine and any of its components.

RECOMMENDATIONS FOR THE FIRST DOSE OF COVID-19 VACCCINE:

Those who can receive the first dose:

1. Patients with non-anaphylactic allergy to food, inhalant/environmental allergens, insects, oral medications, can receive COVID-19 vaccines. Patients with latex allergy should receive a vaccine with non-latex packaging.

2. Patients with delayed reactions and local or systemic reactogenic reactions to OTHER vaccines may receive COVID-19 vaccines.

3. Patients with immunodeficiency, cancer and autoimmune disease (e.g., Guillain-Barre Syndrome, Bell's palsy) may also get vaccinated but they should be informed that there is still not enough data available to establish vaccine safety and efficacy in these conditions. Evaluation and shared-decision making with their physician is advised prior to vaccination.

4. Patients with well-controlled asthma whether on or off inhaled corticosteroids, and those with allergic rhinitis whether on or off intranasal corticosteroids, and those

with atopic dermatitis and chronic urticaria, whether on or off maintenance medications may receive COVID-19 vaccines.

All vaccinated patients should be observed for at least 30 minutes after vaccination in a setting fully equipped to manage anaphylaxis.

Those who need an evaluation by a qualified specialist before receiving the first dose:

1. Patients who have experienced an immediate allergic reaction within 6 hours such as urticaria, angioedema, difficulty of breathing, wheezing, regardless of severity, or anaphylaxis to any OTHER vaccine or injected therapy should be referred to an allergist for evaluation.

2. Patients who had anaphylaxis to oral medications, food, latex, environmental allergens, or insect venom, or to an unclear allergen or etiology should be referred to an allergist for evaluation.

3. Patients with uncontrolled asthma should be referred to their attending physician for evaluation and discussion on adequate attack-free period.

4. Patients with mast cell disorder should be referred to a qualified specialist.

All vaccinated patients should be observed for at least 30 minutes after vaccination in a setting fully equipped to manage anaphylaxis.

Those who should NOT receive the first dose:

1. Patients who have a history of known and proven immediate (within 6 hours) allergic reaction of any severity or anaphylaxis (based on past vaccination experiences or as evaluated by an allergist) to certain vaccine excipients such as polyethylene glycol (PEG), polysorbate, or aluminum hydroxide should not receive the COVID-19 vaccines that contain these excipients.

   Polyethylene glycol (PEG) is found in colonoscopy preparation, or laxatives, while polysorbate is found in some vaccines, vascular graft materials, surgical gels and PEGylated medications. Aluminum hydroxide is found in vaccines, certain drugs and cosmetics. Polyethylene glycol 2000 is an ingredient of the mRNA vaccines, while polysorbate 80 and polysorbate 20 can be found in non-replicating adenovirus vector vaccines and protein subunit vaccines. There is a potential allergenic cross-reactivity between PEG and polysorbate. Aluminum hydroxide is found in inactivated whole virion vaccines. However, there are no reliable diagnostic tests to confirm allergic reactions to PEG, polysorbate or aluminum hydroxide.

   These patients may be referred to an allergist for further evaluation.

RECOMMENDATIONS FOR THE SECOND DOSE OF COVID-19 VACCCINE:

Those who can receive the second dose:

1. Patients with local reactions such as injection site pain, erythema, itch which may appear within a few hours to 4-11 days post vaccination (suggestive of delayed type hypersensitivity reaction) after the first dose of COVID-19 vaccine may receive the second dose on the opposite arm.

2. Patients with systemic reactogenic reactions after the first dose of COVID-19 may receive the second dose.

3. Patients who experienced immunization stress related responses such as VASOVAGAL reactions occurring within 15 minutes after the first dose of COVID-19 vaccines [e.g., feeling warm or cold; pallor, diaphoresis, clammy skin, sensation of facial warmth; dizziness, lightheadedness, syncope (often after prodromal symptoms for a few seconds or minutes), transient hypotension with bradycardia, weakness, changes in vision (such as spots of flickering lights, tunnel vision), changes in hearing, hyperventilation] may receive the second dose.

All vaccinated patients should be observed for at least 30 minutes after vaccination in a setting fully equipped to manage anaphylaxis.

Those who need an evaluation by a qualified specialist before receiving the second dose:

1. Patients who have experienced an immediate moderate non-anaphylactic allergic reaction within 6 hours, such as generalized urticaria, angioedema (except laryngeal edema), throat clearing, itchy throat, and nasal symptoms (e.g., sneezing, rhinorrhea, nasal pruritus, nasal congestion) that is most likely due to the first dose of the COVID-19 vaccine should be referred to a qualified specialist. The specialist is advised to review the type and severity of the symptoms after the first dose, as well as the history of atopy and other risk factors for developing a more severe adverse reaction to the second dose. A shared decision on the risks and benefits of receiving the second dose should be discussed, including the option to avoid or to receive the vaccine under physician supervision in a facility fully equipped to manage anaphylaxis. However, in the absence of a qualified specialist and a fully equipped facility, the second dose should not be given.

2. Patients who have experienced an immediate mild reaction within 6 hours that is non-life threatening such as flushing without urticaria or itch, tingling or itching without urticaria, non-generalized rashes, or other non-specific symptoms after the first dose of COVID-19 vaccine may be referred to a qualified specialist for evaluation. These may not be allergic reactions. The specialist is advised to review the type and severity of the symptoms after the first dose, as well as the history of atopy and other risk factors for developing a more severe adverse reaction to the second dose.

3. Patients who have experienced a late reaction beyond 6 hours such as generalized urticaria, angioedema (except laryngeal edema), delayed cutaneous reactions, purpuric rashes, thrombosis, abnormal laboratory results (e.g., thrombocytopenia) and other worrisome symptoms after the first dose of COVID-19 vaccine may be referred to a qualified specialist for evaluation. These reactions may have other mechanisms.

The decision to give the second dose should be individualized since it is not feasible to describe all possible clinical scenarios, and data on the different COVID-19 vaccines are still evolving. A shared decision between the physician and the patient regarding benefits and risks of receiving the second dose is advised.
All vaccinated patients should be observed for at least 30 minutes after vaccination in a setting fully equipped to manage anaphylaxis.

Those who should NOT receive the second dose:

1. Patients who had severe immediate allergic reaction such as ANAPHYLAXIS (usually within 6 hours; beyond 6 hours if biphasic), or serious adverse reactions such as thrombotic thrombocytopenic syndrome, myocarditis and pericarditis to a previous dose of COVID-19 vaccine and any of its components, should not receive the second dose.

These patients may be referred to an allergist or to an appropriate specialist for further evaluation.

MANAGEMENT OF ADVERSE REACTIONS TO VACCINES

STATEMENT 4.
Reactogenic reactions are managed with supportive care. Mild allergic reactions can be treated with antihistamines. Anaphylaxis should be recognized and managed promptly with EPINEPHRINE. Every patient should be observed for at least 30 minutes post-vaccination.

Adverse reactions to vaccines can occur anytime, thus, the health care facility should be fully equipped with emergency medications. Reactogenic reactions are often mild and can subside within a few days with supportive care (paracetamol, NSAIDs, cold compress).

Mild allergic reactions such as urticaria and rhinitis can be managed with antihistamines. Anaphylaxis should be recognized and treated immediately with EPINEPHRINE (1mg/mL) 0.3-0.5 mL intramuscularly at the mid antero-lateral thigh (Appendix A). Anaphylaxis may increase the risk of mortality if not treated promptly.

Vaccines containing natural rubber latex in their packaging, (vial stoppers, syringe plungers), must not be administered to patients with a history of anaphylaxis to latex. A non-latex containing alternative should be given instead.

Other types of vaccine hypersensitivity reactions are usually managed in the hospital setting and controlled by oral or intravenous steroids, or other systemic immunomodulators, depending on the severity of the reaction. Patients with these reactions must be referred to a qualified specialist for more extensive evaluation and management.

The recent Com-Cov study done in the United Kingdom showed safety and immunogenicity data on the combination of Astra Zeneca and Pfizer/bioNTech vaccines. However, the objectives of the study did not include switching of vaccine type in the second dose due to serious adverse reactions to the first dose. Nevertheless, the study may be used as basis, with caution, in patients who developed serious adverse reactions to the first dose of either Astra Zeneca and Pfizer/bioNTech vaccines. Patients who have contraindications to the second dose of Astra Zeneca vaccine may receive Pfizer/BioNTech vaccine as the second dose, and vice versa. Ideally, this should be a shared decision with the physician. Currently, combinations with other vaccines, such as whole virus vaccines with viral vector, mRNA or protein vaccines have not yet been evaluated for efficacy and safety.

Giving antihistamines and systemic corticosteroids as prophylaxis for vaccination is not consistently effective and often fails to prevent severe reactions and anaphylaxis. Moreover, these medications may mask the early signs and symptoms of anaphylaxis and delay the administration of epinephrine. Antipyretics and NSAIDs are likewise not recommended as prophylaxis for reactogenic reactions. There is lack of data to recommend pharmacologic prophylaxis before vaccination. However, patients maintained on antihistamines for concomitant allergic disease may continue their medications during the vaccination period as this will not interfere with the immunogenic response of the vaccine.

SUMMARY

- The COVID-19 pandemic has been the biggest global health challenge the world has faced.
- COVID-19 vaccination may provide protection and herd immunity which may be a part of the solution to this global health problem.
- Several kinds of vaccines have been developed targeting various antigenic portions of the SARS-COV-2 virus. The mRNA vaccines and viral vector platforms utilize genetic material of the virus to produce the spike protein, the most virulent antigen of the SARS-COV-2 virus, and generate immunity against this. However whole virion and protein subunit vaccines generate immunity to fragments of the virus such as the spike protein or other antigenic regions of the virus.
- Adverse reactions to vaccines may occur and can range from reactogenic reactions to allergic reactions. A REACTOGENIC REACTION is not the same as an ALLERGIC REACTION.
- Majority of COVID-19 vaccine adverse reactions are mild. Reactogenic reactions include pain, tenderness and swelling and can be managed with supportive care. Mild allergic reactions such as rashes can be managed with antihistamines.
- The risk of severe allergic reactions, such as anaphylaxis, is rare in COVID-19 vaccines. However, anaphylaxis should be recognized and managed promptly with EPINEPHRINE 0.3-0.5ml intramuscularly at the mid antero-lateral thigh. It is therefore essential that all vaccinees be observed for at least 30 minutes post-vaccination at vaccination centers.
- Healthcare practitioners who will be vaccinating against COVID-19 must be sufficiently trained to properly recognize and manage anaphylaxis. Vaccination centers must be equipped with the proper medications necessary to manage immediate allergic reactions such as anaphylaxis.
- The contraindications to the second dose of COVID-19 vaccination are severe immediate allergic reaction such as ANAPHYLAXIS, and known serious adverse reactions such as thrombotic thrombocytopenic syndrome, myocarditis and pericarditis to a previous dose of COVID-19 vaccine and any of its components.
- Patients who experienced an immediate moderate non-anaphylactic reaction, delayed mild, non-life threatening reactions or reactions affecting other organ systems after receiving the first dose of COVID-19 vaccine should be referred to a qualified specialist. A shared decision between the physician and the patient regarding benefits and risks of receiving the second dose is advised.
- Patients with anaphylaxis to other types of vaccines and injectable medications, food, inhalant/environmental allergens, insects, latex and oral medications; those with uncontrolled asthma and mast cell disorder should be evaluated by a qualified specialist prior to COVID-19 vaccination.
- Patients with local and systemic reactogenic reactions, immunization stress related reactions such as vasovagal reactions after receiving the first dose of COVID-19 vaccine may receive the second dose.
- Patients with non-anaphylactic reactions to food, inhalant/environmental allergens, insects, latex, oral medications not related to vaccines and their components, can receive COVID-19 vaccines. Patients with latex allergy should not receive a vaccine with latex in its packaging.
- Patients with immunodeficiency, cancer and autoimmune disease (e.g. Guillain-Barre Syndrome, Bell's palsy) may also get vaccinated but they should be informed that there is still not enough data available to establish vaccine safety and efficacy in these conditions. They also must be evaluated and advised by their physicians regarding risks and benefits of vaccination.
- Patients well-controlled asthma, allergic rhinitis, atopic dermatitis and chronic urticaria, whether on maintenance medications or not, can receive COVID-19 vaccines.
- Based on current data, the benefits of these vaccines to the general public far outweigh the potential risks of adverse reaction to COVID-19 vaccines, as well as to the risk of developing severe COVID-19 and death.

ASSESSMENT OF RISK FOR ALLERGIC REACTION TO THE FIRST DOSE OF COVID-19 VACCINE
August 5, 2021

LOW RISK	MODERATE RISK	HIGH RISK
PROCEED WITH VACCINATION Observe for at least 30 minutes	**PRECAUTION TO VACCINATION** Refer to a **qualified specialist** Observe for at least 30 minutes in a setting fully equipped to manage severe adverse reactions	**CONTRAINDICATION TO VACCINATION**
1. NON-ANAPHYLACTIC allergy to **oral medications**[1] (including the oral equivalent of an injectable medication) 2. NON-ANAPHYLACTIC allergy to **food, pet, insect venom, environmental, latex**, etc.[1,2] 3. DELAYED LOCAL reactions (e.g., contact dermatitis) to **OTHER vaccines**[3] 4. **REACTOGENIC** reactions, LOCAL (e.g., pain, redness, swelling on injection site) or SYSTEMIC (e.g., fever, chills, headache, malaise) to **OTHER vaccines** 5. Well-controlled atopic dermatitis, allergic rhinitis, asthma, chronic urticaria, whether on maintenance medications or not 6. Primary or secondary immunodeficiency (after evaluation of clinical status and discussion of ideal vaccine platform with attending physician) 7. Autoimmune disease and Cancer – (after discussing efficacy with attending physician) 8. Family history of allergies[1]	1. ANAPHYLAXIS to **oral medications, food, latex, environmental, or insect venom**[2] **or unclear allergen/etiology**[3] 2. Uncontrolled asthma (discuss with a qualified specialist adequate attack-free period*) 3. Mast cell disorder (discuss with a qualified specialist for evaluation)[4] 4. IMMEDIATE (within 6 hours) **ALLERGIC** reaction of **any severity** [urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or ANAPHYLAXIS] to **OTHER vaccines,** or injectable therapies	• IMMEDIATE (within 6 hours) **ALLERGIC** reaction of **any severity** [urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or ANAPHYLAXIS] to **a component of the COVID-19 vaccine**[1] (e.g., PEG in mRNA vaccine, polysorbate in Janssen and AstraZeneca, aluminum hydroxide in Coronavac/Sinovac)

** Global Initiative For Asthma (GINA) Guidelines at https://ginasthma.org/gina-reports/*

[1] *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-B*

[2] *https://education.aaaai.org/resources-for-a-i-clinicians/reactionguidance_COVID-19*

[3] *Worm M, et al. Practical recommendations for the allergological risk assessment of the COVID-19 vaccination - a harmonized statement of allergy centers in Germany. Allergol Select. 2021 Jan 26;5:72-76.*

[4] *Rama TA, et al. mRNA COVID-19 vaccine is well tolerated in patients with cutaneous and systemic mastocytosis with mast cell activation symptoms and anaphylaxis. J Allergy Clin Immunol. 2021 Mar;147(3):877-878.*

ASSESSMENT OF RISK FOR ALLERGIC REACTION TO THE SECOND DOSE OF COVID-19 VACCINE
August 5, 2021

SYMPTOMS/ SIGNS AFTER FIRST DOSE	RECOMMENDATION FOR SECOND DOSE
1. **No cutaneous or systemic symptoms** after the first dose	• Proceed with second dose at recommended interval
2. **LOCAL** reaction (e.g., erythema, induration, pruritus, painful rash [a]) around the injection site a few hours through the second week after the first dose[b,c]	• Proceed with second dose at recommended interval • Inject on opposite arm
3. **REACTOGENIC reactions**[d] (vaccine side effects) a few hours up to 3 days after the first dose (e.g., fever, chills, fatigue; pain, erythema, or swelling at injection site; lymphadenopathy in same arm as vaccination; headache, myalgia, arthralgia, vomiting, diarrhea)	• Proceed with second dose at recommended interval
4. **VASOVAGAL reactions**[d] occurring within 15 minutes after the first dose [e.g., feeling warm or cold; pallor, diaphoresis, clammy skin, sensation of facial warmth; dizziness, lightheadedness, syncope (often after prodromal symptoms for a few seconds or minutes), transient hypotension with bradycardia, weakness, changes in vision (such as spots of flickering lights, tunnel vision), changes in hearing]	• Proceed with second dose at recommended interval
5. Other **DELAYED** adverse reactions after the first dose (e.g., delayed cutaneous reactions, thrombosis, purpura, thrombocytopenia, etc.)	• Refer to qualified specialist prior to the second dose
6. **IMMEDIATE MILD symptoms within the first 6 hours** after the first dose that are non-life threatening (e.g., non-generalized rash, flushing without urticaria, subjective symptoms such as tingling or itching without urticaria, non-specific symptoms)	• Review the history of atopy and other risk factors and refer to a qualified specialist before the second dose
7. **IMMEDIATE MODERATE NON-ANAPHYLACTIC symptoms within the first 6 hours** after the first dose (urticaria, angioedema other than laryngeal, throat clearing and itch, nasal symptoms)	• Review the history of atopy and other risk factors and refer to a qualified specialist before the second dose
8. **IMMEDIATE SEVERE allergic symptoms within the first 6 hours** after the first dose such as **ANAPHYLAXIS**[a], or **serious adverse reactions as thrombotic thrombocytopenic syndrome, myocarditis and pericarditis**	• **Should NOT proceed with second dose**

[a] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html
[b] https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical considerations.html#Contraindications
[c] *Blumenthal KG, et al. Delayed Large Local Reactions to mRNA-1273 Vaccine against SARS-CoV-2. N Engl J Med. 2021 Mar 3.*
[d] *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-D*

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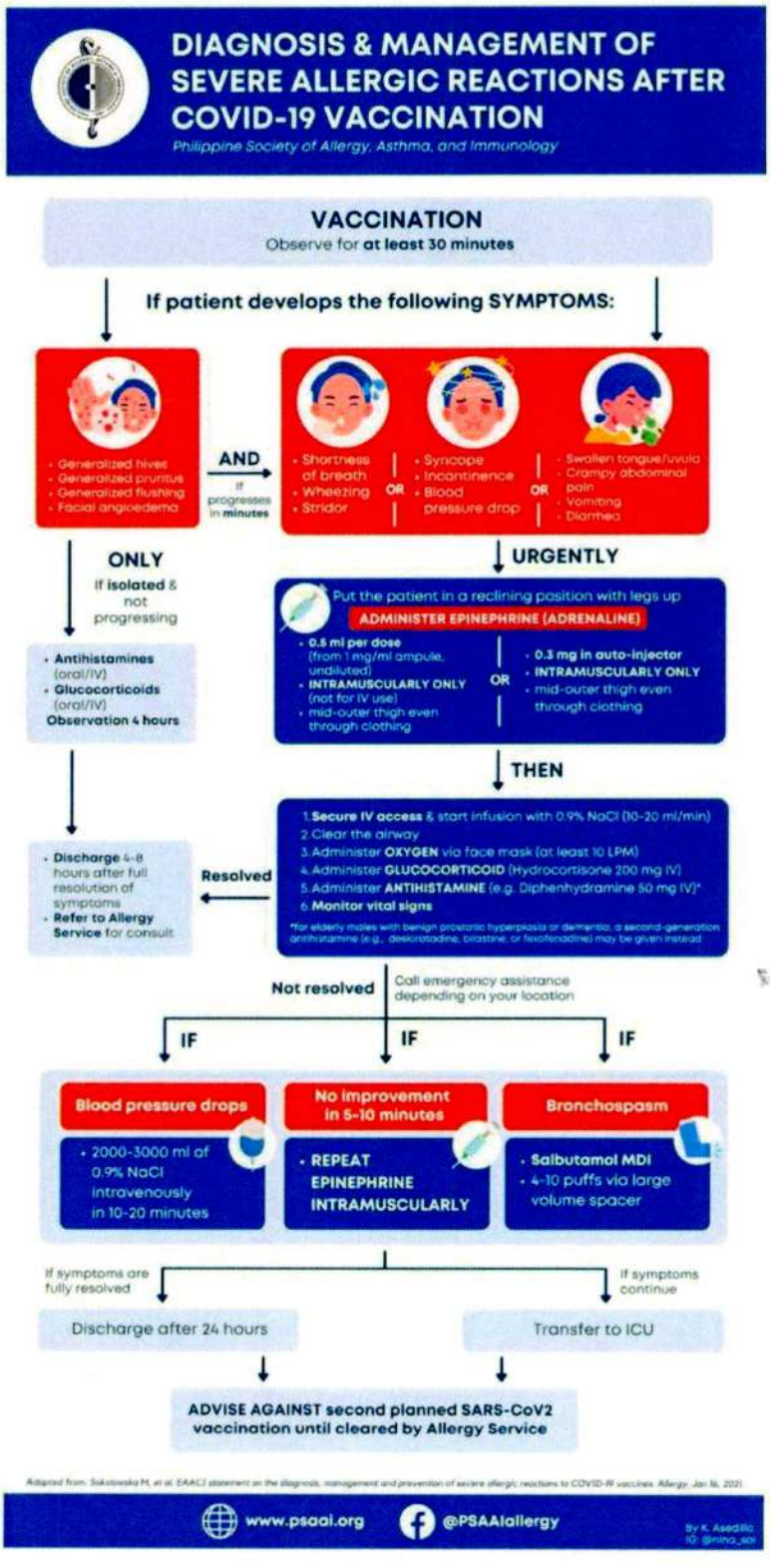
APPENDIX A


DIAGNOSIS & MANAGEMENT OF SEVERE ALLERGIC REACTIONS AFTER COVID-19 VACCINATION
Philippine Society of Allergy, Asthma, and Immunology
VACCINATION
Observe for at least 30 minutes
If patient develops the following SYMPTOMS:
• Generalized hives
• Generalized pruritus
• Generalized flushing
• Facial angioedema
AND
If progresses in minutes
• Shortness of breath
• Wheezing
• Stridor
OR
• Syncope
• Incontinence
• Blood pressure drop
OR
• Swollen tongue/uvula
• Crampy abdominal pain
• Vomiting
• Diarrhea
ONLY
If isolated & not progressing
URGENTLY
Put the patient in a reclining position with legs up
ADMINISTER EPINEPHRINE (ADRENALINE)
• 0.5 ml per dose (from 1 mg/ml ampule, undiluted)
• INTRAMUSCULARLY ONLY (not for IV use)
• mid-outer thigh even through clothing
OR
• 0.3 mg in auto-injector
• INTRAMUSCULARLY ONLY
• mid-outer thigh even through clothing
• Antihistamines (oral/IV)
• Glucocorticoids (oral/IV)
Observation 4 hours
THEN
1. Secure IV access & start infusion with 0.9% NaCl (10-20 ml/min)
2. Clear the airway
3. Administer OXYGEN via face mask (at least 10 LPM)
4. Administer GLUCOCORTICOID (Hydrocortisone 200 mg IV)
5. Administer ANTIHISTAMINE (e.g. Diphenhydramine 50 mg IV)*
6. Monitor vital signs
*For elderly males with benign prostatic hyperplasia or dementia, a second-generation antihistamine (e.g., desloratadine, bilastine, or fexofenadine) may be given instead
• Discharge 4-8 hours after full resolution of symptoms
• Refer to Allergy Service for consult
Resolved
Not resolved
Call emergency assistance depending on your location
IF
IF
IF
Blood pressure drops
• 2000-3000 ml of 0.9% NaCl intravenously in 10-20 minutes
No improvement in 5-10 minutes
• REPEAT EPINEPHRINE INTRAMUSCULARLY
Bronchospasm
• Salbutamol MDI
• 4-10 puffs via large volume spacer
If symptoms are fully resolved
If symptoms continue
Discharge after 24 hours
Transfer to ICU
ADVISE AGAINST second planned SARS-CoV2 vaccination until cleared by Allergy Service
Adapted from: Sokolowska M, et al. EAACI statement on the diagnosis, management and prevention of severe allergic reactions to COVID-19 vaccines. Allergy. Jan 16, 2021
www.psaai.org
@PSAAIallergy
By K. Asedillo
IG: @nina_sci

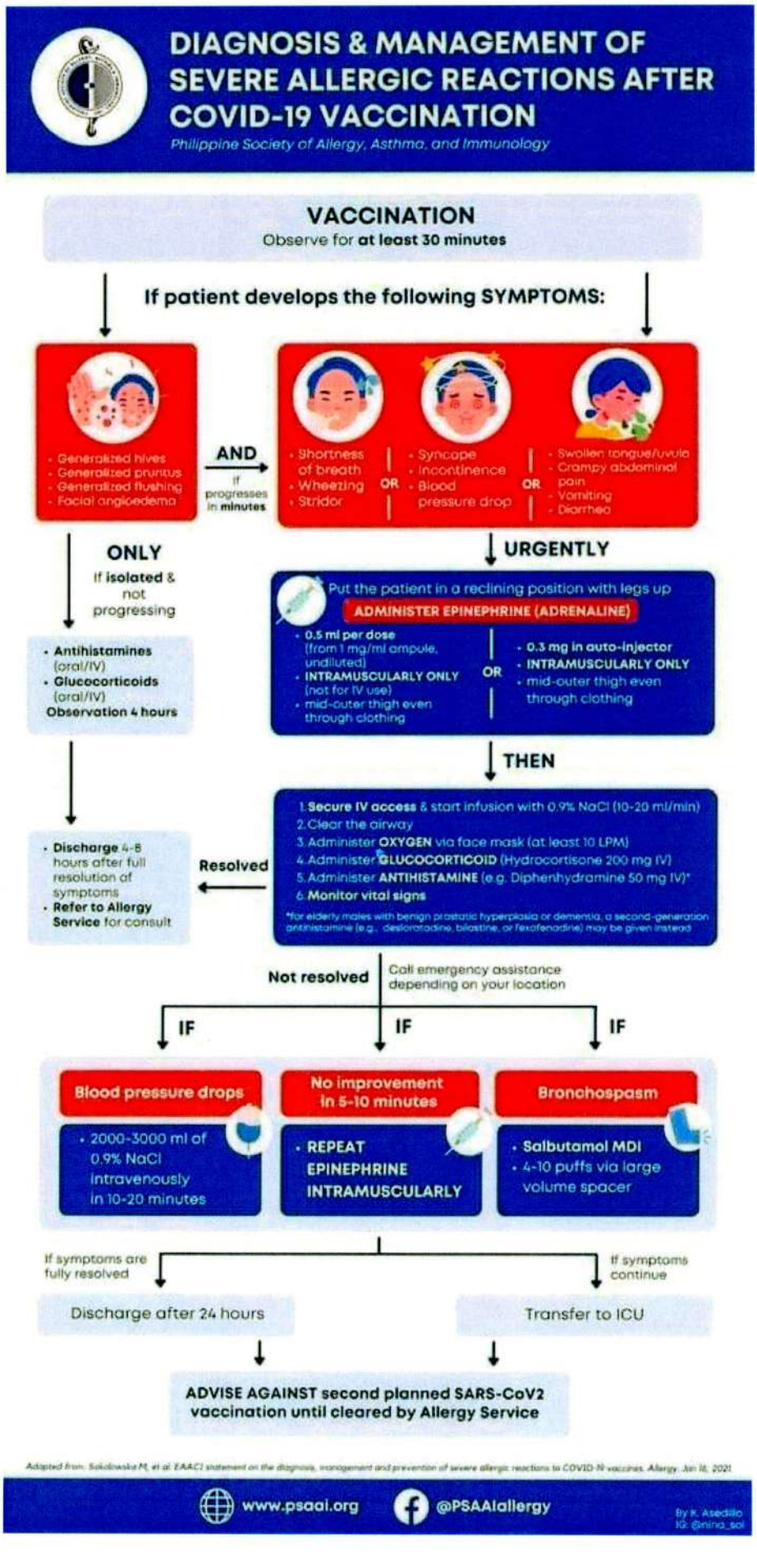
APPENDIX B

WORLD ALLERGY ORGANIZATION (WAO) Systemic Allergic Reaction Grading System

NOT ANAPHYLAXIS		ANAPHYLAXIS		
GRADE 1	**GRADE 2**	**GRADE 3**	**GRADE 4**	**GRADE 5**
Symptoms(s)/sign(s) from 1 organ system present	Symptoms(s)/sign(s) from >/=2 organ system present	LOWER AIRWAY	LOWER AIRWAY	LOWER OR UPPER AIRWAY
CUTANEOUS		Mild bronchospasm, (e.g., cough, wheezing, shortness of breath which responds to treatment)	Severe bronchospasm (e.g., not responding or worsening in spite of treatment)	Respiratory failure AND/OR
Urticaria and/or erythema-warmth and/or pruritus, other than localized at the injection site		AND/OR	AND/OR	CARDIOVASCULAR
AND/OR		GASTROINTESTINAL	UPPER AIRWAY	Collapse / hypotension
Tingling, or itching of the lips [a] or Angioedema (not laryngeal)*		Abdominal cramps* and/or vomiting/diarrhea	Laryngeal edema with stridor	AND/OR
OR UPPER RESPIRATORY		OTHER	Any symptoms(s)/ sign(s) from grades 1 or 3 would be included	Loss of consciousness (vasovagal excluded)
Nasal symptoms (e.g., sneezing, rhinorrhea, nasal pruritus, and/or nasal congestion)		Uterine cramps		Any symptoms(s)/ sign(s) from grades 1,3 or 4 would be included
AND/OR		Any symptoms(s)/ sign(s) from grade 1 would be included		
Throat-clearing (itchy throat)[a]				
AND/OR				
Cough not related to bronchospasm				
OR CONJUNCTIVAL				
Erythema, pruritus, or tearing				
OR OTHER				
Nausea				
Metallic taste				

[a] Application-site reactions would be considered local reactions. Oral mucosa symptoms, such as pruritus, after sublingual immunotherapy (SLIT) administration, or warmth and/or pruritus at a subcutaneous immunotherapy injection site would be considered a local reaction.* Gastrointestinal tract reactions after SLIT or oral immunotherapy (OIT) would also be considered local reactions, unless they occur with other systemic manifestations. SLIT or OIT reactions associated with gastrointestinal tract and other systemic manifestations would be classified as SARs. SLIT local reactions would be classified according to the WAO grading system for SLIT local reactions.

Annex E. *Diagnosis and Management of Severe Allergic Reactions*



ASSESSMENT OF RISK FOR ALLERGIC REACTION TO THE SECOND DOSE OF COVID-19 VACCINE

Philippine Society of Allergy, Asthma, and Immunology

SYMPTOMS / SIGNS AFTER FIRST DOSE	RECOMMENDATION FOR SECOND DOSE
1. **No cutaneous or systemic symptoms** after the first dose	Proceed with second dose at recommended interval
2. Red, itchy, swollen, or painful rash where they got the first COVID vaccine shot or **"COVID arm"**[a]	Proceed with second dose at the opposite arm
3. Delayed-onset LOCAL reaction (eg, erythema, induration, pruritus) around the injection site a few days through the second week after the first dose[b,c]	Proceed with second dose at recommended interval
4. Mild delayed cutaneous generalized reaction (eg, maculopapular exanthems, allergic contact dermatitis)	Proceed with second dose at recommended interval
5. **REACTOGENIC reactions**[d] (vaccine side effects) a few hours up to 3 days after the first dose (eg, fever, chills, fatigue; pain, erythema, or swelling at injection site; lymphadenopathy in same arm as vaccination; headache, myalgia, arthralgia, vomiting, diarrhea)	Proceed with second dose at recommended interval
6. **VASOVAGAL reactions**[d] occurring within 15 minutes after the first dose [eg, feeling warm or cold; pallor, diaphoresis, clammy skin, sensation of facial warmth; dizziness, lightheadedness, syncope (often after prodromal symptoms for a few seconds or minutes), transient hypotension with bradycardia, weakness, changes in vision (such as spots of flickering lights, tunnel vision), changes in hearing]	Proceed with second dose at recommended interval
7. Hypertension alone within 6 hours after the first dose	Refer to a qualified specialist for clearance prior to the second dose
8. **IMMEDIATE onset allergic symptoms within the first 6 hours** after first dose that are **SEVERE** (eg, respiratory distress, laryngeal edema, anaphylaxis)[a]	**Should NOT proceed with second dose**
9. **IMMEDIATE onset allergic symptoms within the first 6 hours** after first dose that are **MILD** (eg, rash, hives, swelling other than laryngeal edema, flushing without urticaria, subjective symptoms such as tingling or itching without urticaria, etc.)	**Should NOT proceed with second dose**
10. Other **SEVERE** adverse reactions, whether **IMMEDIATE** within 6 hours after first dose or **DELAYED** (eg, thrombosis, purpura, etc)	Refer to appropriate qualified specialist for clearance prior to the second dose

[a] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html*
[b] *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications*
[c] *Blumenthal KG, et al. Delayed Large Local Reactions to mRNA-1273 Vaccine against SARS-CoV-2. N Engl J Med. 2021 Mar 3.*
[d] *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-D*

ASSESSMENT OF RISK FOR ALLERGIC REACTION TO THE FIRST DOSE OF COVID-19 VACCINE

Philippine Society of Allergy, Asthma, and Immunology
(Revised March 2021)

LOW RISK

PROCEED WITH VACCINATION

Observe for at least 30 minutes

1. NON-ANAPHYLACTIC allergy to **oral medications**[1] (including the oral equivalent of an injectable medication)
2. NON-ANAPHYLACTIC allergy to **food, pet, insect venom, environmental, latex**, etc.[1,2]
3. DELAYED LOCAL reactions (eg, contact dermatitis) to **OTHER vaccines**[3]
4. **REACTOGENIC** reactions, LOCAL (eg, pain, redness, swelling on injection site) or SYSTEMIC (eg, fever, chills, headache, malaise) to **OTHER vaccines**
5. Well-controlled atopic dermatitis, allergic rhinitis, asthma, chronic urticaria, whether on maintenance medications or not
6. Primary or secondary immunodeficiency (after evaluation of clinical status and discussion of ideal vaccine platform with attending physician)
7. Autoimmune disease – (after discussing efficacy with attending physician)
8. Family history of allergies[4]

MODERATE RISK

PRECAUTION TO VACCINATION

Refer to a qualified specialist. Observe for at least 30 minutes in a hospital setting

1. ANAPHYLAXIS to **oral medications, food, latex, environmental, or insect venom**[3] **or unclear allergen/ etiology**[3]
2. Uncontrolled asthma (discuss with a qualified specialist adequate attack-free period*)
3. Mast cell disorder (discuss with a qualified specialist for evaluation)[4]
4. IMMEDIATE (within 6 hours) **ALLERGIC** reaction of **any severity** [urticaria, angioedema, respiratory distress (eg, wheezing, stridor), or ANAPHYLAXIS]
   a. to **UNRECALLED** vaccines or injectable therapies (only if evaluated by allergist), or
   b. to **OTHER vaccines** or injectable therapies **with components NOT found in COVID vaccines**

HIGH RISK

CONTRAINDICATION TO VACCINATION

- IMMEDIATE (within 6 hours) **ALLERGIC** reaction of **any severity** [urticaria, angioedema, respiratory distress (eg, wheezing, stridor), or ANAPHYLAXIS] to **a component of the COVID-19 vaccine**[1] (eg, PEG in mRNA vaccine, polysorbate in Janssen and AstraZeneca, aluminum hydroxide in Coronavac/Sinovac)

* *Global Initiative For Asthma (GINA) Guidelines at https://ginasthma.org/gina-reports/*

[1] *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-B*
[2] *https://education.aaaai.org/resources-for-a-i-clinicians/reactionguidance_COVID-19*
[3] *Worm M, et al. Practical recommendations for the allergological risk assessment of the COVID-19 vaccination - a harmonized statement of allergy centers in Germany. Allergol Select. 2021 Jan 26;5:72-76.*
[4] *Rama TA, et al. mRNA COVID-19 vaccine is well tolerated in patients with cutaneous and systemic mastocytosis with mast cell activation symptoms and anaphylaxis. J Allergy Clin Immunol. 2021 Mar;147(3):877-878.*

Annex F. *Details and quantities of items needed for of AEFI/AESI Kits*

AEFI kit components on vaccinate site per team (replenished prior to vaccination runs)	
Diagnostic Equipment	**Quantity**
BP apparatus with appropriate cuffs depending on age-groups vaccinated	1 set
Stethoscope	1 set
Pulse oximeter	1 unit
Pen light	1 set
Thermometer digital	1 set
Managements	
IV Catheter, with appropriate gauges depending on age-groups to be vaccinated	1 set
Intravenous tubing, with appropriate gauges depending on age-groups to be vaccinated	1 set
Oxygen tubing with face mask, with appropriate sizes depending on age-groups to be vaccinated	1 set
1mL syringe with disposable syringe gauges (26G, 25G, 23G)	2 set each
Oxygen tank available on-site	as determined
Tourniquet	1 set
Cotton and wool	1 set
Oral Drugs	
Antihistamine (Cetirizine 10 mg)	10 tabs
Glucocorticoids (Prednisone)	
NSAIDs (Paracetamol 500mg)	10 tabs

Oral rehydration salts	1 bottle / at least 2 powdered sachets
Antiemetics	
Muscle relaxant/sedative, (Diazepam 5mg/mL) if with capacity to procure	at least 1 vial
Non-Oral Drugs	
Injection epinephrine (1:1000) solution	At least 3 ampules
Injection hydrocortisone (100mg)	at least 3 vials
Diphenhydramine in IV form (50mg/mL)	at least 3 vials
Salbutamol-metered dose inhaler	1 unit
Plain Normal Saline Solution (0.9%) IV fluids (5% Dextrose)	1 to 2 units each

**Customized for hospitals and for the Pfizer Vaccine only. Some variations in the protocols will be done for non-hospitals, non-health facilities, and other vaccines.*

Adrenaline in the initial management of acute anaphylaxis			
Drug site and route of administration	Frequency of administration	Dose (Adult)	Dose (Child)*
Adrenaline (epinephrine) 1:1000, 1M to the midpoint of the anterolateral aspect of the middle third of the thigh immediately	Repeat in every 5-15 min as needed until there is resolution of the anaphylaxis. Note: Persisting or worsening cough associated with pulmonary edema is an important sign of adrenaline overdose and toxicity.	0.5 mL	According to age; <1 years: 0.05 mL 2-6 years: 0.15 mL 6-12 years: 0.3 mL >12 years: 0.5 mL

Note: The needle used for injection to be sufficiently long to ensure that the adrenaline is injected into muscle. This treatment guide is optional and countries may practice their own country-specific protocols for treatment of anaphylaxis with the drug of choice, steps to be followed, and etc.

Source: DOH AEFI Manual of Procedures 2014

Annex G. *Guidelines on Diagnosing and Treating Myocarditis/ Pericarditis*

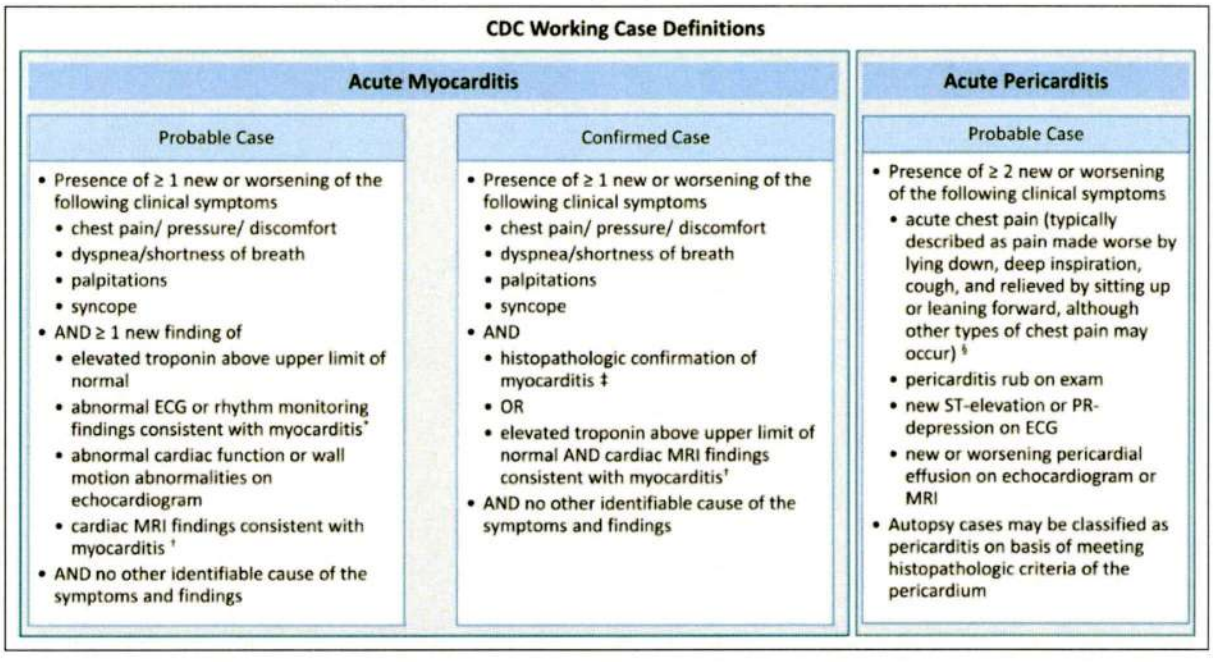
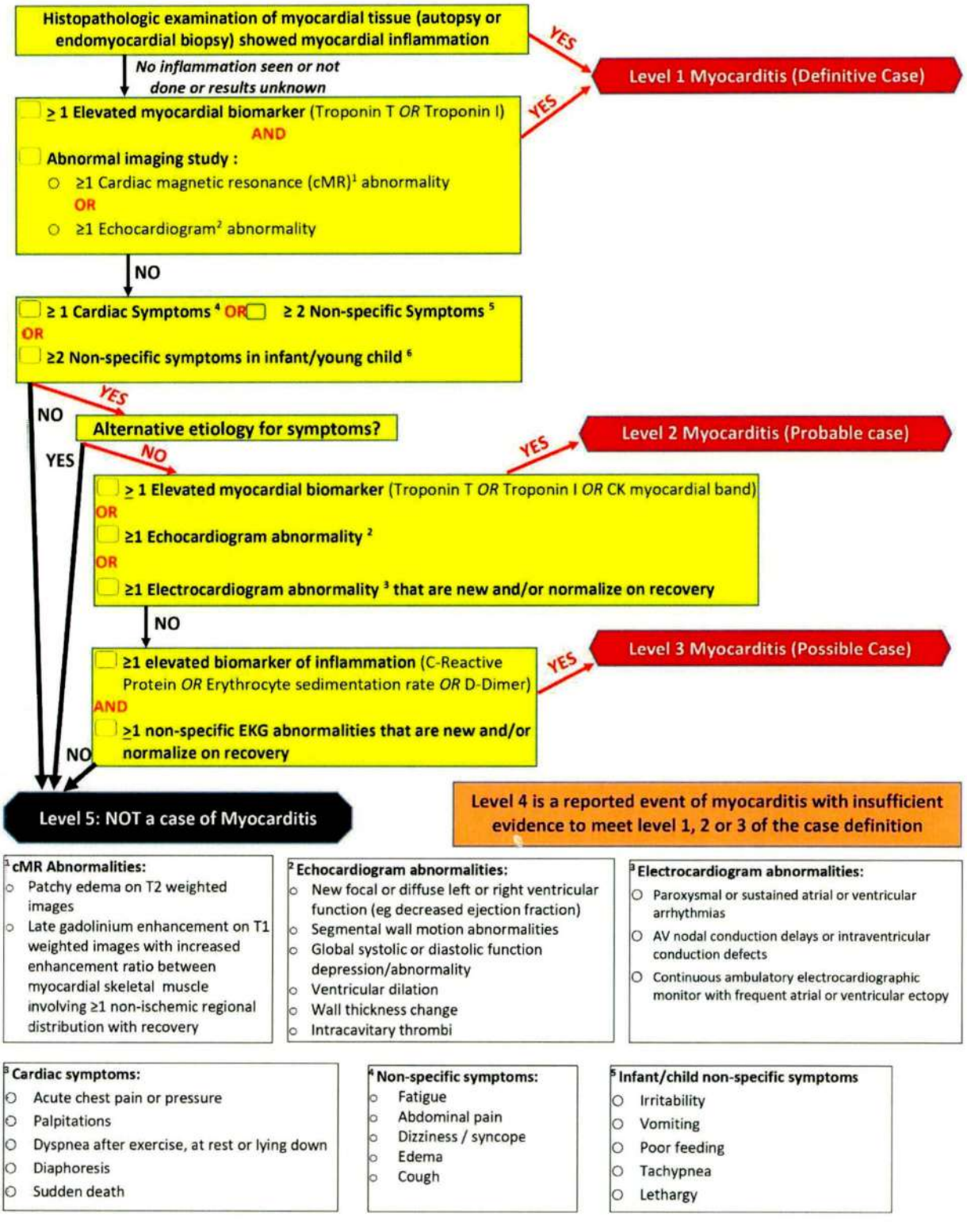
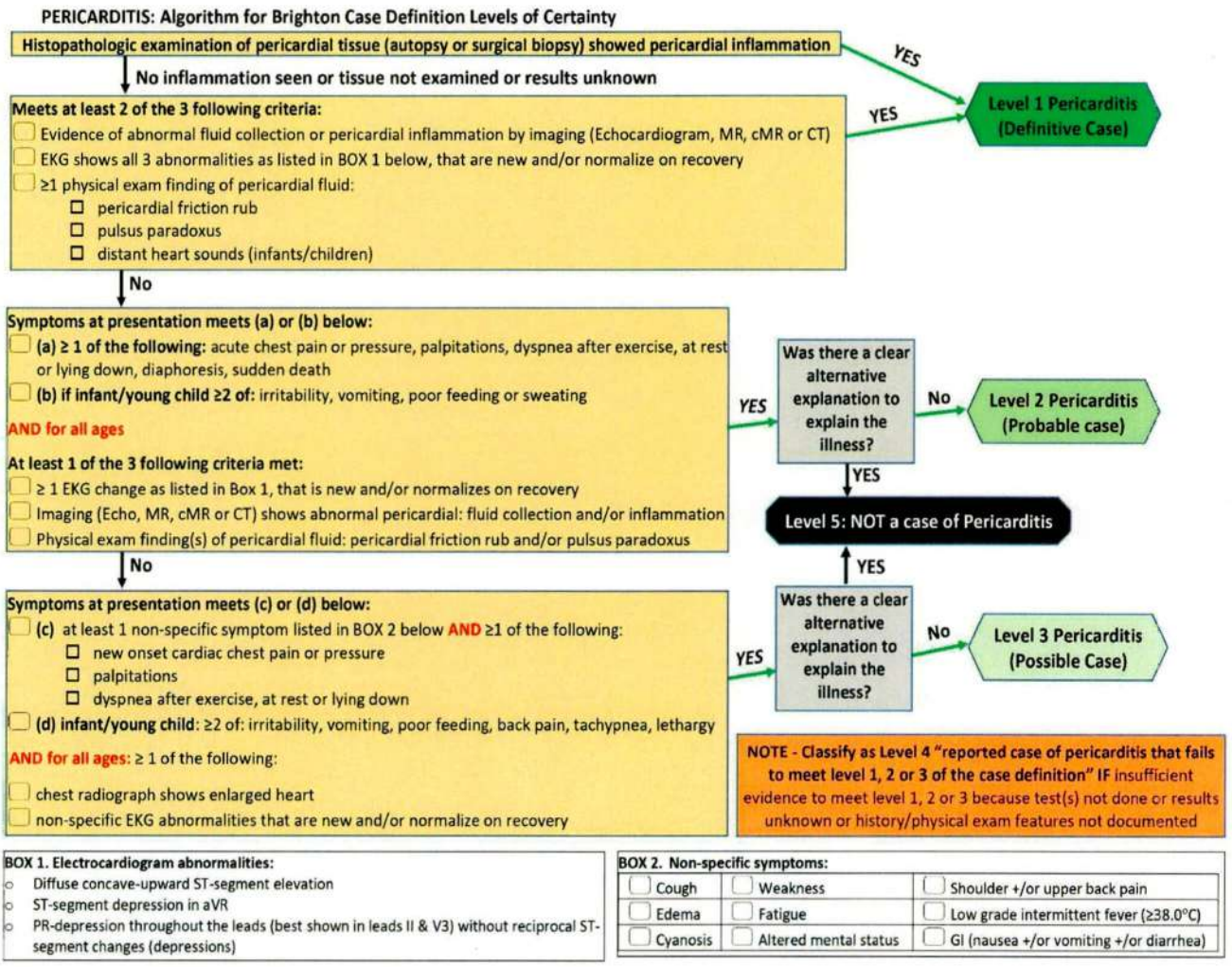


Figure 1. Centers for Disease Control and Prevention working case definitions for acute myocarditis and acute pericarditis. Adapted from Centers for Disease Control and Prevention[5] with permission. Copyright ©2021, Centers for Disease Control and Prevention.

Source: US Center for DIsease Control and Prevention Working Case Definition for Myocarditis / Pericarditis



Source: Brighton Collaboration Myocarditis Case Definition Algorithm (16 July 2021)



Source: Brighton Collaboration Pericarditis Case Definition Algorithm (15 July 2021)

Annex H. *Guide to Immunization-stress related Reaction*

What is an Immunization-stress related response (ISRR)?

"Immunization stress-related response" (ISRR): response to the stress some individuals may feel when receiving an injection and covers the spectrum of manifestations.

ISRR may range from mild feelings of worry and "butterflies" in the stomach to symptoms of sympathetic nervous system stimulation – increased heart rate, palpitations and difficulty in breathing.

How do we prevent ISRR from happening?

Individuals who have a history of vasovagal reactions or risk factors should be immunized in a **seated** or **supine position** and only move to sitting (from supine) or standing (from sitting) if there are no signs of a vasovagal reaction.

Ideally the individual should stay seated for **15 to 30 minutes** following the procedure, and the healthcare provider should monitor them for signs of a vasovagal reaction.

How to diagnose and manage ISRR?

1. **Frequency**: adolescent age group (10–19 years), history of vasovagal syncope, previous negative experience of immunization, an expressed fear of injections or needles and pre-existing conditions such as an anxiety disorder or a developmental disorder such as autism spectrum disorder.
2. **Timing and Duration:** Sudden, occurs before, during or shortly **after (< 5 min)** immunization
3. **Manifestations:** vasovagal reactions ("fainting" or loss of consciousness), hyperventilation or rapid breathing, nausea, sweating, pallor, general weakness
4. **Strict Adherence:** Given the sensitive population, vaccination sites should ensure that proper communication and health education and safety assurance are given,
5. **Take home pre-requisites:** After the vaccination, guardians/recipients **MUST** know:
    a. **Hotline number (**ie. vaccination site, nearest hospitals, LVOC of concern) / **Emergency numbers** if they need a consultation or assistance.

TAKE NOTE: If sudden loss of consciousness occurs more than 5–10 min after immunization, in addition to vasovagal syncope, **anaphylaxis should be considered as a possible diagnosis**. Thus, it is important to exclude anaphylaxis and then to define manifestation of the ISRR.

Prompt Management: the individual should remain in the **supine position**, The nature of the symptoms, must **resolve spontaneously** without the need for medication should be explained. Medication and hospitalization should be avoided.

Reference: WHO. (2019). *Immunization Stress-Related Responses: A Synopsis.*

McMurtry CM. *Managing immunization stress-related response: A contributor to sustaining trust in vaccines*. Can Commun Dis Rep 2020;46(6):210–8. https://doi.org/10.14745/ccdr.v46i06a10

Annex I. Reactogenic Reactions versus COVID-19 symptoms

Category A Symptoms

	COVID-19 Infection	COVID-19 Vaccination Side Effect
Cough	Yes	No
Shortness of Breath	Yes	No
Rhinorrhea (Runny Nose)	Yes	No
Sore Throat	Yes	No
Loss of Taste or Smell	Yes	No

Individuals experiencing symptoms in Category A at any time should stay home until they are evaluated and cleared per usual protocol.

Category B Symptoms

	COVID-19 Infection	COVID-19 Vaccination Side Effect
Fever, Chills	Yes to Both	
Headache		
Body Aches		
Joint Pain		

Individuals experiencing Category B systemic signs and symptoms that are known to occur after vaccination may return to work if:

1. They have no symptoms in Category A at any time
2. They feel well enough, and have a temperature of < 100.0 F
3. Symptoms do not persist longer than 2 days after vaccine

- If symptoms persist for longer than 2 days, individuals should seek advice from their health care provider, continue to stay home, schedule a COVID-19 test, and contact local authorities

Category C Symptoms

	COVID-19 Infection	COVID-19 Vaccination Side Effect
Immediate reactions; Urticaria, Hives, Anaphylaxis	No	Yes
Local Symptoms; Pain swelling	No	Yes

Reactogenic effects of COVID-19 Vaccination must be managed as soon as they arise. Most side effects are not serious and should go away on their own.

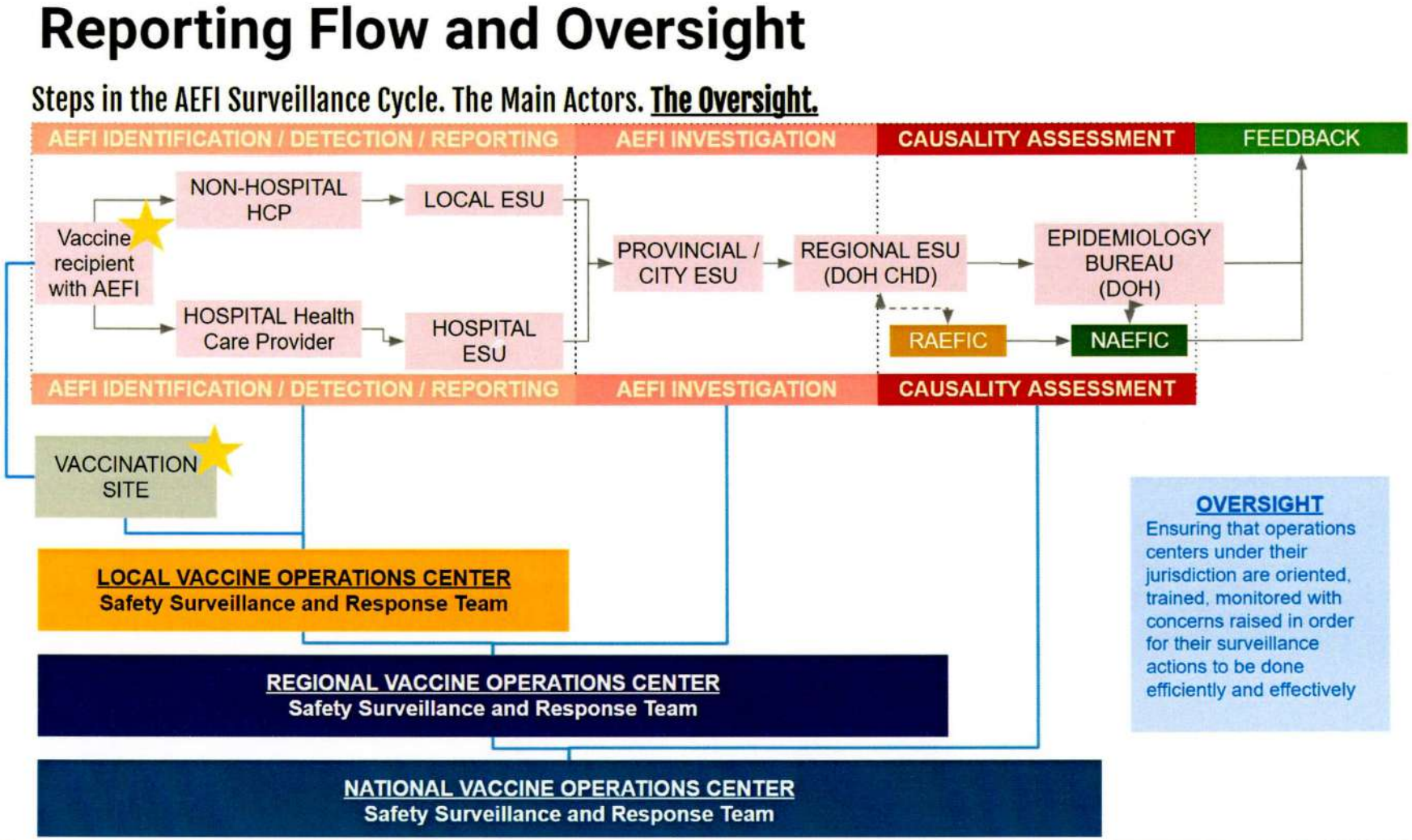
References:

British Columbia Centre for Disease Control. COVID-19 Vaccination Aftercare. bccdc.ca/Health-Info-Site/Documents/COVID-1

9_vaccine/VaccinationAftercare.pdf

Berkeley University Health Services. Post Vaccine Side Effect Information. uhs.berkeley.edu/sites/default/files/covid-vaccine-post-sideeffects.pdf

Annex J. *Steps in the AEFI Surveillance Cycle*



Annex K. *Revised AEFI COVID-19 Vaccine Case Investigation Form Version 2* ***(bit.ly/aefic19ph)***

Philippine Integrated Disease Surveillance and Response

Case Investigation Form

(for COVID-19 Vaccine AEFI)

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* ☐ 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	With Hypertension?* ☐ No ☐ Yes ☐ Unknown				
Indicate pre- and post-vaccination blood pressure	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: _____

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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.

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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. TREATMENT COVERAGE

1. Was the treatment charged from a funding source?* ☐ Yes, completely charged ☐ Yes, partially charged to the patient and funding source ☐ No, fully charged to the patient ☐ Not applicable/No treatment was needed or given

2. If yes, what were the funding sources tapped? ☐ Malasakit Program ☐ PhilHealth ☐ Other funding source: _____

X. 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

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XI. 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 **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

XII. 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

XIII. 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.

XIV. 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)*

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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: _____

Privacy statement

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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.

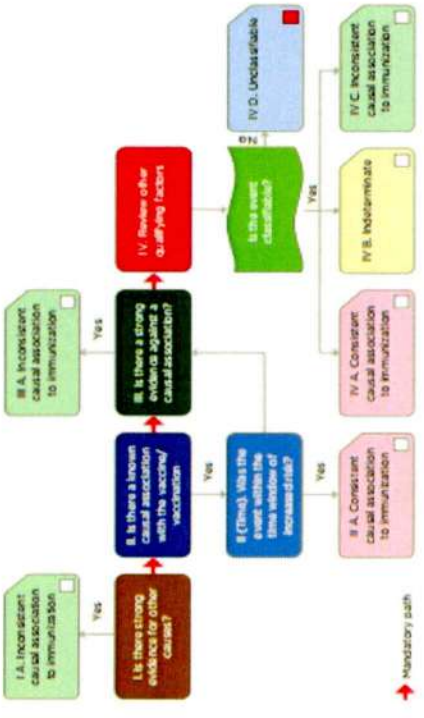
    d. The Epidemiology Bureau shall regularly review the submissions of the RESUs for harmonization and further standardization of the criteria for seriousness of AEFIs.

Appendix 3. Flow of AEFI Surveillance

<table>
<tr><th>Surveillance Cycle Step</th><th>Definition</th><th>Purpose</th><th>Personnel responsible/involved</th></tr>
<tr><td>Detection, Notification</td><td>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</td><td>To recognize and detect AEFI as they occur or when appropriate, to treat or refer patients for treatment</td><td>Vaccine recipient, Parents of immunized infants and children, health care workers, staff in immunization of healthcare facilities</td></tr>
<tr><td>Reporting</td><td>Transmission of information relevant to AEFIs by means of standardized form, telephone call, direct conversation, or specific application</td><td>To provide
key descriptive epidemiological data (time, place and person) that are critical for identifying
clusters and for signal detection</td><td>Vaccine recipient, Parents of immunized infants and children, health care workers, staff in immunization of healthcare facilities</td></tr>
<tr><td>Investigation</td><td>Collection of pertinent details of the patient, vaccine and other drugs potentially received, the event, immunization services</td><td>To establish a more specific case definition (as needed) and formulate a hypothesis to what cause the AEFI</td><td>Healthcare worker who detected the case</td></tr>
<tr><td rowspan="3">Causality Assessment</td><td>Systematic review and evaluation of available data about an adverse event following COVID-19 vaccination</td><td>To determine the likelihood of a causal association between the event(s) and the vaccine received</td><td>Regional and National AEFI Committees</td></tr>
<tr><td colspan="2">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.</td><td>Algorithm (WHO Causality Assessment Manual 2019)
 
</td></tr>
<tr><td colspan="3">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</td></tr>
</table>

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

The following are the guidelines for the use and submission of the Case Investigation Form (version 2) are the following:

1. Upon presentation of an event or condition, the healthcare 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 COVID-19 CIF.

2. The AEFI COVID-19 Vaccine CIF version 2 shall be required to be **completely and accurately filled up** by the reporter, otherwise known as the healthcare professional or corresponding personnel assigned in the disease reporting unit or health facility.
    i. Check if the event is considered as a serious AEFI as defined by the Annex A of DM 2021-0220.
    ii. If confirmed as a non-serious AEFI, only accomplish the first page of the CIF for documentation and reporting. The CIFs for non-serious AEFI cases may be submitted at every end of the week to the respective ESU.
    iii. If assessed to be a serious AEFI, completely fill up all pages of the CIF and follow the next steps for guidance. For all reported serious AEFI cases, regardless if it will undergo investigation or not, the **first to fifth pages** of the CIF shall be filled out by the attending physician and/or corresponding healthcare professional on site.
    iv. Reported cases that shall be investigated and will be subjected to a causality assessment must have **all seven pages** of the CIF completely filled out. *The last two pages, six and seven, of the CIF shall be filled out by the local ESU, local health office, or other investigators that may provide the needed information.* These cases include those that would file for indemnification under the PHIC.
    v. Lastly, if the reporter doubts or cannot provide a definite classification of the AEFI, they may confer with the hospital or their local ESUs.

3. Please answer all the designated fields 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 done 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.

4. For cases detected by a hospital provider, the CIF must initially be reported to the HESU. The Disease Surveillance Officer (DSO) of the hospital shall be required to completely fill up the CIF before submitting to local ESUs. The ESUs may return the CIF when determined that insufficient data was provided in the form. On the other hand, for cases detected by healthcare providers outside of the hospital setting, the CIF must be submitted to their local ESUs.

5. 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 COVID-19 vaccine 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 following hierarchy and criteria:

   i. **Vaccine Injury Compensation** - All cases of individuals with AEFIs referred by PhilHealth for causality assessment, in relation to their Vaccine Injury Benefit Package.

   ii. **Vaccine Confidence**

      1. **Community Concern (Indirect Referral)** - All cases of individuals with AEFIs referred by the Communications Management Unit (CMU) or by the Epidemiology Bureau (EB), as detected from traditional and new media monitoring that may be of potential risk to vaccine confidence.
      2. **Community Concern (Direct Referral)** - All cases of individuals with AEFIs that have been referred by the Epidemiology Bureau (EB), as received from any of the following units (the Epidemiology Bureau, the Regional Epidemiology and Surveillance Unit (RESU), the individual members of NAEFIC, the RAEFIC, the Communications Management Unit (CMU), the Public Health Services Team (PHST), the National/Regional/Local Vaccine Operations Center (N/R/LVOC).

   iii. **Qualitative Signal Detection**

      1. **Serious AEFIs that are AESIs within the Risk Window** - All cases of individuals with serious AEFIs that are classified as an AESI with an onset of illness occurring within the window of risk interval based on the latest vaccine-event combination table approved by the National AEFI Committee.
      2. **Unexpected Serious AEFIs that are non-AESIs with an Acute Onset of Illness** - All cases of individuals with serious AEFIs, that are deemed to be unexpected by the NAEFIC or RAEFIC, with an acute onset of illness (on or before 28 days from the date of vaccination) for the event being assessed.
      3. **RAEFIC-initiated CA** - All cases referred by the RAEFIC that are not in the above definitions but are classified as A1, A2, B1, or B2 by the RAEFIC.

6. For serious AEFI cases, the minimum required or mandatory fields are indicated with asterisks for each section of the 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.

7. The timeline for the submission of the AEFI COVID-19 vaccine CIF shall be based on whether the case has, at the very least, completed the pertinent information needed and as stated, depending on the level of seriousness of the case.

8. The submission of the AEFI COVID-19 vaccine 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 COVID-19 vaccine CIF may be submitted as soon as possible upon completion of the form.

9. Additional forms are found in the appendices. Should the Vaccination Details section found in the first page of the 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.