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

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

HIV infection

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).

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).

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.

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

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 ≥ 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 ≥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 CHO 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 a beneficiary and a 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, Talaq 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/aefici9ph. 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. CABOTAJÉ, 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.

__________________________________________
(Name and Signature)

MD

__________________________________________
(PR C 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

<table>
<thead>
<tr>
<th>Name of Minor</th>
<th>Birthdate</th>
<th>Sex</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
<th>Address</th>
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<table>
<thead>
<tr>
<th>Name of Parent/Guardian</th>
<th>Relationship</th>
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<tbody>
<tr>
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<table>
<thead>
<tr>
<th>Contact Number</th>
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</table>

Vaccination Site: [Blank]

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 trigger. Both myocarditis and pericarditis have the following symptoms: chest pain, shortness of breath, feeling 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 medication 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/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 benefits packages under the Philippine Health Insurance Corporation (PhilHealth). In case the minor 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 reasons:

________________________________________________________

________________________________________________________

Section 3: Minor’s Assent for Vaccination

I ACKNOWLEDGE THAT:

I am being asked to decide if (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 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 parent 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
   https://www.fda.gov/vaccines-blood-biologics/pfizer-biontech-covid-19-vaccine-12-17-years-data-english
2. CDC, September 8, 2021. Information and Frequently Asked Questions COVID-19 Vaccine
# 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**

<table>
<thead>
<tr>
<th>Below 12 years old?</th>
<th>NO</th>
<th>YES</th>
</tr>
</thead>
</table>

| Had a severe allergic reaction to any ingredient of the PFIZER vaccine: mRNA, lipids ((4-hydroxybutyl)azzaazacycloundecane-6, 1-dimethylethyl)-2,2-dimethylcyclohexyl, 1,2-dilauryl-2-(polyethylene glycol) 2000)H-N-dodecyl-1,2-octoxide, 1,2-distearoylsnglycero-3-phosphocholine, and cholesterol, potassium chloride, monobasic potassium phosphate, sodium chloride, disodium phosphate diphosphate, 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 <130 mmHg and/or DBP <80 mmHg? | |  

| Has allergy to food, egg, medicines? Has asthma? | |  

| With SBP >150 mmHg and/or DBP >100 mmHg? | |  

| Has history of bleeding disorders or currently taking anticoagulants? | |  

| If with bleeding history or currently taking anticoagulants, is there a problem securing a gauge 23-25 syringe for injection? | |  

| Manifests any one of the following symptoms? |  
| --- | --- | --- |
| Fever/chills | Fatigue |  
| Headache | Loss of smell/taste |  
| Cough | Nausea/Vomiting |  
| Cold | Myalgia |  
| Sore throat | Rashes |  

| 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 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) |  
| Cancer/ Malignancy (currently undergoing chemotherapy, radiotherapy, immunotherapy, or other treatment) | Under Steroid Medications/ Treatment |  
| Under Steroid Medications/ Treatment | End-stage terminal illness, less than 6 months prognosis |  
| End-stage terminal illness, less than 6 months prognosis | Autoimmune disease |  

### Recipient’s Name:  
---  
### Parent’s/ Legal Guardian’s Name:  
---  
### Birthdate:  
---  
### Signature of Health Worker:  
---  

---

**VACCINATE**

---

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

<table>
<thead>
<tr>
<th>Pangalan ng babakunahan:</th>
<th>Birthdate:</th>
<th>Sex:</th>
</tr>
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<tbody>
<tr>
<td></td>
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</table>

Address:  

<table>
<thead>
<tr>
<th>Pangalan ng magulang/guardian:</th>
<th>Relasyon sa babakunahan:</th>
</tr>
</thead>
<tbody>
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<td></td>
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</table>

Contact Number:  

Vaccination Site:  

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


Ilan sa mga nalalat na side effects ay pananakit, pamumula o pamamaga sa panahon, pagkakapagod, sakit ng ulo, pananakit ng kalamnan, pangginging, pananakit ng kausakawan, tagnant, pagkakabili, pagkakasala, at pamamaga ng kulani. May maalip na pagkakataon magkaraon ng malubhang allergic reaction. Ito ay karaniwang nangyayari ilang minuto hanggang isang oras matapos magpabakuna. Dahil dito, susubaybayan ang nakabakunahan sa vaccination site bago pumwirin para obserbahan ang posibleng pagkakaraon ng anumang tanda ng malubhang allergic reaction tulad ng hirap sa paghinga, pamamaga ng mukha at kalamunan, mabils na pulso, at/o panamumula sa buong katawan. Kasama sa iba pang bihirang side effect ang pansamantalaang paglakad na isang bahagi ng mukha. Gayunpaman, ang mga sintomas na ito ay limbestigahan kung may relasyon sa mtsoong bakuna o wala. Ang imbestigasyon ng mga angkop ng delibhahasa/elksito ay katangian para maunoto kung ang mga sintomas na ito ay dahil sa bakuna o pagkakaon lang.

Sinisubaybayan din ng United States Centers for Disease Control and Prevention (USCD) ang mga ulat tungkol sa myocarditis, o pamamaga ng muscle ng puso, at pericarditis, o pamamaga ng talakap ng puso, matapos magpabakuna upang matukoy kung ito ay may relasyon sa bakuna sa COVID-19. Ang pamamaga ng muscle o talakap ng puso, ay karaniwang bunga ng impexyon. Ilan sa sintomas nito ay panikop ng dibdib, hirap sa paghinga, mabills na pagtibok o pagkakabog ng puso. Lalat ang mga kasong ito (karaniwan 1) sa mga binahayo at kataklakan matapos ang pagpabakuna gamit ang mga mRNA vaccine (tulad ng Pfizer at Moderna). 2) matapos ang ikalawang dosis sa loob ng ilang araw. Karamihan sa nalalat na nakaraon ng myocarditis o pericarditis at nabigyan ng luras ay gumaling din agad.

Gayunpaman, maaaring ang mga pag-aaral at ebidentisyang na ang proteksyon dala sa Pfizer-BioNTech laban sa pagkakasalitang 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 pagpabakuna ng menor de edad

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

Nakatanggap ako ng sahat 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 magtanggang pag-tingat sa paggamit ng Pfizer-BioNTech COVID-19 vaccine. Sa pagpipirma 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 akin/akin na minor-de-edad gamit ang Pfizer BioNTech COVID-19 Vaccine:

**Legda sa Itaas ng Printed Name ng magulang o Legal Guardian / Kinatawan ng Pamahalaan**

__________________________

**Petsa**

Kung tumangging magpabakuna, itatawag ang mga dalaan:

__________________________

__________________________

Section 3: Assent Form para sa babakunahang menor de edad?

**PATUNAY ITO NA:**

__________________________

Hiniling ang desisyon ko (Name)__________________________ (Edad)__________________________

Kung gusto kong makakapagbakuna 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 magtanggang pag-tingat sa paggamit ng Pfizer-BioNTech COVID-19 vaccine. Sa pagpipirma nito at pagbigay ng pahintulot, patunay ito na:

Naintindihan ko ang posibleng peligro ng pagturok
ng bakuna. Bagaman ang karamihan sa side effects ay binayaran at gagaling nang kusa, may malili na pagkakataong magkaroon ng malubhang adverse events tulad ng alerhiya at iba pa. Kahit bihira ang mga malubhang adverse events sa mga talang ulat at pag-aaral, handa ang mga vaccination team para magbigay tunas para dito. Naunawaan ko na maliinaw sa mga pag-aaral at ebidentsya na ang proteksyon ibibigay ng bakuna mula sa pagkakasipit at pagkamatay mula sa malubhang COVID-19 ay mas matimbang sa posibleng peligro nito.

Naunawaan kong maaaring tumigil sa timog-magasa proseso ng pagbakuna nang walang pagtuklas o pagbabalik, at pagbabago sa karampatang medikal na atensyon.

Gusto kong makatanggap ng bakuna sa COVID-19 ngayon.

(Kung sakaling walang kakayahang ang batang menor-de-edad na makapagdesisyon dahil sa sakit tulad ng neurological co-morbidities, intellectual impairment, ang magulang o guardian ay maaaring pumirma sa ngalan ninyo)

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

Petsa

Reference:


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

COVID-19 PEDIATRIC VACCINATION
HEALTH ASSESSMENT ALGORITHM FOR PFIZER
of the Philippine National COVID-19 Vaccine Deployment and Vaccination Program as of October 11, 2021

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

<table>
<thead>
<tr>
<th>NO</th>
<th>YES</th>
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</thead>
<tbody>
<tr>
<td>Age &lt; 12 years old</td>
<td>DO NOT VACCINATE</td>
</tr>
<tr>
<td>Had a severe allergic reaction to any ingredient of the PFIZER vaccine mRNA-LNP ((cetyl trimethylammonium bromide), 1,2-dioleoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sorbitol</td>
<td></td>
</tr>
<tr>
<td>Has a history of exposure to a confirmed COVID-19 case in the past 14 days?</td>
<td></td>
</tr>
<tr>
<td>Has a history of bleeding disorders or currently taking anti-coagulants?</td>
<td></td>
</tr>
<tr>
<td>Symptomatic (Fever/chills, headache, cough, colds, sore throat, malaise, fatigue, weakness, loss of taste or smell, diarrhea, shortness of breath/difficulty in breathing, nausea/vomiting) OR with other symptoms of existing comorbidity</td>
<td></td>
</tr>
<tr>
<td>Have history of exposure to or confirmed COVID-19 case in the past 14 days?</td>
<td></td>
</tr>
<tr>
<td>Have been vaccinated in the past 14 days or plans to receive another vaccine 14 days following vaccination?</td>
<td></td>
</tr>
<tr>
<td>Have been previously diagnosed for COVID-19 AND is still undergoing treatment/recovery?</td>
<td></td>
</tr>
<tr>
<td>Have received convalescent plasma or monoclonal antibodies for COVID-19 in the past 90 days?</td>
<td></td>
</tr>
<tr>
<td>Pregnant and in first trimester of pregnancy?</td>
<td></td>
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</tbody>
</table>

**SPECIAL PRECAUTION**

<table>
<thead>
<tr>
<th>NO</th>
<th>YES</th>
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<tbody>
<tr>
<td>With allergy to food, egg, medicine, and/or with asthma?</td>
<td>OBSERVE FOR 30 MINS</td>
</tr>
<tr>
<td>Using GAUGE 22-25, APPLY BLOOD PRESSURE</td>
<td></td>
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</tbody>
</table>

**REFER**

<table>
<thead>
<tr>
<th>NO</th>
<th>YES</th>
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<tbody>
<tr>
<td>With SBP ≥160 and/or DBP ≥100 AND with signs and symptoms of organ damage, headache, blurred vision, confusion, seizure, chest pain, shortness of breath?</td>
<td>RESCHEDULE UNTIL FULL RECOVERY FROM ILLNESS AND 90 DAYS AFTER DIAGNOSIS</td>
</tr>
<tr>
<td>With SBP ≥160 and/or DBP ≥100 WITHOUT signs and symptoms of organ damage, headache, blurred vision, confusion, seizure, chest pain, shortness of breath?</td>
<td>REFER TO MD AND BRING TO ER</td>
</tr>
</tbody>
</table>

**REFER TO MD**

<table>
<thead>
<tr>
<th>NO</th>
<th>YES</th>
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<tbody>
<tr>
<td>Symptomatic (Fever/chills, headache, cough, colds, sore throat, malaise, fatigue, weakness, loss of taste or smell, diarrhea, shortness of breath/difficulty in breathing, nausea/vomiting) OR with other symptoms of existing comorbidity</td>
<td>RESCHEDULE AFTER FULL RECOVERY</td>
</tr>
<tr>
<td>Have history of exposure to confirmed or suspected COVID-19 case in the past 14 days?</td>
<td>RESCHEDULE AFTER COMPLETION OF 14-DAY QUARANTINE</td>
</tr>
<tr>
<td>Have been vaccinated in the past 14 days or plans to receive another vaccine 14 days following vaccination?</td>
<td>RESCHEDULE AFTER 14-DAY INTERVAL FROM OTHER VACCINE</td>
</tr>
<tr>
<td>Have been previously diagnosed for COVID-19 AND is still undergoing treatment/recovery?</td>
<td>RESCHEDULE AFTER RECOVERY OR TREATMENT COMPLETION</td>
</tr>
<tr>
<td>Have received convalescent plasma or monoclonal antibodies for COVID-19 in the past 90 days?</td>
<td>RESCHEDULE AFTER 90 DAYS</td>
</tr>
<tr>
<td>Pregnant and in first trimester of pregnancy?</td>
<td>RESCHEDULE IF IN FIRST TRIMESTER</td>
</tr>
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</table>

**GET CLEARANCE FROM ATTENDING PEDIATRICIAN/PHYSICIAN**

**RESCHEDULE AFTER FULL RECOVERY**

<table>
<thead>
<tr>
<th>NO</th>
<th>YES</th>
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<tbody>
<tr>
<td>Symptomatic (Fever/chills, headache, cough, colds, sore throat, malaise, fatigue, weakness, loss of taste or smell, diarrhea, shortness of breath/difficulty in breathing, nausea/vomiting) OR with other symptoms of existing comorbidity</td>
<td>RESCHEDULE AFTER FULL RECOVERY</td>
</tr>
<tr>
<td>Have history of exposure to confirmed or suspected COVID-19 case in the past 14 days?</td>
<td>RESCHEDULE AFTER COMPLETION OF 14-DAY QUARANTINE</td>
</tr>
<tr>
<td>Have been vaccinated in the past 14 days or plans to receive another vaccine 14 days following vaccination?</td>
<td>RESCHEDULE AFTER 14-DAY INTERVAL FROM OTHER VACCINE</td>
</tr>
<tr>
<td>Have been previously diagnosed for COVID-19 AND is still undergoing treatment/recovery?</td>
<td>RESCHEDULE AFTER RECOVERY OR TREATMENT COMPLETION</td>
</tr>
<tr>
<td>Have received convalescent plasma or monoclonal antibodies for COVID-19 in the past 90 days?</td>
<td>RESCHEDULE AFTER 90 DAYS</td>
</tr>
<tr>
<td>Pregnant and in first trimester of pregnancy?</td>
<td>RESCHEDULE IF IN FIRST TRIMESTER</td>
</tr>
</tbody>
</table>

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**VACCINATE**

<table>
<thead>
<tr>
<th>NO</th>
<th>YES</th>
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<td>NO</td>
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<td>NO</td>
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<td>NO</td>
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<td>NO</td>
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</tbody>
</table>

---

*By signing the health declaration, all parents assume their child does not have a contraindication to receive the COVID-19 Vaccine.*
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

<table>
<thead>
<tr>
<th>ASSESS THE PATIENT</th>
<th>NO</th>
<th>YES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Below 12 years old?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Had a severe allergic reaction to any ingredient of the PFIZER vaccine: mRNA, lipids (1,2-distearoyl-sn-glycero-3-phosphocholine, 1,2-distearoyl-sn-glycero-3-phosphoethanolamine, 1,2-distearoyl-sn-glycero-diacylglycerol, dimyristoyl phosphatidylcholine, cholesterol, palmitoleic sodium phosphate, sodium chloride, and sucrose)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has severe allergic reaction or an autoimmune reaction (e.g., Vaccine-Induced Thrombotic Thrombocytopenia) after the 1st dose of the PFIZER vaccine?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>With SBP &gt;160 mmHg and/or DBP &gt;100 mmHg?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has allergy to food, egg, medicines, asthma?</td>
<td></td>
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<tr>
<td>Has allergy or asthma, will monitoring the patient for 30 minutes be a problem?</td>
<td></td>
<td></td>
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<tr>
<td>Has history of bleeding disorders or currently taking anti-coagulants?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If with bleeding history or currently taking anti-coagulants, is there a problem securing a gauge 23-25 syringe for injection?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Had a history of myocarditis or pericarditis OR developed myocarditis/pericarditis after a dose of mRNA vaccine?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manifests any one of the following symptoms?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever/chills</td>
<td>Fatigue</td>
<td></td>
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<tr>
<td>Headache</td>
<td>Weakness</td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td>Less of saliva</td>
<td></td>
</tr>
<tr>
<td>Odia</td>
<td>Diarrhea</td>
<td></td>
</tr>
<tr>
<td>Sore throat</td>
<td>Shortness of breath/difficulty in breathing</td>
<td></td>
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<tr>
<td>Myalgia</td>
<td>Rash</td>
<td></td>
</tr>
<tr>
<td>Rash</td>
<td>Other symptoms of existing comorbidity</td>
<td></td>
</tr>
<tr>
<td>Has history of exposure to a confirmed or suspected COVID-19 case in the past 14 days?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If previously diagnosed with COVID-19, is recipient STILL undergoing recovery or treatment?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has received any vaccine in the past 14 days or plans plan to receive another vaccine 14 days following vaccination?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has previously received one or two dose of a COVID-19 vaccine?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has received convalescent plasma or monoclonal antibodies for COVID-19 in the past 90 days?</td>
<td></td>
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<tr>
<td>Pregnancy?</td>
<td></td>
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<tr>
<td>If pregnant, are you in the 1st trimester?</td>
<td></td>
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<tr>
<td>Has any of the following diseases or health condition?</td>
<td></td>
<td></td>
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<tr>
<td>HIV</td>
<td></td>
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<tr>
<td>Cancer/ Malignancy (currently undergoing chemotherapy, radiotherapy, immunotherapy, or other treatment)</td>
<td></td>
<td></td>
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<tr>
<td>Underwent Transplant</td>
<td></td>
<td></td>
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<tr>
<td>Under Steroid Medication / Treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bedridden, terminal illness, less than 6 months prognosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Autoimmune disease</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Recipient's Name:  
Parent's/ Legal Guardian's Name:  
Birthdate:  
Signature of Health Worker:  

If any of the non-grey 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)


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) Reporting System for Vaccination Sites, including Private Sector - Managed Vaccination Sites

*All issuances and associated references are available at bit.ly/aelfc19ph*
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.

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

LOW RISK

PROCEED WITH VACCINATION
Observe for at least 30 minutes

1. NON-ANAPHYLACTIC allergy to oral medications (including the oral equivalent of an injectable medication)
2. NON-ANAPHYLACTIC allergy to food, pet, insect venom, environmental, latex, etc.
3. DELAYED LOCAL reactions (e.g., contact dermatitis) to OTHER vaccines
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 benefits and risks with attending physician)
7. Autoimmune disease and Cancer - (after discussing benefits and risks with attending physician)
8. Family history of allergies

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 or unclear allergen/etiology
2. Uncontrolled asthma (discuss with a qualified specialist: adequate attack-free period+)
3. Mast cell disorder (discuss with a qualified specialist for evaluation)
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
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 (e.g., wheezing, stridor), or ANAPHYLAXIS) to a component of the mRNA vaccine (e.g., PEG)

1. ANAPHYLAXIS to oral medications, food, latex, environmental, or insect venom or unclear allergen/etiology
2. Uncontrolled asthma (discuss with a qualified specialist: adequate attack-free period+)
3. Mast cell disorder (discuss with a qualified specialist for evaluation)
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
5. History of myocarditis, pericarditis and other cardiac conditions

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

www.psaai.org

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*References*

1. Global Initiative for Asthma (GINA) Guidelines at https://GINAasthma.org
2. Philippine Society of Allergy, Asthma, and Immunology (PSAAI) on COVID-19 Vaccines and their Adverse Reactions
3. www.psaai.org

---

*Notes*

1. IMMEDIATE (within 6 hours) ALLERGIC reaction of any severity (urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or ANAPHYLAXIS) to a component of the mRNA vaccine (e.g., PEG)
### 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**

<table>
<thead>
<tr>
<th>SYMPTOMS / SIGNS AFTER FIRST DOSE</th>
<th>RECOMMENDATION FOR SECOND DOSE</th>
<th>SYMPTOMS / SIGNS AFTER FIRST DOSE</th>
<th>RECOMMENDATION FOR SECOND DOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. No cutaneous or systemic symptoms after the first dose</td>
<td>Proceed with second dose at recommended interval</td>
<td>6. Other DELAYED adverse reactions after the first dose (eg, delayed cutaneous reactions, thrombosis, purpura, thrombocytopenia, etc)</td>
<td>Refer to qualified specialist prior to the second dose</td>
</tr>
<tr>
<td>2. LOCAL reaction (eg, erythema, induration, pruritus, painful rash) around the injection site a few hours through the second week after the first dose</td>
<td>Proceed with second dose at recommended interval</td>
<td>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)</td>
<td>Review the history of atopy and other risk factors and refer to a qualified specialist before the second dose</td>
</tr>
<tr>
<td>3. REACTOGENIC reactions (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)</td>
<td>Proceed with second dose at recommended interval</td>
<td>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)</td>
<td>Review the history of atopy and other risk factors and refer to a qualified specialist before the second dose</td>
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<tr>
<td>4. VASOVAGAL reactions 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)</td>
<td>Proceed with second dose at recommended interval</td>
<td>8. IMMEDIATE SEVERE allergic symptoms within the first 6 hours after the first dose such as ANAPHYLAXIS or OTHER SERIOUS adverse reactions as MYOCARDITIS</td>
<td>Should NOT proceed with second dose</td>
</tr>
<tr>
<td>5. Other DELAYED adverse reactions after the first dose (eg, delayed cutaneous reactions, thrombosis, purpura, thrombocytopenia, etc)</td>
<td>Proceed with second dose at recommended interval</td>
<td>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)</td>
<td>Review the history of atopy and other risk factors and refer to a qualified specialist before the second dose</td>
</tr>
</tbody>
</table>

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

[www.psaai.org](http://www.psaai.org)
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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Marysia Stella T. Recto, MD

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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Philippine Society of Allergy, Asthma and Immunology, Inc. August 5, 2021
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>
<thead>
<tr>
<th>Vaccine Brand</th>
<th>Vaccine Type</th>
<th>Excipients</th>
<th>Adverse Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoronaVac (Sinovac)</td>
<td>Inactivated virus</td>
<td>Aluminum hydroxide, disodium hydrogen phosphate, sodium dihydrogen phosphate, sodium chloride, sodium hydrate and water</td>
<td>Injection site pain, pruritus, erythema, swelling and induration, chills, fever, fatigue, myalgia, diarrhoea, 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. Top reported adverse reactions in the Philippines are blood pressure increase (41.25%), 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%).</td>
</tr>
<tr>
<td>Bharat Biotech</td>
<td>Whole virus</td>
<td>Aluminum hydroxide gel, TLR 7/8 agonist, 2-phenoxethanol, phosphate buffered saline</td>
<td>Injection site pain, headache, fever, body ache, abdominal pain, nausea, vomiting, no serious AE reported</td>
</tr>
<tr>
<td>ChAdOx1 nCoV-19-</td>
<td>Viral vector</td>
<td>L-histidine, L-histidine, hydrochloride monohydrate, Magnesium chloride hexahydrate, Polysorbate 80, Ethanol, Sucrose, Sodium chloride, Disodium edetate dihydrate</td>
<td>Injection site tenderness and pain, headache, fatigue, myalgia, malaise, pyrexia, chills, arthralgia and nausea Locally, there have been 573 reported severe allergic reactions. 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 (6.33%). Thrombosis with Thrombocytopenia Syndrome: UK data—four cases per million adults (1 case per 250 000)</td>
</tr>
</tbody>
</table>

Philippine Society of Allergy, Asthma and Immunology, Inc. August 5, 2021
<table>
<thead>
<tr>
<th>Vaccine Brand</th>
<th>Vaccine Type</th>
<th>Excipients</th>
<th>Adverse Reaction</th>
</tr>
</thead>
</table>
| Janssen         | Viral vector        | Citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-
|                 |                     | - cyclohexetrin (HBCD), polysorbate-80, sodium chloride                     | Injection site pain, redness of the skin and swelling, headache, fatigue, myalgia, nausea, and fever.                                             |
|                 |                     | Note: vial stopper not made with natural rubber latex                        | Locally, there have been 1 reported severe allergic reaction.                                                                                   |
|                 |                     |                                                                             | Top reported adverse reactions in the Philippines are blood pressure increase (30.00%), pyrexia (29.69%), headache (23.44%), myalgia (14.06%), arthralgia (12.50%), dizziness (10.94%), malaise (10.94%), chills (9.39%), vaccination/injection site pain (7.81%), pain (6.25%), chest pain (4.69%), vomiting (4.69%). |
|                 |                     |                                                                             | 1 case of anaphylaxis in an ongoing open-label study in South Africa (total participants = 4984)                                               |
| BNT162b2/      | mRNA                | Lipids ((4-hydroxybutyl) azanediyl)bis(hexane-6,1-diyl)bis(2-hexanecanoate), 2
| Tozinameran/    |                     | [(polyethylene glycol)-2000]-N. N-ditetradecylacetamide, 1,2-
| Comirnaty       |                     | -diacylglycerol-3-phosphocholine, Cholesterol, Potassium chloride, Monobasic
<p>| (Pfizer/        |                     | potassium phosphate, Dibasic sodium phosphate dihydrate, and Sucrose         | Injection site pain, 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 |
| BioNTech)       |                     | Note: non-latex vial stopper                                                | Toxinameran/Comirnaty (Pfizer/BioNTech) locally, there have been 80 reported severe anergic reactions. Top reported adverse reactions in the Philippines are blood pressure increase (33.33%), pyrexia (19.44%), headache (13.89%), dizziness (6.52%), cough (7.45%), rash (7.23%), malaise (7.17%), dyspnea (4.87%), chills (4.31%). |
|                 |                     |                                                                             | Delayed local hypersensitivity reactions; morbilliform rashes, Filler reactions (for those w/ history of injection with dermal filters) |
|                 |                     |                                                                             | 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 &amp; 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 a history of myocarditis or pericarditis should take into account the individual's clinical circumstances. |</p>
<table>
<thead>
<tr>
<th>Vaccine Brand</th>
<th>Vaccine Type</th>
<th>Excipients</th>
<th>Adverse Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>mRNA-1273 (Moderna)</td>
<td>mRNA</td>
<td>Lipids [SM-102, Polyethylene glycol (PEG) 2000, Dimyristoyl glycerol (DMG)], Cholesterol, 1,2-distearyl-sn-glycerol-3-phosphocholine (DSPC)], Tromethamine, Tromethamine hydrochloride, Acetic acid, Sodium acetate, and Sucrose. Note: non-latex vial stopper</td>
<td>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</td>
</tr>
<tr>
<td>Gam-COVID-Vac (Sputnik V)</td>
<td>Non-replicating two-component vector (adenovirus) rAd type 26 and rAd type 5</td>
<td>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)</td>
<td>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. 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%). 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)</td>
</tr>
</tbody>
</table>


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

Data source: *VigiFlow, NVOC daily report as 6PM, 25 July 2021
Notes: Additional information may become available in individual cases which may change the figures presented
1 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
2 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.

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.

Philippine Society of Allergy, Asthma and Immunology, Inc. August 5, 2021 10
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 $\geq (2 + 1.2 \times \text{baseline tryptase levels})$ 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 VACCINE:

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 VACCINE:

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**

<table>
<thead>
<tr>
<th>LOW RISK</th>
<th>MODERATE RISK</th>
<th>HIGH RISK</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PROCEED WITH VACCINATION</strong></td>
<td><strong>PRECAUTION TO VACCINATION</strong></td>
<td><strong>CONTRAINdICATION TO VACCINATION</strong></td>
</tr>
<tr>
<td>Observe for at least 30 minutes</td>
<td>Refer to a qualified specialist Observe for at least 30 minutes in a setting fully equipped to manage severe adverse reactions</td>
<td>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 vaccine¹ (e.g., PEG in mRNA vaccine, polysorbate in Janssen and AstraZeneca, aluminum hydroxide in Coronavac/Sinovac)</td>
</tr>
</tbody>
</table>

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.⁴**
3. DELAYED LOCAL reactions (e.g., contact dermatitis) to OTHER vaccines³
4. **REACTOGENIC reactions, LOCAL (e.g., pain, redness, swelling on injection site) or SYSTEMIC (e.g., fever, chills, headache, malaise) to OTHER vaccines**³
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 allergies¹

¹ Global Initiative For Asthma (GINA) Guidelines at https://ginasthma.org/gina-reports/
² https://www.cdc.gov/vaccines/covid-19/info-by-product/c19-clinical-considerations.html#Appendix-B
³ https://education.anaai.org/resources-for-c19-clinicians/reactionguidance-COVID-19
## ASSESSMENT OF RISK FOR ALLERGIC REACTION TO THE SECOND DOSE OF COVID-19 VACCINE

August 5, 2021

### SYMPTOMS/ SIGNS AFTER FIRST DOSE

<table>
<thead>
<tr>
<th>SYMPTOMS/ SIGNS AFTER FIRST DOSE</th>
<th>RECOMMENDATION FOR SECOND DOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. No cutaneous or systemic symptoms after the first dose</td>
<td>• Proceed with second dose at recommended interval</td>
</tr>
<tr>
<td>2. LOCAL reaction (e.g., erythema, induration, pruritus, painful rash) around the injection site a few hours through the second week after the first dose&lt;sup&gt;a&lt;/sup&gt;</td>
<td>• Proceed with second dose at recommended interval</td>
</tr>
<tr>
<td>3. REACTOGENIC reactions&lt;sup&gt;d&lt;/sup&gt; (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)</td>
<td>• Proceed with second dose at recommended interval</td>
</tr>
<tr>
<td>4. VASOVAGAL reactions&lt;sup&gt;a&lt;/sup&gt; 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]</td>
<td>• Proceed with second dose at recommended interval</td>
</tr>
<tr>
<td>5. Other DELAYED adverse reactions after the first dose (e.g., delayed cutaneous reactions, thrombosis, purpura, thrombocytopenia, etc.)</td>
<td>• Refer to qualified specialist prior to the second dose</td>
</tr>
<tr>
<td>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)</td>
<td>• Review the history of atopy and other risk factors and refer to a qualified specialist before the second dose</td>
</tr>
<tr>
<td>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)</td>
<td>• Review the history of atopy and other risk factors and refer to a qualified specialist before the second dose</td>
</tr>
<tr>
<td>8. IMMEDIATE SEVERE allergic symptoms within the first 6 hours after the first dose such as ANAPHYLAXIS&lt;sup&gt;b&lt;/sup&gt;, or serious adverse reactions as thrombotic thrombocytopenic syndrome, myocarditis and pericarditis</td>
<td>• Should NOT proceed with second dose</td>
</tr>
</tbody>
</table>


<sup>ab</sup> [https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications)


<sup>d</sup> [https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-D](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-D)
REFERENCES:


• Fact Sheet for Health Care Providers Emergency Use Authorization of CoronaVac.


• Allergy and Asthma Network COVID-19 vaccine reported allergic reactions. Available from: https://allergyasthmanetwork.org/news/statement-on-covid-vaccine


• Phadia AB. ImmunoCAP Tryptase. Available from: https://dfu.phadia.com/Data/Pdf/56cb2b6a89c23251d0d2c1de.pdf


• American Society of Hematology. Thrombosis with Thrombocytopenia Syndrome (also termed Vaccine-Induced Immune Thrombotic Thrombocytopenia). 29 April 2021. Available from: https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia


APPENDIX A

DIAGNOSIS & MANAGEMENT OF SEVERE ALLERGIC REACTIONS AFTER COVID-19 VACCINATION

VACCINATION
Observe for at least 30 minutes

If patient develops the following SYMPTOMS:

- Swelling of lips or tongue
- Facial edema
- Difficulty in breathing
- Hypertension

AND

If isolated & not progressing

- Antihistamines (oral/IV)
- Glucocorticoids (oral/IV)
Observation 4 hours

If symptoms persist

- Intramuscularly

URGENTLY

Put the patient in a reclining position with legs up

ADMINISTER EPINEPHRINE (ADRENALINE)

- 0.3 mg in auto-injector
- Intramuscularly only

- 0.3 mg in auto-injector
- Intramuscularly only
- Mid-dorsal thigh even through clothing

THEN

- Secure IV access & start infusion with 0.9% NaCl (20-200 ml/hr)
- Clear the airway
- Administer OXYGEN via face mask (at least 10 LPM)
- Administer GLUCOCORTICOIDS (hydrocortisone 200 mg IV)
- Administer ANTIHISTAMINES (e.g., Diphenhydramine 50 mg IV)
- Monitor vital signs

*The elderly, infants, and young people must be especially treated with caution.

IF Not resolved
Call emergency assistance depending on your location

IF Blood pressure drops

- 200-300 ml of 0.9% NaCl
- Intravenous
- In 10-20 minutes

- REPEAT EPINEPHRINE INTRAMUSCULARLY

IF No improvement

- Salbutamol MDI
- + 10 puffs via large volume spacer

IF Branchiospasm

- Salbutamol MDI
- + 10 puffs via large volume spacer

IF symptoms are fully resolved
Discharge after 24 hours

IF symptoms continue
Transfer to ICU

ADVISE AGAINST second planned SARS-CoV2 vaccination until cleared by Allergy Service


 Philippine Society of Allergy, Asthma and Immunology, Inc. August 5, 2021 24
## APPENDIX B

### WORLD ALLERGY ORGANIZATION (WAO) Systemic Allergic Reaction Grading System

<table>
<thead>
<tr>
<th>NOT ANAPHYLAXIS</th>
<th>ANAPHYLAXIS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GRADE 1</strong></td>
<td><strong>GRADE 2</strong></td>
</tr>
<tr>
<td>Symptoms(s)/sign(s) from 1 organ system present</td>
<td>Symptoms(s)/sign(s) from &gt;/=2 organ system present</td>
</tr>
<tr>
<td><strong>CUTANEOUS</strong></td>
<td><strong>Lower AIRWAY</strong></td>
</tr>
<tr>
<td>Urticaria and/or erythema-warmth and/or pruritus, other than localized at the injection site AND/OR</td>
<td>AND/OR</td>
</tr>
<tr>
<td>Tingling, or itching of the lips * or Angioedema (not laryngeal)* OR UPPER RESPIRATORY</td>
<td>Abdominal cramps* and/or vomiting/diarrhea</td>
</tr>
<tr>
<td>Nasal symptoms (e.g., sneezing, rhinorrhea, nasal pruritus, and/or nasal congestion) AND/OR</td>
<td>Uterine cramps</td>
</tr>
<tr>
<td>Throat-clearing (itchy throat)* AND/OR</td>
<td>Any symptoms(s)/sign(s) from grade 1 would be included</td>
</tr>
<tr>
<td>Cough not related to bronchospasm OR CONJUNCTIVAL</td>
<td></td>
</tr>
<tr>
<td>Erythema, pruritus, or tearing OR OTHER</td>
<td></td>
</tr>
<tr>
<td>Nausea Metalic taste</td>
<td></td>
</tr>
</tbody>
</table>

---

* 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.

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Philippine Society of Allergy, Asthma and Immunology, Inc. August 5, 2021 25
Annex E. Diagnosis and Management of Severe Allergic Reactions

**DIAGNOSIS & MANAGEMENT OF SEVERE ALLERGIC REACTIONS AFTER COVID-19 VACCINATION**

**DIAGNOSIS & MANAGEMENT OF SEVERE ALLERGIC REACTIONS AFTER COVID-19 VACCINATION**

**VACCINATION**

Observe for at least 30 minutes

If patient develops the following SYMPTOMS:

- Swollen face
- Generalized pruritus
- Generalized flushing
- Tachypnea

**AND**

- Shortness of breath
- Wheezing
- Stridor
- Syncope
- Incontinence
- Blood pressure drop
- Swollen legs
- Crampy abdominal pain
- Vomiting
- Dermatitis

Only

If isolated & not progressing

- Antihistamines
- Oral
- Intramuscularly
- Observation 4 hours

- Glucocorticoids
- Oral
- Intramuscularly
- Observation 4 hours

**URGENTLY**

Put the patient in a reclining position with legs up

- **ADMINISTER EPINEPHRINE (ADRENALINE)**
  - 0.5 ml per dose
  - From 1 ml/ml ampule
  - **INTRAMUSCULARLY ONLY** (not for IV use)
  - mid-upper thigh even through clothing
  - **OR**
  - 0.3 mg in auto-injector
  - **INTRAMUSCULARLY ONLY**
  - mid-upper thigh even through clothing

Then

- Secure IV access & start infusion with 0.9% NaCl (10-20 ml/min)
- Clear the airway
- **ADMINISTER OXYGEN** via face mask (at least 10 LPM)
- **ADMINISTER DILUVOCORTICOID** (hydrocortisone 200 mg IV)
- **ADMINISTER ANTIHISTAMINE** (e.g., Diphenhydramine 50 mg IV)
- **Monitor vital signs**
- [For elderly patients with bony arterial hypertension or dementia, add second-generation antihistamine or a prophylactic dopamine antagonist, or both, if needed]

Not resolved

Call emergency assistance depending on your location

Blood pressure drops

- **2000-3000 ml of 0.9% NaCl intravenously in 10-20 minutes**

No improvement in 5-10 minutes

- **REPEAT EPINEPHRINE INTRAMUSCULARLY**

If symptoms are fully resolved, discharge after 24 hours

Bronchospasm

- **Salbutamol MDI**
- 4-10 puffs via large volume spacer

If symptoms continue, transfer to ICU

ADVISE AGAINST second planned SARS-CoV2 vaccination until cleared by Allergy Service

Adapted from: Sukhdeva ML et al. EAACI, emphasis on the diagnosis, management and prevention of severe allergic reactions to COVID-19 vaccines. Allergy. Jan 10, 2021

[www.psaol.org](http://www.psaol.org)  [@PSAAIAllergy](http://@PSAAIAllergy)
**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

<table>
<thead>
<tr>
<th>Symptom / Sign</th>
<th>Recommendation for Second Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. No cutaneous or systemic symptoms after the first dose</td>
<td>Proceed with second dose at recommended interval</td>
</tr>
<tr>
<td>2. Red, itchy, swollen, or painful rash where they got the first COVID vaccine shot or “COVID arm”</td>
<td>Proceed with second dose at the opposite arm</td>
</tr>
<tr>
<td>3. Delayed-onset LOCAL reaction (eg, erythema, induration, prurius) around the injection site a few days through the second week after the first dose</td>
<td>Proceed with second dose at recommended interval</td>
</tr>
<tr>
<td>4. Mild delayed cutaneous generalized reaction (eg, maculopapular exanthems, allergic contact dermatitis)</td>
<td>Proceed with second dose at recommended interval</td>
</tr>
<tr>
<td>5. REACTOGENIC reactions’ (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)</td>
<td>Proceed with second dose at recommended interval</td>
</tr>
<tr>
<td>6. VASOVAGAL reactions’ 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)</td>
<td>Proceed with second dose at recommended interval</td>
</tr>
<tr>
<td>7. Hypertension alone within 6 hours after the first dose</td>
<td>Refer to a qualified specialist for clearance prior to the second dose</td>
</tr>
<tr>
<td>8. IMMEDIATE onset allergic symptoms within the first 6 hours after first dose that are SEVERE (eg, respiratory distress, laryngeal edema, anaphylaxis)</td>
<td>Should NOT proceed with second dose</td>
</tr>
<tr>
<td>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.)</td>
<td>Should NOT proceed with second dose</td>
</tr>
<tr>
<td>10. Other SEVERE adverse reactions, whether IMMEDIATE within 6 hours after first dose or DELAYED (eg, thrombosis, purpura, etc)</td>
<td>Refer to appropriate qualified specialist for clearance prior to the second dose</td>
</tr>
</tbody>
</table>

*Sources:*

4. [https://www.psaai.org](https://www.psaai.org)

---

**Position Statements of the Philippine Society of Allergy, Asthma, and Immunology on COVID-19 Vaccines and their Adverse Reactions**  
March 19, 2021 | www.psaai.org
# 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

<table>
<thead>
<tr>
<th>Proceed with Vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observe for at least 30 minutes</td>
</tr>
</tbody>
</table>

1. **Non-anaphylactic allergy to oral medications** (including the oral equivalent of an injectable medication)
2. **Non-anaphylactic allergy to food, pet, insect venom, environmental, latex, etc.**
3. **Delayed local reactions** (e.g., contact dermatitis) to **other vaccines**
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 - (after discussing efficacy with attending physician)
8. Family history of allergies

## Moderate Risk

<table>
<thead>
<tr>
<th>Precaution to Vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refer to a qualified specialist. Observe for at least 30 minutes in a hospital setting</td>
</tr>
</tbody>
</table>

1. **Anaphylaxis to oral medications, food, latex, environmental, or insect venom** or **unclear allergen/etiology**
2. Uncontrolled asthma (discuss with a qualified specialist adequate attack-free period)
3. Mast cell disorder (discuss with a qualified specialist for evaluation)
4. **Immediate (within 6 hours) allergic reaction of any severity** (urticaria, angioedema, respiratory distress, etc.) or **anaphylaxis**
   a. To **unrecalled vaccines or injectable therapies** (only if evaluated by allergist)
   b. To **other vaccines or injectable therapies with components NOT found in COVID vaccines**

## High Risk

<table>
<thead>
<tr>
<th>Contraindication to Vaccination</th>
</tr>
</thead>
</table>
| Immediate (within 6 hours) **allergic reaction of any severity** (urticaria, angioedema, respiratory distress, etc.) or **anaphylaxis** to a component of the COVID-19 vaccine** (e.g., PEG in mRNA vaccine, polysorbate in Janssen and AstraZeneca, aluminium hydroxide in Coronavac/Sinovac)

---

* Global Initiative for Asthma (GINA). Guidelines at https://GINAstatement.org/gina-reports/  
  1. https://www.cdc.gov/vaccines/vac掬/19/who-provided-a-clinical-considerations.html-AppenudesB  
  2. https://GINA_statement.org/resources-for-clinicians/needs_benefits_COVID-19  

Position Statements of the Philippine Society of Allergy, Asthma, and Immunology on COVID-19 Vaccines and their Adverse Reactions  
March 19, 2021 | www.pscai.org
Annex F. Details and quantities of items needed for AEFI/AESI Kits

AEFI kit components on vaccinate site per team (replenished prior to vaccination runs)

<table>
<thead>
<tr>
<th>Diagnostic Equipment</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>BP apparatus with appropriate cuffs depending on age-groups vaccinated</td>
<td>1 set</td>
</tr>
<tr>
<td>Stethoscope</td>
<td>1 set</td>
</tr>
<tr>
<td>Pulse oximeter</td>
<td>1 unit</td>
</tr>
<tr>
<td>Pen light</td>
<td>1 set</td>
</tr>
<tr>
<td>Thermometer digital</td>
<td>1 set</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Managements</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>IV Catheter, with appropriate gauges depending on age-groups to be vaccinated</td>
<td>1 set</td>
</tr>
<tr>
<td>Intravenous tubing, with appropriate gauges depending on age-groups to be vaccinated</td>
<td>1 set</td>
</tr>
<tr>
<td>Oxygen tubing with face mask, with appropriate sizes depending on age-groups to be vaccinated</td>
<td>1 set</td>
</tr>
<tr>
<td>1mL syringe with disposable syringe gauges (26G, 25G, 23G)</td>
<td>2 set each</td>
</tr>
<tr>
<td>Oxygen tank available on-site</td>
<td>as determined</td>
</tr>
<tr>
<td>Tourniquet</td>
<td>1 set</td>
</tr>
<tr>
<td>Cotton and wool</td>
<td>1 set</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Oral Drugs</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Antihistamine (Cetirizine 10 mg)</td>
<td>10 tabs</td>
</tr>
<tr>
<td>Glucocorticoids (Prednisone)</td>
<td></td>
</tr>
<tr>
<td>NSAIDs (Paracetamol 500mg)</td>
<td>10 tabs</td>
</tr>
</tbody>
</table>
**Oral rehydration salts** | 1 bottle / at least 2 powdered sachets
---|---
**Antiemetics** | At least 1 vial
**Muscle relaxant/sedative, (Diazepam 5mg/mL) if with capacity to procure** | At least 1 vial

### Non-Oral Drugs

<table>
<thead>
<tr>
<th>Drug</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection epinephrine (1:1000) solution</td>
<td>At least 3 ampules</td>
</tr>
<tr>
<td>Injection hydrocortisone (100mg)</td>
<td>At least 3 vials</td>
</tr>
<tr>
<td>Diphenhydramine in IV form (50mg/mL)</td>
<td>At least 3 vials</td>
</tr>
<tr>
<td>Salbutamol-metered dose inhaler</td>
<td>1 unit</td>
</tr>
<tr>
<td>Plain Normal Saline Solution (0.9%)</td>
<td>1 to 2 units each</td>
</tr>
<tr>
<td>IV fluids (5% Dextrose)</td>
<td></td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th>Drug site and route of administration</th>
<th>Frequency of administration</th>
<th>Dose (Adult)</th>
<th>Dose (Child)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adrenaline (epinephrine) 1:1000, 1M to the midpoint of the anterolateral aspect of the middle third of the thigh immediately</td>
<td>Repeat in every 5-15 min as needed until there is resolution of the anaphylaxis.</td>
<td>0.5 mL</td>
<td>According to age; &lt;1 years: 0.05 mL; 2-6 years: 0.15 mL; 6-12 years: 0.3 mL; &gt;12 years: 0.5 mL</td>
</tr>
</tbody>
</table>

Note: Persisting or worsening cough associated with pulmonary edema is an important sign of adrenaline overdose and toxicity.

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

### CDC Working Case Definitions

#### Probable Case
- Presence of ≥ 1 new or worsening of the following clinical symptoms
  - chest pain/pressure/discomfort
  - dyspnea/shortness of breath
  - palpitations
  - syncpexe
  - AND ≥ 1 new finding of
    - elevated troponin above upper limit of normal
    - abnormal ECG or rhythm monitoring findings consistent with myocarditis
    - abnormal cardiac function or wall motion abnormalities on echocardiogram
    - cardiac MRI findings consistent with myocarditis
    - AND no other identifiable cause of the symptoms and findings

#### Confirmed Case
- Presence of ≥ 1 new or worsening of the following clinical symptoms
  - chest pain/pressure/discomfort
  - dyspnea/shortness of breath
  - palpitations
  - syncpexe
  - AND
  - histopathologic confirmation of myocarditis
  - OR
  - elevated troponin above upper limit of normal AND cardiac MRI findings consistent with myocarditis
  - AND no other identifiable cause of the symptoms and findings

#### Acute Myocarditis

#### Acute 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
Histopathologic examination of myocardial tissue (autopsy or endomyocardial biopsy) showed myocardial inflammation

NO inflammation seen or not done or results unknown

Level 1 Myocarditis (Definitive Case)

≥1 Elevated myocardial biomarker (Troponin T OR Troponin I)

AND

Abnormal imaging study:
  • ≥1 Cardiac magnetic resonance (cMR) abnormality
  • ≥1 Echocardiogram abnormality

Level 2 Myocarditis (Probable case)

≥2 Cardiac Symptoms

≥2 Non-specific Symptoms

≥2 Non-specific symptoms in infant/young child

Level 3 Myocarditis (Possible Case)

Alternative etiology for symptoms?

≥1 Elevated myocardial biomarker (Troponin T OR Troponin I OR CK myocardial band)

OR

≥1 Echocardiogram abnormality

OR

≥1 Electrocardiogram abnormality that are new and/or normalize on recovery

Level 5: NOT a case of Myocarditis

≥1 elevated biomarker of inflammation (C-Reactive Protein OR Erythrocyte sedimentation rate OR D-Dimer)

AND

≥1 non-specific EKG abnormalities that are new and/or normalize on recovery

Level 4 is a reported event of myocarditis with insufficient evidence to meet level 1, 2 or 3 of the case definition

Cardiac symptoms:
  • Acute chest pain or pressure
  • Palpitations
  • Dyspnea after exercise, at rest or lying down
  • Diaphoresis
  • Sudden death

Non-specific symptoms:
  • Fatigue
  • Abdominal pain
  • Dizziness / syncope
  • Edema
  • Cough

Infant/child non-specific symptoms
  • Irritability
  • Vomiting
  • Poor feeding
  • Tachypnea
  • Lethargy

Source: Brighton Collaboration Myocarditis Case Definition Algorithm (16 July 2021)
PERICARDITIS: Algorithm for Brighton Case Definition Levels of Certainty

Histopathologic examination of pericardial tissue (autopsy or surgical biopsy) showed pericardial inflammation

No inflammation seen or tissue not examined or results unknown

Meets at least 2 of the 3 following criteria:
- (a) Evidence of abnormal fluid collection or pericardial inflammation by imaging (Echocardiogram, MR, cMR or CT)
- (b) EKG shows all 3 abnormalities as listed in BOX 1 below, that are new and/or normalize on recovery
- (c) Physical exam finding of pericardial fluid:
  - pericardial friction rub
  - pulsus paradoxus
  - distant heart sounds (infants/children)

NO

Symptoms at presentation meets (a) or (b) below:
- (a) One of the following: acute chest pain or pressure, palpitations, dyspnea after exercise, at rest or lying down, diaphoresis, sudden death
- (b) If infant/young child ≥2 of: irritability, vomiting, poor feeding or sweating

AND for all ages

At least 1 of the 3 following criteria met:
- ≥1 EKG change as listed in Box 1, that is new and/or normalize on recovery
- Imaging (Echo, MR, cMR or CT) shows abnormal pericardial fluid collection and/or inflammation
- Physical exam finding(s) of pericardial fluid: pericardial friction rub and/or pulsus paradoxus

NO

Symptoms at presentation meets (c) or (d) below:
- (c) At least 1 non-specific symptom listed in BOX 2 below AND ≥1 of the following:
  - New onset cardiac chest pain or pressure
  - Palpitations
  - Dyspnea after exercise, at rest or lying down

- (d) Infant/young child ≥2 of: irritability, vomiting, poor feeding, back pain, tachypnea, lethargy

AND for all ages: ≥1 of the following:
- Chest radiograph shows enlarged heart
- Non-specific EKG abnormalities that are new and/or normalize on recovery

NO

Was there a clear alternative explanation to explain the illness?

YES

Level 1 Pericarditis (Definitive Case)

NO

Was there a clear alternative explanation to explain the illness?

YES

Level 2 Pericarditis (Probable case)

NO

Level 5: NOT a case of Pericarditis

YES

Was there a clear alternative explanation to explain the illness?

YES

Level 3 Pericarditis (Possible Case)

NO

NOTE: Classify as Level 4 "reported case of pericarditis that fails to meet level 1, 2 or 3 of the case definition" if insufficient evidence to meet level 1, 2 or 3 because test(s) not done or results unknown or history/physical exam features not documented

BOX 1. Electrocardiogram abnormalities:
- Diffuse concave-upward ST-segment elevation
- ST-segment depression in aVR
- PR-depression throughout the leads (best shown in leads II & V5) without reciprocal ST-segment changes (depressions)

BOX 2. Non-specific symptoms:
- Cough
- Weakness
- Shoulder &/or upper back pain
- Edema
- Fatigue
- Low grade intermittent fever (≥38.0°C)
- Cyanosis
- Altered mental status
- GI (nausea &/or vomiting &/or diarrhea)

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.

Annex I. Reactogenic Reactions versus COVID-19 symptoms

Category A Symptoms

<table>
<thead>
<tr>
<th></th>
<th>COVID-19 Infection</th>
<th>COVID-19 Vaccination Side Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cough</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Shortness of Breath</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Rhinorrhea (Runny Nose)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Sore Throat</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Loss of Taste or Smell</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

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

Category B Symptoms

<table>
<thead>
<tr>
<th></th>
<th>COVID-19 Infection</th>
<th>COVID-19 Vaccination Side Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever, Chills</td>
<td>Yes to Both</td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body Aches</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Joint Pain</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>COVID-19 Infection</th>
<th>COVID-19 Vaccination Side Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate reactions; Urticaria, Hives, Anaphylaxis</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Local Symptoms; Pain swelling</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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
Annex J. Steps in the AEFI Surveillance Cycle

Reporting Flow and Oversight

Steps in the AEFI Surveillance Cycle. The Main Actors. The Oversight.

AEFI IDENTIFICATION / DETECTION / REPORTING → AEFI INVESTIGATION → CAUSALITY ASSESSMENT → FEEDBACK

<table>
<thead>
<tr>
<th>NON-HOSPITAL HCP</th>
<th>LOCAL ESU</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROVINCIAL / CITY ESU</td>
<td>REGIONAL ESU (DOH CHD)</td>
</tr>
<tr>
<td>EPIDEMIOLOGY BUREAU (DOH)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>VACCINATION SITE</th>
</tr>
</thead>
</table>

| LOCAL VACCINE OPERATIONS CENTER |
| Safety Surveillance and Response Team |

| REGIONAL VACCINE OPERATIONS CENTER |
| Safety Surveillance and Response Team |

| NATIONAL VACCINE OPERATIONS CENTER |
| Safety Surveillance and Response Team |

OVERSIGHT
Ensuring that operations centers under their jurisdiction are oriented, trained, monitored with concerns raised in order for their surveillance actions to be done efficiently and effectively.

**Case Investigation Form**  
(for COVID-19 Vaccine AEFI)

V2 - 2021.07.07

### I. REPORTER’S INFORMATION

<table>
<thead>
<tr>
<th>Name of Facility/Disease Reporting Unit (DRU)*</th>
<th>Facility/DRU Region and Province</th>
<th>Type of Facility/DRU*</th>
<th>Contact Number* (Landline or Mobile)</th>
</tr>
</thead>
</table>

### II. PATIENT INFORMATION

<table>
<thead>
<tr>
<th>First Name*</th>
<th>Middle Name</th>
<th>Last Name*</th>
<th>Suffix</th>
<th>Birthdate (MM/DD/YYYY)*</th>
<th>Age*</th>
<th>Sex*</th>
<th>Male</th>
<th>Female, check if either applies:</th>
<th>Civil status</th>
<th>PhilHealth Number</th>
</tr>
</thead>
</table>

**Nationality**:  

**Priority Group**:  

**Notes**:  
- Specify profession/comorbidity:

### COMPLETE CURRENT ADDRESS AND CONTACT INFORMATION

<table>
<thead>
<tr>
<th>House No./Lot/Building*</th>
<th>Street/Purok/Sitio*</th>
<th>Barangay*</th>
<th>Municipality/City*</th>
<th>Province*</th>
<th>Region*</th>
<th>Contact Number* (Landline or Mobile)</th>
</tr>
</thead>
</table>

**Current Address details**

<table>
<thead>
<tr>
<th>Address 1</th>
<th>Address 2</th>
<th>Address 3</th>
<th>Address 4</th>
</tr>
</thead>
</table>

**Notes**:  
- Full Name: Last Name, First Name, Middle Name.

### 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 copies of the vaccination cards upon submission of this document.

<table>
<thead>
<tr>
<th>Details</th>
<th>Older dose</th>
<th>Latest dose</th>
</tr>
</thead>
</table>

**Vaccination Site**

- Vaccination Site Province: 
- Vaccination Site: 
- Vaccination Site: 
- Vaccination Site: 

**Vaccine procured from**

- DOH: Local Gov't Unit
- Private

**ADVERSE EVENTS**

### IV. ADVERSE EVENTS (check all that apply)

<table>
<thead>
<tr>
<th>Symptom*</th>
<th>Date of onset (MM/DD/YYYY)*</th>
<th>Time of onset (hh:mm)*</th>
<th>Symptom*</th>
<th>Date of onset (MM/DD/YYYY)*</th>
<th>Time of onset (hh:mm)*</th>
</tr>
</thead>
</table>

**Other symptoms**

- With Hypertension:
- Others: 

### 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**:  
- Died 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: 
- 3. Vaccination Site: 
- 4. Date of discharge (MM/DD/YYYY)*: 

**Serious case**:  
- Yes:  
- No: 

**Other important medical event, specify**: 

**Notes**:  
- According to Republic Act No. 11332 Revised RIR 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 providers.
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

<table>
<thead>
<tr>
<th>Last Name of Physician*</th>
<th>First Name of Physician*</th>
<th>Middle Name of Physician</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Contact Number*</th>
<th>PRC Registration Number*</th>
<th>Date Investigated (MM/DD/YYYY)*</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Other source of Information</th>
<th>Nurse</th>
<th>Midwife</th>
<th>Parent/Guardian</th>
<th>Neighbor</th>
<th>Barangay Health Worker</th>
<th>Others, specify:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Last Name of other source of information</th>
<th>First Name of other source of information</th>
<th>Middle Name of other source of information</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Contact Number (Landline or Mobile)</th>
<th>PRC Registration Number (if applicable)</th>
<th>Relation/Designation of other source of information</th>
</tr>
</thead>
</table>

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?* ____________________________
<table>
<thead>
<tr>
<th>Past Medical History, OB-GYN History, and Birth and Developmental History</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family Medical History</td>
</tr>
<tr>
<td>Personal Social History</td>
</tr>
<tr>
<td>Physical Examination on first interaction</td>
</tr>
</tbody>
</table>

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?*

   - 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?

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.

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, electrophysiologic studies, you may attach them as reference. Any dermatologic findings or imaging may be attached.

NOTE: According to Republic Act No. 11332 Revised IRR Rule VI Sec. 6, "The aforementioned details are crucial and indispensable for the formulation of appropriate policies and disease response activities. Hence, health professionals conducting the interview at point of first contact shall obtain such details from a suspected 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 non-cooperation punishable under the Act or this IRR."

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### VIII. COURSE IN THE HOSPITALIZATION

You may opt to attach a medical abstract outlining the chronological course of hospitalization in SOAP format.

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Subjective Findings</th>
<th>Objective Findings</th>
<th>Assessment</th>
<th>Plan/Management Done</th>
</tr>
</thead>
</table>

### 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

<table>
<thead>
<tr>
<th>Information</th>
<th>Yes / No N/A</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Did a similar diagnosis, episode/s, or event/s occur in the past, independent of any vaccination?*</td>
<td>[ ] / [ ]</td>
<td>&quot;Similar event&quot; 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.</td>
</tr>
<tr>
<td>2. Was the patient exposed to a potential factor (other than vaccine) prior to the event (e.g. allergen, drug, herbal product, etc.)*</td>
<td>[ ] / [ ]</td>
<td>If pregnant, indicate AOG:</td>
</tr>
<tr>
<td>3. For adult women, currently pregnant? currently breastfeeding?</td>
<td>[ ] / [ ] [ ] / [ ] / [ ]</td>
<td>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.</td>
</tr>
<tr>
<td>4. Did this patient have an illness, pre-existing condition or risk factor that could have contributed to the event?</td>
<td>[ ] / [ ]</td>
<td></td>
</tr>
<tr>
<td>5. Was or is the patient on any concurrent medication for any illness prior to the vaccination? (indicate the name of drug, indication, doses, &amp; date)</td>
<td>[ ] / [ ]</td>
<td></td>
</tr>
<tr>
<td>6. Has the patient tested COVID-19 positive prior to vaccination?</td>
<td>[ ] / [ ]</td>
<td>Specimen Collection Date (MM/DD/YYYY):</td>
</tr>
<tr>
<td>7. History of hospitalization in the past 30 days; if yes, indicate the inclusive dates and cause*</td>
<td>[ ] / [ ]</td>
<td></td>
</tr>
<tr>
<td>8. Recent history of trauma; if yes, indicate the date, cause and site*</td>
<td>[ ] / [ ]</td>
<td></td>
</tr>
<tr>
<td>9. Did a similar diagnosis, episode/s, or event/s occur in the past after the administration of a similar vaccine?*</td>
<td>[ ] / [ ]</td>
<td></td>
</tr>
</tbody>
</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."

---

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Relative date of vaccination</th>
<th>Adverse Event experienced</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

4
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 injury or illness 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 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 ESU (HESU) 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.

<table>
<thead>
<tr>
<th>Last Name of Investigator*</th>
<th>First Name of Investigator*</th>
<th>Middle Name of Investigator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Designation of the Investigator*</td>
<td>Contact Number* (Landline or Mobile)</td>
<td>Date of Investigation (MM/DD/YYYY)*</td>
</tr>
</tbody>
</table>

Privacy statement

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

NOTE: According to Republic Act No. 11332 Revised IRR Rule VI Sec. 6, “The aforementioned details are crucial and indispensable for the formulation of appropriate policies and disease response activities. Hence, health professionals conducting the interview at point of first contact shall obtain such details from a suspect case, properly informing the data subject that the information sought to be obtained is being processed in accordance with Republic Act No. 10173, or the "Data Privacy Act of 2012," and that deliberately providing false or misleading personal information to the part of the person, or the next of kin in case of the 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 collection 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.
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 act of bias in case of a person's incapacity, may constitute as non-cooperation punishable under the Act or this IRR."

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.
### Privacy statement

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

**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. 10175 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 the 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 medical-legal purposes, or performance of medical or clinical audit to the management of the healthcare provider/s.
Appendix 1. AEFI Definitions

<table>
<thead>
<tr>
<th>Non-serious AEFI</th>
<th>Serious AEFI</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>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.</td>
</tr>
</tbody>
</table>

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 prevent 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.

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/VCIP. Information submitted here may not be used for medicolegal purposes, or performance of medical or clinical audit to the management of the health care provider/s.
### Surveillance Cycle Step

<table>
<thead>
<tr>
<th>Step</th>
<th>Definition</th>
<th>Purpose</th>
<th>Personnel responsible/involved</th>
</tr>
</thead>
<tbody>
<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>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>
<td></td>
</tr>
</tbody>
</table>

### Causality Assessment

#### Case Classifications

**A. Consistent causal association to immunization**

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

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

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

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

**B. Indeterminate**

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

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

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

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

### Algorithm (WHO Causality Assessment Manual 2019)

![Algorithm Diagram](https://www.who.int/vaccine_safety/initiative/tools/CIOMS_report_WG_vaccine.pdf)

### References


**NOTE:** According to Republic Act No. 11332 Revised IRR Rule VI Sec. 9, "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 the 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 VICTP. 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 providers.
Appendix 4: Additional sheet for Vaccination Details

### PATIENT INFORMATION

<table>
<thead>
<tr>
<th>First Name*</th>
<th>Middle Name</th>
<th>Last Name*</th>
<th>Suffix</th>
</tr>
</thead>
</table>

### 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.

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

- DOH: Department of Health
- Local Gov’t Unit: Local Government Unit
- Private: Private Sector
- Unknown: Unknown
- Others: Other Sources
Appendix 5. Additional form for case-based survey of pregnant women inoculated with COVID-19 vaccine

<table>
<thead>
<tr>
<th>I. PREGNANCY INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occupation of Individual*</td>
</tr>
<tr>
<td>☐ Health care worker (e.g., hospitals, treatment facilities, vaccination sites, etc.)</td>
</tr>
<tr>
<td>☐ Frontliner</td>
</tr>
<tr>
<td>☐ Others, please specify ____________________________</td>
</tr>
<tr>
<td>Name of Current Employer, Office or Agency</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Confirmation of pregnancy by test*</td>
</tr>
<tr>
<td>☐ YES, please specify means of confirmation</td>
</tr>
<tr>
<td>☐ NO</td>
</tr>
<tr>
<td>Current Status of Pregnancy*</td>
</tr>
<tr>
<td>☐ Still pregnant ☐ Abortion (fetal death of less than 14 weeks) ☐ Carried preterm and delivered ☐ Carried to term and delivered</td>
</tr>
<tr>
<td>Status of Mother*</td>
</tr>
<tr>
<td>☐ Died (maternal death) ☐ Alive (with no comorbidities) ☐ Alive (with comorbidities), specify ____________________________</td>
</tr>
<tr>
<td>Number of pregnancies: _______</td>
</tr>
<tr>
<td>Number of abortions (spontaneous or therapeutic): _______</td>
</tr>
<tr>
<td>II. COMORBIDITIES AND PAST MEDICAL HISTORY</td>
</tr>
<tr>
<td>Maternal medical complication in past pregnancies</td>
</tr>
<tr>
<td>☐ Hypertensive disorders (eclampsia) ☐ LBW or SGA infants ☐ Others, please specify ____________________________</td>
</tr>
<tr>
<td>Conditions that increase the risk for obstetric complications for current pregnancy</td>
</tr>
<tr>
<td>☐ Incompetent cervix ☐ Placenta previa ☐ Oligo-polyhydramnios ☐ None or not applicable</td>
</tr>
<tr>
<td>Active/recent maternal infection with HIV, HepB, Hep C, TB, Malaria, STI, maternal group B, Streptococcus, and other Chronic infections</td>
</tr>
<tr>
<td>Existing medical conditions or comorbidities prior to pregnancy</td>
</tr>
<tr>
<td>Maternal status at the time of vaccination</td>
</tr>
<tr>
<td>1st COVID-19 vaccine dose</td>
</tr>
<tr>
<td>☐ Normal ☐ Morbidity present, please specify morbidity and signs and symptoms</td>
</tr>
<tr>
<td>Administration of other vaccines during pregnancy*</td>
</tr>
<tr>
<td>Past history of adverse reactions to vaccines before pregnancy*</td>
</tr>
<tr>
<td>Administration of concomitant medications including immunomodulatory agents during pregnancy</td>
</tr>
<tr>
<td>Maternal use of alcohol, drugs, use of nutritional or other supplements</td>
</tr>
<tr>
<td>Receipt of blood products one month before or after vaccination</td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th>AESI Tier</th>
<th>Description</th>
<th>Tier 1</th>
<th>Tier 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>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.</td>
<td>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).</td>
<td></td>
</tr>
</tbody>
</table>
| 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.

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 RAEIFC, 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 RAEIFC, with an acute onset of illness (on or before 28 days from the date of vaccination) for the event being assessed.
   3. RAEIFC-initiated CA - All cases referred by the RAEIFC that are not in the above definitions but are classified as A1, A2, B1, or B2 by the RAEIFC.

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.