Addendum to the
Position Statements
of the

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

mRNA Vaccines and Adverse Reactions in Adolescents 12 -17 years old

REVISED October 15, 2021

This addendum was developed by the COVID-19 Vaccine Adverse Reactions Task Force of the Philippine Society of Allergy, Asthma, and Immunology (PSAAI) in response to the Philippine Food & Drug Administration's (FDA) having given Emergency Use Authorization (EUA) to the following vaccine companies for use in adolescents aged 12-17 years old: Pfizer/BioNTech (BNT162b2/Tozinameran/Comirnaty), given EUA on June 08, 2021, and Moderna (mRNA-1273), given EUA on September 03, 2021. This document will be updated periodically.

Summary statements on COVID-19 and burden of the disease:

- Adolescents and children with COVID-19 generally experience a milder course than adults, however, severe disease and deaths may still occur, especially in those with co-morbidities.
- The Delta strain has become the predominant strain worldwide and its increased transmissibility has also led to more adolescents and children being infected.
- In the Philippines, a total number of 2,659,758 cases have been documented as of October 13, 2021, with pediatric cases (0-19 years old) accounting for 11% (301,163 cases). Deaths were highest in the < 4 year old group followed by those in the 15-19 year old group, reflecting the same bimodal age distribution in other countries.
- Healthcare organization records have revealed that males aged 12 to 17 are most likely to develop myocarditis within three months of a COVID-19 infection at a rate of about 450 cases per million.
- Israel, USA, Singapore (Pfizer/BioNTech) and Canada (Pfizer/BioNTech and Moderna), amongst other countries, have authorized the administration of mRNA vaccines to those aged 12-17 years. An EUA has likewise been granted by the Philippine FDA to Pfizer/BioNTech and Moderna for vaccination of the same age group.
- Based on current data, the benefits of vaccination to the individual person and community outweigh the risks of adverse reaction to these vaccines.

Summary statements on adverse reactions to Pfizer/BioNTech and Moderna vaccines:

- Post-authorization monitoring of reactions to the mRNA vaccines in adolescents showed that reactogenic reactions, both local and systemic, are common, mostly mild, and usually

occur within 2 days after the first or second dose and resolve after a few days. Systemic reactogenic reactions (eg. fever) are more commonly found after the second dose. As with adults, these are managed with supportive care. Prophylactic antipyretics are not advised.

- Syncope, which is separate from anaphylaxis, is a reaction to vaccines almost unique to adolescents and with a female preponderance. Providers must be able to anticipate and provide support in such a scenario during and post-vaccination.
- Myocarditis associated with the mRNA vaccines became evident during post-approval safety surveillance of vaccinations and was seen to peak in males aged 12-17 years. Though its mechanism is not yet understood, it usually occurs after the second dose, with most having a mild course and with resolution in 95% of cases. As monitoring of these patients continue, no mortality has so far been directly attributed to the vaccine. Though rare, vaccinees and/or their legitimate guardians must be familiarized with this risk to aid in timely detection. At the same time, a seven-fold higher risk of acquiring myocarditis after COVID-19 compared to vaccination must be emphasized.
- Anaphylaxis, immune thrombocytopenia, or other significant reactions have not been reported in clinical trials. However, there is a possibility that these adverse reactions may occur. Therefore, careful history-taking and risk assessment are a must prior to and after each vaccination. Anaphylaxis is managed with prompt injection of epinephrine at a dose of 0.01 ml/kg intramuscularly into the mid antero-lateral thigh. Most adolescents will fall within the adult dose range of 0.3-0.5 ml. Monitoring for 30 minutes post-vaccination is recommended.

Summary statements on recommendations before the first and second doses of the mRNA vaccines (see tables on risk assessment)

- Patients with anaphylaxis to other types of vaccines and injectable medications, food, inhalant/environmental allergens, insects, latex, and oral medications; and those with uncontrolled asthma or mast cell disorders should be evaluated by a qualified specialist prior to vaccination.
- Patients with non-anaphylactic reactions to food, inhalant/environmental allergens, insects, latex, and oral medications not related to vaccines and their components may receive the vaccines.
- Patients with well-controlled asthma, allergic rhinitis, atopic dermatitis, and chronic urticaria, whether or not on maintenance medications, may receive the vaccines.
- Patients with immunodeficiency, cancer, and autoimmune disease (e.g. Guillain-Barre Syndrome, Bell's palsy) may also get vaccinated after being informed that there is as yet not enough data available to establish vaccine safety and efficacy in these conditions. A proper evaluation and a thorough discussion of vaccine risks and benefits must be conducted by their respective physicians.
- The decision to vaccinate an individual with a history of myocarditis or pericarditis unrelated to the COVID-19 vaccines should take into account the individual's clinical circumstances. A proper evaluation and a thorough discussion of vaccine risks and benefits must be conducted by a specialist.

- Patients with local and systemic reactogenic reactions and immunization stress-related reactions such as syncope after receiving the first dose of vaccine may receive the second dose.
- Contraindications to the second dose of the vaccine are severe immediate allergic reactions such as anaphylaxis and known serious adverse events such as myocarditis to a previous dose of the vaccine. A referral to a qualified specialist for evaluation is recommended.

Epidemiology of COVID-19 in Adolescents

COVID-19 is generally known to cause milder infection in children and adolescents as compared to adults. However, severe illness resulting in hospitalization, mechanical ventilation, complications (such as multi system inflammatory syndrome [MIS-C]) (Fernandes et al., 2021) and death may still occur. Healthcare organization records have revealed that males aged 12 to 17 are most likely to develop myocarditis within three months of a COVID-19 infection at a rate of about 450 cases per million infections (Wilson, 2021). Symptoms of the infection may even persist for more than a month (Ashkenazi-Hoffnung et al., 2021). From March 2020 to April 2021 in the US, hospitalization rates for COVID-19 in adolescents were found to be three times that for influenza, and 1/3 of these patients required admission to the ICU.

In the week alone ending September 16, 2021, nearly 226,000 new pediatric infections were diagnosed in the US and made up about a quarter of all new infections. This represented the third highest weekly count since the onset of the pandemic, preceded by an exponential increase in new pediatric cases in a span of four weeks. (American Academy of Pediatrics and the Children's Hospital Association, 2021)

It was further found that 70% of the admitted patients had co-morbidities (Havers et al., 2021). This echoes the findings in adults wherein those with co-morbidities have a higher risk of more severe disease (Kompaniyets et al., 2021). The B.1.617.2 or "Delta" strain has become the predominant strain worldwide since July 2021. It is unknown as to whether the Delta strain causes more severe disease compared to the previously circulating strains. Data at present indicate that severe illness remains uncommon in children. Studies on its long-term effects are ongoing. Because of its known increased transmissibility, however, the number of pediatric infections and the corresponding percentage of severe illness have likewise increased since the time that Delta has become the predominant strain. In the US, the Centers for Disease Control (CDC) had reported an increase in cases, ER visits, and hospitalizations from June to August 2021 in persons aged 0-17 years; the highest rates of hospitalization were found in those 4 years old and below and in the 12-17 year-old age groups (Siegel et al., 2021). This bimodal age distribution was similarly found in other studies (Kainth et al., 2020). The CDC had also observed that in states with the lowest rates of vaccination, the percentage of COVID-19 ER visits and hospitalizations in a two-week period in August was at least three times higher compared to states with the highest vaccination rates (Siegel et al., 2021).

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the < 4 year old group followed by those in the 15-19 year old group, reflecting the same bimodal age distribution mentioned above. (Republic of the Philippines Department of Health, 2021).

Adverse Reactions to Pfizer/BioNTech (BNT162b2/Tozinameran/Comirnaty) Vaccine

Based on the results of a Phase 3 clinical trial, the Pfizer/BioNTech vaccine was given an EUA in the US for adolescents aged 16-17 years on December 11, 2020; and for those aged 12-15 years on May 10, 2021. Preauthorization trials of the vaccine reported the development of local and systemic mild (still able to perform usual activities) and moderate (some inability to perform usual activities) reactions in adolescents aged 12–17 years. Specifically in the 12-15 year old age group, 90.9% of recipients had local reactions, and 90.7%, systemic reactions. Resolution of symptoms occurred in a median of 1-2 days. (Frenck et al., 2021) This data was further corroborated by post-authorization reports of mostly mild reactions by the vaccinated adolescents to the US vaccine safety monitoring systems VAERS and v-safe.

As of July 16, 2021, VAERS had received 9,246 reports (or about 1 in 1,000 vaccinees), with 58.1% occurring in the 12–15 year old group and 41.9% in the 16–17 year old group. The most common reactions were dizziness (20.1%), syncope (13.3%), and headache (11.1%). Among the 901 individuals who met the standard case definition of syncope, the median age of occurrence was 15 years, with 60.8% occurring in females. (Hause et al., 2021)

On the other hand, around 129,000 adolescents enrolled in the v-safe system after vaccination (66,350 aged 16-17 years and 62,709 aged 12-15 years). For both age groups, local and systemic reactions were noted in the week after receipt of the first dose, though systemic reactions were more common in the week after the second dose (63.4% in the 12-15 year old bracket and almost 70% in the 16-17 year old bracket). For both age groups combined, about 30% developed fever in the week after the second dose. Other frequent symptoms noted the day after vaccination were pain at the injection site, fatigue, headache**,** and myalgia. Only 56 adolescents (0.04%) needed to be hospitalized. (Hause et al., 2021)

About 10.7% of the recipients further developed severe (inability to perform usual activities) local and systemic reactions, consisting mostly of fatigue, fever, headache, chills, and injection site pain. Similar to the reports of the vaccine safety monitoring systems, the reactions were more commonly found after the second dose. (Wallace et al., 2021)

In general, 90.7% of the VAERS reports were for non-serious events and 9.3% were for serious events that included myocarditis (4.3%) and death. The median age for serious events was 15 years and 70.6% occurred in males. The most commonly reported conditions were chest pain (56.4%); increased troponin levels (41.7%); myocarditis (40.3%); and increased C-reactive protein (30.6%). (Hause et al., 2021)

Myocarditis (which also encompasses myopericarditis) had been observed during post-authorization monitoring. It primarily occurred in young males within a week after the second dose (Shay et al., 2021; Israeli Ministry of Health, 2021). Using data as of June 11, 2021, crude reporting rates of its occurrence in the US revealed 40.6 cases per million second doses of mRNA vaccines in males 12-29 years old as compared to 2.4 cases per million second doses in those 30 years old

and above. Rates in females were 4.2 and 1 per million second doses, respectively. The highest incidence overall was found in males 12-17 years old (62.8 per million second doses of the mRNA vaccines) and males 18-24 years old (50.5 per million second doses). (Gargano et al., 2021)

It is not known as to why post-vaccination myocarditis occurs. According to the CDC, it should be considered in adolescents or young adults who develop symptoms of acute chest pain, shortness of breath, or palpitations. An ECG, determination of troponin level and inflammatory markers, and consultation with a cardiologist are recommended, while COVID-19 infection itself must be ruled out.

At least 95% of patients have recovered but follow-up of all patients is still ongoing. The Advisory Committee on Immunization Practices (ACIP) after doing a risk assessment has recommended that vaccination in adolescents should continue, as its benefits to individual persons and the population as a whole outweigh its risks. The EUA now includes information on post-mRNA vaccination myocarditis. Patient and provider education materials were also developed to ensure its prompt recognition and management. (Gargano et al., 2021)

Meanwhile, the Singapore government on June 11, 2021 had recommended avoidance of strenuous physical activity for a week following either the first or second dose of the vaccine as a precautionary measure for myocarditis (Liew & Baharudin, 2021).

As of July 16, 2021, the CDC had also reviewed 14 reports of death after vaccination in individuals aged 12-17 years. Apparent causes of death were pulmonary embolism, suicide, intracranial hemorrhage, heart failure, and hemophagocytic lymphohistiocytosis and disseminated Mycobacterium chelonae infection. Pending receipt of additional information for some decedents, none of the deaths were attributed by VAERS to myocarditis. (Hause et al., 2021)

Adverse Reactions to Moderna (mRNA-1273/Spikevax) Vaccine

In the US, only the Pfizer/BioNTech vaccine has been given EUA for adolescents. In Canada, the Pfizer/BioNTech vaccine was authorized to be given to adolescents aged 16-17 years in December 2020 and to those aged 12-15 years on May 5, 2021. On August 27, 2021, the Moderna vaccine was likewise authorized to be given to adolescents aged 12-17 years. The safety and reactogenicity of the Moderna vaccine in the ongoing Phase 2/3 TeenCOVE trial in adolescents was found similar to that seen in adults aged 18-64 years in the Phase 3 COVE trial.

Between December 9, 2020, and February 28, 2021, 2,489 adolescents had been randomly assigned to receive the Moderna vaccine and 1,243 to the placebo at 26 sites in the US; about 75% were from the 12-15 year old age bracket and 25% were from the 16-17 year old age bracket. (Ali et al., 2021)

Local reactions were mostly mild to moderate in severity and occurred both after the first (94.2%) and second doses (93.4%). The most common was injection-site pain, with 5% reporting it as Grade 3 in severity (interfering with daily activity). Axillary lymphadenopathy occurred in 23.3% after dose 1 and in 21% after dose 2. The majority of local reactions occurred within the first 1-2

days after each dose and persisted for a median of 3-4 days. Only 1.3% had local reactions that began after 7 days from either the first or second dose (redness, swelling, and axillary swelling or tenderness). Local reactions that persisted beyond 7 days were higher after the first injection (6.4%) than the second injection (1.6%) and primarily consisted of axillary lymphadenopathy. (Ali et al., 2021)

The most commonly experienced systemic reactions were fatigue, headache, and myalgia. Other reactions were chills, joint pain, nausea/vomiting, and fever. Most of them were reported within 1-2 days after receiving the second dose (86.1% vs. 68.5% after the first dose) and lasted for a median of 2 days. Only 0.7% had reactions that began after 7 days. On the other hand, reactions that persisted after 7 days were not significantly different between the vaccine and placebo groups. (Ali et al, 2021)

In general, solicited reactions occurred at the same frequency in the 12-15 year old and the 16-17 year old age brackets. Unsolicited reactions were monitored for up to 1 month after having received the first or the second dose. These occurred in 20.5% of the vaccine group (most common of which were axillary lymphadenopathy in 4.3% and headache in 2.4%) and in 15.9% of the placebo group. Overall**, v**accine-related reactions occurred in 12.6% and again were similar in the 12-15 year old and 16-17 year old age brackets. There were no deaths nor cases of myocarditis and other unusual events. (Ali et al., 2021)

Post-authorization US Vaccine Safety Datalink (VSD) data in individuals aged 12-39 years had shown relatively higher frequencies of myocarditis after receipt of the second dose of Moderna compared to Pfizer/BioNTech: 19.8 per million second doses [95% CI: 9.9 to 35.5] and 8 per million second doses [95% CI: 3.2 to 16.5], respectively. The reported differences in rates were not statistically significant. (Shimabukuro, 2021)

The Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) and Canada Vigilance Database (CVD) as of August 7, 2021 had likewise detected an unusually higher number of myocarditis and/or pericarditis cases in younger age groups than expected. The National Advisory Committee on Immunization (NACI) then restricted its analysis of the cases to those that had met the Brighton Collaboration Levels 1-3 definitions of myocarditis and pericarditis. (Ontario Agency for Health Protection and Promotion (Public Health Ontario), 2021).

Of the 204 well-defined cases, 6.4 per million first doses and 8.7 per million second doses were reported for the Pfizer/BioNTech vaccine; and 6.6 per million first doses and 28.2 per million second doses for the Moderna vaccine. About 80% of the cases were males, with the highest incidence occurring in the 18-24 year old age group. This group alone developed 37.4 incidents per million second doses of the Pfizer/BioNTech vaccine and 263.2 incidents per million second doses of the Moderna vaccine. When the analysis was restricted only to events after vaccination was begun on or after June 1, 2021 (n=54) to account for the enhanced surveillance of myocarditis/pericarditis cases and the expanded Moderna vaccine supply in June, males aged 18-24 years experienced 35.5 myocarditis events per million second Pfizer/BioNTech doses and 198.6 myocarditis events per million second Moderna doses. Additional analyses to verify the differences between the two vaccines are ongoing and no official recommendations have been changed.

In Europe, Nordic countries have collaborated on a health registry which detects and investigates rare side effects. Recent data have indicated an increased incidence of myocarditis after the second dose of the Moderna vaccine. As the Nordic registry study has not yet been completed, final conclusions have yet to be made by the European Medicines Agency (EMA). However, the monitoring data from Ontario, Canada and observations from the US have prompted the Norwegian Institute of Public Health (NIPH) to issue advice to offer only the Pfizer/BioNTech vaccine to those under 18 years of age, and to consider choosing it over the Moderna vaccine in men under 30 years of age as a precautionary measure. Those under the age of 18 who had received the first dose of Moderna vaccine should receive the Pfizer/BioNTech as their second dose. (Norwegian Institute of Public Health, 2021)

On October 6, 2021, Sweden halted the use of the Moderna vaccine for those aged 30 years and below while Finland's national health authority, THL, announced the following day that it would follow suit. They plan to offer the Pfizer/BioNTech vaccine instead to this group. (Taylor, 2021)

Overall, however, myocarditis following the mRNA vaccines remains a rare adverse event following immunization (AEFI), defined by the Canadian Immunization Guide as occurring at a frequency of 0.01%-<0.1% even in the age groups where the highest rates had been observed (Berard et al., 2021). The vaccines continue to be recommended and are found highly effective at preventing symptomatic and severe COVID-19, which in itself is associated with a 7-fold increased risk of myocarditis when compared to the risk after vaccination (Wilson, 2021). For both mRNA vaccines, informed consent should include a disclosure of the rare risk of myocarditis following vaccination; and advice to seek immediate medical attention if chest pain, shortness of breath, or palpitations are experienced.

ASSESSMENT OF RISK FOR ADVERSE REACTIONS TO THE FIRST DOSE OF mRNA VACCINES IN ADOLESCENTS 12-17 YEARS OLD

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

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

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

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

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

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

ASSESSMENT OF RISK FOR ADVERSE REACTIONS TO THE SECOND DOSE OF mRNA VACCINES IN ADOLESCENTS 12-17 YEARS OLD

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

[a] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html*

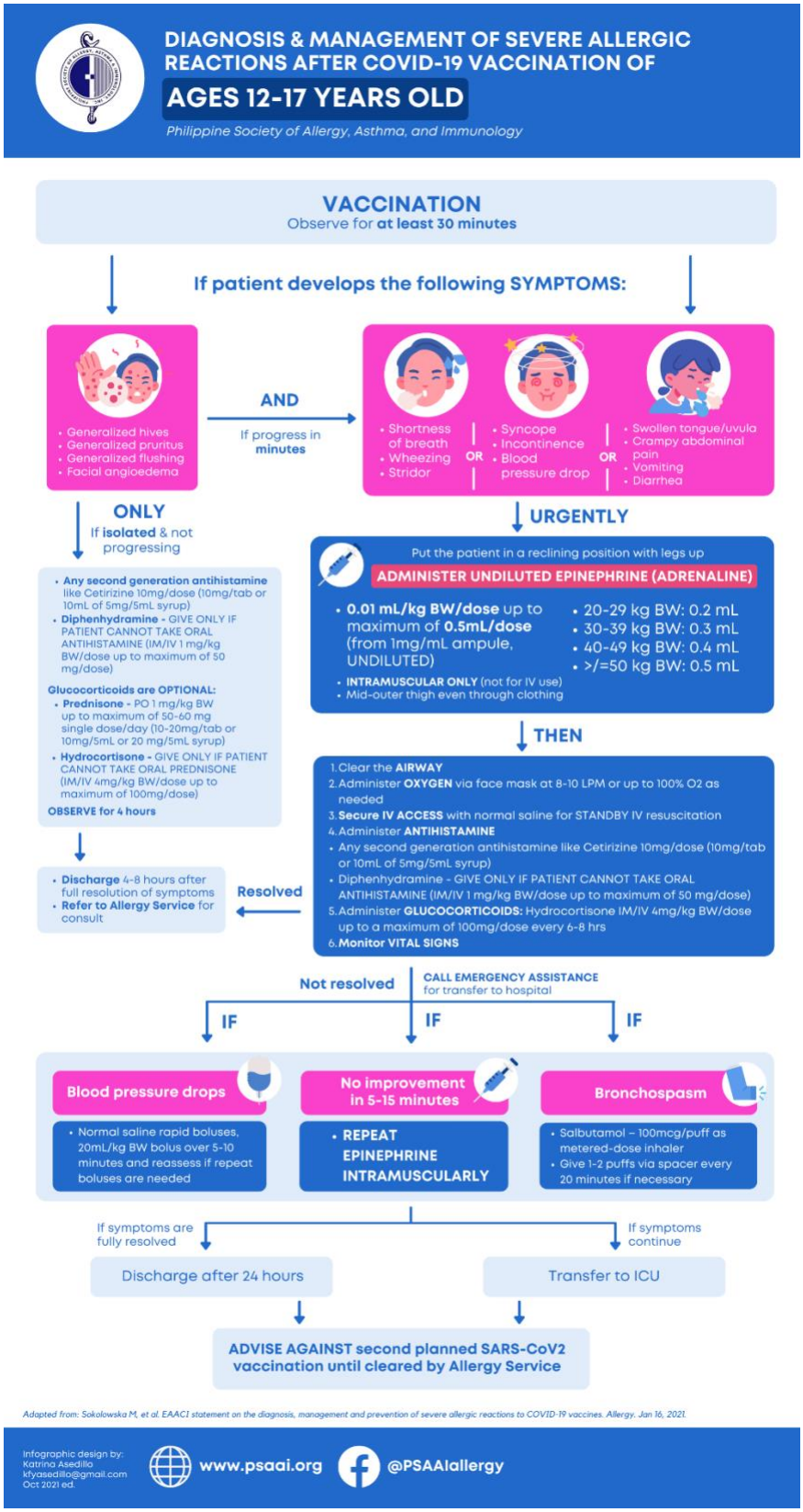
[b] *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical considerations.html#Contraindications*

[c] *Blumenthal KG, et al. Delayed Large Local Reactions to mRNA-1273 Vaccine against SARS-CoV-2. N Engl J Med. 2021 Mar 3.*

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

[e] https://www.google.com/url?sa=t&source=web&rct=j&url=https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/05-COVID-Wallace-508.pdf&ved=2ahUKEwje0vfuisDzAhVRPHAKHWsmAIgQFnoECAcQAQ&usg=AOvVaw0bOTsHqtUlZ2YR5EKCnW6

APPENDIX A


DIAGNOSIS & MANAGEMENT OF SEVERE ALLERGIC REACTIONS AFTER COVID-19 VACCINATION OF
AGES 12-17 YEARS OLD
Philippine Society of Allergy, Asthma, and Immunology
VACCINATION
Observe for at least 30 minutes
If patient develops the following SYMPTOMS:
• Generalized hives
• Generalized pruritus
• Generalized flushing
• Facial angioedema
AND
If progress in minutes
• Shortness of breath
• Wheezing
• Stridor
OR
• Syncope
• Incontinence
• Blood pressure drop
OR
• Swollen tongue/uvula
• Crampy abdominal pain
• Vomiting
• Diarrhea
ONLY
If isolated & not progressing
URGENTLY
• Any second generation antihistamine like Cetirizine 10mg/dose (10mg/tab or 10mL of 5mg/5mL syrup)
• Diphenhydramine - GIVE ONLY IF PATIENT CANNOT TAKE ORAL ANTIHISTAMINE (IM/IV 1 mg/kg BW/dose up to maximum of 50 mg/dose)
Glucocorticoids are OPTIONAL:
• Prednisone - PO 1 mg/kg BW up to maximum of 50-60 mg single dose/day (10-20mg/tab or 10mg/5mL or 20 mg/5mL syrup)
• Hydrocortisone - GIVE ONLY IF PATIENT CANNOT TAKE ORAL PREDNISONE (IM/IV 4mg/kg BW/dose up to maximum of 100mg/dose)
OBSERVE for 4 hours
Put the patient in a reclining position with legs up
ADMINISTER UNDILUTED EPINEPHRINE (ADRENALINE)
• 0.01 mL/kg BW/dose up to maximum of 0.5mL/dose (from 1mg/mL ampule, UNDILUTED)
• 20-29 kg BW: 0.2 mL
• 30-39 kg BW: 0.3 mL
• 40-49 kg BW: 0.4 mL
• >/=50 kg BW: 0.5 mL
• INTRAMUSCULAR ONLY (not for IV use)
• Mid-outer thigh even through clothing
THEN
1. Clear the AIRWAY
2. Administer OXYGEN via face mask at 8-10 LPM or up to 100% O2 as needed
3. Secure IV ACCESS with normal saline for STANDBY IV resuscitation
4. Administer ANTIHISTAMINE
• Any second generation antihistamine like Cetirizine 10mg/dose (10mg/tab or 10mL of 5mg/5mL syrup)
• Diphenhydramine - GIVE ONLY IF PATIENT CANNOT TAKE ORAL ANTIHISTAMINE (IM/IV 1 mg/kg BW/dose up to maximum of 50 mg/dose)
5. Administer GLUCOCORTICOIDS: Hydrocortisone IM/IV 4mg/kg BW/dose up to a maximum of 100mg/dose every 6-8 hrs
6. Monitor VITAL SIGNS
• Discharge 4-8 hours after full resolution of symptoms
• Refer to Allergy Service for consult
Resolved
Not resolved
CALL EMERGENCY ASSISTANCE for transfer to hospital
IF
IF
IF
Blood pressure drops
• Normal saline rapid boluses, 20mL/kg BW bolus over 5-10 minutes and reassess if repeat boluses are needed
No improvement in 5-15 minutes
• REPEAT EPINEPHRINE INTRAMUSCULARLY
Bronchospasm
• Salbutamol – 100mcg/puff as metered-dose inhaler
• Give 1-2 puffs via spacer every 20 minutes if necessary
If symptoms are fully resolved
If symptoms continue
Discharge after 24 hours
Transfer to ICU
ADVISE AGAINST second planned SARS-CoV2 vaccination until cleared by Allergy Service
Adapted from: Sokolowska M, et al. EAACI statement on the diagnosis, management and prevention of severe allergic reactions to COVID-19 vaccines. Allergy. Jan 16, 2021.
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APPENDIX B

EMERGENCY MEDICATIONS FOR ADVERSE REACTIONS IN ADOLESCENTS 12 -17 YEARS OLD

FIRST-LINE TREATMENT FOR ANAPHYLAXIS:

Medication	Preparation	Dose
Epinephrine	1mg/ml ampule **undiluted** (1:1,000)	IM **0.01ml/kg/dose** up to maximum of 0.5 ml/dose every 5-15 mins 20-29 kg BW: 0.2 ml 30-39 kg BW: 0.3 ml 40-49 kg BW: 0.4 ml 50 kg BW and above: 0.5 ml ***CALL Emergency Assistance** for transfer to hospital **if patient fails to respond after first dose**

OTHER TREATMENTS FOR ANAPHYLAXIS & FOR MILD ALLERGIC REACTIONS:

Medication	Preparation	Dose
Any second generation antihistamine (eg. Cetirizine) **OR** Diphenhydramine	10 mg tab 5 mg/5 ml syrup 50 mg ampule	PO 1 tab/day PO 10 ml single dose/day GIVE ONLY IF PATIENT CANNOT TAKE ORAL ANTIHISTAMINE: IM or IV, 1 mg/kg/**dose** up to maximum of 50 mg/dose every 4-6 hours
Prednisone **OR** Hydrocortisone	50 mg tab 20 mg tab 10 mg tab 10 mg/5 ml or 20 mg/5 ml syrup 200 mg/vial. 250 mg/vial	PO 1 mg/kg up to maximum of 50-60 mg single dose/day (depending on available preparation at the vaccination site) IM or IV 4 mg/kg/dose up to maximum of 100 mg/dose every 6-8 hrs
Salbutamol	100 mcg/puff as metered-dose inhaler	1-2 puffs via spacer every 20 mins for the first hour if necessary then every 4-6 hours

MEDICATIONS FOR REACTOGENIC REACTIONS (such as fever, pain at the injection site)

Medication	Preparation	Dose
Paracetamol	500 mg tab 250 mg/5 ml syrup	PO 10 mg/kg/dose up to maximum of 500 mg/dose every 4-6 hrs

*** BW- body weight; PO – orally; IM – intramuscular; IV- intravenous**

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