



A DOSE OF TRUTH

INFOVAX

BULLETIN FOR HEALTHCARE PROFESSIONALS

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INFOVAX is a community education and awareness series on Covid-19 vaccines brought to you by:

- Malaysian Medical Association Public Health Society (MMA PHS)
- National Cancer Society Malaysia (NCSM)
- NCD Malaysia.

This bulletin summarises the key points from our discussions with experts.

Watch the session at
bit.ly/infovaxallergy

Feel free to ask questions and clear your doubts about Covid-19 vaccines by emailing us at **infovax21@gmail.com**

Your questions and answers will be collated and answered in the following sessions.

MANAGING ALLERGIES AND ANAPHYLAXIS IN VACCINATION

CRITICAL INSIGHTS FOR HEALTHCARE PROFESSIONALS

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Disclaimer: This information is accurate and updated as of the date of this publication

Highlights

- Anaphylaxis is a severe and potentially life-threatening allergic reaction that happened rarely after COVID-19 vaccination. Based on the U.S Vaccine Adverse Event Reporting System, there were 11.1 cases of anaphylaxis per million vaccine doses administered in the early safety monitoring of the Pfizer-BioNTech vaccine.
- There are few contraindications to Covid-19 vaccination, including:
 1. Severe allergies, or anaphylaxis after getting vaccinated with the first dose of Covid-19 vaccine.
 2. Previous history of allergies to the ingredients of a Covid-19 vaccine.
- Polyethylene glycol (PEG) and polysorbate are both common allergens that can be found in mRNA Pfizer-BioNTech vaccine and Oxford AstraZeneca vaccine, respectively. If your patient presents with an allergy to PEG or polysorbate, please refer to the flowchart on the next page.
- In general, most people are allergic to excipients in vaccines, with very few people exhibiting allergies to the vaccines themselves. Excipients are additional substances added into a vaccine or drug to stabilise the vaccine/drug or to improve its absorption into the body.
- Most vaccines/drugs have common excipients. To determine if the patient will be allergic to a new vaccine/drug, find out what vaccine/drug the patient was allergic to previously.

The table below shows excipients which are contained in three vaccines currently authorised in Malaysia's national Covid-19 vaccination programme:

Types of Covid-19 vaccines	Pfizer-BioNTech vaccine	CoronaVac/Sinovac vaccine	Oxford AstraZeneca vaccine
Types of vaccine	mRNA	Inactivated Virus	Viral vector
Excipients	2[(polyethylene glycol {PEG})-2000]-N, N-ditetradecylacetamide	Aluminium hydroxide	Polysorbate 80
	(4-hydroxybutyl azanediyl) bis(hexane-6,1-diyl) bis(2-hexyldecanoate)	Disodium hydrogen phosphate	L-Histidine
	1,2-Distearoyl-sn-glycero-3-phosphocholine	Monosodium dihydrogen phosphate	L-Histidine hydrochloride monohydrate
	Cholesterol	Sodium chloride	Magnesium chloride hexahydrate
	Potassium chloride	Sodium hydroxide	Ethanol
	Potassium dihydrogen phosphate	Water for injection	Sucrose
	Sodium chloride		Sodium chloride
	Disodium hydrogen phosphate dihydrate		Disodium edetate dihydrate
	Sucrose		Water for injection
	Water for injection		

Table 1. Types of Covid-19 vaccines and their excipients

Adapted from the Ministry of Health Malaysia Clinical Guidelines on Covid-19 Vaccination (1)

- Individuals with a history of allergy and anaphylaxis are required to complete the pre-vaccination assessment prior to Covid-19 vaccination. General practitioners or medical specialists can document the pre-vaccination assessment based on the recommendations below:

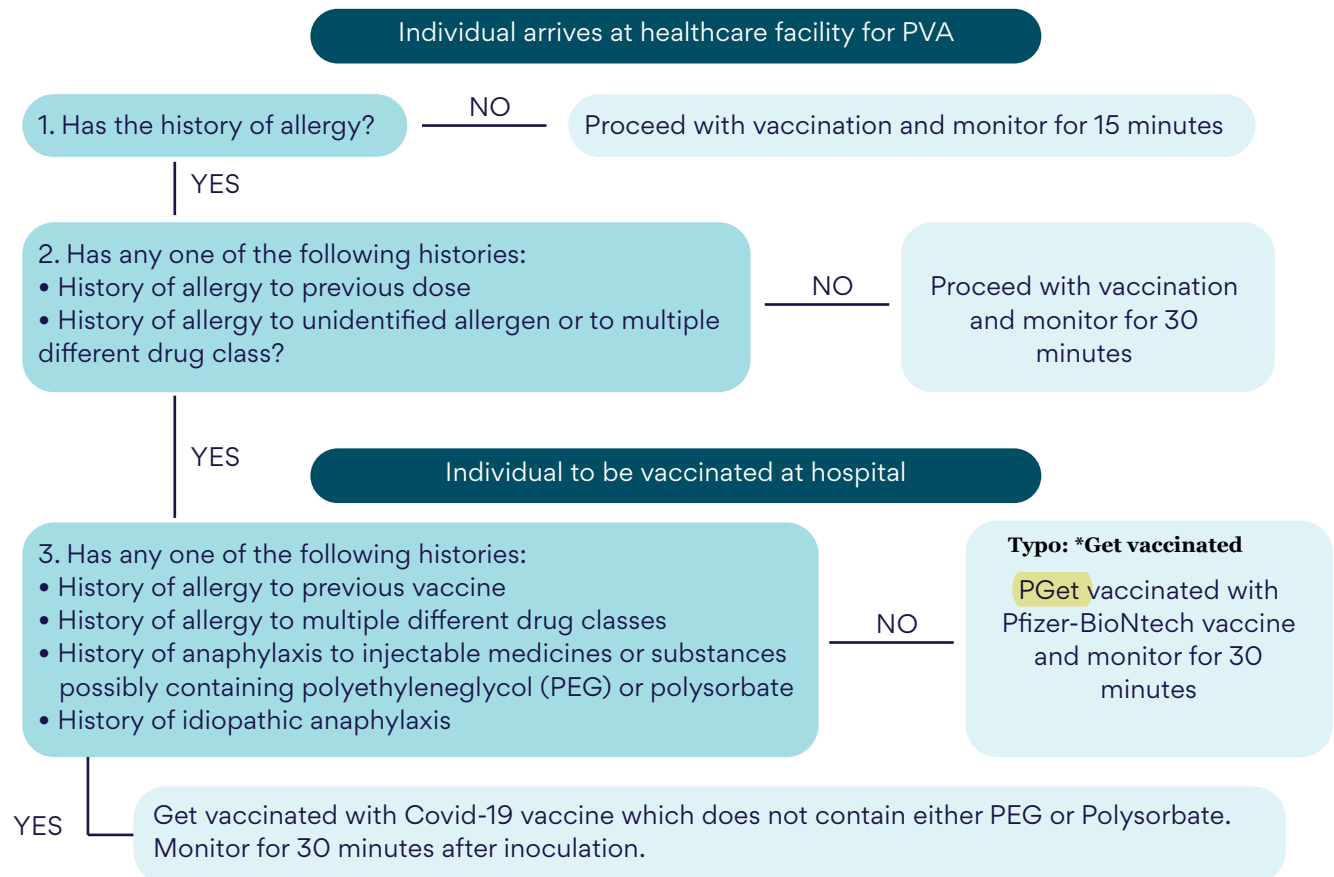


Figure 1. Flowchart of procedures for patients with a history of anaphylaxis
Adapted from the Ministry of Health Malaysia Clinical Guidelines on Covid-19 Vaccination (1)

- Anaphylaxis is life threatening, thus rapid action is required. Primary care facilities administering Covid-19 vaccine should always have adrenaline available.
- Signs and symptoms of anaphylaxis are:
 - Feeling faint
 - Wheezing
 - Clammy skin
 - Losing consciousness
 - Allergy symptoms, such as an irritated, raised rash (hives); feeling nauseated or sick; swelling (angioedema) or stomach-ache.
 - Difficulty breathing– e.g. fast, shallow breathing
 - Fast heartbeat
 - Confusion and anxiety
- As soon as the vaccinated individual begins exhibiting signs that an anaphylactic reaction may be beginning:
 - 1. Call for help. Dial 999 and the emergency call centre (999) must be informed that the patient has anaphylaxis so that an ambulance with an advanced cardiac team will be sent.
 - 2. Manage ABC (Airway, Breathing and Circulation). Lie patient flat with legs elevated and establish airway if threatened. Give 100% supplemental oxygen and continue monitoring the patient, their airways, and vital signs.
 - 3. Administer adrenaline 0.5 mg (0.5 ml of 1:1000) intramuscularly at mid lateral thigh.
 - 4. If the patient's condition worsens and the ambulance still has not arrived, a second dose of adrenaline may be necessary.
- For more information regarding the management of anaphylaxis please visit Clinical Guidelines on Covid-19 Vaccination in Malaysia, <http://bit.ly/cgocovid19> (Page 55-56)

Frequently Asked Questions (FAQs)

1. If a patient does not have any adverse reactions to the flu vaccine, **is it for them** to develop adverse reactions to the Pfizer-BioNTech vaccine?

No, it is not. Flu vaccines have polysorbate, and studies have shown that most people have developed polysorbate sensitivity.

However, if a patient is allergic to the flu vaccine, further investigation would be required to determine if the patient has a PEG allergy.

The good thing is that if patients have had no allergic reaction to a previously administered flu vaccine, they can take the Oxford Astra-Zeneca vaccine which also has a polysorbate excipient and vice versa for the Pfizer-Bion-Tech vaccine

2. Can patients with a history of Steven Johnson syndrome get vaccinated with the Pfizer-BioNTech vaccine?

The patient is at a higher risk for anaphylaxis and would be recommended to (conduct further assessment or) opt for a different vaccine.

3. Will treating a patient with an allergic reaction induced by a Covid-19 vaccine with prednisolone affect the vaccine effectiveness?

No, it will not. However, it is recommended that adrenaline be used as the first line of treatment for an anaphylactic reaction. In the cases of mild allergic reactions, antihistamines can be administered.

4. How can primary care health care professionals stabilise a patient experiencing anaphylaxis post-vaccination? Does the patient have to be transferred to a hospital setting?

Anaphylaxis is life threatening, thus rapid action is required. Primary care facilities administering Covid-19 vaccinations should always have adrenaline available.

Refer to previous page for the steps to be taken.

5. Is it safe for people with food allergies (i.e., seafood, eggs) to get vaccinated with the mRNA vaccines?

Based on the recommendation from the American College of Allergy as well as the Immunology & World Allergy Organisation, these individuals are categorised as having a medium level of risk. They are safe to get vaccinated with the mRNA vaccine.

6. Is it safe for people with a history of an anaphylaxis reaction to a food allergen (i.e., peanuts, eggs) to get vaccinated with the mRNA vaccines?

Based on the recommendation from the American College of Allergy as well as the Immunology & World Allergy Organisation, these individuals are also categorised as with medium risk. They are safe to get vaccinated with the mRNA vaccine.

(Based on the recommendation from the Ministry of Health, these individuals are safe to get Covid vaccine. However, they should be observed longer in a controlled environment after vaccination.)

7. Which of the Covid-19 vaccines are recommended for individuals with a PEG allergy?

PEG is currently only present in Pfizer-BioNTech vaccine in Malaysia. For individuals with a PEG allergy, it is recommended to administer them with the viral vector (i.e., Oxford AstraZeneca) or inactivated virus (i.e., CoronaVac/Sinovac) types of vaccine. All the Covid-19 vaccines currently available are safe and effective.

8. How should patients with a vaccination induced Immunisation Stress Related Response (ISRR), phobia or vasovagal reaction be managed?

These patients firstly need to be identified beforehand so that in the event of an adverse reaction, they can be differentiated from a patient with anaphylaxis. Patients with ISRR just need to be treated kindly and gently during the vaccination process. However, if unsure of the ability to manage them, the patient can be sent to a hospital setting where there are more staff dedicated to monitoring post-vaccination reactions. This could also help alleviate some of the patient's anxiety.

Key Points

- If patients present with allergic reaction after the first dose of vaccination, the patients should not be administered with the same vaccine. A different COVID-19 vaccine that is not contraindicated will be given if it is available
- Patients with known allergies to drugs or vaccines should be investigated in-depth to determine to pinpoint the exact allergen and if so, suitable Covid-19 vaccines not containing these allergens can then be offered to them for vaccination.
- Patients who may have allergies but are unclear on them should have a detailed history taken in terms of previous drugs or vaccines taken and whether they specifically did or did not cause any allergic reaction. Deductive analysis may be used as part of the clinical consultation process to determine that a patient is not, in fact, allergic to a component in a particular Covid-19 vaccine, enabling them to be vaccinated.



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