Frequently Asked Questions about COVID-19 vaccines for people with pre-existing allergic conditions

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This Frequently Asked Questions (FAQ) document has been created as supplemental information to aid vaccinators and other front-line healthcare professionals (GPs, Occupational Health etc.). The document provides information on how to advise allergic individuals according to their specific allergy history. This draft provides guidance with regard to three COVID-19 vaccines: *Comirnaty® (Pfizer-BioNTech), COVID-19 Vaccine Moderna®* and *COVID-19 Vaccine Astra Zeneca*. The ARIA-EAACI statement on severe allergic reactions to COVID-19 vaccines is available at the following link: https://onlinelibrary.wiley.com/doi/epdf/10.1111/all.14726

This FAQ relates **ONLY** to questions about pre-existing allergic conditions that vaccinators might encounter during consent. Specific vaccine administration questions are covered in existing NIAC guidance. This document is **NOT** a guide on how to treat anaphylaxis. All registered vaccinators have completed anaphylaxis training.

Background

Vaccine-associated anaphylaxis is extremely rare. The estimated rate is 1.3 per million vaccine doses. However, any vaccine can cause anaphylaxis. The risk of reaction is related to the components of the vaccine and the specific vulnerabilities of the individual vaccine recipient. Vaccination with *Comirnaty® (Pfizer-BioNTech)* vaccine commenced in the UK in December 2020. Following two suspected severe allergic reactions in the early stages of the programme, the UK authorities (MHRA) advised no one with a history of allergy should get the vaccine. This advice has now changed. However, this initial information may raise questions among vaccinators and those receiving the vaccine. Data collected by the CDC in the US indicates a rate of anaphylaxis of 6-11 per million doses of all mRNA vaccines used to date. All cases must be assessed carefully. While it is important that avoidable allergic reactions to vaccine do not happen, it is also important that vaccination is not avoided by persons because of unfounded concerns.

Many so-called “reactions” to vaccinations are not allergic in origin. Immediate symptoms after vaccination are more likely to be caused by vasovagal episodes or anxiety. Large local reactions at the injection site, fever, headaches and myalgia are expected/normal immune responses to the vaccine, not an abnormal response due to allergy.

Q1. What should I look for when asking a person about their report of previous anaphylaxis?

A. Anaphylaxis is a severe, potentially life-threatening systemic allergic reaction characterised by rapid onset (usually within 15 minutes but up to 2 hours, rarely longer). If previous anaphylaxis is reported, vaccinators should check for the following typical features:

- Two or more of the following after exposure to a **likely** allergen (e.g. food, insect sting, medication):
    - Skin/mucosal tissue involvement (flushing, itch, urticaria rash / hives, swelling)
    - Difficulty breathing (wheeze, stridor, heavy chest / tightness)
    - Reduced blood pressure (BP) or suggestive symptoms (e.g. dizziness, visual loss)
    - Persistent severe gastrointestinal (GI) symptoms.
- Reduced blood pressure (BP) after exposure to known allergen (e.g. food, insect sting, medication)
- Acute onset of **both** skin/mucosal tissue involvement, airway compromise, reduced BP or associated symptoms, persistent severe GI symptoms, without an identifiable cause (unexplained or idiopathic anaphylaxis).

Useful Link: Differentiating vasovagal episodes from ananphylaxis

Q2. Many people report food and medication allergy. Are there large numbers of people who should not receive COVID-19 vaccine?

A. No. There are very few people who cannot receive the current vaccines due to pre-existing allergies or history of anaphylaxis. Most people with a history of anaphylaxis can receive a COVID-19 vaccine but they should all be observed for 30 minutes post-vaccination.

The only allergy related contraindications are:

- anaphylaxis to a previous dose of the same COVID-19 vaccine
- anaphylaxis to any components of the COVID-19 vaccine (See Question 4 below)

Q3. How do I establish whether a person, with a history of unexplained anaphylaxis, is not allergic to one of the COVID-19 vaccine components?

A. Most cases of anaphylaxis can be explained by a detailed allergy focused history. A history will usually reveal if the anaphylaxis was related to food, medication, bee stings etc.

People with a history of unexplained anaphylaxis to an unidentified injectable medication should have their vaccine deferred and efforts made to establish the underlying cause by their GP, hospital doctors or specialists.

Q4. The vaccine components seem complicated. What are the main potential allergens in COVID-19 vaccines?

A. *Comirnaty® (Pfizer-BioNTech)* and *COVID-19 Vaccine Moderna®* both contain polyethylene glycol/macrogol (PEG), which is a known allergen found in some medicines and also in household goods and cosmetics. Allergy to PEG is extremely rare but would contraindicate receipt of these vaccines.

COVID-19 Vaccine Astra Zeneca contains Polysorbate-80, a High MW polysaccharide also reported to cause allergic reactions.

COVID-19 Vaccine Moderna® contains a buffer called TROMETAMOL, which has been implicated in one report of contrast medium anaphylaxis relating to gadolinium-based contrast agents (GBCAs) used in MRI radiological studies. Patients with documented anaphylaxis to TROMETAMOL or to GBCAs should not receive the *Moderna®* vaccine but should be offered the Pfizer/BioNTech Comirnaty® or Astra Zeneca/Oxford vaccine. (See Question 9 below).

Q5. How would I identify a person with a potentially unrecognised PEG allergy?

A. PEG allergy should be suspected in people reporting anaphylaxis after:

- drinking oral laxative bowel preparations for colonoscopy procedures and laxatives such as Movicol®, Mirilax®, Dulcolax®
- steroid joint injections (methylprednisolone acetate - Depo-Medrone®)
- depot progesterone contraceptive (Depo-Provera®)
- Teedex®.

People presenting with a history of anaphylaxis to multiple classes of drugs may also have an undiagnosed PEG or Polysorbate 80 allergy. Persons that report anaphylaxis to PEG containing compounds should have vaccination deferred until alternative vaccine available. Consider discussing with allergist/immunologist.

Q6. If a person has had a mild allergic reaction to an unknown medication, is it safe to proceed with COVID-19 vaccination?

A. Yes. Mild allergic reaction to drugs is not a contraindication itself to COVID-19 vaccination.

Q7. Some people report reactions to NSAIDs such as ibuprofen (e.g. Brufen®), and occasionally also to diclofenac (e.g. Voltarol® and Difene®); can these people receive a COVID-19 vaccine?

A. Yes. NSAID allergy is actually very common. People allergic to NSAIDS are not at greater risk from COVID-19 vaccines.

Q8. Can people with multiple antibiotic allergies receive a COVID-19 vaccine?

A. Yes. A person with a history of penicillin allergy or allergies to other antibiotics can be vaccinated. If they have a convincing history of anaphylaxis, then they should be observed for 30 minutes after receiving their vaccine.

Q9. Can a person with a history of anaphylaxis to intravenous contrast dye receive a COVID-19 vaccine?

A. Yes. They should receive the vaccine, unless it was documented that it was a gadolinium-based contrast agent (GBCA, see Question 4 above) during MRI scan. In that particular case, they should not be given *COVID-19 vaccine Moderna®.* They can be offered the *Comirnaty® (Pfizer-BioNTech)* or the *COVID-19 Vaccine Astra Zeneca* (see Question 4 above). As with all patients with a history of anaphylaxis, they should be monitored for 30 minutes following vaccination.

Q10. Can a person with a history of reactions or contact allergy with patch testing positive to nickel, perfumes, and cosmetics receive a COVID-19 vaccine?

A. Yes.

Q11. Can people with a history of anaphylaxis to a specific foodstuff receive a COVID-19 vaccine?

A. Yes. People reporting immediate (IgE) food allergy, including a history of anaphylaxis, delayed (non IgE) mediated food allergy and food intolerance are all suitable candidates for this vaccine. Only those with a convincing history of anaphylaxis are required to wait 30 minutes after their vaccine.

Q12. Can people who have had reactions (including anaphylaxis) to any influenza vaccine receive a COVID-19 vaccine?

A. Yes. There are no specific associations between currently available COVID-19 vaccines and influenza vaccines.

Q13. Can a person with a history of anaphylaxis to HPV vaccine receive a COVID-19 vaccine?

A. Most people who have had a reaction to HPV vaccine have had non-allergic reactions such as redness at the site or feeling faint, and these are not allergic reactions and are not a contraindication to receiving a COVID-19 vaccine.

Q14. Is venom allergy a risk factor for reacting to a COVID-19 vaccine?

A. No. People who have experienced large local reactions, but not anaphylaxis (as defined above) to bee or wasp stings do not need to be observed for longer than 15 minutes.

Q15. Are people with chronic urticaria/angioedema more likely to have an allergic reaction to a COVID-19 vaccine?

A. No. However, people with this condition may experience mild urticaria after receiving the vaccine as their rashes are often triggered by stressors. This should be considered before declaring them allergic to the vaccine. People with chronic urticaria should take their normally prescribed antihistamine on the day of vaccination. They do not need to be observed for longer than 15 minutes.

Q16. Can an individual on asthma medication receive a COVID-19 vaccine?

A. Yes. Underlying asthma is not a contraindication.

Q17. Can a person who has had "a reaction" to the first dose of a COVID-19 vaccine receive a 2nd dose?

A. Most people who have had a "reaction" to the first dose of a COVID-19 vaccine, have had non-allergic reactions such as redness at the site, feeling faint etc. These are not allergic reactions. (Useful link: Common side effects after the COVID-19 vaccine).
Anyone who has had mild allergic signs such as urticaria with the first dose (without a history of chronic urticaria) would need observation for 30 minutes after the second dose.
Persons who have had a confirmed anaphylaxis to a first dose of a COVID-19 vaccine should not receive a second dose of that same vaccine type. The individual should be referred to an allergist/immunologist for evaluation.

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