The Immunisation Advisory Centre

COVID-19 EDUCATION

Update around management of those with allergic reaction to their first dose of Comirnaty™ or history of PEG allergy

Key points

True anaphylaxis to Comirnaty™, the Pfizer COVID-19 vaccine, occurs at a higher rate than after other vaccinations such as influenza vaccine. It is most common in females and usually presents rapidly. Although initially it was thought those with anaphylaxis should not be revaccinated, increasing experience now shows they may be revaccinated, but only in specialist immunology clinics.

Some patients develop delayed allergic type symptoms. These people can usually be revaccinated.

Most patients with a history of anaphylaxis to other medications, other vaccines, foods and venom can be safely vaccinated.

Further information

Shortly after the first use of the mRNA COVID vaccine (Comirnaty; Pfizer/BioNTech) it was noted that the rate of anaphylaxis to the vaccine (5–11 per million doses) is higher than after most other vaccines. This led to precautions in those with a history of polyethylene glycol (PEG) allergy and those who have an allergic reaction to their first dose. Experience has since been gathered which shows some of these people may proceed to vaccination in certain situations.

In a recent review of adverse events following both mRNA vaccines given in America nearly all confirmed anaphylaxis occurred in females (95%), on the day of vaccination (98%), and after dose one (82%); most individuals had a history of allergies (78%) and had symptom onset within 30 minutes (87%). The estimated incidence rate of confirmed anaphylaxis was 4.8 (95%CI, 3.2–6.9) per million doses of Comirnaty.

Polyethylene glycol with a molecular weight (MW) of 2000 is used in mRNA vaccines, such as Comirnaty. It is suspected to be the cause of allergic reactions. PEG is widely used in medications, cosmetics, personal hygiene products and processed foods. Allergy to PEG is rare and is predominantly seen in products with MW higher than 3350. It is likely that patients have an individual threshold (dose and MW) for reactions. The mechanism of PEG allergy is unclear and may not be IgE-mediated. Skin tests are not advised as they may be negative in patients with PEG anaphylaxis.

Prior allergy or anaphylaxis

Individuals can receive the COVID-19 vaccine with:

- a prior history of allergy to an inhalant, food or venom
- a family history of allergies
- allergic conditions such as asthma, atopic dermatitis or allergic rhinitis.

History of anaphylaxis to another vaccine and/or multiple drugs

Those with a history of anaphylaxis to another vaccine and/or multiple drugs (injectable and/or oral) tend to react to unrelated medications. (The relative incidence of anaphylaxis following administration of these mRNA COVID-19 vaccines was seven times higher for recipients with a prior history of anaphylaxis in one series.) In this case, they can receive the vaccine but should be carefully observed for 30 minutes. As well as being observed for longer, they should be given clear post vaccination advice.

History of anaphylaxis to any component of the vaccine

Those with a history of anaphylaxis to any component of the vaccine, including PEG, should be discussed with local immunologist or not have the vaccine. If no immunologist is available, discuss them with an IMAC medical advisor (via 0800 IMMUNE/0800 466 863 or 0800Immune@auckland.ac.nz). These patients can be offered an alternative vaccine once one is available, although, specialist immunology clinics here are proceeding to vaccinate these patients under carefully controlled conditions.

History of allergic reaction to PEG-asparaginase

Among patients who have developed an allergic reaction to PEG-asparaginase during treatment, most are allergic to the asparaginase component of the chemotherapy. If the patient has a known PEG-asparaginase anaphylaxis, the recommendation remains to vaccinate against COVID-19, but to proceed with caution. Vaccines can be given in larger sites at or within close proximity to hospital. A post-vaccination observation time of a minimum of 30 minutes is required.

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Suspected allergic reaction or anaphylaxis to first dose

Delayed reactions such as swelling around the eyes or face (typically within 24 hours) and systemic hives or rash (developing from a few hours to days) will usually respond to antihistamine or settle spontaneously. Most patients with such allergic symptoms with the first dose can be safely given the second dose in the community.

Anaphylaxis has a sudden onset and rapid progression with a variety of dermatologic (urticaria, generalised pruritus with rash), cardiovascular and respiratory (wheeze, rapid respiration associated with increased use of respiratory muscles or recession or grunting) symptoms. It is easy to confuse vasovagal or immunisation stress-related response symptoms with anaphylaxis.

If anaphylaxis has occurred the patient should be referred to an immunology clinic for second dose administration run by the Immunology Services in Auckland, Wellington and Christchurch. This is a small service solely for those patients with anaphylaxis to first dose or with a history of anaphylaxis to one of the vaccine components (e.g. PEG).

All other patients, including those with urticaria and/or angioedema not involving the airway, can be revaccinated. They may take an antihistamine (e.g. cetirizine or loratadine 10–20mg) prior to or following the second dose. Up to half of these patients will have a similar milder reaction with the second dose. There is no evidence to suggest that these mild reactions will increase in severity or progress to anaphylaxis; data suggests that severe reactions are not IgE-mediated and do not behave in the same way.

For more information contact 0800IMMUNE or 0800Immune@auckland.ac.nz

See also **covid.immune.org.nz** for further written resources related to the management of anaphylaxis and clinical review of adverse events following immunisation (AEFI).

References

Desai AP, Desai AP and Loomis GJ. Relationship between pre-existing allergies and anaphylactic reactions post mRNA COVID-19 vaccine administration. Vaccine https://doi.org/10.1016/j.vaccine.2021.06.058

Klein NP, Lewis N, Goddard K et al. Surveillance for adverse events after COVID-19 mRNA vaccination. JAMA. doi:10.1001/jama.2021.15072 Published online September 3, 2021.

Krantz MS, Kwah JH, Stone CA et al. Safety evaluation of the second dose of messenger RNA COVID-19 vaccines in patients With immediate reactions to the first dose. JAMA July 26, 2021. doi:10.1001/jamainternmed.2021.3779

Xu J, Vanijcharoenkarn K, Sexton ME, et al. Delayed hypersensitivity reactions following first dose of the SARS-CoV2 mRNA vaccines. J Gen Intern Med DOI: 10.1007/s11606-021-07015-w

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