

Allergic Reactions to Covid19 (Sars-Cov-2) Vaccine

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1. Background

The recent approval of various covid vaccines will result in massive immunization of the public with these vaccines. Cases of allergic reactions such as rashes, urticaria, anaphylaxis have been reported worldwide. The following is a summary, from an allergist's perspective, of the components found to be present in situations where the patient has experienced an allergic reaction to the Covid 19 vaccine.

The FDA granted an Emergency Use Authorization of the Pfizer-BioNTech COVID-19 vaccine on December 11, 2020 and the Moderna vaccine on December 18, 2020.

The Covid19 vaccine (BNT 162b2) from Pfizer- BioNTech pharmaceuticals contains various excipients. Among these, there is one excipient with the ability to cause allergic reactions, ALC -0159, since it contains polyethylene glycol (PEG) or macrogol.

After immunization with this vaccine, reports of reactions occurred during December 2020 in Alaska at Fairbanks Memorial Hospital. The reaction was a systemic, anaphylactic type and treated with epinephrine, corticoids and antihistamines.

Reports of reactions to the vaccine have also occurred in England and Spain. Dr June Raine, Chief Executive of the Medicines and Healthcare products Regulatory Agency in the UK, made the following statement to vaccination centers regarding COVID-19 vaccination with the Pfizer/ BioNTech vaccine: "Any person with a history of anaphylaxis to a vaccine, medicine or food should not receive the Pfizer/BioNTech vaccine. A second dose should not be given to anyone who has experienced anaphylaxis following administration of the first dose of this vaccine.

CDC considers a history of the following to be a contradiction to vaccination with both the Pfizer BioNTech and Moderna COVID-19 vaccine:

Severe allergic reaction (eg anaphylaxis) after a previous does of an mRNA COVID-19 vaccine or any of its components.

Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol (PEG)).

Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG).

These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (eg under observation, in a setting with advanced medical care available).

The ACAAI (American College of Allergy Asthma and Immunology) on Dec 21st 2020 stated that reactions to vaccines, in general, are rare with the incidence of anaphylaxis estimated at 1.31 in 1 million doses given. Nevertheless, the ACAAI's COVID-19 Vaccine Task Force recommends the following guidance for physicians and other providers related to risk of an allergic reaction on vaccination.

The mRNA COVID-19 vaccines should be administered in a health care setting where anaphylaxis can be treated. All individuals must be observed for at least 15-30 minutes after injection to monitor for any adverse reaction. All anaphylactic reactions should be managed immediately with IM epinephrine as the first line treatment.

The mRNA COVID-19 vaccines should not be administered to individuals with a known history of a severe allergic reaction to any component of the vaccine. Although the specific vaccine component causing the anaphylaxis has not been identified, polyethylene glycol is one of its ingredients and has been known to cause anaphylaxis.

Data related to risk in individuals with a history of allergic reactions to previous vaccinations and/or mast cell activation syndrome/idiopathic anaphylaxis is very limited and evolving. A clinical decision to administer

either of the mRNA COVID-19 vaccines should be undertaken by the physician or other provider administering the vaccine using their professional judgment and in consultation with the patient, balancing the benefits and risks associated with taking the vaccine.

Individuals with common allergies to medications, foods, inhalants, insects and latex are no more likely than the general public to have an allergic reaction to the mRNA COVID-19 vaccines. Those patients should be informed of the benefits of the vaccine versus its risks.

The mRNA COVID-19 vaccines are not live vaccines and can be administered to immunocompromised patients. Physicians and other providers should inform such immunocompromised patients of the possibility of a diminished immune response to the vaccines.

Anyone with questions related to the risk of an allergic reaction to either of the mRNA COVID-19 vaccines should contact their local board-certified allergist/immunologist. This ends the ACAAI's statement.

Allergic individuals have experienced allergic reactions to a variety of compounds. One compound frequently causing these reactions is PEG composition. An understanding of PEG composition may help reduce the risk of an allergic reactions to the vaccine such as rashes, urticaria, anaphylaxis, pruritus, tingling, flushing, hypotension and bronchospasm.

PEG compounds are frequently used as excipients in medicine such as pill binders, tablet coatings, parenteral liquid preparations, lubricants, gels, ointments, etc., and produce allergic reactions. Polyethylene glycols (H(OCH₂CH₂)_nOH) are synthesized via polymerization of ethylene oxide. Resulting PEG polymers vary in chain length and molecular weight (MW). Their MW has variations ranging from 200 to 35,000 and 100,000 MW. PEG molecules with a MW less than 400 are clear viscous liquids use in preparations such as toothpaste PEG6, skin antiseptic PEG-9, moisturizer cream PEG-75, PEG-100 in optic solutions, shampoos, hair gels, hair dyes, lipsticks, oral hygiene products, shaving creams and food additives including polysorbate 80 in ice creams. PEG with more than 1000 MW usually are solids used in products such as GI preparations including laxative and cough syrup. PEG with over 6000 MW are used in antibiotic tablets as amoxicillin clavulanate and ciprofloxacin.

Polyethylene glycol may be the major allergen in depo preparations reported to produce severe allergic reactions. Depo medroxyprogesterone acetate injected intramuscular (PEG 3,350 MW), depo methylprednisone and depo penicillin and intra articular preparations frequently used in injectables have been reported as producing systemic allergic reactions. No reactions were noted on the soluble preparation of prednisolone. Polyethylene glycol (PEG or macrogol) is used in both covid19 vaccines. Polyethylene glycol -2000 is an ingredient in the covid 19 vaccine preparation of Pfizer/biontech BNT 6262.

The excipients contained in the Pfizer-Biotec Covid 19 vaccine BNT162b2 are:

ALC-0315 = 4-hydroxybutyl azanediy1)bis (hexane-6,1-diy1)bis(2-hexyldecanoate),

ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-

glycerol-3-phosphocholine, cholesterol, potassium chloride, potassium dihydrogen phosphate,

sodium chloride, disodium hydrogen phosphate dihydrate, sucrose, water for injections.

Side effects associated with this vaccine are injection site pain, fatigue, headache, muscle pain, chills, joint pain, fever, nausea, swollen lymph nodes, malaise and injection site swelling and or redness. Many of these symptoms have been noted to be more severe after the second injection appearing one- or two-days following vaccination.

The Moderna COVID-19 Vaccine contains a synthetic messenger ribonucleic acid (mRNA) encoding the pre-fusion stabilized spike glycoprotein (S) of SARS-CoV-2 virus. The vaccine also contains the following ingredients: lipids (SM-102, 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 [PEG2000-DMG], cholesterol, and 1,2-distearoyl-snglycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose. A FDA Meeting on December 17, 2020 reported the following regarding allergic reactions to the Moderna vaccine. Overall, the most frequently reported systemic AR was fatigue, reported by 68.5% of vaccine recipients and 36.1% of placebo recipients. After any dose, Grade 3 fatigue was reported by 9.6% of vaccine participants and 1.3% of placebo recipients. Grade 4 fatigue was reported by 1 participant in the vaccine group and none in the placebo group. After dose 1, any/Grade 3 fatigue was reported by 37.2%/1.0% of vaccine recipients and after dose 2 any/Grade 3 fatigue was reported by 65.2%/9.7% of vaccine recipients. The median duration for fatigue in vaccine recipients was 2 days after any dose. The highest rates of fatigue were reported by participants 18 to 64 years after the 2nd dose, with 67.6% reporting any fatigue, 10.6% reporting Grade 3, and 1 participant reporting Grade 4 (after Dose 1). Rates of other solicited systemic AR were: headache 63.0% vaccine group vs. 36.5% placebo group; myalgia 59.6% vaccine group vs. 20.1% placebo group; arthralgia 44.8% vaccine group vs. 17.2% placebo group; and chills 43.4% vaccine group vs. 9.5% placebo group. The rates of Grade 3 AR were: headache 5.5% vaccine group vs. 2.2% placebo group; myalgia 8. No systemic anaphylactic reactions were reported.

AstraZeneca, a biopharmaceutical company, worked with Oxford University's Jenner Institute and the Oxford Vaccine Group (Vaccitech) to develop the covid vaccine AZD1222 a coronavirus vaccine candidate formerly known as ChAdOx1 nCoV-19. This vaccine is made from a virus ChAdOx1 (a weakened version of a cold virus adenovirus causing infections in chimpanzees). Proteins from the SARS-CoV-2 coronavirus called Spike glycoprotein (S) were then added to the ChAdOx resulting in AZD1222. This vaccine was approved and is being used in mass vaccinations in England. This same vaccine is now being manufactured and used in India. The Serum Institute of India, the largest vaccine producer in the world, Meanwhile, a private Indian company, Bharat Biotech, and the government-run Indian Council of Medical Research (ICMR) jointly developed the Covaxin vaccine, and are manufacturing it locally.

The Russian COVID-19 vaccine, gamaleya Sputnik V (Gam-COVID-Vac), is an adenoviral-based vaccine against the SARS-CoV-2 coronavirus. It was developed by a state institute, the Gamaleya National Research Centre of Epidemiology and Microbiology; this is the same government lab that developed what is claimed to be the vaccine "effective against the Ebola virus", as well as a vaccine against the MERS virus. The surface

protein of SARS-CoV-2, the virus that causes COVID-19, was added to the adenovirus. The first shot used adenovirus 26 (Ad26) as the vector for the coronavirus surface protein, called spike, while the second shot used adenovirus 5 (Ad5). They report that this vaccine, does not have any side effects. A commentary in *The Lancet* by McElrath raised concerns about using Ad5 as a vehicle for COVID-19 vaccines, because it was linked to a catastrophe in an HIV vaccine study 13 years ago. In that trial, vaccine recipients had higher rates of HIV infection than those in the placebo group. The Sputnik V has been used for immunization in Russia and has been purchased by the Argentine government for mass immunization there.

The Chinese COVID-19 vaccine, Coronavac, is produced by Sinovac based in Beijing. It was made from the actual coronavirus which was chemically crippled so that it cannot produce the disease. A similar procedure was used to produce the rabies vaccine. Coronavac was used for immunizations in Brazil and now Brazil in the process of producing Coronavac in that country.

The other Chinese COVID-19 vaccine is called BBIBP- corV and is produced by Sinopharma's China National Biotec group. This vaccine is produced with an inactivated Sars-Covid-v2 virus; there have been reports of numerous side effects with this vaccine.

J & J vaccine: Johnson and Johnson's single-dose vaccine has been shown to be 66% effective at preventing moderate to severe infection, but it is less effective against the new South African variant. The vaccine is a recombinant, replication-incompetent adenovirus serotype 26 (Ad26) vector that encodes the full-length spike (S) protein found on the surface of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) There is no documentation as yet regarding allergy reactions to this vaccine.

The Maryland-based company Novavax has developed a protein-based coronavirus vaccine called NVX-CoV2373. The vaccine produced strikingly high levels of antibodies in early clinical trials. In September, the vaccine entered a Phase 3 clinical trial in the United Kingdom, and another one in the United States at the end of December. In January, Novavax announced that in the British trial, the vaccine had an efficacy rate of 89 percent.

In conclusion, a physician should be aware of the vaccine components as well as the history of the patient receiving the vaccine. If there is a reaction, providers should attempt to determine whether the reaction reported following vaccination are consistent with immediate allergic reactions versus other types of reactions commonly observed following vaccination, such as vasovagal reaction or post-vaccination side effects. It is recommended that patients experiencing an allergic reaction to the Covid 19 vaccine have the following studies done: total IgE; CBC w differential; CRP; sedimentation rate; basophil histamine release; Tryptase; C1Q, C3, C4; allergy testing.

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