

Pfizer-Biontech COVID-19 Vaccine Allergy and Moderna COVID-19 Vaccine Allergy

(As of February 28, 2021)

Background: There were 2 reports of anaphylaxis and 1 report of allergic reaction following the Pfizer-Biontech COVID-19 vaccine immunization in England. Following the incidents, the Medicines and Healthcare Products Regulatory Agency (MHRA) of the Great Britain issued the following warnings:

- 1) Any person with a history of anaphylaxis to a vaccine, medicine or food should not receive the vaccine;
- 2) Any person who has anaphylaxis to the first dose of the vaccine should not receive the second booster dose which is scheduled 3 weeks after the first dose.¹

Current (February 2021) United States FDA recommendation regarding absolute contraindication for getting the Pfizer-Biontech COVID-19 Vaccine and Moderna COVID-19 Vaccine (should not get the vaccine): the specific vaccine allergy is the only medical reason not to get the vaccine

- 1) Any person who had a severe allergic reaction after a previous dose of the vaccine;
- 2) Any person who had a severe allergic reaction to any ingredient of this vaccine (mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose).²

Current (February 2021) estimated COVID-19 vaccine anaphylaxis (severe allergic reaction) rate in the United States (estimated rates from 12/14/2020 – 2/12/2021; Pfizer-Biontech COVID-19 vaccine and Moderna COVID-19 Vaccine):

1. 4.7 cases per million doses given for Pfizer-Biontech COVID-19 vaccine;
2. 2.5 cases per million doses given for Moderna COVID-19 Vaccine
3. Reference point: allergic reaction to vaccine in general is about 1.3 per million
4. My opinion: rate of allergic reaction to the Pfizer and Moderna COVID-19 vaccines is extremely rare; rate of reaction is not significantly higher for COVID-19 vaccines than for other vaccines.³

Current (February 2021) United States FDA recommendation regarding precaution for administering the Pfizer-Biontech COVID 19 vaccine and the Moderna COVID-19 vaccine in patients with allergy:

- 1) Waiting in a health care facility for 15 minutes if the patient has history of food, pet, insect, bee venom, fire ant, latex allergies;
- 2) Waiting in a health care facility for 30 minutes (or deferral of vaccination) if the patient has a history of anaphylaxis (more severe allergic reaction like problem breathing or passing out) to another vaccine or an injectable medication.⁴

¹ Confirmation of guidance to vaccination centres on managing allergic reactions following COVID-19 vaccination with the Pfizer/BioNTech vaccine - GOV.UK (<https://www.gov.uk/government/news/confirmation-of-guidance-to-vaccination-centres-on-managing-allergic-reactions-following-covid-19-vaccination-with-the-pfizer-biontech-vaccine>)

² <https://www.fda.gov/media/144414/download>

³ <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-01/06-COVID-shimabukuro.pdf>

⁴ <https://www.fda.gov/media/144414/download>

Adverse effect (not allergy and not contraindication) for the Pfizer-Biontech COVID 19 Vaccine:

- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)

The above symptoms are expected occasional side effects after getting this type of COVID-19 vaccine and are not allergies or anaphylaxis. They are not contraindication for getting the second dose of the same vaccine.

Conclusion (Dr. Schuman Tam): ⁵

- 1) Everybody over 16 years old who wants to get the Pfizer-Biontech vaccine should get it (priority is based on CDC recommendation);
- 2) Everybody over 18 years old who wants to get the Moderna vaccine should get it (priority is based on CDC recommendation);
- 3) Patients who have allergy in general may have higher chance of allergic reaction to the COVID-19 vaccine just because they are prone to have allergies;
- 4) A person who has a history of mild allergy (like allergic rhinitis, asthma) or food allergy should be ok to get the vaccine with 15 minutes wait in a healthcare facility equipped to treat him or her, in case of anaphylaxis;
- 5) Anaphylaxis rate due to current COVID-19 vaccine is extremely low and is not significantly higher than other available vaccines;
- 6) A person who has a history of anaphylaxis after receiving prior vaccination of any type or after receiving an injectable medication should be observed for 30 minutes in a healthcare facility equipped to treat him or her in case of anaphylaxis;

⁵ **DISCLAIMER:** This document is intended to provide educational information only and IS ONLY PROVIDED AS A CONVENIENCE; it is not to be considered as a valid resource for information or contact or communication with a Asthma & Allergy Clinic of Marin and San Francisco, Inc. ("AASTHMA") physician, our practice or its staff. The information on this document is not intended or implied to be a substitute for professional medical advice, diagnosis or treatment. All content, including text and information, contained on or available through this document is for general information purposes only. AASTHMA makes no representation and assumes no responsibility for the accuracy of information contained on or available through this document, and such information is subject to change without notice. You are encouraged to confirm any information obtained from or through this document with other sources, and review all information regarding any medical condition or treatment with your physician. NEVER DISREGARD PROFESSIONAL MEDICAL ADVICE OR DELAY SEEKING MEDICAL TREATMENT BECAUSE OF SOMETHING YOU HAVE READ ON OR ACCESSED THROUGH THIS DOCUMENT. AASTHMA does not recommend, endorse or make any representation about the efficacy, appropriateness or suitability of any specific tests, products, procedures, treatments, services, opinions, health care providers or other information that may be contained on or available through this document. AASTHMA IS NOT RESPONSIBLE NOR LIABLE FOR ANY ADVICE, COURSE OF TREATMENT, DIAGNOSIS OR ANY OTHER INFORMATION OR SERVICES THAT YOU OBTAIN THROUGH THIS DOCUMENT.

- 7) A person who has a history of anaphylaxis to the first dose of the Pfizer-Biontech vaccine, or a first dose of Moderna vaccine, or a history of anaphylaxis to any component of the vaccine should not receive the vaccine. In this special circumstance in my opinion, the patient should be referred to an allergy and immunology specialist for potential skin testing before the administration of the vaccine;
- 8) At the present time, allergists and immunologists believe that allergic reaction to the Pfizer and Moderna vaccines is due to polyethylene glycol, an inactive ingredient, in the 2 COVID vaccines. The newly authorized Janssen COVID 19 vaccine contains polysorbate 80 which is similar to polyethylene glycol. Skin testing to these ingredients is possible⁶;
- 9) The authorized COVID 19 vaccines can be given to an allergic patient if the administration is given carefully, after evaluation of the patient and after discussion with the risk and benefits with the patient, by a physician experienced in dealing with drug allergy.

⁶ <https://doi.org/10.1016/j.jaip.2020.12.047>