Information on Vaccine Contents and Handling Potential Reactions

This information is directly copied from Appendices B, C, and D of the US CDC's "Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States", which can be found here: <u>https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html</u> It is provided as a convenient separate source of this information.

Appendix B: Triage of people with a history of allergies or allergic reactions

Triage of persons presenting for Pfizer-BioNTech COVID-19 vaccination

CONTRAINDICATION TO COVID- 19 VACCINATION	PRECAUTION TO COVID- 19 VACCINATION	MAY PROCEED WITH COVID- 19 VACCINATION	
 History of the following: Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine[†] Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of a COVID-19 vaccine[†] 	 Among people without a contraindication, a history of: Any immediate allergic reaction* to other vaccines or injectable therapies‡ Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa. See footnote for additional information on additional measures to take in these people.# 	 Among people without a contraindication or precaution, a history of: Allergy to oral medications (including the oral equivalent of an injectable medication) History of food, pet, insect, venom, environmental, latex, etc., allergies Family history of allergies 	
Actions:	Actions:	Actions:	
 Do not vaccinate. Consider referral to allergist-immunologist. Consider other vaccine alternative.[†] 	 Risk assessment Consider referral to allergist- immunologist 30-minute observation period if vaccinated 	 30-minute observation period: people with history of anaphylaxis (due to any cause) 15-minute observation period: all other people 	

* See Appendix C for a list of ingredients. People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna).
* Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or

anaphylaxis that occur within four hours following administration.

[‡]People with a history of an immediate allergic reaction to a vaccine or injectable therapy that contains multiple components, one or more of which is a component of a COVID-19 vaccine, have a precaution to vaccination with that COVID-19 vaccine, even if it is unknown which component elicited the allergic reaction.

#Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. People with a contraindication to mRNA COVID-19 vaccines (including due to a known allergy to PEG) have a precaution to Janssen COVID-19 vaccine. Among people who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 vaccine (administered at least 28 days after the mRNA COVID-19 dose). People with a contraindication to Janssen COVID-19 vaccine (including due to a known allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. For people with these precautions, referral to an allergist-immunologist should be considered. Healthcare professionals and health departments may also request a consultation from the <u>Clinical Immunization Safety Assessment COVIDvax</u> project. In patients with these precautions, vaccination should only be undertaken in an appropriate setting under the supervision of a healthcare professional experienced in the management of severe allergic reactions.

Appendix C: Ingredients included in COVID-19 vaccines

The following is a list of ingredients for the <u>Pfizer-BioNTech</u>, <u>Moderna</u>, and <u>Janssen</u> COVID-19 vaccines reported in the prescribing information for each vaccine.*

Description	Pfizer-BioNTech (mRNA)	Moderna (mRNA)	Janssen (viral vector)
Active ingredient	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Recombinant, replication- incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein
Inactive ingredients	2[(polyethylene glycol (PEG))- 2000]-N,N-ditetradecylacetamide	PEG2000-DMG: 1,2- dimyristoyl-rac-glycerol, methoxypolyethylene glycol	Polysorbate-80
	1,2-distearoyl-sn-glycero-3- phosphocholine	1,2-distearoyl-sn-glycero-3- phosphocholine	2-hydroxypropyl-β- cyclodextrin
	Cholesterol	Cholesterol	Citric acid monohydrate

Ingredients included in Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines

Description	Pfizer-BioNTech (mRNA)	Moderna (mRNA)	Janssen (viral vector)
	(4- hydroxybutyl)azanediyl)bis(hexane- 6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8- ((2-hydroxyethyl) (6-oxo-6- (undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate
	Sodium chloride	Tromethamine	Sodium chloride
	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Potassium chloride	Acetic acid	
	Dibasic sodium phosphate dihydrate	Sodium acetate	
	Sucrose	Sucrose	

Ingredients included in Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines

* None of the vaccines contain eggs, gelatin, latex, or preservatives. All COVID-19 vaccines are **free from metals** such as iron, nickel, cobalt, lithium, rare earth alloys or any manufactured products such as microelectronics, electrodes, carbon nanotubes, or nanowire semiconductors.

Note: Both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain polyethylene glycol (PEG). PEG is a primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures, an inactive ingredient or excipient in many medications, and is used in a process called "pegylation" to improve the therapeutic activity of some medications (including certain chemotherapeutics). Additionally, cross-reactive hypersensitivity between PEG and polysorbates (included as an excipient in some vaccines and other therapeutic agents) can occur. Information on active or inactive ingredients for vaccines and medications can be found in the package insert. <u>CDC's vaccine excipient summary</u> and the National Institutes of Health <u>DailyMed database</u> can also be used as a resource.

Appendix D: Potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects following COVID-19 vaccination

In patients who experience post-vaccination symptoms, determining the etiology (including allergic reaction, vasovagal reaction, or vaccine side effects) is important to determine whether a person can receive additional doses of the vaccine (including the second dose of an mRNA COVID-19 vaccine). The following table of signs and symptoms is meant to serve as a resource but might not be exhaustive, and patients might not have all signs or symptoms. Vaccination providers should use their clinical judgement when assessing patients to determine the diagnosis and management.

Potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects following COVID-19 vaccination

Characteristic	Allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)
Timing after vaccination	Most occur within 15- 30 minutes of vaccination	Most occur within 15 minutes	Median of 1 to 3 days after vaccination (with most occurring the day after vaccination)
Signs and symptoms			
Constitutional	Feeling of impending doom	Feeling warm or cold	Fever, chills, fatigue
Cutaneous	Skin symptoms present in ~90% of people with anaphylaxis, including pruritus, urticaria, flushing, angioedema	Pallor, diaphoresis, clammy skin, sensation of facial warmth	Pain, erythema, or swelling at injection site; lymphadenopathy in same arm as vaccination
Neurologic	Confusion, disorientation, dizziness, lightheadedness, weakness, loss of consciousness	Dizziness, lightheadedness, syncope (often after prodromal symptoms for a few seconds or minutes), weakness, changes in vision (such as spots of flickering lights, tunnel vision), changes in hearing	Headache
Respiratory	Shortness of breath, wheezing, bronchospasm, stridor, hypoxia	Variable; if accompanied by anxiety, might have an elevated respiratory rate	N/A
Cardiovascular	Hypotension, tachycardia	Variable; might have hypotension or bradycardia during syncopal event	N/A
Gastrointestinal	Nausea, vomiting, abdominal cramps, diarrhea	Nausea, vomiting	Vomiting or diarrhea might occur
Musculoskeletal	N/A	N/A	Myalgia, arthralgia

Potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects following COVID-19 vaccination

Characteristic	Allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)	
Vaccine and clinical management recommendations				
If vaccinated with mRNA COVID-19 vaccine as first dose, recommended to receive second mRNA vaccine dose?	No	Yes	Yes	