



## Hand out for AMA Webinar on mRNA vaccines: January 12, 2021

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### **mRNA vaccines: Clarification of dosing intervals**

- 4 day grace period for giving 2nd dose early
- No maximum interval between the doses for either vaccine
- VE after 2 doses: 94-95%
  - Pfizer-- 2 doses (0, 21): 30 mcg each (0.3 cc)
  - Moderna-- 2 doses (0,28): 100 mcg each (0.5cc)
- Need BOTH doses for optimal protection
- mRNA vaccine products are NOT interchangeable
- Use same product for BOTH doses

### **Four platforms for Vaccine Development**

1. **Live attenuated & inactivated virus vaccines**
2. **Viral vector vaccines**
  - Astra Zeneca/ Oxford vaccine candidate AZD 1222
  - J & J's Janssen vaccine candidate Ad26 COV S1
  - (Merck V591)
3. **Protein based / recombinant vaccines**
  - Novavax NVX CoV 2373 (with Matrix M adjuvant)
  - Sanofi /GSK : (with ASO3 adjuvant)
4. **Nucleic acid vaccines**
  - Moderna's mRNA 1273
  - Pfizer/ BioNTech's mRNA BNT 162
  -

**1. Details of trials:** 1.Moderna FDA Briefing Document COVID-19 Vaccine, December 17, 2020

<https://www.fda.gov/media/144434/download>

2. Pfizer /BioNTech FDA Briefing Document COVID-19 Vaccine, December 10, 2020

<https://www.fda.gov/media/144245/download>

**2. Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States** <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

### **3. Covid vaccination during pregnancy (ACOG)**

<https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19>

### **4. ACIP's Recommendations for Covid Vaccine Allocation (phased approach)**

Phase 1a:

- healthcare personnel
- residents of LTCF

Phase 1b:

- persons ≥75 years of age

- frontline essential workers...*Frontline essential workers are those at greatest risk because their work-related duties must be performed onsite and being in close proximity to public or coworkers.*

Phase 1c:

- persons 65-74 years of age
- persons 16-64 years of age with high-risk medical conditions
- other essential workers.

#### **Post Vaccine Considerations for Healthcare Personnel**

- <https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-healthcare-personnel.html>

## Appendix A: Triage of persons presenting for mRNA COVID-19 vaccination

	MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	<p><b>CONDITIONS</b></p> <ul style="list-style-type: none"> <li>Immunocompromising conditions</li> <li>Pregnancy</li> <li>Lactation</li> </ul> <p><b>ACTIONS</b></p> <ul style="list-style-type: none"> <li>Additional information provided*</li> <li>15 minute observation period</li> </ul>	<p><b>CONDITIONS</b></p> <ul style="list-style-type: none"> <li>Moderate/severe acute illness</li> </ul> <p><b>ACTIONS</b></p> <ul style="list-style-type: none"> <li>Risk assessment</li> <li>Potential deferral of vaccination</li> <li>15-minute observation period if vaccinated</li> </ul>	<p><b>CONDITIONS</b></p> <ul style="list-style-type: none"> <li>None</li> </ul> <p><b>ACTIONS</b></p> <ul style="list-style-type: none"> <li>N/A</li> </ul>
ALLERGIES	<p><b>ALLERGIES</b> History of allergies that are unrelated to components of an mRNA COVID-19 vaccine<sup>†</sup>, other vaccines, injectable therapies, or polysorbate, such as:</p> <ul style="list-style-type: none"> <li>Allergy to oral medications (including the oral equivalent of an injectable medication)</li> <li>History of food, pet, insect, venom, environmental, latex, etc., allergies</li> <li>Family history of allergies</li> </ul> <p><b>ACTIONS</b></p> <ul style="list-style-type: none"> <li>30-minute observation period: Persons with a history of anaphylaxis (due to any cause)</li> <li>15-minute observation period: All other persons</li> </ul>	<p><b>ALLERGIES</b></p> <ul style="list-style-type: none"> <li>History of any immediate allergic reaction<sup>‡</sup> to vaccines or injectable therapies (except those related to component of mRNA COVID-19 vaccines<sup>†</sup> or polysorbate, as these are contraindicated)</li> </ul> <p><b>ACTIONS:</b></p> <ul style="list-style-type: none"> <li>Risk assessment</li> <li>Consider deferral of vaccination and/or referral to allergist-immunologist</li> <li>30-minute observation period if vaccinated</li> </ul>	<p><b>ALLERGIES</b> History of the following are contraindications to receiving either of the mRNA COVID-19 vaccines<sup>†</sup>:</p> <ul style="list-style-type: none"> <li>Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components</li> <li>Immediate allergic reaction<sup>‡</sup> of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components<sup>§</sup> (including polyethylene glycol)<sup>¶</sup></li> <li>Immediate allergic reaction of any severity to polysorbate<sup>**</sup></li> </ul> <p><b>ACTIONS</b></p> <ul style="list-style-type: none"> <li>Do not vaccinate<sup>¶</sup></li> <li>Consider referral to allergist-immunologist</li> </ul>

\* See Special Populations section for information on patient counseling in these groups

† Refers only to mRNA COVID-19 vaccines currently authorized in the United States (i.e., Pfizer-BioNTech, Moderna COVID-19 vaccines)

‡ 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.

§ See Appendix B for a list of ingredients. Note: Polyethylene glycol (PEG), an ingredient in both mRNA COVID-19 vaccines, is structurally related to polysorbate and cross-reactive hypersensitivity between these compounds may occur. Information on ingredients of a vaccine or medication (including PEG, a PEG derivative, or polysorbates) can be found in the package insert.

\*\* 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 (e.g., under observation, in a setting with advanced medical care available)

## Appendix B: Ingredients included in Pfizer–BioNTech and Moderna mRNA COVID–19 vaccines

An immediate allergic reaction to any component or previous dose of an mRNA COVID-19 vaccine is a contraindication to vaccination with both the Pfizer-BioNTech and Moderna vaccines. The following is a list of ingredients for the [Pfizer-BioNTech](#) and [Moderna](#) COVID-19 vaccines, as reported in the prescribing information for each vaccine.

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine
mRNA	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
Lipids	2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	Cholesterol	Cholesterol
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diy))bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate
Salts, sugars, buffers	Potassium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Sodium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose

\* Neither vaccine contain eggs, gelatin, latex, or preservatives

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 whether a medication contains PEG, a PEG derivative, or polysorbates as either active or inactive ingredients can be found in the package insert. The National Institutes of Health [DailyMed database](#) may also be used as a resource. Medications that contain PEG and/or polysorbate are also described in the supplementary materials of Stone CA, et al.

"Immediate hypersensitivity to polyethylene glycols and polysorbates: more common than we have recognized." *The Journal of Allergy and Clinical Immunology: In Practice* 7.5 (2019): 1533-1540.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6706272/pdf/nihms-1019221.pdf>