Centers for Disease Control and Prevention
Center for Preparedness and Response

# COVID-19 Vaccines: Update on Allergic Reactions, Contraindications, and Precautions

Clinician Outreach and Communication Activity (COCA) Webinar

Wednesday, December 30, 2020

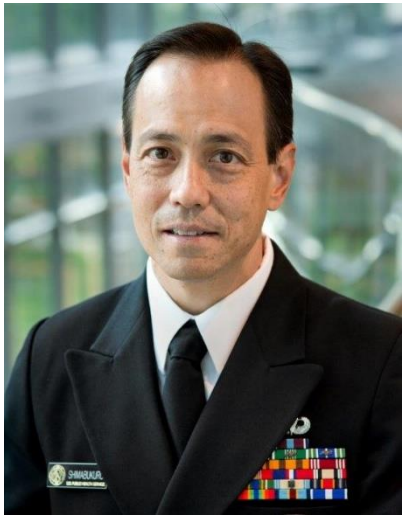
## Continuing Education

Continuing education will not be offered for this COCA Call.

# To Ask a Question

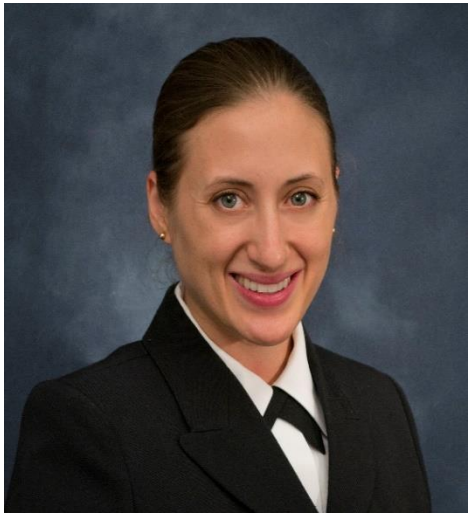
- All participants joining us today are in listen-only mode.
- Using the Webinar System
  - Click the “Q&A” button.
  - Type your question in the “Q&A” box.
  - Submit your question.
- The video recording of this COCA Call will be posted at https://emergency.cdc.gov/coca/calls/2020/callinfo_123020.asp and available to view on-demand a few hours after the call ends.
- If you are a patient, please refer your questions to your healthcare provider.
- For media questions, please contact CDC Media Relations at 404-639-3286, or send an email to media@cdc.gov.

# Today's First Presenter



**Tom Shimabukuro, MD, MPH, MBA**
CAPT, U.S. Public Health Service
Vaccine Safety Team Lead
COVID-19 Response
Centers for Disease Control and Prevention

# Today's Second Presenter



**Sarah Mbaeyi, MD, MPH**
CDR, U.S. Public Health Service
Clinical Guidelines Team
COVID-19 Response
Centers for Disease Control and Prevention

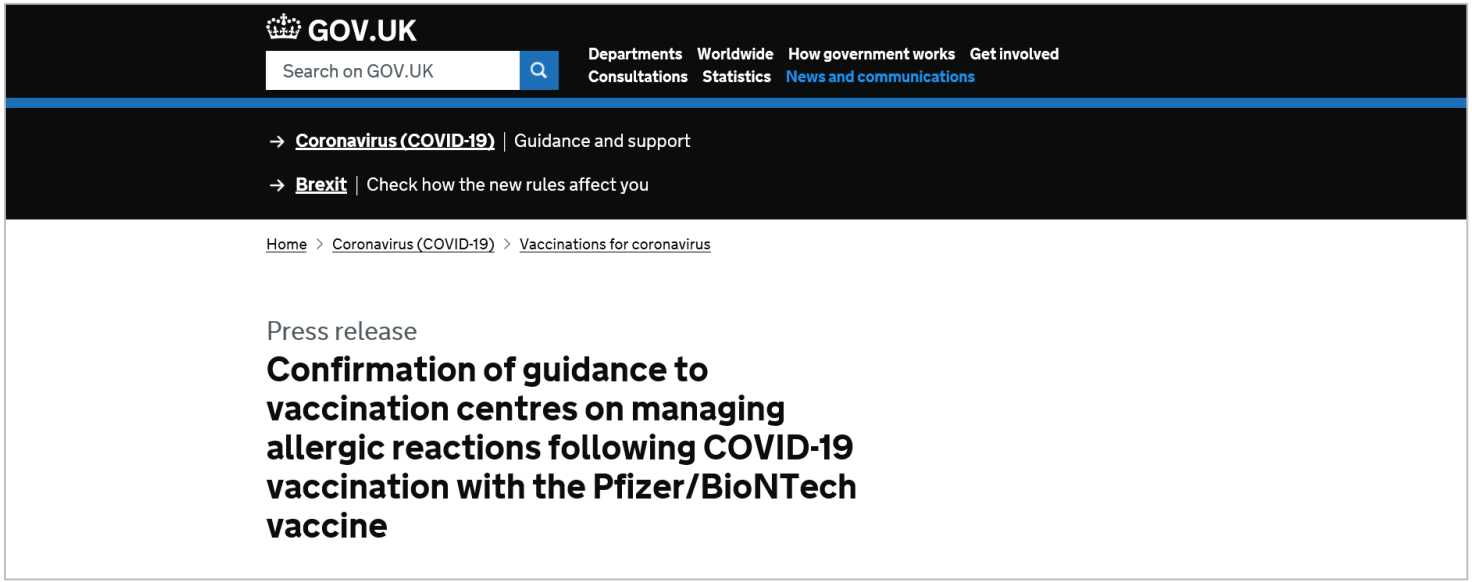
# Anaphylaxis following mRNA COVID-19 vaccination

**Tom Shimabukuro, MD, MPH, MBA**
**CDC COVID-19 Vaccine Task Force**
**Vaccine Safety Team**

Slides adapted from December 19-20, 2020 ACIP meeting presentation: Anaphylaxis Following m-RNA COVID-19 Vaccine Receipt, by Thomas Clark, MD, MPH, https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-19/05-COVID-CLARK.pdf

# Anaphylaxis following COVID-19 vaccination in the UK

- Dec 8, 2020 – UK initiated vaccination with Pfizer-BioNTech COVID-19 vaccine
- Dec 9, 2020 – UK authorities confirmed 2 cases of anaphylaxis after vaccination




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

# ACIP recommendations and CDC guidance for COVID-19 vaccination

- ACIP considered anaphylaxis risk during deliberations on Pfizer-BioNTech COVID-19 vaccine during Dec 11-12, 2020 meetings
  - Issued interim recommendation for use of Pfizer-BioNTech COVID-19 vaccine
- CDC issued:
  - Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites

https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm
https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

# Anaphylaxis in the U.S. following COVID-19 vaccination

- Dec 19-20, 2020 ACIP meeting safety presentation:
  - CDC had identified 6 case reports of anaphylaxis following Pfizer-BioNTech vaccine meeting Brighton Collaboration criteria for anaphylaxis
  - Cases occurred within recommended observation window and were promptly treated
  - All suspect cases were notified through VAERS or CDC notification processes
  - As of December 19, 2020, 9:45am EST – 272,001 doses of Pfizer-BioNTech COVID-19 vaccine had been administered

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-19/05-COVID-CLARK.pdf

# CDC actions

- Close coordination with FDA on safety monitoring
- Continued enhanced monitoring for anaphylaxis cases through the Vaccine Adverse Event Reporting System (VAERS)
- Case reviews and consultation with allergy/immunology experts to provide guidance on evaluation of persons following anaphylaxis to COVID-19 vaccine

# Your role

## Healthcare providers

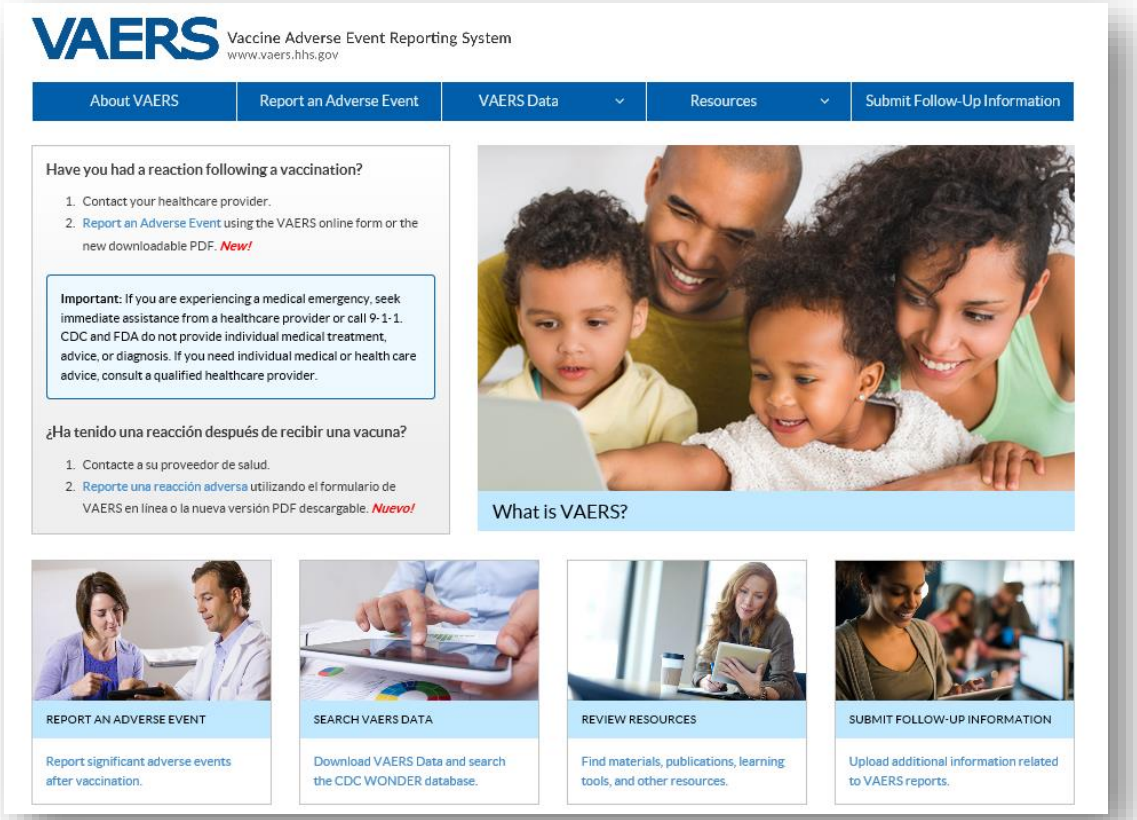
- Recognize, respond, and report anaphylaxis following COVID-19 vaccination to **VAERS** ✓
- Report adverse events to **VAERS** in accordance with FDA EUA reporting requirements and CDC guidance ✓
- Participate in CDC's **v-saf**e program yourself when you get vaccinated and encourage patients to participate in **v-safe** ✓
- **Communicate** with patients on vaccine safety ✓

# VAERS is the nation's early warning system for vaccine safety

**Vaccine Adverse Event Reporting System**

co-managed by CDC and FDA

vaers.hhs.gov



# How to report an adverse event to VAERS

- Go to vaers.hhs.gov
- Submit a report online

For help:

call
1-800-822-7967

email
info@VAERS.org

video instructions
https://youtu.be/sbCWhcQADFE


- For COVID-19, FDA will issue VAERS reporting requirements under EUA; in addition, CDC encourages reporting of any clinically important adverse event following immunization


## Resources

cdc.gov/vsafe

cdc.gov/coronavirus/2019-ncov/vaccines/safety/troubleshooting

cdc.gov/coronavirus/2019-ncov/vaccines/safety/faq

## CDC asks that:

- Healthcare providers help us get as many people to use **v-safe** as possible
  - give a one-page **info sheet** to patients at the time of vaccination
  - counsel patients on the importance of enrolling in **v-safe**
- CDC has created an electronic version of the **v-safe** info sheet for distribution to public health and healthcare partners

## How to report an AE to VAERS

- Go to vaers.hhs.gov and submit a report online
- For help: Call 1-800-822-7967 Email info@VAERS.org
- Video instructions www.youtube.com/watch?v=sbCWhcQADFE

## V-safe resources

cdc.gov/vsafe

cdc.gov/coronavirus/2019-ncov/vaccines/safety/troubleshooting

cdc.gov/coronavirus/2019-ncov/vaccines/safety/faq

## General safety information

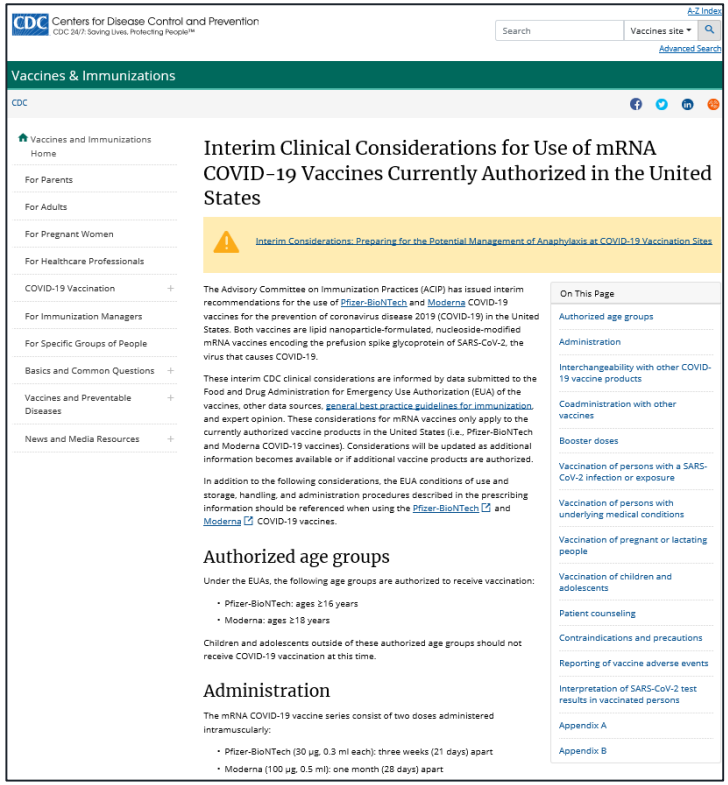
cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index

cdc.gov/coronavirus/2019-ncov/vaccines/safety

# Contraindications and Precautions to mRNA COVID-19 vaccination

# Updated contraindications and precautions to vaccination

- Recommendations apply to both Pfizer-BioNTech and Moderna COVID-19 vaccines
- Guidance may change as further information becomes available
- Definition of immediate allergic reaction to vaccine or medication:
  - Any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration



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## Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States

Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites

The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of Pfizer-BioNTech and Moderna COVID-19 vaccines for the prevention of coronavirus disease 2019 (COVID-19) in the United States. Both vaccines are lipid nanoparticle-formulated, nucleoside-modified mRNA vaccines encoding the prefusion spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19.

These interim CDC clinical considerations are informed by data submitted to the Food and Drug Administration for Emergency Use Authorization (EUA) of the vaccines, other data sources, general best practice guidelines for immunization, and expert opinion. These considerations for mRNA vaccines only apply to the currently authorized vaccine products in the United States (i.e., Pfizer-BioNTech and Moderna COVID-19 vaccines). Considerations will be updated as additional information becomes available or if additional vaccine products are authorized.

In addition to the following considerations, the EUA conditions of use and storage, handling, and administration procedures described in the prescribing information should be referenced when using the Pfizer-BioNTech and Moderna COVID-19 vaccines.

### Authorized age groups

Under the EUAs, the following age groups are authorized to receive vaccination:

- Pfizer-BioNTech: ages ≥16 years
- Moderna: ages ≥18 years

Children and adolescents outside of these authorized age groups should not receive COVID-19 vaccination at this time.

### Administration

The mRNA COVID-19 vaccine series consist of two doses administered intramuscularly:

- Pfizer-BioNTech (30 µg, 0.3 ml each): three weeks (21 days) apart
- Moderna (100 µg, 0.5 ml): one month (28 days) apart

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Administration
Interchangeability with other COVID-19 vaccine products
Coadministration with other vaccines
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Vaccination of children and adolescents
Patient counseling
Contraindications and precautions
Reporting of vaccine adverse events
Interpretation of SARS-CoV-2 test results in vaccinated persons
Appendix A
Appendix B

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

# Contraindications to mRNA COVID-19 vaccination

Pfizer-BioNTech and Moderna COVID-19 vaccines

- Contraindications to either of the mRNA COVID-19 vaccines:
  - Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or to 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)*

- Persons with an immediate allergic reaction to the first dose of an mRNA vaccine should not receive additional doses of either of the mRNA COVID-19 vaccines

* 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).

# Ingredients* included in mRNA COVID-19 vaccines

| Description | Pfizer-BioNTech | Moderna |
|---|---|---|
| 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-diyl)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 |

*As reported in the prescribing information

# Ingredients* included in mRNA COVID-19 vaccines

| Description | Pfizer-BioNTech | Moderna |
|---|---|---|
| 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-diyl)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 |

*As reported in the prescribing information

# Polyethylene glycol (PEG)

- Primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures
- Inactive ingredient or excipient in medications
- Used in a process called pegylation to improve therapeutic activity of some medications
- Cross-reactive hypersensitivity between PEG and polysorbates can occur
  - Polysorbates are included as an excipient in some vaccines and other therapeutic agents

Information on whether a medication contains PEG, a PEG derivative, or polysorbates can be found in the package insert. The NIH DailyMed database may also be used as a resource
Medications that contain PEG and/or polysorbate are described in the supplemental 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

# Distinguishing allergic reactions from other types of reactions

| Characteristic | Immediate 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 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, may have an elevated respiratory rate | N/A |
| **Cardiovascular** | Hypotension, tachycardia | Variable; may have hypotension or bradycardia during syncopal event | N/A |
| **Gastrointestinal** | Nausea, vomiting, abdominal cramps, diarrhea | Nausea, vomiting | Vomiting or diarrhea may occur |
| **Musculoskeletal** | N/A | N/A | Myalgia, arthralgia |
| **Vaccine recommendations** | | | |
| **Receive 2nd dose of mRNA COVID-19** | No | Yes | Yes |

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| **Musculoskeletal** | N/A | N/A | Myalgia, arthralgia |
| Vaccine recommendations | | | |
| **Receive 2nd dose of mRNA COVID-19** | No | Yes | Yes |

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| **Gastrointestinal** | Nausea, vomiting, abdominal cramps, diarrhea | Nausea, vomiting | Vomiting or diarrhea may occur |
| **Musculoskeletal** | N/A | N/A | Myalgia, arthralgia |
| **Vaccine recommendations** | | | |
| **Receive 2nd dose of mRNA COVID-19** | No | Yes | Yes |

# Distinguishing allergic reactions from other types of reactions

| Characteristic | Immediate allergic reactions (including anaphylaxis) | Vasovagal reaction | Vaccine side effects (local and systemic) |
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| **Gastrointestinal** | Nausea, vomiting, abdominal cramps, diarrhea | Nausea, vomiting | Vomiting or diarrhea may occur |
| **Musculoskeletal** | N/A | N/A | Myalgia, arthralgia |
| **Vaccine recommendations** | | | |
| **Receive 2nd dose of mRNA COVID-19** | No | Yes | Yes |

# Precautions to mRNA COVID-19 vaccines

Pfizer-BioNTech and Moderna COVID-19 vaccines

- Any immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate)

- Unknown risks of developing a severe allergic reaction should be balanced against the benefits of vaccination

- Deferral of vaccination and/or consultation with an allergist-immunologist may be considered

# Considerations for risk assessment for mRNA COVID-19 vaccination in persons with a precaution to vaccination

- Risk of exposure to SARS-CoV-2
  - e.g., residence in a congregate setting such as a long-term care facility, occupation
- Risk of severe disease or death due to COVID-19
  - e.g., age, underlying medical conditions
- Previous infection with SARS-CoV-2
  - Vaccination is recommended for persons with a history of COVID-19; persons with a precaution to vaccination and recent COVID-19 may choose to defer vaccination until further information is available
- The unknown risk of anaphylaxis following mRNA COVID-19 vaccination persons with a history of an immediate allergic reaction to other vaccines or injectable therapies
- Ability of the patient to be vaccinated in a setting where appropriate medical care is immediately available for anaphylaxis

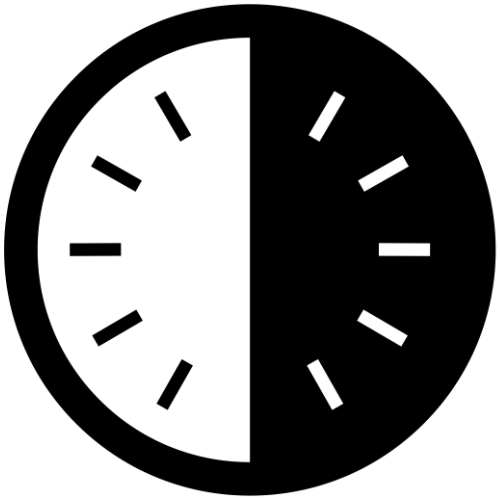
# Neither contraindications nor precautions to vaccination

Pfizer-BioNTech and Moderna COVID-19 vaccines

- History of allergic reactions not related to vaccines, injectable therapies, components of mRNA COVID-19 vaccines, or polysorbates, including:
  - Food
  - Pet dander
  - Venom
  - Environment
  - Oral medications
  - Latex
  - Eggs
  - Gelatin

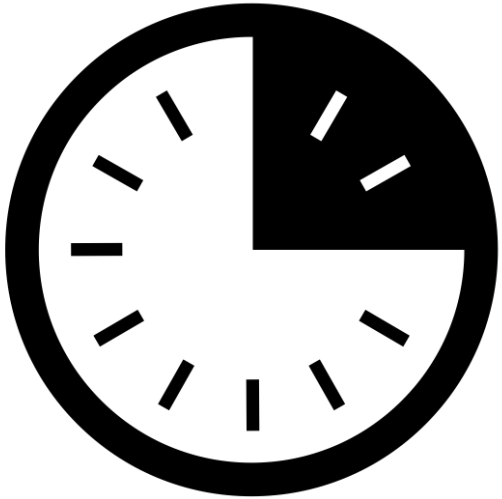
# Observation period following vaccination

**Persons with a precaution to vaccination or a history of anaphylaxis (due to any cause)**



**30 minutes**

**All other persons**



**15 minutes**

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

| MAY PROCEED WITH VACCINATION | PRECAUTION TO VACCINATION | CONTRAINDICATION TO VACCINATION |
|---|---|---|
| **ALLERGIES**<br>History of allergies that are unrelated to components of an mRNA COVID-19 vaccine†, other vaccines, or injectable therapies, such as:<br>• Allergy to oral medications (including the oral equivalent of an injectable medication)<br>• History of food, pet, insect, venom, environmental, latex, etc., allergies<br>• Family history of allergies<br><br>**ACTIONS**<br>• 30 minute observation period: Persons with a history of anaphylaxis (due to any cause)<br>• 15 minute observation period: All other persons | **ALLERGIES**<br>• History of any immediate allergic reaction‡ to vaccines or injectable therapies (except those related to component of mRNA COVID-19 vaccines† or polysorbate, as these are contraindicated)<br><br>**ACTIONS:**<br>• Risk assessment<br>• Consider deferral of vaccination and/or referral to allergist-immunologist<br>• 30 minute observation period if vaccinated | **ALLERGIES**<br>History of the following are contraindications to receiving either of the mRNA COVID-19 vaccines†:<br>• Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components<br>• Immediate allergic reaction‡ of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its componentsˆ (including polyethylene glycol)#<br>• Immediate allergic reaction of any severity to polysorbateˆ#<br><br>**ACTIONS**<br>• Do not vaccinate#<br>• Consider referral to allergist-immunologist |

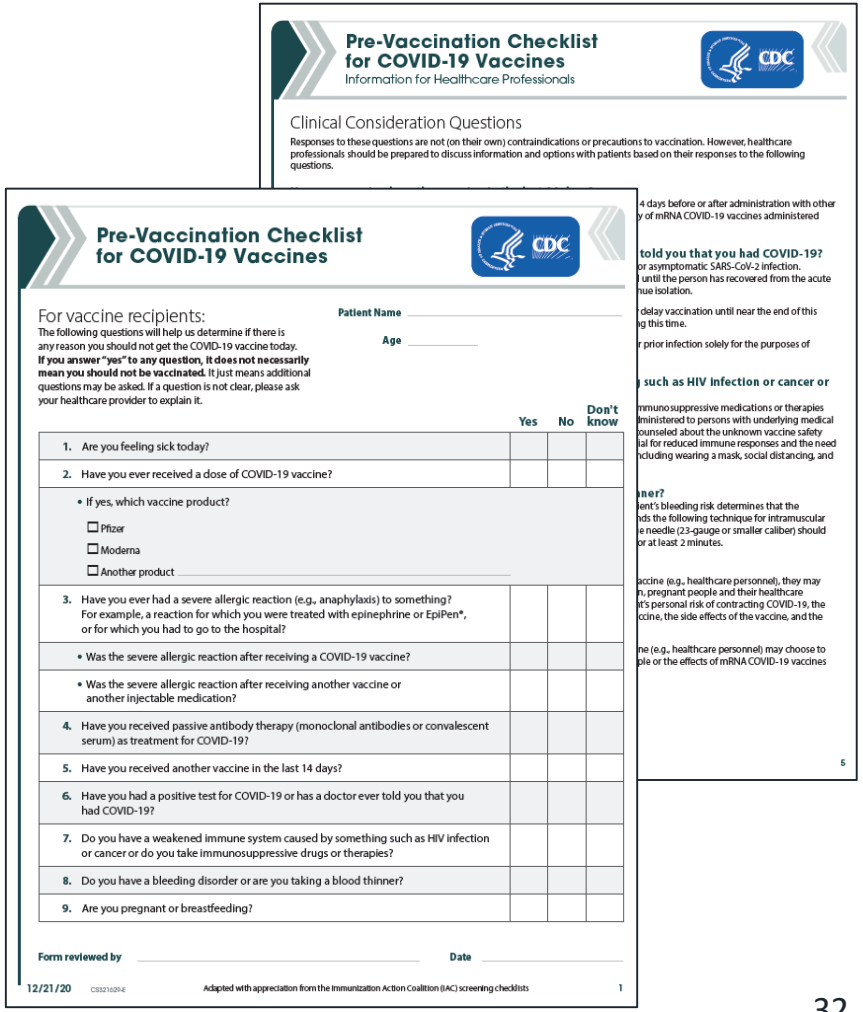
† Refers only to mRNA COVID-19 vaccines currently authorized in the United States (i.e., Pfizer-BioNTech, Moderna COVID-19 vaccines)

‡ 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.

ˆ See Appendix A 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)

# Additional tools to identify persons with contraindications and precautions to vaccination



**Pre-Vaccination Checklist for COVID-19 Vaccines**
Information for Healthcare Professionals

Clinical Consideration Questions

Responses to these questions are not (on their own) contraindications or precautions to vaccination. However, healthcare professionals should be prepared to discuss information and options with patients based on their responses to the following questions.

**Pre-Vaccination Checklist for COVID-19 Vaccines**

For vaccine recipients:

The following questions will help us determine if there is any reason you should not get the COVID-19 vaccine today. **If you answer "yes" to any question, it does not necessarily mean you should not be vaccinated.** It just means additional questions may be asked. If a question is not clear, please ask your healthcare provider to explain it.

Patient Name _____

Age _____

| | Yes | No | Don't know |
|---|---|---|---|
| 1. Are you feeling sick today? | | | |
| 2. Have you ever received a dose of COVID-19 vaccine? | | | |
| • If yes, which vaccine product? ☐ Pfizer ☐ Moderna ☐ Another product _____ | | | |
| 3. Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something? For example, a reaction for which you were treated with epinephrine or EpiPen®, or for which you had to go to the hospital? | | | |
| • Was the severe allergic reaction after receiving a COVID-19 vaccine? | | | |
| • Was the severe allergic reaction after receiving another vaccine or another injectable medication? | | | |
| 4. Have you received passive antibody therapy (monoclonal antibodies or convalescent serum) as treatment for COVID-19? | | | |
| 5. Have you received another vaccine in the last 14 days? | | | |
| 6. Have you had a positive test for COVID-19 or has a doctor ever told you that you had COVID-19? | | | |
| 7. Do you have a weakened immune system caused by something such as HIV infection or cancer or do you take immunosuppressive drugs or therapies? | | | |
| 8. Do you have a bleeding disorder or are you taking a blood thinner? | | | |
| 9. Are you pregnant or breastfeeding? | | | |

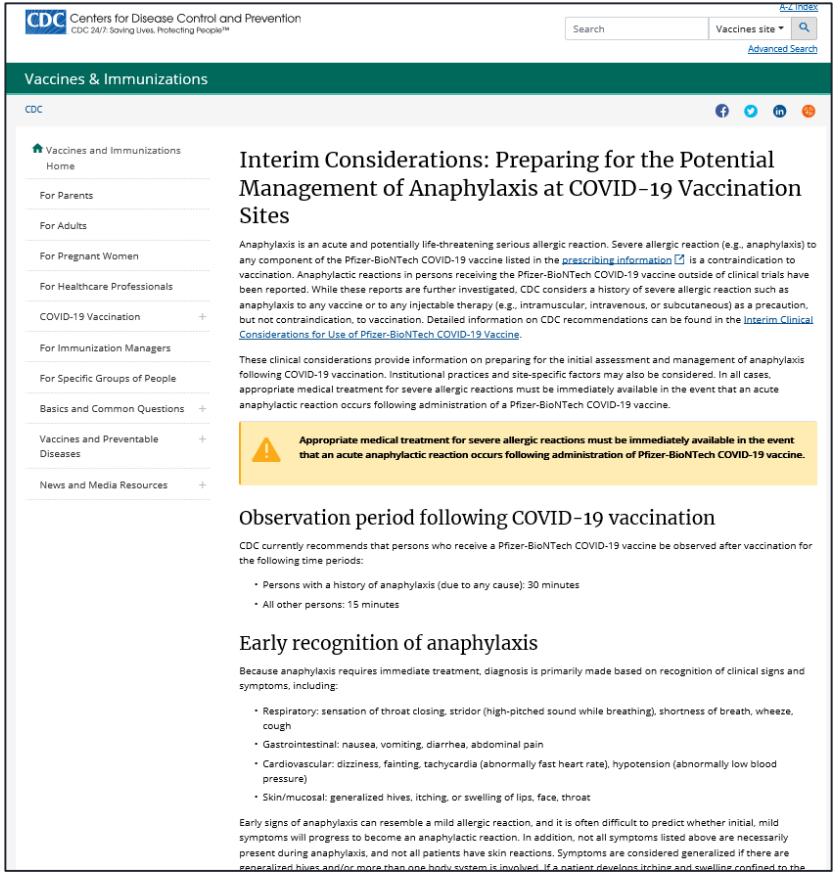
Form reviewed by _____ Date _____

12/21/20 CS321629-E Adapted with appreciation from the Immunization Action Coalition (IAC) screening checklists 1

https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf

# Interim considerations:

# Preparing for the potential management of anaphylaxis at COVID-19 vaccination sites



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## Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites

Anaphylaxis is an acute and potentially life-threatening serious allergic reaction. Severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 vaccine listed in the prescribing information is a contraindication to vaccination. Anaphylactic reactions in persons receiving the Pfizer-BioNTech COVID-19 vaccine outside of clinical trials have been reported. While these reports are further investigated, CDC considers a history of severe allergic reaction such as anaphylaxis to any vaccine or to any injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) as a precaution, but not contraindication, to vaccination. Detailed information on CDC recommendations can be found in the Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine.

These clinical considerations provide information on preparing for the initial assessment and management of anaphylaxis following COVID-19 vaccination. Institutional practices and site-specific factors may also be considered. In all cases, appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a Pfizer-BioNTech COVID-19 vaccine.

**Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 vaccine.**

### Observation period following COVID-19 vaccination

CDC currently recommends that persons who receive a Pfizer-BioNTech COVID-19 vaccine be observed after vaccination for the following time periods:

- Persons with a history of anaphylaxis (due to any cause): 30 minutes
- All other persons: 15 minutes

### Early recognition of anaphylaxis

Because anaphylaxis requires immediate treatment, diagnosis is primarily made based on recognition of clinical signs and symptoms, including:

- Respiratory: sensation of throat closing, stridor (high-pitched sound while breathing), shortness of breath, wheeze, cough
- Gastrointestinal: nausea, vomiting, diarrhea, abdominal pain
- Cardiovascular: dizziness, fainting, tachycardia (abnormally fast heart rate), hypotension (abnormally low blood pressure)
- Skin/mucosal: generalized hives, itching, or swelling of lips, face, throat

Early signs of anaphylaxis can resemble a mild allergic reaction, and it is often difficult to predict whether initial, mild symptoms will progress to become an anaphylactic reaction. In addition, not all symptoms listed above are necessarily present during anaphylaxis, and not all patients have skin reactions. Symptoms are considered generalized if there are generalized hives and/or more than one body system is involved. If a patient develops itching and swelling confined to the

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

# Key messages

## Preparing for the potential management of anaphylaxis at COVID-19 vaccination sites

**Early recognition of anaphylaxis symptoms**

**Prompt treatment with epinephrine**

**Activation of emergency medical services**

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

# Recommended medications and supplies for the management of anaphylaxis at COVID-19 vaccination sites

| Should be available at all sites | Include at sites where feasible |
|---|---|
| Epinephrine prefilled syringe or autoinjector* | Pulse oximeter |
| H1 antihistamine (e.g., diphenhydramine)† | Oxygen |
| Blood pressure cuff | Bronchodilator (e.g., albuterol) |
| Stethoscope | H2 antihistamine (e.g., famotidine, cimetidine) |
| Timing device to assess pulse | Intravenous fluids |
| | Intubation kit |
| | Adult-sized pocket mask with one-way valve (also known as cardiopulmonary resuscitation (CPR) mask) |

*COVID-19 vaccination sites should have at least 3 doses of epinephrine on hand at any given time.

†Antihistamines may be given as adjunctive treatment and should not be used as initial or sole treatment for anaphylaxis. Additionally, caution should be used if oral medications are administered to persons with impending airway obstruction.

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

# Additional resource: Clinical Immunization Safety Assessment COVIDvax project

- Healthcare personnel or health departments in the United States can request a consultation for a complex COVID-19 vaccine safety question about an individual patient residing in the United States not readily addressed by CDC guidance:

  https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html

# To Ask a Question

- Using the Zoom Webinar System
  - Click on the “Q&A” button.
  - Type your question in the “Q&A” box.
  - Submit your question.
- For media questions, please contact CDC Media Relations at 404-639-3286 or email media@cdc.gov.

## Today's COCA Call Will Be Available On-Demand

- **When:** A few hours after the live call
- **What:** Video recording
- **Where:** On the COCA Call webpage at https://emergency.cdc.gov/coca/calls/2020/callinfo_123020.asp

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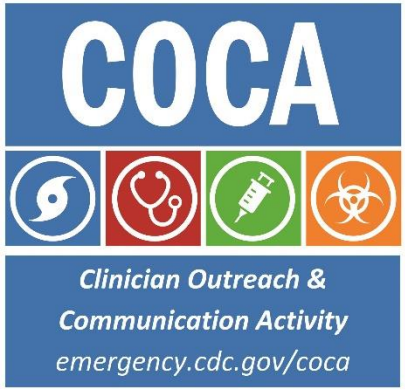


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