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](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](mailto: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

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

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

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

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
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V-safe resources

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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

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

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*As reported in the prescribing information
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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](https://www.nlm.nih.gov/dailymed/) 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.

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### Vaccine recommendations

| Receive 2nd dose of mRNA COVID-19 | No | Yes | Yes |
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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**

**ALLERGIES**
History of allergies that are unrelated to components of an mRNA COVID-19 vaccine†, other vaccines, or injectable therapies, such as:
- 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**
- 30 minute observation period: Persons with a history of anaphylaxis (due to any cause)
- 15 minute observation period: All other persons

**PRECAUTION TO VACCINATION**

**ALLERGIES**
- 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)

**ACTIONS:**
- Risk assessment
- Consider deferral of vaccination and/or referral to allergist-immunologist
- 30 minute observation period if vaccinated

**CONTRAINDICATION TO VACCINATION**

**ALLERGIES**
History of the following are contraindications to receiving either of the mRNA COVID-19 vaccines†:
- Severe allergic reaction (e.g., anaphylaxis) after a previous dose 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)^
- Immediate allergic reaction of any severity to polysorbate^#

**ACTIONS**
- Do not vaccinate#
- 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.
^ 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

Interim considerations:

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

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

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

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<tr>
<td>Epinephrine prefilled syringe or autoinjector*</td>
<td>Pulse oximeter</td>
</tr>
<tr>
<td>H1 antihistamine (e.g., diphenhydramine)†</td>
<td>Oxygen</td>
</tr>
<tr>
<td>Blood pressure cuff</td>
<td>Bronchodilator (e.g., albuterol)</td>
</tr>
<tr>
<td>Stethoscope</td>
<td>H2 antihistamine (e.g., famotidine, cimetidine)</td>
</tr>
<tr>
<td>Timing device to assess pulse</td>
<td>Intravenous fluids</td>
</tr>
<tr>
<td></td>
<td>Intubation kit</td>
</tr>
<tr>
<td></td>
<td>Adult-sized pocket mask with one-way valve (also known as cardiopulmonary resuscitation (CPR) mask)</td>
</tr>
</tbody>
</table>

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

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](https://emergency.cdc.gov/coca/calls/2020/callinfo_123020.asp)
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- COCA Call Announcements contain all information subscribers need to participate in COCA Calls. COCA Calls are held as needed.

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