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In reply, please refer to:
File:

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MEDICAL ADVISORY #19—CORONAVIRUS DISEASE 2019 (COVID-19): COVID-19 VACCINATION CONTRAINDICATIONS, PRECAUTIONS, AND ADVERSE EVENT REPORTING

- **CONTRAINDICATIONS AND PRECAUTIONS FOR THE USE OF PFIZER-BIONTECH AND MODERNA COVID-19 VACCINES**
- **VACCINE ADVERSE EVENT REPORTING**
- **VACCINATION CLINICAL RESOURCES**

Dear Healthcare Provider:

While rare, anaphylactic reactions have been reported following vaccination with mRNA COVID-19 vaccines. For the Pfizer-BioNTech COVID-19 vaccine, 21 cases of anaphylaxis were reported after administration of 1,893,360 first doses (11.1 cases per million doses); 71% of these occurred within 15 minutes of vaccination[1]. For the Moderna COVID-19 vaccine, 10 cases of anaphylaxis were reported after administration of 4,041,396 first doses (2.5 cases per million doses administered). In nine cases, onset occurred within 15 minutes of vaccination[2].

1. Vaccinating persons with a history of allergies

Contraindications

Persons with a history of an immediate allergic reaction (of any severity) to an mRNA COVID-19 vaccine or any of its components might be at greater risk for anaphylaxis. An immediate allergic reaction is defined as 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.

Precautions

CDC considers a history of any immediate allergic reaction to **any** other vaccine or injectable therapy as a **precaution but not a contraindication** to vaccination for both the Pfizer-BioNTech and Moderna COVID-19 vaccines. Consider deferral of vaccination and/or referral to an allergist-immunologist.

Observation periods following vaccination with mRNA COVID-19 vaccines

Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause should be observed for 30 minutes. All other persons should be observed for 15 minutes.

CDC guidance on COVID-19 vaccine contraindications and precautions is summarized in Appendix A. Additional clinical considerations for use of mRNA COVID-19 vaccines are available on the CDC website.

2. Reporting of vaccine adverse events

- **VAERS**
  - Adverse events that occur in a recipient following mRNA COVID-19 vaccination should be reported in VAERS.
  - Vaccination providers are required by the Food and Drug Administration to report the following that occur after mRNA COVID-19 vaccination under Emergency Use Authorization:
    - Vaccine administration errors
    - Serious adverse events
    - Cases of Multisystem Inflammatory Syndrome
    - Cases of COVID-19 that result in hospitalization or death
  - Reporting is encouraged for any other clinically significant adverse event even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.
- **V-safe**
  - Healthcare providers are encouraged to support their patients in participating in V-safe to report possible side effects following vaccination.
  - V-safe is CDC's new, voluntary smartphone-based tool. This tool uses text messaging and web surveys to perform health check-ins after patients receive COVID-19 vaccination. Reports to v-safe indicating a medically significant health impact are followed up by the CDC/v-safe call center.

3. Considerations for clinical judgement

Because patients with a history of severe or immediate allergic reaction to any injectable therapy may be at higher risk of adverse reactions, it is preferable for these individuals to be vaccinated under direct observation and in a setting where advanced medical care is readily available. These patients are not being vaccinated at Department of Health (DOH)-run vaccination Points of Dispensing (POD). Those with a history of other allergies can be vaccinated at DOH-run PODs with a 30 min observation period.

As vaccine becomes more widely available individual clinical judgement will play its usual role and vaccine providers may choose to vaccinate some individuals not vaccinated in mass-vaccine settings, with appropriate safeguards, counseling, and availability of advanced medical care.

4. For more information and updates

- COVID-19 vaccination website for healthcare professionals
- Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States | CDC

Healthcare personnel or health departments in the United States can request a consultation from the Clinical Immunization Safety Assessment COVIDvax project for a complex COVID-19 vaccine safety question about an individual patient residing in the United States not readily addressed by CDC guidance.

Information and guidance on COVID-19 continues to evolve. To ensure you are accessing the latest information, please visit HDOH's COVID-19 webpage or CDC's COVID-19 website. If you have any questions or need to report a patient with suspected/confirmed COVID-19, please contact us at one of the numbers below.

Oahu (Disease Reporting Line)……..... (808) 586-4586
Maui District Health Office..... (808) 984-8213
Kauai District Health Office..... (808) 241-3563
Big Island District Health Office (Hilo)..... (808) 933-0912
Big Island District Health Office (Kona)..... (808) 322-4877
After hours on Oahu..... (808) 600-3625
After hours on neighbor islands.....(800) 360-2575 (toll free)

We appreciate your partnership to prevent the spread of COVID-19 in our communities.

Sincerely,

Sarah Kemble, MD
Acting State Epidemiologist

REFERENCES

1. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14–23, 2020. MMWR Morb Mortal Wkly Rep 2021;70:46–51. DOI: http://dx.doi.org/10.15585/mmwr.mm7002e1

2. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine — United States, December 21, 2020–January 10, 2021. MMWR Morb Mortal Wkly Rep. ePub: 22 January 2021. DOI: http://dx.doi.org/10.15585/mmwr.mm7004e1

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

	MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	**CONDITIONS** • Immunocompromising conditions • Pregnancy • Lactation **ACTIONS** • Additional information provided* • 15 minute observation period	**CONDITIONS** • Moderate/severe acute illness **ACTIONS** • Risk assessment • Potential deferral of vaccination • 15-minute observation period if vaccinated	**CONDITIONS** • None **ACTIONS** • N/A
ALLERGIES	**ALLERGIES** History of allergies that are unrelated to components of an mRNA COVID-19 vaccine†, other vaccines, injectable therapies, or polysorbate, 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	**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	**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

* 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.

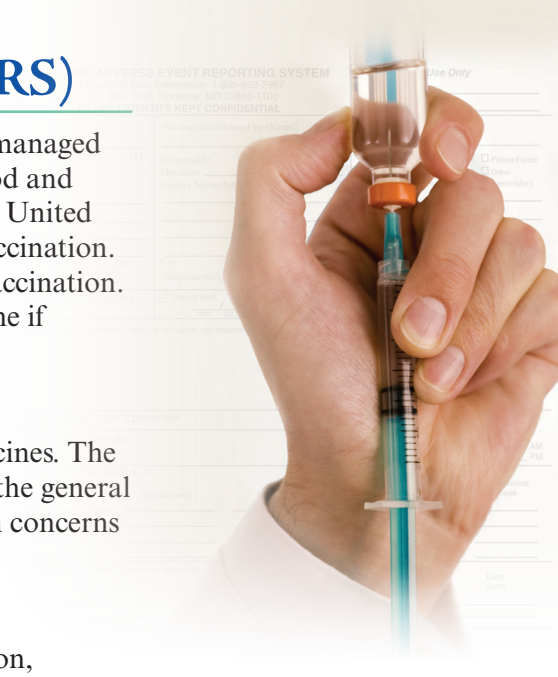
These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available)

VAERS

Vaccine Adverse Event Reporting System

A National Program for Monitoring Vaccine Safety

Vaccine Adverse Event Reporting System (VAERS)



The Vaccine Adverse Event Reporting System (VAERS), is a national program managed by the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) to monitor the safety of all vaccines licensed in the United States. VAERS collects and reviews reports of adverse events that occur after vaccination. An "adverse event" is any health problem or "side effect" that happens after a vaccination. VAERS cannot determine if a vaccine caused an adverse event, but can determine if further investigation is needed.

VAERS provides valuable information

VAERS is an early-warning system that detects problems possibly related to vaccines. The system relies on reports from healthcare providers*, vaccine manufacturers, and the general public. Reporting gives CDC and FDA important information to identify health concerns and ensure vaccines are safe in order to protect the public's health.

VAERS staff evaluate reports of adverse events

VAERS defines a "serious adverse event" as life-threatening illness, hospitalization, prolongation of an existing hospitalization, permanent disability or death. Once adverse events are identified using VAERS, they may be monitored in other immunization safety systems to confirm if a particular adverse event is related to a vaccination and identify any specific risk factors.

Anyone can report to VAERS

Anyone can submit a report to VAERS, including patients, family members, healthcare providers, vaccine manufacturers and the general public. CDC and FDA encourage anyone who experiences an adverse event after receiving a vaccine to report to VAERS.

How to report to VAERS

You can report to VAERS online at https://vaers.hhs.gov/index.

For further assistance reporting to VAERS, visit https://vaers.hhs.gov/index or contact VAERS directly at info@VAERS.org or 1-800-822-7967.

VAERS data are available to the public

VAERS data can be downloaded at https://vaers.hhs.gov/data/index or searched at http://wonder.cdc.gov/vaers.html. Privacy is protected and personal identifying information (such as name, date of birth and address) is removed from the public data.

For more information about VAERS:

E-mail: info@vaers.org

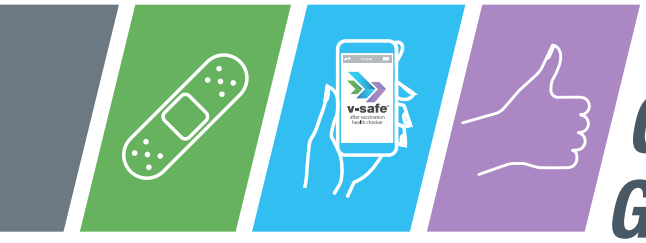
Phone: 1-800-822-7967

Web site: www.vaers.hhs.gov

*Healthcare providers are encouraged to report all clinically significant adverse events after vaccination to VAERS even if it is uncertain whether the vaccine caused the event. They are also required to report to VAERS adverse events found in the Reportable Events Table (RET) at https://vaers.hhs.gov/resources/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

FACT SHEET

CS267401



Get vaccinated. Get your smartphone. Get started with v-safe.

What is v-safe?

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through ***v-safe***, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And ***v-safe*** will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's ***v-safe*** makes a difference—it helps keep COVID-19 vaccines safe.

How can I participate?

Once you get a COVID-19 vaccine, you can enroll in ***v-safe*** using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from ***v-safe*** around 2pm local time. To opt out, simply text "STOP" when ***v-safe*** sends you a text message. You can also start ***v-safe*** again by texting "START."

How long do v-safe check-ins last?

During the first week after you get your vaccine, ***v-safe*** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions ***v-safe*** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, ***v-safe*** will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

Is my health information safe?

Yes. Your personal information in ***v-safe*** is protected so that it stays confidential and private.*

*To the extent ***v-safe*** uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act, and the Freedom of Information Act.

v-safe℠
after vaccination health checker

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.

Sign up with your smartphone's browser at vsafe.cdc.gov

OR

Aim your smartphone's camera at this code

12/01/20

How to register and use v-safe

You will need your smartphone and information about the COVID-19 vaccine you received. This information can be found on your vaccination record card; if you cannot find your card, please contact your healthcare provider.

Register

1. Go to the ***v-safe*** website using one of the two options below:

Use your smartphone's browser to go to

vsafe.cdc.gov

OR

Aim your smartphone's camera at this code

2. Read the instructions. Click **Get Started**.
3. Enter your name, mobile number, and other requested information. Click **Register**.
4. You will receive a text message with a verification code on your smartphone. Enter the code in ***v-safe*** and click **Verify**.
5. At the top of the screen, click **Enter your COVID-19 vaccine information**.
6. Select which COVID-19 vaccine you received (found on your vaccination record card; if you cannot find your card, please contact your healthcare provider). Then enter the date you were vaccinated. Click **Next**.
7. Review your vaccine information. If correct, click **Submit**. If not, click **Go Back**.
8. **Congrats! You're all set!** If you complete your registration before 2pm local time, ***v-safe*** will start your initial health check-in around 2pm that day. If you register after 2pm, ***v-safe*** will start your initial health check-in immediately after you register—just follow the instructions.

   You will receive a reminder text message from ***v-safe*** when it's time for the next check-in—around 2pm local time. Just click the link in the text message to start the check-in.

Complete a v-safe health check-in

1. When you receive a ***v-safe*** check-in text message on your smartphone, click the link when ready.
2. Follow the instructions to complete the check-in.

Troubleshooting

How can I come back and finish a check-in later if I'm interrupted?

- Click the link in the text message reminder to restart and complete your check-in.

How do I update my vaccine information after my second COVID-19 vaccine dose?

- ***V-safe*** will automatically ask you to update your second dose information. Just follow the instructions.

Need help with *v-safe*?
Call 800-CDC-INFO (800-232-4636)
TTY 888-232-6348
Open 24 hours, 7 days a week
Visit www.cdc.gov/vsafe