

What Every Clinician Should Know about COVID-19 Vaccine Safety

Clinician Outreach and Communication Activity (COCA) Webinar

Monday, December 14, 2020

Continuing Education

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- 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 Presenters

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Healthcare Infection Control Team COVID-19 Response Centers for Disease Control and Prevention



CDC post-authorization/post-licensure safety monitoring of COVID-19 vaccines:

The Vaccine Adverse Event Reporting System (VAERS) and v-safe

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

Top 3 takeaways



- 1. The U.S. vaccine safety system is strong and robust
- 2. New safety systems are being added for COVID-19 vaccines
- 3. You can play an important role in helping CDC monitor the safety of COVID-19 vaccines



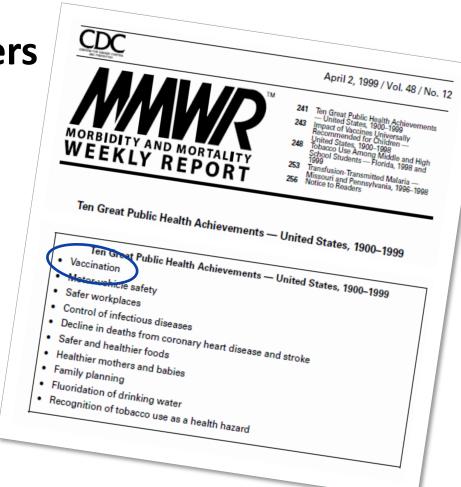
Why vaccine safety matters

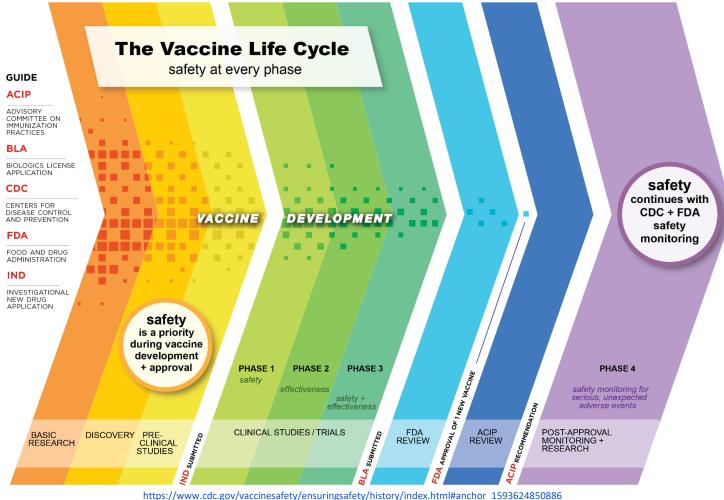
Safety +
Effectiveness

equals

Vaccination Program Success

in the past and looking forward





safety is a priority

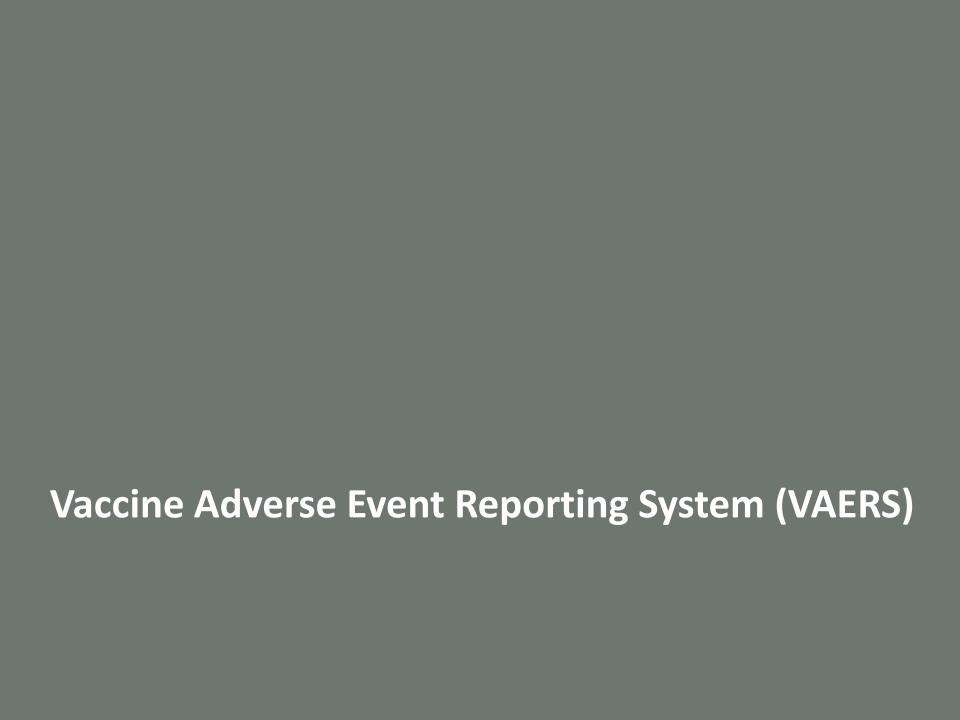
during all phases of vaccine development, authorization or approval, and use

Why?

post-authorization/post-licensure safety monitoring

after FDA authorizes or licenses a vaccine

- Safety standards for vaccines are high
- Clinical trials used to authorize or license vaccines for use
 - may not detect all types of adverse events, especially ones that are rare or take longer to occur (delayed onset)
 - don't always look at special populations (e.g., pregnant women and people with certain pre-existing medical conditions)



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



VAERS covers the entire U.S. population



- 320 million U.S. residents as a covered population for safety monitoring
- All ages, races, occupations (including healthcare workers) states/jurisdictions, healthy people, those with chronic health problems, long-term care facility residents, older adults living in the community, etc.



VAERS

VAERS accepts all reports from everyone regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event

Key strengths

- rapidly detects potential safety problems
- can detect rare adverse events

Key limitations

- inconsistent quality and completeness of information
- generally cannot determine cause and effect

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/sbCWh
cQADFE



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





Active safety monitoring for COVID-19 vaccines

- V-safe is a new CDC smart-phone based monitoring program for COVID-19 vaccine safety
 - uses text messaging and web surveys to check-in with vaccine recipients after vaccination
 - participants can report side effects and health impact events after COVID-19 vaccination
 - includes active telephone follow-up by CDC for reports of significant health impact
 - captures information on pregnancy status and enables follow-up on pregnant women





Timing of health check-ins

- V-safe conducts electronic health checkins with vaccine recipients
 - daily for first week post-vaccination; weekly thereafter until 6 weeks post-vaccination
 - additional health checks at 3, 6, and 12 months post-vaccination
 - timeline resets at 2nd dose



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 a toolkit for distribution to public health and healthcare partners



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. To opt out, simply text "STOP" when *v-safe* sends you a text message. You can also start *v-safe* again by texting "START."

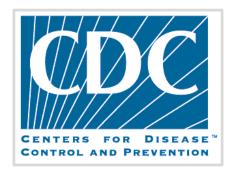
How long do v-safe check-ins last?

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



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.





1. Text message check-ins from CDC (daily 1st week; weekly thru 6 weeks; then 3, 6, and 12 mo.)

vaccine recipient completes web survey



- 2. Clinically important health impact reported
- ✓ missed work
- ✓ unable to do normal daily activities
- √ received medical care





Call center



3. A CDC representative conducts active telephone follow-up on a clinically important health impact event and takes a report if appropriate







Resources

cdc.gov/vsafe

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

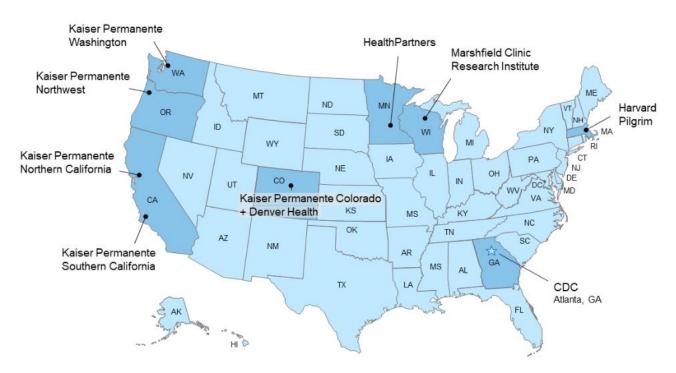
cdc.gov/coronavirus/2019-ncov/vaccines/safety/faq

CDC's Vaccine Safety Datalink (VSD) and Clinical Immunization Safety Assessment (CISA) Project





Vaccine Safety Datalink



9 participating integrated healthcare organizations

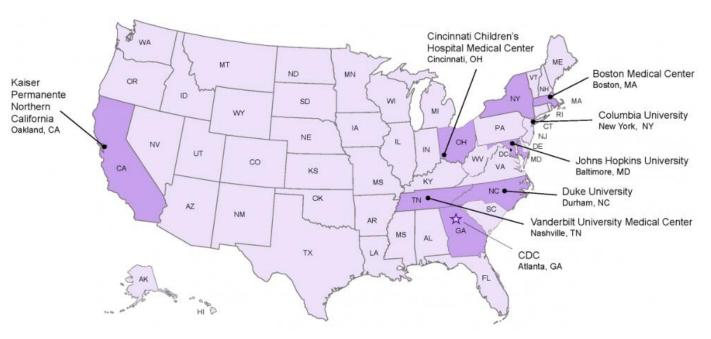
data on over **12 million** persons per year



CISA

Clinical Immunization Safety Assessment (CISA) Project

7 participating medical research centers with vaccine safety experts



- clinical consult services[†]
- clinical research

[†]More information about clinical consults available at http://www.cdc.gov/vaccinesafety/Activities/CISA.html

Your role

COVID-19 vaccine safety gets stronger with your participation

Healthcare providers

- Participate in **v-safe** yourself when you get vaccinated **✓**
- Encourage patients to participate in v-safe ✓
- Report adverse events to VAERS ✓
- Communicate with patients on vaccine safety ✓

Top 3 takeaways



- 1. The U.S. vaccine safety system is strong and robust
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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

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<u>cdc.gov/vsafe</u>
<u>cdc.gov/coronavirus/2019-ncov/vaccines/safety/troubleshooting</u>
cdc.gov/coronavirus/2019-ncov/vaccines/safety/faq
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General safety information

cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/indexcdc.gov/coronavirus/2019-ncov/vaccines/safety



Considerations for healthcare personnel and long-term care residents with systemic signs and symptoms following COVID-19 vaccination

David T. Kuhar, M.D.

COVID-19 Response

Healthcare Infection Control Team

Centers for Disease Control and Prevention

Background

- Residents and healthcare personnel (HCP) should continue to follow all current CDC infection prevention and control recommendations to protect themselves and others from SARS-CoV-2 infection, regardless of their vaccination status.
- Positive viral (nucleic acid or antigen) tests for SARS-CoV-2, if performed, should not be attributed to the COVID-19 vaccine, as vaccination does not influence the results of these tests.

Background

- Systemic signs and symptoms following COVID-19 vaccination can include fever, fatigue, headache, chills, myalgia, and arthralgia. Most are
 - mild to moderate in severity
 - occur within the first 3 days of vaccination
 - resolve within 1-2 days of onset
- Systemic adverse reactions were more commonly reported after the second dose than after the first dose and were generally more frequent and severe in persons aged 18–55 years than in those aged >55 years.*
- Cough, shortness of breath, rhinorrhea, sore throat, or loss of taste or smell are not consistent with post-vaccination symptoms.

^{*} https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm

Healthcare Personnel (HCP)

Infection prevention and control considerations for healthcare personnel with systemic signs and symptoms following COVID-19 vaccination

Overview

- HCP with postvaccination signs and symptoms could be mistakenly considered infectious and restricted from work unnecessarily.
- Strategies to evaluate and manage post-vaccination signs and symptoms among HCP are needed to avoid
 - Unnecessarily excluding HCP with only post-vaccination signs and symptoms from work
 - Inadvertently allowing HCP with SARS-CoV-2 or another transmissible infection to work
- The strategies are intended for use by occupational health programs and public health officials.
- They apply to all HCP working in healthcare settings.

Considerations to minimize the impact of post-vaccination systemic signs and symptoms on healthcare staffing

- Vaccinating HCP preceding 1-2 days off, during which they are not required to be in the facility.
- Staggering delivery of vaccine to HCP in the facility so that not all HCP in a single department, service, or unit are vaccinated at the same time.

Considerations continued...

- Informing HCP about the potential for short-term systemic signs and symptoms post-vaccination and potential options for mitigating them.
- Developing a strategy to provide timely assessment of HCP with systemic signs and symptoms post-vaccination, including providing or identifying options for SARS-CoV-2 viral testing, so it is readily available if indicated.
- Offering nonpunitive sick leave options (e.g., paid sick leave) for HCP with systemic signs and symptoms post-vaccination to remove barriers to reporting these symptoms.

Suggested approaches to evaluating and managing new-onset systemic post-vaccination signs and symptoms

- Approaches apply to HCP who
 - have received COVID-19 vaccination in the prior 3 days (including day of vaccination, which is considered day 1) and
 - are not known to have had unprotected exposure to SARS-CoV-2 in the previous 14 days.
- Ultimately, clinical judgement should determine the likelihood of infection versus post-vaccination symptoms.

Signs and symptoms unlikely to be from COVID-19 vaccination

Signs and Symptoms

- Presence of ANY systemic signs and symptoms consistent with SARS-CoV-2 infection (e.g., cough, shortness of breath, rhinorrhea, sore throat, loss of taste or smell) or another infectious etiology that are not typical for post-vaccination signs and symptoms.
- Suggested approach
 - Exclude from work pending evaluation for possible etiologies, including SARS-CoV-2 infection, as appropriate.
 - Criteria for return to work depends on the suspected or confirmed diagnosis.

Signs and symptoms that may be from either COVID-19 vaccination, SARS-CoV-2 infection, or another infection

- Signs and Symptoms
 - Presence of ANY systemic signs and symptoms (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) that are consistent with a post-vaccination reaction, SARS-CoV-2 infection, or another infectious etiology.
- Suggested approach
 - HCP who meet the following criteria may be considered for return to work without viral testing for SARS-CoV-2:
 - Feel well enough and are willing to work, and
 - Are afebrile, and
 - Systemic signs and symptoms are limited only to those observed following vaccination.

Continued...

- Suggested approach
 - If symptomatic HCP return to work and symptoms are not improving or persist for more than 2 days
 - Exclude from work, pending evaluation, and consider viral testing
 - HCP with fever should, ideally, be excluded from work pending further evaluation, including consideration for SARS-CoV-2 testing.
 - If an infectious etiology is not suspected or confirmed as the source of their fever,
 they may return to work when they feel well enough.
 - When critical staffing shortages are anticipated or occurring, HCP with fever and systemic signs and symptoms limited only to those observed following vaccination could be considered for work if they feel well enough and are willing.
 - HCP should be re-evaluated, and viral testing for SARS-CoV-2 considered, if fever does not resolve within 2 days.

Long-Term Care Residents

Infection prevention and control considerations for residents of long-term care facilities with systemic signs and symptoms following COVID-19 vaccination

Overview

- Strategies to appropriately evaluate and manage post-vaccination signs and symptoms among long-term care residents are needed to balance
 - the risk of unnecessary testing and implementation of Transmission-Based Precautions for residents with only post-vaccination signs and symptoms with that of
 - inadvertently allowing residents with infectious COVID-19 or another transmissible infectious disease to expose others in the facility.

Suggested approaches to evaluating and managing systemic new onset post-vaccination signs and symptoms for residents in long-term care facilities

- Approaches apply to residents who have received COVID-19 vaccination in the prior 3 days (including day of vaccination, which is considered day 1).
- Approaches should be tailored to fit the characteristics of each case.

Signs and symptoms *unlikely* to be from COVID-19 vaccination

Signs and Symptoms

Presence of <u>ANY</u> systemic signs and symptoms consistent with SARS-CoV-2 (e.g., cough, shortness of breath, rhinorrhea, sore throat, loss of taste or smell) or another infectious etiology that are **not** typical for post-vaccination signs and symptoms.

Suggested approach

- Evaluate for possible infectious etiologies, including testing for SARS-CoV-2 and/or other pathogens, as appropriate.
- Pending evaluation, these residents should be placed in a single person room (if available) and cared for by HCP wearing appropriate Personal Protective Equipment (PPE) recommended for residents with suspected or confirmed SARS-CoV-2 infection. They should **not** be cohorted with residents with confirmed SARS-CoV-2 infection **unless** they are also confirmed to have SARS-CoV-2 infection through testing.
- Criteria for when Transmission-Based Precautions may be discontinued depend on the results of the evaluation.

Signs and symptoms that may be from either COVID-19 vaccination, SARS-CoV-2 infection, or another infection

- Signs and Symptoms
 - Presence of ANY systemic signs and symptoms (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) that are consistent with postvaccination signs and symptoms, SARS-CoV-2 infection, or another infectious etiology (e.g., influenza).
- Suggested approach
 - Evaluate the resident
 - These residents should be restricted to their current room (except for medically necessary procedures) and closely monitored until:
 - Fever (if present) resolves and
 - Symptoms improve

Continued...

- Suggested approach
 - HCP caring for these residents should wear all PPE recommended for residents with suspected or confirmed SARS-CoV-2 infection while evaluating the cause of these symptoms.
 - If the resident's symptoms resolve within 2 days, precautions can be discontinued.
 - Fever, if present, should have resolved for at least 24 hours before discontinuing precautions.
 - Viral testing for SARS-CoV-2 should be considered for residents if their symptoms are not improving or persist for longer than 2 days.
 - Residents residing in facilities with active transmission, or who have had prolonged close contact with someone with SARS-CoV-2 infection in the prior 14 days, should be tested for SARS-CoV-2 infection.

Additional Resources

MMWR: https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm

Post Vaccine Considerations for Healthcare Personnel:

https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-

healthcare-personnel.html

Long-Term Care Residents: https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-

vaccine-considerations-residents.html

Direct Service Providers: https://www.cdc.gov/coronavirus/2019-ncov/hcp/direct-

service-providers.html

For more information, contact CDC 1-800-CDC-INFO (232-4636) TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



To Ask a Question

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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 121420.asp

Upcoming COCA Calls

- Topic: Practical Decision Making for Crisis Standards of Care at the Bedside
- Date: Thursday, December 17, 2020
- **Time:** 2:00-3:00 PM ET
- Visit our COCA Call page at <u>emergency.cdc.gov/coca</u>.
- Subscribe at https://emergency.cdc.gov/coca/subscribe.asp.

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