



What Every Clinician Should Know about COVID-19 Vaccine Safety

Clinician Outreach and Communication Activity (COCA) Webinar

Monday, December 14, 2020

Continuing Education

Continuing education is not 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_121420.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 Presenters

- **Dana Meaney Delman, MD, MPH**
Co-lead, Vaccine Task Force
COVID-19 Response
Centers for Disease Control and Prevention
- **Tom Shimabukuro, MD, MPH, MBA**
Captain, U.S. Public Health Service Vaccine Safety
Team Lead
COVID-19 Response
Centers for Disease Control and Prevention
- **David T. Kuhar, MD**
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

COVID-19 vaccine safety monitoring
Top 3 takeaways

AT
THE
TOP

- 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**



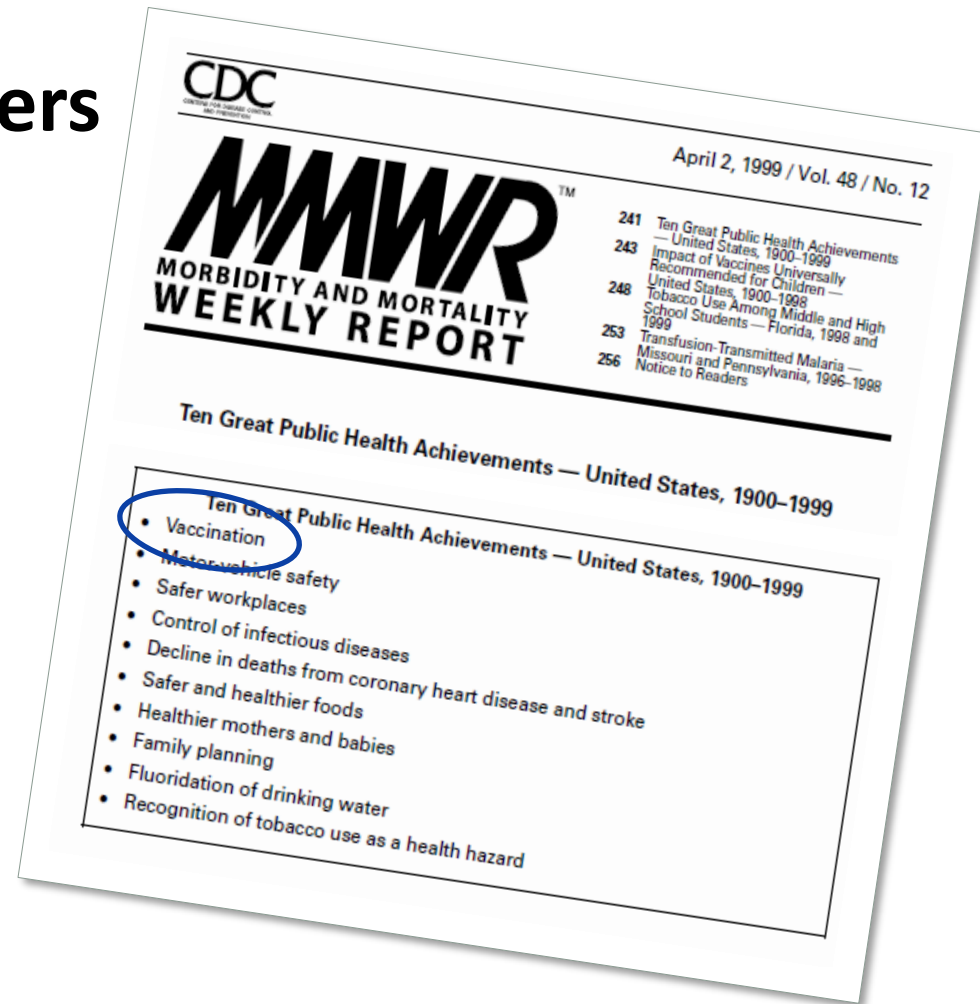
Why vaccine safety matters

Safety +
Effectiveness

equals

Vaccination
Program Success

in the past and looking forward



The Vaccine Life Cycle

safety at every phase

GUIDE

ACIP

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

BLA

BIOLOGICS LICENSE APPLICATION

CDC

CENTERS FOR DISEASE CONTROL AND PREVENTION

FDA

FOOD AND DRUG ADMINISTRATION

IND

INVESTIGATIONAL NEW DRUG APPLICATION

VACCINE

DEVELOPMENT

safety is a priority during vaccine development + approval

safety continues with CDC + FDA safety monitoring

PHASE 1 safety
PHASE 2 effectiveness
PHASE 3 safety + effectiveness

PHASE 4 safety monitoring for serious, unexpected adverse events

BASIC RESEARCH DISCOVERY PRE-CLINICAL STUDIES **IND SUBMITTED** CLINICAL STUDIES / TRIALS **BLA SUBMITTED** FDA REVIEW **FDA APPROVAL OF 1 NEW VACCINE** ACIP REVIEW **ACIP RECOMMENDATION** POST-APPROVAL MONITORING + RESEARCH

safety is a priority

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

https://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html#anchor_1593624850886

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)

Vaccine Adverse Event Reporting System (VAERS)

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



VAERS

Vaccine Adverse Event Reporting System

co-managed by
CDC and FDA

vaers.hhs.gov

The screenshot shows the VAERS website homepage. At the top, the VAERS logo is followed by the text 'Vaccine Adverse Event Reporting System' and the URL 'www.vaers.hhs.gov'. Below this is a navigation bar with five items: 'About VAERS', 'Report an Adverse Event', 'VAERS Data', 'Resources', and 'Submit Follow-Up Information'. The main content area is divided into two columns. The left column contains a question 'Have you had a reaction following a vaccination?' with two numbered steps: '1. Contact your healthcare provider.' and '2. Report an Adverse Event using the VAERS online form or the new downloadable PDF. *New!*'. Below this is an 'Important' box with text: 'Important: If you are experiencing a medical emergency, seek immediate assistance from a healthcare provider or call 9-1-1. CDC and FDA do not provide individual medical treatment, advice, or diagnosis. If you need individual medical or health care advice, consult a qualified healthcare provider.' Underneath is a Spanish version of the question: '¿Ha tenido una reacción después de recibir una vacuna?' with two numbered steps: '1. Contacte a su proveedor de salud.' and '2. Reporte una reacción adversa utilizando el formulario de VAERS en línea o la nueva versión PDF descargable. *Nuevo!*'. The right column features a large image of a family (a man, a woman, and two children) looking at a laptop. Below the image is the text 'What is VAERS?'. At the bottom of the page, there are four tiles, each with an image and a title: 'REPORT AN ADVERSE EVENT' (with a photo of a doctor and a patient), 'SEARCH VAERS DATA' (with a photo of hands using a tablet), 'REVIEW RESOURCES' (with a photo of a woman reading a tablet), and 'SUBMIT FOLLOW-UP INFORMATION' (with a photo of a woman at a computer). Each tile also has a short description of the action.

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

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](tel:1-800-822-7967)

email
info@VAERS.org

video instructions
<https://youtu.be/sbCWhcQADFE>



The screenshot shows the VAERS (Vaccine Adverse Event Reporting System) website. The header includes the VAERS logo and the text "Vaccine Adverse Event Reporting System" with the URL "www.vaers.hhs.gov". The navigation menu has five items: "About VAERS", "Report an Adverse Event", "VAERS Data", "Resources", and "Submit Follow-Up Information". The main content area features a question: "Have you had a reaction following a vaccination?" with two numbered steps: "1. Contact your healthcare provider." and "2. Report an Adverse Event using the VAERS online form or the new downloadable PDF. *New!*". A red arrow points to step 2. Below this is an "Important" box with text: "If you are experiencing a medical emergency, seek immediate assistance from a healthcare provider or call 9-1-1. CDC and FDA do not provide individual medical treatment, advice, or diagnosis. If you need individual medical or health care advice, consult a qualified healthcare provider." Below that is a Spanish version of the question: "¿Ha tenido una reacción después de recibir una vacuna?" with two numbered steps: "1. Contacte a su proveedor de salud." and "2. Reporte una reacción adversa utilizando el formulario de VAERS en línea o la nueva versión PDF descargable. *Nuevo!*". To the right of the text is a photograph of a family (father, mother, and two children) looking at a laptop. Below the photo is the text "What is VAERS?". At the bottom of the page are four tiles: "REPORT AN ADVERSE EVENT" (with a photo of a doctor and patient), "SEARCH VAERS DATA" (with a photo of hands on a tablet), "REVIEW RESOURCES" (with a photo of a woman reading), and "SUBMIT FOLLOW-UP INFORMATION" (with a photo of a woman at a computer).

- 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 check-ins 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



**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. 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?

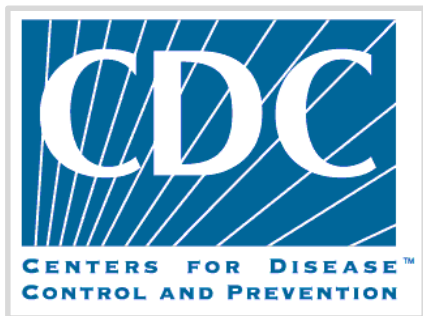
During the first week after you get your vaccine, **v-safe** will send you a text message each day to ask how you are doing. Then you



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.





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



This Photo by Unknown Author is licensed under CC BY-SA

Vaccine recipient

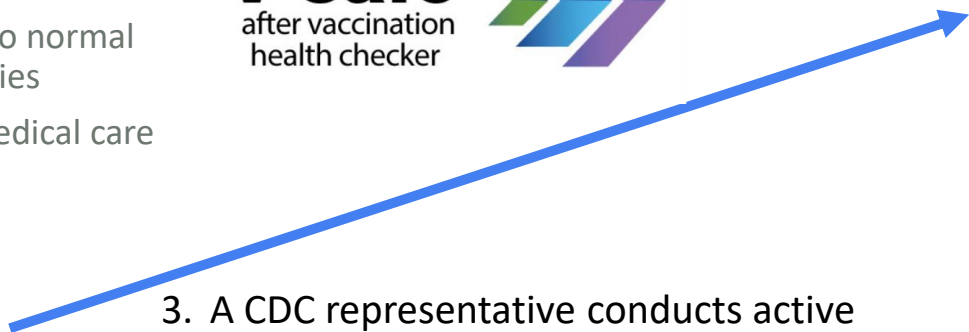


2. Clinically important health impact reported

- ✓ missed work
- ✓ unable to do normal daily activities
- ✓ received medical care

Call center

This Photo by Unknown Author is licensed under CC BY-SA



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

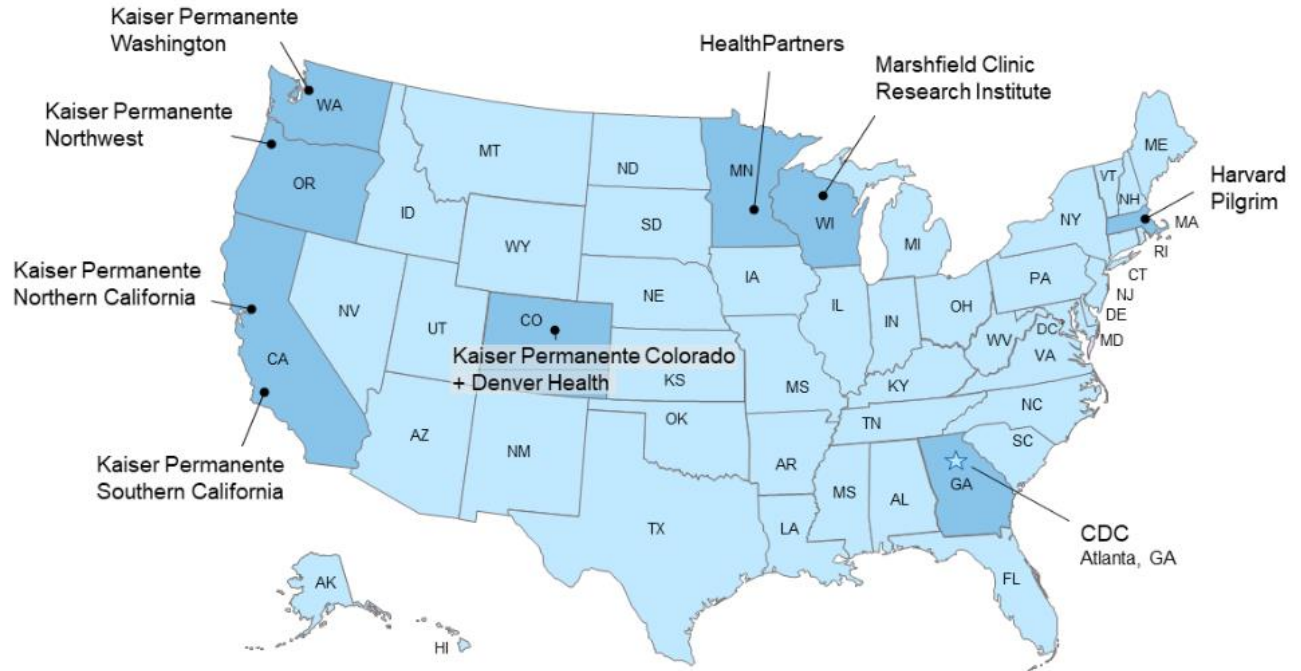
cdc.gov/coronavirus/2019-ncov/vaccines/safety/faq

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



VSD

Vaccine Safety Datalink



9 participating integrated healthcare organizations

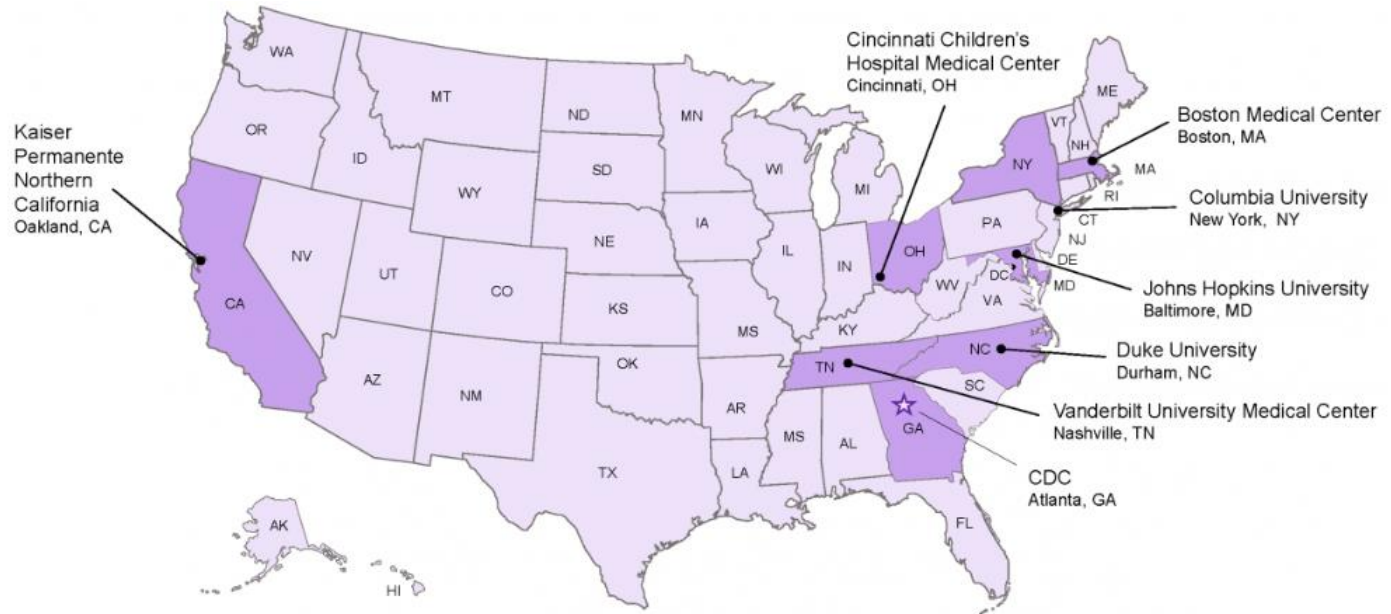
data on over **12 million** persons per year



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 ✓

COVID-19 vaccine safety monitoring
Top 3 takeaways

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- 3. You can play an important role in helping CDC monitor the safety of COVID-19 vaccines**



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



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 **ANY** 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 post-vaccination 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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 - 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_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 emergency.cdc.gov/coca.
- Subscribe at <https://emergency.cdc.gov/coca/subscribe.asp>.

COCA Products & Services

		COCA Call
		CDC Clinician Outreach and Communication Activity

COCA Call Announcements contain all information subscribers need to participate in COCA Calls. COCA Calls are held as needed.

		COCA Learn
		CDC Clinician Outreach and Communication Activity

Monthly newsletter that provides information on CDC training opportunities, conference and training resources, the COCA Partner Spotlight, and the Clinician Corner.

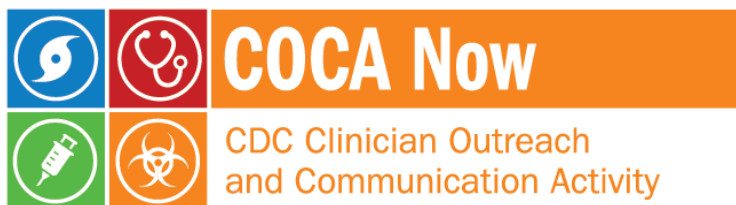
		Clinical Action
		CDC Clinician Outreach and Communication Activity

As-needed messages that provide specific, immediate action clinicians should take. Contains comprehensive CDC guidance so clinicians can easily follow recommended actions.

COCA Products & Services



Monthly newsletter providing updates on emergency preparedness and response topics, emerging public health threat literature, resources for health professionals, and additional information important during public health emergencies and disasters.



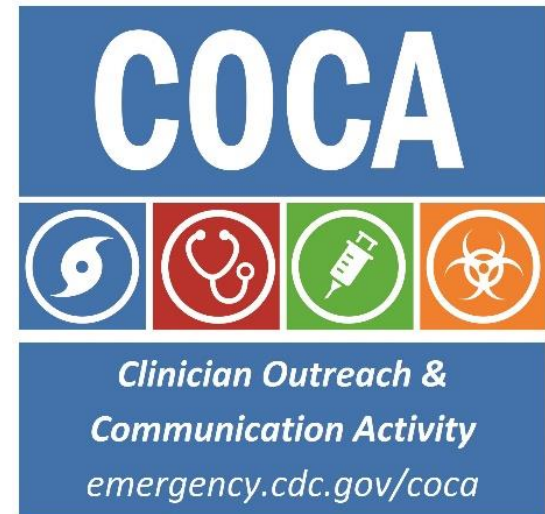
Informs clinicians of new CDC resources and guidance related to emergency preparedness and response. This email is sent as soon as possible after CDC publishes new content.



CDC's primary method of sharing information about urgent public health incidents with public information officers; federal, state, territorial, and local public health practitioners; clinicians; and public health laboratories.

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 - Health Alert Network (HAN) messages
 - CDC emergency response activations
 - Emerging public health threats
 - Emergency preparedness and response conferences
 - Training opportunities



emergency.cdc.gov/coca/subscribe.asp

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The screenshot shows the Facebook profile for COCA (CDC Clinician Outreach and Communication Activity). The profile picture features a group of six diverse healthcare professionals. The cover photo shows a group of five healthcare professionals. The page name is "CDC Clinician Outreach and Communication Activity - COCA" with the handle "@CDCClinicianOutreachAndCommunicationActivity". The page is categorized as a "Government Organization in Atlanta, Georgia". It has 21,420 likes and 21,217 followers. A recent post from October 31, 2017, at 1:18pm, reads: "Clinicians, you can earn FREE CE with this COCA Call! Join us for this COCA Call November 7, 2017 at 2:00PM." The page also includes navigation links for Home, About, Posts, Photos, Events, and Community, along with a "Create a Page" button.

Thank you for joining us today!



emergency.cdc.gov/coca