



# **What Clinicians Need to Know About Johnson & Johnson's Janssen COVID-19 Vaccine**

Clinician Outreach and Communication Activity (COCA) Webinar

Tuesday, March 2, 2021

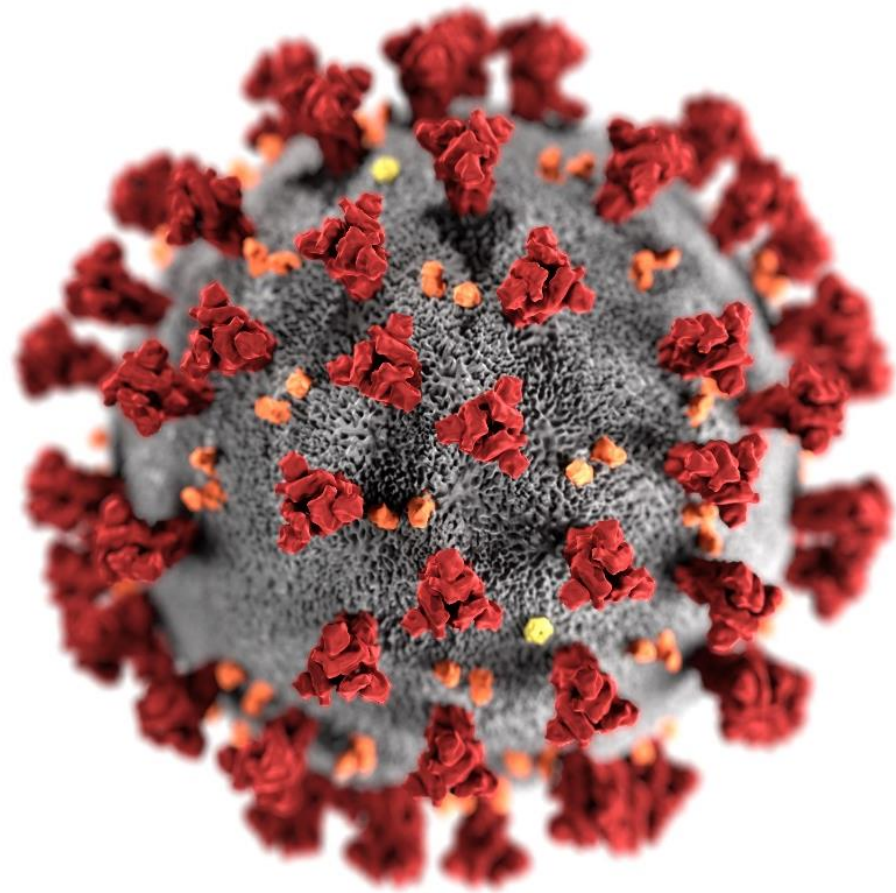
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  - Click the “Q&A” button.
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- If you are a patient, please refer your questions to your healthcare provider.
- For media questions, please contact CDC Media Relations at 404-639-3286, or send an email to [media@cdc.gov](mailto:media@cdc.gov).

# Today's Presenters

- **Sarah Mbaeyi, MD, MPH**  
CDR, U.S. Public Health Service  
Medical Officer  
National Center for Immunization and Respiratory  
Diseases  
Centers for Disease Control and Prevention
- **Sara Oliver, MD**  
LCDR, U.S. Public Health Service  
Co-lead, Advisory Committee for Immunization Practices  
COVID-19 Vaccines Work Group  
COVID-19 Response  
Centers for Disease Control and Prevention
- **Kathleen Dooling, MD, MPH**  
Medical Officer  
Co-lead, Advisory Committee for Immunization Practices  
COVID-19 Vaccines Work Group  
COVID-19 Response  
Centers for Disease Control and Prevention

## What Clinicians Need to Know about Johnson and Johnson's Janssen COVID-19 vaccine



Sara Oliver MD, MSPH  
Sarah Mbaeyi MD, MPH  
Kathleen Dooling MD, MPH

March 2, 2021



## Outline:

- 1) Safety and efficacy of Janssen COVID-19 vaccines  
Dr. Sara Oliver
- 2) Clinical considerations for use of Janssen COVID-19 vaccine  
Dr. Sarah Mbaeyi
- 3) Implementation considerations for Janssen COVID-19 vaccine  
Dr. Kathleen Dooling

# Safety and Efficacy of Janssen COVID-19 vaccines: Data from Phase III clinical trial



# Summary of the Available Evidence:

## Vaccine Efficacy

- The clinical trial demonstrated efficacy against symptomatic, laboratory-confirmed COVID-19. The overall efficacy was **66.3%** (95% CI: 59.9%, 71.8%).
- For COVID-19 associated hospitalization, 31 events occurred, 29 in the placebo group, 2 in the vaccine group. Vaccine efficacy against hospitalization was **93%** (95% CI: 71%, 98%).
- For all-cause deaths, 5 occurred in the vaccine group and 20 in the placebo group. Vaccine efficacy against all-cause death was **75%** (95% CI: 33%, 91%)

# Summary of the Available Evidence:

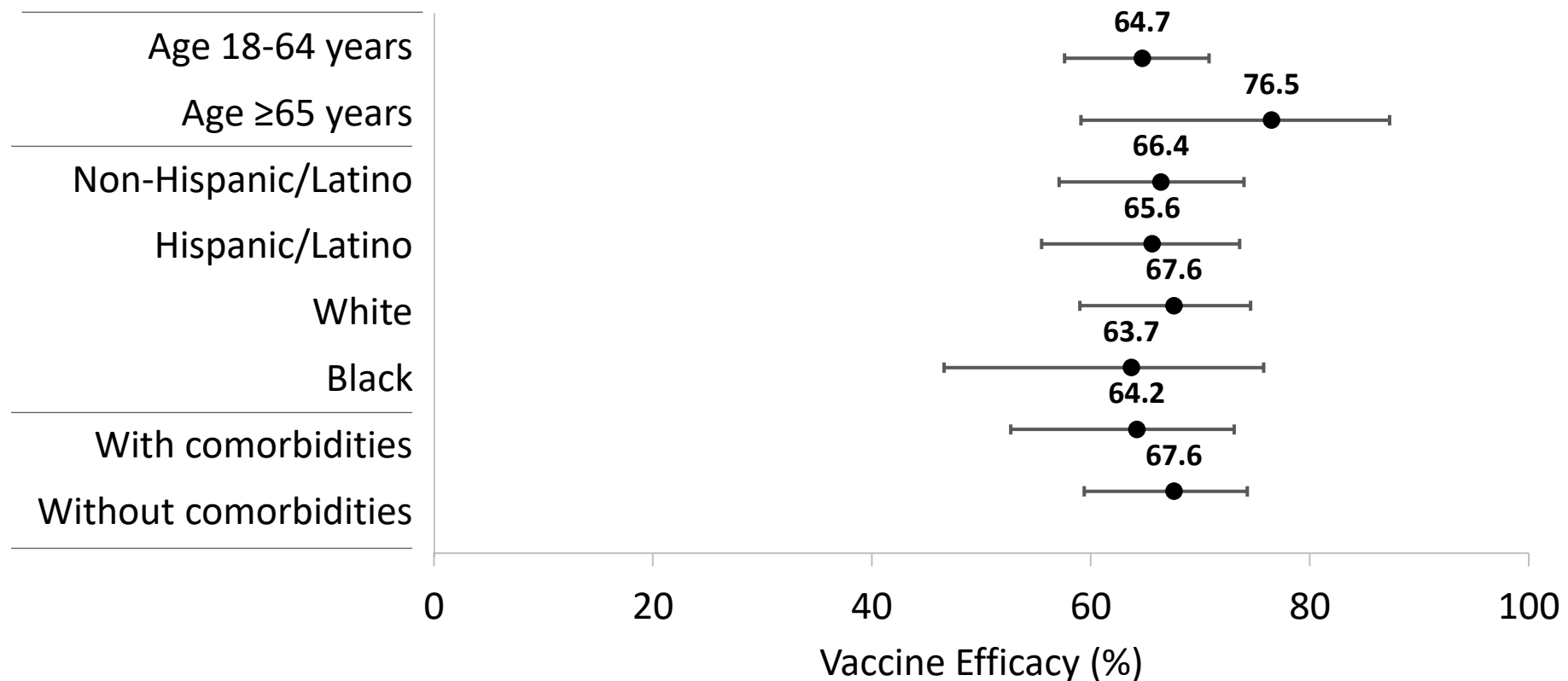
## Vaccine Efficacy

- Preliminary data were available to assess vaccine efficacy against seroconversion between days 29 and 71, based on the first 7% of specimens tested.
- Analysis was based on detection of N-binding antibody among persons who remained asymptomatic and did not have a positive SARS-CoV-2 PCR at any time in the study.
- Between four and ten weeks after vaccination with the Janssen COVID-19 vaccine, 10/1346 participants (**0.7%**) seroconverted, compared to 37/1304 (**2.8%**) of those receiving placebo. Vaccine efficacy against seroconversion was **74%** (95% CI: 48%, 87%).



# Summary of the Available Evidence: Vaccine Efficacy

- **Similar** efficacy for across age, sex, race, and ethnicity categories, and those with underlying medical conditions at  $\geq 14$  days post-vaccination



# Summary of the Available Evidence: Vaccine Efficacy

- **Higher** efficacy against **severe** outcomes than for any symptomatic COVID-19\*
  - VE against **deaths** due to COVID-19: **100%**
- Efficacy estimates for severe outcomes **assessed  $\geq 28$  days** post vaccination were **higher: 83.5%** for severe disease<sup>†</sup>, **100%** for hospitalization
- Efficacy against severe disease<sup>†</sup> remained high across world regions (**73-82%\***), suggesting protection against severe illness with variant strains

<sup>†</sup>**Definition:** Respiratory Rate  $\geq 30$ , Heart Rate  $\geq 125$ , SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level or PaO<sub>2</sub>/FIO<sub>2</sub>  $< 300$  mm Hg; OR respiratory failure or Acute Respiratory Distress Syndrome (ARDS), defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO; OR evidence of shock (systolic blood pressure  $< 90$  mmHg, diastolic BP  $< 60$  mmHg or requiring vasopressors); OR significant acute renal, hepatic or neurologic dysfunction; OR admission to an intensive care unit or death

\*Assessed  $\geq 14$  days post vaccination

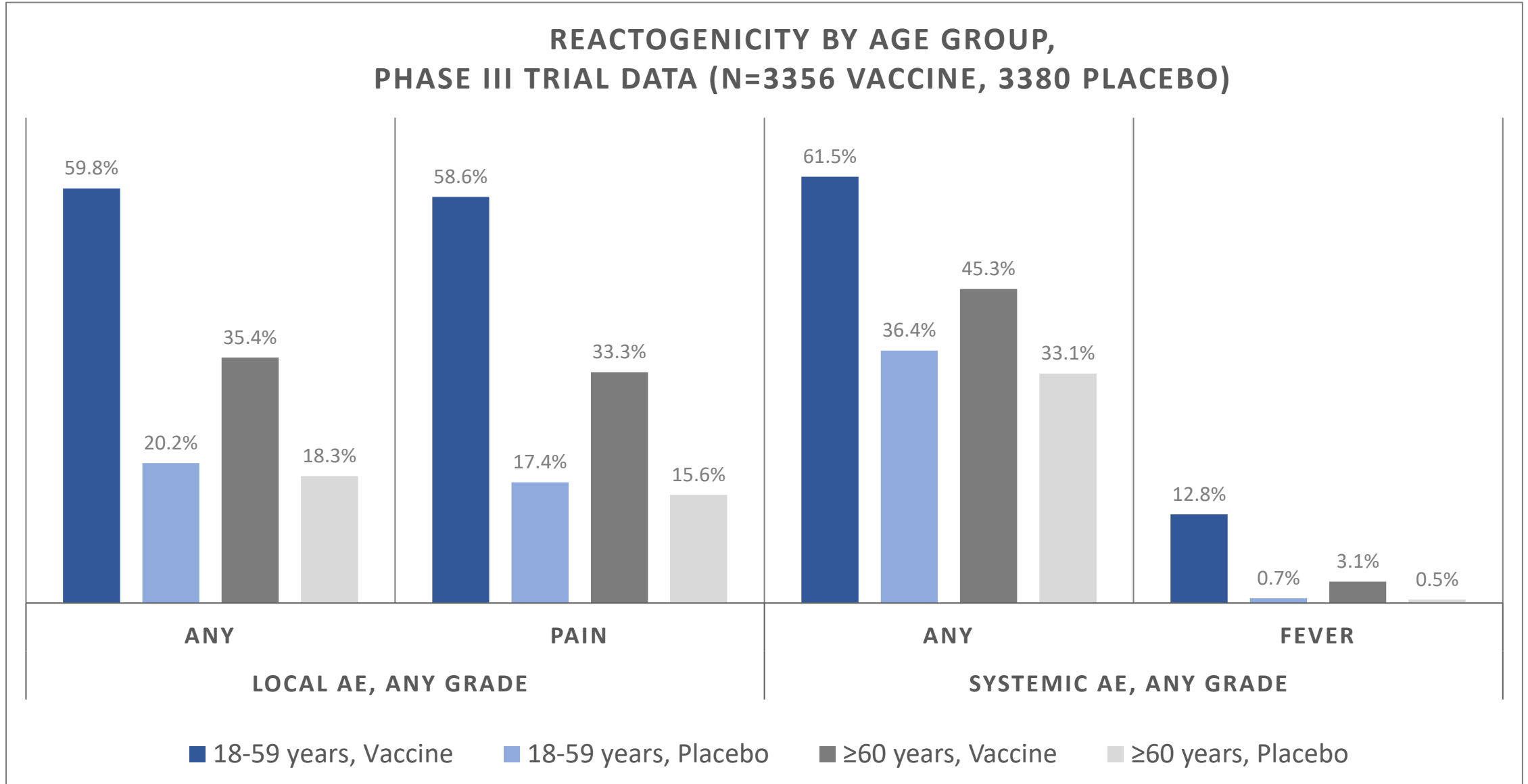
# Summary of the Available Evidence: Safety and Reactogenicity

- Serious adverse events were reported in a similar proportion among recipients of vaccine and placebo (0.4% vs 0.4%).
- Severe reactions were more common in vaccine recipients; any grade  $\geq 3$  reaction was reported by 2.5% of vaccinated versus 0.7% of placebo group.

# Summary of the Available Evidence: Safety and Reactogenicity

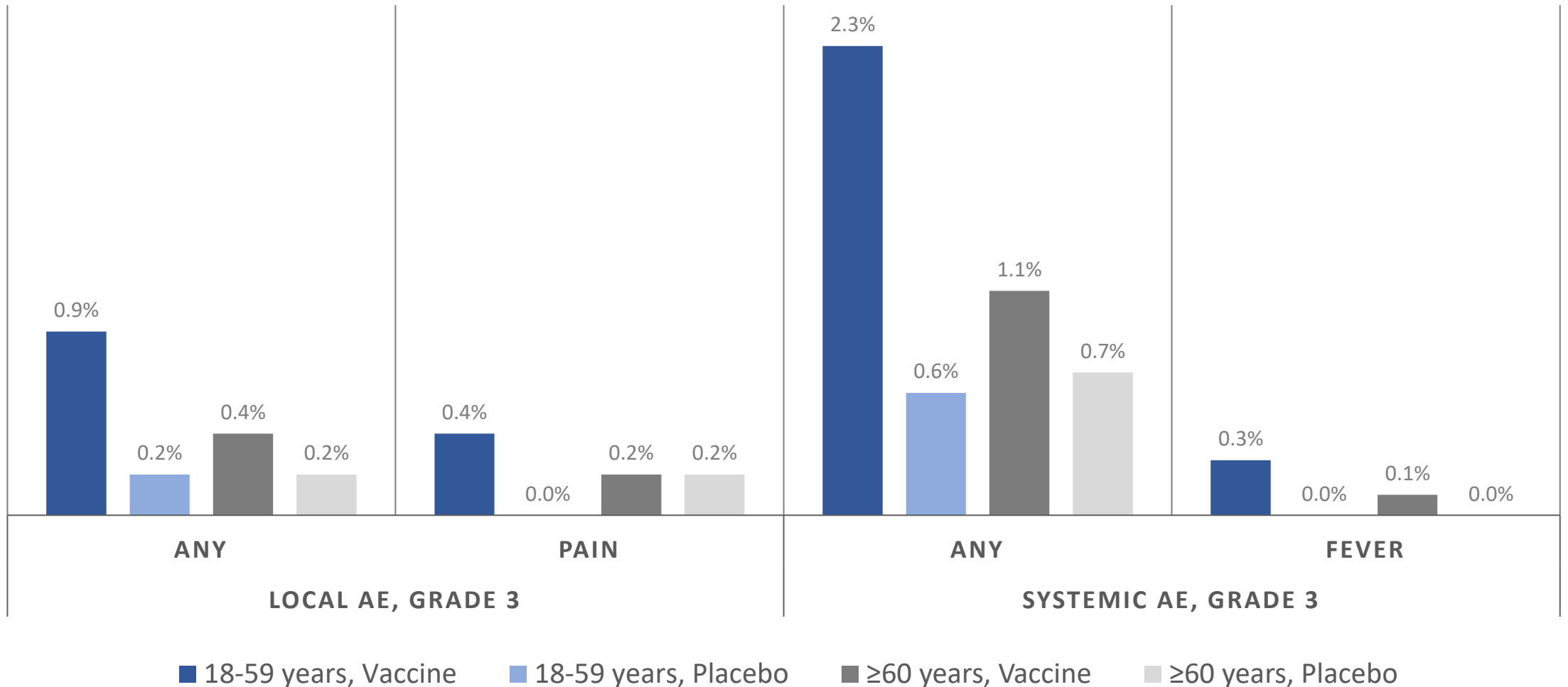
- **Local** reactions within 7 days occurred in ~50% vaccine recipients
  - Pain at the injection site most common
- **Systemic** reactions within 7 days occurred in ~55% vaccine recipients
  - Headache, fatigue, and myalgia most common
- Most symptoms resolved after 1-2 days

# Summary of Available Evidence: Reactogenicity



# Summary of Available Evidence: Reactogenicity

GRADE 3 REACTOGENICITY BY AGE GROUP,  
PHASE III TRIAL DATA (N=3356 VACCINE, 3380 PLACEBO)



# Summary of the Available Evidence: Safety and Reactogenicity

Adverse event imbalances of note:

- **Urticaria** events: vaccine n=5; placebo n=1
  - Possibly related to the vaccine\*
- **Tinnitus**: vaccine n=6; placebo n=0
  - Insufficient data to determine causal relationship\*
- **Thromboembolic** events: vaccine n=15; placebo n=10
  - Many of the participants had predisposing conditions. FDA determined contributory effect of vaccine not excluded, insufficient data to determine causal relationship\*
  - FDA recommends surveillance for further evaluation of thromboembolic events

\*Causal determination per FDA

# Summary of the Evidence:

## All authorized COVID-19 vaccines

- No trials compared efficacy between vaccines in the **same** study at the **same** time
  - All Phase 3 trials differed by calendar time and geography
  - Vaccines were tested against different circulating variants and in settings with different background incidence
- All authorized COVID-19 vaccines demonstrated efficacy (range 65 to 95%) against symptomatic lab-confirmed COVID-19
- All authorized COVID-19 vaccines demonstrated **high** efficacy ( $\geq 89\%$ ) against COVID-19 severe enough to require **hospitalization**
- In the vaccine trials, **no** participants who received a COVID-19 vaccine **died** from COVID-19
  - The Moderna and Janssen trials each had COVID-19 deaths in the placebo arm



# Clinical Considerations for Use of the Janssen COVID-19 vaccine



# Clinical considerations for use of mRNA COVID-19 vaccines

- CDC clinical considerations for mRNA COVID-19 vaccines published previously:
  - <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>
- Clinical considerations are being updated to include Janssen COVID-19 vaccine
  - Viral vector COVID-19 vaccine

## 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 after COVID-19 vaccination](#)

### Summary of recent changes (last updated February 10, 2021):

- New recommendations for preventing, reporting, and managing mRNA COVID-19 vaccine administration errors (Appendix A).
- Clarification on contraindications and precautions. Persons with a known (diagnosed) allergy to PEG, another mRNA vaccine component, or polysorbate, have a contraindication to vaccination. Persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is PEG, another mRNA vaccine component or polysorbate, but in whom it is unknown which component elicited the immediate allergic reaction have a precaution to vaccination.
- Updated information on delayed, local injection-site reactions after the first mRNA vaccine dose. These reactions are neither a contraindication or precaution to the second dose.
- Updated quarantine recommendations for vaccinated persons. Fully vaccinated persons who meet criteria will no longer be required to quarantine following an exposure to someone with COVID-19. Additional considerations for patients and residents in healthcare settings are provided.
- Additional information and updated recommendations for testing for TB infection. TB testing can be done before or at the same time as mRNA COVID-19 vaccination, or otherwise delayed for  $\geq 4$  weeks after the completion of mRNA COVID-19 vaccination.

### On This Page

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- [Interchangeability with other COVID-19 vaccine products](#)
- [Coadministration with other vaccines](#)
- [Booster doses](#)
- [Vaccination of persons with a SARS-CoV-2 infection or exposure](#)
- [Vaccination of persons with underlying medical conditions](#)
- [Vaccination of pregnant or lactating people](#)
- [Vaccination of children and adolescents](#)
- [Patient counseling](#)

Sign up to receive email updates when clinical considerations are updated: <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

# Summary of the Janssen vaccine characteristics

- Authorized for persons aged  $\geq 18$  years
- Intramuscular injection (0.5 ml)
- Vaccine shipment and storage (3 months) at refrigerator temperatures (2-8°C)\*
- Single-dose series
- No diluent required

\* Long-term storage at standard freezer temperatures (-20°C)

# Interchangeability of COVID-19 vaccine products

- Any COVID-19 vaccine can be used when indicated; no product preference
- COVID-19 vaccines are **not** interchangeable
  - Safety and efficacy of a mixed series has not been evaluated
- If first dose of mRNA COVID-19 vaccine was received but patient unable to complete series with same or different mRNA vaccine
  - Single dose of Janssen COVID-19 vaccine may be administered at minimum interval of 28 days from mRNA dose\*
  - Considered to have received valid, single-dose Janssen vaccination, not mixed vaccination series (mRNA/viral vector)

\*Persons with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine. In these patients, vaccination should be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to allergist-immunologist.

# Coadministration of COVID-19 vaccines with other vaccines

- Currently authorized COVID-19 vaccines are all inactivated vaccines
- COVID-19 vaccine should be administered alone with minimum interval of 14 days before or after administration of other vaccines
- A shorter interval may be used in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks (e.g., tetanus toxoid vaccine for wound management, etc.) or to avoid barriers or delays to vaccination

# COVID-19 vaccination of persons with underlying medical conditions

- Any currently authorized COVID-19 vaccine can be administered to persons with underlying medical conditions who have no contraindications to vaccination, including:
  - Immunocompromised persons
  - People with autoimmune conditions
  - People with history of Guillain-Barré syndrome, Bell's palsy, dermal filler use
- Clinical trials demonstrate similar safety and efficacy profiles in persons with underlying medical conditions, including those that place them at increased risk for severe COVID-19, compared to persons without comorbidities

# COVID-19 vaccination of immunocompromised persons

- Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19
- Immunocompromised persons may receive COVID-19 vaccine unless otherwise contraindicated
  - All currently authorized vaccines are inactivated vaccines
- Individuals should be counseled about:
  - Unknown vaccine safety and efficacy profiles in immunocompromised persons
  - Potential for reduced immune responses
  - Need to continue to follow current guidance to protect themselves against COVID-19

# COVID-19 vaccination of pregnant people

- COVID-19 and pregnancy
  - Increased risk of severe illness (ICU admission, mechanical ventilation and death)
  - Might be an increased risk of adverse pregnancy outcomes
- Currently limited data on safety of COVID-19 vaccines in pregnant people
  - No concerns demonstrated in animal developmental and reproductive toxicity (DART) studies
  - Janssen adenovirus vector platform previously used for other clinical development programs that included pregnant people, including a large-scale Ebola vaccine trial
- Currently authorized COVID-19 vaccines are all inactivated vaccines
- Clinical trials to evaluate safety and efficacy of COVID-19 vaccines in pregnant people planned or underway



# COVID-19 vaccination of pregnant people

- Pregnant people may choose to receive COVID-19 vaccine when eligible
  - A conversation between the patient and their clinical team may assist with decision, but is not required
  - Conversation should consider:
    - Level of COVID-19 community transmission
    - Personal risk of contracting COVID-19
    - Risks of COVID-19 to patient and fetus
    - Efficacy and side effects of vaccine
    - Limited data about vaccine during pregnancy

# Contraindications and precautions for COVID-19 vaccines

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
<p>History of the following:</p> <ul style="list-style-type: none"> <li>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine<sup>†</sup></li> <li>Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine<sup>†</sup></li> </ul> <p>Actions:</p> <ul style="list-style-type: none"> <li>Do not vaccinate.</li> <li>Consider referral to allergist-immunologist.</li> <li>Consider other vaccine alternative.<sup>†</sup></li> </ul>	<p>Among persons without a contraindication, a history of:</p> <ul style="list-style-type: none"> <li>Any immediate allergic reaction* to other vaccines or injectable therapies<sup>‡</sup></li> </ul> <p>Actions:</p> <ul style="list-style-type: none"> <li>Risk assessment</li> <li>Consider referral to allergist-immunologist</li> <li>30-minute observation period if vaccinated</li> </ul>	<p>Among persons without a contraindication or precaution, a history of:</p> <ul style="list-style-type: none"> <li>Allergy to oral medications (including the oral equivalent of an injectable medication)</li> <li>History of food, pet, insect, venom, environmental, latex, etc., allergies</li> <li>Family history of allergies</li> </ul> <p>Actions:</p> <ul style="list-style-type: none"> <li>30-minute observation period: persons with history of anaphylaxis (due to any cause)</li> <li>15-minute observation period: all other persons</li> </ul>

<sup>†</sup> See [Appendix C](#) for a list of ingredients. Persons with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna).

\* 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.

<sup>‡</sup> Includes persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but in whom it is unknown which component elicited the immediate allergic reaction.

# Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. Persons with a contraindication to mRNA COVID-19 vaccines (including due to a known [diagnosed] allergy to PEG) have a precaution to Janssen COVID-19 vaccine. Among persons who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 vaccine (administered at least 28 days after the mRNA COVID-19 dose). Persons with a contraindication to Janssen COVID-19 vaccine (including due to a known [diagnosed] allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. In patients with these precautions, vaccination should be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to allergist-immunologist.

# Implementation Considerations for Use of the Janssen COVID-19 vaccine



# Janssen COVID-19 Vaccine

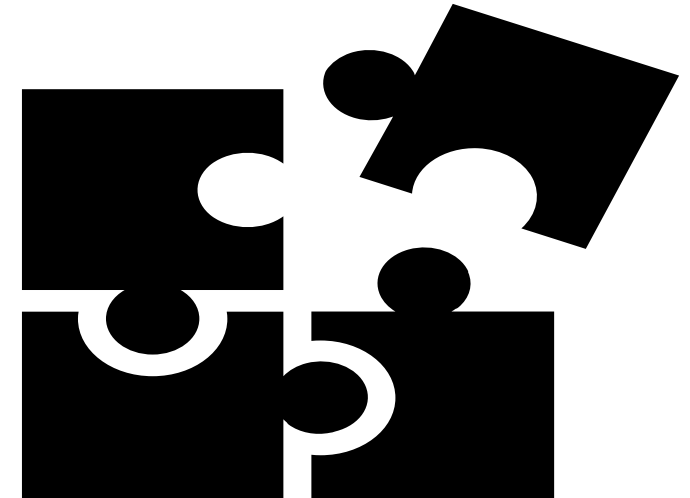
- ACIP states no preference for any of the three authorized vaccines
  - Results of Janssen Phase III trials not comparable with mRNA vaccines
    - Different calendar time
    - Different geography
- } Different circulating variants  
Higher background incidence
- Strong protection against severe COVID-19
    - 93% VE against hospitalizations (2 cases in vaccinated vs. 29 in placebo)
    - No COVID-associated deaths in vaccinated vs. 7 in placebo

# Janssen COVID-19 Vaccine

## How does it best fit?

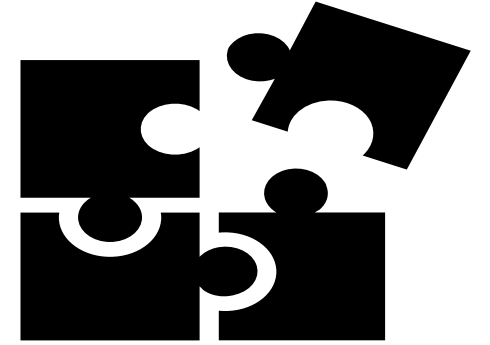
### Characteristics of the vaccine

- 1 dose
- Transport, and storage (x3m) at 2-8°C
- No diluent/reconstitution necessary



# Janssen COVID-19 Vaccine

## Considerations for utilization



### Where?

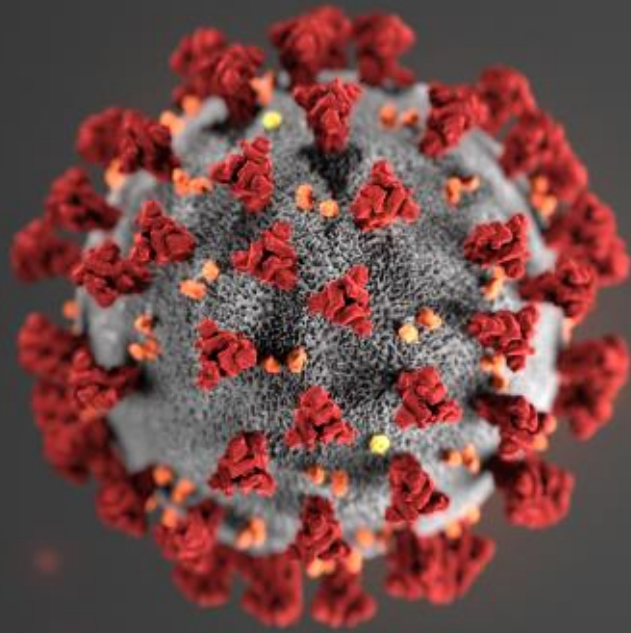
- Mobile/pop-up clinics
- Newly established vaccine administration sites
- Sites that do not have freezer capacity (e.g. adult HCP offices)

### Who?

- People who want to be fully vaccinated quickly
- People who don't want to return or can't return for a second dose
- Mobile populations or homebound populations

# COVID-19 Vaccine Work Group considerations

- During a pandemic, under EUA, offering Janssen COVID-19 vaccine to persons 18 years and older, according to established allocation and eligibility recommendations in a given jurisdiction, is an effective implementation strategy
  - Allows for jurisdictional flexibility
  - Supports rapid vaccination and increases in population immunity
  - Does not single out any group
  - Allows individuals to be vaccinated with the earliest vaccine available



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

# Thank you

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.
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# 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/2021/callinfo\\_030221.asp](https://emergency.cdc.gov/coca/calls/2021/callinfo_030221.asp)

# Upcoming COCA Calls

- **When:** Thursday, March 11 at 2 PM ET
- **Topic:** The Role of Telehealth in Expanding Access to Healthcare During the COVID-19 Pandemic: Considerations for Vaccine Uptake and Monitoring for Adverse Events
- **For more information:**  
[https://emergency.cdc.gov/coca/calls/2021/callinfo\\_031121.asp](https://emergency.cdc.gov/coca/calls/2021/callinfo_031121.asp)
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CDC Clinician Outreach  
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Monthly newsletter that provides information on CDC training opportunities, conference and training resources, the COCA Partner Spotlight, and the Clinician Corner.



**Clinical Action**



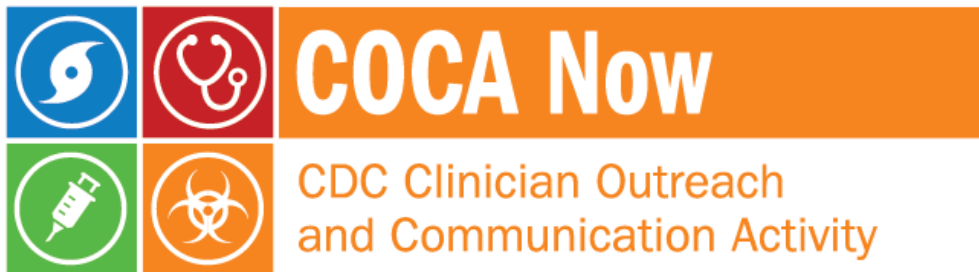
CDC Clinician Outreach  
and Communication Activity

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.



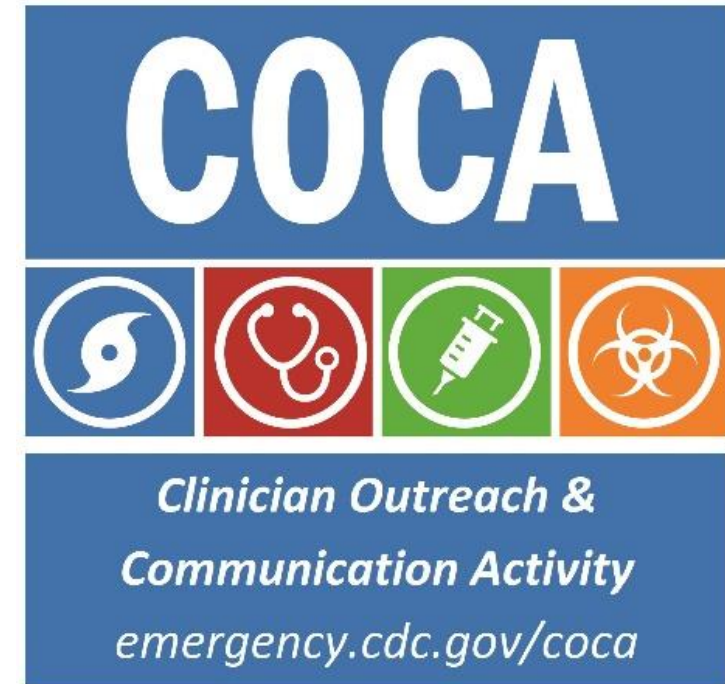
Informs clinicians of new CDC resources and guidance related to emergency preparedness and response. This email is sent as soon as possible after CDC publishes new content.



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