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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Today's Presenters

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- **Sara Oliver, MD**
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  Co-lead, Advisory Committee for Immunization Practices
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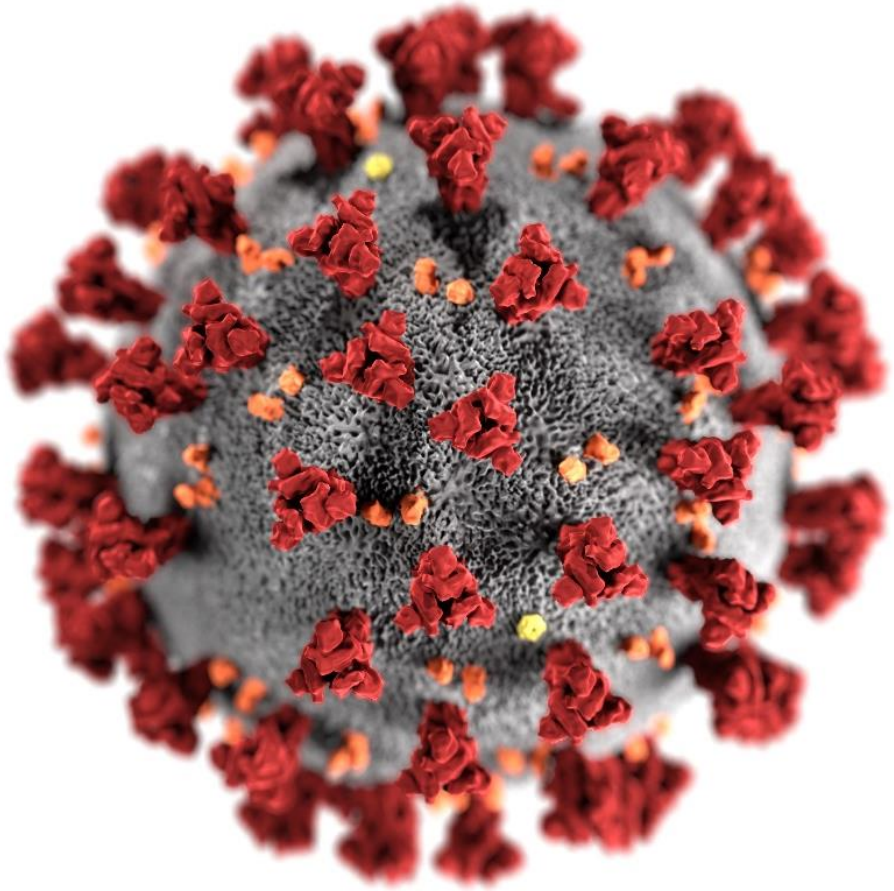
What Clinicians Need to Know about Johnson and Johnson's Janssen COVID-19 vaccine



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%).

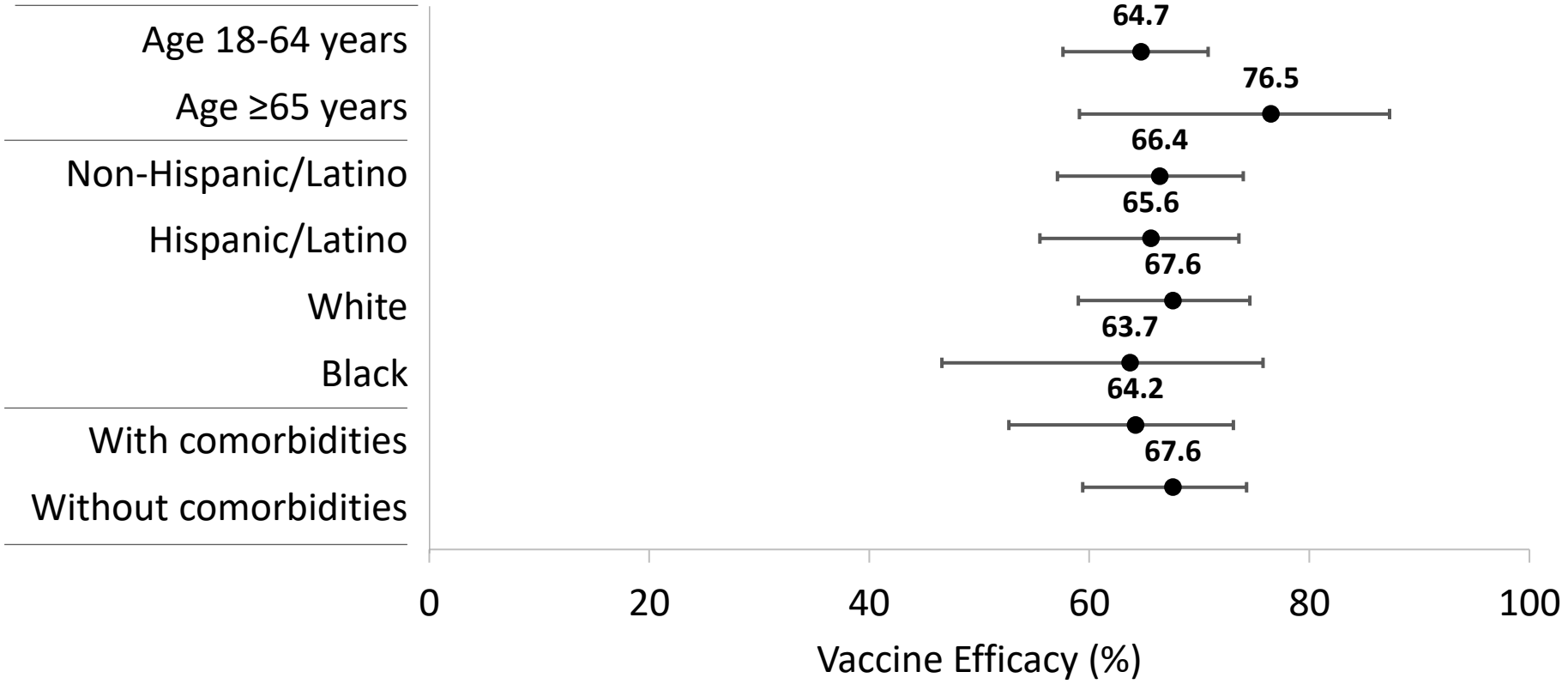
- For all-cause deaths, 5 occurred in the vaccine group and 20 in the placebo group. Vaccine efficacy against all-cause death was **75%** (95% CI: 33%, 91%)

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 ≥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 ≥28 days** post vaccination were **higher**: **83.5%** for severe disease†, **100%** for hospitalization

- Efficacy against severe disease† remained high across world regions (**73-82%***), suggesting protection against severe illness with variant strains

†**Definition**: Respiratory Rate ≥ 30, Heart Rate ≥125, SpO2≤ 93% on room air at sea level or PaO2/FIO2< 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 <90mmHg, diastolic BP<60mmHg or requiring vasopressors); OR significant acute renal, hepatic or neurologic dysfunction; OR admission to an intensive care unit or death

*Assessed ≥ 14 days post vaccination

Summary of the Available Evidence:
Safety and Reactogenicity

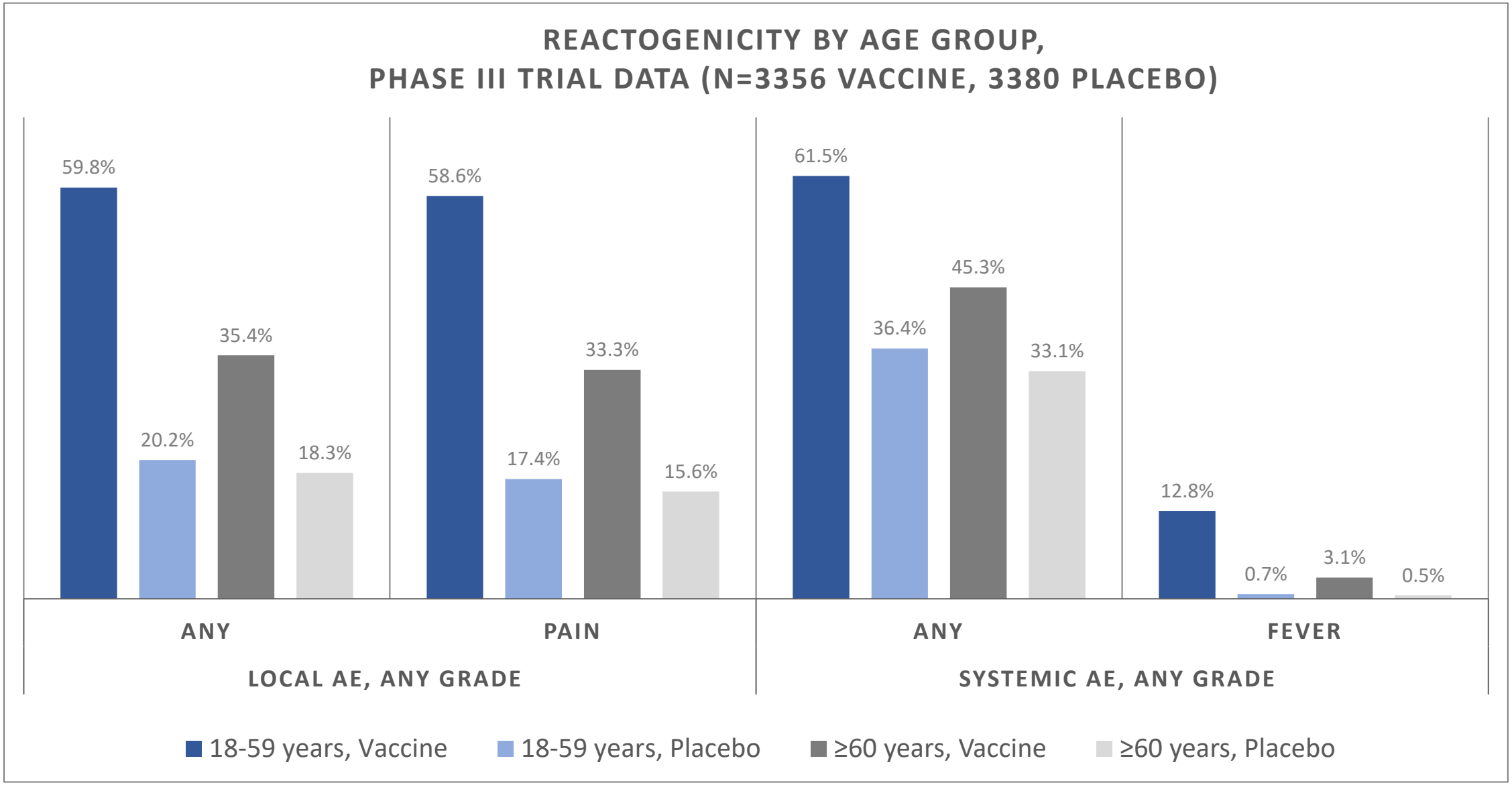
- Serious adverse events were reported in a similar proportion among recipients of vaccine and placebo (0.4% vs 0.4%).

- Severe reactions were more common in vaccine recipients; any grade ≥3 reaction was reported by 2.5% of vaccinated versus 0.7% of placebo group.

Summary of the Available Evidence:
Safety and Reactogenicity

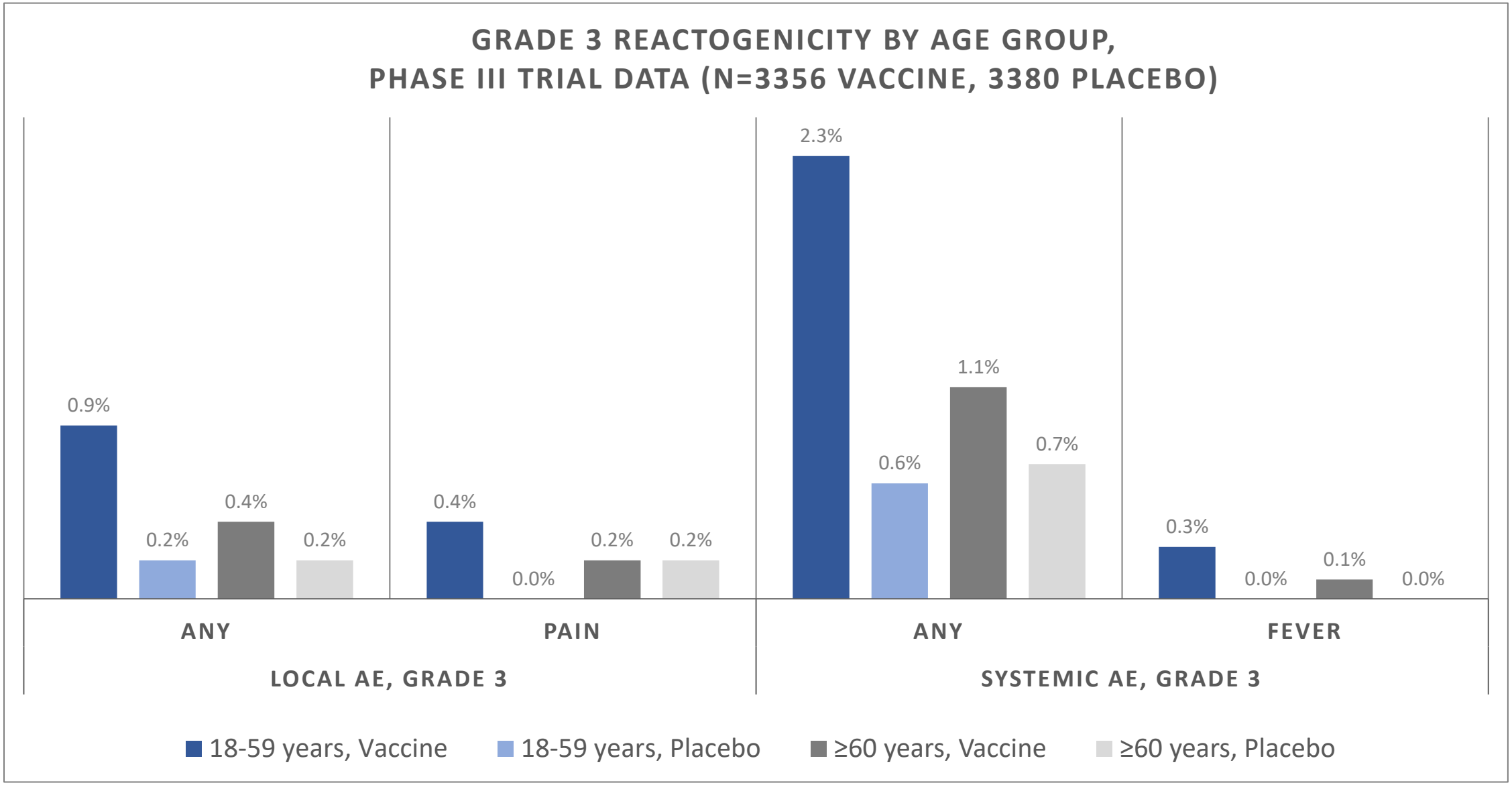
- **Local** reactions within 7 days occurred in ~50% vaccine recipients
  - Pain at the injection site most common
- **Systemic** reactions within 7 days occurred in ~55% vaccine recipients
  - Headache, fatigue, and myalgia most common
- Most symptoms resolved after 1-2 days

Summary of Available Evidence: Reactogenicity



Abbreviations, AE= Adverse Events

Summary of Available Evidence: Reactogenicity



Abbreviations, AE= Adverse Events

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

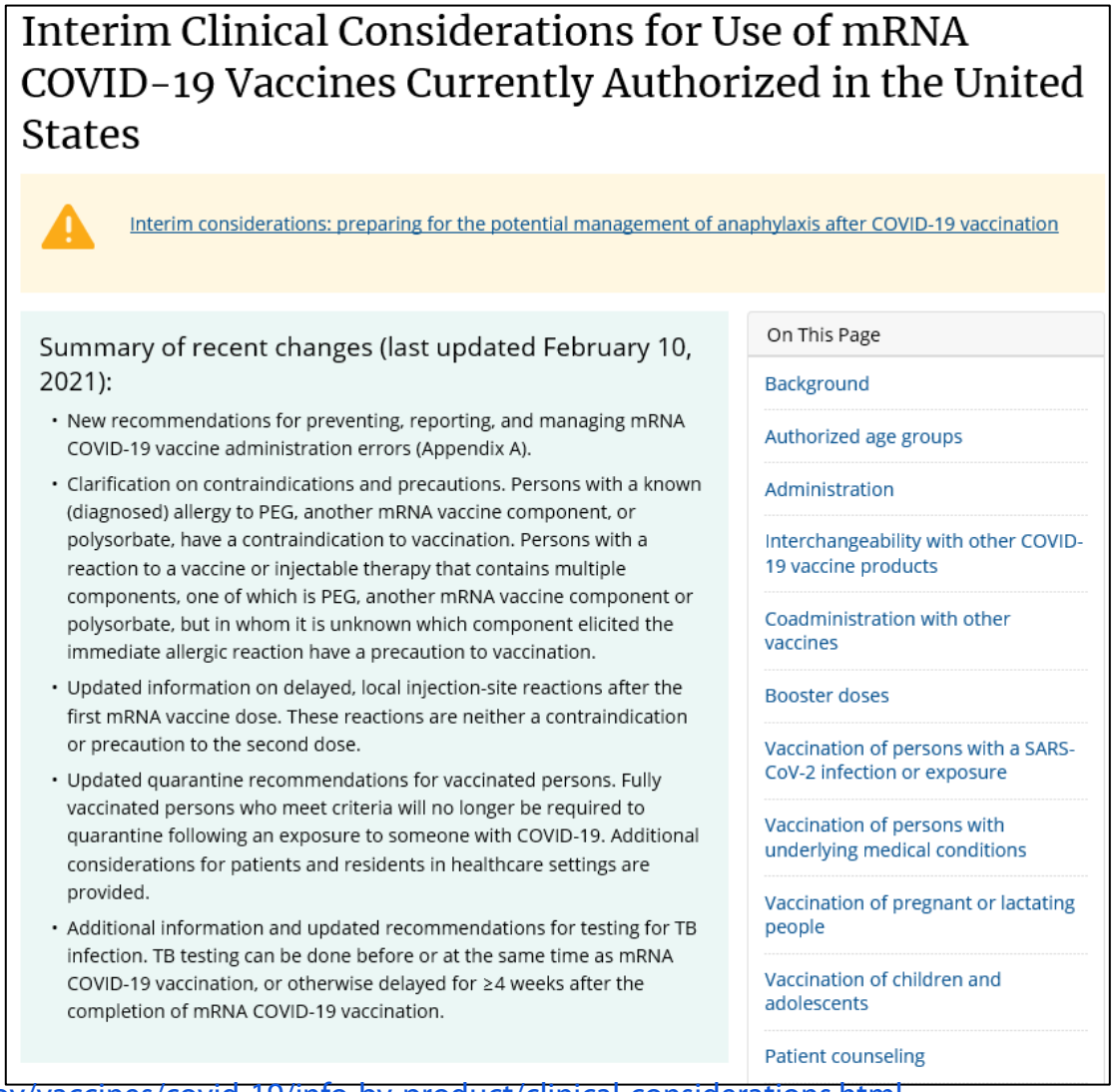
Summary of the Evidence:
All authorized COVID-19 vaccines

- 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 (≥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 ≥4 weeks after the completion of mRNA COVID-19 vaccination.

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Vaccination of children and adolescents
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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 ≥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 compete 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

https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

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

https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html
https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#phrecs

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

https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnancy-breastfeeding.html
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/special-situations.html

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
History of the following: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine† • Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine† Actions: • Do not vaccinate. • Consider referral to allergist-immunologist. • Consider other vaccine alternative.†	Among persons without a contraindication, a history of: • Any immediate allergic reaction* to other vaccines or injectable therapies‡ Actions: • Risk assessment • Consider referral to allergist-immunologist • 30-minute observation period if vaccinated	Among persons without a contraindication or precaution, a history of: • 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 history of anaphylaxis (due to any cause) • 15-minute observation period: all other persons

† 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.

‡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

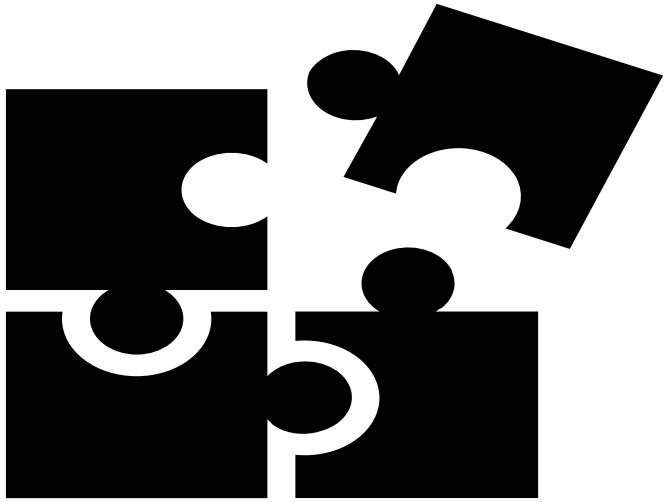
} Different circulating variants
Higher background incidence

- 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

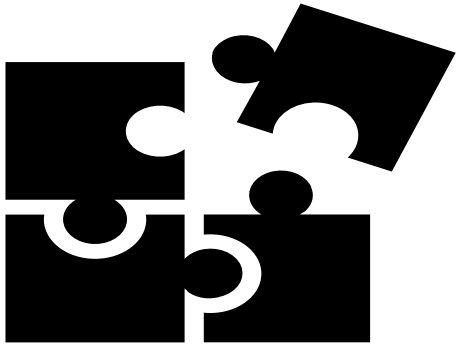
Janssen COVID-19 Vaccine
How does it best fit?

Characteristics of the vaccine

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



Janssen COVID-19 Vaccine Considerations for utilization



Where?

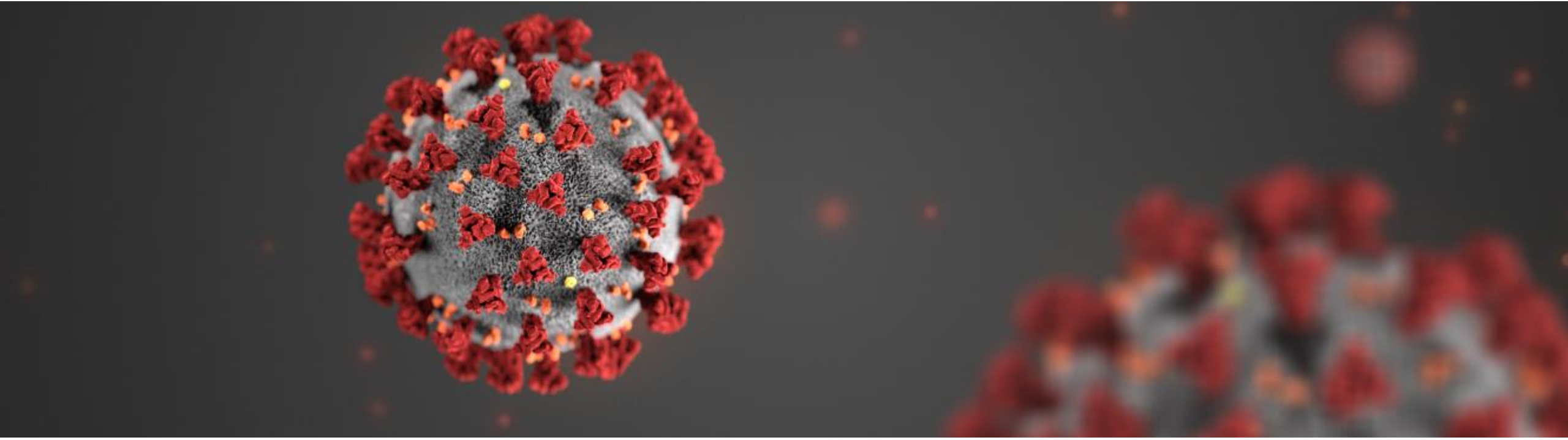
- Mobile/pop-up clinics
- Newly established vaccine administration sites
- Sites that do not have freezer capacity (e.g. adult HCP offices)

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

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.

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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/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

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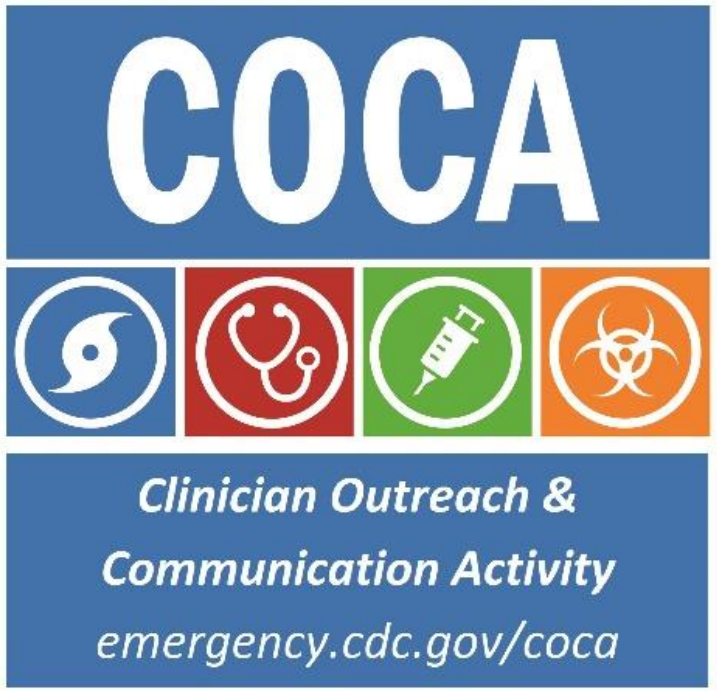

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