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

- **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%)
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

<table>
<thead>
<tr>
<th>Age 18-64 years</th>
<th>Age ≥65 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Hispanic/Latino</td>
<td>Hispanic/Latino</td>
</tr>
<tr>
<td>White</td>
<td>Black</td>
</tr>
<tr>
<td>With comorbidities</td>
<td>Without comorbidities</td>
</tr>
</tbody>
</table>

Vaccine Efficacy (%)

- 64.7
- 66.4
- 65.6
- 67.6
- 63.7
- 64.2
- 67.6
- 76.5
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
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

#### Reactogenicity

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Local AE, Any Grade</th>
<th>Systemic AE, Any Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-59 years, Vaccine</td>
<td>59.8%</td>
<td>61.5%</td>
</tr>
<tr>
<td>18-59 years, Placebo</td>
<td>20.2%</td>
<td>36.4%</td>
</tr>
<tr>
<td>≥60 years, Vaccine</td>
<td>35.4%</td>
<td>45.3%</td>
</tr>
<tr>
<td>≥60 years, Placebo</td>
<td>18.3%</td>
<td>33.1%</td>
</tr>
</tbody>
</table>

**Abbreviations, AE= Adverse Events**

#### Reactogenicity by Age Group, Phase III Trial Data (N=3356 Vaccine, 3380 Placebo)

- **ANY**: 59.8%, 58.6%, 61.5%, 12.8%
- **PAIN**: 20.2%, 17.4%, 15.6%, 0.7%
- **LOCAL AE, ANY GRADE**
  - 18-59 years, Vaccine: 59.8%
  - 18-59 years, Placebo: 20.2%
  - ≥60 years, Vaccine: 35.4%
  - ≥60 years, Placebo: 18.3%
- **SYSTEMIC AE, ANY GRADE**
  - 18-59 years, Vaccine: 61.5%
  - 18-59 years, Placebo: 36.4%
  - ≥60 years, Vaccine: 45.3%
  - ≥60 years, Placebo: 33.1%

**Abbreviations, AE= Adverse Events**
Summary of Available Evidence: Reactogenicity

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

<table>
<thead>
<tr>
<th></th>
<th>18-59 years, Vaccine</th>
<th>18-59 years, Placebo</th>
<th>≥60 years, Vaccine</th>
<th>≥60 years, Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANY, LOCAL AE, GRADE 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>0.9%</td>
<td>0.2%</td>
<td>0.4%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Fever</td>
<td>2.3%</td>
<td>0.6%</td>
<td>1.1%</td>
<td>0.3%</td>
</tr>
</tbody>
</table>

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](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

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

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/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

**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.†

### PRECAUTION TO VACCINATION

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

### MAY PROCEED WITH VACCINATION

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

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†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 2-8°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
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:** 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

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  [https://emergency.cdc.gov/coca/calls/2021/callinfo_031121.asp](https://emergency.cdc.gov/coca/calls/2021/callinfo_031121.asp)

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