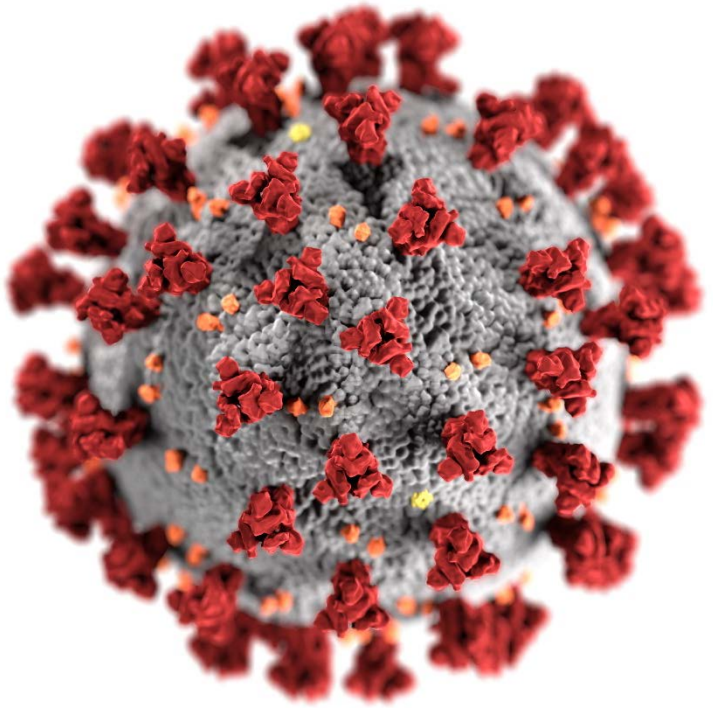
# Interim Clinical Considerations for Moderna and Janssen COVID-19 Vaccine Booster Doses

**Sujan Reddy, MD MSc**

October 21, 2021



cdc.gov/coronavirus

# Outline of Presentation

- Indications for COVID-19 vaccine booster doses
- Heterologous (mix-and-match) booster doses
- COVID-19 vaccine booster administration
- Fully vaccinated definition
- Coadministration with other vaccines
- Contraindications and precautions

# Indications for a Booster Dose Following mRNA COVID-19 Primary Series

- The following recipients of an mRNA primary series **should receive** a single mRNA COVID-19 vaccine booster dose ≥ 6 months after completion of primary series
  - ≥65 years
  - ≥18 years and reside in long-term care settings
  - Aged 50-64 years with certain underlying medical conditions
- The following recipients of an mRNA primary series **may receive** a single mRNA COVID-19 vaccine booster dose ≥6 months after completion of primary series based on their individual risks and benefits
  - Aged 18-49 years with certain underlying medical conditions
  - Aged 18-64 years at increased risk for SARS-CoV-2 exposure and transmission because of occupational or institutional setting
- In general, the same product that was used for the primary regimen should be used for the booster.

# Individual Risk-Benefit Assessment for People who "may receive" mRNA Booster Dose

- Individual risk factors for SARS-CoV-2 infection
  - Risk of exposure (occupational and institutional settings)
  - Risk for infection (time since completion of primary series)
- Potential impact of SARS-CoV-2 infection
  - Risk for severe infection (underlying conditions)
  - Risk associated with a person's circumstances (living with/caring for at-risk individuals or consequences of inability to meet obligations due to infection)
- Potential benefits of booster
  - Reduced risk of infection, including severe infection
- Potential risks of booster
  - Rare risks of serious adverse events (myocarditis, pericarditis, anaphylaxis)
  - Common risks of transient local and systemic symptoms

# Indications for Booster Dose Following Janssen COVID-19 Primary Dose

- People aged ≥18 years who received a single dose Janssen primary series **should** receive a single Janssen COVID-19 booster dose at least 2 months after completing their primary series

# Heterologous (Mix-and-Match) Booster Dose

- The same product that was used for the primary regimen should be used for the booster.
  - If that is not available or another product is preferred, heterologous boosting with a single dose of any of the authorized COVID-19 vaccine boosters is acceptable
- Heterologous dosing may be considered for the **booster dose** only.
  - All doses of the primary series and additional dose (if indicated for moderately to severely immunocompromised people who received 2 doses of mRNA vaccine) should utilize the same vaccine product.
- Individual benefit-risk assessment may inform which booster product to use.
  - Availability of booster product
  - Risk profile of vaccine boosters, including rare events

# Additional Considerations for Heterologous (Mix-And-Match) Booster Dose

- Interval should follow the interval recommended by the primary series
  - People who received a single dose Janssen primary series can receive a mRNA COVID-19 booster dose at least 2 months after completing primary series

- If Moderna vaccine booster is used, the booster dose and volume should be utilized (50µg in 0.25ml)
  - Pfizer-BioNTech and Janssen booster doses are the same dose as primary vaccine
  - If an individual who is moderately to severely immunocompromised received a primary dose of Janssen vaccine and receives a booster dose using Moderna, the 50µg dose should be used

# Administration of COVID-19 Vaccines

| Vaccine | Primary series/dose | | | Additional dose in immunocompromised [+] | | | Booster dose[+] | | |
|---|---|---|---|---|---|---|---|---|---|
| | Dose (volume) | N doses (interval) | Age (y) | Dose (volume) | N doses (interval since primary series) | Age (y) | Dose (volume) | N doses (interval since primary series)[#] | Age (y) |
| Pfizer-BioNTech | 30 µg (0.3 ml) | 2 (21 d) | ⩾12 | 30 µg (0.3 ml) | 1 (≥28 d) | ≥12 | 30 µg (0.3 ml) | 1 (≥6 m) | ≥18[§] |
| Moderna | 100 µg (0.5 ml) | 2 (28 d) | ≥18 | 100 µg (0.5 ml) | 1 (≥28 d) | ≥18 | 50 µg (0.25 ml) | 1 (≥6 m) | ≥18[§] |
| Janssen | $5 \times 10^{10}$ VP (0.5 ml) | 1 (N/A) | ≥18 | (see booster dose) | | | $5 \times 10^{10}$ VP (0.5 ml) | 1 (≥2 m) | ≥18 |

N = number, y = years, ml = milliliters, m = months, d = days, µg = micrograms, VP= viral particles

[+] Moderately to severely immunocompromised people

[§] Minimum authorized age group

[#]Booster interval based on homologous dosing (booster product is the same as primary series). Heterologous (mix-and-match) booster interval is dependent on the recommendation for the primary series

# Definition of ‘fully vaccinated’

- For public health purposes, people who have completed a primary vaccine series (i.e., 2-dose mRNA vaccine series or a single dose of the Janssen vaccine) are considered fully vaccinated ≥2 weeks after completion of the primary series
- The above definition applies to all people including those recommended to receive an additional single dose due to moderate to severe immunocompromise and those recommended to receive a booster dose
- People who have received a booster dose should continue to follow guidance for fully vaccinated persons to minimize spread of SARS-CoV-2

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html

# Coadministration with Other Vaccines

- COVID-19 vaccine booster dose (Pfizer-BioNTech, Moderna, or Janssen) may be given with other vaccines, without regard to timing.
- This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day.
- If multiple vaccines are administered at a single visit, administer each injection in a different injection site.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Coadministration

# Contraindications Related to Allergy

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine
- Known polysorbate allergy is a contraindication to Janssen COVID-19 and a precaution to mRNA COVID-19 vaccination
  - People with a contraindication to the mRNA COVID-19 vaccines (including a known allergy to polyethylene glycol [PEG]) have a precaution to Janssen COVID-19 vaccine

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Contraindications

# Anaphylaxis

- Anaphylactic reactions have been rarely reported following receipt of COVID-19 vaccines.

## How to recognize anaphylaxis

Healthcare personnel should consider anaphylaxis when patients present with generalized signs or symptoms such as **hives, serious or life-threatening symptoms** (e.g., hypotension, respiratory distress, or significant swelling of the tongue or lips), or **symptoms that involve more than one body system**.

**Respiratory:**
- sensation of throat closing
- stridor (high-pitched sound while breathing)
- shortness of breath
- wheeze, cough

**Gastrointestinal:**
- nausea
- vomiting
- diarrhea
- abdominal pain

**Cardiovascular:**
- dizziness
- fainting
- tachycardia (abnormally fast heart rate)
- hypotension (abnormally low blood pressure)

**Skin/mucosal:**
- generalized hives
- itching
- swelling of lips, face, or throat

**Neurological:**
- agitation
- convulsions
- acute change in mental status
- sense of impending doom (a feeling that something bad is about to happen)

https://www.cdc.gov/vaccines/covid-19/downloads/IntermConsid-Anaphylaxis-covid19-vaccine-sites.pdf

# Potential Risks after mRNA Booster Dose: Myocarditis and Pericarditis

- Rare risks of myocarditis and pericarditis after receiving an mRNA vaccine
  - Based on current data from primary series, the highest risk is observed in males aged 12-30 years

- For people who developed myocarditis or pericarditis after mRNA vaccine, recommend deferral of COVID-19 booster dose at least until clinical syndrome has completely resolved
  - Conversations with patient and their clinical team may assist with decisions about proceeding with subsequent dose and timing

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#underlying-conditions

# Potential Risks after Janssen Booster Dose: Thrombosis with Thrombocytopenia Syndrome (TTS)

- Rare risk of thrombosis with thrombocytopenia syndrome (TTS)
  - Based on current data from primary dose, the highest risk is observed in women aged 18-49 years
- For people who developed TTS after Janssen COVID-19 primary vaccine:
  - A booster dose of Janssen vaccine is not recommended
  - These individuals may receive a dose of mRNA COVID-19 vaccine as a booster at least 2 months following the Janssen dose and after the clinical condition has stabilized
  - Conversations with patient and their clinical team may assist with decisions about the use of mRNA COVID-19 vaccine booster and timing of the booster

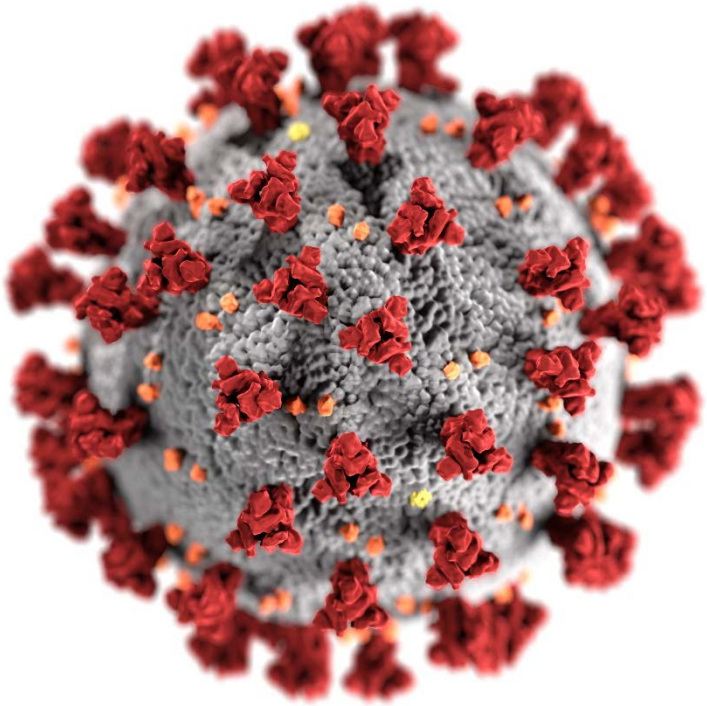
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#janssen-vaccine-certain-populations

# Potential Risks after Janssen Booster Dose: Guillain-Barré Syndrome

- Rare risk of Guillain-Barré Syndrome (GBS)
- For people who had GBS after Janssen primary vaccine:
  - No data are available on the safety of administering either Janssen or mRNA booster dose for this situation
  - These individuals should be made aware of the option to receive an mRNA COVID-19 vaccine booster at least 2 months after the Janssen dose
  - Janssen may still be used as a booster in these individuals, particularly if the GBS occurrence was >42 days after vaccination or was assessed as related to a non-vaccine factor
  - Conversations with patient and their clinical team may assist with decisions about administration of the COVID-19 vaccine booster and timing of the booster

# Acknowledgements


- Mary Chamberland
- Kristine Schmit
- Neela Goswami
- Sarah Mbaeyi
- Kathleen Dooling
- Karen Broder
- Margaret Cortese
- Andrew Kroger
- Rachel Gorwitz
- Erin Tromble



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.