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

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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

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Primary series/dose</th>
<th>Additional dose in immunocompromised</th>
<th>Booster dose*</th>
<th>Age (y)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dose (volume)</td>
<td>N doses (interval)</td>
<td>Age (y)</td>
<td>Dose (volume)</td>
</tr>
<tr>
<td>Pfizer-BioNTech</td>
<td>30 µg (0.3 ml)</td>
<td>2 (21 d)</td>
<td>≥12</td>
<td>30 µg (0.3 ml)</td>
</tr>
<tr>
<td>Moderna</td>
<td>100 µg (0.5 ml)</td>
<td>2 (28 d)</td>
<td>≥18</td>
<td>100 µg (0.5 ml)</td>
</tr>
<tr>
<td>Janssen</td>
<td>5 × 10^{10} VP (0.5 ml)</td>
<td>1 (N/A)</td>
<td>≥18</td>
<td>(see booster dose)</td>
</tr>
</tbody>
</table>

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.

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](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)

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-vaccinesus.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-vaccinesus.html#janssenvaccine-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
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