## At-a-glance: mRNA COVID-19 Vaccines

### Summary of interim clinical recommendations for Pfizer-BioNTech and Moderna COVID-19 vaccines

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Pfizer-BioNTech (BNT162b2)</th>
<th>Moderna (mRNA-1273)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUA</td>
<td>Issued December 11, 2020</td>
<td>Issued December 18, 2020</td>
</tr>
<tr>
<td>Fact sheet</td>
<td>• Health care providers</td>
<td>• Health care providers</td>
</tr>
<tr>
<td></td>
<td>• Recipients/caregivers</td>
<td>• Recipients/caregivers</td>
</tr>
<tr>
<td>ACIP</td>
<td>Interim recommendation for use: Persons aged ≥16 years for prevention of COVID-19</td>
<td>Interim recommendation for use: Persons aged ≥18 years for prevention of COVID-19</td>
</tr>
<tr>
<td>Dose</td>
<td>30 mcg (0.3 mL each)</td>
<td>100 mcg (0.5 mL each)</td>
</tr>
<tr>
<td>Schedule</td>
<td>First dose: Day 0</td>
<td>First dose: Day 0</td>
</tr>
<tr>
<td></td>
<td>Second dose: Day 21</td>
<td>Second dose: Day 28</td>
</tr>
<tr>
<td>Storage and handling</td>
<td>• Long-term storage: -80° to -60°C (-112° to -76°F)</td>
<td>• Long-term storage: -25° to -15°C (-13° to 5°F)</td>
</tr>
<tr>
<td></td>
<td>• Refrigeration: 2° to 8°C (35° to 46°F) for up to 5 days</td>
<td>• Refrigeration: 2° to 8°C (35° to 46°F) for up to 30 days</td>
</tr>
<tr>
<td></td>
<td>• Room temp: up to 5 hours (unpunctured) *Must be at room temp at least 30 minutes before dilution</td>
<td>• Room temp: up to 12 hours (unpunctured) *Thaw in refrigerated conditions for at least 2.5 hours, then let the vial stand at room temp for at least 15 minutes before administering.</td>
</tr>
<tr>
<td></td>
<td>• After first use: Room temp up to 6 hours</td>
<td>• After first use: Room temp up to 6 hours</td>
</tr>
<tr>
<td>Efficacy</td>
<td>95% efficacy in 43,538 volunteers beginning 7 days after second dose</td>
<td>94.1% in 30,420 volunteers beginning 14 days after second dose</td>
</tr>
<tr>
<td>Contraindications</td>
<td>Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine</td>
<td></td>
</tr>
<tr>
<td>Postvaccination symptoms</td>
<td>• Local: pain, swelling, erythema at the injection site, localized axillary lymphadenopathy (80%-89% of vaccinated persons*)</td>
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<td></td>
<td>• Systemic: fever, fatigue, headache, chills, myalgia, arthralgia (55%-83% of vaccinated persons*; acetaminophen or ibuprofen may be used)</td>
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<td></td>
<td>• These symptoms tend to be more common after the second dose and resolve 1-3 days after vaccination.</td>
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</tr>
<tr>
<td></td>
<td>• Anaphylaxis following vaccination was not observed in clinical trials.</td>
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</tr>
<tr>
<td></td>
<td>• Access a comprehensive summary of local reactions, systemic reactions, adverse events, and serious adverse events for the Pfizer or Moderna COVID-19 vaccines. *Depending on the vaccine, age group, and vaccine dose</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations used: EUA, emergency use authorization; ACIP, Advisory Committee on Immunization Practices.
Administration

- **Dosing interval**
  - **Recommended interval:**
    - 21 days +/- 4 days (Pfizer-BioNTech)
    - 28 days +/- 4 days (Moderna) from the first dose
  - **Earliest interval:** 4 days prior to recommended interval
    - 17 days (Pfizer-BioNTech)
    - 24 days (Moderna) from the first dose (for all of these should only be for exceptions)
  - **Latest interval:** 6 weeks (42 days) from first dose for both vaccines
  - If the second dose is administered beyond these intervals, there is no need to restart the series.

<table>
<thead>
<tr>
<th>Dosing Interval</th>
<th>Pfizer-BioNTech</th>
<th>Moderna</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recommended Interval</strong></td>
<td>21</td>
<td>28</td>
</tr>
<tr>
<td><strong>Earliest Interval</strong></td>
<td>17</td>
<td>24</td>
</tr>
<tr>
<td><strong>Latest Interval</strong></td>
<td></td>
<td>42*</td>
</tr>
</tbody>
</table>

*Limited data exists on efficacy beyond a 42 day (6 week) interval.*
Interchangeability:

- mRNA COVID-19 vaccine products are not interchangeable.
- Every effort should be made to determine which vaccine product a patient received as the first dose in order to ensure completion of the vaccine series with the same product.
- In exceptional situations in which the first-dose vaccine product cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses of different products to complete the series.
- There is limited data on safety and efficacy with interchanging vaccine products.
- If two doses of different mRNA COVID-19 vaccine products are administered for a vaccine series, additional doses of either product are not recommended at this time.

CDC lists the following strategies to help ensure that patients receive the second dose with the appropriate product and interval between doses:

- Providing COVID-19 vaccination record cards to vaccine recipients, asking recipients to bring their card to their appointment for the second dose, and encouraging recipients to make a backup copy (e.g., by taking a picture of the card on their phone).
- Making an appointment for the second dose before the vaccine recipient leaves, to increase the likelihood that patients will present at the same vaccination site for the second dose.
- Encouraging vaccine recipients to enroll in VaxTextSM, a free text message-based platform to receive COVID-19 vaccination second-dose reminders.
- Recording each recipient’s vaccination in the state/local and/or other immunization information system (IIS), as required.
- Recording vaccine administration information in the patient’s medical record.

Coadministration with other vaccines: Administer alone at least 14 days before or after administration of other vaccines.

- If inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.
- If the patient received another vaccine within 14 days but won’t be able to return for the COVID-19 vaccine, do not miss the opportunity to administer the COVID-19 vaccine.
- If a live vaccine must be given, administer the COVID-19 vaccine first, then administer the live vaccine 14 days later.

Booster doses: No more than two doses are recommended at this time.
Summary of interim clinical recommendations for Pfizer-BioNTech and Moderna COVID-19 vaccines

Storage and handling

- **Extra doses:**
  - A total of six doses can be withdrawn from a Pfizer-BioNTech vaccine vial. A **low dead-volume syringe and/or needle** should be used to consistently withdraw six full doses from each vial. If standard syringes and needles are used, there may be insufficient volume to extract a sixth dose, regardless of syringe or needle type used.
  - FDA has advised that it is acceptable to **use every full dose** obtainable from each vial. However, since the vials are preservative free, any remaining product with a volume less than a full dose should not be pooled from multiple vials to create one dose.
  - Complete storage and handling information can be found in the fact sheets for health care providers in the table above and “Minimizing COVID-19 Dose Variability” in APhA’s COVID-19 Resources: Know the Facts library, provides recommendations for vaccine withdrawal and administration.
  - USP’s recently published toolkit on COVID-19 Vaccine Handling: Operational Considerations for Healthcare Practitioners contains additional guidance on preparation and handling, including guidance on pre-drawing vaccine doses and storing within syringes.
  - Never refreeze either COVID-19 vaccine product.

Contraindications and precautions

- **Contraindication:** Recommend against use in individuals with known history of severe allergic reaction to any component of the vaccine.
- **Precaution:** Counsel about the unknown risks of developing a severe allergic reaction for patients with a history of severe allergic reaction (anaphylaxis) to any other vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous).

  - Vaccine providers should observe patients after vaccination to monitor for immediate adverse reactions:
    - **30 minutes:** Persons with a history of anaphylaxis
    - **15 minutes:** All other persons
  - See table below for the ingredients within each vaccine.
Summary of interim clinical recommendations for Pfizer-BioNTech and Moderna COVID-19 vaccines

Underlying medical conditions

- mRNA COVID-19 vaccines may be administered to persons with underlying medical conditions unless there is a contraindication. Persons with some underlying medical conditions, including those that place them at increased risk for severe COVID-19, were found to have similar safety and efficacy profiles compared to persons without comorbidities in clinical trials.

- Data are limited or not currently available for the following specific underlying conditions. Unless there is a contraindication, patients with the following conditions may consider receiving one of the COVID-19 vaccines.

  > **Immunocompromised:** Counsel on the potential for reduced immune response to the vaccine and the need to follow current guidance to protect themselves against COVID-19 (e.g., masks, social distancing)

    - **Note:** Persons with stable HIV infections were included in clinical trials.

  > **Autoimmune conditions:** No imbalances were observed in the occurrence of symptoms consistent with autoimmune conditions or inflammatory disorders in clinical trial participants.

  > **Guillain-Barré syndrome:** No cases have been reported among participants following vaccination.

  > **Bell's palsy:** Cases were reported following vaccination in participants in clinical trials; however, FDA does not consider these to be above the frequency expected in the general population and has not concluded that these cases were causally related to vaccination.

  > **Dermal Filler Use:** Swelling near the dermal filler injection site is possible and is expected to resolve. Persons with a history of dermal filler use should be advised to contact their doctor if swelling occurs.
Pregnancy and lactation

- **Pregnancy:** May be vaccinated. No data are available on the safety of COVID-19 vaccines in pregnant women; studies are ongoing, and more are planned. Conversation between the individual and their clinician may assist, but not required prior to vaccination.
  
  > Consider risk versus benefit. Issues to consider:
  
  - Level of COVID-19 community transmission (risk of acquisition)
  - Her personal risk of contracting COVID-19 (by occupation or other activities)
  - Risks of COVID-19 to her and potential risks to the fetus
  - Vaccine efficacy
  - Known adverse effects of the vaccine
  - Lack of data about the vaccine during pregnancy
  
  > Pregnant women who experience fever following vaccination should be counseled to take acetaminophen, as fever has been associated with adverse pregnancy outcomes.

- **Breastfeeding/lactating women:** May be vaccinated. No data are available on the safety of COVID-19 vaccines in lactating women or the effects of mRNA vaccines on the breastfed infant or on milk production/excretion.
  
  > mRNA vaccines are not considered live virus vaccines and are not thought to be a risk to the breastfeeding infant.

Considerations related to SARS-CoV-2 infection

- **Persons with a history of SARS-CoV-2 infection**
  
  > Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection.
  
  > Since current evidence suggests that the risk of reinfection is low after initial infection, persons with a recent history of infection may temporarily delay vaccination while vaccine supplies remain limited.
  
  > Viral or serologic testing for acute or prior infection, respectively, is not recommended for the purpose of vaccine decision making.
Summary of interim clinical recommendations for Pfizer-BioNTech and Moderna COVID-19 vaccines

• **Persons with known current SARS-CoV-2 infection**
  > Vaccination should be deferred until recovery from acute illness (if person had symptoms) and criteria have been met to discontinue isolation.
  > There is no minimal recommended interval between infection and vaccination.
    - Reinfection is uncommon in the 90 days after initial infection, so persons may defer vaccination until the end of this period, if desired.

• **Persons who previously received passive antibody therapy for COVID-19**
  > Vaccination should be deferred for at least 90 days to avoid interference of the treatment with vaccine-induced immune responses.

• **Persons with a known SARS-CoV-2 exposure**
  > Community or outpatient setting: Defer vaccination until quarantine period has ended.
  > Residents of congregate health care settings (e.g., long-term care facilities) can be vaccinated. Employ appropriate infection prevention and control procedures.

**Impact on SARS-CoV-2 testing**

• **Viral tests**
  > Prior receipt of mRNA COVID-19 vaccine will not affect the results of SARS-CoV-2 nucleic acid amplification or antigen tests.

• **Antibody tests**
  > Currently available antibody tests for SARS-CoV-2 assess IgM and/or IgG to spike or nucleocapsid proteins.
  > mRNA COVID-19 vaccine encodes the spike protein; thus, a positive test for spike protein IgM/IgG could indicate either prior infection or vaccination.
  > To evaluate for evidence of prior infection in an individual with a history of mRNA COVID-19 vaccination, use a test specifically evaluating IgM/IgG to the nucleocapsid protein.
### Ingredients included in Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines

<table>
<thead>
<tr>
<th>Description</th>
<th>Pfizer-BioNTech COVID-19 vaccine</th>
<th>Moderna COVID-19 vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>mRNA</td>
<td>Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2</td>
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</tr>
<tr>
<td>Lipids</td>
<td>2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide</td>
<td>Polyethylene glycol (PEG) 2000 dimyristoyl glycerol (DMG)</td>
</tr>
<tr>
<td></td>
<td>1,2-distearoyl-sn-glycero-3-phosphocholine</td>
<td>1,2-distearoyl-sn-glycero-3-phosphocholine</td>
</tr>
<tr>
<td></td>
<td>Cholesterol</td>
<td>Cholesterol</td>
</tr>
<tr>
<td></td>
<td>(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diy)bis(2-hexyldecanoate)</td>
<td>SM-102 (proprietary to Moderna)</td>
</tr>
<tr>
<td>Salts, sugars,</td>
<td>Potassium chloride</td>
<td>Tromethamine</td>
</tr>
<tr>
<td>buffers</td>
<td>Monobasic potassium phosphate</td>
<td>Tromethamine hydrochloride</td>
</tr>
<tr>
<td></td>
<td>Sodium chloride</td>
<td>Acetic acid</td>
</tr>
<tr>
<td></td>
<td>Dibasic sodium phosphate dihydrate</td>
<td>Sodium acetate</td>
</tr>
<tr>
<td></td>
<td>Sucrose</td>
<td>Sucrose</td>
</tr>
</tbody>
</table>

Source: Adapted from CDC’s [Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States; Appendix A](https://www.cdc.gov/vaccines/covid-19/interim-clinical-considerations/mrna.html).

“As of January 21, 2021, mRNA COVID-19 vaccines are the only currently available vaccines in the United States that contain PEG, though several vaccines contain polysorbate (more information can be found in [CDC’s vaccine excipient summary](https://www.cdc.gov/vaccines/technology/ingredients/index.html)).”

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